

525 Clinton Street  
Bow, NH 03304  
Voice: 603-228-2830  
Fax: 603-228-2464



61 Elm Street  
Montpelier, VT 05602  
Voice: 802-229-0002  
Fax: 802-223-2336

[www.bistatepca.org](http://www.bistatepca.org)

August 17, 2015

Office of Pharmacy Affairs  
Healthcare Systems Bureau  
Health Resources and Services Administration  
5600 Fishers Lane  
Mail Stop 08W05A  
Rockville, MD 20857

Submitted via [www.regulations.gov](http://www.regulations.gov)

**RE: 340B Civil Monetary Penalties for Manufacturers and Ceiling Price Regulations (RIN 0906-AA89)**

Bi-State Primary Care Association appreciates the opportunity to comment on the proposed rule on 340B Civil Monetary Penalties for Manufacturers and Ceiling Price Regulations (RIN 0906-AA89).

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.

Bi-State is focusing its comments primarily on issues that are of particular importance to Health Centers and the patients they serve. Bi-State's comments begin with an overview of FQHCs and the importance of the 340B program to their patients and their ongoing sustainability followed by a summary of comments and then detailed comments. 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 uses their template and parallels their comments and concerns.

### **FQHCs and the 340B Program**

Nationally, FQHCs represent over 20% of the covered entities currently participating in the 340B program. With over 9,000 sites nationwide, FQHCs provide affordable, high quality, comprehensive primary care to over 24 million medically underserved persons. Bi-State's combined Vermont and New Hampshire membership includes 22 FQHCs delivering primary care at over 80 sites and serving 236,000 people. A hallmark of FQHCs is their commitment to serve all individuals, regardless of their insurance status or ability to pay. Over 70% of FQHC 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, they pay reduced fees based on a sliding scale. Thus, we feel that FQHCs are exactly the type of safety net provider that Congress intended the 340B program to support.

In a recent NACHC survey, 96% of FQHC respondents deemed the 340B program “highly important” to their ongoing operations for two reasons. First, 340B plays a critical role in enabling FQHCs to provide affordable drugs to their patients. In fact, prior to the creation of the 340B program, many Health Centers were unable to provide any pharmacy access to their patients. Second, 340B savings enable FQHCs to stretch their limited resources to further expand services for those in need of care. Many FQHCs use these savings to directly strengthen their pharmacy programs by establishing and supporting clinical pharmacy programs. In addition, over 60% of FQHC respondents in the survey reported using the savings to support activities beyond pharmaceutical services, such as equipment purchases, hiring additional providers, and/or extending evening or weekend hours. Due to their slim operating margins, many FQHCs would not be able to sustain their current operations without 340B savings.

## **SUMMARY OF COMMENTS**

### Subpart A: §10.3 – Definition of “Covered Outpatient Drugs”

Bi-State recommends that:

- HRSA should limit the definition of “covered outpatient drugs” to Section 1927(k)(2) of the Social Security Act, eliminating the reference to the “limiting definition” in Section 1927(k)(3), in order to:
  - Prevent manufacturers from limiting 340B pricing to drugs that are reimbursed separately, as opposed to those reimbursed under a bundled payment methodology, and
  - Ensure that FQHCs and other covered entities can use 340B drugs when these drugs are provided “incident to” a service provided by a physician or non-physician practitioner.
- If HRSA is unwilling to drop the reference to Section 1927(k)(3), HRSA should explicitly state in both the preamble and regulatory text that this definition of “covered outpatient drug” does not permit manufacturers to limit 340B pricing to those drugs that are reimbursed separately, as opposed to those reimbursed under a bundled payment methodology.

### Subpart B: 340B Ceiling Price Calculation

Bi-State supports HRSA’s plans to publish the 340B ceiling price rounded to two decimal places, as this will make it easier for covered entities to check if they are being charged appropriately. Bi-State also supports HRSA’s proposal to codify the long-standing “penny pricing” policy.

However, Bi-State recommends that HRSA:

- Explicitly cite its statutory authority to issue regulations on how 340B ceiling prices are calculated.
- Require manufacturers to issue refunds for all overcharges, not just overcharges on new drugs.

