

March 24, 2017

The Honorable Douglas A. Ducey  
Governor of the State of Arizona  
1700 West Washington  
Phoenix, Arizona 85007

Dear Governor Ducey:

Laws 2016, Chapter 122, Section 11, includes the following requirement related to 340B drug pricing:

*“On or before November 1, 2016, the administration shall report to the governor, the president of the senate, the speaker of the house of representatives and the joint legislative budget committee regarding the technological feasibility and costs of applying this section to licensed hospitals and outpatient facilities that are owned or operated by a licensed hospital”*

### **Background**

Administered by the Health Resources and Services Administration (HRSA), the 340B program allows certain organizations (“covered entities”) to register and receive reduced-price outpatient drugs. Section 340B(a)(4) of the Public Health Service Act establishes the eligibility requirements for covered entities. These include Federally-Qualified Health Centers (FQHCs), certain types of clinics, and six types of hospitals (Children’s, Critical Access, Disproportionate Share, Freestanding Cancer, Rural Referral and Sole Community).<sup>1</sup> Entities must register with HRSA and agree to the requirements of the program. In addition, Medicaid may not receive a drug rebate on drugs purchased through the 340B program (known as a prohibition on “duplicate discounts”).

In addition, 340B covered entities may only purchase the 340B drugs at discounted prices for patients with whom they have an established relationship and for whom they maintain records of their health care.<sup>2</sup> Thus, there may be, in limited cases, scenarios in which a 340B entity may not be able to receive a drug on the 340B pricing file at the 340B price.

### **AHCCCS Reimbursement**

Beginning in 2011, AHCCCS limited reimbursement to FQHC pharmacies for 340B drugs to the 340B price, plus a dispensing fee of \$8.75 (which is higher than the standard dispensing fee of \$1.25).<sup>3</sup>

Laws 2016, Chapter 122, Section 11 requires AHCCCS, beginning on January 1, 2017, or upon CMS approval, to reimburse for drugs identified in the 340B pricing file and dispensed by 340B covered entities or administered by 340B covered entity providers at the 340B price plus a professional fee, regardless of whether or not the drugs are purchased under the 340B pricing program. AHCCCS is working to implement these requirements. Hospitals and outpatient facilities owned or operated by

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<sup>1</sup> <http://www.hrsa.gov/opa/eligibilityandregistration/index.html>

<sup>2</sup> <http://www.hrsa.gov/opa/programrequirements/federalregisternotices/patientandentityeligibility102496.pdf>

<sup>3</sup> A.A.C. R9-22-710(C)

hospitals are exempt from this requirement, but AHCCCS is required to report on the feasibility of applying this requirement to these entities.

AHCCCS used an external consultant, Magellan, to analyze the current hospital-related spend on prescription drugs and reprice those claims and encounters to reflect a maximum payment of the 340B ceiling price. This analysis was complex and required the conversion of the utilization reported on claims and encounters to the units used to report 340B pricing through HRSA because the HRSA pricing file does not match the standard pharmacy reference sources used by PBMs and AHCCCS to adjudicate claims and encounters.

Magellan’s analysis found that these changes could reduce spending on the ingredient cost of the drugs by approximately \$18.5 million in Total Funds annually. However, AHCCCS then must calculate a dispensing fee to cover the costs associated with preparing and dispensing the medication. The current AHCCCS dispensing fee for non-340B drugs is \$1.25; the current dispensing fee for 340B drugs is \$8.75.<sup>4</sup> The increased dispensing fee costs of shifting these drugs to 340B pricing is \$1.6 million, for a net total impact of the shift of approximately \$17 million in Total Funds.<sup>5</sup> Of this amount, approximately \$2.7 million would be from the state General Fund, and the remainder would be from federal and other funding sources. However, due to federal regulations as described below, AHCCCS believes any reductions achieved by moving to 340B pricing would need to be offset with some other rate increase to assure continued access to care for AHCCCS members.

Below is a table that displays the estimated impact of the ingredient pricing changes by hospital:

Hospital	Total Funds Saving on Ingredient Cost
Banner Casa Grande Medical Center	\$147,124
Banner Desert Medical Center	\$894,991
Banner Estrella	\$190,691
Banner Gateway	\$773,588
Banner Ironwood	\$90,114
Banner Thunderbird Medical Center	\$1,006,459
Banner University Medical Center - South	\$1,641,778
Banner University Medical Center - Tucson	\$3,300,788
Canyon Vista Medical Center	\$135,646
Cobre Valley Regional Medical Center	\$100,882
Dignity Health Hospitals	\$865,413

<sup>4</sup> The dispensing fee is set higher for 340B purchased drugs in order to compensate for the portion of ingredient cost reimbursements that typically cover part of the cost of dispensing.

