April 19, 2017

Thomas E. Price
Secretary
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

James Macrae
Acting Administrator
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20852

BY ELECTRONIC DELIVERY

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

Dear Secretary Price and Acting Administrator Macrae:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to provide feedback in response to the 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation Interim Final Rule (the "Interim Final Rule") published in the Federal Register on March 20, 2017.[1] BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

BIO agrees with and appreciates the Health Resources and Services Administration's (HRSA's) decision to delay the effective date of the 340B Ceiling Price and Civil Monetary Penalties (CMP) Final Rule, published on January 5, 2017, and seek stakeholder feedback on a further delay. As a threshold matter, a delay will allow the Agency the necessary time to consider the Final Rule in the context of current Trump Administration priorities, including the so-called "Priebus Memorandum"[2]—which delayed the original effective date until such a time as questions of fact, law, and policy raised by the Final Rule could be reviewed by the new Administration—and the Administration's broader goal of removing or minimizing unwarranted economic and regulatory burdens related to the Affordable Care Act (ACA), the law that added provisions to the 340B statute that are the subject of the Final Rule.[3]

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[1] 82 Fed. Reg. 14,332 (March 20, 2017).
[2] The White House, 2017 (January 20), Memorandum for the Heads of Executive Departments and Agencies, available at: https://www.whitehouse.gov/the-press-office/2017/01/20/memorandum-heads-executive-departments-and-agencies (last accessed April 14, 2017).
[3] The White House, 2017 (January 20), Executive Order Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal, available at: https://www.whitehouse.gov/the-press-office/2017/01/2/executive-order-minimizing-economic-burden-patient-protection-and (last accessed April 14, 2017).

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More specifically, BIO strongly supports a delay of the effective date based on HRSA's own statements that this is necessary to allow the Agency to collect, synthesize, and discuss additional stakeholder feedback.[4] As such, we appreciate the current 60-day delay until May 22, and are supportive of delay until October 1, at the very minimum. We also agree with and appreciate HRSA's recognition that "there are substantive questions raised" by the Final Rule, and the Agency's stated intention "to engage in longer rulemaking." Thus, based on HRSA's statements in the Interim Final Rule and the substantive concerns BIO will identify in the balance of this letter, we strongly urge HRSA to delay the effective date of the Final Rule until the Agency can complete additional rulemaking that meaningfully addresses these concerns. In particular, HRSA's future rulemaking must address the overly burdensome nature of many of the regulatory requirements included in the Final Rule, as well as several persistent policy concerns presented by several Final Rule provisions. If HRSA decides to delay the effective date and that date occurs in the middle of a calendar quarter, the Agency should adopt an enforcement date on the first day of the following calendar quarter.

In the balance of this letter, we discuss each of our concerns in detail, focusing on the need to delay the effective date of the Final Rule until HRSA can complete revisions to the Final Rule through notice-and-comment rulemaking that address:

- The significant burden of the "penny pricing" policy finalized in the Final Rule;
- The need to revise the regulatory definition of the "knowing and intentional" standard to comply with its statutory intent; and
- The need to revise the treatment of ceiling price calculations for newly-launched drugs and the definition of "instances of overcharging" to mitigate the significant and undue burden these Final Rule provisions place on manufacturers.

To bolster and further detail these concerns and recommendations, we have attached as an appendix our previous comments to HRSA in response to the 2015 Proposed Rule[5] and 2016 Notice that reopened the comment period on the Proposed Rule.[6]

I. HRSA Should Delay the Effective Date of the Final Rule until the Agency Can Complete Additional Rulemaking to Address the Substantial Regulatory Burden Posed by the Problematic Penny Pricing Policy.

BIO continues to raise significant concerns with the penny pricing in the Final Rule. Specifically, HRSA finalized requirements that, "when the 340B ceiling price calculation resulted in an amount less than $0.01, a manufacturer charge a $0.01 per unit of measure."[7] BIO reiterates our objection to this policy on the following grounds:

- HRSA still has not articulated a non-arbitrary, non-capricious reason as to why a $0.01 price is reasonable, even though HRSA has regularly identified a $0 ceiling price as "unreasonable."[8]

[4] 82 Fed. Reg. 1210 (January 5, 2017).
[5] 80 Fed. Reg. 35,583 (June 17, 2015).
[6] 81 Fed. Reg. 22,960 (April 19, 2016).
[7] 82 Fed. Reg. 1210, 1214-1215 (January 5, 2017).
[8] See, e.g., HRSA, Clarification of Penny Pricing Policy, Release No. 2011-2 (Nov. 21, 2011); 80 Fed. Reg. at 34,585; 81 Fed. Reg. at 22,960. 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

- HRSA's penny pricing proposal is likely to result in drug shortages—a problem that HRSA itself recognizes[9]—and manufacturers should not be required to adopt burdensome and costly "alternate allocation procedures" in order to correct for the market-distorting effect of the policies adopted by HRSA.[10]
- Moreover, for controlled substances, products subject to FDA-approved Risk Evaluation and Mitigation Strategies (REMS), or for which a grey or black market exists, the proposal also would result in the potential for stockpiling, diversion, harm to patients, and abuse.

We believe that the duty of parties to the Pharmaceutical Pricing Agreement (PPA) to operate in "good faith"[11] would be met by a reasonable pricing methodology that meets the following four criteria:

1. Is readily and objectively verifiable (i.e., not tied to costs or margin) so that covered entities know what they should be paying;
2. Is 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);
3. Represents a favorable discount to covered entities that is, in all cases, lower than AMP minus the MDRP basic rebate percentage; and
4. Does not create the same incentives as a $0.01 price per unit of sale, such as inappropriate use, misuse, and diversion of 340B products.

In our comments submitted in response to the 2016 Notice (see Appendix p. 10), we identified three reasonable pricing methodologies that meet these four criteria and are thus consistent with this duty (listed in alphabetical order): federal ceiling price; nominal pricing (e.g., 10 percent of AMP); and last positive prior quarter. We also made a recommendation in the event that HRSA wishes to adopt a uniform policy: specifically, we believe that the Agency should require manufacturers to charge covered entities the Federal Ceiling Price (FCP) (or FSS, where there is no FCP) when the calculation of the 340B ceiling price results in an amount less than $0.01 per unit. There are, however, circumstances in which there is no FCP or FSS (e.g., for generic products approved under an abbreviated new drug application (ANDA)), as well as rare instances where the FCP or FSS price might result in a value that fails to meet the above criteria (1) through (4), and thus reliance on this pricing benchmark would not address BIO's concerns with HRSA's penny pricing policy proposal, briefly described above and in more details in BIO's prior comments. In those instances, manufacturers should have the ability to rely upon the pricing methodology of their choice (e.g., nominal, last positive prior quarter) that meets each of the four criteria described above, including that it mitigates the risk of drug shortages, diversion, and abuse.

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must be set aside. 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." This standard is not met with respect to the penny pricing policy as it is articulated in the Proposed Rule. 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); Motor Vehicle Ass'n v. State Farm Mut. Auto Ins. Co., 463 U.S. 29, 43 (1983) (internal quotations marks and citations omitted).

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

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

Given the persistent and significant concerns with the finalized penny pricing policy described above and in further detail in the Appendix, BIO urges HRSA to delay the effective date of the Final Rule until the Agency can complete additional rulemaking that addresses these concerns. If HRSA decides to delay the effective date and that date occurs in the middle of a calendar quarter, the Agency should adopt an enforcement date on the first day of the following calendar quarter.

II. HRSA Must Amend the Definition of "Knowing and Intentional" to Ensure It Is Applied Consistently and That Its Implementation Meets the High Intent Standard Imposed by Congress.

BIO urges HRSA to delay the effective date of the Final Rule until the Agency can complete rulemaking that reconsiders the decision not to define the terms "knowing" and "intentional" in the Final Rule as they apply to CMPs. The absence of a more specific definition will lead to a lack of standardization in applying the definition, which in turn, can lead to regulatory uncertainty and unpredictability. The absence of a more specific definition also gives short shrift to the fact that "knowingly and intentionally" is an unusual and high intent standard for a civil statute, as BIO has noted in our previous comments to HRSA.[12] 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. It is not permissible that the regulatory regime implementing this statutory standard effectively redefines these terms to capture lesser forms of misconduct.

Thus, to ensure that the regulatory text upholds the statutory standard as a matter of law, HRSA should delay the effective date of the Final Rule until the Agency can complete notice-and-comment rulemaking that garners stakeholder feedback on defining the term "knowingly and intentionally" to include only "conduct undertaken by the manufacturer with the specific intent to overcharge a customer that the manufacturer actually knows is a registered covered entity."[13] We believe that this definition more precisely captures the intent of the statute than the definition outlined in the Final Rule. In the process of re-engaging stakeholders on this issue, BIO also asks HRSA to elicit feedback on the inclusion of the "circumstances where HHS would assume that a manufacturer did not 'knowingly and intentionally' overcharge a covered entity" in the regulatory text itself to codify these instances. This is particularly important in cases that adhere to the examples of a manufacturer making "an isolated inadvertent, unintentional, or unrecognized error in calculating the 340B ceiling price" and "[w]hen a covered entity did not initially identify the purchase to the manufacturer as 340B-eligible at the time of purchase[.]" In such cases, the actions clearly fall short of the "knowingly and intentionally" standard, and stating so in final regulatory text will be important to ensure that the statutory CMP provisions are appropriately effectuated.

III. HRSA Should Delay the Effective Date of the Final Rule until Additional Rulemaking Can Be Completed That Removes the Overly

[12] See Appendix p. 16

[13] We continue to believe that 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.

Burdensome Requirements on Manufacturers and Addresses Identified Policy Concerns That Would Negatively Impact Manufacturers' Ability to Comply in a Timely Manner.

A. HRSA should delay the effective date of the Final Rule until the Agency can complete additional rulemaking that addresses the policy concerns that the Final Rule requirements regarding newly launched drugs are overly burdensome to manufacturers.

BIO appreciates that HRSA finalized the recommendation that the ceiling price for new-to-market drugs should be calculated based on the Wholesale Acquisition Cost (WAC) minus the applicable Medicaid Drug Rebate Program (MDRP) basic rebate percentage.[14] However, we remain concerned that the Final Rule still requires that a refund or credit be issued to covered entities once AMP is available based on a recalculation of the ceiling price for the first three quarters.[15] BIO urges HRSA to delay the effective date of the Final Rule until additional rulemaking can be completed that addresses our significant policy concerns related to this provision.

As a threshold matter, HRSA must undertake additional rulemaking to establish a definition for AMP that addresses precisely how it should be calculated for purposes of the actual ceiling price of a newly-launched drug. Specifically, the Final Rule is ambiguous with regard to whether manufacturers should use the first available full quarter of AMP or if partial-quarter AMPs should be used (e.g., for a mid-Q1 launch, once Q2 AMP is measureable, should manufacturers use the Q2 AMP or the Q1 partial-quarter AMP to calculate the actual ceiling price).

Our strong recommendation that HRSA further delay the effective date of the Final Rule stems from BIO's significant concerns that, without revision through new rulemaking, the newly-launched drug provisions of the Final Rule require manufacturers and covered entities to process subsequent adjustments and true-ups, which is extremely burdensome on both parties, as HRSA recognized in its 1995 *Federal Register* guidance.[16] We note that the manufacturer burden of processing these adjustments has only increased since that time, given the rapid growth in covered entity participation in the program in recent years.[17] Some manufacturers estimate that they would be required to issue nearly 6,600 refunds to entities under the Final Rule provisions (a number which will vary by manufacturer). We provide the following, more detailed, example as an illustration of the significant burden this requirement places on manufacturers: to comply with the scale of refunds and credits that would result from the implementation of the Final Rule, a manufacturer may have to invest from $100,000 to several million dollars—or more—in initial system enhancements to calculate refunded amounts to each covered entity.

We also note that because HRSA has not met its ACA duty to establish a refund mechanism or procedures governing refunds, manufacturers would need to establish processes and procedures for issuing the refunds and credits once calculated, which may not be uniform across the industry. There are two general ways to do so: (1) the

[14] 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).
[15] 82 Fed. Reg. 1,210, 1,218 (January 5, 2017).
[16] 60 Fed. Reg. at 51,488.
[17] 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).

manufacturer could contract with the prime vendor, which could cost the former approximately $200,000 per quarter, depending on the volume of covered entities in question, or approximately $800,000 per year; or (2) a manufacturer could create a separate system to directly refund the thousands of covered entities that participate in the 340B program, which would also require establishing a good faith process to ensure that entities receive the credit. The cost of the latter option, including dedicated staff resources and system upgrades, is difficult to estimate, but would clearly be substantial. Several companies estimate that it would take approximately 3,320 personnel hours annually to implement the ceiling price provisions for new drugs, and another 3,300 hours annually to implement the CMP provisions (discussed in detail in section I(B) and II below). Regardless of the exact approach pursued, HRSA's estimate that an additional one-half of one compliance officer would be required to monitor the necessary procedures and processes to comply with this Final Rule provision significantly underestimates the true resource burden that manufacturers would face.

As HRSA engages in additional rulemaking, BIO reiterates our original recommendation that the Agency adopt a uniform estimated ceiling price of WAC on the first day of the applicable quarter minus the MDRP basic rebate percentage, depending on the drug's statutorily defined classification percent. As HRSA notes in the 2016 Notice, "this price would eliminate the need to estimate the price for the first three quarters and would result in a reasonable ceiling price."[18] A more detailed discussion of this recommendation can be found in the Appendix (see Appendix pp. 13-15).

Additionally, in delaying the effective date of the Final Rule and re-opening the rulemaking process as BIO recommends, we further urge HRSA to recognize that, in some instances, the dollar amounts in question do not justify the administrative burden of processing them. This is particularly problematic where, as HRSA had finalized, the credits and refunds operate only in one direction (i.e., credits and refunds are offered to covered entities when estimated ceiling prices are too high, but not to manufacturers when estimated ceiling prices are too low). This is not only inconsistent with the MDRP's two-way refund mechanism, but permitting offsets in only one direction also could result in manufacturers being required to offer a price below the new-to-market drug ceiling price, notwithstanding the fact that such discounts are clearly identified as voluntary by the 340B statute itself.[19] Due to the refund mechanism, HRSA would essentially compel manufacturers of new-to-market drugs to either estimate a lower price than the ceiling price to avoid the refund process, or give discounts at the ceiling price, and subsequently be required to engage in the resource-intensive refund process. Thus, BIO urges HRSA to delay the effective date until this issue can be addressed through additional rulemaking. Such additional rulemaking should seek stakeholder feedback on establishing a *de minimis* standard that would apply where the amount of the overcharge is so minimal that it would not justify the significant resource burden a manufacturer would have to incur to issue the credit or refund and the covered entity would incur to process the receipt of the refund.

