

# THE 340B COALITION

---

---

May 19, 2016

**VIA Federal eRulemaking Portal: <http://www.regulations.gov>**

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

**Re: RIN 0906-AA89  
Supplemental Comments on HRSA Proposed Rule—340B Drug Pricing Program  
Ceiling Price and Manufacturer Civil Monetary Penalties Regulation**

Dear Capt. Pedley:

The 340B Coalition appreciates the opportunity to submit supplemental comments on the proposed rule, *340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation*. The 340B Coalition is a broad coalition of providers and programs representing thousands of hospitals, community health centers, and clinics in support of protecting and preserving the 340B program, a resource critical for the survival of America's safety net.

On June 17, 2015, the Health Resources and Services Administration (HRSA) issued a notice of proposed rulemaking related to 340B ceiling prices and the imposition of civil monetary penalties (CMPs) on manufacturers under the 340B Drug Pricing Program (340B program). The proposed rule would implement provisions of the Affordable Care Act (ACA) that require the Secretary of Health and Human Services (HHS) to develop and publish standards for calculating ceiling prices and to impose CMPs on manufacturers that knowingly and intentionally charge covered entities in excess of the 340B ceiling price. On April 19, 2016, HRSA reopened the comment period on the proposed rule and specifically sought comments on three areas: 1) HRSA's "penny pricing" policy for ceiling prices that are less than \$0.01; 2) estimation of ceiling prices for new drugs; and 3) definition of "knowing and intentional" for purposes of manufacturer CMPs.

As explained more fully below, the 340B Coalition's position on the above three areas is as follows:

- HRSA should reject any proposed alternatives to the penny pricing policy because they

- are contrary to the 340B statute and congressional intent.
- HRSA should reject the proposed methodology for estimating the ceiling prices for new drugs based on wholesale acquisition cost (WAC) minus specified percentages because it would, in many cases, result in excessive overcharges to covered entities. For this reason, it is not a reasonable alternative to HRSA's proposed methodology.
- HRSA should adopt the Office of Inspector General's (OIG) definition of "knowingly" and should reject the proposed alternative definitions because they would set a standard so high that the CMP program would be undermined.

### **Ceiling Price for a Covered Outpatient Drug Exception**

The 340B Coalition supports HRSA's codification of its penny pricing policy, which should help ensure that covered entities receive appropriate pricing on 340B drugs.<sup>1</sup> The 340B Coalition opposes the alternatives that HRSA is considering because they are contrary to the 340B statute, would undermine statutory penalties imposed when manufacturers increase prices that exceed inflation, and would compromise the ability of covered entities to serve more patients and provide more services.

The June 17, 2015 proposed rule would calculate a ceiling price for a covered outpatient drug that is equal to "the Average Manufacturer Price (AMP) for the smallest unit of measure minus the Unit Rebate Amount (URA)" calculated to six decimal places. HRSA will then multiply this figure by the drug's package size and case package size, calculated to two decimal places. Section 10.10 of the proposed rule notes an exception to this AMP calculation. When the AMP is equal to the URA, or the difference between the two figures is less than \$0.01, the ceiling price will be set at \$0.01 per unit. The proposed rule refers to this as "penny pricing." HRSA states in the June 17, 2015 preamble that "[m]anufacturers may not use the prior quarter's pricing, WAC, or any other non-340B contract price in the place of the penny pricing."

#### **I. The Proposed Alternatives Are Contrary to the 340B Statute, Which Plainly Contemplates Ceiling Prices of Zero**

HRSA received comments suggesting the following alternatives to penny pricing: 1) the federal ceiling price; 2) a ceiling price from previous quarters in which the ceiling price was greater than zero; or 3) nominal pricing as used in the Medicaid rebate program. The 340B Coalition opposes these alternatives and strongly supports penny pricing and HRSA's clarification in the proposed rule that manufacturers may not use alternative methods to set the 340B price of a drug when the 340B ceiling price calculation results in an amount less than a penny.

---

<sup>1</sup> HRSA's current penny pricing policy is stated in Policy Release 2011-2, Clarification of Penny Pricing Policy, available at <http://www.hrsa.gov/opa/programrequirements/policyreleases/pennypricingclarification112111.pdf>.

