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May 19, 2016

Captain Krista Pedley
Director, Office of Pharmacy Affairs (OPA)
Health Resources and Services Administration
5600 Fishers Lane, Mail Stop 08W05A
Rockville, Maryland 20857

Submitted via www.regulations.gov

Subject: RIN 0906- AA89: Concerns re: Potential Alternatives to "Penny Pricing"

Dear Captain Pedley:

Bi-State Primary Care Association is pleased to respond to the reopened comment period on the Notice of Proposed Rulemaking regarding Ceiling Prices and Manufacturer Civil Monetary Penalties under the 340B program.

Established in 1986, Bi-State is a nonpartisan, nonprofit 501(c)(3) charitable organization that promotes access to effective and affordable primary care and preventive services for all, with special emphasis on underserved populations in Vermont and New Hampshire. Bi-State works with federal, state and regional health policy organizations, foundations and payers to develop strategies, policies and programs that provide and support community-based primary health care services in medically-underserved areas. Our members include Community Health Centers, which include Federally Qualified Health Centers (hereafter interchangeably referred to as Health Centers or FQHCs); Rural Health Clinics; private and hospital-supported primary care practices; Community Action Programs; Health Care for the Homeless programs; Area Health Education Centers; Clinics for the Uninsured, and social service agencies.

A fundamental characteristic of FQHCs is their commitment to serve all individuals, regardless of their insurance status or ability to pay. Nationally, over 70% of Health Center patients live below the poverty line; if these individuals are uninsured, they pay no more than a nominal fee to receive the full range of FQHC services. An additional 20% of FQHC patients are between 100% and 200% of the poverty line; if uninsured, these patients are generally charged reduced fees based on a sliding scale. 47% of Health Center patients are on Medicaid; 28% are uninsured, although these percentages can vary enormously across individual states, due to local and state conditions (including, but not limited to, whether the state has expanded Medicaid to the 0-133% FPL population). Some states report uninsured rates as high as 54%.

In Vermont and New Hampshire, FQHCs are part of the essential primary care fabric and health care ecosystem. Collectively, our Health Centers serve over 236,000 patients in underserved communities across our two states. The 340B program is essential to the Vermont and New Hampshire FQHCs; allowing them to provide affordable pharmacy services to their patients. FQHCs are the classic example of the type of safety net provider that the 340B program was intended to support and savings from 340B are a fundamental portion of FQHCs' budgets and are critical to their ability to sustain ongoing operations.

In addition to our comments, we fully endorse the National Association of Community Health Center's (NACHC) letter that will be submitted before the deadline. With NACHC's permission, our letter parallels their comments and concerns.

We begin with a summary of our comments, and then address each one individually.

Summary of Bi-State Primary Care Association's Comments on Alternatives to "Penny Pricing"

Bi-State Primary Care Association is very concerned that HRSA/OPA is seeking comments on potential alternatives to its long-standing "penny-pricing" strategy, because:

1. Any alternative to penny pricing would directly violate the ceiling price formula established in statute, and exceed the minimum price that might be necessary for legal and practical purposes.
2. Any alternative to penny pricing would reward manufacturers for raising prices faster than inflation.
3. Any alternative to penny pricing directly contradicts the intent of the 340B program, by increasing costs for FQHCs and other covered entities.
4. Manufacturers are already permitted to implement distribution plans that ensure that covered entities do not purchase inappropriate quantities of penny-priced drugs.

Specific Comments:

1. Any alternative to penny pricing would directly violate the ceiling price formula establish in statute, and exceed the minimum price that might be necessary for legal and practical purposes.

Section (a)(1) of the 340B statute requires that the 340B price for a covered outpatient drug:

> "does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2)."

In other words, the 340B ceiling price may not exceed the Average Manufacturers Price minus the Unit Rebate Amount (AMP – URA = maximum ceiling price).

Paragraph (2) refers to the unit rebate percentage outlined in Section 1927(c). As you are aware, this section includes an "inflationary penalty," which causes the rebate percentage to increase when a manufacturer increases the price of a brand-name drug faster than inflation. Because of this penalty, if a drug's price increases significantly faster than inflation, the rebate amount can equal or exceed the average manufacturers' price (AMP). In these situations, the statutory formula yields a ceiling price that is at or below zero.

To avoid setting ceiling prices below zero, Section 1927(c)(2)(D) of the Social Security Act limits the URA to 100% of the AMP. Thus, 340B for drugs whose regular price has increased significantly faster than inflation, the statutory formula yield a price of zero (if URA = AMP, then AMP – URA = 0).

