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ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM

340B FQHC & FQHC Look-Alike Pharmacy Billing and Reimbursement Requirements

A.A.C. R9-22-710 (C)

Frequently Asked Questions

1. What is the 340B Drug Pricing Program?

The Veterans Health Care Act of 1992 established the 340B Drug Pricing Program in Section 340B of the Public Health Service Act. The 340B Drug Pricing Program, codified as 42 USC §256b, requires the Secretary of the United States Department of Health and Human Services to enter into agreements with drug manufacturers to provide discounts for outpatient drugs sold to “covered entities” if those drugs are reimbursed through the Medicaid Program. The Health Resources and Services Administration (HRSA), Office of Pharmacy Affairs (OPA), administers the 340B Drug Pricing Program.

2. What is a 340B “covered entity”?

A 340B “covered entity” (also referred to as a 340B entity) is an organization eligible to participate and purchase outpatient drugs at a discount through the 340B Drug Pricing Program. “Covered entities” include FQHC’s, FQHC Look-Alikes, and disproportionate share hospitals. A list of “covered entities” eligible for the 340B Drug Pricing Program can be found on the HRSA Website at www.hrsa.gov/opa/introduction.htm.

3. Where is the AHCCCS Rule that describes the 340B billing requirements and the AHCCCS reimbursement methodology?

AHCCCS Rule A.A.C. R9-22-710 (C) can be found on the AHCCCS website at:
www.azahcccs.gov/reporting/Downloads/UnpublishedRules/NOER_340B_FQHC_010512.pdf

4. What is the purpose of AHCCCS Rule R9-22-710 (C) and the 340B billing requirements?

The purpose of AHCCCS Rule R9-22-710 (C) is to ensure that the savings associated with 340B drugs are passed on to the State. This Rule describes the prescription billing requirements and the reimbursement for FQHC and FQHC Look-Alike Pharmacies for drugs identified in the 340B Drug Pricing Program. Billing and reimbursement requirements apply to all drugs identified in the 340B Drug Pricing Program whether or not the drugs are purchased by the FQHC or FQHC Look-Alike under the 340B Program.

The Rule also describes AHCCCS reimbursement to FQHC and FQHC Look-Alikes pharmacies for drugs *not* eligible for purchase under the 340B Drug Pricing Program. In addition, the Rule delineates AHCCCS reimbursement to pharmacies contracted with any 340B entity, clarifying that AHCCCS will not reimburse pharmacies that contract or have an arrangement with a 340B entity for 340B drugs. AHCCCS will reimburse pharmacies contracted with a 340B entity for non 340B drugs, however, the pharmacy must have a contract with the Administration or Managed Care Contractor PBM in order to be reimbursed.

5. What 340B entities are affected by the new 340B Rule billing requirements?

Reimbursement for FQHC and FQHC Look-Alike Pharmacies is described in AHCCCS Rule R9-22-710 (C). In addition, the Rule sets forth the reimbursement methodology for FQHC and FQHC Look-Alike contracted pharmacies.

6. Does this Rule apply to all FQHC and FQHC Look-Alike Pharmacies?

Yes, Rule R9-22-710 (C) applies to all FQHC and FQHC Look-Alike Pharmacies filling prescriptions for AHCCCS members in the AHCCCS FFS Program as well as members enrolled with Managed Care Contractors. The rule also applies to all pharmacies contracted with any 340B entity.

7. What is the implementation date of R9-22-710(C)?

AHCCCS will begin implementation of the Rule on April 11, 2012. The effective date of the Rule is the later of February 1, 2012 or CMS approval of the State Plan Amendment (SPA). Although CMS approved the SPA effective February 1, 2012, AHCCCS will implement the requirements on April 11, 2012 in order to provide entities with sufficient time to comply with the new provisions.

The CMS approval letter can be found on the AHCCCS website at:

<http://www.azahcccs.gov/reporting/Downloads/MedicaidStatePlan/Amendments/2011/SPA11-015ApprovalLetter.pdf>

8. What are the 340B billing requirements for FQHC and FQHC Look-Alike Pharmacies?

For all drugs identified in the 340B Drug Pricing Program, the FQHC and FQHC Look-Alike Pharmacies are required to submit claims to the AHCCCS FFS and MCO Contractor PBMs at the lesser of: the Actual Acquisition Cost (AAC) of the drug or the 340B ceiling price. This billing requirement applies whether or not the drug is purchased under the 340B pricing file. The FQHC and FQHC Look-Alike Pharmacies will be paid the lesser of the AAC or the 340B ceiling price plus a dispensing fee for drugs eligible for purchase under the 340B Drug Pricing Program.