The proposed alternatives are contrary to the plain language of the 340B statute, and HRSA should reject them. The 340B statute states that the 340B ceiling price is “equal to the average manufacturer price for the drug under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] in the preceding calendar quarter, reduced by the rebate percentage,” which is defined as “(i) the average total rebate required under section 1927(c) of the Social Security Act [42 U.S.C. 1396r–8(c)] with respect to the drug (for a unit of the dosage form and strength involved) during the preceding calendar quarter; divided by (ii) the average manufacturer price for such a unit of the drug during such quarter.”<sup>2</sup> In 2011, HRSA accurately described this statutory formula as follows:

$$340B \text{ Ceiling Price} = [(AMP) - (URA)] * \text{Drug Package Size}^3$$

If the AMP increases more quickly than the rate of inflation, § 1927(c)(2)(A) adds a supplemental rebate amount to the URA.<sup>4</sup> Section 1927(c)(2)(D) of the Social Security Act ensures that the URA does not exceed the AMP.<sup>5</sup> The URA may, however, equal the AMP, resulting in a 340B ceiling price of zero.

We acknowledge that HRSA has tempered the impact of the statutory 340B ceiling price formula on manufacturers by permitting companies to charge a penny for drugs with a ceiling price calculation of zero, as the agency concluded that “it is not reasonable for a manufacturer to set a zero 340B ceiling price.”<sup>6</sup> Importantly, the penny pricing policy “has been expressed since the start of the program.”<sup>7</sup> The alternatives that HRSA is currently considering, however, are plainly contrary to the statute and are unreasonable from a policy perspective. All of the alternatives—the federal ceiling price; a ceiling price from previous quarters in which the ceiling price was greater than zero; or nominal pricing as used in the Medicaid rebate program—could result in prices well above zero in instances where the statutory formula results in zero ceiling prices. These increases could go well beyond the de minimis increase of the penny pricing policy and would flout the will of Congress as expressed in the statute.

## **II. Congress Recently Considered the Statutory Formula and Expressly Enacted the Calculation That Results in Ceiling Prices of Zero**

Congress recently considered the Medicaid rebate at § 1927(c)(2) and expressly *endorsed* rebates that are equal to the AMP calculation. Prior to 2010, § 1927(c)(2) could result

---

<sup>2</sup> 42 U.S.C. § 256b(a)(1)-(2)(A).

<sup>3</sup> Policy Release 2011-2, Clarification of Penny Pricing Policy, *available at* <http://www.hrsa.gov/opa/programrequirements/policyreleases/pennypricingclarification112111.pdf>.

<sup>4</sup> 42 U.S.C. § 1396r-8(c)(2)(A).

<sup>5</sup> *Id.* § 1396r-8(c)(2)(D).

<sup>6</sup> Policy Release 2011-2, Clarification of Penny Pricing Policy, *available at* <http://www.hrsa.gov/opa/programrequirements/policyreleases/pennypricingclarification112111.pdf>.

<sup>7</sup> Department of Health and Human Services Office of Inspector General (OIG), HHS Review of 340B Prices 27 (July 2006).

in a URA that exceeded the AMP, resulting in a negative ceiling price calculation for the drug. Section 2501 of the Patient Protection and Affordable Care Act (ACA) amended § 1927(c)(2) to set a “maximum rebate amount” of 100% of AMP.<sup>8</sup> By this amendment, Congress plainly intended that the URA could equal AMP, which necessarily results in a 340B ceiling price of zero. Just last year, Congress extended the inflationary penalty in the Medicaid rebate provision to generic drugs, effective January 1, 2017, again confirming that the URA may equal AMP.<sup>9</sup> The Medicaid rebate program provides no exception for a manufacturer to pay a lower rebate amount, which would increase what Medicaid ultimately pays for drugs. Given the interconnectedness of the Medicaid rebate and 340B pricing formulas, no rationale exists for providing an exception for the 340B program when no similar exception exists for the Medicaid rebate program. Thus, the proposed alternatives to the penny pricing policy may not be implemented because they would violate the 340B statute.