B. Prior to establishing an effective date for the Final Rule, HRSA must complete rulemaking that addresses the policy concerns that the Final Rule provisions related to "instances of overcharging" will impose an undue burden on manufacturers, requiring them to to employ significant resources over a significant period of time.

[18] 81 Fed. Reg. at 22,920.
[19] 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).").

BIO urges HRSA to delay the effective date of the Final Rule until the Agency can complete additional rulemaking that meaningfully addresses significant concerns with regard to the finalized policy on the imposition of CMP in the instance of overcharging. In the Final Rule, HRSA describes that such instances "may occur at the time of initial purchase or when subsequent ceiling price recalculations occur and the manufacturer refuses to refund or issue a credit to a covered entity."[20] Our significant concerns with this provision stem from the undue burden that would be placed on manufacturers and covered entities in processing routine adjustments (e.g., subsequent restatements of AMP), which has the potential to surpass the burden described above with regard to newly launched drugs given the routine nature of restatements and true-ups. This burden is exacerbated by the fact that manufacturers must have specific agreements in place with each covered entity—of which there are thousands—to use the common practice of netting overcharges and undercharges, which may otherwise have mitigated the regulatory burden of these provisions. Establishing such agreements will require significant time and resources on the part of the manufacturer, and may not be feasibly achieved in all instances.

Moreover, the regulatory burden will be compounded by the lack of a *de minimis* threshold, as an overcharge could amount to cents, which would be orders of magnitude less than the costs associated with processing the refund. It would similarly be impractical for manufacturers to negotiate *de minimis* thresholds with each covered entity. Finally, we reiterate that the statute directs HRSA to establish procedures for manufacturers to issue refunds, and requiring the issuing of refunds—as the Final Rule does—prior to establishing such procedures is logically inconsistent and can lead to a lack of standardization that will engender confusion and inefficiency in program operations across stakeholders.[21] Thus, we urge HRSA to delay the effective date of the Final Rule until these policy concerns can be addressed through rulemaking.

C. HRSA should delay the effective date of the Final Rule until the Agency can complete rulemaking that addresses policy concerns presented by the existing Final Rule, through future rulemaking, to guide efforts to prepare for its implementation and ensure that its implementation is standardized.

BIO believes that, in delaying the effective date of the Final Rule and re-opening rulemaking as we have recommended, HRSA will have an important opportunity to address concerns that the Final Rule is ambiguous with regard to certain elements of the newly-launched drug policy. Specifically, the Final Rule would require manufacturers to repay covered entities "within 120 days of the determination by the manufacturer that an overcharge occurred."[22] However, this requirement is ambiguous, as it is not clear exactly when the 120-day period begins (e.g., whether this begins when the first full quarter AMP has been validated in the Drug Data Reporting for Medicaid (DDR) system).

IV. HRSA Should Resolve Policy Concerns presented by Final Rule Provisions Related to Rounding Ceiling Price Calculations.

In the Final Rule, HRSA "concluded that the data utilized for the 340B ceiling price calculation should be in the same format as reported to CMS[,]"[23] which is rounded to six digits, with the fifth and sixth digit included as zeros when the data are reported to the DDR

[20] 82 Fed. Reg. 1210, 1225 (January 5, 2017).
[21] 42 U.S.C. 256b(d)(1)(B)(ii).
[22] 82 Fed. Reg. 1,210, 1,218 (January 5, 2017).
[23] 82 Fed. Reg. 1210, 1214 (January 5, 2017).

system.[24] Furthermore, HRSA "decided that data utilized for the calculation of the 340B ceiling price will be rounded to six decimal places…[and then] the 340B ceiling price [will be made] available in the secure 340B ceiling price system rounded to two decimal places in an effort to ensure certainty in the market place."[25] In considering this discussion of the final policy provisions, we urge HRSA to provide additional clarity on several issues, including: whether the 340B pricing that should be reported to HRSA is intended for the database that remains under development will be reported at two or six digits. We note that manufacturers report prices to wholesalers at the two-digit level and showing prices at the six-digit level can lead to an unintended consequence of potential overcharges due to the rounding of six digits to two digits. While this may seem like fractions of a penny, multiplying fractions of pennies against hundreds of drug units could lead to considerable overcharges based on rounding errors. In turn, such rounding errors will create confusion in the marketplace. Delaying the implementation of the Final Rule will allow the Agency to resolve both of these issues to the benefit of both manufacturers and HRSA through additional rulemaking.

V. Conclusion

BIO appreciates the opportunity to offer feedback on HRSA's effective delay of the 340B Ceiling Price and CMP Final Rule. Based on the totality of our outstanding legal and policy concerns, we strongly recommend that HRSA delay the effective date of the Final Rule until further rulemaking can be completed that addresses these concerns. Delaying the Final Rule will allow HRSA time to work with stakeholders to mitigate the significant burden several of the final provisions will place on manufacturers and to address existing policy concerns presented by several provisions to ensure the efficient effectuation of the 340B statute related to ceiling price calculations and the imposition of CMPs.

Please do not hesitate to contact us with any questions or for further information on the issues identified in this letter. We look forward to continuing the dialogue with the Agency on these important issues, and thank HRSA for their attention to this letter and our recommendations.

Respectfully submitted,

/s/

Laurel Todd
Vice President
Healthcare Policy and Research

Enclosures

[24] CMS, 2000 (April 18), *Medicaid Drug Rebate Program Manufacturer Release #46*, available at: https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-046.pdf (last accessed April 2, 2017).
[25] 82 Fed. Reg. 1210, 1214 (January 5, 2017).

Biotechnology Innovation Organization

May 19, 2016

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

Dear Secretary Burwell and Captain Pedley:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to submit the following comments in response to the Notice issued by the Health Resources and Services Administration (HRSA) on April 19, 2016 (the "Notice"),[1] reopening the comment period for the June 17, 2015 proposed rule entitled *340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation* [RIN-0906-AA89] (the "Proposed Rule").[2]

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 as well as the Notice. We note that BIO timely submitted comments in response to HRSA's Advance Notice of Proposed Rulemaking (ANPRM) on the topic of CMPs in November 2010,[3] the Proposed Rule,[4] as well as the Agency's proposed Information Collection Requests (ICRs)

[1] 81 Fed. Reg. 22,960 (Apr. 19, 2016).
[2] 80 Fed. Reg. 34,583 (June 17, 2015).
[3] 75 Fed. Reg. 57,230 (Sept. 20, 2010).
[4] Supra note 2.

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related to the collection of manufacturer data to verify 340B ceiling price calculations in both November 2014 and May 2015.[5] We have included each of these comment letters as enclosures to this letter for your reference.

We remain concerned 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. We also continue to take issue with the Proposed Rule's lack of a Regulatory Impact Analysis, as well as a number of specific proposals that were addressed in that rule, such as HRSA's proposals to arbitrarily subject manufacturers to CMPs based solely on a manufacturer's use of a limited distribution network,[6] and to prohibit manufacturers from offsetting overcharges with other discounts. We therefore urge HRSA to take into consideration BIO's prior comments on these and other topics before issuing a final rule.

That said, we are very pleased that HRSA has re-opened the comment period regarding three of the most problematic aspects of the Proposed Rule. As directed by the Agency, the scope of this comment letter is limited to those three topics open for public comment, which include: (1) alternatives to HRSA's problematic "penny pricing" proposal; (2) an alternative methodology for calculating new drug prices; and (3) a definition of "knowingly and intentionally" for purposes of HRSA's manufacturer CMP authority. We address each of these topics, in turn.

I. BIO Continues to Urge HRSA to Eliminate the Agency's Problematic Penny Pricing Proposal and Instead Allow Manufacturers to Select a Reasonable Pricing Methodology in Accordance with Their Duty of Good Faith under the PPA.

In the Proposed Rule, HRSA proposed that, when the calculation of the 340B ceiling price resulted in an amount less than $0.01, the ceiling price would be $0.01 per unit of measure, a policy referred to as "penny pricing." In our Proposed Rule comments, BIO strongly objected to this proposal on a number of grounds, including that:

- HRSA did not articulate a non-arbitrary, non-capricious reason as to why a $0.01 price is reasonable, even though HRSA has regularly identified a $0 ceiling price as "unreasonable."[7]

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[5] 79 Fed. Reg. 58,791 (Sept. 30, 2014); 80 Fed. Reg. 22,207 (Apr. 21, 2015).

[6] As noted in BIO's letter in response to the Proposed Rule, 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.").

[7] See, e.g., HRSA, Clarification of Penny Pricing Policy, Release No. 2011-2 (Nov. 21, 2011); 80 Fed. Reg. at 34,585; 81 Fed. Reg. at 22,960. 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. 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." This standard is not met with respect to the penny pricing policy as it is articulated in the

- HRSA's penny pricing proposal is likely to result in drug shortages—a problem that HRSA itself recognizes[8]—and BIO strongly disagrees that manufacturers should be required to adopt burdensome and costly "alternate allocation procedures" in order to correct for the market-distorting effect of the policies adopted by HRSA.[9]
- Moreover, for controlled substances, products subject to FDA-approved Risk Evaluation and Mitigation Strategies (REMS), or for which a grey or black market exists, the proposal also would result in the potential for stockpiling, diversion, harm to patients, and abuse.
- Particularly when read together with the 340B statute's "must offer" requirement, the penny pricing proposal does not appear to be "just compensation" for the taking of private property.[10]

For these reasons, BIO is very pleased that HRSA is now considering alternatives to the problematic "penny pricing" proposal.

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."[11] Federal common law, in turn, requires that the parties "gap fill" by operating under a duty to each other of "good faith."[12] 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.[13]

We believe that this duty of good faith would be met by a reasonable pricing methodology that meets the following four criteria: (1) is readily and objectively verifiable (i.e., not tied to costs or margin) so that covered entities know what they should be paying;

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

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

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

[10] 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 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).

[11] PPA § VII(e).

[12] 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.").

[13] 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).

(2) is 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); (3) represents a favorable discount to covered entities that is, in all cases, lower than AMP minus the MDRP basic rebate percentage; and (4) does not create the same incentives as a $0.01 price per unit of sale, such as inappropriate use, misuse, and diversion of 340B products. In our comments submitted in response to the Proposed Rule, we identified the following three reasonable pricing methodologies that meet these four criteria and are thus consistent with this duty (listed in alphabetical order):

1. **Federal Ceiling Price:** As noted in BIO's prior comments, a methodology whereby manufacturers would charge a ceiling price based on the federal ceiling price (or by reference to the federal supply schedule (FSS) price where there is no federal ceiling price) would meet this duty of good faith. This methodology not only was established as part of the same legislation as the 340B program,[14] 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,[15] the federal ceiling price and the federal supply schedule's must offer obligation were codified simultaneously,[16] evidencing that the federal ceiling price is an approach that Congress supports with respect to drug pricing in the context of a supply obligation. The federal ceiling price is also verified by the Veteran's Administration, providing additional methodological safeguards.

2. **Nominal Pricing:** We also identified nominal pricing methodology (or 10 percent of AMP for manufacturers that do not offer nominal pricing) as another 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.[17] 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.[18] 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 liability.[19] 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

[14] See Veterans Health Care Act of 1992, Public Law 102-585 §§ 601-603 (Nov. 4, 1992).
[15] See ACA § 7102(b)(1).
[16] See Veterans Health Care Act of 1992, Public Law 102-585 § 603 (Nov. 4, 1992).
[17] Under the Medicaid Drug Rebate Program regulations, nominal price means a price that is less than 10 percent of the average manufacturer price (AMP) in the same quarter for which the AMP is computed. 42 C.F.R. § 447.502.
[18] See generally 42 U.S.C. § 1396r-8.
[19] 42 U.S.C. § 1396r-8(c)(1)(D).

quarter's AMP, recognizing the two-quarter lag.[20] Using nominal pricing also provides additional assurances that this methodology is based on a price, i.e., AMP, which is verifiable by the Department of Health and Human Services Office of Inspector General (OIG), and others.

3. **Last Positive Prior Quarter:** As articulated in our prior comments, another methodology, under which ceiling prices would be calculated based on earlier quarters of non-penny 340B sales, would be similarly consistent with these criteria and manufacturers' duty of good faith. We note that a similar approach is permitted in the closely related MDRP—the pricing metrics for which are used to calculate the 340B ceiling price—which looks to the most recent prior period's positive value,[21] 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.

We continue to believe that the Agency should continue to permit manufacturers the flexibility to select a reasonable pricing methodology that meets these criteria 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. However, to the extent that HRSA wishes to adopt a uniform policy, we believe that the Agency should require manufacturers to charge covered entities the Federal Ceiling Price (FCP) (or FSS, where there is no FCP) when the calculation of the 340B ceiling price results in an amount less than $0.01 per unit. There are, however, circumstances in which there is no FCP or FSS (e.g., for generic products approved under an abbreviated new drug application (ANDA)), as well as rare instances where the FCP or FSS price might result in a value that fails to meet the above criteria (1) through (4), and thus reliance on this pricing benchmark would not address BIO's concerns with HRSA's penny pricing policy proposal, briefly described above and in more details in BIO's prior comments. In those instances, manufacturers should have the ability to rely upon the pricing methodology of their choice (e.g., nominal, prior quarter) that meets each of the four criteria described above, including that it mitigates the risk of drug shortages, diversion, and abuse.

II. BIO Continues to Urge HRSA to Calculate the Price for New Drugs Based on WAC Minus the Medicaid Drug Rebate Program Basic Rebate Percentage.

As HRSA noted 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

[20] 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.").

