



August 17, 2015

Sylvia M. Burwell, Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

CDR Krista M. Pedley, PharmD, MS, USPHS
Director
Office of Pharmacy Affairs
Healthcare Systems Bureau
Health Resources and Services Administration
5600 Fishers Lane
Parklawn Building, Room 10C-03
Rockville, MD 20857

RE: 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation [RIN 0906-AA89]

Dear Secretary Burwell and Commander Pedley:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to submit the following comments to the Department of Health and Human Services (HHS) in response to the proposed rule issued by the Health Resources and Services Administration (HRSA) on June 17, 2015, entitled *340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation* [RIN-0906-AA89] (the "Proposed Rule").¹

BIO represents an industry devoted to discovering new treatments and ensuring patient access to them. Accordingly, we support the 340B program as a way to improve access to therapies for needy patients. We believe that compliance with 340B program requirements by all parties—including manufacturers—is an important part of ensuring the sustainability of the 340B program.

We appreciate HRSA's efforts to implement the manufacturer civil monetary penalty (CMP) provision added to the 340B statute by the Affordable Care Act (ACA), as well as to provide further clarity regarding the calculation of 340B ceiling prices, via the Proposed Rule. We note that BIO submitted comments in response to HRSA's Advance Notice of Proposed Rulemaking (ANPRM) on the topic of CMPs in November 2010,² as well as the Agency's proposed Information Collection Requests (ICRs) related to the collection of manufacturer data to verify 340B ceiling price calculations in both November 2014 and

¹ 80 Fed. Reg. 34,583 (June 17, 2015).

² 75 Fed. Reg. 57,230 (Sept. 20, 2010).

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May 2015,³ and we have attached each of these comment letters for your reference.

I. Overview of BIO's Comments

With respect to the Proposed Rule at issue here, BIO first notes our deep concern that HRSA has issued a proposed rule that aims to address only a limited number of the program integrity provisions added by the ACA, as opposed to implementing these requirements in a coordinated and logical fashion. Moreover, BIO takes issue with a number of the assumptions HRSA has made in coming to the conclusion that the Proposed Rule does not constitute a "significant regulatory action" and is thus exempt from the regulatory impact analysis requirements outlined in Executive Orders 12,866 and 13,536.

With the above concerns in mind, BIO strongly urges HRSA to issue a new Notice of Proposed Rulemaking (NPRM) that both implements the ACA's 340B program integrity requirements in a coordinated and comprehensive manner (as opposed to the piecemeal manner evidenced by the Proposed Rule and earlier ICRs) and includes the necessary regulatory impact analysis, taking into account the stakeholder feedback received in response to this NPRM. To the extent that HRSA nonetheless moves forward with manufacturer CMPs first, we urge the Agency to simultaneously establish at least certain interrelated and interdependent ACA provisions such that stakeholders have an opportunity to meaningfully comment on these proposals in context. Moreover, at a minimum, we would urge HRSA not to invoke manufacturer CMPs and covered entity sanctions until after implementing all of the ACA's program integrity provisions, in particular those provisions directly related to the CMP authority, in order to give program participants proper notice with respect to the standards on which they would be held accountable.

In addition, BIO has serious concerns with respect to HRSA's proposal to codify the Agency's "penny pricing" policy. Specifically, we are concerned that this policy is likely to result in negative consequences, including the potential for both drug shortages and program integrity violations, namely diversion. HRSA has failed to explain in the Proposed Rule how this policy is non-arbitrary and non-capricious. We therefore urge HRSA to reconsider this policy and instead continue to permit manufacturers to comply with their duty of good faith under the Pharmaceutical Pricing Agreement (PPA) by selecting a reasonable pricing methodology (i.e., one that is readily and objectively verifiable, statutorily supported, and represents a favorable discount to covered entities) for purposes of calculating an appropriate 340B ceiling price in quarters for which the average manufacturer price (AMP) equals the unit rebate amount (URA).

We also are gravely concerned that, in implementing the 340B statute's manufacturer CMP provisions, HRSA has impermissibly diverged from the statutory "knowing and intentional" standard. For instance, HRSA has proposed that an instance of overcharging can occur when subsequent ceiling price recalculations result from pricing data submitted to the Centers for Medicare & Medicaid Services (CMS), or as the result of actions by other parties (e.g., wholesalers and distributors). BIO strongly disagrees that such actions constitute "knowing and intentional" overcharges and thus urges HRSA to

³ 79 Fed. Reg. 58,791 (Sept. 30, 2014); 80 Fed. Reg. 22,207 (Apr. 21, 2015).

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eliminate language to this effect from its rulemaking. BIO further urges HRSA to clarify that manufacturers may not be subject to CMPs based on a manufacturer's use of a limited distribution network, where such a network would not violate HRSA's standards for non-discrimination,⁴ as well as to eliminate the Agency's proposal that an instance of overcharging may not be offset by other discounts.

Relatedly, BIO urges HRSA to revise its proposed definition of an "instance" of overcharging a registered covered entity for purposes of manufacturer CMPs to refer solely to actions that are within a manufacturer's control, regardless of the volume of orders. Specifically, we believe that an "instance" can permissibly be defined to include only: (1) each incorrect ceiling price calculation reported to HRSA that actually results in overcharges to one or more registered covered entities; and (2) each incorrect treatment of an organization that meets all three parts of HRSA's proposed "covered entity" definition,⁵ and that notified the manufacturer at the time of purchase of both its status and desire to order at the 340B price. By contrast, defining an "instance" based on the volume of covered entity orders, as HRSA has proposed, would result in manufacturer penalties based on an action wholly outside of manufacturer control (i.e., the number of orders placed and filled by third parties), in a manner inconsistent with Congress' clear intent to penalize only "knowing and intentional" manufacturer misconduct.

In addition to these concerns, and as described in greater detail, below, BIO strongly urges HRSA to make the following changes with respect to the Agency's ceiling price calculation proposals:

- Omit the definition of "340B drug," as this term is not used in the Proposed Rule nor the 340B statute;
- Recognize throughout the Proposed Rule the two-quarter lag inherent in the 340B ceiling price calculation between when a sales transaction occurs and when the 340B price takes effect;
- Require that an organization be registered and appear on the 340B database as a participating member at the time of purchase in order to meet the proposed definition of "covered entity," and clarify that this must be true for "the quarter" in which the transaction occurred;
- Clarify that an organization must meet all of the proposed elements of HRSA's proposed "covered entity" definition in order to claim the 340B ceiling price for a given quarter;
- Certify to the accuracy of the 340B database to enable manufacturers to reasonably rely on the database in extending 340B pricing to entities listed on it;
- Require that quarterly ceiling prices be reported and calculated in dollars and

⁴ As noted subsequently in this letter, distribution models vary across products for a variety of reasons (e.g., regulatory, shipping considerations, patient population). HRSA does not have the authority to regulate these distribution models. Instead, for 340B purposes, the key inquiry is not what distribution network the manufacturer uses, but rather whether the manufacturer is making the 340B price available to registered covered entities. See 42 U.S.C. § 256b(a) (providing that the PPA "shall require that the manufacturer offer each covered entity outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.").

⁵ We note that all references to the term "covered entity" throughout this letter refer to organizations that meet all three parts of the "covered entity" definition outlined in the Proposed Rule.

cents (i.e., 99999.99) to reduce both the price-reporting burden on manufacturers and the likelihood of disputes under the procedures proposed in the Agency's earlier ICRs;

- Eliminate the proposal to multiply the ceiling price calculation by "case package size" in order to conform to longstanding HRSA policy and the policies of the inextricably intertwined Medicaid Drug Rebate Program (MDRP); and
- Replace the proposed pricing methodology for new drugs, and instead impose a uniform estimated ceiling price of WAC minus the MDRP basic rebate percentage, based on the drug's classification percent,⁶ for the first two quarters of sales for all covered outpatient drugs, which should not be subject to revisions or the need for true-ups.

Finally, while BIO supports HRSA's proposal to delegate authority to the Department of Health and Human Services Office of Inspector General (OIG) to bring CMP actions against manufacturers under section 340B(d)(1)(B)(vi), we urge HHS to both officially delegate this authority to the OIG, and to work with OIG to provide additional standards with respect to the CMP provisions that would be applicable and appropriate in this context.

I. HRSA Should Implement the ACA's 340B Program Integrity Requirements in a Coordinated and Comprehensive Manner.

The 340B statute, as amended by the ACA, anticipates that HRSA will establish eleven unique systems and processes to ensure compliance by both manufacturers and covered entities with respect to 340B program requirements.⁷ In the Proposed Rule, HRSA proposes to implement just one of these program integrity improvements: the imposition of CMPs on manufacturers for knowing and intentional overcharges of covered entities

⁶ These percentages are statutorily defined as: 23.1 percent for innovator drugs; 17.1 percent for clotting factor products and products approved exclusively for pediatric indications; and 13.1 percent for non-innovator drugs. 42 U.S.C. § 1396r-8(c)(1)(B).

⁷ These include: (1) the development of a system to verify the accuracy of ceiling prices calculated by manufacturers and charged to covered entities (42 U.S.C. § 256b(d)(1)(B)(i)); (2) the establishment of procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturer (42 U.S.C. § 256b(d)(1)(B)(ii)); (3) the provision of secure access by covered entities to the applicable ceiling prices for covered outpatient drugs as calculated and verified by HRSA (42 U.S.C. § 256b(d)(1)(B)(iii)); (4) the development of a mechanism by which rebates and other discounts provided by manufacturers to other purchasers subsequent to the sale of covered outpatient drugs to covered entities are reported to HRSA, and appropriate credits and refunds are issued to covered entities if such discounts or rebates have the effect of lowering the applicable ceiling price for the relevant quarter for the drugs involved (42 U.S.C. § 256b(d)(1)(B)(iv)); (5) selective auditing of manufacturers and wholesalers to ensure program integrity (42 U.S.C. § 256b(d)(1)(B)(v)); (6) the imposition of sanctions on manufacturers in the form of civil monetary penalties for each instance of knowing and intentionally overcharging a covered entity (42 U.S.C. § 256b(d)(1)(B)(vi)); (7) the development of procedures to enable and require covered entities to regularly update (at least annually) the information on the HRSA's 340B database (42 U.S.C. § 256b(d)(2)(B)(i)); (8) the development of a system for HRSA to verify the accuracy of information regarding covered entities that is listed on such database (42 U.S.C. § 256b(d)(2)(B)(ii)); (9) the development of more detailed guidance describing methodologies and options available to covered entities for billing covered outpatient drugs to State Medicaid agencies in a manner that avoids duplicate discounts (42 U.S.C. § 256b(d)(2)(B)(iii)); (10) the establishment of a single, universal, and standardized identification system by which each covered entity site can be identified by manufacturers, distributors, covered entities, and HRSA for purposes of facilitating the ordering, purchasing, and delivery of covered outpatient drugs under the 340B program (42 U.S.C. § 256b(d)(2)(B)(iv)); and (11) the imposition of sanctions on covered entities, in appropriate cases as determined by the Secretary (42 U.S.C. § 256b(d)(2)(B)(v)).

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pursuant to section 340B(d)(1)(B)(vi). HRSA also proposes to provide certain, limited clarification, regarding the calculation of 340B ceiling prices pursuant to section 340B(d)(1)(B)(i)(I), which requires the “[d]evelopment and publishing through an appropriate policy or regulatory issuance, *precisely defined standards and methodology* for the calculation of ceiling prices”⁸—a requirement that Congress intended to be part of a “system to verify the accuracy of ceiling prices calculated by manufacturers and charged to covered entities.”⁹

BIO is strongly opposed to HRSA’s proposal to implement the ACA’s program integrity provisions in the piecemeal manner evidenced by the Proposed Rule and the ICRs released in September 2014, and April 2015. Each of these provisions is not only interrelated, but interdependent. Thus, in order for stakeholders to have a meaningful opportunity to comment on HRSA’s proposed approach with respect to each of these program integrity provisions, it is necessary to understand how HRSA proposes to implement many, if not all, of the other provisions. Accordingly, we urge HRSA to implement *all* of the ACA’s 340B program integrity improvements in a coordinated and comprehensive manner, ideally by issuing a new, comprehensive NPRM.

To the extent that HRSA nonetheless insists on implementing these provisions one-by-one, due to resource constraints or otherwise, BIO respectfully requests that HRSA not invoke its CMP authority unless and until the Agency has taken steps to implement *at least* the following such provisions in order to give manufacturers notice with respect to the standards on which they would be held accountable:

1. *Outline, via a policy or regulatory issuance, “precisely defined standards and methodology” regarding the 340B ceiling price calculation under 340B(d)(1)(B)(i)(I):* Manufacturers should not be subject to penalties for knowingly and intentionally charging prices over the ceiling price unless and until HRSA has provided clarity to stakeholders on the applicable standards and methodologies (including to finalize those policies proposed in the earlier ICRs), taking into account both the concerns articulated throughout this and previous BIO comment letters, and the clearly defined pricing standards outlined in both the 340B and MDRP statutes.
2. *Establish procedures to enable manufacturers to accurately identify covered entities, including systems to enable and require covered entities to regularly update their listing in HRSA’s 340B database and for HRSA to verify the contents of such listings, as well as the creation of a single, universal, and standardized identification system for identifying covered entities by all stakeholders under § 340B(d)(2)(B)(i), (ii), and (iv):* CMPs for knowingly and intentionally overcharging covered entities should not be imposed unless and until there is a reliable mechanism for manufacturers to identify who is, and is not, a registered covered entity eligible for 340B pricing during a given quarter. Examples of ways in which HRSA can improve the Agency’s 340B database and Medicaid Exclusion File include by: (1) imposing a single identifier type for purposes of both the Medicaid Exclusion File and Medicaid claims data (e.g., NPI);

⁸ 42 U.S.C. § 256b(d)(1)(B)(i)(I) (emphasis added).