### III. The Proposed Alternatives Would Encourage Manufacturers to Raise Prices

Moreover, the proposed alternatives would undermine the inflationary penalty established and recently affirmed by Congress, and create a perverse incentive for a manufacturer to raise its prices more than it would under the penny pricing policy. Take the example of a manufacturer that sells two different drugs, Drug A and Drug B. If the 340B ceiling price calculation for Drug A results in a price of \$1.00, the manufacturer must charge covered entities no more than a \$1.00 for Drug A. Under the penny pricing policy, if the ceiling price calculation for Drug B results in a price of \$0.00, the manufacturer must charge covered entities no more than \$0.01. If HRSA were instead to adopt one of the proposed alternatives, such as a ceiling price from a previous quarter in which the ceiling price was greater than \$0.00, the manufacturer could still charge no more than \$1.00 for Drug A but would be able to charge more than \$0.01 for Drug B. If the most recent ceiling price greater than \$0.00 for Drug B was \$5.00, then the manufacturer could charge covered entities \$5.00 for Drug B, instead of \$0.01 under the current penny pricing policy. The 340B price for Drug B would then be *higher* than the 340B price for Drug A, even though the statutory ceiling price formula resulted in a *lower* calculated price for Drug B.

Such a policy would create an incentive for manufacturers to raise prices for many drugs in order to intentionally push the 340B ceiling price to zero, thus triggering an alternative price. Under the example above, the manufacturer would have been better off if it had increased the price of Drug A even more than it had. By doing so, the manufacturer could have caused the ceiling price calculation to result in a price of \$0.00, thereby triggering HRSA’s alternative pricing policy and allowing the manufacturer to charge a price potentially higher than \$1.00. This example illustrates how the proposed alternative pricing policies would incentivize a manufacturer to raise its prices more than it would under the penny pricing policy. As Turing

---

<sup>8</sup> Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2501, 124 Stat. 119, 309 (2010).

<sup>9</sup> Bipartisan Budget Act of 2015, Pub. L. No. 114-75, § 602, 129 Stat. 584, 596-597 (to be codified at 42 U.S.C. § 1396r-8(c)(3)(C)).

Pharmaceuticals' 5,000% price increase for its drug Daraprim demonstrated, manufacturers sometimes greatly increase drugs prices. HRSA should not adopt a policy that rewards manufacturers for such conduct.

#### **IV. The Proposed Alternatives Would Undermine Congressional Intent to Enable Covered Entities to Treat More Patients and Provide More Services**

The cost of pharmaceuticals is skyrocketing. Congress made a public policy choice in enacting the 340B statute to provide low-cost drugs to safety-net providers. The proposed alternatives would undermine congressional intent to enable covered entities to serve vulnerable patients. Twenty-four years ago, Congress enacted the 340B program to give eligible safety-net providers access to discounts to allow these providers to stretch their scarce resources, so that they may "reach more patients" and furnish "more comprehensive services."<sup>10</sup> Covered entities use 340B savings in a variety of ways to benefit the vulnerable patients they serve. The Government Accountability Office (GAO) has found that providers report using 340B to offset losses incurred from treating some patients, continue providing existing pharmaceutical and clinical services, lower drug costs for low-income patients and serve more patients, and provide additional services, such as case management to facilitate access to appropriate care.<sup>11</sup> The proposals are contrary to congressional intent because they would deprive covered entities of much-needed 340B savings.

#### **V. The Penny Pricing Policy Does Not Create Drug Shortages, as Some Manufacturers Have Argued**

Some manufacturers, in comments on the proposed rule, claimed that the penny pricing policy contributes to drug shortages, selectively citing a 2011 GAO report.<sup>12</sup> This report, however, demonstrates that these concerns are unfounded because the current penny pricing policy adequately addresses the potential for shortages. While, as the GAO report states, an order may have been placed for a penny priced drug that "exceeded the manufacturer's current national supply by 50 percent," the report continues that "[i]n response, this manufacturer consulted with HRSA to ensure compliance with the agency's nondiscrimination guidance and restricted the distribution of drugs at 340B prices by allocating its supply based on the projected demand in the market and providers' past purchasing patterns."<sup>13</sup> Shortages are a false threat under the penny pricing policy, as manufacturers have demonstrated that they are easily able to develop appropriate limited allocation protocols when facing penny pricing.<sup>14</sup> Under HRSA's November 2011 clarification of its penny pricing policy, a manufacturer can

---

<sup>10</sup> H. Rep. 102-384, 102d Cong., pt.2, at 12 (2d Sess. 1992).

<sup>11</sup> Government Accountability Office, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 17 (Sept. 2011).

<sup>12</sup> *Id.* at 21.

