

October 21, 2011

*Via E-Mail ([AHCCCSrules@azahcccs.gov](mailto:AHCCCSrules@azahcccs.gov)) and  
First Class Mail*

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RE: Comments on Proposed Rule Titled “340B Pricing for FQHC Pharmacy Reimbursement”

Dear Ms. Ugarte:

Thank you for the opportunity to submit comments on the Arizona Health Care Cost Containment System’s (AHCCCS’s) proposed rule titled “340B Pricing for FQHC Pharmacy Reimbursement.” The proposed rule would require certain covered entities to bill AHCCCS and its contractors at the 340B ceiling price plus a dispensing fee of \$8.75. As discussed below, the undersigned organizations, which represent safety net providers that participate in the 340B program, have grave concerns about such a policy and believe that it is contrary to federal law. We recommend that AHCCCS instead consider a reimbursement policy that may have greater savings potential wherein AHCCCS and covered entities share the savings generated when drugs are purchased with the 340B discount.

**A. The Proposed Rule Conflicts with the Federal Exemption of 340B Drugs from Managed Care Rebates**

The preamble to the proposed rule states that AHCCCS is imposing this rule as a result of the Patient Protection and Affordable Care Act (PPACA), which required all state Medicaid programs, including AHCCCS, to participate in the federal drug rebate program. The preamble further states that 340B drugs are not eligible for rebates and that this prohibition is intended to protect manufacturers from paying two discounts on a drug – the 340B discount and the Medicaid rebate. Finally, the preamble explains that it is imposing this lower reimbursement rate in order to address the disparity between the actual acquisition cost of drugs subject to 340B pricing and the current reimbursement rate received from pharmacy benefit managers (PBMs).

Prior to PPACA, drugs furnished by Medicaid managed care plans were exempt from rebate requirements. PPACA extended Medicaid fee-for-service drug rebate requirements to Medicaid managed care. By imposing an obligation on states to collect rebates, PPACA created a new revenue stream for states. Importantly, 340B drugs were specifically exempted from this requirement and the new revenue stream for states.<sup>1</sup> The purpose of this exemption was not to

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<sup>1</sup> 42 USC 1396r-8(j)(1).

protect managed care organizations from duplicate discounts, as there is already language in the 340B statute prohibiting covered entities from requesting payment under Medicaid for 340B drugs. Rather, the intent was to protect 340B covered entities and the vulnerable patients they serve by exempting the 340B program from the new revenue stream created for the states. In this way, Congress preserved the existing status quo. States were not receiving revenue from 340B managed care drugs prior to PPACA, and the exemption ensured that they would not receive any such revenue as a result of PPACA. AHCCCS's proposal to mandate billing to managed care organizations at the 340B ceiling price conflicts with the federal exemption for 340B from the Medicaid managed care rebate requirements, and is therefore pre-empted by PPACA.<sup>2</sup>

This federal protection is consistent with Congressional intent with regard to the 340B program. Congress created the 340B program to enable safety-net providers to stretch their scarce resources so that they may "reach more patients" and furnish "more comprehensive services."<sup>3</sup> This purpose cannot be achieved if 340B covered entities have to pass on all of the savings they receive from third parties. The difference between a 340B drug's lower acquisition cost and standard non-340B reimbursement represents the very benefit that Congress intended to give providers when it established the 340B program. As discussed in a recent report by the Government Accountability Office (GAO), 340B providers are using the additional revenue they receive to further the program's purpose, such as by maintaining services and lowering medication costs for patients.<sup>4</sup> The GAO also reported that many covered entities do not generate enough revenue from the 340B program to offset drug related costs.<sup>5</sup> AHCCCS's proposal undermines the very nature of the 340B program and will result in fewer services and other assistance for vulnerable patient populations.