[21] 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.")

calendar quarter ending two quarters prior.[22] 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 proposed in the Proposed Rule that manufacturers estimate the 340B ceiling price for the first three quarters that a new covered outpatient drug is available for sale.[23] HRSA further proposed 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."[24]

As we articulated in our Proposed Rule Comments, BIO finds this proposal concerning for a number of reasons. We therefore continue to urge HRSA to instead adopt a uniform estimated ceiling price of WAC on the first day of the applicable quarter minus the MDRP basic rebate percentage, depending on the drug's statutorily defined classification percent.[25] We have included regulatory text that would implement this policy as an enclosure to this letter. As HRSA notes in the Notice, "this price would eliminate the need to estimate the price for the first three quarters and would result in a reasonable ceiling price."[26]

In the 340B context, estimating, and then subsequently restating, prices for new drugs is extremely problematic for two reasons. First, it improperly extends commercial discounts with respect to 340B prices beyond what is envisioned by the 340B statute. 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 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 Proposed Rule 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.

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[22] We continue 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.
[23] 42 C.F.R. § 10.10(c) (proposed).
[24] Id.
[25] 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).
[26] 81 Fed. Reg. at 22,920.

Second, the proposed methodology would require the need for manufacturers and covered entities to process subsequent adjustments and true-ups, which is extremely burdensome on both parties, as HRSA recognized in its 1995 *Federal Register* guidance.[27] We note that the manufacturer burden of processing these adjustments has only increased since that time, given the rapid growth in covered entity participation in the program in recent years.[28] And, in some instances, the dollar amounts in question do not justify the administrative burden of processing them. This is particularly problematic where, as HRSA had proposed, the credits and refunds operate only in one direction (i.e., credits and refunds are offered to covered entities when estimated ceiling prices are too high, but not to manufacturers when estimated ceiling prices are too low). This is not only inconsistent with the Medicaid Drug Rebate Program's (MDRP's) two-way refund mechanism, but permitting offsets in only one direction also 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.[29]

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 avoid the improper extension of commercial rebates and not be subject to subsequent adjustments or the need for true-ups. This approach would produce 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. It also can be statutorily supported in that it uses an established benchmark already utilized by the Medicaid Drug Rebate Program, the price types from which form the basis for calculating the 340B ceiling price.

In the Notice, HRSA also seeks comment regarding "at which quarter a manufacturer should refund or credit a covered entity if there is an overcharge."[30] In the Proposed Rule, HRSA's proposed that manufacturers 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. Rather, we urge the Agency to align the timeframe for such refunds with the MDRP's 12-quarter restatement period.

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[27] 60 Fed. Reg. at 51,488.
[28] 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).
[29] 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).").
[30] 81 Fed. Reg. at 22,960-61.

III. HRSA's Definition of "Knowingly and Intentionally" Must Comport with the High Statutory Intent Standard.

The 340B law only permits manufacturer CMPs for "knowingly and intentionally" overcharging covered entities.[31] However, as HRSA explains in the Notice, the term "knowingly and intentionally" was not defined in the Proposed Notice. HRSA now seeks comment on a definition for this term. We agree with other commenters that this term is essential to the application of manufacturer CMPs under the 340B statute, and thus must be defined before such CMPs may be imposed. We therefore commend HRSA's efforts to reopen the comment period in order to solicit stakeholder input as to how this critical term should be defined.

As BIO has explained in our prior comment letters, "knowingly and intentionally" is an unusual and high intent standard for a civil statute. 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. HRSA is not permitted to redefine these terms to capture lesser forms of misconduct.

The 340B statute specifically applies CMPs to a manufacturer that "knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the [ceiling] price."[32] Deconstructing this language, it must be "knowing[] and intentional[]" on the part of the manufacturer that both: (1) the amount charged exceeds the ceiling price; and (2) the entity charged is, in fact, a covered entity. To fully effectuate this language, the term "knowingly and intentionally" should therefore be defined to include only "conduct undertaken by the manufacturer with the specific intent to overcharge a customer that the manufacturer actually knows is a registered covered entity."[33] We believe that this definition more precisely captures the intent of the statute than the definition outlined in the Notice.

In particular, we are extremely concerned by HRSA's suggestion that mere "*knowledge* by the manufacturer, its employees, *or its agents* of the instance of overcharge" could be sufficient basis for CMPs.[34] First, reference to "knowledge" alone could be read to include scenarios where a manufacturer (or its employees or agents) only learn about an "instance of overcharge" after the fact, which would hardly render the overcharge intentional. Permitting such inferences would significantly dilute the congressionally-mandated standard that a CMP could only issue when a manufacturer "knowingly and *intentionally*" overcharges a covered entity. Second, HRSA has not specified the sort of entity it might consider an "agent" of a manufacturer, which arguably could range from wholesalers to software vendors.

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[31] 42 U.S.C. § 256b(d)(1)(B)(vi).
[32] 42 U.S.C. § 256b(d)(1)(B)(vi)(III).
[33] We continue to believe that 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.
[34] 81 Fed. Reg. at 22,961 (emphasis added).

The knowledge or intent of those entities independent from the knowledge or intent of the manufacturers themselves should have no bearing on whether the statutory standard is met. We also are deeply concerned that defining the term "knowingly and intentionally" to include "acting in a way practically certain to result in an overcharge" or "acting consciously and with awareness of the acts leading to the instance of overcharge" would improperly lower the "intentionally" standard to mere "recklessness," contrary to the clear language of the statute.

In addition, building upon the examples HRSA provides in the Notice of insufficient intent, HRSA should further expressly recognize that the term "knowingly and intentionally" necessarily does not include inadvertent, accidental, or negligent conduct; unrecognized error in computing the ceiling prices; conduct undertaken with the honest belief that the facts were otherwise; 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.

However, it is not enough for HRSA to define the term "knowingly and intentionally," with or without examples of insufficient intent. Rather, this standard must apply across all of the CMP-related provisions of the rule. We therefore remain concerned that other CMP-related aspects of the Proposed Rule suggest that HRSA may be seeking to impermissibly apply CMPs to actions that could not be construed to be "knowingly and intentionally"—words specifically chosen by Congress for purposes of applying manufacturer CMPs under the 340B statute.[35] For instance, contrary to what was proposed in the Proposed Rule, the term "instance"—also critical for determining the applicability and scope of manufacturer CMPs—absolutely *cannot* be defined by reference to factors out of a manufacturer's control (e.g., how many orders covered entities place for a particular covered outpatient drug).[36] Subsequent ceiling price recalculations resulting from pricing data submitted to the Centers for Medicare & Medicaid Services (CMS)—which are not only routine and permitted, but often occur due to factors outside a manufacturers' control—similarly cannot be considered "knowing[] and intentional[]" overcharges.[37] Moreover, while we appreciate HRSA's recognition in the notice that CMPs are not appropriate "[w]hen a manufacturer has established alternative allocation procedures where there is an inadequate supply of product to meet market demand, as long as covered entities are able to purchase on the same terms as all other similarly-situated providers," there are other aspects of the Agency's distribution plan-related language in the Proposed Rule, which similarly must be reconsidered in order to align with the statutory "knowingly and intentionally" standard. We encourage HRSA to thoroughly consider BIO's comments on these and other topics before moving forward with this rule.

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[35] 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.

[36] 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." 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." 42 C.F.R. § 10.11(b) (proposed).

[37] 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. 42 C.F.R. § 10.11(b)(4) (proposed).

On a related topic, we also urge HRSA to carefully review BIO's prior comments on the process for pursuing CMP actions to ensure that there are mechanisms in place for verifying that penalties apply only to those actions that were, indeed, "knowing[] and intentional[]." For instance, BIO continues to 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.

IV. Conclusion

BIO appreciates the opportunity to comment on the Notice. 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/

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Enclosures

Recommended Regulatory Text Regarding Prices for New Drugs

(c) *Prices for new covered outpatient drugs.* A manufacturer must calculate a ceiling price for a new covered outpatient drug as of the date the drug is first available for sale, and for two quarters after the drug is available for sale, in accordance with this subsection. The ceiling prices calculated for new drugs under this subsection shall not be subsequently revised or restated, absent an error in their calculation. Beginning with the third quarter the drug is available for sale, the manufacturer must calculate the ceiling price as described in subsection (a). The ceiling price for each new covered outpatient drug shall be calculated by the manufacturer as follows:

(i) for a single source drug or innovator multiple source drug, the ceiling price equals the drug's Wholesale Acquisition Cost (WAC) on the first day of the applicable quarter minus the minimum basic rebate percentage set forth at 42 U.S.C. § 1396r-8(c)(1)(B); and

(ii) for a covered outpatient drug (other than single source drugs and innovator multiple source drugs), the ceiling price equals the drug's WAC on the first day of the applicable quarter minus the minimum basic rebate percentage set forth at 42 U.S.C. § 1396r-8(c)(3)(B).

BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

November 19, 2010

BY ELECTRONIC DELIVERY

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Re: Comments on the Civil Monetary Penalties

Dear Mr. Lang:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to respond to HRSA's September 20, 2010 advance notice of proposed rulemaking and request for comments ("ANPRM") seeking to obtain information and public comment on how to efficiently and effectively implement the civil monetary penalty ("CMP") authority provided by Section 7102(a) of the Patient Protection and Affordable Care Act ("Affordable Care Act"), Pub. L. 111-148. *See* 75 Fed. Reg. 57,230 (Sept. 20, 2010). BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. It represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial, and environmental biotechnology products. BIO supported passage of the Affordable Care Act.

BIO appreciates that HRSA is proceeding with care to develop standards for exercising the CMP authority extended to the agency in the Affordable Care Act. We believe that changes to the 340B Program of this significance require stakeholders to have an opportunity to fully review, analyze, and comment on any proposal to ensure that all perspectives are accounted for before any proposal is finalized. We proceed to address each of the topics on which HRSA is expressly seeking comment. Additionally, we have included in the appendix a letter that BIO previously sent to HRSA outlining a number of areas in which we seek additional guidance.

I. Existing Models

BIO agrees that the Department of Health and Human Services ("HHS") and other federal agencies have experience creating and implementing CMP provisions in a variety of

contexts, portions of which can provide useful guidance in designing and implementing CMPs in the 340B Program.

BIO has reviewed aspects of the CMP authority exercised by the HHS Office of Inspector General ("OIG") and Centers for Medicare and Medicaid Services ("CMS"), *see* 42 C.F.R. Parts 402, 1003, and 1005, as well as the CMP authority exercised by the Federal Aviation Administration ("FAA"), *see* 14 C.F.R. Part 13; the Department of Treasury ("Treasury"), *see* 31 C.F.R. Part 27; the Food and Drug Administration ("FDA"), *see* 21 C.F.R. Part 17; the Department of Agriculture, *see* 7 C.F.R. Part 1, Subparts H, L; and the Federal Deposit Insurance Corporation ("FDIC"), 12 C.F.R. Part 308, Subparts A, B, and H. We have also reviewed the HHS Office of Inspector ("OIG") reports *Deficiencies in Oversight of the 340B Drug Pricing Program* (October 2005) (OEI-05-02-00072) and *Review of 340B Prices* (July 2006) (OEI-05-02-00073), and Robert Fabrikant, *et al.*, *Health Care Fraud: Enforcement and Compliance* § 5.03 (2010 ed.).

The comments that follow refer to specific aspects of these various existing CMP regulations in making suggestions about how HRSA should structure CMP regulations for the 340B Program to ensure fairness and efficiency throughout the process.

II. Before Implementing Any CMP Procedures, HRSA Must First Adopt Standards and Processes Regarding the Ceiling Price Calculation, Covered Entity Identification, and True-Ups

The initial question for HRSA to address is *when* it should exercise the new CMP authority it received in the Affordable Care Act. The Affordable Care Act authorizes CMPs as a sanction for "knowingly and intentionally charg[ing] a covered entity a price for purchase that exceeds the maximum applicable price"—*i.e.*, knowing and intentional overcharges to covered entities. As a threshold matter, BIO believes HRSA should not invoke its CMP authority until the agency has taken steps to provide clarity on open issues regarding the calculation of the ceiling price and the identification of covered entities entitled to 340B prices. These steps include:

(1) developing and publishing, through a regulatory process that allows for public comment, the precise standards and methodology that manufacturers must use to calculate ceiling prices;

(2) establishing a single, universal, and standardized identification system through which manufacturers, distributors, and the Secretary can readily identify the covered entities to which the 340B ceiling price applies; and

(3) establishing procedures for manufacturers to issue credits and refunds to covered entities in the event of an overcharge or a subsequent rebate or discount that lowers the applicable ceiling price for the relevant quarter. One option that could facilitate this process is an arrangement to offer credits to covered entities though wholesalers.

Section 7102 of the Affordable Care Act, which requires the creation of the CMP process, also mandates the creation of these three standards and processes—and for good reason. If HRSA seeks to exercise CMP authority before it issues guidance to all interested parties specifying the written procedures for calculating the 340B price, the agency's "general lack of detailed procedures for calculating the 340B ceiling price" means that its CMP proceeding would be based on "unreliable data" and "could lead to inappropriate enforcement actions." HHS OIG, *Deficiencies in Oversight of the 340B Drug Pricing Program* at 12 (Oct. 2005) (OEI-05-02-0072). As the HHS OIG recognized, the government's calculation of the 340B ceiling price has faced problems with accuracy, *id.* at 11, and until those problems are resolved, HRSA cannot have confidence that it is fairly and appropriately invoking its CMP authority. *See also* HHS OIG, *Review of 340B Prices* at 18-19 (July 2006) (OEI-05-02-00073) (finding that 1,673 of the entity purchases in an analyzed sample appeared to be an overcharge based on HRSA data but were in reality a charge at or below the ceiling price once the correct pricing data was used; explaining that "[i]f HRSA had used its ceiling prices to assess the appropriateness of prices paid by 340B entities, it would have erroneously identified overpayments as transactions that were actually at or below the ceiling price, which could have led to inappropriate enforcement actions").

The information available to manufacturers for use in identifying participating covered entities has, historically, also been limited and at times inaccurate. The lack of an accurate database previously hindered manufacturers' ability to effectively identify entities eligible for the discount program. HHS OIG, *Deficiencies in Oversight of the 340B Drug Pricing Program*, *supra*, at 6. While OPA has made great strides in improving the database's accuracy, the absence of a single, universal, and standardized identifier still hampers manufacturer efforts to ensure covered entities get the discounts to which they are entitled. These hurdles must be resolved before HRSA can consider invoking CMP authority.