⁹ See 42 U.S.C. § 256b(d)(1)(B)(i).

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- (2) listing a start and end date for covered entity eligibility, as well as for when covered entities elect to “carve-in” for purposes of the Medicaid Exclusion File; and
- (3) establishing a unique identifier for each covered entity and contract pharmacy relationship, and including a start and end date for each such relationship.

In addition, we strongly urge the Agency to implement the refund processes required by the 340B statute, either prior to or coincident with, the Agency’s implementation of the CMP provisions, such that manufacturers and covered entities understand the applicable processes that will apply should an overcharge occur (although we emphasize both here, and throughout the letter, that not all “overcharges” constitute a “knowing and intentional” overcharge for purposes of manufacturer CMPs).¹⁰ We note that establishing these processes before or at the same time as the CMP provisions is especially important, given that it is practically impossible to provide appropriate feedback on the burden likely to be imposed by Proposed Rule without knowing what this procedure or mechanism will look like.¹¹ These refund processes require HRSA to:

1. *Create standardized procedures for manufacturers to issue credits and refunds to covered entities in the event of an overcharge under § 340B(d)(1)(B)(ii):* While HRSA notes in the Proposed Rule that “[a]ny civil monetary penalty assessed will be in addition to repayment for an instance of overcharging as required by section 340B(d)(1)(B)(ii) of the PHSA,”¹² the Agency has not yet established the procedures expressly required under this section of the 340B statute. Manufacturers should not be required to issue refunds until HRSA has established this statutorily required refund process. Specifically, HRSA should propose specific elements for such a system in a manner that imposes the fewest burdens on both manufacturers and covered entities (e.g., by establishing a reasonable timeframe for issuing refunds that takes into account the 12-quarter MDRP restatement period, as well as a fixed-dollar *de minimus* threshold for refunds that does not exceed the cost of processing such refunds [e.g., \$100]¹³). In establishing this process, HRSA should accept and

¹⁰ The 340B statute suggests that both “routine instances of retroactive adjustment to relevant pricing data and exceptional circumstances such as erroneous or intentional overcharging for covered outpatient drugs,” constitute “overcharges” for which credits and refunds must be remitted to covered entities. See 42 U.S.C. § 256b(d)(1)(B)(ii)(II). However, the statute clearly imposes CMPs only on “knowing and intentional” overcharges, a standard that cannot be met, for instance, by “routine instances of retroactive adjustment to relevant pricing data,” as described in greater detail in section (III)(B)(3), below. See 42 U.S.C. § 256b(d)(1)(B)(vi).

¹¹ Please refer to the discussion in section (IV), below, which notes our concern that this process will unquestionably impose burdens on manufacturers, but that this burden is difficult to assess given that HRSA has yet to take steps to implement it.

¹² See 80 Fed. Reg. at 34,585.

¹³ We note that establishing a *de minimus* exception to the refund requirement would be consistent with a long-standing line of case law holding that agencies may establish *de minimus* requirements to statutes they administer unless Congress has clearly precluded such exceptions—which is not the case here. See, e.g., Ass’n of Admin. Law Judges v. FLRA, 397 F.3d 957, 962 (D.C. Cir. 2005) (“Categorical exceptions may . . . be permissible as an exercise of agency power, inherent in most statutory schemes, to overlook circumstances that in context may fairly be considered *de minimus* . . . The ability to create a *de minimus* exception is not an ability to depart from the statute, but rather a tool to be used in implementing the legislative design. Unless it has been extraordinarily rigid in expressing itself to the contrary . . . Congress is always presumed to intend that pointless expenditures of effort be avoided.”) (internal quotations and citations omitted). We further note that *de minimus* standards have been employed in analogous circumstances with respect to refund requirements, including by CMS with respect to the MDRP. With respect to the refund processes contemplated under the 340B statute, we believe that a \$100 *de minimus* threshold is appropriate for purposes of balancing

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consider comments from the 340B stakeholder community, and issue final guidance in order to establish the obligation and certainty before imposing penalties for non-compliance. We note that, while the parenthetical above tries to capture two of the types of logistical issues that manufacturers assume would need to be addressed with respect to such a refund process, our comments and recommendations could change depending on the procedure or mechanism that is ultimately proposed (e.g., the frequency of refunds and/or credits, as well as how such payments would be processed, including whether wholesalers, distributors, or some other agent would function as an intermediary).

2. *Establish a process for the issuance of credits and refunds to covered entities in the event of a subsequent rebate or discount that lowers the applicable ceiling price for the relevant quarter under § 340B(d)(1)(B)(iv):* Particularly given the frequency with which routine restatements of pricing data may occur, standardization of this process is necessary to ensure that manufacturers have an efficient and streamlined mechanism to restate pricing data and provide appropriate refunds. We urge HRSA to ensure that this process imposes as little burden as possible on manufacturers and covered entities (e.g., by establishing a reasonable timeframe for issuing refunds that takes into account the 12-quarter MDRP restatement period, as well as a fixed-dollar *de minimus* threshold for refunds that does not exceed the cost of processing the refund [e.g., \$100]), and to recognize that this process must provide ample time for manufacturers to identify, investigate, and correct pricing data. For reasons articulated throughout this letter, we further urge HRSA to recognize that, for purposes of 340B manufacturer CMPs, “knowing and intentional” overcharges cannot occur based on routine restatements of pricing data.

We similarly believe that HRSA needs to address program integrity across all 340B program participants in order to meet the intent of the changes made by the ACA. For example, holding manufacturers liable for overcharging covered entities without also holding covered entities responsible for excess discounts obtained from manufacturers—including as the result of diversion and duplicate discounts—is inherently inconsistent with the ACA’s efforts to improve program integrity across all 340B program participants. We therefore urge HRSA to implement covered entity sanctions under section 340B(d)(2)(B)(v) in tandem with manufacturer CMPs.

Relatedly, BIO firmly believes that HRSA, in collaboration with CMS, should take immediate steps to establish mechanisms to address duplicate discounts per 340B(d)(2)(B)(iii) to ensure that manufacturers are similarly not subject to double dipping, to include a formal mechanism whereby HRSA and/or manufacturers will work with covered entities and, as appropriate, states, to resolve any potential duplicate discounts and ensure the repayment of the affected manufacturer(s). In addressing duplicate discounts, it also is imperative that HRSA provide some consequence for either engaging in double dipping, or failing to work with the affected manufacturer(s) to resolve the issue (e.g., prospective ineligibility for the 340B program), in order to provide an incentive for covered entities to

the administrative burden on covered entities and manufacturers, with the need to ensure that covered entities are not overcharged for covered outpatient drugs.

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promptly address, and work to resolve, any such issues with the affected manufacturer(s). Currently, the lack of any such consequences incentivizes covered entities to delay, or even deny, repayment requested by manufacturers, which, in turn, discourages manufacturers from attempting to address potential duplicate discounts with them. We note that any mechanisms established by HRSA in accordance with this provision would in no way minimize the authority of manufacturers to audit covered entities for violations of the statutory prohibition against duplicate discounts under section 340B(a)(5)(C).

II. Ceiling Price Calculation

Section 340B of the Public Health Service Act instructs HHS to enter into a pharmaceutical pricing agreement (PPA) with certain drug manufacturers.¹⁴ When a manufacturer signs a PPA, it agrees that the prices charged for covered outpatient drugs to covered entities will not exceed defined 340B ceiling prices, which are based on quarterly pricing data reported to CMS.¹⁵ In the Proposed Rule, HRSA aims to provide further clarity with respect to these ceiling price calculations.

As an initial matter, BIO questions HRSA's authority to promulgate regulations with respect to the 340B statute's ceiling price calculation.¹⁶ Even if the Agency does have rulemaking authority here, we note that, under no circumstances, may such authority exceed defining "precisely defined standards and methodology for the calculation of ceiling prices."¹⁷ Moreover, any such standards and methodologies—whether issued via

¹⁴ 42 U.S.C. § 256b(a)(1).

¹⁵ 42 U.S.C. § 256b(a)(1)-(2).

¹⁶ HRSA does not have broad rulemaking authority with respect to the 340B program. See Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs., 43 F. Supp. 3d 28, 40-45 (D.D.C. 2014). Instead, HRSA must rely on specific grants of authority in Section 340B itself. Congress plainly gave HRSA authority to issue regulations regarding the 340B statute's manufacturer CMP provisions, directing that the CMP provisions be implemented via "regulations to be promulgated by the Secretary." 42 U.S.C. § 256b(d)(1)(B)(vi). When it came to calculating the ceiling price, however, Congress took a different tack. It directed HRSA to establish "precisely defined standards and methodology for the calculation of ceiling prices" via "an appropriate policy or regulatory issuance." Id. § 256b(d)(1)(B)(i)(I).

In choosing different words to describe HRSA's powers with regard to ceiling-price calculations, it is reasonable to assume that Congress intended to give HRSA different authority with respect to the ceiling-price calculations than CMPs. Courts "refrain from concluding" that "differing language in . . . two subsections has the same meaning in each." Russello v. United States, 464 U.S. 16, 23 (1983). Moreover, the different language between the ceiling-price-calculation and CMP provisions cannot be explained away as a difference in phrasing. As the D.C. Circuit has explained in rejecting a similar argument, "it is through the 'dint of . . . phrasing' that Congress speaks, and where it uses different language in different provisions of the same statute, [a court] must give effect to those differences." Ford v. Mabus, 629 F.3d 198, 206 (D.C. Cir. 2010) (ellipses in original). After all, if Congress intended HRSA to have authority to issue binding regulations regarding ceiling-price calculations, it "knew how to"—it could have used the same "regulations to be promulgated by the Secretary" language it used in the CMP provision. Central Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A., 511 U.S. 164, 176 (1994).

The different language in Section 340B's CMP and ceiling-price-calculation provisions could reasonably be viewed as Congress intending that HRSA's ceiling-price-calculation guidance be nonbinding. Agencies often speak through such nonbinding guidance, which are alternatively labeled "interpretive rules" or "policy statements." McLouth Steel Prods. Corp. v. Thomas, 838 F.2d 1317, 1322 n.3 (D.C. Cir. 1988). It therefore makes perfect sense for Congress to have directed that HRSA clarify its position on how to calculate the ceiling price through "an appropriate policy or regulatory issuance" while at the same time withholding from HRSA the power to issue a binding legislative rule on the topic.

¹⁷ 42 U.S.C. § 256b(d)(1)(B)(i)(I).

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regulations or, as appropriate, guidance—must be consistent not only with the 340B statute, but also the MDRP statute, as the two statutes are inextricably intertwined,¹⁸ and should provide adequate opportunity for stakeholders to comment.

A. Definitions

BIO appreciates HRSA's efforts to define certain, key ceiling price-related terms in the Proposed Rule. We have some concerns and recommendations with respect to these proposed definitions, however.

First, in the Proposed Rule, HRSA proposes to define the term "340B Drug" as "a covered outpatient drug, as defined in section 1927(k) of the Social Security Act, purchased by a covered entity at or below the ceiling price required pursuant to a pharmaceutical pricing agreement with the Secretary."¹⁹ On the one hand, we appreciate that this term would be defined by reference to a "covered outpatient drug" as that term is defined in "section 1927(k) of the Social Security Act." We note that this definition would align with the definition of covered outpatient drug in the 340B statute and the Proposed Rule, which incorporate by reference, all of 1927(k), including both the general definition (1927(k)(2)) and the limiting definition (1927(k)(3)).²⁰

We are concerned, however, that HRSA has proposed to define the term "340B drug" in the first instance, as this term is not used in the 340B statute, or even in the proposed regulatory text. Given that stakeholders have no idea how this term will be applied, if at all, we strongly urge HRSA to eliminate this definition from the Proposed Rule, as there is no way for stakeholders to provide meaningful feedback. In its place, we urge HRSA to ensure that the term "covered outpatient drug" is consistently used by reference to section 1927(k) of the SSA, in conformity with the 340B statute and HRSA's longstanding guidance.²¹

Second, HRSA proposes to define the term "quarter" as a "calendar quarter unless otherwise specified."²² While we agree that ceiling prices should be calculated on the basis of calendar quarters, we note that the Proposed Rule does not recognize the two-quarter lag between when a sales transaction occurs and when the applicable 340B ceiling price becomes effective.²³ Indeed, in the preamble to the Proposed Rule, HRSA incorrectly states that the ceiling price is calculated based on the *immediately preceding* calendar quarter—a statement we strongly urge HRSA to correct in issuing a Final Rule or new NPRM (i.e., by

¹⁸ See County of Santa Clara v. Astra USA, 563 U.S. ___, n. 6 (2011) ("Because the Ninth Circuit focused on the 340B Program in isolation, it failed to recognize that the interests of States under the Medicaid Drug Rebate Program and covered entities under the 340B Program may conflict. . . . HHS can use its expertise to ascertain and balance the competing interests.").

¹⁹ 80 Fed. Reg. at 34,587; 42 C.F.R. § 10.3 (proposed).

²⁰ See 42 U.S.C. § 256b(b)(1) ("In this section, the term[] . . . "covered outpatient drug" have the meaning given such term[] in section 1927(k) of the Social Security Act.").