<sup>13</sup> *Id.*

<sup>14</sup> See, e.g., Open Letter to HRSA Office of Pharmacy Affairs Regarding the Yasmin® Limited Distribution System, available at <http://www.hrsa.gov/opa/programrequirements/manufacturereletters/2008/yasmin09302008.pdf>.

allocate the supply of a penny-priced drug if the company is concerned about a potential shortage, as long as the allocation method does not discriminate against covered entities. The 340B Coalition supports this policy as a reasonable mechanism to ensure that high demand drugs are distributed equitably. If manufacturers believe that the penny pricing policy creates negative side effects, they should address their concerns to Congress, not HRSA, because the penny pricing policy aligns with Congress's statutory formula for calculating ceiling prices.

### **New Drug Price Estimation**

The 340B Coalition supports HRSA's codification in the June 17, 2015 proposed rule of its new drug pricing policy and opposes the alternatives identified in the April 19, 2016 notice.<sup>15</sup> Section 10.10 of the proposed rule contains a special provision for new drugs. A manufacturer must estimate a drug's ceiling price for the first three quarters the drug is available for sale. In the fourth quarter, manufacturers must begin calculating the ceiling price in accordance with the above described formula (AMP – URA) and must calculate "actual ceiling prices" for the first three quarters. If the actual ceiling prices are less than the estimated ceiling prices for the first three quarters, the rule requires manufacturers to provide a refund or credit to covered entities that purchased the drug at the higher estimated price. Refunds or credits for the first three quarters must be provided to covered entities by the end of the fourth quarter. This rule appropriately ensures that covered entities will be able to obtain 340B pricing when a drug first comes to market.

HRSA is seeking comment on an alternative methodology that would set the price of a new covered outpatient drug at WAC minus the applicable rebate percentage, which is 23.1% for most single-source and innovator drugs, 17.1% for clotting factors and drugs approved exclusively for pediatric indications, and 13% for generic drugs and over-the-counter drugs. The proposed alternative policy could make safety-net providers pay significantly higher prices for new drugs.

According to Apexus, WAC pricing is 20% higher than GPO pricing.<sup>16</sup> This difference may be even greater. The basis for WAC pricing is not publicly available. 340B Health has been informed by industry stakeholders that, based on an analysis of pricing data available as of March 17, 2016, WAC pricing is on average 33% higher than group purchasing organization (GPO) pricing for generic drugs and 22% higher for brand named drugs. The 340B Coalition encourages HRSA to work with Apexus to confirm the difference between WAC and GPO pricing and to specify the price differences between WAC and GPO pricing for brand name and generic drugs. Otherwise, charging covered entities WAC minus 13% for new generic drugs, WAC minus 23.1% for new brand named drugs, and WAC minus 17.1% for clotting factors and

---

<sup>15</sup> HRSA's current pricing policy for new drugs is stated at 60 Fed. Reg. 51,488 (Oct. 2, 1995).

<sup>16</sup> See slide 26 of Apexus's February 2016 340B University presentation. Available at [https://docs.340bpvp.com/documents/public/resourcecenter/340B\\_University/02.17.2016/340BU-Slides-021616.pdf](https://docs.340bpvp.com/documents/public/resourcecenter/340B_University/02.17.2016/340BU-Slides-021616.pdf).

pediatric drugs might cause covered entities to pay prices for some drugs that are even higher than GPO or commercial pricing. The product Coagadex, a clotting factor, provides a helpful example. The WAC price for Coagadex is 23.1% percent higher than the commercial price. If Coagadex were a new product subject to the alternative pricing methodology being considered by HRSA, a covered entity would pay more for Coagadex through the 340B program (i.e., WAC-17.1%) than it would outside the program (WAC-23.1%). This amounts to a difference of \$0.47 cents per unit of Coagadex. Since a typical patient might receive a dose of 1,750 units of Coagadex, the covered entity would pay \$822.50 more per dose if it were to purchase the product through the 340B program instead of at the commercial price.

Such high prices are contrary to the 340B program's purpose. Requiring a safety-net provider to pay 340B prices that might be higher than pricing available to the covered entity outside the 340B program does not allow the entity to reach more patients and provide more comprehensive services. Accordingly, the proposed policy is contrary to congressional intent that the 340B program enable covered entities to serve more patients and provide more services.