<sup>5</sup> In addition, CMS has recently required states to do a comprehensive survey of dispensing fees and adopt a dispensing fee that approximates the market dispensing fee. When AHCCCS conducted this analysis for 340B drugs, the calculated market dispensing fee was \$10.11. A shift to this higher dispensing fee would mean the net impact of the 340B shift for hospitals and outpatient facilities would be \$16.7 million.

Emergency Group of Arizona Professional	-\$51
Fastrax Urgent Care (Kingman Regional Medical Center)	\$312,067
Holy Cross Hospital (formerly Carondelet)	\$41,319
Honor Health Hospitals	\$230,917
La Paz Regional Hospital	\$115,988
Maricopa Integrated Health Systems	\$1,993,549
Mt Graham Regional Medical Center	\$56,501
Northern Arizona Healthcare (Flagstaff Medical Center)	\$110,855
Northern Cochise Community Hospital	\$132
Phoenix Children's Hospital	\$5,200,232
San Luis Walk-in Clinic	\$21
St Joseph's Hospital (formerly Carondelet)	\$30,207
St Mary's Hospital (formerly Carondelet)	\$135,393
Summit Healthcare Regional Medical Center	\$507,386
Tucson Medical Center	\$118,733
Verde Valley Medical Center	\$21,871
Wickenburg Community Hospital	\$10,494
Winslow Memorial Hospital (dba Little Colorado MC)	\$3,716
Yavapai Community Hospital	\$203,367
Yuma Regional Medical Center	\$325,617
<b>TOTAL</b>	<b>\$18,565,788</b>

Several hospitals have developed estimates of the impact of this shift that are significantly higher than the figures presented above. AHCCCS has not been able to reconcile the difference between its estimates and the hospitals'. However, AHCCCS does acknowledge that due to the extreme lack of transparency in pharmacy acquisition costs, it is challenging to develop reliable estimates of the impact, and the actual impacts on hospitals could be higher. In addition, hospitals have noted the significant administrative cost of implementing these changes and report that in other markets, similar changes have resulted in hospitals leaving the 340B program.

**Access to Care Implications**

Statutory requirements in section 1902(a)(30)(A) of the Social Security Act direct the State to have “methods and procedures . . . to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.” In addition, states are required to assure their managed care organizations have a network adequate to serve the needs of their members.

42 CFR § 447.203 requires AHCCCS to develop an access monitoring review plan beginning in 2016 for the fee-for-service population and to update the plan by July of each subsequent year. The regulation also requires AHCCCS to complete an analysis of the data specified in the access monitoring review plan,

beginning in 2016, with a separate analysis of any services for which the state proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access to care. A shift in pharmaceutical pricing methodologies to limit reimbursement to the 340B price would require AHCCCS to demonstrate that this reduction in revenue would not diminish access to care.

In 2014, AHCCCS retained an independent consultant to complete a separate hospital-focused access to care study. This report, *Arizona Medicaid Access to Hospital Care – 2014 Evaluation*, is available on the AHCCCS website. Hospital reimbursement is 16-20% below 2009 rates, and the evaluation noted that AHCCCS rates have been pushed to the low end of pay-to-cost ratios compared to other states. The evaluators warned about the potential for further reductions to impact access. AHCCCS has also expressed significant concern about further reductions to hospital and other provider rates and the potential impact on access to care and our ability to meet federal requirements to ensure access. In addition, AHCCCS has been monitoring and adjusting rates for high-acuity pediatric services because of access concerns, and the hospitals that provide those services are among those with the highest impacts for a potential 340B change. Therefore, if the 340B reduction was implemented, AHCCCS would need to increase hospital reimbursement rates in some other offsetting manner to ensure continued access.

### **Conclusion**

Given the administrative complexity of implementing these changes and given the documented concerns about further reductions to hospital reimbursement, AHCCCS does not believe there are fiscal savings associated with limiting 340B hospital pharmacy reimbursement policies to 340B prices.

Sincerely,



Beth Kohler  
Deputy Director

cc: The Honorable Steve Yarbrough, Senate President  
The Honorable J.D. Mesnard, Speaker of the House of Representative  
The Honorable Debbie Lesko, Arizona State Senate  
The Honorable Don Shooter, Chairman, Joint Legislative Budget Committee  
Lorenzo Romero, Governor's Office of Strategic Planning and Budgeting  
Bret Cloninger, Governor's Office of Strategic Planning and Budgeting  
Christina Corieri, Governor's Office, Senior Policy Advisor  
Richard Stavneak, Director, Joint Legislative Budget Committee