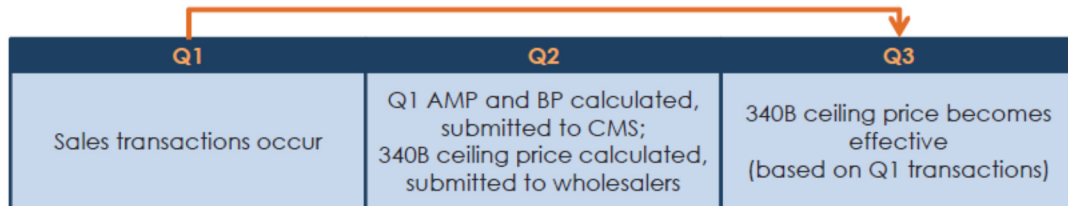
²¹ See 59 Fed. Reg. 25,110, 25,113 (May 13, 1994).

²² 80 Fed. Reg. at 34,588; 42 C.F.R. § 10.3 (proposed).

²³ To illustrate, for a sales transaction that occurs in Q1, the price reporting data that underlie the 340B ceiling price calculation (i.e., Best Price and AMP) are reported to CMS in Q2. The 340B ceiling price also is calculated in Q2, but does not become effective until Q3.

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referring to the data *reported to CMS* in the immediately preceding calendar quarter).²⁴ Calculating the 340B ceiling price for a particular calendar quarter based on the AMP and URA calculated from sales made in the immediately preceding calendar quarter *is not possible*, because AMPs and Best Prices for quarter one are not calculated and reported to CMS until 30 days into quarter two. This lag is illustrated by the following graphic from a recent 340B University deck prepared by Apexus:²⁵



Therefore, manufacturers must calculate the 340B ceiling price for an upcoming quarter based on AMPs and URAs from sales that occurred *two quarters* earlier. We strongly urge HRSA to recognize this two-quarter lag. Specifically, in addition to correcting the misstatement in the preamble, we urge HRSA to recognize, either in the definition of “quarter,” or in the provision regarding the calculation of ceiling prices,²⁶ that ceiling price calculations are “based on sales transactions from two calendar quarters prior.”

Third, HRSA proposes to define the term “covered entity” as “an entity that is listed within section 340B(a)(4) of the PHSA, meets the requirements under section 340B(a)(5) of the PHSA, and is registered and listed in the 340B database.”²⁷ BIO strongly supports this proposed definition. Specifically, in addition to citing the statutory eligibility criteria for 340B covered entities, we strongly support that this definition would include a recognition of the fact that, in order to be considered a “covered entity,” an organization must both: (1) not have committed a duplicate discount or diversion violation; and (2) be registered and appear on the 340B database as a participating entity during the quarter in which the transaction is made

We note that the proposed element of the “covered entity” definition related to diversion and duplicate discounts comports with the 340B statute’s eligibility criteria, as the statute defines a “covered entity” as an entity that falls within the specified categories and “meets the requirements described in [section 340B(a)](5).”²⁸ Notably, section 340B(a)(5) contains both the diversion and duplicate discount prohibitions.²⁹ For purposes of ensuring compliance with this definition, we believe that HRSA should rely, at a minimum, on the Agency’s audit findings and instances of covered entity self-disclosures

²⁴ See 80 Fed. Reg. at 34,585.

²⁵ https://docs.340bpvp.com/documents/public/resourcecenter/340BUniversity_session.pdf.

²⁶ 42 C.F.R. § 10.10 (proposed) (“[a] manufacturer is required to calculate 340B ceiling prices for each covered outpatient drug by National Drug Code (NDC) on a quarterly basis”).

²⁷ 42 C.F.R. § 10.3 (proposed).

²⁸ 42 U.S.C. § 256b(a)(4).

²⁹ HRSA has proposed to define a “covered entity” to mean “an entity that is listed within Section 340B(a)(4) of the PHSA, meets the requirements under section 340B(a)(5) of the PHSA, and is registered in the 340B database.” 42 C.F.R. § 10.3 (proposed) (emphasis added).

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to identify those organizations ineligible as a result of uncorrected instances of diversion and duplicate discounts. Such ineligibility should persist until the instance(s) of diversion and/or duplicate discount(s) are resolved. On a related note, we urge HRSA to ensure that the Agency's efforts to ensure covered entity eligibility pursuant to this provision do not have negative price-reporting implications for manufacturers. Specifically, to the extent that a manufacturer has relied on HRSA's database to determine a covered entity's eligibility for 340B, any ceiling prices extended to such covered entity should be considered a justifiable extension of a 340B discount to a covered entity for price reporting purposes, even if the entity is later found ineligible for 340B by virtue of a duplicate discount or diversion violation. As HRSA lacks authority over other price reporting programs (e.g., the MDRP), the Agency may wish to make such ineligibility determinations solely on a prospective basis in order to address this concern.

We further support the aspect of the proposed "covered entity" definition that would require the covered entity to register and appear on the 340B database as a condition of 340B eligibility. We believe this proposed requirement is particularly important because, while there are entities that may, theoretically, be eligible for the 340B program under section 340B(a)(4), there is no way of identifying these organizations as eligible for 340B pricing unless and until those organizations register with HRSA as covered entities and appear in the 340B database. We note, however, that eligibility for the 340B program can fluctuate over time. For example, an entity may meet the qualifying criteria to be considered a covered entity one quarter, but fail to meet those requirements the subsequent quarter. We therefore urge HRSA to add to the end of the proposed covered entity definition a clarification that the covered entity be registered and listed in the 340B database "for the quarter." Moreover, given that the 340B database has, historically, been limited and at times inaccurate,³⁰ in order to enable manufacturers to confidently rely on the information in HRSA's 340B database, as noted above, we urge HRSA to develop a system to routinely "verify the accuracy of information regarding covered entities" that is listed on the 340B database—as required under section 340B(d)(2)(B)(ii)—to include a certification from HRSA that these data are both up-to-date and accurate. We also strongly urge HRSA to clarify that an organization must meet *all* of the definitional elements of the "covered entity" definition under proposed 42 C.F.R. § 10.3 in order to claim the ceiling price under the 340B program for the quarter.

Finally, we have a technical recommendation with respect to the proposed definition of "wholesaler."³¹ Specifically, we urge HRSA to uniformly refer to the applicable sections of the Social Security Act (as opposed to by reference to the United States Code) for purposes of consistency and to avoid any potential confusion.

³⁰ See OIG, Deficiencies in Oversight of the 340B Drug Pricing Program, OEI-05-02-00072 (Oct. 2005) (noting that 38% of sampled entities listed as enrolled in the HRSA database were not participants in the 340B program and that errors in the database hinder manufacturers' ability to effectively identify entities eligible for the discount program); OIG, State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs, OEI-05-09-00321 (June 2011).

³¹ 42 C.F.R. § 10.3 (proposed).

B. Calculation of 340B Ceiling Price

1. Applicable Average Manufacturer Price

The Proposed Rule provides that “[t]he 340B ceiling price for a covered outpatient drug is equal to the Average Manufacturer Price (AMP) for the smallest unit of measure minus the Unit Rebate Amount (URA).”³² However, it is not clear from this language, or from the definitions section—which proposes to define AMP by reference to section 1927(k)(1) of the SSA³³—whether this proposal refers to monthly or quarterly AMP, as both data points are reported by manufacturers to CMS. Because the 340B ceiling price is to be calculated on a quarterly basis, we urge HRSA to clarify that this calculation should be based on the *quarterly* AMP. We note that this interpretation aligns with the fact that monthly AMPs did not exist at the time that the 340B program was established,³⁴ providing a strong indication that Congress clearly intended for quarterly AMPs to be used for this purpose.

In addition, we urge HRSA to make clear that any reference to a unit of drug is consistent with for the approach used for purposes of MDRP reporting. Thus, rather than referring to the AMP “for the smallest unit of measure” minus the URA, HRSA should instead refer to AMP for “the unit of measure for the drug in question that is used for purposes of Medicaid Drug Rebate Program price reporting.”

2. Decimal Places

HRSA proposes to calculate the ceiling price using six decimal places.³⁵ HRSA would then “publish” these ceiling prices, rounded to two decimal places, on a secure site available to covered entities.³⁶ We suggest that the quarterly ceiling prices be instead reported and calculated in dollars and cents (i.e., 99999.99). As we noted in our May 2015 comment letter to HRSA regarding the Agency’s estimated information collection burden, the requirement for additional decimal places, beyond two, likely would increase the price reporting burden on manufacturers due to any disputes that could arise under the process HRSA proposed through that ICR.

BIO also is concerned that the Proposed Rule states that HRSA will “*publish* the 340B ceiling price,”³⁷ but does not address confidentiality, the mechanism for this “publication,” or the safeguards HRSA will establish to limit access to such prices to covered entities while preventing any “unauthorized re-disclosure.” Maintaining the security of any pricing data obtained from manufacturers is critical, and we emphasize that these security

³² 42 C.F.R. § 10.10(a) (proposed). We note that this proposal is somewhat different from the language in the Agency’s 340B Quarterly Pricing Data Text File for Transfer to HRSA, which provides in the section on “Data Field Definitions” that the “340B Price” should be “[c]alculate[d] to 6 decimal places and truncate[d] to 4 decimal places, pad positions 5 and 6 with zeros.”

³³ 42 C.F.R. § 10.3 (proposed).

³⁴ See Deficit Reduction Act of 2005, Pub. L. No. 109-171 § 6001 (adding the requirement that manufacturers report monthly AMPs for purposes of the MDRP).

³⁵ 42 C.F.R. § 10.10(a) (proposed).

³⁶ 80 Fed. Reg. at 34,585.

³⁷ *Id.* at 34,588; 42 C.F.R. § 10.10(a) (proposed) (emphasis added).

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requirements also apply to any pricing data that HRSA obtains from CMS.³⁸ In line with prior BIO comments to the Agency, we urge HRSA to detail its plans for safeguarding this highly sensitive and proprietary pricing data and for ensuring that any confidential disclosures of ceiling prices conform strictly to all of the safeguards set forth in the 340B statute.³⁹

Among other things, HRSA should specify the safeguards it will adopt to ensure that: (1) HRSA will not, in any circumstance, disclose any proprietary information it obtains, except HRSA-verified ceiling prices; (2) any ceiling price disclosures are made only in strict accordance with the 340B statute and *after* HRSA develops, tests, and implements systems ensuring that ceiling prices can only be disclosed to authorized covered entity representatives, only through the HHS website, and only “in a manner (such as through the use of password protection) that limits such access to covered entities”; and (3) any password-protected disclosure of ceiling prices to authorized covered entity representatives “adequately assures security and protection of privileged [ceiling price] data from unauthorized re-disclosure.”⁴⁰ Along these lines, we also urge HRSA to eliminate the word “publish”—which typically denotes disclosure to the general public—and refer instead to “providing verified ceiling prices to covered entities in a confidential manner that complies with the requirements of section 340B(d)(1)(B)(iii) and other applicable laws.”

3. Package Size and Case Package Size

In the Proposed Rule, HRSA further proposes that, in order “to ensure the final price is operational in the marketplace,” the 340B ceiling price would be multiplied “by the drug’s package size and case package size.”⁴¹ However, neither the term “package size” nor “case package size” is defined in the Proposed Rule. Moreover, as illustrated by the following slide from a recent 340B University run by Apexus, HRSA’s longstanding policy has been to multiply the 340B ceiling price solely by the “Units per Package.”

³⁸ This pricing information is protected by the Trade Secrets Act, which prohibits federal agencies from disclosing trade secrets and confidential commercial and financial information “in any manner or to any extent not authorized by law.” 18 U.S.C. § 1905. In addition, the PPA provides that “information disclosed by the Manufacturer in connection with the [PPA], except as otherwise required by law, will not be disclosed by the Secretary or his designee in a form which reveals the Manufacturer, except as necessary to carry out the provision of section 340B of the [PHS] Act, and to permit review by the Comptroller General.” PPA § V(a).

³⁹ HRSA can only make a limited disclosure of one data point—HRSA-verified ceiling prices—and only “in a manner . . . that limits such access to covered entities and adequately assures security and protection of privileged pricing data from unauthorized disclosure.” 42 U.S.C. § 256b(d)(1)(B)(iii).

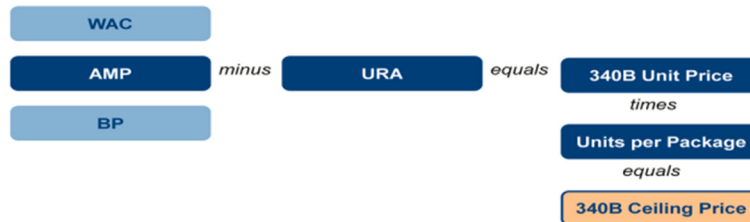
⁴⁰ We note that this second activity will require a range of carefully designed security measures, including published guidelines clearly warning covered entity representatives that gain access to verified ceiling prices of what constitutes “unauthorized re-disclosure” and requiring them to certify that they will comply with the ban on unauthorized re-disclosure before they can obtain access to ceiling prices through the HHS website, as well as requiring appropriate training and compliance programs by covered entities. HRSA also should specify that any covered entities that engage in unauthorized re-disclosure will be subject to sanctions in order to promote compliance with these requirements.

⁴¹ 42 C.F.R. § 10.10(a) (proposed).