## **B. The Proposed Rule Interferes with Federal Requirements Governing Medicaid Managed Care Plans**

Imposing fee schedules that managed care organizations must follow may impermissibly interfere with federal statutory requirements. The provisions in the Medicaid statute that govern use of managed care arrangements specifically state that payment to managed care entities is to be made on a prepaid capitation basis.<sup>6</sup> The statute is clear that this involves the allocation of risk.<sup>7</sup> Under this model, states pay a prospective amount per recipient to the managed care

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<sup>2</sup> The U.S. Supreme Court recognizes that, pursuant to the Supremacy Clause of the Constitution, any state law that conflicts with a federal law is without effect. *Altria Group, Inc. v. Good*, 555 U.S. 70 (2008). Conflict exists when it is impossible to comply with both laws, or when the state law serves as an obstacle to accomplishing and executing Congressional objectives. *Edgar v. Mite Corp.*, 457 U.S. 624, 631 (1982)(quoting from *Florida Lime & Avacado Growers, Inc. v. Paul*, 373 U.S. 132, 142-123 (1963); *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941); and *Jones v. Rath Packing Co.*, 430 U.S. 519, 526, 549-541 (1977)).

<sup>3</sup> H.R. Rep. 102-384, pt.2, at 12 (1992).

<sup>4</sup> Drug Pricing Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement, GAO-1-836 (Sept. 2011).

<sup>5</sup> *Id.*

<sup>6</sup> 42 USCS §§ 1396b(m)(2)(A) and (m)(2)(A)(iii).

<sup>7</sup> *Id.*

organization in return for the organization providing all covered services to Medicaid recipients. In order for the managed care organization to furnish the care within the payment amount received, the organization must *manage* the recipients' care, which involves negotiating payment rates with providers, utilization review, etc.<sup>8</sup> By imposing reimbursement requirements on managed care companies, AHCCCS is interfering with the allocation of risk and the organization's obligation to manage enrollees' care, which conflicts with the federal requirements cited above.

### **C. The Proposed Rule Violates Federal Confidentiality Requirements, HRSA Guidance, and Requests Information that 340B Entities Currently Do Not Possess**

The proposed rule also contains a provision that requires 340B entities to "provide the 340B pricing file to the AHCCCS Administration upon request." This requirement violates federal confidentiality requirements, guidance issued by the Health Resources and Services Administration ("HRSA"), and copyright laws. Moreover, covered entities do not have access to any ceiling prices that they can be assured are accurate and are prohibited from sharing estimated ceiling prices they receive from wholesalers.

The 340B ceiling price is defined in Section 340B of the Public Health Services statute as "the maximum price that covered entities may permissibly be required to pay" for a 340B drug.<sup>9</sup> The ceiling price is calculated based on a drug's average manufacturer price and "best price," both of which are defined in section 1927 of the Social Security Act.<sup>10</sup> The Medicaid statute, the 340B pharmaceutical pricing agreement ("PPA"), and HRSA guidance all provide, with some variation, that the information disclosed by the manufacturer is confidential and prohibits disclosure of this information.<sup>11</sup> The Medicaid drug rebate statute, at Section 1927(b)(3)(D) of the Social Security Act, specifies that drug pricing information "shall not be disclosed by the

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<sup>8</sup> An exception to this general rule is found in §1903(m)(1)(A)(ix) of the Social Security Act, which requires managed care organizations to reimburse FQHCs no less than they would reimburse other providers for comparable services. The purpose of this provision is to mitigate the potential incentives managed care organizations have to underpay FQHCs, since states are required under federal law to pay the difference between the FQHC's Prospective Payment System (PPS) rate and the managed care organization's payment rate.

<sup>9</sup> 42 USC 256b(a)(1).

<sup>10</sup> 42 U.S.C. § 1396r-8(b)(3)(D). The "average manufacturer price" is defined as the average price paid by wholesalers for drugs distributed to retail community pharmacies and by retail community pharmacies that purchase drugs directly from the manufacturer. 42 U.S.C. § 1396r8(k)(1). The "best price" of a 340B medication is defined by statute as the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, non-profit entity, or governmental entity within the United States in any pricing structure under the manufacturer's pharmaceutical pricing agreement. 42 U.S.C. § 1396r-8(c)(1)(C).