The proposed alternative policy would, in many instances, result in new drug prices well above the prices that would be determined in the fourth quarter according to the statutory 340B pricing calculation. These overcharges would, in effect, force safety-net providers to give manufacturers short-term, interest-free loans until the manufacturers provide refunds or credits to the entities for any overcharges. This is a result that would clearly be unreasonable in light of the tenuous financial position of many safety-net providers, particularly when compared to the large and profitable pharmaceutical companies that these providers would be subsidizing.

The proposed alternative would also give manufacturers too much discretion to determine prices for new drugs for which there is no WAC. If a manufacturer sells a drug directly to providers instead of using wholesalers to distribute the drug, then there would be no agreement between the manufacturer and a wholesaler defining WAC. Unless HRSA were to specify rules governing the WAC price in these instances, the manufacturer would have unchecked discretion to set WAC for purposes of estimating new drug prices. This would potentially lead to manufacturers overcharging covered entities during the first three quarters that the drug is available.

To ensure that manufacturers are properly calculating 340B ceiling prices and refunds and credits, we ask that HRSA incorporate information from its 1995 guidance on new drug pricing that clarifies a manufacturer's 340B pricing obligations during the third and fourth quarters.<sup>17</sup> Consistent with the 1995 guidance, a manufacturer should offer a 340B price in the third quarter based on the basic rebate amount because the manufacturer has AMP and best

---

<sup>17</sup> Final Notice Regarding New Drug Pricing, 60 Fed. Reg. 51488 (Oct. 2, 1995).

price data from the first quarter to calculate the basic rebate amount.<sup>18</sup> The manufacturer should offer a 340B price in the fourth quarter based on the total rebate amount, including the basic rebate amount and any additional rebate amount.<sup>19</sup> In the fourth quarter, the manufacturer has AMP and best price data from the second quarter to calculate the basic rebate amount and a baseline AMP from the second quarter to calculate whether an additional rebate should be included in the 340B ceiling price.<sup>20</sup>

Finally, the 340B Coalition requests that HRSA require manufacturers to issue refunds or credits to covered entities for overcharges on a new drug by the end of the fourth quarter that the drug is on the market.

### **Definition of “Knowing and Intentional” for Purposes of Manufacturer CMPs**

The 340B statute requires the Secretary to impose CMPs on manufacturers that have “knowingly and intentionally” charged a covered entity more than the 340B ceiling price.<sup>21</sup> In the June 17, 2015 proposed rule, HRSA included a provision that would assess penalties according to the OIG’s procedures used to impose CMPs under 42 C.F.R. Part 1003 and would give OIG authority to bring 340B CMP actions. The 340B Coalition supports this proposal. The 340B Coalition urges HRSA to adopt OIG’s definition of “knowingly” and to define “intentionally” as any overcharge that is not due to inadvertent error. Furthermore, the 340B Coalition requests that HRSA revise the CMP regulation to include as an “instance of overcharging” a manufacturer’s failure to offer a covered outpatient drug to a covered entity at the 340B ceiling price to the same extent the manufacturer makes the drug available to non-340B providers.

#### **I. HRSA Should Reject the Proposed Alternatives and Adopt OIG’s Definition of “Knowingly” Because the Alternatives Would Undermine Congress’s CMP Requirement**

Many of the organizations that comprise the 340B Coalition submitted a comment letter<sup>22</sup> requesting that HRSA adopt the definition of “knowingly” from OIG’s CMP regulations.<sup>23</sup> Under OIG regulations, an entity “knowingly” submits an improper claim if it had actual knowledge that the claim was improper, acted in deliberate ignorance of the truth or falsity of the information presented, or acted in reckless disregard of the truth or falsity of the

---

<sup>18</sup> *Id.* at 51489.

<sup>19</sup> *Id.*

<sup>20</sup> *Id.*

<sup>21</sup> 42 U.S.C. § 256b(d)(1)(B)(vi).

<sup>22</sup> Joint Comments on HRSA Proposed Rule-340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation 7-8 (Aug. 17, 2015), *available at* [http://www.340bhealth.org/files/joint\\_comments\\_hrsa\\_340b\\_cpc.pdf](http://www.340bhealth.org/files/joint_comments_hrsa_340b_cpc.pdf).