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- 340B ceiling price



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We note that “Units per Package” is not only a longstanding variable used by HRSA, but that a similar value is used for NDC-11 product reporting for purposes of the MDRP.⁴² We therefore believe that HRSA should rely on the “Units per Package” for the NDC-11, and the CMS Unit Type used to convert a manufacturer’s NDC-11 sales package data into the per-unit values used in Medicaid AMP, Best Price, and URA metric calculations for the associated 340B ceiling price calculation. For this purpose, HRSA should adopt definitions of “Unit” and “Package Size” that are not only consistent with those used in the MDRP metrics calculations, but that are consistent with each other, such that it yields the correct NDC-11-level ceiling price when the per-unit ceiling price is multiplied by the package size. Adopting consistent definitions of these terms is important to help ensure that manufacturers, covered entities, and HRSA are clear as to how the per-unit ceiling price translates into the per-package ceiling price that is ultimately offered to covered entities.

In addition, we urge HRSA to eliminate its proposal to use the variable “case package size” for purposes of the 340B ceiling price calculation. We believe that the introduction of this new variable would result in substantial confusion for manufacturers, covered entities, and HRSA. We also note that “case package size” is not a recognized variable for purposes of the MDRP,⁴³ and thus manufacturer reporting of this information for purposes of the 340B program would increase the burden on manufacturers of both calculating the ceiling price and of reporting ceiling price data to HRSA for purposes of the Agency’s ceiling price verification activities described in its recent ICRs.

⁴² The CMS Drug Data Reporting System (DDR) defines “Units Per Package Size” as the “[t]otal number of units in the smallest dispensable amount for the 11-digit NDC. Numeric values, 11-digit field: 7 whole numbers, the decimal (‘.’) and 3 decimal places; right-justified, zero-filled.”

⁴³ See CMS Record Specification DDR Drug Product Data Text File for Transfer to CMS (Aug. 2010); CMS Record Specification DDR Quarterly Pricing Data Text File for Transfer to CMS (Jan. 1, 2008).

C. Penny Pricing

HRSA proposes that a manufacturer charge \$0.01 per unit of measure for a drug with a ceiling price of \$0.⁴⁴ While this proposal is consistent with the Agency's statement of its "penny pricing" policy issued in 2011, we have serious concerns with respect to this approach.

To start, we have a hard time understanding how a \$0.01 price is reasonable, given that there is no material difference between \$0.01 and \$0, and HRSA has regularly identified a \$0 ceiling price as "unreasonable."⁴⁵ Indeed, in order to sell a covered outpatient drug to a covered entity, manufacturers incur costs in the form of distribution and handling fees that well exceed a penny. Moreover, HRSA's application of the penny pricing policy to date has led to some problematic consequences. For instance, HRSA notes in its own policy release on this topic that, "[w]hen a 340B price drops to a penny price, a manufacturer may anticipate challenges with equitable market distribution of the drug" due to the potential for drug shortages,⁴⁶ illustrating that HRSA's policy is undermining efforts undertaken by the Food and Drug Administration (FDA)—its sister agency—to address the challenges of drug shortages in today's market.⁴⁷ Moreover, there is evidence to suggest that penny pricing results in stockpiling of affected drugs by covered entities, as well as apparent violations of the 340B statute's prohibition against diversion (i.e., reselling or otherwise transferring a 340B-purchased product to a "person who is not a patient of the entity")—which should be of particular concern to HRSA.⁴⁸

We also note that HRSA's penny pricing policy appears particularly unreasonable when viewed together with the 340B statute's "must offer" requirement.⁴⁹ Specifically, applying both the penny pricing and "must offer" policies together would have a particularly high potential to result in drug shortages. Although HRSA has articulated its policy that manufacturers can adopt alternate allocation procedures when the penny pricing policy is implicated,⁵⁰ we do not believe that manufacturers can or should be required to adopt these burdensome and costly allocation processes, the cause of which is the market-distorting effect of the policies adopted by HRSA. We further question whether applying a ceiling price of \$0.01, particularly in the context of a "must offer" obligation, would pass constitutional muster—specifically whether it could be considered "just compensation" for the taking of private property under the Fifth Amendment to the U.S. Constitution.⁵¹

⁴⁴ 42 C.F.R. § 10.10(b) (proposed).

⁴⁵ See, e.g., HRSA, Clarification of Penny Pricing Policy, Release No. 2011-2 (Nov. 21, 2011).

⁴⁶ Id.

⁴⁷ See, e.g., FDA, FDA Works to Lessen Drug Shortage Impact, <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm258152.htm> ("Food and Drug Administration (FDA) officials are working closely with industry, health care providers, and patients to prevent and mitigate shortages of 'medically necessary' medicines.").

⁴⁸ 42 U.S.C. § 256b(a)(5)(B).

⁴⁹ While we continue to emphasize that this "must offer" language is not operational unless and until it has been incorporated into the PPA, as described in greater detail below, we note that it is HRSA's current position that manufacturers "must offer" their products to covered entities at the ceiling price.

⁵⁰ HRSA, Clarification of Non-Discrimination Policy, Release No. 2011-1.1 (May 23, 2012).

⁵¹ The Fifth Amendment's "takings clause" constrains all types of economic regulation by requiring the payment of "just compensation" if a regulation causes enough injury to constitute the "taking" of property from the regulated person or firm. In light of the 340B statute's "must offer" requirement, as well as the fact that participation in 340B is a condition of Medicaid coverage, participating manufacturers can be analogized to

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It also is worth mentioning that simultaneously applying these two policies could result in particularly problematic results with respect to controlled substances, products subject to FDA-approved Risk Evaluation and Mitigation Strategies (REMS), and products for which a grey or black market exists, as HRSA would effectively be requiring manufacturers to make available an unlimited supply of such products at virtually no cost to covered entities, resulting in the potential for not only drug shortages and diversion, but also harm to patients and abuse. To illustrate, when one manufacturer of controlled substances initially complied with HRSA's penny pricing policy, it saw a significant increase in sales volume to 340B covered entities. This manufacturer became concerned that diversion might be occurring and, despite engaging in monitoring to identify possible diversion, the manufacturer was limited by 340B program policy from refusing to sell to covered entities suspected of such program violations. Rather, program policy provides that the manufacturer should continue to sell product to the covered entity while the manufacturer investigates whether diversion (or other misconduct) is occurring. Investigation of diversion of controlled substances, such as opioids, "after the fact" (i.e., through HRSA or manufacturer audits) is lengthy and cumbersome, as well as an unacceptable approach for this product line, as the public health risks associated with diversion and abuse are not remedied through such audits. At a minimum, we believe that HRSA should make an effort to adopt policies that limit the risk for diversion in the first instance.

In light of these concerns, together with Congress's clear intent that the 340B program not result in improper diversion, we are particularly troubled by the absence of any explanation in the Proposed Rule as to why \$0.01 is a non-arbitrary and non-capricious choice. It is well-established that Agency actions "found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" violate the Administrative Procedure Act and therefore must be set aside.⁵² In determining whether an Agency action has run afoul of this "arbitrary and capricious" standard, reviewing courts are tasked to determine whether the agency has "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made."⁵³ This standard is not met with respect to the penny pricing policy as it is articulated in the Proposed Rule.

Indeed, HRSA did not provide *any* rationale in the instant rulemaking regarding why or how the Agency interpreted the statute in this way—or if, indeed, the Agency was interpreting the statute at all—aside from the cursory statement that "[u]sing the prior

public utilities, in the sense that manufacturers are under a legal obligation to serve certain customers. *See, e.g., Mora v. Mejias*, 223 F.2d 814, 817-18 (1st Cir. 1955) (concluding that rice importers required to sell at a loss were entitled to the same constitutional protection as utilities). The guiding principle has been that the Constitution protects utilities from being limited to a charge for their property serving the public which is so "unjust" as to be confiscatory. *See, e.g., Duquesne Light Co. v. Barasch*, 488 U.S. 299, 307 (1989).

⁵² *See, e.g., City of Kansas City v. Dep't of Hous. & Urban Dev.*, 923 F.2d 188, 189 (D.C. Cir. 1991) (even "assuming[] arguendo" that the agency had ample statutory authority, its action was devoid of "reasoned decision-making," and was therefore arbitrary and capricious).

⁵³ *Motor Vehicle Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983) (internal quotations marks and citations omitted).

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quarter pricing or some other price would nullify the pricing formula.”⁵⁴ Rather, HRSA appears to simply re-issue its 2011 policy, suggesting that the Agency continues to rely on the rationale articulated there, namely that “[u]sing 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.”⁵⁵ However, this 2011 policy was predicated on a faulty presumption, namely that the MDRP’s “Additional Rebate” is punitive and that the 340B ceiling price must therefore “punish” manufacturers in instances in which this rebate applies (i.e., by requiring penny pricing). While the Additional Rebate is often colloquially referred to as the “CPI-U Penalty,” we find no support in the statute or legislative history for the notion that the Additional Rebate term is intended to be punitive. Indeed, while the MDRP statute includes a “Penalties” provision and contemplates the imposition of CMPs, neither of these provisions addresses, let alone punishes, increases in AMP.⁵⁶ Moreover, that Congress declined to subject these pricing increases to penalties is supported by the fact that AMP values can fluctuate for a number of policy-neutral reasons, none of which are prohibited by law. As courts consistently have stricken down regulatory interpretations that are built upon a false premise,⁵⁷ HRSA’s penny pricing policy cannot be supported by this erroneous justification.

We also take issue with HRSA’s statement in the preamble to the Proposed Rule that “[t]his proposed regulation would allow HRSA to enforce the [penny pricing] policy.”⁵⁸ First, as noted previously, BIO questions the Agency’s authority to issue regulations with respect to the ceiling price calculation in the first instance. Second, even if HRSA does have rulemaking authority with respect to the ceiling price calculation, such authority would be limited to the applicable “standards and methodologies,” and under no circumstances would the penny pricing policy be retrospective in application. Indeed, while HRSA does not indicate in the Proposed Rule whether any final rule would apply prospectively only, or retrospectively as well, as a general matter, any retrospective application would be unlawful under basic principles of administrative law.⁵⁹ Moreover, HRSA itself acknowledges that the penny pricing policy currently is not binding, and states that a number of manufacturers have informed HRSA that they are not charging a penny per unit when the ceiling price rounds or calculates to zero.⁶⁰ If HRSA implements the penny pricing policy as a final rule, it should do so prospectively only, as it would be unfair to retroactively impose obligations that were previously not binding. In addition, any final rule should

⁵⁴ 80 Fed. Reg. at 34,585.

⁵⁵ HRSA, Clarification of Penny Pricing Policy, Release No. 2011-2 (Nov. 21, 2011) (emphasis added).

⁵⁶ See 42 U.S.C. § 1396r-8(b)(3)(B)-(C).

⁵⁷ *Oklahoma Dep’t of Env’tl Quality v. EPA*, 740 F.3d 185, 195 (D.C. Cir. 2014) (finding that agency action that is “based upon an assumption that is incorrect as a matter of law” is “plainly erroneous” and warrants no deference from the court.) (quoting *Auer v. Robbins*, 519 U.S. 452, 461 (invalidating agency interpretation built on a false “assumption”).)

⁵⁸ 80 Fed. Reg. at 34,586-87.

⁵⁹ See *Bowen v. Georgetown University Hospital*, 488 U.S. 204, 208-209 (1988) (finding that, as a general matter, statutory grants of rulemaking authority will not be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by express terms).

⁶⁰ HRSA notes in the Regulatory Impact Statement included with the Proposed Rule that “[a] small number of manufacturers have informed HRSA over the last several years that they charge more than \$0.01 for a drug with a ceiling price below \$0.01. . . . This proposed regulation would allow HRSA to enforce the policy in a manner that would require the manufacturer to charge \$0.01, and it is likely that manufacturers would charge \$0.01 in order to avoid the imposition of a civil monetary penalty for overcharging a covered entity.” 80 Fed. Reg. at 34,586.

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afford manufacturers sufficient time to come into compliance with the penny pricing policy, as penny pricing would constitute a new compliance requirement.

In light of these serious concerns with respect to HRSA's penny pricing approach, we believe that the Agency should instead continue to permit manufacturers the flexibility to select a reasonable pricing methodology for purposes of calculating an appropriate ceiling price in quarters for which AMP equals the URA, in accordance with their duty of good faith under the PPA.

In our view, since the 340B statute clearly did not anticipate a situation in which the statutory formula for calculating the 340B ceiling price could not be squared with the requirement that covered entities "purchase" a drug, we believe that the parties should be proceeding under the PPA. As you know, the PPA specifically provides that the agreement "shall be construed in accordance with Federal common law."⁶¹ Federal common law, in turn, requires that the parties "gap fill" by operating under a duty to each other of "good faith."⁶² We note that there is precedent for relying on this duty with respect to zero drug prices, as this is the manner in which the Veteran's Administration proceeds under the comparable Master Agreement.⁶³

We believe that this duty of good faith would be met to the extent that a manufacturer selects a reasonable pricing methodology, namely one that is: readily and objectively verifiable (i.e., not tied to costs or margin); statutorily supported (e.g., the same or related to a price calculated for purposes of another government program that is reasonably related to the 340B program); and represents a favorable discount to covered entities that is, in all cases, lower than AMP minus the MDRP basic rebate percentage. To illustrate, we believe that there are at least three pricing methodologies that are reasonable and thus consistent with this duty, including: (1) nominal pricing; (2) reliance on non-penny 340B pricing from prior quarters; and (3) use of the federal ceiling price (or federal supply schedule pricing).