<sup>11</sup> Guidance Regarding Section 602 of the Veterans Health Care Act of 1992 Limitation on Prices of Drugs Purchased by Covered Entities, 58 Fed. Reg. 27,289 (May 7, 1993), accord 42 U.S.C. § 1396r-8(b)(3)(D); OPA, Pharmaceutical Pricing Agreement, <ftp://ftp.hrsa.gov/bphc/pdf/opa/pricingagreement.pdf> (last visited March 23, 2011). <https://www.cms.gov/MedicaidDrugRebateProgram/downloads/rebateagreement.pdf> (last visited March 23, 2011). Although AMP has been confidential in the past, we recognize that the Deficit Reduction Act of 2005 directed the Centers for Medicare & Medicaid Services ("CMS") to make AMP available to the public. Until December 2010, an injunction had been in place preventing CMS from finalizing its rule to make AMP public. Once CMS finalizes new AMP guidance pursuant to the Affordable Care Act, AMP may be available to the public. Nevertheless, the remaining components of the 340B ceiling price are confidential.

[Government] . . . in a form which discloses the identity of a specific manufacturer or wholesaler, [or] the prices charged for drugs” except as necessary to carry out the provisions of the Act or for certain other limited purposes, including the Medicaid rebate program.<sup>12</sup> HRSA has taken the position that 340B ceiling prices could be considered this type of “form” that would reveal manufacturers’ prices. In line with this reasoning, HRSA has interpreted this provision to mean that covered entities may not disclose 340B ceiling prices.<sup>13</sup> Pharmaceutical manufacturers rely on this guidance and are quick to take action when they believe their calculated 340B ceiling prices have been improperly disclosed.

We are aware that, pursuant to PPACA, the Department of Health and Human Services (HHS) is required to make 340B ceiling prices available to covered entities on a password-protected website.<sup>14</sup> Nothing in PPACA, however, authorizes a covered entity to disclose its 340B prices to a payer. Likewise, there is nothing in the Medicaid statute, PPA, or HRSA guidance that establishes an exception to 340B confidentiality standards when a covered entity bills its 340B drugs. Therefore, mandating disclosure of ceiling prices violates federal law.

In addition, covered entities currently do not have access to this information. The pricing information from manufacturers that is necessary to calculate the ceiling price is not publicly available. It is for this reason that PPACA included language requiring that HHS make ceiling prices available to covered entities, as there is currently no way for them to determine whether they are being charged the correct 340B ceiling price. Covered entities must rely on 340B price lists that are published by wholesalers, though there is no way for them to evaluate whether the price on the list truly represents the 340B ceiling price. Such lists, however, are not available to the public and wholesalers and manufacturers have not authorized covered entities to disclose this information. Manufacturers consider such information to be proprietary and object to the sharing of such information.

#### **D. AHCCCS Should Evaluate the Potential Savings to be Gained by Sharing a Higher Percentage of the 340B Discount with Covered Entities**

The proposed rule sets a dispensing fee for 340B drugs of \$8.75. We have been told that this rate is well below the cost of dispensing for the vast majority of covered entities affected by the proposed rule. As mentioned above, the GAO recently found that covered entities use the savings from the 340B discount to maintain services and lower medication costs for patients, though for many, savings from the 340B program is insufficient to cover drug related costs. Lowering reimbursement to cost and establishing a below-cost dispensing fee could have a catastrophic impact on these covered entities and their patients. It is also likely to lead to less

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<sup>12</sup> § Social Security Act § 1927(b)(3)(D), 42 U.S.C. § 1396r-8(b)(3)(D).

<sup>13</sup> Guidance Regarding Section 602 of the Veterans Health Care Act of 1992 Limitation on Prices of Drugs Purchased by Covered Entities, 58 Fed. Reg. 27,289 (May 7, 1993). We recognize that AAC of a 340B drug might include a wholesaler markup or delivery charge if purchased directly from a manufacturer. Since such add-ons are small and standardized, a payer could easily deduce the 340B price by subtracting any adjustments.

<sup>14</sup> Patient Protection and Affordable Care Act (“PPACA”), P.L. 111-148, 111<sup>th</sup> Congress § 7102(a), 124 Stat. 119 (2010).

savings for AHCCCS than could be achieved with a dispensing fee that was closer to covered entities' true costs.

