



**Center for Medicaid and CHIP Services**

**Disabled and Elderly Health Programs Group**

March 9, 2012

Tom Betlach, Director  
Arizona Health Care Cost Containment System  
801 East Jefferson Street  
Phoenix, AZ 85034

Dear Mr. Betlach:

I am responding to your request to approve Arizona State Plan Amendment (SPA) 11-015, received in the Regional Office on August 31, 2011. This proposed SPA would implement a change to Medicaid reimbursement for 340B drugs furnished by Federally Qualified Health Centers (FQHC) and FQHC Look-Alikes at the lesser of charges billed to the State by the FQHC or FQHC Look-Alike or the 340B ceiling price, with a dispensing fee of \$8.75.

Section 340B of the Public Health Services Act, 42 U.S.C. § 256b, “imposes ceilings on prices drug manufacturers may charge for medications sold to specified health care facilities,” including FQHCs and FQHC look-alikes. *Astra USA, Inc. v. Santa Clara County*, 131 S. Ct. 1342, 1345 (2011). The 340B program requires manufacturers to enter into a Pharmaceutical Pricing Agreement (PPA) with the Secretary of Health and Human Services. Under the 340B program and in accordance with the PPA, pharmaceutical manufacturers agree to charge at or below statutorily defined prices, known as the 340B ceiling prices, for sales to qualified 340B entities. The Health Resources Services Administration (“HRSA”) oversees the 340B Program, which includes monitoring the PPA. Participation in the 340B program is voluntary; eligible entities must notify HRSA of their intention to participate by completing appropriate registration forms. Upon receipt and approval of the forms, HRSA adds the entity to its covered entity database, which is available on HRSA’s web site. The 340B entity is responsible for alerting wholesalers and manufacturers of its participation and referring them to the database for confirmation so it can purchase covered outpatient drugs at or below the ceiling prices.

The SPA proposed by Arizona would limit Medicaid reimbursement for prescription drugs furnished by FQHCs and FQHC Look-Alikes to the lesser of billed charges or the 340B ceiling price, with a \$8.75 dispensing fee. The current State plan pays FQHCs and FQHC Look-Alikes at the Medicaid payment rate, although FQHCs and FQHC Look-Alikes are eligible to purchase pharmaceuticals at substantial discounts under the 340B Program that are not available to all pharmacies.

While we review proposed SPAs to ensure their consistency with the relevant provisions of the Social Security Act (the Act), we conducted our review of your submittal with particular attention to the statutory requirements at section 1902(a)(30)(A) of the Act (“Section 30(A)"). Section 30(A) of the Medicaid Act requires that State plans contain “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.” 42 U.S.C. § 1396a(a)(30)(A). As we explain in greater detail below, we find that the State’s submission is consistent with the requirements of the Act, including those set forth in section 1902(a)(30)(A).

States must submit information sufficient to allow CMS to determine whether a proposed amendment to a State plan is consistent with the requirements of section 1902 of the Act. However, consistent with the statutory text, CMS does not require a State to submit any particular type of data, such as provider cost studies, to demonstrate compliance. See Proposed Rule, Dep't of Health & Human Servs., Ctrs. For Medicare & Medicaid Servs., 76 Fed. Reg. 26342, 26344 (May 6, 2011). Rather, as explained in more detail in the May 6, 2011 proposed rule, CMS believes that the appropriate focus of section 1902(a)(30)(A) is on beneficiary access to quality care and services. CMS has followed this interpretation for many years when reviewing proposed SPAs.<sup>1</sup>