First, a nominal pricing methodology is one example of a reasonable pricing policy that is consistent with this duty of good faith, in that it is statutorily supported, fair to both parties, and would result in favorable discounts to covered entities. Unlike the term or concept of a "penny price" (which simply does not exist anywhere in statute), the terms "nominal price" or "a price merely nominal in amount" appear nine times in the MDRP statute.⁶⁴ Furthermore, Congress has notably demonstrated its support for applying the concept of nominal pricing in the context of the 340B program. Specifically, covered entities are listed first among the six potential recipients to whom manufacturers may extend a nominal price without concern that those prices would affect Medicaid rebate

⁶¹ PPA § VII(e).

⁶² United States v. Basin Elec. Power Co-Op, 248 F.3d 781, 796-97 (8th Cir. 2001) (finding that the duty of good faith and fair dealing serves "as a gap filler to deal with circumstances not contemplated by the parties at the time of contracting.").

⁶³ Specifically, when a zero or negative Non-FAMP exists, manufacturers report it and then call their contracting officer to negotiate a fair price. See Marci Anderson, Senior Auditor, VA Office of Inspector General, VHCA § 603: Calculating the Non-Federal Average Manufacturer Price (Non-FAMP) and the Federal Ceiling Price, Presentation at ACI's "Big Four" Rx Pricing Boot Camp, slide 58 (May 21, 2013) (presentation on file).

⁶⁴ See generally 42 U.S.C. § 1396r-8.

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liability.⁶⁵ Furthermore, a nominal pricing policy addresses many of the concerns that HRSA articulated in issuing its penny pricing policy in the first instance, in the sense that it is not the prior quarter's price, WAC, or a non-340B contract price, and instead would be derived from the prior quarter's AMP, recognizing the two-quarter lag.⁶⁶

Second, a methodology under which ceiling prices would be calculated based on earlier quarters of non-penny 340B sales would be similarly consistent with manufacturers' duty of good faith. We note that a similar approach is permitted in the MDRP, which looks to the most recent prior period's positive value,⁶⁷ and results in more reasonable pricing than \$0.01 per unit of sale. Such prices carried forward still represent a significant discount and are consistent with previous period ceiling prices. Moreover, discounted, non-penny prices reduce the incentives for inappropriate use, misuse, and diversion of 340B products, including controlled substances and other restricted or high-risk products.

Finally, we note that a methodology whereby manufacturers would charge a ceiling price based on the federal ceiling price (or by reference to the federal supply schedule price where there is no federal ceiling price) would similarly meet this duty of good faith. This methodology not only was established as part of the same legislation as the 340B program,⁶⁸ but is the basis for prices paid by the federal government, and thus would serve as a reasonable basis for setting drug prices for covered entities. We further note that the federal supply schedule, like the 340B statute, has a "must offer" obligation, pursuant to which manufacturers are required to supply drugs to the federal government at the calculated prices. While Congress added the "must offer" requirement to the 340B statute 18 years after the ceiling price calculation was codified,⁶⁹ the federal ceiling price and the federal supply schedule's must offer obligation were codified simultaneously,⁷⁰ evidencing that the federal ceiling price is an approach that Congress supports with respect to drug pricing in the context of a supply obligation.

We note that these methodologies are provided only as examples, and that maintaining manufacturer choice in this area is of paramount importance, as no particular methodology may be appropriate in every instance. For example, there are circumstances in which the federal supply schedule price also is at a penny, and thus reliance on this pricing benchmark would not address BIO's concerns with HRSA's penny pricing policy proposal, described above.

⁶⁵ 42 U.S.C. § 1396r-8(c)(1)(D).

⁶⁶ See HRSA, Clarification of Penny Pricing Policy, Release No. 2011-2 (Nov. 21, 2011) ("It is not appropriate for a manufacturer to use the prior quarter pricing, wholesale acquisition cost (WAC), or any other non-340B contract price in place of the penny pricing because 340B ceiling prices must be based on the immediately preceding calendar quarter.").

⁶⁷ <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-091.pdf> ("A manufacturer is required to report monthly and quarterly AMP data for all drugs reported to the MDR program. We are aware that there may be a monthly or quarterly period where the AMP calculation may result in a negative or zero value. In accordance with Manufacturer release No. 80 dated January 5, 2010, when this occurs, manufacturers should report the most recent prior month's or quarter's positive AMP value.")

⁶⁸ See Veterans Health Care Act of 1992, Public Law 102-585 §§ 601-603 (Nov. 4, 1992).

⁶⁹ See ACA § 7102(b)(1).

⁷⁰ See Veterans Health Care Act of 1992, Public Law 102-585 § 603 (Nov. 4, 1992).

D. Estimated Price for New Drugs

As HRSA notes in the Proposed Rule, calculation of the ceiling price for each covered outpatient drug for the current calendar quarter is based on pricing data gathered from the calendar quarter ending two quarters prior.⁷¹ Therefore, for new drugs for which pricing data are unavailable for that prior quarter, there will be no sales data to determine 340B ceiling prices. To address this, HRSA proposes that manufacturers estimate the 340B ceiling price for the first three quarters that a new covered outpatient drug is available for sale.⁷² HRSA further proposes that, once pricing data are available, “[a] manufacturer must calculate the actual 340B ceiling price for the first three quarters the drug was available for sale and refund or credit covered entities that purchased the covered outpatient drug above the calculated 340B ceiling price no later than the end of the fourth quarter after the drug is available for sale.”⁷³ BIO strongly urges HRSA to reconsider this proposal, which is problematic in a number of respects, and instead adopt a uniform estimated ceiling price of WAC minus the MDRP basic rebate percentage, depending on the drug’s statutorily defined classification percent.⁷⁴

As an initial matter, we note that data *do* exist to calculate a 340B ceiling price for the third quarter of sales, meaning that this is not an estimated price point. Specifically, although the first-quarter sales may not be complete, manufacturers are able to calculate and report Medicaid values for those first-quarter sales, which can be used to calculate a ceiling price for the product’s third quarter on the market. Accordingly, HRSA should make clear that it is only the first *two* quarters for which estimated prices are, in fact, necessary. Any language on the need for estimation should therefore ensure that estimates are made through two quarters. With respect to the third quarter, manufacturers should begin normal calculations, based on a two-quarter lag.

We also note that the Proposed Rule does not define what constitutes a “new drug” for purposes of the Agency’s price estimation proposals. To these ends, we urge HRSA to recognize that a new NDC-11 or package size would take the existing pricing from the product code family—defined at the NDC-9 level—and thus would not need an estimated price for the first two quarters.

But, more importantly, BIO has serious concerns with respect to the Agency’s entire estimation and adjustment proposal, which among other things, would improperly extend commercial discounts with respect to 340B prices, and thus BIO strongly urges the Agency to reconsider this policy. Specifically, commercial contract prices impact the Medicaid rebate and the 340B price in equal regard, but 340B prices are affected on a two-quarter lag from the date of the contracts. To illustrate, a commercial contract that discounted sales between January 1 and December 31 of 2014 would affect the Medicaid URA

⁷¹ As noted previously, we urge HRSA to correct the misstatement in the preamble to the Proposed Rule, which states that ceiling prices are calculated based on data from the “immediately preceding calendar quarter.” See 80 Fed. Reg. at 34,585.

⁷² 42 C.F.R. § 10.10(c) (proposed).

⁷³ Id.

⁷⁴ These percentages are statutorily defined as: 23.1 percent for innovator drugs; 17.1 percent for clotting factor products and products approved exclusively for pediatric indications; and 13.1 percent for non-innovator drugs. 42 U.S.C. § 1396r-8(c)(1)(B).

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applicable to Medicaid utilization between 1Q2014 and 4Q2014. Because of the two-quarter lag described previously, this same contract would impact 340B ceiling prices starting two quarters later (i.e., 3Q2014-2Q2015). So, while both the Medicaid rebate and the 340B price would be impacted by this contract over the course of four quarters, they are not the same four quarters (i.e., 1Q2014-4Q2014 for Medicaid vs. 3Q2014-2Q2015 for 340B). However, using this same example, retroactively changing the first two quarters of the 340B price (1Q2014-2Q2014) to reflect the 340B price in 3Q2014—as would be the case under HRSA’s proposal—would actually extend the 340B impact of the price concession for *six*, as opposed to four, quarters (1Q2014-2Q2015, rather than 3Q2014-2Q2015), as the 340B price would be impacted two quarters after the end of the contract owing to the two-quarter lag. This result—which would allow the 340B price to be disproportionately affected by commercial discounts as compared to Medicaid discounts—is not supported by the 340B statute.

Recognizing that there is no “actual” ceiling price for the first two quarters of sales, we therefore urge HRSA to instead establish a set ceiling price for this period, which would not be subject to subsequent adjustments or the need for true-ups. This approach would avoid the improper extension of commercial rebates, described here, while producing the added benefits of creating an even playing field across manufacturers, establishing a price that covered entities could easily verify, and reducing the administrative burden across all stakeholders. As noted above, we specifically suggest that HRSA consider using WAC minus the MDRP basic rebate percentage, depending on the drug’s statutorily defined classification percent for this purpose.

To the extent that HRSA nonetheless adopts its proposed estimation/adjustment methodology, in spite of these concerns, we urge the Agency to take into account the following:

- HRSA’s proposed process appears to require manufacturers to recalculate price points by the end of the fourth quarter. As HRSA is aware, the ceiling price calculation leverages data points from the Medicaid drug rebate process, which has a 12-quarter time period for restatements. To require manufacturers to recalculate price points on a much shorter timeframe—specifically by the end of the fourth quarter—and be in a position to determine and issue any refunds or credits within that period would be unduly burdensome, particularly as there is nothing in the 340B statute that requires the provision of true-ups on any timeframe. In light of these concerns, the need to provide true-ups by the fourth quarter of sales should not be required.
- HRSA’s proposal relies, in part, on a cross-reference to the Agency’s 1995 *Federal Register* Notice. Yet stakeholders did not have the opportunity to comment on specific policies articulated in that Notice based on today’s circumstances. Moreover, it is not clear whether the entirety of this Notice is incorporated by reference and, if not, which aspects of the Notice HRSA intends to apply going forward.⁷⁵ As a result, merely referring to the 1995 Notice in the preamble to the

⁷⁵ For example, the 1995 Notice states that “[CMS] will provide [OPA] with the data necessary for [OPA] to determine the ceiling price which will be used” for a number of program purposes. However, HRSA’s recent

Proposed Rule does not provide stakeholders with adequate information as to how the Notice would apply together with the requirements outlined in the Proposed Rule and HRSA's recent ICRs, thereby undermining stakeholders' ability to provide meaningful comments with respect to the Proposed Rule.

- We are concerned that the Proposed Rule discusses only credits and refunds to covered entities when estimated ceiling prices are too high, but not credits and refunds to manufacturers when estimated ceiling prices are too low. We note that the 340B program is inextricably intertwined with the MDRP, given that it incorporates, by reference, the rebate calculations and definitions from the Medicaid rebate statute. It is therefore appropriate and consistent with the intent and operation of the 340B program to incorporate a two-way refund mechanism that has always existed in the closely related MDRP context. Moreover, as described in greater detail in section (II)(B)(2), below, permitting offsets in only one direction could result in manufacturers being required to offer a sub-ceiling price, notwithstanding the fact that such discounts are clearly identified as voluntary by the 340B statute itself.⁷⁶
- The Proposed Rule fails to recognize the role of the covered entity in obtaining credits and refunds for purposes of the pricing adjustments. This can be contrasted with the Agency's 1995 *Federal Register* guidance, which expressly stated that "there was an attempt [by HRSA] to evenly split the administrative burden of the process between the manufacturer and the entity. If an entity wishes a pricing adjustment, the dollar amount in question, one would expect, must be significant enough to balance the administrative burden involved in documenting and developing the request."⁷⁷ As the burden on manufacturers of issuing 340B refunds in connection with new drugs has greatly *increased* since 1995, due largely to the rapid growth in participation by covered entities in the program,⁷⁸ HRSA should continue its approach, in place since 1995, of requiring covered entities to request a refund in order to balance this growing administrative burden. Likewise, HRSA could specify that a covered entity is not obliged to make a payment to a manufacturer when it pays an estimated ceiling price for a new drug that falls below an actual ceiling price, unless and until the manufacturer makes an express written request for such an adjustment. HRSA also may wish to establish a reasonable *de minimis* threshold (e.g., \$100) for this purpose.

III. Manufacturer Civil Monetary Penalties

As HRSA notes in the Proposed Rule, pursuant to provisions of the 340B statute added by the ACA, any manufacturer with a PPA that knowingly and intentionally charges a registered covered entity more than the ceiling price for a covered outpatient drug may

information collection request would require manufacturers to report these data to HRSA (in addition to CMS) for such purposes. See 80 Fed. Reg. 22,207 (Apr. 21, 2015).

⁷⁶ 42 U.S.C. § 256b(a)(10) ("Nothing in this subsection shall prohibit a manufacturer from charging a price for a drug that is lower than the maximum price that may be charged under paragraph (1).").

⁷⁷ 60 Fed. Reg. at 51,488.

⁷⁸ For example, the Government Accountability Office (GAO) reports that *forty percent* of U.S. hospitals now participate in the 340B program. GAO, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals (June 2015).

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be subject to a CMP not to exceed \$5,000 for each instance of overcharging. BIO has a number of concerns with respect to various aspects of the Proposed Rule intended to implement this requirement.