### Subpart C: Civil Monetary Penalties (CMPs)

- Bi-State supports HRSA’s plan to delegate authority to implement CMPs to the HHS Office of the Inspector General (OIG). Bi-State recommends that HRSA strengthen this process by:
  - Explicitly stating this delegation in the regulatory text.
  - Incorporating key definitions from OIG regulations into the 340B CMP program. Specifically, a manufacturer should be subject to CMPs based on the manufacturer’s actual knowledge, deliberate ignorance, or reckless disregard of an overpayment.
- To the extent feasible, NACHC supports directing funds collected from CMPs to the HRSA Office of Pharmacy Affairs to support its 340B program responsibilities.
- NACHC recommends that HRSA define “instance of overcharging” on a per-unit basis rather than on a per-order basis. This will give OIG the flexibility to impose penalty amounts that are significant enough to act as a deterrent to overcharging on large and/or high-cost orders, while also appropriate to the cause and size of the overcharge.

## **DETAILED COMMENTS**

### **Subpart A: §10.3 – Definition of “Covered Outpatient Drugs”**

The NPRM proposes to define “covered outpatient drug” using the Medicaid definition located at Sections 1927(k)(2) and (3) of the Social Security Act. Section 1927(k)(2) provides a general definition, while Section 1927(k)(3) contains a “Limiting Definition” which states that:

“The term “covered outpatient drug” does not include any drug, biological product, or insulin provided *as part of, or as incident to* and in the same setting as, any of the following (and *for which payment may be made under this subchapter as part of payment for the following and not as direct reimbursement for the drug*):” (emphasis added)

The statute then lists a series of services, including inpatient, hospice, nursing facility and physician services.

Bi-State fully supports the proposal to incorporate Section 1927(k)(2) into this regulation. However, we have serious concerns about including Section 1927(k)(3). Specifically, the language in parentheses can be interpreted to mean that any drug that is reimbursed as part of a bundled payment, as opposed to separately, is not eligible for 340B. As you are aware, FQHCs are reimbursed under both Medicare and Medicaid using a Prospective Payment System (PPS.) The PPS is essentially a bundled payment covering the full range of services provided during a typical visit. While the Medicare PPS does not cover outpatient drug costs, in many states the Medicaid FQHC PPS includes outpatient drug costs. Thus, *if Section 1927(k)(3) is incorporated into the Final Rule, FQHCs in these states will no longer be able to access 340B drugs for any Medicaid patients.* In addition, CMS is increasingly moving towards the use of bundled payments and other types of value-based purchasing, with the goal of 50% of all Medicare payments being made under “alternative payment models” (such as bundled payments) by 2018. Thus, it is highly likely that an increasing number of covered entities will no longer be eligible for 340B pricing for Medicare patients if Section 1927(k)(3) is incorporated into this regulation.

Also, anecdotal evidence suggests that some manufacturers are already adopting this interpretation, refusing to offer 340B prices for drugs that are not reimbursed separately. Thus, if HRSA is unwilling to drop the reference to Section 1927(k)(3), we request that—at minimum—the agency explicitly state in both the preamble and regulatory text that this definition of “covered outpatient drug” does not permit manufacturers to limit 340B pricing to those drugs that are reimbursed separately, as opposed to those reimbursed under a bundled payment methodology.

In addition, the “incident to” language in Section 1927(k)(3) is also problematic, as it would require FQHCs (and other covered entities) to distinguish which drugs are used “incident to” a provider’s services, as opposed to those that are administered by the patient at home. While very few drugs are provided “incident to,” this requirement would create a significant administrative burden for FQHCs (and other covered entities) which would likely far outweigh the potential savings to manufacturers.

Finally, Bi-State would like to be very clear that we understand and agree that the 340B program was intended to be limited to drugs provided in an outpatient setting and that nothing in this recommendation is intended to suggest that we are asking to have this changed.

### **Subpart B: 340B Ceiling Price Calculation**

- Given concerns that have been raised in the past about HRSA’s rulemaking authority, Bi-State recommends that HRSA begin this section of the preamble by citing its statutory authority in this area.
- Bi-State greatly appreciates that HRSA plans to “publish the 340B ceiling price rounded to two decimal places.” This should make it much simpler for covered entities to determine if they are being charged appropriately by manufacturers.

- Bi-State appreciates HRSA's proposal to codify its long-standing policies around "penny pricing" and price estimation for new drugs.
- Bi-State appreciates HRSA's proposal to require manufacturers to issue refunds for overcharges on new drugs. However, nothing in this NPRM indicates that this requirement applies to overcharges for existing drugs. We suspect that this is an oversight and recommend that HRSA state explicitly that the requirement to issue refunds relates to overcharges for all drugs.