This interpretation--which declines to adopt a bright line rule requiring the submission of provider cost studies--is consistent with the text of Section 30(A) for several reasons. First, Section 30(A) does not mention the submission of any particular type of data or provider costs; the focus of the Section is instead on the availability of services generally. Second, the Medicaid Act defines the "medical assistance" provided under the Act to mean "payment of *part* or all of the cost" of the covered service. See 42 U.S.C. § 1396d(a) (emphasis added). Third, when Congress has intended to require states to base Medicaid payment rates on the costs incurred in providing a particular service, it has said so expressly in the text of the Act. For example, the now-repealed Boren Amendment to the Medicaid Act required states to make payments based on rates that "are reasonable and adequate to meet the costs which must be incurred by efficiently and economically operated facilities." 42 U.S.C. § 1396a(a)(13)(A). By contrast, Section 30(A) does not set forth any requirement that a state consider costs in making payments. Finally, CMS observes that several federal courts of appeals have interpreted Section 30(A) to give States flexibility in demonstrating compliance with the provision's access requirement and have held that provider costs need not always be considered when evaluating a proposed SPA. See *Rite Aid of Pa., Inc. v. Houstoun*, 171 F.3d 842, 853 (3d Cir. 1999); *Methodist Hosps., Inc. v. Sullivan*, 91 F.3d 1026, 1030 (7th Cir. 1996); *Minn. Homecare Ass'n v. Gomez*, 108 F.3d 917, 918 (8th Cir. 1997) (per curiam). These decisions suggest that CMS's interpretation of Section 30(A) is a reasonable one. In this respect, CMS's interpretation differs from that first adopted by the Ninth Circuit in *Orthopaedic Hosp. v. Belshe*, 103 F.3d 1491, 1496 (9th Cir. 1997), which established a bright line rule requiring a State to rely on "responsible cost studies, its own or others', that provide reliable data as a basis for its rate setting."<sup>2</sup>

CMS's interpretation does not, of course, *prevent* states or CMS from considering provider costs. Indeed, we recognize that for certain proposed SPAs, such as the SPA at issue here, provider cost information may be useful to CMS as it evaluates proposed changes to payment methodologies. This is in part because, under the authority of section 1902(a)(30)(A), the Secretary has issued regulations prescribing the state rate setting procedures and requirements for covered outpatient drugs. Longstanding requirements in Federal regulations, presently codified at 42 C.F.R. § 447.512, provide that payments for drugs are to be based on ingredient costs of the drug (calculated based on estimated acquisition costs) and a reasonable dispensing fee. When federal regulations expressly base payment rates for a particular service on costs, CMS believes it is reasonable to consider costs as part of the SPA approval process. Moreover, CMS believes that costs are relevant here to the statutory factors of efficiency and economy, as the proposed SPA ensures that FQHCs and FQHC Look-Alikes are not paid substantially in excess of their costs. Because we recognize the substantial discounts that these providers receive as a result of their participation in the 340B program and the limits of what drug manufacturers may charge 340B entities, there is no basis for us to conclude that the proposed SPA would diminish access or quality of care.

In addition, the State furnished documentation and supplemental information which CMS evaluated in the course of its SPA review. In particular, CMS relied on the following factors identified by the State as justification for the proposed SPA's compliance with section 1902(a)(30)(A)'s access requirement:

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<sup>1</sup> See, e.g., Br. of the United States as Amicus Curiae, *Douglas v. Independent Living Ctr.*, No. 09-958, at 9-10 (2010); Br. of United States as Amicus Curiae, *Belshe v. Orthopaedic Hosp.*, 1997 WL 33561790, at \*6-\*12 (1997).

<sup>2</sup> CMS also reserves the right to insist on cost studies to show compliance with Section 30(A) in certain limited circumstances – particularly when considering a SPA that involves reimbursement rates that are substantially higher than the cost of providing services, thus implicating concerns about efficiency and economy.