A. Delegation of authority to OIG

HRSA is proposing that, “[p]ursuant to a delegation of authority, the HHS Office of Inspector General (OIG) will have the authority to bring 340B CMP actions utilizing standards applied to other civil monetary penalties under 42 CFR parts 1003 and 1005.”⁷⁹ BIO appreciates HRSA’s intention to delegate this authority to OIG, given the OIG’s experience with CMPs. Indeed, as noted in a recent proposed rule on other CMP provisions, the OIG generally is delegated the Department’s authority with respect to CMPs and has ample experience to bring to bear in this area.⁸⁰ We have two important concerns, however, with respect to HRSA’s proposed approach.

First, in order to implement this proposal, the Secretary needs to actually delegate this authority to OIG, as this authority has not officially been delegated to date. We note that it is not sufficient for this purpose to define the term “Secretary” to include “any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated,” as HRSA has proposed in the Proposed Rule.⁸¹

Second, we note that most of the standards of 42 C.F.R. part 1003 are not applicable, or even appropriate, for the imposition of manufacturer CMPs under the 340B statute. For example, some of these provisions, as currently written, establish definitions, penalty or assessment amounts, exclusion authorities, collection of penalty and assessment amounts, and other standards that are inconsistent with, inapplicable to, or not appropriately tailored for, the standards outlined in the 340B statute. Moreover, there remain open questions as to how the 340B manufacturer CMPs would be pursued, even after these standards are applied. As a result, stakeholders are being denied a meaningful opportunity to comment on the application of 340B manufacturer CMPs per HRSA’s proposal.

We therefore urge HRSA, together with OIG, to issue a new NPRM (ideally a comprehensive NPRM that addresses all of the ACA’s program integrity provisions, as described above) to: (1) identify those provisions of 42 C.F.R. part 1003 that are *not* applicable to 340B manufacturer CMPs; (2) identify those provisions that *are* applicable; and (3) amend certain other provisions such that they can appropriately be applied in this context.

As to this first category, we urge HRSA clarify that the following provisions of 42 C.F.R. part 1003 are *not* applicable to 340B manufacturer CMPs:

⁷⁹ 80 Fed. Reg. at 34,585.

⁸⁰ 79 Fed. Reg. 27,079, 27,081 (May 12, 2014) (“Since 1981, Congress has created other CMP authorities covering numerous types of fraud and abuse. These new authorities were also delegated by the Secretary to OIG and were added to part 1003.”).

⁸¹ See 42 C.F.R. § 10.3 (proposed).

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- 42 C.F.R. § 1003.104 (amount of assessment)
- 42 C.F.R. § 1003.105 (exclusion from participation in Medicare, Medicaid and all federal health care programs)
- 42 C.F.R. § 1003.107 (determinations regarding exclusion)
- 42 C.F.R. § 1003.129 (notice to other agencies)
- 42 C.F.R. § 1003.133 (statistical sampling)
- 42 C.F.R. § 1003.134 (effect of exclusion)
- 42 C.F.R. § 1003.135 (reinstatement)

In particular, BIO believes that section 1003.129 should not apply in this context because, in addition to the fact that the state and other agencies identified in this provision would have no discernable interest in 340B manufacturer CMP proceedings, the privileged and confidential pricing data that are likely to be at the center of a CMP proceeding makes it more appropriate to restrict the notice and involvement of outside parties to avoid any unauthorized disclosure of this information. BIO further believes that, given the Agency's burden to establish knowing and intentional overcharges in the 340B manufacturer CMP process, the statistical sampling permitted in other, limited HHS circumstances under section 1003.133 should not be permitted here.

With respect to this second category, we urge HRSA to expressly identify as applicable to the 340B manufacturer CMP process the following provisions of part 1003, as well as all of 42 C.F.R. part 1005, which applies by reference per section 1003.109(b):

- 42 C.F.R. § 1003.109 (notice for proposed determinations and opportunity to appeal)
- 42 C.F.R. § 1003.126 (recognizing the authority of the parties to settle, including without the consent of the officer(s) presiding over the hearing)
- 42 C.F.R. § 1003.127 (judicial review)
- 42 C.F.R. § 1003.132 (limitations)

We note that, while BIO supports the application of 1003.109 to 340B manufacturer CMPs, we would urge HRSA, together with OIG, to ensure that manufacturers subject to CMP proceedings also receive certain, additional information, specific to the alleged overcharge in question as part of the required notification. Specifically, in terms of the "description of the . . . incidents with respect to which the penalty. . . are proposed,"⁸² we believe that manufacturers should be provided with a notice of the ceiling price that HRSA has identified as the correct ceiling price, as well as information as to how HRSA identified that value, including the AMP, URA, and package size data that HRSA used in the calculation. This notice also should specify the covered entities subject to any alleged overcharge. It is critical that manufacturers receive this information in order to be able to understand and be able to respond to the allegations against them, particularly given the past problems in the government's calculation of the ceiling price,⁸³ and maintenance of an accurate covered entity database.⁸⁴

⁸² 42 C.F.R. § 1003.109(a)(2).

⁸³ OIG, Deficiencies in Oversight of the 340B Drug Pricing Program, OEI-05-02-00072 at 14 (Oct. 2005)

⁸⁴ *Id.* at 14-15.

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With respect to this third category, we urge HRSA, together with OIG, to amend the following provisions of 42 C.F.R. parts 1003 and 1005, such that they can appropriately be applied for purposes of 340B manufacturer CMPs:⁸⁵

- 42 C.F.R. § 1003.101 (definitions)
- 42 C.F.R. § 1003.100 (basis and purpose)
- 42 C.F.R. § 1003.102 (basis for civil monetary penalties and assessments)
- 42 C.F.R. § 1003.103 (amount of penalty)
- 42 C.F.R. § 1003.106 (determinations regarding the amount of the penalty and assessment)⁸⁶
- 42 C.F.R. § 1003.128 (collection of penalty and assessment)
- 42 C.F.R. § 1005.1 (definitions)

Perhaps most critically, a definition for the term “knowingly and intentionally” would need to be added to section 1003.101. HRSA has not proposed a definition for this term, which also is not currently defined in parts 1003 or 1005.⁸⁷ As this term is essential to the application of manufacturer CMPs under the 340B statute, it must be defined before such CMPs may be imposed. We note that certain proposals made in the Proposed Rule, discussed in greater detail below, suggest that HRSA may be seeking to impermissibly redefine “knowingly and intentionally”—words specifically chosen by Congress for purposes of applying manufacturer CMPs under the 340B statute.⁸⁸ Many civil fraud statutes use the term “knowingly” by itself, and most criminal statutes use “knowingly and willfully.” However, here, Congress chose an even higher, more exacting state-of-mind requirement, which clearly indicates that Congress intended this CMP remedy to be used only for very serious offenses.

Taken together, “knowing and intentionally” should be defined to include only conduct undertaken with the specific intent to overcharge a customer that the manufacturer actually knows is a registered covered entity. HRSA is not permitted to redefine these terms to capture lesser forms of misconduct. This phrase cannot include, therefore, inadvertent, accidental, or negligent conduct, unrecognized error in computing the ceiling prices, conduct undertaken with the honest belief that the facts were otherwise,

⁸⁵ Alternatively, these could be incorporated into HRSA’s regulations at 42 C.F.R. § 10.1, et seq.

⁸⁶ While we do believe that it is necessary for there to be standards for the imposition of penalties, the standards in section 1003.106, as written, are not appropriately tailored to 340B manufacturer penalties. Indeed, all of the provisions of this section are identified as specific to the penalties outlined under sections 1003.102 and 1003.103, none of which are 340B manufacturer CMPs under the current regulatory text. Moreover, even if the standards were broadly interpreted to apply to penalties outside of those identified, many of these standards could not reasonably be applied to overcharges of covered entities by drug manufacturers (e.g., “[t]he nature and scope of the required medically necessary item or service not provided and the circumstances under which it was not provided”). Thus, it is not clear which, if any, of these standards would apply. We articulate recommendations for more tailored standards, below.

⁸⁷ 42 C.F.R. 1003.102(e) does define the term “knowingly.” However, the term “knowingly and intentionally” imposes a higher intent standard than mere knowledge and is not currently defined.

⁸⁸ We note that HRSA does recognize in the Regulatory Impact Analysis included with the Proposed Rule that “[f]or the penalties to be used as defined in the statute and in this rule, a manufacturer would only be subject to those penalties when the overcharge was the result of a knowing and intentional act. Based on anecdotal information received from covered entities, HHS anticipates that this would occur very rarely, if at all.” 80 Fed. Reg. at 34,586. We appreciate this statement, but encourage HHS to incorporate a more formal recognition of the knowing and intentional standard into the rule itself.

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situations where there is a reasonable disagreement and no established law or agency guidance on point, or any other situation not presenting circumstances of deliberate misconduct.

Moreover, the “knowing and intentional” language should not implicate conduct or penalize a manufacturer when dealing with non-customers or non-covered entities. With the proliferation of alternate handling arrangements and corporate structures, a manufacturer should not be subject to CMPs where it refuses to sell at or below the 340B ceiling price when it cannot identify an organization as a legitimate registered covered entity or it is unable to discern a valid and enforceable relationship between an organization and a valid registered covered entity. We ask HRSA to make clear that the CMPs are only available for those rare instances in which a registered covered entity that meets all three prongs of HRSA’s proposed “covered entity” definition has been overcharged, not some organization purportedly acting on the covered entity’s behalf.

In addition, knowing and intentional overcharges to registered 340B covered entities would have to be listed as a basis for the imposition of CMPs under 42 C.F.R. §§ 1003.100 and 102, the amount of the penalty (\$5,000 per instance) would have to be added to section 1003.103, appropriately tailored standards for the imposition of these penalties also would need to be added to section 1003.106, and the definition of “civil money penalty cases” in section 1005.1 would need to be revised, as it currently refers to proceedings arising under “any of the statutory bases for which the OIG has been delegated authority to impose [CMPs] under Medicare or a state health program”—but not the 340B law.

With respect to the standards under section 1003.106, we believe that this provision should be amended to provide that any CMP assessments should take into account the following factors, some of which were articulated in HRSA’s ANPRM, and all of which echo BIO’s recommendations in response thereto:

- The amount by which a manufacturer has knowingly and intentionally overcharged a registered covered entity;
- Whether this amount is *de minimus* (at a threshold to be proposed by HRSA or OIG through subsequent rulemaking, potentially based on either a fixed dollar amount (e.g., \$100) or a percent change in the 340B price (e.g., 1 percent)⁸⁹);
- Whether any overcharge is offset by corresponding undercharges resulting from other restated ceiling prices during a one-year timeframe;
- Whether the manufacturer acted promptly to evaluate any alleged overcharge and correct it if an overcharge, in fact, occurred;
- The frequency of the conduct;
- Whether, when considered in proportion to the manufacturer’s sales of all covered outpatient drugs to all covered entities, the occurrence rate for an overcharge is small;

⁸⁹ BIO has proposed a 2% *de minimus* standard be applied in the restatement context. We would hope that a *de minimus* standard in the CMP context would, at a minimum, meet and preferably exceed that standard, given the enforcement context.

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- The manufacturer's compliance history; and
- Whether the legal basis for asserting that an overcharge occurred had been established by statute, regulation, or published Agency guidance prior to the conduct at issue.

We note that this last factor is critically important. Indeed, BIO strongly believes that HRSA should not institute a CMP proceeding where the alleged overcharge involved circumstances not addressed by written Agency requirements. In situations outside of those addressed by existing Agency requirements, there can be no basis for HRSA (or OIG) to allege in a CMP proceeding that a manufacturer has engaged in a knowing and intentional overcharge—and only knowing and intentional overcharges permit the exercise of this CMP authority, as described above.

Finally, section 1003.128 would need to be amended to provide for the collection of 340B manufacturer CMPs by either OIG or HRSA (as opposed to CMS). In amending this provision, BIO urges HRSA, together with OIG, to consider adding additional standards for the collection of these penalties. For instance, we urge HRSA to specify that the Agency will not pursue a civil action to recover amounts due, if at all, until manufacturers have had at least 60 days from the ultimate conclusion of any appeal or judicial review. In addition, to the extent any interest is charged on penalties, we urge HRSA to impose any such interest as of the date of a filing of a notice of intent to assess a CMP, not from the overcharge itself. Given the routine restatements of AMP that are permitted and regularly occur during the 12 quarters following a manufacturer's initial AMP statement, it makes sense that interest should not be calculated until the ceiling price is finally adjusted and a CMP proceeding asserts that an overcharge occurred.

On that topic, BIO requests that HRSA directly address one additional aspect of exercising CMP authority not mentioned in the Proposed Rule: the statute of limitations for such proceedings. Manufacturers have 12 quarters to restate a drug's AMP, and its Best Price in the case of an innovator product, during which time the ceiling price can correspondingly move upwards or downwards.⁹⁰ As noted below, BIO questions whether routine restatements of AMP and Best Price will meet the "knowingly and intentionally" standard that is required under the statute for imposition of a CMP and we believe that HRSA should clarify that simple and periodic restatements such as these that do not implicate the CMP authority. Moreover, given that AMP and BP will likely change during that 12-quarter (i.e., three-year) window, BIO recommends that HRSA set a four-year statute of limitations for any CMP proceeding. Four years would balance HRSA's need for time to investigate with the burden on covered entities and manufacturers of extending the recordkeeping requirements beyond the 12-quarter period for restatement of AMP/Best Price. This four-year limitations period would extend from the first day of the quarter on which a ceiling price at issue was in effect.

