

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 9. HEALTH SERVICES

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

ADMINISTRATION

Editor's Note: The following Notice of Final Rulemaking was reviewed per Executive Order 2012-03 as issued by Governor Brewer. (See the text of the executive order on page 1705.) The Governor's Office authorized the notice to proceed through the rulemaking process on August 9, 2011.

[R13-108]

PREAMBLE

- | <u>1. Articles, Parts, and Sections Affected</u> | <u>Rulemaking Action</u> |
|--|--------------------------|
| R9-22-710 | Amend |
- 2. Citations to the agency's statutory rulemaking authority to include both the authorizing statute (general) and the implementing statute (specific):**
Authorizing statute: A.R.S. §§ 36-2903.01, 36-2907
Implementing statute: A.R.S. § 36-2904(B)
- 3. The effective date of the rule:**
August 9, 2013
- 4. Citations to all related notices published in the Register to include the Register as specified in R1-1-409(A) that pertain to the record of the final rulemaking package:**
Notice of Exempt Rulemaking: 18 A.A.R. 212, January 27, 2012
Notice of Exempt Rulemaking: 18 A.A.R. 1971, August 17, 2012
Notice of Rulemaking Docket Opening: 19 A.A.R. 232, February 15, 2013
Notice of Proposed Rulemaking: 19 A.A.R. 227, February 15, 2013
- 5. The agency's contact person who can answer questions about the rulemaking:**
- | | |
|------------|-------------------------------------|
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- 6. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:**
AHCCCS originally promulgated this rulemaking pursuant to Laws 2011, Ch. 31, § 34 (SB 1619). The following year Laws 2012, Ch. 299, § 7 (SB 1528) repealed the SB 1619 rulemaking authority. Laws 2012, Ch. 299, § 8 further stipulated that rules adopted through the SB 1619 rulemaking authority would no longer be effective as of December 31, 2013 unless the rules were supported by specific statutory authority. However, AHCCCS had at the time of the rulemaking, and has today, specific statutory authority to establish reimbursement methodologies: The statutory authority for the reimbursement methodology is found in A.R.S. § 36-2904(B) which authorizes the Administration

Notices of Final Rulemaking

to pay for services not covered by a managed care contractor based on a capped fee-for-service schedule established by the Administration. This rule describes how capped fee-for-service payments are made for certain drugs dispensed by Federally Qualified Health Centers (FQHC) and FQHC Look-Alike pharmacies. The capped fee-for-service payment amounts themselves are exempt from the requirements of formal rulemaking. See A.R.S. § 41-1005(A)(9). Consequently, AHCCCS' adoption of the drug reimbursement methodology in this rulemaking is authorized by statute consistent with Arizona Laws 2012, Ch. 299, § 8.

As background for this rulemaking, 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, administered by the Health Resources and Services Administration (HRSA), 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 federally qualified health centers as well as other entities described under 42 U.S.C. 256b(a)(4). According to HRSA, there are over 21,500 hospitals and clinics nationwide that purchase drugs through 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. Although the AHCCCS reimbursement scheme for these entities is not mandated under the federal Medicaid Act or the federal 340B program, AHCCCS implemented this reimbursement scheme in its efforts to "implement a program within available appropriations." As noted in the prior rulemaking, this modification in reimbursement is estimated to reduce the cost of the AHCCCS program by more than \$7 million annually.

On January 27, 2012, a Notice of Exempt Rulemaking appeared in the *Arizona Administrative Register* amending R9-22-710 to implement a "reimbursement methodology specific to 340B drugs dispensed by FQHC and FQHC Look-Alike Pharmacies." 18 A.A.R. 212 (http://www.azsos.gov/public_services/Register/2012/4/exempt.pdf). This rulemaking applies only to FQHC's and FQHC Look-Alike pharmacies that participate as AHCCCS providers and that purchase drugs through the 340B program. There are 27 unique entities that are subject to this rulemaking including the Maricopa Integrated Health System which operates FQHC "look-like" clinics at 23 locations in the county and that are also subject to this rule (<http://www.azahcccs.gov/commercial/FQHC-RHC.aspx>).

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

A study was not referenced or relied upon when repromulgation of these regulations.

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

Not applicable

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

The Administration anticipates no economic impact on the implementing agency, small businesses and consumers as a result of this repromulgation.

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

No significant changes were made between the proposed rulemaking and the final rulemaking, only grammatical or formatting changes have been made.

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

No comments were received as of the close of the comment period of March 18, 2013.

12. All agencies shall list other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:

No other matters are applicable.

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:

Not applicable

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:

42 U.S.C. § 256b; 42 CFR 447.205; 45 CFR 160; and 45 CFR 162 are applicable to the subject of the rule, but the rule is not more stringent.

Notices of Final Rulemaking

- 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:

Not applicable

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

None

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

Not applicable

15. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

CHAPTER 22. ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM (AHCCCS)
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. No change
- 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. FOHC Pharmacy reimbursement.
1. For purposes of this 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 pharmacy 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(1)(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. "FOHC or FOHC Look-Alike pharmacy" means a pharmacy that dispenses drugs to FOHC or FOHC-LA patients and that is owned and/or operated by an FOHC/FOHC-LA or by an entity that reports the costs of an FOHC/FOHC-LA on its Medicare Cost Report, whether or not collocated with an FOHC or an FOHC Look-Alike.
 2. Effective the later of February 1, 2012, or CMS approval of a State Plan Amendment, an FOHC or FOHC 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.

Notices of Final Rulemaking

- 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 FOHC and the FOHC 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 FOHC and FOHC Look -Alike pharmacies, whether or not purchased under the 340B pricing file, at the amount submitted under subsection (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 AHCCCS Administration and Managed Care Contractors shall not reimburse such claims.
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 FOHC 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.