### **Subpart C: Civil Monetary Penalties (CMPs)**

#### ***Delegation of Enforcement Authority to the HHS OIG***

Bi-State appreciates HRSA's recognition of HHS OIG authority over 340B CMPs in the preamble to the regulatory text. However, we are concerned that the regulatory language, as currently written, may not be broad enough to ensure that the OIG will consistently be able to apply the full range of its enforcement mechanisms. Specifically:

- The proposed regulatory text does not explicitly state that the enforcement authority lies with the HHS OIG. This failure to explicitly mention the OIG could enable another (less-experienced) entity to be given the responsibility to enforce the CMPs, provided that they do so in a manner that is consistent with 42 CFR Parts 1003 and 1005.
- The reference to "the procedures" might be read narrowly, as incorporating only official actions, and not incorporating standards and definition (such as the definition of "knowingly and intentionally").

To avoid these unintended outcomes, Bi-State recommends that HRSA expand the regulatory text at §10.11 (a), which reads:

*"This penalty will be imposed pursuant to the procedures at 42 CFR part 1003 and 1005."*

as follows:

*"Pursuant to a delegation of authority, the HHS Office of Inspector General (OIG) will have the authority to bring 340B CMP actions utilizing the definitions, standards, and procedures applied to civil monetary penalties under 42 CFR Parts 1003 and 1005."*

#### ***Use of Funds Generated from CMPs***

The proposed rule does not specify how funds collected from CMPs will be used. To the extent feasible, Bi-State supports directing funds collected from CMPs to the HRSA Office of Pharmacy Affairs to support its 340B program responsibilities.

#### ***Definition of an "Instance of Overcharging"***

Bi-State strongly believes that an "instance of overcharging" should be defined on a per unit basis rather than a per order basis. Thus, if a covered entity is overcharged for 100 units of a covered drug in a single transaction, this should be considered 100 instances of overcharging subject to a CMP. This approach will give OIG the flexibility to impose penalty amounts that are significant enough to act as a deterrent to overcharging on large and/or high-cost orders, while not excessive relative to the cause and size of the overcharge.

The primary goal of the CMPs is to serve as a deterrent to prevent manufacturers from intentionally overcharging for 340B drugs. However, if "instances of overcharging" are defined on a per-order basis, then a maximum fine of \$5,000 seems relatively small in situations where an order includes a large number of units, and/or multiple units of a high-price drug. In these situations, *the potential benefit of overcharging (i.e., the*

**Bi-State Primary Care Association Comments RE: Proposed Rule for 340B Civil Monetary Penalties for Manufacturers and Ceiling Price Regulations (RIN 0906-AA89)**

August 17, 2015

Page 5

*savings due to overcharging on a large quantity of lower-cost drugs, or even a low quantity of high-cost drugs) could easily outweigh the risk of paying a \$5,000 maximum fine.* Therefore, to ensure that CMPs are a strong enough deterrent to discourage overcharging on large and/or high-cost orders, OIG must have the authority to impose penalties that are appropriate to the level of transgression. Defining an “instance of overcharging” on a per-unit basis provides OIG with the discretion to set penalties at a level that are high enough to be a deterrent and appropriately reflect the factors behind the overcharge (these factors were described in the Advanced NPRM published in 2010 and include the amount and frequency of overcharges, the manufacturer’s history of 340B compliance, the number of covered entities affected, and the reasonableness of the manufacturer’s defense).

Bi-State recognizes that for orders including a large number of units, our recommended approach will result in a large number of “instances” of overcharging. However, the law does not require that the manufacturer be fined \$5,000 for each instance. Rather, the statute and regulatory text are clear penalties may be *up to* \$5,000 per instance, but can be less—presumably as low as one-cent per “instance.” Therefore, defining “instances of overcharging” on a per-unit basis will ensure that the potential penalties can be high enough to serve as a significant deterrent to overcharging, while also ensuring that OIG has the discretion to set penalties at levels that are not excessive given the specific situation and the factors described in the Advanced NPRM.

\* \* \*

Thank you for the opportunity to comment on this proposed rule. Please do not hesitate to contact me at (603) 228-2830 extension 112 or via e-mail at [tkuenning@bistatepca.org](mailto:tkuenning@bistatepca.org) if you require clarification on the comments presented above.

Sincerely,



Tess Stack Kuenning, CNS, MS, RN  
President and Chief Executive Officer  
Bi-State Primary Care Association