⁹⁰ See 42 C.F.R. § 447.510(b)(1).

B. Instance of Overcharging

1. Definition of “Instance”

As articulated in the 340B statute, CMPs are to apply to each “instance” of overcharging a registered covered entity. In order to implement this requirement, HRSA proposes to define “an instance of overcharging” as “any order for a certain covered outpatient drug, which results in a covered entity paying more than the ceiling price . . . for a covered outpatient drug.”⁹¹ HRSA further proposes that “[e]ach order for an NDC will constitute a single instance, regardless of the number of units of each NDC in that order” and that “[t]his includes any order placed directly with a manufacturer or through a wholesaler, authorized distributor or agent.”⁹²

As a threshold matter, we note that defining an “instance” as “any order for a certain covered outpatient drug, which results in a covered entity paying more than the ceiling price . . . for a covered outpatient drug,” is not practical. A more reasonable definition of one “instance,” would be all mispriced *purchases* within a quarter on a particular drug to a particular customer.

However, as we articulated in our comments in response to the ANPRM, BIO fundamentally disagrees with HRSA’s proposal to define an “instance” based on how many purchases (or orders) or how many covered entities make those purchases (or orders), as these are factors outside of a manufacturer’s control, and rather in the hands of the covered entities that make such purchases (or place such orders) and the wholesalers and distributors that generally fill those orders. The ordering patterns and practices of these third parties are based on factors unique to these entities that are outside of manufacturers’ control. Accordingly, this approach is not consistent with the statute’s intent requirement, nor its focus on penalizing manufacturer *misconduct*. It is the knowing and intentional violation of the 340B law’s ceiling price requirement that should trigger a penalty; yet the Proposed Rule could convert such a violation into potentially hundreds of penalty-triggering “instances” tied to entirely random events, such as a covered entity’s purchasing (or ordering) practices during a particular quarter.

The 340B law only permits manufacturer CMPs for “knowingly and intentionally” overcharging covered entities:⁹³ an unusual and high intent standard in a civil statute, as described above. Congress would not have adopted this exacting requirement that CMPs can be imposed only for “knowing and intentional” misconduct, but then decided that the number of “instances”—and thus the manufacturer’s CMP liability—could hinge on random events outside the manufacturer’s control. Such a reading of the law is not sensible or coherent, as it assumes that Congress—having scrupulously defined the applicable intent standard—would then *untether the manufacturer’s liability from the manufacturer’s culpable acts*, converting the CMP provision from a carefully-drawn provision into a liability lottery.

⁹¹ 42 C.F.R. § 10.11(b) (proposed).

⁹² 42 C.F.R. § 10.11(b)(1) (proposed).

⁹³ 42 U.S.C. § 256b(d)(1)(B)(vi).

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HRSA's proposed "instance" definition also is at odds with case law under the civil False Claims Act, which permits a penalty for each false claim submitted (or caused to be submitted) against the government, and contains a *lower* (i.e., "knowing") intent requirement than the 340B law's CMP provision. In this context, the U.S. Supreme Court has held that the number of penalties must reflect the number of culpable acts by the defendant—not the number of actions taken by a third party that are outside the defendant's control. For example, in *United States v. Bornstein*,⁹⁴ a subcontractor sent three shipments of mislabeled parts to a government contractor, which, in turn, submitted 35 invoices to the government for products containing those parts. Reasoning that the statute "imposes liability only for the commission of acts which cause false claims to be presented," the Supreme Court held that the subcontractor's three shipments were the culpable acts on which a civil penalty could be levied.⁹⁵ On the other hand, the Court refused to assess penalties for each of the 35 invoices resulting from the fraud, because the submission of those invoices was "*completely fortuitous and beyond the knowledge or control*" of the defendant.⁹⁶

Under the 340B law's CMP provision there is even less reason to think that Congress authorized penalties based on "completely fortuitous" events, such as the number of orders for NDCs placed and filled by third parties. But that is what the Proposed Rule's "instance" definition would do. This would create an irrational scheme that could generate penalties grossly disproportionate to the manufacturer's culpability and far beyond those appropriate to serve the provision's goals of punishing and deterring intentional manufacturer misconduct. We therefore urge HRSA to abandon this approach and instead link "instances" to culpable acts by the manufacturer, as Congress intended. Specifically, we urge HRSA to define an "instance" of an overcharge based on actions that are within a manufacturer's control, namely:

1. *Each intentionally incorrect ceiling price reported to HRSA that actually results in overcharges to one or more registered covered entities:* Any overcharges in a given quarter that are based on a knowingly and intentionally incorrectly calculated ceiling price will flow from the single calculation that the manufacturer made as to the ceiling price for the particular product, and reported to HRSA. Unlike the number of orders placed for a covered outpatient drug, this calculation is entirely within the control of the drug manufacturer. This calculation should therefore be considered a single "instance," regardless of the volume of purchases (or orders) made by covered entities.
2. *Each incorrect treatment by a manufacturer of a registered covered entity as an organization ineligible for the 340B ceiling price:* A manufacturer's knowing and intentional treatment of an organization that meets the entirety of HRSA's proposed "covered entity" definition, and that notified the manufacturer at the time of purchase of its status and desire to order at the 340B price, as an organization not entitled to a correctly calculated ceiling price is similarly an action that is within the

⁹⁴ 423 U.S. 303 (1976).

⁹⁵ *Id.* at 312.

⁹⁶ *Id.* (emphasis added).

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manufacturer's control that should be considered a single "instance," regardless of the volume of purchases (or orders) made by covered entities.

Related to this second category of an appropriate "instance," we urge HRSA to expressly clarify that a manufacturer may not be subject to CMPs for failure to provide the 340B ceiling price to an organization that does not meet all three prongs of HRSA's proposed definition of "covered entity" in a given quarter. For instance, sales above the ceiling price to a covered entity that has violated the prohibition against diversion or duplicate discounts should not constitute a knowing and intentional instance of overcharging a covered entity in line with this proposed definition. We believe that this approach comports with the 340B statute's eligibility criteria: because Section 340B(a)(5) contains both the diversion and duplicate discount prohibitions, an entity engaged in such activities is not a "covered entity" under the statute; thus a manufacturer cannot be liable for a failure to offer the 340B ceiling price to such an entity.⁹⁷ The same concept should apply to an organization that is not listed on HRSA's covered entity database for the quarter in question, as a manufacturer should be able to reasonably rely on HRSA's database for purposes of determining which entities are, and are not, eligible for the 340B ceiling price in a given quarter.

We believe that this recommendation aligns with aspects of the Proposed Rule that recognize the need for an "instance" to be within a manufacturer's control. For instance, HRSA has proposed to clarify that "[a] manufacturer's failure to provide the ceiling price is not considered an instance of overcharging when the covered entity did not initially identify the purchase to the manufacturer as 340B-eligible at the time of purchase."⁹⁸ We strongly support this clarification, although, the meaning of "initially" in this sentence is unclear in light of the various inventory replenishment models in use by both covered entities and wholesalers. It therefore would be helpful for HRSA to provide clarity to covered entities and manufacturers with respect to how this principle would be applied with respect to current covered entity ordering and invoicing or rebilling processes to replenish inventory for product dispensed to patients over the course of many months, or even years, to which the ceiling price request is outside reasonable business arrangement between the manufacturer and wholesaler. We also believe that this proposal could be strengthened by taking further steps to improve resources for identifying covered entities, as noted previously, and further urge the Agency to clarify that this same principle applies for quarters in which a covered entity's information in the 340B database is inaccurate or missing.

HRSA has similarly clarified in the Proposed Rule that "[c]overed entity orders of non-340B priced drugs will not subsequently be considered an instance of overcharging unless the manufacturer's documented refusal to sell or make drugs available at the 340B price resulted in the covered entity purchasing at the non-340B price."⁹⁹ We support this proposal, as there are a number of reasons that a 340B covered entity would purchase a

⁹⁷ HRSA has proposed to define a "covered entity" to mean "an entity that is listed within Section 340B(a)(4) of the PHSA, meets the requirements under section 340B(a)(5) of the PHSA, and is registered in the 340B database." 42 C.F.R. § 10.3 (proposed) (emphasis added).

⁹⁸ 42 C.F.R. § 10.11(b)(5) (proposed).

⁹⁹ 42 C.F.R. § 10.11(b)(5) (proposed).

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product at a non-340B price, such as when the covered entity elects to “carve out” (i.e., dispense non-340B drugs to Medicaid patients) pursuant to HRSA’s longstanding guidance on the prevention of duplicate discounts.¹⁰⁰ It is important that manufacturers are not assessed CMPs for selling such non-340B-priced drugs to covered entities in such instances. HRSA does note in the preamble text, however, that “[w]hen a manufacturer’s documented refusal to sell or make drugs available at the 340B price results in the covered entity purchasing at the non-340B price, a manufacturer’s sale at the non-340B price could be considered an instance of overcharging.”¹⁰¹ We urge HRSA to provide more clarity as to what constitutes a “documented refusal” for this purpose. Specifically, we ask HRSA to clarify that communications between a manufacturer (or wholesaler) and covered entity verifying eligibility for 340B prices prior to a sale should not be considered a “refusal” for this purpose.

2. Offsets

HRSA proposes that “[a]n instance of overcharging is considered at the NDC level and may not be offset by other discounts provided on any other NDC or discounts provided in the same NDC on other transactions, orders, or purchases.”¹⁰² We strongly disagree with this proposed approach. To the extent that manufacturers restate their pricing data, they do so across NDCs, which can result in increased ceiling prices for some NDCs and decreased ceiling prices for others. For purposes of efficiency, manufacturers may correct for these changes—which often each represent low-dollar amounts—by offsetting prices across NDCs. Given that manufacturers generally employ this practice uniformly across all customer types, prohibiting this practice in the context of the 340B program would be contrary to HRSA’s non-discrimination policy, as manufacturers would be directed to treat their 340B customers in a manner distinct from commercial and other customers.

We further note our concern that HRSA’s proposal to disallow offsets—together with its proposed requirement that manufacturers issue refunds in the event that restatements in AMP or Best Price result in a recalculated ceiling price—would risk forcing manufacturers to offer sub-ceiling prices. That is, if the correct 340B ceiling price is a price determined by restatements of Medicaid rebate metrics, then the initial 340B prices will sometimes be too high and sometimes be too low, but, as proposed, the manufacturer would not be permitted to net out the overcharges and undercharges that would result. Calculating refunds based only on restatements that lower the ceiling price, without any way to account for restatements that raise the ceiling price would thus transform the voluntary option of providing sub-ceiling prices into a requirement, and is thus an impermissible read of the statutory scheme established by Congress.¹⁰³

¹⁰⁰ See HRSA, Clarification on Use of the Medicaid Exclusion File, Release No. 2013-2 (Feb. 7, 2013).

¹⁰¹ 80 Fed. Reg. at 34,586.

¹⁰² 42 C.F.R. § 10.11(b)(3) (proposed).

¹⁰³ Although undercharges are not referenced in the 340B statute explicitly, prohibiting them, as HRSA has proposed, is not consistent with the fact that the extension of sub-ceiling prices is expressly considered to be voluntary under the 340B statute. See *Utility Air Regulatory Group v. EPA*, 573 U.S. ____ (2014) (relying upon the fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme).

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For these reasons, we urge HRSA to eliminate this language effectively prohibiting manufacturer offsets from the Proposed Rule. We further urge HRSA to expressly allow manufacturers to offset undercharges to covered entities with overcharges when determining the refunds due when the Agency establishes the reliable and efficient procedures for payment of refunds, as required by the ACA.¹⁰⁴

3. Subsequent Ceiling Price Recalculations

HRSA further proposes that an instance of overcharging can occur not only at time of initial purchase, but also when subsequent ceiling price recalculations resulting from pricing data submitted to CMS occur and the manufacturer refuses to refund or issue a credit to a covered entity.¹⁰⁵ BIO has serious concerns with respect to this proposal.

For one, we note that there likely will be a high volume of true-ups and refunds based on price changes flowing from routine restatements of AMP and Best Price, which are calculated to seven decimal places and rounded to six, as well as the rising volume of products, covered entities, and manufacturers participating in the 340B program. However, as noted previously, HRSA has yet to establish a process to restate and reconcile ceiling price numbers, as required under section 340B(d)(1)(B)(iv). At a minimum, we believe that HRSA should not impose CMPs based on recalculations until this process has been established, as is required by statute.¹⁰⁶

But, perhaps more troublingly, BIO has substantial concerns with respect to HRSA's suggestion that subsequent ceiling price recalculations would necessarily result in a "knowing and intentional" overcharge to a covered entity for purposes of the 340B statute's CMP provision. We note that recalculations of the pricing metrics that underlie the ceiling price (AMP and URA) are required pursuant to applicable laws and regulations by virtue of manufacturer participation in the MDRP and often arise due to factors outside of a given manufacturer's control. For example, manufacturers typically use estimates for some price concessions to report initial Best Price calculations to CMS within 30 days after a calendar quarter end and perform recalculations to incorporate lagged data (e.g., chargebacks, rebates) subsequent to the initial calculation. Moreover, changes that may appropriately be made to AMP and Best Price within 12 quarters from their initial submissions to CMS do not constitute actual mistakes or calculation errors. It would be inequitable for HRSA to impose CMPs against a manufacturer for properly following the laws and regulations that govern the MDRP, which are purposely designed to account for lagged transactional data that cannot be known at the time the 340B ceiling price is calculated. Moreover, the "routine" nature of these adjustments is recognized in the 340B statute itself, which expressly directs HRSA to develop a mechanism whereby the resulting refunds and credits would be issued to covered entities.¹⁰⁷ We further note that there are instances in which a covered entity does not accept a refund (e.g., because the covered entity has ceased

¹⁰⁴ 42 U.S.C. § 256b(d)(1)(B)(ii).