The Office of the Inspector General (OIG) recently issued a report evaluating State Medicaid policies related to the 340B-purchased drugs.<sup>15</sup> The OIG concluded that many states misunderstand federal policy regarding 340B billing and that states could save money through shared savings arrangements with covered entities even if the state paid such entities higher dispensing fees.<sup>16</sup> By requiring covered entities to bill their actual acquisition cost (AAC), Medicaid agencies are leading nearly 60 percent of covered entities to carve-out their Medicaid drugs from 340B purchases.<sup>17</sup> When a covered entity carves-out, it does not have access to the 340B discount and Medicaid pays its standard reimbursement rate for the drugs and the state receives only the Medicaid rebate as its discount. Typically, the 340B price is significantly lower than the standard Medicaid rate after rebate, therefore, as a result of the AAC billing policies, States are foregoing higher discounts on drugs than they currently receive through the rebate program. Covered entities carve-out in these situations because the dispensing fee associated with the AAC payment rate is much lower than the covered entities' actual cost to dispense the drug, resulting in a significant loss when dispensing 340B drugs.

Recognizing the potential for higher drug savings, some states have developed reimbursement policies that set payment levels to encourage covered entities to use 340B drugs for their Medicaid patients. In this way, states and providers share the spread between the 340B discount and the standard Medicaid reimbursement rate. These "shared savings" policies result in a win-win for both state Medicaid programs and covered entities.

For example, Massachusetts took steps in 2007 to increase its payment for 340B drugs with the goal of encouraging covered entities to carve-in to Medicaid. By offering an enhanced dispensing fee for 340B retail drugs of \$10.00, Massachusetts Medicaid dramatically increased the number of providers carving in their 340B drugs. When Massachusetts began looking into this issue in 2002, only three covered entities carved-in to Medicaid.<sup>18</sup> By 2010, the carve-in rate for DSH was over 75%, representing 68 registered sites.<sup>19</sup> As a result, Massachusetts netted \$6.5 million in additional revenue in 2010 alone.<sup>20</sup> Importantly, Massachusetts used its shared savings arrangement to improve access to lifesaving medications for the state's low-income population.<sup>21</sup>

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<sup>15</sup> State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs (OEI-05-09-00321)(OIG Report) (June 2011)

<sup>16</sup> *Id.* at pgs 9 & 16.

<sup>17</sup> OIG Report, p. 4.

<sup>18</sup> Presentation by Diane Goyette, Medicaid Billing and Reimbursement: Evolution of Shared Savings, 340B Coalition Conference, July 13, 2011.

<sup>19</sup> Health Res. and Servs. Admin. Office of Pharmacy Affairs Covered Entity Database, <http://opanel.hrsa.gov/opa/CE/CEExtract.aspx> (last visited May 19, 2011).

<sup>20</sup> See Presentation by Diane Goyette, Medicaid Billing and Reimbursement: Evolution of Shared Savings, 340B Coalition Conference, July 13, 2011.

<sup>21</sup> *Id.*

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AHCCCS has the opportunity to establish a win-win situation with 340B entities in Arizona. Failure to do so is likely to result in some covered entities having to close their doors and other covered entities opting to carve-out their 340B drugs from Medicaid. Both situations result in lower savings for AHCCCS and potentially irreversible harm to the patients served by these covered entities. We strongly encourage AHCCCS to revisit the amount of the dispensing fee and to set the rate at a level that more closely reflects the true dispensing costs of the covered entities affected by this proposed rule.

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We appreciate the opportunity to submit these comments. Should you have any questions, please feel free to contact William von Oehsen, SNHPA General Counsel at [william.vonoehsen@snhpa.org](mailto:william.vonoehsen@snhpa.org) or 202-872-5890 or Maureen Testoni, SNHPA Assistant General Counsel at [maureen.testoni@snhpa.org](mailto:maureen.testoni@snhpa.org) or 202-552-5851.

Sincerely,

The Hemophilia Alliance  
National Association of Community Health Centers  
National Association of Public Hospitals and Health Systems  
National Family Planning and Reproductive Health Association  
National Health Care for the Homeless Council, Inc.  
National Rural Health Association  
Safety Net Hospitals for Pharmaceutical Access