

NOTICE OF EXEMPT RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 22. ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM

ADMINISTRATION

PREAMBLE

1. Article, Part, or Section Affected (as applicable) Rulemaking Action:

R9-22-710

Amend

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

Authorizing statute: A.R.S. § 36-2903.01, 36-2907

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

Statute or session law authorizing the exemption: Laws 2011, Ch. 31, § 34

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

August 1, 2012

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:

Notice of Proposed Exempt Rulemaking: 18 A.A.R. 1429, June 29, 2012

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

The close of the comment period was July 9, 2012.

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 An agency's justification and reason why a rule should be made, amended, repealed, or renumbered to include an explanation about the rulemaking:

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 contracted pharmacies for drugs that are subject to 340 B 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 340 B entity as part of the 340 B drug pricing program.

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

Arizona Law 2011, Chapter 31, Section 34, which authorizes this exempt rule making, requires public notice with an opportunity for public comment of at least 30 days. Public notice of this rule making 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 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:

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

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 any changes between the proposed rulemaking, including any supplemental proposed rulemaking, and the final rulemaking package (if applicable):

No substantive changes were made between the proposed rule and the final rule.

11. An agency’s summary of the public or stakeholder comments made about the rulemaking and the agency response to the comments, if applicable:

No comments were received by the end 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. When applicable, matters shall include, but not be 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:

Not applicable

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than

the federal law and if so, citation to the statutory authority to exceed the requirements of federal law:

Not applicable

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:

No analysis was submitted.

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

None

14. Whether the rule was previously made, amended, repealed or renumbered as an emergency rule. If so, the agency

shall state where the text changed between the emergency and the exempt rulemaking packages:

Not applicable

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) 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 the following terms are defined:

- a. "340B Drug Pricing Program" means the discount drug purchasing program described in Section 256b of Title 42 of the United States Code.
- 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(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) 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.