9. What is the dispensing fee to be paid for a drug eligible for purchase under the 340B Drug Pricing Program?

The dispensing fee is \$8.75 unless a contract between the 340B entity and a Managed Care Contractor PBM specifies a different dispensing fee. The dispensing fee can be found on the AHCCCS Capped Fee-For-Service Schedule at:

<http://www.azahcccs.gov/commercial/ProviderBilling/rates/Pharmacy.aspx>

10. What reimbursement is made to pharmacies that contract with FQHCs and FQHC Look-Alikes to dispense 340B drugs as part of the 340B Drug Pricing Program?

AHCCCS Rule R9-22-710(C) states that the AHCCCS Administration and Managed Care Contractors will not reimburse contracted pharmacies for drugs dispensed under an agreement with a 340B entity as part of the 340B Drug Pricing Program.

11. Is a compounded prescription claim that includes an ingredient eligible for purchase on the 340B Drug List considered a 340B prescription claim?

Yes. A compounded prescription billed with one or more ingredients that may be eligible for purchase under the 340B Drug Pricing Program is considered a 340B prescription claim. The compounded prescription must be billed and reimbursed as specified in the Rule. These claims are not eligible for rebates under the federal rebate program.

12. What reimbursement is made to pharmacies that contract with FQHCs and FQHC Look-Alikes for drugs not dispensed under an agreement with the 340B entity as part of the 340B program?

For drugs *not* dispensed under an agreement with the 340B entity as part of the 340B Drug Pricing Program, the Rule states that the AHCCCS Administration and Managed Care Contractors will reimburse contracted pharmacies at the price and dispensing fee set forth in the contract between the AHCCCS FFS and its Managed Care Contractors' PBMs and the contracted pharmacy. However, the AHCCCS Administration and its Managed Care Contractors will not reimburse a pharmacy that does not have a contract with the Administration or the MCO's PBM.

13. How should a FQHC/FQHC Look-Alike Pharmacy bill AHCCCS and its MCO Contractors' PBMs for 340B drugs that are priced at zero?

When the Federal Rebate Program Unit Rebate Amount (URA) of a drug equals the Average Manufacturer Price (AMP) of that drug, the net price of the drug for the 340B Drug Pricing Program is zero. HRSA issued a policy release, "*Clarification of Penny Pricing Policy*", on November 21, 2011 to clarify their long-standing policy with regards to drugs priced at zero, also known as penny pricing. The link to the HRSA policy letter is:

www.hrsa.gov/opa/Docs/PolicyReleasePennyPricing.pdf

The policy release states, "it is not reasonable for a manufacturer to set a zero 340B ceiling price. In these cases, the manufacturer should charge \$0.01 per unit of measure for zero priced drugs." The letter also provided the following examples:

- *If the smallest unit of measure used to calculate AMP and URA as reported to CMS is a single tablet, and the drug is packaged in bottles of 100, then the 340B price for that bottle would be \$1.00 ($\$0.01 * 100 = \1.00).*
- *If the smallest unit of measure used to calculate the AMP and URA is the bottle of 100 tablets, then the appropriate charge for that bottle is \$0.01.*
- *If the smallest unit of measure used to calculate AMP and URA as reported to CMS is a milliliter of liquid, and the drug is packaged in a 100 ml bottle, then the 340B price for that bottle would be \$1.00 ($\$0.01 * 100 = \1.00).*

AHCCCS considers the charge of \$0.01 per unit of measure, as described in the HRSA "*Clarification of Penny Pricing Policy*" letter, to be the actual acquisition cost of drugs when the URA equals the AMP. The FQHC and FQHC Look-Alike Pharmacies shall submit claims to the AHCCCS FFS and MCO Contractors' PBMs utilizing this methodology for these products.

14. When will the AHCCCS FFS and MCO PBMs receive the 340B Calculated Drug Pricing File?

The 340B Calculated Drug Pricing File will be provided to MCOs on or before July 1, 2012.

15. How will the FQHC and FQHC Look-Alike Pharmacies be monitored?

AHCCCS will monitor the Actual Acquisition Cost submitted by the FQHCs and FQHC Look-Alikes until such time that AHCCCS provides the 340B Calculated Drug Pricing File to the MCOs.

16. Will the AHCCCS FFS and MCOs' PBMs be responsible for recouping costs for 340B claims submitted incorrectly?

Prior to the provision of the 340B Calculated Drug Pricing File to MCOs, AHCCCS will notify MCOs of 340B claims that were submitted with incorrect pricing. The MCO shall direct their PBMs regarding all recoupment responsibilities and activities. After the 340B Calculated Drug Pricing File has been distributed to the MCOs, the MCOs' PBMs will be responsible for auditing prescriptions claims in accordance with the AHCCCS Rule R9-22-710 (C).