<sup>23</sup> *See* 42 C.F.R. § 1003.101-.102.

information presented.<sup>24</sup> The 340B organizations also requested that HRSA define “intentionally” as “not due to a mathematical miscalculation, clerical oversight or similar inadvertent error.”<sup>25</sup>

HRSA is now seeking comments on the definition of “knowingly and intentionally.” HRSA has proposed the following potential definitions:

- 1) actual knowledge by the manufacturer, its employees, or its agents of the instance of overcharge;
- 2) willful or purposeful acts by, or on behalf of, the manufacturer that lead to the instance of overcharge;
- 3) acting consciously and with awareness of the acts leading to the instance of overcharge; and/or
- 4) acting with a conscious desire or purpose to cause an overcharge or acting in a way practically certain to result in an overcharge.

HRSA should not recreate the wheel when the OIG already has a definition of “knowingly.” HRSA proposed delegating authority for the imposition of CMPs to the OIG and having penalties be assessed according to the OIG’s procedures. HRSA should permit OIG, the agency charged with bringing CMP actions, to use OIG’s definition of “knowingly.” There is no reason for HRSA to create a brand new definition and impose it on OIG when OIG has a wealth of experience with CMPs.

The 340B Coalition is particularly concerned that HRSA’s proposed definitions could set the bar so high that HRSA would rarely be able to impose CMPs on manufacturers. CMPs are the only viable penalty that HRSA can impose on manufacturers that violate their 340B pricing obligations. The only other potential penalty available to HRSA would be to terminate a manufacturer’s 340B Pharmaceutical Pricing Agreement (PPA). However, terminating a manufacturer’s PPA is not a realistic option because doing so would likely mean that Medicaid and Medicare Part B patients could no longer receive the manufacturer’s drugs. This is because manufacturers’ drugs cannot be reimbursed by Medicaid and Medicare Part B unless the manufacturer has a PPA.

HRSA’s proposed definitions would be contrary to Congress’s intent to provide HRSA with a meaningful enforcement tool. The CMP provision in the ACA grew from congressional hearings in 2005 in response to an OIG report documenting manufacturer overcharges and HRSA’s inability to impose sanctions. That report, *Deficiencies in the Oversight of the 340B Drug Pricing Program*, found that “HRSA lacks the oversight mechanisms and authority to ensure that

---

<sup>24</sup> See *id.* § 1003.101-.102.

<sup>25</sup> Joint Comments on HRSA Proposed Rule Regarding 340B Ceiling Prices and Manufacturer Civil Monetary Penalties 8 (Aug. 17, 2015), available at [http://www.340bhealth.org/files/joint\\_comments\\_hrsa\\_340b\\_cpc.pdf](http://www.340bhealth.org/files/joint_comments_hrsa_340b_cpc.pdf).

340B entities pay at or below the 340B ceiling price.”<sup>26</sup> In 2003 alone, six manufacturers overcharged covered entities by \$6.1 million.<sup>27</sup>

In response, the House Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce held a hearing on oversight and administration of the 340B program.<sup>28</sup> Stuart Wright, the OIG Deputy Inspector General for Evaluation and Inspections, testified that “HRSA should seek legislative authority to impose civil monetary penalties for situations of noncompliance.”<sup>29</sup> CMPs were necessary “because the current penalty of kicking manufacturers out of Medicaid and the 340B program is so draconian that it's not likely to be utilized.”<sup>30</sup> In the ACA, Congress granted CMP powers to HRSA to provide the agency with the necessary oversight authority. HRSA should ensure that its implementing regulations are robust and consistent with Congress’s intent that HRSA have meaningful oversight and enforcement authority.

HRSA concedes in the April 19, 2016 notice that “[m]anufacturers do not need to intend specifically to violate the 340B statute; but rather to have knowingly and intentionally overcharged the 340B covered entity.” Yet, HRSA’s proposed definitions of “knowingly and intentionally” would appear to require just such a specific intent. The proposed definitions would require “actual knowledge,” “willful or purposeful acts,” or “conscious” actions, which appear to be equivalent to the specific intent standard that HRSA purports to reject in the April notice. Although OIG’s defines “knowingly” as “actual knowledge,” OIG also includes in the definition of “knowingly” the lesser standards of “deliberate ignorance” and “reckless disregard.”<sup>31</sup> HRSA’s proposals would omit these lower standards of proof and would, therefore, require a burden of proof that HRSA or OIG would rarely meet, thus permitting manufacturers to overcharge covered entities with no consequences. HRSA’s proposed definitions would eviscerate the CMP program and leave HRSA without any means to penalize manufacturers.