Finally, until there is a clear and mandatory procedure for a manufacturer to issue credits or refunds, as circumstances warrant, HRSA should not seek to assess a CMP against a manufacturer for failing to use currently non-existent mechanisms to true-up prices paid by covered entities. Standardization of this process will be an important step, given the high volume of true-ups and refunds that are likely to occur based on price changes flowing from routine restatements of average manufacturer price ("AMP") and best price ("BP") (which are calculated to seven decimal places and rounded to six) as well as the volume of products, covered entities, and manufacturers participating in the program.

III. Threshold Determination, Including Statute of Limitations

Once the above three sets of standards and processes have been implemented, BIO fully supports HRSA's adoption of a CMP process. BIO also agrees with OPA that its decision as to whether to initiate a CMP process should consider the amount by which a manufacturer has knowingly and intentionally overcharged a covered entity, the frequency of the conduct, and the manufacturer's compliance history. To be clear, however, BIO believes that such factors only become relevant once HRSA has concluded that knowing and intentional overcharges have occurred. Only once HRSA has reached that conclusion should those factors become relevant.

In such cases, BIO further suggests that HRSA consider the following additional factors when deciding whether to initiate a CMP proceeding: (1) whether an overcharge is *de minimus* (at a threshold to be proposed by HRSA through rulemaking, potentially based on either a fixed dollar amount or a percent of sales[1]); (2) whether any overcharge is offset by corresponding undercharges resulting from other restated ceiling prices during a one year time frame; (3) whether the manufacturer acted promptly to evaluate any alleged overcharge and correct it if an overcharge in fact occurred; (4) whether, when considered in proportion to the manufacturer's sales of all covered drugs to all covered entities, the occurrence rate for an overcharge is small; and (5) whether the legal basis for asserting that an overcharge occurred had previously been established by statute, regulation, or published agency guidance.

This last factor is critically important. BIO strongly believes that HRSA should not institute a CMP proceeding where the alleged overcharge involved circumstances not addressed by written and binding agency standards. In situations outside of those addressed through agency guidance or regulation, there can be no basis for HRSA to allege in a CMP proceeding that a manufacturer has engaged in a knowing and intentional overcharge—and only knowing and intentional overcharges permit HRSA to exercise its CMP authority. *See* Affordable Care Act, Section 7102. For example, HRSA has no regulations pertaining to situations in which the ceiling price is negative. While HRSA recommends that manufactures charge the entity a penny in such circumstances, "HRSA has not provided official guidance on this issue or updated its records to reflect this expectation." HHS OIG, *Deficiencies in Oversight of the 340B Drug Pricing Program, supra*, at 14. As the OIG itself has recognized, "[i]f HRSA uses data containing negative ceiling prices to determine if entities paid at or below 340 ceiling prices, the results will be skewed" and could result in "false positives that might cause HRSA to draw invalid conclusions about compliance with discount requirements." *Id.* at 14-15.

Finally, BIO requests that HRSA directly address one additional aspect of exercising CMP authority: the statute of limitations for such proceedings. Manufacturers have three years to restate a drug's AMP, and its BP in the case of an innovator product, during which time the ceiling price can correspondingly move upwards or downwards. *See* 42 C.F.R. § 447.510(b)(1). Clearly, routine restatements of AMP and BP will not 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 this is the case. However, given that AMP and BP may change during that three year window, BIO recommends that HRSA set a four year statute of limitations, through rulemaking, 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 three year period for restatement of AMP/BP. The four year limitations period would extend from the first day of the quarter on which a ceiling price at issue was in effect.

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[1] BIO has proposed a 2% de minimus standard be applied in the restatement context. See Appendix hereto. 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.

IV. Administrative Process Elements

BIO agrees that it is important for HRSA to articulate thoroughly in a subsequent notice of proposed rulemaking all of the details for any process HRSA proposes for administering its CMP authority.

Notice for Proposed Determinations. BIO suggests that, as in the CMS and OIG context of CMPs, HRSA's notice of intent to assess a CMP should include (1) a description of the facts and conduct demonstrating an overcharge; (2) an explanation as to why the stated violation justifies the CMP; (3) the amount of the proposed penalty; (4) any and all circumstances that were considered when determining the amount of the proposed penalty; (5) any aggravating and mitigating factors that HRSA considered; and (5) instructions for responding to the notice, including information about the recipient's right to a hearing, or any other procedure to contest the CMP, and the time within which the recipient must act to protect that right. If HRSA intends to propose that a failure to timely respond would permit HRSA to impose the proposed CMP and eliminate the right of appeal, the notice must make that clear as well. *See, e.g.*, 42 C.F.R. §§ 402.5, 402.7, 402.9; *see also, e.g.*, 12 C.F.R. § 308.18(b). The notice should be served in accordance with Rule 4 of the Federal Rules of Civil Procedure.

In providing a description of any alleged overcharge, the notice of intent should specify the ceiling price that HRSA has identified as the correct ceiling price and identify how HRSA reached that value, including stating the AMP, unit rebate amount ("URA"), and package size data that HRSA used in the calculation. It should also identify the covered entities subject to any alleged overcharge. Specifying the ceiling price and the covered entities involved is critical given the past problems in the government's calculation of the ceiling price and maintenance of an accurate covered entity database. *See* HHS OIG, *Deficiencies in Oversight of the 340B Drug Pricing Program, supra*, at 6 (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); *id.* at 11 (noting that the government's calculation of the 340B ceiling price was inaccurate 8% of the time because the government did not include the URA, which resulted in an overstated 340B ceiling price).

In addition, if the alleged overcharge involves sales of a drug to a covered entity through a distributor or wholesaler, as opposed to or in addition to sales directly from the manufacturer, the notice of intent should include HRSA's understanding as to why the alleged overcharge resulted from an overstated ceiling price as opposed to an error or additional charge made by the wholesaler or distributor. *See* HHS OIG, *Deficiencies in Oversight of the 340B Drug Pricing Program, supra*, at 4 (recognizing that "it is acceptable for wholesalers to charge covered entities 340B ceiling prices plus a distribution fee").

As in the Treasury CMP process, BIO also recommends that a recipient of a notice of intent to assess a CMP be provided 20 days to request an opportunity to review any documents or other evidence compiled or relied upon by the agency in determining to issue the notice, subject to privileges available under law. *See* 31 C.F.R. § 27.5(d)(4). If a recipient requests this

information, the time for responding should be stayed until 20 days after that information is made available to the recipient.

Procedural Process. BIO suggests that there should be six procedural steps in the CMP process: (1) a notice of intent to assess a CMP; (2) an opportunity to review the documents or evidence compiled or relied upon by the agency in determining to issue the notice; (3) an informal procedure to resolve the CMP; (4) a hearing; (5) an appeal within HHS to the Department Appeals Board ("DAB"); and (6) judicial review in the federal Courts of Appeals and the Supreme Court of the United States. All or some combination of these steps are included in the CMP processes articulated in regulations issued by OIG, CMS, the FAA, and the FDIC, among others. Each step, with citation to the relevant regulations, is discussed in more detail in the relevant section of these comments.

If HRSA provides recipients a right to review the documents or evidence on which the agency relied in issuing the notice of intent to assess a CMP, one additional option that HRSA should consider is providing for an automatic reduction of the CMP amount if the recipient, after reviewing those documents or evidence, waives its right to a hearing and consents to the CMP. There is precedent for this sort of reduction in CMP procedures. For example, under 42 C.F.R. § 488.436, a CMP is reduced by 35 percent if a long-term care facility waives its right to a hearing and agrees to pay a CMP proposed by CMS. A similar process could work well for the 340B Program. It would reduce the costs to HRSA to administer the CMPs and would provide an incentive for manufacturers not to contest the CMP in the presence of particularly strong or compelling evidence that the manufacturer knowingly and intentionally overcharged a covered entity.

BIO also requests that HRSA consider an informal resolution procedure similar to that used by FAA for situations in which a recipient does not agree with a CMP. In response to a notice of proposed penalty, the FAA regulations provide a recipient with an option to engage in an informal procedure before requesting a formal hearing. *See* 14 C.F.R. § 13.16(f). If a recipient opts for the informal procedures, the recipient can submit to the FAA written information, including documents and witness statements, demonstrating that there was no violation or that the amount of the penalty is not warranted, requesting a reduction of the proposed penalty, along with the reasons and documentation supporting a reduction, and request an informal conference to discuss the matter with the agency. *Id.* §§ 13.16(f)(2), 13.16(g). We understand that in the FAA context, parties invoke this informal procedure the vast majority of the time—and regularly resolve any proposed penalty through this mechanism, which is less costly and burdensome for the parties and the agency than a full-blown hearing.

Finally, the regulations should make clear that HRSA and a manufacturer can agree to settle or compromise a CMP proceeding without an admission of liability or wrongdoing, as often occurs in other settlement contexts. In such a settlement, no finding of liability will be made against the settling party.

Involvement of covered entities; notice to third parties and the public. BIO is not aware of any policy or program rational for providing notice of a proposed CMP to third parties or the

public or for involving covered entities in the process (other than through necessary third-party discovery or third-party subpoenas compelling testimony as discussed below). None of the other CMP processes that we reviewed permit third parties to play an active role in a CMP proceeding (again, outside of third-party discovery or third-party subpoenas). Especially given the privileged and confidential pricing data that are likely to be at the center of a CMP proceeding, it makes better sense to restrict the notice and involvement of outside parties to avoid any unauthorized disclosure of that information. The appropriate forum for involvement by covered entities is the separate and independent dispute resolution process, not the CMP process.

Additional Procedures in 42 C.F.R. § 1003. BIO recommends that HRSA make clear that if a case proceeds to a hearing, the consent of the officer(s) presiding over the hearing is not required for settlement of the CMP proceeding. *See* 42 C.F.R. § 1003.126. In addition, given the agency's burden to establish knowing and intentional overcharges in the 340B CMP process, BIO believes that the agency cannot use the sort of statistical sampling or extrapolation that is permitted in other limited HHS contexts. *See* 42 C.F.R. § 1003.133; 42 U.S.C. § 1395ddd(f)(3).

V. Hearing

BIO recommends that the agency provide a fair, impartial hearing as a matter of right. Civil penalty hearings, across agencies, typically take place before an administrative law judge ("ALJ") or presiding officer. If HRSA instead opts to propose a decision making body comprised of multiple individuals, BIO requests that any representation for covered entities be equally balanced with representation for manufacturers. An ALJ, or any other individual involved as part of a decision-making body, must be conversant with the requirements of the 340B Program and existing HRSA program guidance. To ensure that is the case, HRSA should request that the CMP proceedings be handled exclusively by a limited subset of ALJs, who then should be trained in the program's requirements. In the comments that follow below, BIO refers to the decision-making entity as the ALJ for simplicity.

Ex Parte Contacts. There should be no *ex parte* contacts at any stage of the proceeding. That includes any contact between the ALJ and any person connected with the proceeding from a manufacturer, covered entity, or the agency, including those connected as an advocate or in an investigative capacity. *See, e.g.*, 42 C.F.R. § 1005.5 ("No party or person (except employees of the ALJ's office) will communicate in any way with the ALJ on any matter at issue in a case, unless on notice and opportunity for all parties to participate."); 21 C.F.R. § 17.20 (same). A party should be permitted to file a motion requesting that the ALJ be disqualified from a proceeding, *see, e.g.*, 14 C.F.R. § 13.205(c), including for engaging in *ex parte* communications with HRSA, a manufacturer, or a covered entity.

Prehearing conferences. HRSA should consider authorizing prehearing conferences to permit the ALJ to discuss with the party and the agency, among other things, the necessity or desirability for a more definite statement of wrongdoing, a schedule for any needed discovery, including third-party discovery, and potential settlement of the case. *See* 42 C.F.R. § 1005.6; 21 C.F.R. § 17.21.

Discovery and subpoenas. Discovery is a critical administrative process element that should be addressed in any proposed rule. A manufacturer may need to obtain materials to defend itself at a hearing, including from non-parties to the CMP proceeding, such as wholesalers, distributors, and covered entities. Program guidance makes clear that manufacturers must make their drugs available through wholesalers, and that the use of wholesalers is for the convenience of both the manufacturers and the covered entities. *See* 59 Fed. Reg. 25110 (May 13, 1994). But unless a manufacturer has access to third-party discovery, it will not be able to ensure that it can obtain the necessary documents and testimony necessary to defend itself.

Numerous other CMP mechanisms provide for third-party discovery by authorizing the officer presiding over a hearing to issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation. *See, e.g.*, 12 C.F.R. §§ 308.5(b)(2), 308.11(d), 308.26; 14 C.F.R. §§ 13.205(3), 13.220, 13.228; 21 C.F.R. §§ 17.19(a)(5), 17.27; 42 C.F.R. § 1005.9. HRSA should do the same. In addition, a party defending against a CMP should be able to move for an order compelling discovery if an individual or entity on whom discovery is served objects to providing full and complete discovery responses. *See* 42 C.F.R. § 1005.7.

Evidence. The hearing should not be bound by the Federal Rules of Evidence, although the ALJ should exclude evidence that is irrelevant, immaterial or privileged, that was part of a settlement offer, or where the probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues or considerations of undue delay or needless presentation of cumulative evidence. 21 C.F.R. § 17.39; 42 C.F.R. § 1005.17; *see also* 14 C.F.R. § 13.222(c) ("The fact that evidence submitted by a party is hearsay goes only to the weight of the evidence and does not affect its admissibility."); 12 C.F.R. § 308.36(3) ("Evidence that would be inadmissible under the Federal Rules of Evidence may not be deemed or ruled to be inadmissible in a proceeding conducted pursuant to this subpart if such evidence is relevant, material, reliable and not unduly repetitive."). Rebuttal witness and evidence should be permitted. *See* 42 C.F.R. § 1005.17.

Other Hearing Elements. BIO encourages HRSA to adopt other hearing process elements from the CMP provisions within HHS. These process elements permit attorney representation at a hearing, 42 C.F.R. § 1005.3; outline procedures for the exchange of witness lists, witness statements, and exhibits, *id.* § 1005.8; establish the parameters of a motions practice before the ALJ, *id.* § 1005.13; authorize cross-examination and exclusion of witnesses, *id.* § 1005.16; ensure an official record of the proceeding, *id.* § 1005.18; and authorize written testimony in addition to oral testimony, *id.* § 1005.16.