Bi-State recognizes that there are legal and practical reasons that prevent manufacturers, distributors, and covered entities from transferring drugs with a zero price under a contract[1]. To balance these concerns with the statutory requirement for a zero price, HRSA/OPA has had a long-standing policy of charging the minimum price feasible – namely, one penny per unit. While technically the one-penny rule is inconsistent with the statutory requirement

[1]In Release No, 2011-2, HRSA stated that "it is not reasonable for a manufacturer to set a zero 340B ceiling price" but did not explain why. Our understanding is that is because sales contracts are only binding if both sides give something of value. If a drug were provided for free, then the seller would not be providing anything of demonstrable value. Therefore, a minimum price – one penny per unit – is necessary for the contracts to be legally enforceable.

for a zero price, it has been an appropriate balance between 340B statutory requirements and the legal and practical concerns around sales contracts.

However, any policy that would impose a price greater than one penny for drugs whose URA exceeds AMP would directly contradict the statute, without providing any legal or practical benefit that is necessary for the program to function as intended. Therefore, if HRSA/OPA does permit higher ceiling price on these drugs, we request an explanation of the statutory authority which they believe allows this policy.

2. Any alternative to penny pricing would reward manufacturers for raising prices faster than inflation.

The inflationary penalty used to calculate the URA was intentionally established by Congress to discourage manufacturers from raising the price of drugs faster than inflation. In the past six years, Congress has twice updated the Medicaid rebate formula, which contains this penalty – first in the Affordable Care Act in 2010 and then in the Bipartisan Budget Act of 2015. Both times, Congress demonstrated its continued support for the inflationary penalty by leaving it untouched.

If HRSA/OPA were to replace its penny pricing policy with a policy allowing higher prices for drugs for which URA exceeds AMP, it would be rewarding manufacturers for raising prices faster than inflation. Specifically, once prices rose fast enough for the URA to exceed AMP, then the ceiling price would jump from relatively low to whatever level is set under a new policy. In other words, beyond a certain point, higher prices on the regular market would be rewarded by higher 340B ceiling prices. As discussed above, this outcome is in direct contradiction to Congressional intent.

HRSA/ OPA made this point clearly in Release 2011-02, "Clarification of Penny Pricing Policy," which stated:

> "Using the prior quarter pricing or some other price in place of penny pricing would nullify the pricing penalty (AMP increasing faster than inflation) when the 340B ceiling price decreases because of changes to the AMP."

3. Any alternative to penny pricing directly contradicts the intent of the 340B program, by increasing costs for FQHCs and other covered entities.

As you are aware, the central goal of the 340B program is to enable covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Any alternative to penny pricing for drugs whose URA exceeds AMP is in direction contradiction to this Congressional intent. This is because any alternative would result in higher ceiling prices for these drugs, which will result in increased drug spending for FQHCs and other covered entities. As a result, they will have fewer resources available for "reaching more eligible patients and providing more comprehensive services."

Increased costs for drug spending will have a detrimental impact on both Vermont and New Hampshire Health Centers and the patients they serve. Savings from 340B are a fundamental portion of FQHCs' budgets and are critical to their ability to sustain ongoing operations. Much of the savings from 340B is redirected to services that are critical to Health Center operations, but not reimbursable by third-party payers. These services are often enabling services that address a person's whole health needs and social determinants of health. Reducing resources to those services would have a negative impact on both the Health Centers' ability to meet their missions while also impacting client health and well-being outcomes.

Note that this increased spending would go directly to drug manufacturers, as a reward for increasing their prices faster than inflation. There would be no benefit to any public programs.

4. **Manufacturers are already permitted to implement distribution plans that ensure that covered entities do not purchase inappropriate quantities of penny-priced drugs.**

Bi-State recognizes that manufacturers may have concerns about equitable distribution of drugs that are made available to covered entities under the penny pricing policy. However, as discussed Program Notices 2011-1.1 and 2011-02, manufacturers are permitted to develop and implement "alternative allocation procedures" for these drugs. These procedures, which should be submitted to HRSA/OPA for posting on their website, permit manufacturers to restrict distribution of specific drugs, provided that 340B providers are treated the same as non-340B providers. By implementing these procedures, manufacturers can ensure that covered entities do not purchase inappropriate quantities of penny-priced drugs.

* * *

In closing, we appreciate the opportunity to provide input on this issue. If you require any clarification on our comments, please contact me at 603-228-2830 ext. 112 or via email at tkuenning@bistatepca.org.

Sincerely,

Tess Kuenning

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President and Chief Executive Officer
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