¹⁰⁵ 42 C.F.R. § 10.11(b)(4) (proposed).

¹⁰⁶ 42 U.S.C. § 256b(d)(1)(B)(ii).

¹⁰⁷ 42 U.S.C. § 256b(d)(1)(B)(iv).

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operation), and any rules should account for this by allowing manufacturers to retain any such unclaimed amounts.

BIO therefore urges HRSA to eliminate its proposal that an instance of overcharging can occur due to subsequent ceiling price recalculations resulting from pricing data submitted to CMS.

4. Distribution Arrangements

HRSA also proposes that “[m]anufacturers have an obligation to ensure that the 340B discount is provided through distribution arrangements made by the manufacturer.”¹⁰⁸ In the preamble, HRSA further states that “[a]ll requirements for offering the 340B ceiling price apply regardless of distribution system” and that “specialty distribution, regardless of justification, must ensure 340B covered entities purchase covered outpatient drugs at or below the ceiling price.”¹⁰⁹ BIO has two very serious concerns with respect to this proposal.

First, we believe that this proposal is inconsistent with the 340B statute’s CMP provision. As an initial matter, we note our concern that the proposed regulatory text, together with the cited preamble language, could be read to suggest that HRSA believes that it would be authorized to treat a refusal to sell a covered outpatient drug as potentially actionable through the CMP process. This is not the case. Instead, the statute clearly restricts applicability of the CMP provision to knowing and intentional overcharges. Refusal to sell is not an overcharge and thus may not be penalized under the 340B statute’s CMP provision.¹¹⁰

Furthermore, we note that this proposal would constitute an impermissible departure from the 340B statute’s “knowing and intentional” standard for purposes of manufacturer CMPs. Under the 340B statute, CMPs are restricted to situations in which a manufacturer “knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds” the statutorily defined ceiling price.¹¹¹ However, in the preamble text regarding this proposal, HRSA notes that “[t]his regulation and associated penalties applies solely to manufacturers, even though other parties, such as wholesalers, have a role in ultimately ensuring the covered entity receives a 340B price at or below the ceiling prices” and that “[a] manufacturer’s failure to ensure that covered entities receive the appropriate 340B discount through its distribution arrangements may be grounds for the assessment of civil monetary penalties under this regulation.”¹¹² While we agree that the

¹¹⁰ We further note that there is no blanket obligation to make drugs available to covered entities under the 340B statute, nor is there a requirement that such drugs be provided through any given distribution system. Instead, the statute merely provides, as noted below, that manufacturers are required to “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 at any price*”—an obligation that we continue to emphasize is not operational unless and until this language has been incorporated into the PPA. See 42 U.S.C. § 256b(a)(1) (emphasis added).

¹¹¹ 42 U.S.C. § 256b(d)(1)(B)(vi)(III).

¹¹² 80 Fed. Reg. at 34,586.

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340B statute makes manufacturers ultimately responsible for program compliance, in order to impose CMPs for manufacturer non-compliance in this instance, there is a need to establish causation between a manufacturer's knowing and intentional actions and a wholesaler or distributor's failure to provide a covered outpatient drug to a registered covered entity at the 340B ceiling price. As noted throughout this letter, we urge HRSA to clarify that manufacturers will not be subject to CMPs for any actions that do not meet this standard. Relevant to this particular proposal, HRSA should expressly clarify that manufacturers that comply with their obligation to sell at or below the 340B ceiling price should not be subject to CMPs to the extent that wholesalers or distributors add a tax or other charges to that price.

Second, we are concerned that HRSA's proposed language may not be consistent with the Agency's current non-discrimination policy, codified by the ACA,¹¹³ which expressly permits manufacturers to establish "alternate allocation procedures" that meet certain requirements. We note that such procedures may be necessary not only for instances in which "available supply of a covered outpatient drug is not adequate to meet market demands,"¹¹⁴ but also to implement Risk Evaluation and Mitigation Strategies (REMS) approved by the FDA, to promote quality patient care and safety, and for other reasons. Thus, while BIO agrees that the 340B price must be made available to those registered covered entities that purchase through a limited distribution arrangement, we are very concerned by the implication that such distribution arrangements do not meet this obligation. We therefore strongly urge HRSA not to finalize its proposed regulatory language with respect to distribution arrangements.

Alternatively, at a minimum, we believe that HRSA should establish a safe harbor from the CMP provisions for limited distribution plans that would not violate HRSA's standards for non-discrimination articulated in this policy, recognizing also that these arrangements could not be associated with any overcharges, let alone knowing and intentional overcharges. Specifically, the Agency should confirm that HRSA (and OIG) will not pursue CMPs against manufacturers that limit distribution of covered outpatient drugs through a subset of distributors or pharmacies, provided that this limited distribution model is applied equally to all 340B and non-340B customers, and provided that the subset of distributors or pharmacies is available to distribute to registered 340B covered entities at 340B prices. Under such a model, any covered entity would have at least one way to access covered outpatient drugs at the 340B ceiling price. Manufacturers cannot be subject to CMPs merely to accommodate the covered entity's desire to use another distributor for discounting preferences or other reasons.

5. Use of CMP Funds

Although the 340B statute does not address HRSA's ability to use funds collected from manufacturers in the form of CMPs, if any, we urge HRSA to address this topic through

¹¹³ The ACA added a requirement to the 340B statute that the PPA "shall require 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 at any price." It is important to note, however, that HRSA has not yet amended the PPA to include this language.

¹¹⁴ HRSA, Clarification of Non-Discrimination Policy, Release No. 2011-1.1 (May 23, 2012).

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a subsequent NPRM, subject to public comment. Specifically, consistent with the statutory changes made by the ACA to establish a system of accountability, integrity, and controls across all 340B stakeholders—of which the CMP provision is a part—we urge the Agency to ensure that any such funds are specifically used to promote program integrity efforts, including to conduct audits of 340B-participating entities.

IV. Regulatory Impact Analysis

HRSA estimates that the Proposed Rule does not constitute a “significant regulatory action” on the grounds it is not an “economically significant” rule (i.e., a rule with economic impacts of \$100 million or more in a given year) pursuant to section 3(f)(1) of Executive Order 12866, and thus concludes that a regulatory impact analysis (RIA) is not required. BIO takes issue with a number of the assumptions that HRSA has made in coming to this conclusion and believes that, taking into account various costs this rule would undoubtedly impose on the industry, there is strong reason to believe it does, in fact, constitute a “significant regulatory action” necessitating a RIA.

As an initial matter, BIO supports HRSA’s statements that the use of manufacturer CMPs under the 340B statute “would probably be rare” because, as HRSA notes, and consistent with the statutory language, CMP actions would only be brought with respect to overcharges that result from a “knowing and intentional act,” as opposed to “technical errors in the [ceiling price] calculation.”¹¹⁵ We are concerned, however, that HRSA has underestimated the time and resources necessary to comply with the rule, as well as the ACA’s program integrity provisions necessarily antecedent to the implementation thereof.

First, we disagree that the ceiling price calculation portion of the Proposed Rule would have no impact on manufacturers, as HRSA has suggested.¹¹⁶ For instance, as articulated above, HRSA has proposed adopting a new variable—“case package size”—which is not reported to CMS for purposes of the Medicaid program, nor is it part of HRSA’s current ceiling price calculations, which is based on AMP minus the URA, multiplied by the units per package, as described above. Moreover, HRSA has proposed calculating the ceiling price using six decimal places, which—as noted both above and in prior BIO comments—is likely to increase the cost of compliance for manufacturers by increasing the likelihood of disputes under HRSA’s proposed ICRs.

Second, BIO is concerned with HRSA’s description of the Agency’s estimated impact of its penny pricing approach. Primarily, we question whether HRSA has the authority to “enforce the policy in a manner that would require the manufacturer to charge \$0.01”—as noted earlier.¹¹⁷ But, more pertinent to the question of the financial burden, BIO disagrees that the economic impact of this proposal can be written off merely because it is a “cost transfer from the covered entity to the manufacturer.”¹¹⁸ This “cost transfer” would have

¹¹⁵ 80 Fed. Reg. at 34,586.

¹¹⁶ *Id.* (“Because the components of the ceiling price are already calculated by manufacturers under the Medicaid program and reported to CMS, HHS does not believe this portion of the proposed rule would have an impact on manufacturers.”).

¹¹⁷ *Id.*

¹¹⁸ *Id.* at 34,587.

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a real, negative economic impact on manufacturers, which should be taken into account in the Agency's economic assessment of the rule.

Finally, while "HHS recognizes that some administrative costs would be incurred for compliance with this proposed rule," we disagree that it is "reasonable to assume that manufacturers would use one-half to one full-time compliance officer to ensure compliance with the requirements" thereof.¹¹⁹ As BIO noted at the outset of this letter, the CMP provisions cannot and should not be implemented unless and until HRSA has adopted certain other program integrity provisions. These include, among others: (1) a standardized process for manufacturers to issue credits and refunds to covered entities in the event of an overcharge per section 340B(d)(1)(B)(i)(I); and (2) a process for the issuance of credits and refunds to covered entities in the event of a subsequent rebate or discount that lowers the applicable ceiling price for the relevant quarter per section 340B(d)(1)(B)(iv). Before manufacturers can operationalize new requirements of this nature, it will be necessary for them to, at a minimum: review HRSA's instructions, update their technology systems, run system and performance testing, adjust their compliance policies and procedures, train personnel, and take other steps to ensure compliance with the new obligations. Furthermore, once these procedures are implemented, it will be extremely time consuming for manufacturers to process all of the attendant credits and refunds, which is a cumulative process that will occur each quarter.

These burdens are compounded by the sheer number of covered entities that participate in the 340B program, which mean that manufacturers must set up and maintain these processes, including a process for issuing credits and refunds, with respect to 30,000 or more entities, for whom addresses, parent/child site relationships, and bill to/ship to arrangements are constantly in flux. Verification of this information, in reliance on HRSA's database, will be necessary on a quarterly basis.

Furthermore, the sheer volume of covered entities is complicated by the fact that 340B sales are generally made through arrangements with wholesalers, which also are subject to change on a regular basis. Thus, with respect to the burden of remitting credits and refunds to covered entities due to subsequent pricing adjustments (which may occur up to three years after the date of sale), some entities may have changed wholesalers and it may be difficult to track them down to ensure that they will receive the adjustment. The most effective manner to do this for compliance purposes is to have HRSA set up a confidential database that manufacturers can link to that lists start date of entity, its W-9 information, and their banking automatic clearing house numbers so that manufacturers can remit funds. HRSA should set this up before manufacturers should be required to issue refunds—although compliance with this system would certainly impose additional burdens on manufacturers. Moreover, aside from HRSA's proposal to assign liability to manufacturers for third parties' failure to pass on these refunds to covered entities—about which BIO has serious concerns, as articulated above—there also is the reality that any third party willing to locate the covered entity and provide the refund on behalf of the manufacturer is likely to charge a fee. Such fees similarly have not been contemplated in the Proposed Rule.

¹¹⁹ Id.

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The precise amount of time and resources necessary to implement these steps and incur these costs will certainly vary from manufacturer to manufacturer—and it is difficult to estimate the precise burdens that will be imposed, particularly given that the Proposed Rule lacks certain critical details, as described in this letter, and HRSA has not taken steps to implement most of the program-integrity processes required by the ACA. Moreover, as noted previously in this letter, and in prior BIO comment letters to the Agency, the amount of time and resources associated with each of these steps depends, in large degree, on the manner in which the processes implemented by HRSA align with manufacturers' existing obligations (e.g., standards and timeframes under the interrelated MDRP), and otherwise minimize the burden on manufacturers (e.g., by establishing a *de minimus* threshold for credits and refunds). Nonetheless, we question whether HRSA has made even a general estimate of the time and effort these steps would require. For instance, we note that manufacturers often use more staff than the "one-half to one full-time compliance officer" described in the Proposed Rule for purposes of ensuring compliance with the MDRP, a program that involves 50 states, as opposed to the 30,000 covered entities and countless associated third parties involved in 340B.

In sum, we believe that this rule does, in fact, constitute a significant regulatory action, and therefore believe that HRSA must issue a new NPRM with a RIA, as required under Executive Orders 12,866 and 13,563. These Executive Orders are binding on the Agency and cannot be ignored. Issuing a new NPRM that includes the required RIA is therefore necessary in order to provide stakeholders with the requisite opportunity to comment on this analysis. As noted previously, we strongly urge HRSA to comprehensively address all of the ACA's program integrity requirements in issuing this new NPRM.

V. Conclusion

BIO appreciates the opportunity to comment on the Proposed Rule. We hope that the Agency finds this letter to be constructive as it begins the process of implementing the ACA's program integrity requirements. Please feel free to contact us at 202-962-9200 if you have any questions regarding any of the issues raised in these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

Laurel L. Todd
Managing Director,
Reimbursement and Health Policy

Erin Estey Hertzog, J.D., M.P.H.
Director
Health Law and Policy