

NOTICE OF PROPOSED 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):**
Authorizing statute: A.R.S. § 36-2903.01, 36-2907
Implementing statute: A.R.S. § 36-2904
- 3. Citations to all related notices published in the Register as specified in R1-1-409(A) that pertain to the record of the proposed rule:**
Notice of Exempt Rulemaking: 18 A.A.C. 212, January 27, 2012
Notice of Exempt Rulemaking: 18 A.A.C. 1971, August 17, 2012
Notice of Rulemaking Docket Opening: [to be filled in by SOS editor]
- 4. The agency’s contact person who can answer questions about the rulemaking:**
Name: Mariaelena Ugarte
Address: AHCCCS
Office of Administrative Legal Services
701 E. Jefferson, Mail Drop 6200
Phoenix, AZ 85034
Telephone: (602) 417-4693
Fax: (602) 253-9115
E-mail: AHCCCSRules@azahcccs.gov
Web site: www.azahcccs.gov
- 5. An agency’s justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:**
Due to recent legislative direction within Laws 2012, Chapter 299, Section 7 of the bill repealed the rule-making authority and Section 8 stipulated that rules adopted through the previous year’s authority would expire December 31, 2013 without specific statutory authority.

After an evaluation of our overall statutory authority regarding covered services, rates and eligibility, AHCCCS has determined that it requires statutory changes to continue measures it enacted under the Chapter 299 authority that prohibits AHCCCS from continuing after December 31, 2013 any “program changes” made pursuant to Section 34 of Senate Bill 1619. Therefore, the Administration is re-promulgating rules in regard to the 340B program.

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.

6. 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.

7. 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.

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

The AHCCCS Administration believes that the re-promulgated rule for the 340B program will not have a different economic impact as reported in previous rulemaking and therefore include appropriate reimbursement for claims paid at the 340B pricing. Although no economic impact is associated with the proposed rule, 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.

9. The agency's contact person who can answer questions about the economic, small business and consumer impact statement:

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

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

Proposed rule language will be available on the AHCCCS website www.azahcccs.gov the week of January 28, 2013. Please send written or email comments to the above address by the close of the comment period, 5:00 p.m., March 18, 2013.

Date: March 18, 2013
Time: 1:00 p.m.
Location: AHCCCS
701 East Jefferson
Phoenix, AZ 85034
Nature: Public Hearing

Date: March 18, 2013
Time: 1:00 p.m.
Location: ALTCS: Arizona Long-Term Care System
1010 N. Finance Center Dr, Suite 201
Tucson, AZ 85710
Nature: Public Hearing

Date: March 18, 2013
Time: 1:00 p.m.
Location: 2717 N. 4th St. STE 130
Flagstaff, AZ 86004
Nature: Public Hearing

11. 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 have been prescribed.

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:

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.

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

None

13. 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.
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.