- The State met with FQHC providers, issued a Public Notice and Consultation Meeting with Tribes, and obtained assurances that pharmacy providers will continue to provide services to the Medicaid enrollees.
- The State’s payment methodology is based on the actual costs for 340B drugs calculated in accordance with section 340B of the Public Health Service Act. The calculation for the 340B ceiling price for Medicaid-covered outpatient drugs is determined by subtracting the Unit Rebate Amount (URA) from the Average Manufacturer Price (AMP), consistent with the statutory pricing formula for the 340B Drug Pricing Program. The maximum amount paid for the Medicaid-covered outpatient drug would be the lesser of the billed charges or the 340B ceiling price. In accordance with the 340B Program, drug manufacturers participating in the Medicaid Drug Rebate Program are required to provide covered outpatient drugs to certain health care entities, including FQHC and FQHC Look-Alikes, at or below 340B ceiling prices. The State’s proposed payment is consistent with the 340B payment rates provided by drug manufacturers under the 340B Program.
- By reimbursing FQHC and FQHC Look-Alikes at the lesser of billed charges or the 340B ceiling price, the possibility of duplicate discounts for drugs dispensed through the 340B program would be reduced. In accordance with section 1927(a)(5) of the Act and section 340B of the Public Health Service Act, States may not seek Medicaid rebates for discounted drugs provided to covered entities under the 340B program. This proposal would ensure compliance with these provisions and with the recommendations in the June 2011 Office of Inspector General report, “State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs” (OEI-05-09-003621) that States develop methods to identify 340B claims.
- The State supplied documentation for the increased dispensing fee based on the 340B dispensing fees in use or proposed for other State agencies, including Florida, Louisiana, Massachusetts, and West Virginia. These States have established payment for 340B drugs based on the rates established in the 340B Program. The State also provided and relied on a cost study report entitled, “Development and Testing of a Prescription Drug Benefit Reimbursement Methodology for South Carolina Medicaid,” as well as a CMS published chart entitled, “Medicaid Prescription Reimbursement Information by State – Quarter Ending March 2010” that details dispensing fee reimbursement. The State converted the dispensing fees paid by these other State Medicaid agencies for 340B purchased drugs to an Arizona-equivalent dollar amount using the Medicare Geographic Practice Cost Indices. The median value was determined and an inflation factor from the Bureau of Labor Statistics was applied to inflate the result from April 2010 to September 2011.

Data concerning these payment rates were submitted to ensure access for State Fiscal Years (SFY) 2012 and 2013.

Applying our interpretation of section 1902(a)(30)(A) to your proposed SPA, we believe that the data the State has provided is sufficient to support its proposed payment change. Although section 1902(a)(30)(A) of the Act does not require States to base payment rates on the costs incurred by providers, this payment proposal is designed to provide payment based on the actual costs of the drugs subject to this proposed plan amendment. In accordance with section 1927 of the Act and section 340B of the Public Health Service Act, entities that participate in the 340B program are entitled to receive drugs at the 340B ceiling price – the ceiling rate at which such drugs would be paid under this proposed plan amendment. In addition, consistent with studies submitted by the State, the increased dispensing fee would reasonably cover the costs of dispensing. When a State is considering adjusting payment rates, we believe that it is reasonable for States to consider payment rates that we have approved in other State plans. See 72 Fed. Reg. 39142, 39161 (July 17, 2007). In formulating its proposed dispensing fee for 340B entities, Arizona relied on payment rates that we have approved for Florida, Massachusetts, West Virginia, and Louisiana. To reach its proposed dispensing fee of \$8.75, Arizona used

Medicare Geographic Practice Cost Indices to adjust those rates for difference in regional costs, averaged them, and then adjusted for inflation. We believe the resulting proposal of \$8.75 is a reasonable amount.<sup>3</sup>

Accordingly, we believe the State plan, as modified by the proposed SPA, will be consistent with the access requirement under section 1902(a)(30)(A) of the Act. In particular, the State has obtained assurances that the modified rate, coupled with the increased dispensing fees, should cover the costs of providing these drugs to Medicaid beneficiaries and ensure continued access.

