

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 2081.) The Governor's Office authorized the notice to proceed through the rulemaking process on August 9, 2011.

[R11-154]

PREAMBLE

- 1. Sections Affected**
R9-22-710
- Rulemaking Action**
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:**
January 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 October 23, 2011.
Name: Mariaelena Ugarte
Address: AHCCCS
Office of Administrative and 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
- 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.
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. AHCCCS Administration has chosen to develop a pol-

Notices of Exempt Rulemaking

icy and a rule that include the reimbursement methodology applicable to covered entities and their contacted pharmacies for drugs that are subject to 340B pricing. AHCCCS Administration shall include the reimbursement methodology in the State Medicaid agency's state plan and request approval from CMS.

Previously, as part of the 1115 Waiver, the Arizona Medicaid Program (AHCCCS) did not participate in the Federal Medicaid Drug Rebate Program. The reason for not participating in the program and receiving this waiver from CMS was due to the fact that only drugs paid for by state Medicaid agencies were eligible for the rebates. Drugs provided through the Medicaid Managed Care Organizations (MCOs) were not eligible for rebates through the federal rebate program. Therefore, only drugs provided to Fee-for-Service (FFS) members by retail and long-term care pharmacies were eligible for the federal rebates. Drugs provided through IHS/638 facilities, FQHCs, disproportionate share hospitals or other entities eligible to purchase drugs through the 340B pricing program are not eligible for the federal rebates. Prior to the Patient Protection and Affordable Care Act (PPACA), the costs to administer the federal rebate program for the Fee-for-Service program would have exceeded the revenues generated by the rebates, therefore, the CMS waiver exempted AHCCCS from participation in the program.

As of March 23, 2010, the Patient Protection and Affordable Care Act required all state Medicaid programs, including AHCCCS, to participate in the federal drug rebate program. The state Medicaid program is required to submit utilization claims data for rebates for drugs provided by contracted MCOs. Currently, AHCCCS works with a contracted vendor to obtain rebates on all eligible drugs. Drugs that are not eligible for rebates are those provided by covered entities that purchase drugs under the 340B pricing program. Numerous entities are permitted to participate in the 340B program and purchase drugs at these discounted prices. Entities that purchase drugs at 340B pricing are providing those drugs to AHCCCS members and submitting claims to AHCCCS or its Contractors and are reimbursed at a discounted retail price negotiated by the Pharmacy Benefit Managers (PBMs). The cost differential is significant and substantial when comparing the 340B entity's actual acquisition cost of the drug to the PBM's reimbursement rate paid to the 340B entity.

To address the disparity between the actual acquisition cost of drugs subject to 340B pricing and the current reimbursement rate, the AHCCCS Administration is proposing a rule to require a specific reimbursement methodology for drugs subject to the 340B pricing program dispensed by Federally Qualified Health Centers (FQHCs) and FQHC Look-Alikes and their contracted pharmacies. Drugs purchased under the 340B pricing program are not eligible for rebates because the 340B pricing provided by pharmaceutical manufacturers are at discounted rates. The pharmaceutical manufacturers have provided deeply discounted front-end pricing of the drug and therefore the manufacturers are not required to provide additional discounts. AHCCCS must identify all claims data for drugs purchased under the 340B pricing program and cannot submit these claims for rebates, eliminating the potential for duplicate discounts which would violate the regulations of the federal rebate program Fed regulations SSA § 1927.

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 September 23, 2011. 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 first 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

Notices of Exempt Rulemaking

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

The AHCCCS Administration believes that the cost differential, when comparing 340B pricing to the PBM reimbursement rate paid to the 340B entity and its contracted pharmacy, can be saved and benefit the state. The proposed rule prohibits the 340B entity and its contracted pharmacy from submitting a claim with an ingredient cost in excess of the 340B entity's actual acquisition cost, thus allowing AHCCCS to participate in the savings. The net savings is estimated to be \$7.1M annually. In addition to reimbursing claims at the lesser of 1) the submitted ingredient cost or 2) the 340B ceiling price, the AHCCCS Administration and Contractors will reimburse the 340B entity and its contracted pharmacy a dispensing fee determined by the study referred in item 7. Beginning January 1, 2012, the dispensing fee calculated for reimbursement of 340B purchased drugs will be \$8.75. The dispensing fee will be available on the capped fee schedule for the public at: www.azahcccs.gov.

The estimated net cost savings resulting from requiring the covered entities to submit claims for the 340B actual acquisition cost plus the enhanced dispensing fee of \$8.75 is \$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, however, the new reimbursement methodology applies to all drugs subject to 340B pricing which are dispensed by 340B entities and their contracted pharmacies.

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 October 23, 2011.

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).

Notices of Exempt Rulemaking

- 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 contracted provider or a provider having a subcontract with a Pharmacy Benefit Manager (PBM) contracted with AHCCCS. Except as specified in subsection (C), the 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 Federally Qualified Health Center (FOHC) or an FOHC Look-Alike registered with HRSA as a covered entity in the 340B drug purchasing program.
 - d. “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.
 - e. “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.
 - f. “Pharmacy Benefit Manager (PBM)” means an organization that provides administrative services in processing and analyzing prescription claims for pharmacy benefit and coverage programs.
 2. Effective January 1, 2012, a 340B entity shall:
 - a. Notify the AHCCCS provider registration unit within 30 days of the effective date of this Section or within 30 days of the 340B “Covered entity” registering for the 340B program with the Health Resources and Services Administration (HRSA).
 - b. Notify AHCCCS of 340B contractual arrangement/agreements with pharmacies to dispense and/or administer drugs subject to the 340B pricing within 30 days of the arrangement/agreement.
 - c. 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.
 - d. Identify 340B point-of-sale drug claims submitted to the AHCCCS FFS PBM/Program or the AHCCCS Contractors’ PBMs/Programs for reimbursement to a 340B entity or its contracted pharmacy. The 340B drug claim identifier shall be consistent with claim instructions issued and required by AHCCCS to identify such claims.
 3. The AHCCCS Fee-for-Service and Contractors PBMs shall reimburse claims submitted by a 340B entity and its contracted pharmacy for drugs subject to 340B pricing at the dispensing fee listed in the AHCCCS Capped Fee-For-Service Schedule and the lesser of:
 - a. The submitted ingredient cost, or
 - b. The 340B ceiling price.
 4. The 340B entities and their contracted pharmacies shall not submit claims with the ingredient cost greater than the 340B entity’s actual acquisition cost.
 5. AHCCCS may periodically conduct audits to ensure compliance with this Section.