HRSA should bear the burden of proof on all issues other than affirmative defenses or mitigating circumstances, and the burden of proof should be a preponderance of the evidence as is generally applicable in civil matters. *Id.* § 1005.15; *see also, e.g.*, 14 C.F.R. § 13.224 (agency bears burden of proof); 21 C.F.R. § 17.33 (same). We also recommend post-hearing briefs and proposed findings of fact and conclusions of law, supported by citations to relevant authorities

and the relevant portions of the record. *See* 12 C.F.R. § 308.37; 21 C.F.R. § 17.43; 42 C.F.R. § 1005.19.

ALJ Authority. The ALJ should be authorized to affirm, increase, or decrease the amount of the CMP based solely on the record. 42 C.F.R. § 1005.20. When determining the amount of a civil penalty, the ALJ should be required to articulate in an opinion the reasons that support the penalty imposed, including discussing any circumstances that aggravate or mitigate the violation and any affirmative defenses. 21 C.F.R. §§ 17.34, 17.45. This information will be critical for any internal appeal and for judicial review. The regulations should also contain a catchall provision regarding aggravating and mitigating circumstances to make clear that the ALJ can consider any such circumstances in a given case, regardless of whether they are specifically identified in the regulation. *See* 42 C.F.R. § 1003.106; 42 C.F.R. § 402.11.

We recommend that the regulations specifically state that an ALJ is authorized to withhold from third parties or the public any record, evidence or testimony disclosing privileged information and/or confidential pricing data. *See, e.g.,* 14 C.F.R. § 13.266 ("The administrative law judge may order that any information in the record be withheld from public disclosure."); 12 C.F.R. § 308.5 (ALJ has authority "[t]o establish time, place and manner limitations on the attendance of the public and the media for any public hearing"). There should be specific procedures for filing under seal when the public filing of any document would disclose such information or be contrary to the public interest. HRSA could consider permitting redacted versions of such filings to be made public.

VI. Appeals Process

BIO recommends that HRSA include standards for both interlocutory appeals and appeals after an ALJ final decision in the CMP regulations.

Interlocutory appeals. A number of CMP mechanisms provide for interlocutory appeals in certain circumstances. For instance, the FDIC regulations permit interlocutory review if the ruling at issue involves a controlling question of law or policy as to which substantial grounds exist for a difference of opinion, immediate review may materially advance the ultimate termination of the proceeding, subsequent modification at the conclusion of the hearing would be inadequate, or subsequent modification would cause unusual delay or expense. 12 C.F.R. § 308.28(b). The FDA regulations provide for an interlocutory appeal if the officer presiding over a hearing "certifies on the record or in writing that immediate review is necessary to prevent exceptional delay, expense, or prejudice to any participant, or substantial harm to the public interest." 21 C.F.R. § 17.18(b). FDA also authorizes the filing of a brief on the interlocutory appeal issues. *Id.* § 17.18(c). *See also* 14 C.F.R. § 13.219 (FAA regulation addressing interlocutory appeals for cause and as of right).

BIO recommends that HRSA adopt the FDIC's interlocutory review standard. It simply makes sense, as well as encourages efficiency and helps to ensure fairness in hearings, to permit interlocutory review in situations presenting a controlling question of law or policy as to which substantial grounds exist for a difference of opinion. Neither the agency nor parties should bear

the costs of a full-fledged hearing where the ALJ agrees that the legal basis for the CMP itself or a particular ruling underlying the hearing is a novel question of law lacking a clear answer.

Appeal of Final Order Within HHS. The ALJ's ultimate decision about whether to assess a CMP and the size of that CMP should be appealable in all circumstances. The first level of appeal should be within HHS to the DAB and should be triggered by a notice of appeal, followed by a written brief. *See, e.g.*, 21 C.F.R. § 17.47. The ALJ's decision should include a written statement describing how and when to file a notice of appeal with the DAB. *See* 42 C.F.R. § 1005.20. The appeal should be a matter of right for which fact issues are reviewed under a substantial evidence standard and legal conclusions reviewed de novo. *See* 42 C.F.R. § 1005.21. In addition to affirming or reversing an ALJ decision, the DAB should be able to remand for consideration of additional evidence if new evidence has become available or there were reasonable grounds for failure to adduce such evidence in the hearing before the ALJ.

Filing a request for review with the DAB should automatically stay the ALJ decision, and once the DAB renders its decision, a party should be able to request for a stay pending judicial review. 42 C.F.R. § 1005.22; *see also* 12 C.F.R. § 308.41 (permitting stay of decision pending judicial review).

Judicial review. A party should be able to seek judicial review of the DAB's decision. *See, e.g.*, 42 C.F.R. § 402.21; 42 C.F.R. § 1003.127. That judicial review should occur in the United States Court of Appeals for the District of Columbia Circuit or the circuit in which the manufacturer resides or in which the alleged overcharge occurred. The Court of Appeals should have authority to affirm, modify, remand for further consideration, or set aside in whole or part, the DAB's decision. The Court may order that further evidence be taken before the ALJ upon a showing by any party that additional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the hearing before the ALJ.

VII. Definitions

Instance. The Affordable Care Act limits a CMP to no more than $5,000 for "each instance" of knowingly and intentionally overcharging a covered entity. Because only knowing and intentional conduct can be subject to a CMP, the term "instance" should be defined to include actions within a manufacturer's control. Accordingly, the term "instance" should be defined to include (1) each incorrect ceiling price that actually results in an overcharge to a covered entity and (2) each incorrect determination by a manufacturer that a covered entity is not a covered entity entitled to the ceiling price that actually results in the covered entity purchasing products at higher than ceiling prices.

Defining "instance" in these two ways ensures that the number of "instances" flows from decisions within a manufacturer's control. As to the first prong, any overcharges in a given quarter that are based on in incorrectly calculated ceiling price will flow from the single calculation that the manufacturer made as to the ceiling price for the particular product. That calculation should be considered a single "instance." The number of "instances" should not be based on how many units of a product are purchased or how many covered entities make those

purchases. Those factors are outside the manufacturer's control. Similarly, under the second prong, an "instance" of overcharging also should include a manufacturer's incorrect determination that a customer is not a covered entity entitled to a correctly calculated ceiling price—also a determination within the manufacturer's control that may result in a covered entity being overcharged.

Finally, BIO strenuously objects to HRSA's suggestion that it would be authorized to treat a refusal to sell a covered outpatient drug as potentially actionable through the CMP process. First, CMPs are restricted to situations involving an overcharge, and a refusal to sell is not an overcharge. Second, even if a refusal to offer the ceiling price was considered to be an overcharge, a manufacturer will not have an obligation to offer covered drugs at the ceiling price until HRSA issues a new Provider Participation Agreement ("PPA") and manufacturers contractually obligate themselves to offer the ceiling price to covered entities by signing it. Until the Affordable Care Act was enacted, manufacturers had no obligation to offer their products to 340B covered entities. Nowhere in the 340B Program is there a mandate to offer products or a specific requirement that all, or any particular portion of, a 340B entity's request to purchase product be fulfilled. Consistent with the Program requirements, the PPA currently in effect only governs the price that manufacturers can charge covered entities for covered outpatient drugs.

In recognition of the current program requirements, Section 7102(b) of the Affordable Care Act amends the 340B Program to add a must-offer obligation through a new term to the Secretary's PPA: that "the manufacturer offer each covered entity covered drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." There can certainly be no CMP proceeding based on this new "must offer" provision until it is implemented through a new PPA or an amendment to manufacturers' existing PPA.

Knowingly and Intentionally. The ANPRM suggests that HRSA is considering permitting inferences of intentionality to be drawn from scenarios where, for example, one employee or agent of a manufacturer knows a customer is a covered entity and another employee or agent knows that customer is being charged more than the ceiling price, or where a manufacturer repeatedly miscalculates a ceiling price (which could result from numerous wholly *unintentional* circumstances, like a software problem). Permitting such inferences would significantly dilute the congressionally-mandated standard that a CMP could only issue when a manufacturer "knowingly and intentionally" overcharges a covered entity. As an initial matter, HRSA has not specified the sort of entity it might consider an "agent" of a manufacturer, which arguably could range from wholesalers to software vendors. The knowledge or intent of those entities independent from the knowledge or intent of the manufacturers themselves should have no bearing on whether the statutory standard is met.

Based on the above statements in the ANPRM, it appears that HRSA may be seeking to impermissibly redefine "knowingly" and "intentionally," words specifically chosen by Congress. Many civil fraud statutes use the term "knowingly" by itself, and most criminal statutes use "knowingly and willfully." But 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. HRSA should not be permitted to redefine these terms to capture

lesser forms of misconduct. While Congress has at times defined "knowing," on its own, to require something less than actual knowledge, including "reckless disregard" or "deliberate ignorance"—for example, in the federal civil False Claims Act, 31 U.S.C. § 3729(b)(1)—here, the statute plainly requires more by referring only to conduct that is both knowing and intentional. Taken together, "knowingly 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 covered entity. The 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, 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.

VIII. Penalty Computation

In computing the penalty, the ANPRM proposes consideration of certain factors. BIO seeks clarification about certain of those criteria. The ANPRM refers to a manufacturer's "previous record of overcharging." So long as this factor only encompasses instances in which a manufacturer admits it overcharged a covered entity in the 340B Program or was adjudicated to have done so, BIO agrees that its consideration is appropriate. This factor cannot include instances of non-adjudicated allegations of overcharging, alleged instances of overcharging 340B covered entities that were dismissed or settled without an admission of wrongdoing, or alleged instances of overcharging outside the 340B Program. BIO also believes that the number of covered entities and the impact on patient access should be entitled to little, if any, weight in the analysis because these are not factors within a manufacturer's control.

BIO further recommends the inclusion of a number of additional factors in computing the penalty amount: (1) the nature and circumstances of the overcharge; (2) the degree of culpability of the entity against whom a CMP is proposed; (3) whether the manufacturer promptly took corrective steps after the error was discovered, such as developing and implementing a corrective action plan, reinforcing its internal compliance program, or taking disciplinary action against any employee who engaged in misconduct or failed to follow or utilize the entity's internal compliance program; (4) the materiality and total amount of any miscalculated ceiling price and resulting overcharge; and (5) whether the manufacturer self-reported the violation. Other CMP proceedings consider these factors, as well as a catchall factor permitting consideration of any other matter as justice may require. *See* 42 C.F.R. § 1003.106; 42 C.F.R. § 402.11.

IX. Payment of Penalty

BIO agrees that HRSA should establish methods for transferring any penalty assessed to the government. BIO also agrees that to the extent a penalty is not paid in a timely manner—not to be less than 60 days from the ultimate conclusion of any appeal or judicial review—HRSA could pursue a civil action to recover the amounts due.

BIO disagrees that interest should be available from the date of the overcharge. While interest should potentially be available for any credit or refund due to the overcharged entities,

interest on a civil penalty should be triggered by the 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 three years 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.

X. Integration of CMPs with Other Provisions in the Affordable Care Act

BIO reiterates that the CMP authority should not be exercised until HRSA has established procedures to verify ceiling prices, created a process for manufacturers to refund or credit overcharges, and provided a mechanism to confirm a covered entity's entitlement to the 340B ceiling prices. Those are necessary preliminary steps that must be taken to ensure that HRSA's CMP authority can be exercised in a fair, reasonable, and non-arbitrary manner that provides sufficient notice to manufacturers on key compliance principles. *See, supra*, 2-3.

Conclusion

BIO looks forward to working with HRSA over the coming months and years to implement the CMP authority. We hope that the agency finds this letter to be helpful as it begins this process. Please feel free to contact Laurel Todd at 202-962-9220 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 Todd
Managing Director, Reimbursement and Health Policy

Sandra Dennis
Deputy General Counsel, Health

APPENDIX

September 3, 2010

BY ELECTRONIC DELIVERY

Commander Krista Pedley
Director
Health Resources and Services Administration (HRSA)
5600 Fishers Lane
Rockville, MD 20857

Re: Implementation of the Patient Protection and Affordable Care Act, as Amended by the Health Care and Education Reconciliation Act of 2010

Dear Commander Pedley:

The Biotechnology Industry Organization (BIO) is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products. Accordingly, we were pleased to support passage of the Patient Protection and Affordable Care Act (PPACA) and the Health Care and Education Reconciliation Act of 2010 (HCERA) (collectively, the Act).

Now that PPACA and HCERA have been enacted, we recognize HRSA has responsibility for implementing many of the Act's provisions relating to the 340B drug pricing program. We understand that HRSA is considering issuing a rulemaking to implement these requirements. BIO applauds HRSA for pursuing this approach, as we believe that changes of this significance should be implemented only through a notice-and-comment rulemaking process, allowing stakeholders to fully review, analyze, and comment on those proposals ensuring all perspectives are accounted for before any proposal is finalized.

In this regard, and to assist the agency in its implementation work, BIO would like to take this opportunity to bring to your attention a number of issues that we believe need to be addressed in any guidance or proposed rules HRSA issues related to sections 7101 and 7102 of PPACA, and section 2302 of HCERA, which make changes to section 340B of the Public Health Services Act. We also highlight ongoing issues relating to enforcement of the existing statutory prohibitions on duplicate discounts and diversion under the 340B statute.

I. Expansion of 340B Program and Retroactive Rebates

Section 7101(a) of PPACA amended the definition of a covered entity under section 340B to include new categories of hospitals. HRSA has implemented a rolling admission

process for these new entity types, beginning August 2, 2010 through September 30, 2010. Neither HRSA's July 28 webinar regarding this enrollment process nor the enrollment guidance provided on HRSA's website state that the new covered entity types are eligible for retroactive rebates back to January 1, 2010, the effective date of section 7101. By comparison, when HRSA issued its guidance regarding registration of children's hospitals pursuant to the Deficit Reduction Act of 2005 (DRA), its Final Notice expressly authorized those entities to request retroactive rebates and defined the process for doing so.[1] BIO interprets the absence of guidance to date regarding retroactive rebates for the section 7101 new entity types to mean that HRSA is not permitting those entities to seek such rebates and requests that HRSA confirm that is the case.