We also conclude that the proposed SPA is consistent with the efficiency and economy requirements in section 1902(a)(30)(A) of the Act. We have generally considered a proposed payment rate as being inefficient or uneconomical if it was substantially above the cost of providing covered services. *See Pa. Pharmacists Ass'n v. Houstoun*, 283 F.3d 531, 537 (3d Cir. 2002) (“What sort of payments would make a program inefficient and uneconomical? Payments that are *too high*.”). For this reason we do not believe that it is appropriate for States to address potential access concerns by setting rates unreasonably high in relation to costs—such rates would necessarily be neither efficient nor economical. Consistent with this view, HHS has promulgated Upper Payment Limit (“UPL”) regulations that “place an upper limit on overall aggregate payments” for certain types of services. 65 Fed. Reg. 60151-01. As these provisions reflect, we believe that States must balance access concerns with efficiency and economy concerns. Applying our interpretation of the statute to the proposed SPA at issue here, we believe that paying actual acquisition cost for the ingredient plus a reasonable dispensing fee is both economical and efficient, as doing so ensures that providers are not paid substantially in excess of their costs.

Furthermore, we conclude that that the proposed payment methodology is consistent with the quality of care requirement in section 1902(a)(30)(A) of the Act. CMS does not interpret section 1902(a)(30)(A) of the Act as requiring a State plan by itself to ensure quality of care. As the text of the statute reflects, payments must be “consistent” with quality of care, but they do not need to directly assure quality of care by themselves. CMS therefore believes that Section 30(A) leaves room to rely on factors external to a State plan to ensure quality of care. In this particular instance, for example, CMS relies on applicable statutes and regulations, including those promulgated by the Food and Drug Administration, to ensure the quality of covered outpatient drugs provided through the Medicaid program. CMS believes that it is reasonable to assume that covered outpatient drugs provided to Medicaid patients through pharmacies at 340B entities will continue to meet FDA quality standards. *But see Orthopaedic*, 103 F.3d at 1497 (“The Department, itself, must satisfy the requirement that the payments themselves be consistent with quality care.”).

Finally, the State’s implementation of these payment rates on February 1, 2012, was permissible under the Medicaid statute and our regulations, as set forth in 42 C.F.R. § 430.20 and 42 C.F.R. § 447.256. Those regulations provide that a State may implement amendments to its State plan prior to CMS approval. *See* Letter Br. of the United States as Amicus Curiae, *Douglas v. Independent Living Ctr.*, No. 09-958, at 7 (Nov. 11, 2001). Consistent with those provisions, a SPA that is approved may become effective as early as the first day of the quarter in which the amendment is submitted; however, Federal Financial Participation is not available until the SPA is approved. (We note that annual appropriations statutes make Federal Financial Participation available as of the first day of the quarter in which a SPA is submitted.)<sup>4</sup>

Based on the foregoing, we believe the State has demonstrated 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

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<sup>3</sup> The State also submitted a study conducted in South Carolina that suggested a reasonable dispensing fee was between \$8.00 and \$10.00. While the study surveyed pharmacies in South Carolina, the study indicates that the results were consistent with other studies that have examined dispensing costs nationwide. The proposed dispensing fee is within this range and is consistent with the dispensing fees that have been adopted by other States that pay 340B entities at actual acquisition cost.

<sup>4</sup> *See, e.g.*, P.L. 110-161, Division G – Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2008, Title II – Department of Health and Human Services (H.R. 2764, Consolidated Appropriations Act, 2008)(“Payment under title XIX may be made for any quarter with respect to a State plan or plan amendment in effect during such quarter, if submitted in or prior to such quarter and approved in that or any subsequent quarter.”).

under the plan at least to the extent that such care and service are available to the general population in the geographic area.

Because we find that this amendment complies with all applicable requirements, we are pleased to inform you that the Arizona SPA 11-015 is approved, effective February 1, 2012. A copy of the CMS-179 form, as well as the pages approved for incorporation into the Arizona State Plan will be forwarded by the San Francisco Regional Office. If you have any questions regarding this approval, please contact Terry Simananda (410) 786-8144.

Sincerely,

/s/

Larry Reed  
Director  
Division of Pharmacy

cc: Monica Coury, Arizona Health Care Cost Containment System  
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