HRSA further requests comments on when intent should be inferred. The 340B Coalition renews the suggestion that HRSA define this term as “not due to a mathematical miscalculation, clerical oversight or similar inadvertent error.” In addition, HRSA should adopt a definition from the Health Care Fraud statute at 18 U.S.C. § 1347. That statute establishes a “knowingly and willfully” standard and clarifies that “a person need not have actual knowledge of this section or specific intent to commit a violation of this section.”<sup>32</sup> The terms “knowingly

---

<sup>26</sup> OIG, Deficiencies in the Oversight of the 340B Drug Pricing Program ii (Oct. 2005).

<sup>27</sup> *Id.* at 17.

<sup>28</sup> Oversight and Administration of The 340B Drug Discount Program: Improving Efficiency and Transparency: Hearing Before the H. Subcommittee on Oversight and Investigations of the Comm. on Energy and Commerce, 109th Cong. (Dec. 15, 2005).

<sup>29</sup> *Id.* at 20.

<sup>30</sup> *Id.*

<sup>31</sup> *See id.* § 1003.101-.102.

<sup>32</sup> 18 U.S.C. § 1347(b).

and intentionally” and “knowingly and willfully” are virtually identical. HRSA should amend the CMP rule to state that a manufacturer “need not have actual knowledge of this section or specific intent to overcharge a covered entity.”

We are very concerned about HRSA’s proposal that a manufacturer would not be considered to have requisite intent when “a manufacturer acted on a reasonable interpretation of agency guidance.” A “reasonable interpretation” could have many meanings and could leave manufacturers to subjectively determine what interpretations are “reasonable.” At a minimum, HRSA should clarify that a “reasonable interpretation” constitutes an objective reasonableness standard to be determined by HRSA and/or OIG based upon 340B policy. As proposed, the exception is overly broad and would form a loophole for manufacturers to avoid facing the imposition of CMPs.

Covered entities depend upon HRSA to ensure that manufacturers comply with 340B requirements and do not overcharge for 340B drugs. In a recent Supreme Court case, *Astra, USA, Inc. v. Santa Clara County, Cal.*, the 340B Coalition filed an amicus brief discussing OIG findings that manufacturers overcharge covered entities millions of dollars per year. The 340B Coalition argued that the ACA CMP provisions represent a fundamental reform that will improve HRSA’s enforcement capabilities. The Supreme Court agreed, noting that manufacturers overcharge covered entities and emphasizing the importance of the CMP provisions in which “Congress thus opted to strengthen and formalize HRSA’s enforcement authority . . .” as a critical check on manufacturers.<sup>33</sup> HRSA should not undermine its statutorily conferred authority to issue CMPs by implementing an unduly restrictive definition of “knowingly and intentionally.” HRSA should instead adopt OIG’s definition of “knowingly” and develop a definition of “intentional” that is not based on a subjective “reasonableness” standard.

## **II. HRSA Should Revise the CMP Regulation to Subject a Manufacturer to CMPs If It Sells a Covered Outpatient Drug to a Non-340B Entity but Fails to Offer the Drug to a Covered Entity at or below the 340B Ceiling Price to the Same Extent**

HRSA requested input regarding “the concept that manufacturers would not be considered to have the requisite intent ... [w]hen a manufacturer has established alternative allocation procedures where there is an inadequate demand, as long as covered entities are able to purchase on the same terms as all other similarly-situated providers.” As with the “reasonable interpretation” exception discussed above, we are concerned that this exception is overly broad and could be used by manufacturers to avoid being subjected to CMPs. Instead of creating such an exception, we ask that HRSA revise the proposed CMP rule at 42 C.F.R. § 10.11 to address a manufacturer’s failure to make 340B drugs available to covered entities to the same extent those drugs are sold to non-340B providers and to create a safe harbor for manufacturers with valid limited distribution plans. The 340B statute requires HRSA to assess

---

<sup>33</sup> *Astra USA, Inc. v. Santa Clara County, Cal.*, 563 U.S. 110, 121-22 (2011).