To the extent that HRSA will permit these newly eligible entities to seek retroactive rebates on covered outpatient drugs back to January 1, 2010, it is crucial that HRSA require the entity to demonstrate its eligibility for the entire period for which rebates are sought and also to certify its satisfaction of program requirements during that same period, consistent with OPA's previously defined approach for children's hospitals that seek retroactive rebates. BIO believes that HRSA should implement this same procedure with regard to retroactive rebates requested by the new covered entity hospital types, if such rebates are permitted, because manufacturers have experience in coordinating with covered entities regarding such requests. Consistent with this approach, HRSA also should limit the time period for covered entity requests for rebates to a period of 30 days post enrollment. Finally, BIO asks that HRSA include in its system for verifying the accuracy of information provided by covered entities, as discussed further below, a distinct identifier for those entities eligible for retroactive pricing and discounts.

II. Amendment to Pharmaceutical Pricing Agreement (PPA)

Section 7102(b) of PPACA amends section 340B to add two new requirements for the Secretary's PPA with the manufacturer. The first requirement is for manufacturer submission of ceiling price data to the Secretary and the second requirement is that "the manufacturer offer each covered entity covered drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." BIO asks that HRSA confirm that these new requirements will be implemented either through a new PPA or an amendment to manufacturers' existing PPA and that HRSA notify manufacturers regarding when HRSA expects to issue this new agreement or amendment.

As to the second, "must offer," requirement, we also request that HRSA confirm that manufacturers may use a reasonable allocation methodology, so long as that methodology does not discriminate based on a customer's 340B status. Where the FDA imposes requirements on the manufacturer regarding the distribution of a drug, such as Risk Evaluation and Mitigation Strategies, or REMS, and those FDA mandates limit a manufacturer's distribution avenues for particular products and/or impose compliance requirements on those entities that wish to dispense or administer a particular drug to a patient, HRSA should make clear that the manufacturer need not offer a product for sale to a covered entity unless and until the covered

[1] 74 Fed. Reg. 45206 (Sep. 1, 2009).

entity can qualify under those FDA-required standards. Finally, we request that should a manufacturer choose to seek guidance from the agency regarding implementation of such an allocation procedure, HRSA identify a point of contact to address such questions.

III. Program Integrity Changes to 340B Program

A. Ceiling Price Website

We understand that section 7102 requires the Secretary to develop a system to verify the accuracy of ceiling prices calculated by manufacturers and also to make 340B prices accessible to covered entities through an Internet website. BIO recommends that this website allow manufacturers to load their pricing data directly, similar to the Drug Data Reporting (DDR) system manufacturers currently use to report pricing and product data under the Medicaid drug rebate program, and that manufacturers be required to enter such data by the first day of the start of each quarter. The website also should include a flag to indicate to covered entities when the ceiling price for a particular drug has been updated, as discussed further below.

In implementing this provision, the Secretary is required to provide covered entities with access to these pricing data "in a manner (such as through the use of password protection) that limits such access to covered entities and adequately assures security and protection of privileged pricing data from unauthorized redisclosure." BIO is concerned that password protection alone is not sufficient to protect manufacturer data from unauthorized redisclosure, as required by the statute. We urge HRSA to implement additional safeguards to adequately protect against such redisclosure, including the establishment of penalties for covered entities that disclose ceiling price data. In developing these safeguards, we also ask that HRSA create procedures that address specific scenarios that are likely to arise, such as where a covered entity loses eligibility, or where an employee leaves one covered entity and becomes employed by another. HRSA's security procedures should address how it will manage passwords and control access to manufacturer data in such circumstances to ensure unauthorized disclosure does not occur.

B. True-Up of Ceiling Prices

Section 7102 requires the Secretary to establish procedures for manufacturers to issue appropriate refunds to covered entities in the event of an "overcharge," including where the overcharge results from a routine restatement of average manufacturer price (AMP) or Best Price (BP) data. BIO requests that HRSA confirm that any such procedures will apply prospectively only. BIO also strongly recommends that in establishing procedures for such refunds, HRSA include a materiality standard, a right to offset against undercharges, and a standardized process for issuing refunds, as discussed below. Finally, while BIO includes proposals below regarding how to operationalize the true-up and refund process, BIO strongly encourages HRSA to create a working group of stakeholders to further review and advise HRSA regarding the creation and implementation of such operational concerns.

1. The True-Up Requirement Should Apply Prospectively Only

Section 7102 requires HRSA to provide for the "establishment of procedures" and the "development of a mechanism" for the issuance of refunds to covered entities in the event of a change in a prior ceiling price. Although PPACA section 7101(e)(2) states that the amendments made by section 7102 shall be effective on January 1, 2010 and shall apply to drugs purchased after that date, it more specifically directs that a process must be established from appropriated funds so that manufacturers may make the refund payments. BIO believes, therefore, that the proper reading of the statute is that these processes, once created, will apply on a prospective basis only. We also recommend that these processes be reflected in the new PPA or PPA amendment, as discussed in Section II above. BIO also believes that this is the only workable approach from an operational perspective. The application of these processes, which are still undefined and will be complex to implement even on a prospective basis, will almost certainly present even greater if not insurmountable barriers if any attempt is made to apply them to prior periods. As should be apparent from the proposals discussed below, the implementation of the true-up and refund requirements will involve tremendous operational complexity for manufacturers of all sizes, as well as the entities who will benefit. Such complexities can be addressed and overcome when the parties have notice and time to develop and implement appropriate systems on a prospective basis. Application of such systems to prior periods, where the data and processes in place before were not designed to account for such requirements, will almost certainly result in errors and enormous administrative burdens on all parties involved.

2. HRSA Should Establish a Materiality Standard

Routine restatements of AMP and/or BP data have the potential to cause changes to prior ceiling prices that are material and where a refund to the covered entity would be appropriate under PPACA. However, BIO understands that such AMP and BP revisions (these figures are calculated to seven decimal places and rounded to six) are equally likely to result in ceiling price changes that are *de minimis*, such that only nominal refunds, whether issued by credit memo or check, would be due. Requiring manufacturers to issue such nominal refunds to each of the over 14,800 covered entities that may have purchased a drug at the prior ceiling price anytime there is a change to that price would be tremendously burdensome on manufacturers, OPA, covered entities, and wholesalers. BIO therefore urges HRSA establish a *de minimis* or materiality threshold for ceiling price changes that require refunds, such that the manufacturer would not be obligated to issue a refund where the restatement of AMP or BP for the quarter results in a decrease that is less than 2.0 percent of the original ceiling price paid by the covered entity. Where the change in the ceiling price exceeds this threshold, we further recommend that HRSA require refunds only where the total amount due the covered entity for all material ceiling price changes for that quarter across all products is at least $200.00. We note that the administrative cost to the manufacturer of issuing a check of any sort typically is approximately $100.00 and so is the appropriate materiality threshold for refunds.

Numerous federal standards, including those adopted by the Department of Health and Human Services, support the application of a materiality standard in different contexts where government funds are at issue. While the above proposed materiality standards would apply to

the payment of refunds to covered entities, and so would not involve refunds to the federal government itself, the government's own willingness to apply such standards to its own fiscal matters clearly supports the reasonableness of doing so as to covered entities as well. The standards we discuss below are the government's Cost Accounting Standards (CAS) as well as three materiality standards from the Department of Health and Human Services (HHS), all of which rely on a 5% materiality threshold – significantly higher than what BIO is requesting here.

The CAS are a set of accounting principles intended to improve uniformity and consistency in the measurement, assignment, and allocation of costs to government contracts. They apply to negotiated contracts and subcontracts in excess of $650,000, subject to certain exceptions.[2] Under CAS, the contractor's Administrative Contracting Officer (ACO) must determine whether CAS noncompliance or changes to the contractor's cost accounting practices results in increased costs to the Government. As part of that review, the ACO makes a determination of materiality of the cost impact. If the change or noncompliance is deemed to have an immaterial cost impact, then no contract adjustments are made.[3] The materiality standard is set forth at 48 C.F.R. § 9903.305:

> In determining whether amounts of cost are material or immaterial, the following criteria shall be considered where appropriate; no one criterion is necessarily determinative:
>
> > (a) The absolute dollar amount involved. The larger the dollar amount, the more likely that it will be material.
> >
> > (b) The amount of contract cost compared with the amount under consideration. The larger the proportion of the amount under consideration to contract cost, the more likely it is to be material.
> >
> > (c) The relationship between a cost item and a cost objective. Direct cost items, especially if the amounts are themselves part of a base for allocation of indirect costs, will normally have more impact than the same amount of indirect costs.
> >
> > (d) The impact on Government funding. Changes in accounting treatment will have more impact if they influence the distribution of costs between Government and non-Government cost objectives than if all cost objectives have Government financial support.

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[2] There are exceptions to application of CAS for, among other things, contracts and subcontracts with small businesses, fixed-price contracts, and subcontracts for commercial items, etc. 48 CFR 9903.201-1,2.

[3] 48 C.F.R. § 30.602.

> (e) The cumulative impact of individually immaterial items. It is appropriate to consider whether such impacts:
>
> > (1) Tend to offset one another, or
> > (2) Tend to be in the same direction and hence to accumulate into a material amount.
>
> (f) The cost of administrative processing of the price adjustment modification shall be considered. If the cost to process exceeds the amount to be recovered, it is less likely the amount will be material.

We believe these factors, which weigh both the absolute and proportionate dollar amount involved as well as the costs of administrative processing, are equally applicable to and supportive of the creation of a materiality threshold for ceiling price revisions and covered entity refunds.

Within HHS, the Office of Inspector General (OIG) has adopted a five percent materiality threshold with regard to the Independent Review Organization (IRO) review of a manufacturer's reported average manufacturer prices (AMPs) and average sales prices (ASPs) pursuant to a Corporate Integrity Agreement (CIA) with the OIG. In at least three separate CIAs, the OIG has applied a threshold of "a net dollar error rate of 5% or greater" for purposes of the IRO's review.[4] Under this standard, if the Error Rate is lower than five percent, the data is not reviewed by the OIG at all.

Again with HHS, the National Institutes of Health has adopted a materiality standard in relation to cost accounting under federal grants, where charges to a grant for salaries and wages of persons working on the grant are based on the percentage of time the employee spends on the grant versus other institutional work the employee performs. For example, if the employee spends 50 percent of his/her time on the grant, then 50 percent of his/her salary can appropriately be charged to the grant. The rate at which a salary is charged to a grant typically is set at the

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[4] Merck CIA, available at http://oig.hhs.gov/fraud/cia/cia_list.asp#b (Feb. 5, 2008) ("If any discovery sample defined in Section II.C.1 reveals a net dollar Error Rate of 5% or greater, Merck and the IRO shall hold an interim conference with the OIG to discuss the IRO's findings."); Bristol-Myers Squibb Company CIA, available at http://oig.hhs.gov/fraud/cia/cia_list.asp#b (Sep. 26, 2007) ("The IRO shall test a probe sample of 30 Transactions from each universe of Transactions Types for the selected quarter. If the IRO finds a net dollar error rate of 5% or more of the total sample size in any probe sample, BMS and the IRO shall hold an interim conference with the OIG to discuss the IRO's preliminary findings."); Aventis Inc. et al. CIA, available at http://oig.hhs.gov/fraud/cia/cia_list.asp#b (Aug. 29, 2007) ("The IRO shall test a probe sample of 30 Transactions from each universe of Transactions Types for the selected quarter. If the IRO finds a net dollar error rate of 5% or more of the total sample size in any probe sample, API and the IRO shall hold an interim conference with the OIG to discuss the IRO's preliminary findings.").

outset of the grant based on anticipated effort, before the work is performed, and then reviewed after a set period to verify the accuracy of the effort. If there is a "significant" change between the actual effort versus budgeted effort, an adjustment needs to be made.[5] There is no specific definition of "significant", but the NIH has adopted a general rule that a change of five percent or more of an employee's total effort would require an adjustment to the effort report (and accordingly, the amount chargeable to the grant).[6]

The Medicare program also applies a materiality standard with respect to the substitution of the average sales price (ASP) for purposes of setting Medicare reimbursement. Section 1847A(d)(3) of the Social Security Act permits the Secretary of HHS in setting reimbursement rates under Medicare Part B to disregard the ASP of a drug and substitute an alternative price as the basis for Part B reimbursement rates where an ASP exceeds the widely available market price (WAMP) or the AMP for the drug by an applicable threshold. Congress established an initial threshold of five percent through 2006, likely based on its own balancing of the savings generated by such price substitutions versus the burden imposed on both CMS and Medicare contractors by such substitutions. Although the Secretary has discretion under the statute to adjust the threshold for years after 2006, the Secretary has yet to do so.

These materiality criteria and standards make clear that the government itself, and HHS specifically, has recognized that the balancing of the dollars involved versus the burden of all parties is an appropriate consideration when determining refund obligations to the government. There is no reason why the same should not be true with respect to refund obligations to a covered entity. Based on the government's prior adoption of these factors, we believe the only question left for HRSA to consider is what the materiality standard should be. We believe our suggested thresholds are appropriate and reasonable, particularly given that HHS itself has adopted a higher 5% threshold in similar contexts.

3. HRSA Should Permit a Right of Offset

Where AMP and/or BP changes require changes to prior ceiling prices, we also urge HRSA to permit manufacturers to offset any overcharges due to retroactive decreases to ceiling prices by the amount of any undercharges made to the same covered entity that result from AMP and/or BP changes that cause ceiling prices to increase. The new statutory true-up requirement is intended to correct prior ceiling prices so that they accurately reflect any changes in the underlying pricing data. Those AMP and BP changes are as likely to move the ceiling price up as they are to move the price down. The new statutory language does not prohibit such upward adjustment to ceiling prices but rather specifies the need for "appropriate" credits and refunds. To ensure that ceiling price corrections fully reflect the actual underlying pricing data, we believe a fair approach would be to require manufacturers to true-up ceiling prices in both directions but allow manufacturers to offset upward adjustments in ceiling prices only up to the

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[5] OMB Circular A-21, Cost Principles for Educational Institutions.