CMPs on “any manufacturer with an agreement under this section that knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum applicable price under subsection (a)(1).”<sup>34</sup> Subsection (a)(1) requires that “the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser.”<sup>35</sup>

Subsection (a)(1) thus forbids manufacturers from discriminating against covered entities and requires manufacturers to make covered outpatient drugs available to covered entities to the same extent as to other purchasers. If a manufacturer sells a covered outpatient drug to non-340B providers but does not make the drug available to a covered entity at or below the 340B ceiling price to the same extent, the manufacturer effectively “charges a covered entity a price for purchase of a drug that exceeds the maximum applicable price under subsection (a)(1).”<sup>36</sup> A manufacturer’s failure to comply with the nondiscrimination provision in subsection (a)(1) thus constitutes an overcharge for purposes of the CMP provision at subsection (d)(1)(B)(vi). HRSA should revise the CMP definition of “instance of overcharging” to include a manufacturer’s failure to offer a covered outpatient drug to a covered entity to the same extent that the drug is offered to other purchasers.

This situation perhaps will most commonly occur when drugs are subject to an actual or potential shortage. HRSA addressed the shortage issue last year in its proposed Omnibus Guidance, which establishes requirements for limited distribution plans.<sup>37</sup> HRSA could establish a safe harbor for manufacturers that establish and valid limited distribution plans. Such a manufacturer could be deemed to comply with the nondiscrimination provision at subsection (a)(1) for drugs covered by the plan, and the manufacturer would not be subject to CMPs unless it charged a covered entity a price greater than the 340B ceiling price.

---

<sup>34</sup> 42 U.S.C. § 256b(d)(1)(B)(vi).

<sup>35</sup> *Id.* § 256b(a)(1).

<sup>36</sup> 42 U.S.C. § 256b(d)(1)(B)(vi).

<sup>37</sup> 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52,300, 52,312-13 (Aug. 28, 2015).

Capt. Krista Pedley, Director

May 19, 2016

Page 13 of 15

### **Conclusion**

HRSA should finalize its proposal to codify the penny pricing policy. The new drug estimation policy should not be altered as proposed in the April 19, 2016 notice, except that HRSA should incorporate information from its 1995 guidance that clarifies a manufacturer's 340B pricing obligations during the third and fourth quarters a drug is first available for sale. HRSA should adopt OIG's definition of "knowingly" and not define intent as based on a subjective interpretation of 340B rules. HRSA should revise the CMP rule to impose CMPs on manufacturers that sell covered outpatient drugs to non-340B entities without making them available at the 340B price to covered entities to the same extent. The 340B Coalition thanks HRSA for the opportunity to provide these additional comments on the proposed rule.

Sincerely,

The 340B Coalition

**Organizational Contacts**

Colleen Meiman  
Director of Regulatory Affairs  
National Association of Community Health Centers  
202-296-0158; cmeiman@nachc.org

Joe Pugliese  
President  
The Hemophilia Alliance  
215-439-7173; joe@hemoalliance.org

Amy Yenyo  
Senior Policy Counsel  
Planned Parenthood Federation of America  
202-973-4870; amy.yenyo@ppfa.org

Mindy McGrath  
Policy Director  
National Family Planning & Reproductive Health Association  
202-293-3114 ext. 206; mmcgrath@nfprha.org

Britten Pund  
Associate Director, Health Care Access  
National Alliance of State & Territorial AIDS Directors  
202-434-8044; bpund@nastad.org

Stephanie Arnold Pang  
Director of Policy and Communications  
National Coalition of STD Directors  
202-715-3865; sarnold@ncsddc.org

Brian Bowden  
Associate Legislative Director, Health  
National Association of Counties  
202-942-4275; bbowden@naco.org

Diane Calmus  
Government Affairs and Policy Manager  
National Rural Health Association  
202-639-0550 ext. 2075; dcalmus@nrharural.org

Capt. Krista Pedley, Director

May 19, 2016

Page 15 of 15

John Lozier

Executive Director

National Health Care for the Homeless Council

615-226-2292 ext. 224; jlozier@nhchc.org

Liz Parry

Associate Director

Children's Hospital Association

202-753-5392; liz.parry@childrenshospitals.org

Beth Feldpush

Senior Vice President of Policy and Advocacy

America's Essential Hospitals

202-585-0111; bfeldpush@essentialhospitals.org

Maureen Testoni

Senior Vice President & General Counsel

340B Health

202-552-5851; maureen.testoni@340bhealth.org