[6] Joe Ellis, Acting Director of NIH's Office of Extramural Research Administration, Effort Reporting: Total Professional Activity vs. Institutional Activity (Enclosure A) (undated).

amount of any credit that otherwise is due to an entity for downward adjustments to ceiling prices. Specifically, these offsets would be on an entity-wide and quarterly basis, so that any refunds owed to an entity for any (material) ceiling price decreases in a past quarter would be offset by undercharges to that same covered entity for (material) ceiling price increases in that same quarter. *In this way, covered entities would never be obligated to make affirmative supplemental payments in relation to prior purchases; only the amount of any credit otherwise due would be decreased.*[7]

While we believe this offset approach is fair in its own right, we also believe that any OPA policy that prohibits manufacturers from offsetting refunds to covered entities in this manner would violate the provisions of the 340B statute and PPA, which both specifically permit but do not require manufacturers to offer sub-ceiling prices. We understand HRSA may view AMP/BP revisions that would cause a ceiling price to increase as converting a previous price set at the ceiling price level into a voluntary sub-ceiling price that therefore cannot be adjusted. This position ignores actual manufacturer intent and practice in setting the original price. A good faith ceiling price offered by a manufacturer is not transformed into a voluntary sub-ceiling price merely based on later, unintended, and legally mandated changes to AMP and/or BP. The 340B statute[8] and PPA[9] both make clear that manufacturers are permitted, but not required, to offer sub-ceiling prices. A policy that does not permit manufacturers to upwardly reconcile ceiling prices due to AMP/BP changes would, we believe, act as a de facto sub-ceiling mandate and a violation of the statute and agreement terms. We also believe manufacturers are entitled to such offsets based on principles of common law restitution.

We understand that HRSA may believe that refund offsets due to upward adjustments to ceiling prices may be unfair because the covered entity relied on the original, lower, ceiling price when making a purchase decision. The argument, as we understand it, is that if the covered entity had been aware that the ceiling price at which it originally purchased a particular drug would be upwardly adjusted, the covered entity instead would have purchased any equivalent product that was available at a price lower than the restated ceiling price. To the extent this argument may have merit, it would be valid only in following limited circumstances

1. The drug at issue would have to be a multiple source covered outpatient drug, because only multiple source drugs can be interchangeable such that price alone could be (although is not necessarily) the determining purchase criterion, *and*
2. The alternative multiple source drug would have to have been available at a price that is both higher than the original ceiling price of the product the covered entity did purchase, but still lower than the restated price, because only a product with a price between the

[7] Upward adjustments to ceiling prices should be subject to the same *de minimis* threshold applicable to downward adjustments to ceiling prices.
[8] 42 U.S.C. § 256b.
[9] 58 Fed. Reg. 27293 (May 7, 1993) (requiring manufacturers to enter into a pricing agreement); Department of Health and Human Services, Pharmaceutical Pricing Agreement (PPA) at 8 (Feb. 8, 2006).

original and restated ceiling prices price could be viewed as more attractive based on price alone.

Given the limited circumstances in which this concern could have any merit, it cannot provide a basis for barring offsets for all covered outpatient drugs in all circumstances. In the case of BIO member products specifically, which generally are biologics and therefore not multiple source drugs, this argument is simply not applicable at all.

To address those limited situations in which these concerns may be applicable, BIO believes it would be appropriate for HRSA to permit the covered entity to demonstrate to the manufacturer that there was another, alternative multiple source product available at the time of the original purchase that was priced less than the restated price but more than the initial price. It is appropriate to require the covered entity to raise this issue because only the covered entity will have access to the ceiling prices of the alternative multiple source drugs – manufacturers will not have access to ceiling price data from other manufacturers. For the same reason, we ask that HRSA review and validate such claims to confirm that an alternative drug was in fact available at the lower price. Where the covered entity is able to make such a showing, as verified by HRSA, the manufacturer would be required to modify its offset of any refund to the entity by recalculating the undercharge based on the difference between the new, higher ceiling price and the price of the alternative multiple source product (rather than the original ceiling price). For example, assume that a covered entity purchased a unit of a multiple source covered outpatient drug at a ceiling price of $1.00, and that this price subsequently was revised to $1.10 as a result of an AMP/BP restatement. If the covered entity is able to demonstrate that an alternative product was available at the time of the purchase at a price of $1.05, the manufacturer would be permitted to offset any refunds to the covered entity only by the amount of $0.05 per unit, rather than $0.10 per unit.

4. HRSA Should Establish a Standardized Process for Issuing Refunds

Finally, BIO strongly recommends that HRSA establish a standardized process for manufacturer issuance of refunds to covered entities that minimizes the administrative burden for manufacturers, covered entities, wholesalers, and HRSA itself. The standardization of this process is important because of the high volume of true-ups and refunds that are likely to occur due to the volume of products, covered entities, and manufacturers participating in the program. For example, manufacturers could be required to update the manufacturer's prices on the OPA website (as discussed above) to reflect revisions to ceiling prices. In this way, the OPA website could provide a centralized notification system through which covered entities could learn of price changes and the potential availability of refunds, particularly if the OPA ceiling price website includes a "flag" that indicates prices that have been updated. Such an indicator may be particularly useful in light of the fact that manufacturers are obligated to correct their AMP and BP figures within three years of when those figures originally were due, and some manufacturers may make corrections multiple times during that period.[10]

[10] See 42 C.F.R. §447.510(b).

We further recommend that HRSA define the refund process to be one in which the manufacturers are responsible for calculating refund amounts due and issuing those refunds to covered entities via designated contact, such as through the issuance of credits to a specified wholesaler. Where the credit is not taken by the covered entity within one year of being issued and after reasonable follow-up by the manufacturer, including seeking HRSA's assistance as needed, we recommend that the manufacturer be permitted to cancel the credit. The manufacturer would be required to maintain documentation regarding the calculation of the refund due, which would have to be made available to the covered entity upon request, but would not otherwise be required to be affirmatively issued to the covered entity. The covered entity identification system that the Secretary is required to develop, as discussed further below, should include the identification of either the entity's designated wholesaler to which refund credits should be issued on the entity's behalf (preferably the wholesaler through which the entity purchased the product), or other contact for receipt of refunds. The covered entity would be responsible for keeping this information current as well as following up with the manufacturer, as needed, with questions regarding such credits. Finally, manufacturers should be given at least 90 days after the revision of any AMP/BP figures to calculate the resulting price changes and credits due before being obligated to update the prior pricing data, to provide sufficient time to ensure that the revised pricing and credits are accurate. Manufacturers should be permitted to seek an extension to this 90-day time period in extraordinary circumstances, such as where a particularly high volume of price changes, drugs, or covered entities are involved. We also recommend that HRSA's dispute resolution procedures, as discussed further in Section IV, specifically address disputes regarding these issues.

Historically, the 340B program has sought to share the administrative burdens of the program between the manufacturer and the covered entity and so the recommended process above does so as well. For example, for new covered outpatient drugs for which AMP and BP data are not yet available, the manufacturer must estimate the ceiling price in accordance with OPA guidance because there are no historic AMP or URA data with which to calculate the ceiling price.[11] The manufacturer must provide a refund *as requested by a covered entity* where the estimated ceiling price exceeds the actual ceiling price for that same quarter. As OPA explained in its Final Notice, the mechanism for retroactive pricing adjustment reflects "an attempt 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."[12] Consistent with this historic approach, BIO believes setting forth the streamlined, cooperative process for issuing credits described above will ensure that covered entities receive accurate refunds in the most rapid and efficient manner while also limiting the administrative burden on all parties involved.

[11] 60 Fed. Reg. 51488 (Oct. 2, 1995).
[12] Id.

We understand that the 340B Program's prime vendor may be particularly and uniquely suited to play a role in the development and administration of this process. While BIO welcomes the prime vendor's valuable input on these issues, and certainly believes the prime vendor should be a member of any workgroup, as proposed below, created to discuss implementation processes, BIO also believes it will continue to be important to give all parties – manufacturers and covered entities – the choice as to whether to partner with the prime vendor on these operational matters. As is currently the case in the 340B program, we believe HRSA should continue to encourage but not require program participants to work with the prime vendor as to any aspect of the 340B Program.

Finally, given the highly operational nature of the issues related to establishing a single standardized process for issuing refunds to covered entities in the event of a ceiling price change, BIO recommends that HRSA create a working group of stakeholders that includes covered entities, manufacturers, and wholesalers to collaborate on the implementation of this process and any related operational concerns that may arise. Only through such a group is HRSA sure to fully identify and consider the multitude of operational issues that will play a role in implementing this new statutory requirement.

C. Verification of Covered Entity Eligibility and Implementation of a Standard Identifier

Section 7102 obligates the Secretary to develop a procedure to enable and require covered entities to regularly update their eligibility information and for HRSA to verify the accuracy of that information. In validating covered entity eligibility, HRSA should not permit those entities that no longer meet the statutory definition of a covered entity to continue receiving discounts under the 340B program while they work towards eligibility during that period. The 340B statute expressly limits the manufacturer's obligation to provide the ceiling price to covered entities as defined by the statute and does not permit a "grace period" for those non-eligible entities seeking to re-qualify. BIO also requests that HRSA address whether its system for verifying covered entity eligibility will include auditing or spot-checks of the registration information provided by the covered entity to ensure that such information is accurate.

PPACA also requires the Secretary to establish "a single, universal, and standardized identification system by which each covered entity site can be identified" for purposes of facilitating ordering, purchasing and delivery of covered outpatient drugs as well as the processing of chargebacks. BIO recommends that HRSA use Health Industry Numbers (HINs) for this purpose, because these universal identification numbers are already used by many end-customers, wholesalers and manufacturers alike, including for identifying end-customers in chargeback-based sales. HRSA should continue to assign and use the 340B ID number as well for back-up identification, because not all entities have a HIN. If both identification numbers are listed for each covered entity on the OPA database, manufacturers will be better able to identify and validate covered entity eligibility for ceiling prices and ensure those discounts are provided

as appropriate. We ask that HRSA require that covered entities submit both identifiers to the wholesaler at all times.

IV. Administrative Dispute Resolution Regulations and Process for Imposition of Sanctions

PPACA requires the Secretary to promulgate regulations to establish and implement an administrative process for resolution of claims by covered entities and manufacturers, within 180 days of enactment. The Secretary also must establish a process for determining non-compliance by manufacturers and covered entities and for imposition of sanctions. In implementing these requirements, BIO urges HRSA to include in its proposed rule and process the following elements, to best protect the interests of all parties:

- The evidentiary standard (e.g., a preponderance of the evidence);
- Right to discovery and discovery procedures;
- Available remedies, if any, beyond those specified by the statute; and
- Confidentiality of the proceedings and the resolution.

V. Audits of Manufacturers and Wholesalers

Section 7102 of PPACA requires the Secretary to provide for "[s]elective auditing of manufactures and wholesalers." BIO requests that to the extent HRSA permits covered entities to conduct such audits, it apply the same standards that currently apply to audits by manufacturers under HRSA's existing audit guidelines.[13] These safeguards, including submission of an audit work plan documenting reasonable cause for the audit and retention of an independent auditor, will help to minimize the risk of disclosure of the manufacturer's confidential information as well as reduce the administrative burden on manufacturers.

VI. Audits of Covered Entities

The 340B statute permits the Secretary or a manufacturer to audit the records of the covered entity directly pertaining to the entity's compliance with the statute with respect to the manufacturer's covered outpatient drugs.[14] BIO requests that HRSA address whether the HHS Office of the Inspector General (OIG) will regularly audit participating covered entities for compliance with the requirements for eligibility and participation under the 340B program, as well as whether the OIG will audit a particular covered entity within a reasonable timeframe of a manufacturer's request. BIO believes that the OIG is best suited for such reviews because of its audit expertise and believes any such reviews should focus on covered entity eligibility, diversion, and duplicate discount compliance.

VII. Exemption for Drugs Designated as Orphan Drugs

[13] 61 Fed. Reg. 65406 (Dec. 12, 1996).
[14] 42 U.S.C. § 256b(a)(5)(C).

BIO understands that certain covered entities that previously were enrolled in the 340B program as disproportionate share hospitals may seek to re-enroll in the program as one of the new covered entity hospital types added by PPACA. We request that HRSA confirm our understanding that the exception to the ceiling price obligation for drugs that are designated as orphan drugs applies effective with the covered entity's change in designation, such that the manufacturer is no longer obligated to offer that drug at the 340B ceiling price to the covered entity.

Similarly, we ask that HRSA confirm that where a covered entity meets the requirements for more than one type of covered entity under 42 USC 256b(a)(4), the applicability of the exception for orphan drugs is determined based on the "Entity Type" of the covered entity that is making the purchase, as set forth in HRSA's covered entity database. For example, a manufacturer would not be obligated to offer the ceiling price on an orphan drug to a covered entity that is identified in HRSA's database as a children's hospital, regardless of whether that hospital may also qualify as an eligible hemophilia treatment center under the 340B statute.

Finally, we also ask HRSA to confirm that the orphan drug exception does not apply to purchases made by children's hospitals during the period prior to enactment of HCERA. Section 2302 of HCERA, which created the orphan drug exception, amended the 340B statute itself (as amended by PPACA). While certain of PPACA's amendments to the 340B statute have a stated effective date of January 1, 2010, this provision in HCERA has no stated effective date and so we believe the orphan drug exception is effective only as of HCERA's enactment. We ask HRSA to confirm that interpretation.

VIII. Enforcement of Prohibitions on Duplicate Discounts and Diversion

PPACA and HCERA expanded the Medicaid rebate program to Medicaid managed care organization (MCO) utilization, but simultaneously exempted from Medicaid rebates those covered outpatient drugs subject to discount under the 340B program. This exclusion is consistent with the existing prohibition on duplicate discounts on Medicaid fee-for-service utilization. BIO urges HRSA to implement standards that will provide Medicaid MCOs and state Medicaid programs with the information necessary to exclude such utilization from their rebate claims to manufacturers. Although HRSA has defined such standards with respect to Medicaid fee-for-service utilization, state Medicaid agencies have not always been diligent in ensuring that such 340B utilization is excluded from their rebate claims. Adopting an effective policy for enforcing the duplicate discount prohibition will only become more important as the number of Medicaid enrollees increases under the various other provisions of PPACA and HCERA. BIO urges HRSA to implement a policy to more stringently enforce this provision, including a mechanism for manufacturers to seek enforcement where needed, either on their own or through the Secretary.

BIO also asks that HRSA address the issue of diversion of drugs purchased at the 340B discount to individuals who are not patients of the covered entity, including any controls that

HRSA is developing to ensure compliance with the existing prohibition on such diversion. In connection with this effort, we urge HRSA to finalize its January 2007 Notice regarding the definition of a "patient" for purposes of the 340B program.[15] As HRSA stated in that Notice, it is possible that some covered entities may have interpreted the current definition of a "patient" too broadly, resulting in the potential for diversion of 340B-priced drugs.[16] BIO believes providing covered entities with the explicit guidance set forth in the January 2007 notice regarding the necessary relationship between the covered entity and the individual patient is critical to reducing the risk of diversion of drugs purchased under the 340B program.

In particular, the January 2007 notice reiterates guidance issued by HRSA more than ten years ago making clear that employees of a covered entity must meet the definition of patient in order to be considered "patients" of the covered entity:

> *Comment*: Employees of covered entities should be either specifically precluded or included as eligible patients to receive discounted drug products.
>
> *Response*: Any employee of a covered entity who meets the criteria of the definition of covered entity "patient" would be eligible to access 340B pricing.[17]

To the extent that covered entities have been extending 340B pricing to their non-patient employees, they have been doing so contrary to this long-standing, public declaration by HRSA that employees are not patients of the covered entity unless they meet the three prongs of the patient definition test. The January 2007 Notice explicitly incorporates this pre-existing standard and puts to rest the apparent misconception by covered entities that their employees can qualify as patients either by virtue of being employed by the covered entity or under some lesser standard than that required for non-employees.[18] BIO strongly supports finalizing this clarification in order to protect the integrity of the 340B program.

Finally, BIO believes that it is particularly important that HRSA address the procedures and controls it will use to limit diversion and duplicate discounts now as covered entities implement multiple contract pharmacy arrangements pursuant to HRSA's March 2010 Final Notice.[19] The participation of additional contract pharmacies may increase the risk that 340B-priced drugs are diverted to individuals who are not patients of the covered entity and that Medicaid rebates are sought on 340B discounted drugs. BIO urges HRSA to address these considerations as it continues to implement measures to enforce the statutory prohibitions on duplicate discounts and diversion.

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[15] 72 Fed. Reg. 1543 (Jan. 12, 2007).
[16] Id. at 1544.
[17] See 61 Fed. Reg. 55156, 55157 (Oct. 24, 1996).
[18] See 72 Fed. Reg. at 1546.
[19] 75 Fed. Reg. 10272 (March 5, 2010).

IX. Applicability of Changes to Medicaid Rebate Formula

PPACA implemented a number of changes to the Medicaid rebate formula, effective for rebate periods beginning January 1, 2010, including an increase in the Medicaid base rebate, a change in the rebate calculation for a line extension of a single source or innovator multiple source drug that is an oral solid dosage form, and a cap on the total unit rebate amount for all single source and innovator multiple source drugs equal to 100% of the AMP. BIO requests that HRSA confirm that these changes to the Medicaid rebate formula do not impact the calculation of the 340B ceiling price until the third quarter 2010. This is consistent with long-standing HRSA guidance directing that manufacturers may calculate the ceiling price using Medicaid data for a period that is two quarters prior to the effective quarter of the ceiling price.[20] As HRSA has not issued any change to this guidance, we ask that HRSA confirm our understanding that the Medicaid rebate amounts calculated under the revised rebate formula must be reflected in the ceiling price calculation beginning with the third quarter 2010.

X. Conclusion

BIO looks forward to working with HRSA over the coming months and years to implement PPACA and HCERA. We hope that the agency finds this letter to be a helpful tool as it begins the process. Please feel free to contact Laurel Todd at (202) 962-9220 if you have any questions regarding any of the issues raised herein. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

Laurel Todd
Managing Director, Reimbursement and Health Policy

[20] See HRSA, Dear Manufacturer and Wholesaler Letter (Aug. 17, 1993); see also HRSA, Letter to Joel Bobula from Marsha Alvarez (Feb. 25, 1993); HRSA, Dear Manufacturer Letter (Apr. 15, 1993); HRSA, Dear Manufacturer and Wholesaler Letter (Feb. 1, 1995).

Biotechnology Industry Organization

August 17, 2015

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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).

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)).

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).

(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

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.

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).

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.

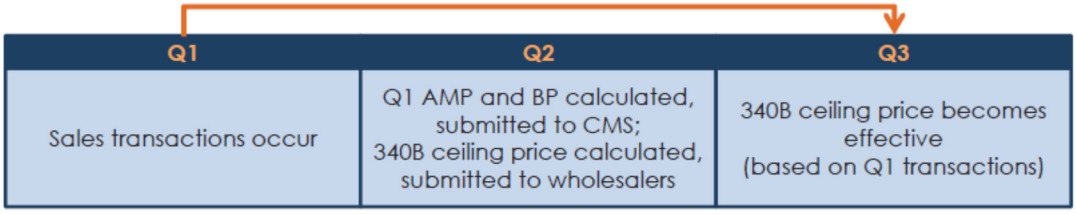
First, in the Proposed Rule, HRSA proposes to define the term "340B Drug" as "a covered outpatient drug, as defined in section 1927(k) of the Social Security Act, purchased by a covered entity at or below the ceiling price required pursuant to a pharmaceutical pricing agreement with the Secretary."[19] 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.

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 celling 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).

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 SSA[33]—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).

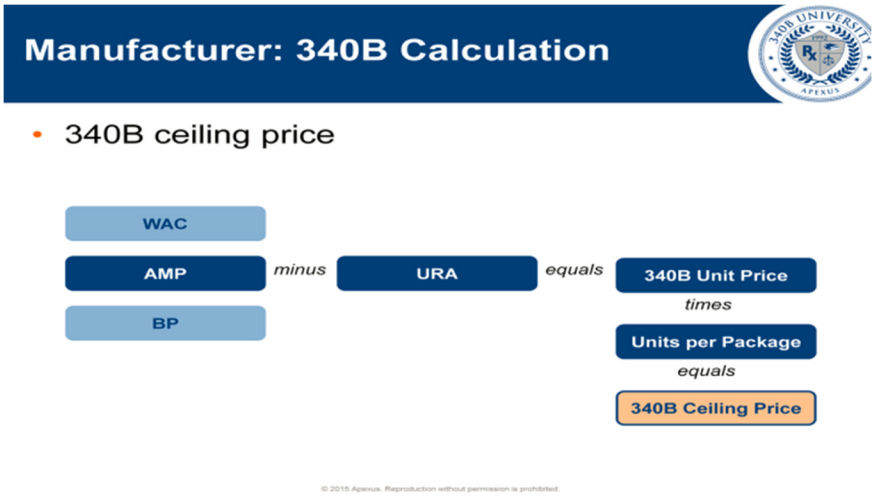
requirements also apply to any pricing data that HRSA obtains from CMS.[38] In line with prior BIO comments to the Agency, we urge HRSA to detail its plans for safeguarding this highly sensitive and proprietary pricing data and for ensuring that any confidential disclosures of ceiling prices conform 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).



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]

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[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

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 opiods, "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).

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 Envt'l 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.

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.

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.

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[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).

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).

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:

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[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).

- 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.

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.

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.

- 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 form 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).

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).

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).

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]

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[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).

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).

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.

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).

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.

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.

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/

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Re: Agency Information Collection Activities: Proposed Collection: Comment Request: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program and Collection of Manufacturer Data to Verify 340B Drug Pricing Program Price Calculations (OMB No. 0915-0327-[Revision])

Dear Commander Pedley:

The Biotechnology Industry Organization (BIO) is pleased to submit the following comments in response to the Health Resources and Services Administration's (HRSA's) proposed Information Collection Notice entitled "Proposed Collection: Comment Request: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program and Collection of Manufacturer Data to Verify 340B Drug Pricing Program Price Calculations"[1] (the "Notice"). BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States and around the globe. BIO members are involved in the research and development of healthcare, agricultural, industrial, and environmental biotechnology products.

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 also agree with HRSA that covered entities should have "confidence that the amounts being charged are in accordance with statutorily-defined ceiling prices."[2] We are concerned, however, that the proposed information collection request is both unnecessary and potentially unduly burdensome for manufacturers.

The following comments address three of the topics on which HRSA has solicited feedback, including: (1) the necessity and utility of the proposed information collection for the proper performance of HRSA's functions; (2) the accuracy of the estimated burden; and (3) use of

[1] 79 Fed. Reg. 58,791 (Sept. 30, 2014).
[2] Id. at 58,792.

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automated collection techniques or other forms of information technology to minimize the information collection burden. We begin, however, with our concerns with HRSA's apparent belief that amendments to the applicable statutes and regulations are incorporated into the Pharmaceutical Pricing Agreement (PPA) without need to amend that agreement, and conclude with a request that the agency provide appropriate context and security protections with respect to the proposed Internet platform for posting validated ceiling prices.

I. The ACA's "Must Offer" Requirement Is Not Self-Implementing.

Section 340B(a)(1) of the Public Health Service Act (PHS Act) requires the Secretary of Health and Human Services (HHS) to enter into an agreement (i.e., the Pharmaceutical Pricing Agreement [PPA]) with manufacturers, under which the amount to be paid by 340B covered entities for the manufacturer's covered outpatient drugs may not exceed the statutory "ceiling price." Section 7102 of the Patient Protection and Affordable Care Act (ACA) added two new requirements to this section, including that the PPA require that "the manufacturer offer each covered entity covered drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."

In an apparent reference to the ACA's amendment of the 340B statute to require the PPA to include this new "must offer" language, the Notice states that "[b]y signing the PPA, the manufacturer agrees to comply with all applicable statutory and regulatory requirements, including any changes that occur after execution of the PPA."[3] This statement ignores, however, that the PPA must be amended, or a new PPA must be issued, in order for the "must offer" language to be binding on 340B-participating manufacturers.

The PPA notably lacks a provision requiring parties to comply with all applicable laws, let alone any amendments thereto.[4] Moreover, the PPA also expressly requires that any substantive amendments to the agreement be made "in writing" and "signed by both parties."[5] Thus, while the "PPAs simply incorporate statutory and obligations and record the manufacturers' agreement to abide by them,"[6] in the absence of a contract clause that expressly authorizes HRSA to revise, add, or delete a clause without a manufacturer's consent—as is the case here—any attempt by the Agency to bind a manufacturer to a unilateral clause change—even one required by federal law—would be a breach of contract.[7] Accordingly, HRSA must issue a new PPA agreement or amendment in order for this "must offer" language to be operative.

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[3] Id. (emphasis added).

[4] See generally Pharmaceutical Pricing Agreement. This can be contrasted with a term in the Medicaid Drug Rebate Agreement, which requires manufacturers "[t]o comply with the conditions of 42 U.S.C. section 1396s, changes thereto and implementing regulations as the Secretary deems necessary and specifies by actual prior notice to the manufacturer." Rebate Agreement Between the Secretary of Health and Human Services and Manufacturer, Enclosure A § II(c).

[5] Pharmaceutical Pricing Agreement § VII(c)(e) ("[e]xcept for changes of addresses, the Agreement will not be altered except by an amendment in writing signed by both parties. No person is authorized to alter or vary the terms unless the alteration appears by way of a written amendment, signed by duly appointed representatives of the Secretary and the Manufacturer.").

[6] Astra USA, Inc., et al. v. Santa Clara County, 131 S. Ct. 1342, 1348 (March 29, 2011).

[7] See Mobile Oil Exploration & Producing Southeast, Inc. v. United States, 530 U.S. 604, 616 (2000). See also United States v. Winstar Corp., 518 U.S. 839 (1996) ("[t]he Court has often said, as a general matter, that the 'rights and duties' contained in a government contract 'are governed generally by the law applicable to contracts between private individuals.'") (citing Lynch v. United States, 292 U.S. 517, 579 (1934); Perry v. United States, 294 U.S. 330 (1935); Sinking Fund Cases, 99 U.S. 700 (1879) ("The United States are as much bound by their contracts as are individuals. . . . "); United States v. Klein, 80 U.S. 128 (1872) (same)).

II. The Proposed Information Collection Is Not Necessary for the Proper Performance of HRSA's Functions and Is Inconsistent with the PRA's Prohibition on Duplicative Reporting Obligations.

In the notice, HRSA cites the new requirement that the Secretary develop a system to verify HRSA-calculated 340B ceiling prices based on data maintained by the Centers for Medicare & Medicaid Services (CMS) by comparing such ceiling prices to the quarterly data submitted by manufacturers to the Medicaid Drug Rebate Program (MDRP).[8] However, rather than rely on the data already reported to and maintained by CMS, the notice proposes to require participating manufacturers to report all of the following quarterly pricing data to HRSA for each covered outpatient drug:

- Average Manufacturer Price (AMP);
- Unit Rebate Amount (URA);
- Package Sizes;
- National Drug Code (NDC); and
- Manufacturer calculated ceiling price.

We are concerned that this proposed information collection is neither necessary nor permitted. As an initial matter, we note that the statutory requirement to verify ceiling prices does not necessarily require that HRSA obtain all of its quarterly pricing data directly from manufacturers. Instead, the statute requires "the Secretary to verify the accuracy of ceiling prices calculated by manufacturers" by, among other things, "[c]omparing regularly the ceiling prices calculated by the Secretary with the quarterly reporting data that is reported by manufacturers to the Secretary."[9] In all three instances, the term "Secretary" refers to the Secretary of HHS—the Department that includes both HRSA and CMS. This is relevant because manufacturers are already required to report AMP, package size, and NDC on a quarterly basis to the Secretary (i.e., CMS) pursuant to the MDRP statute.[10] It is not likely that Congress intended for manufacturers to report this same pricing data twice to the same individual (the "Secretary").

In short, reading the 340B and Medicaid statutes together, it appears that Congress intended that HRSA would verify the accuracy of manufacturer-calculated ceiling prices, at least in part, by comparing the HRSA-calculated ceiling prices with the quarterly pricing data that is reported by manufacturers to CMS. Furthermore, we note that an alternative interpretation (i.e., that manufacturers must report AMP, package size, and NDC to HHS twice) would be inconsistent with the federal Paperwork Reduction Act (PRA). The PRA was enacted in order to reduce the total amount of paperwork burden the federal government imposes on private businesses and citizens, including through the coordination and integration of federal information resources management policies and practices.[11] To these ends, the PRA expressly

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[8] Id.
[9] PHS Act § 340B(d)(1)(B)(i)(II) (emphasis added).
[10] Social Security Act (SSA) § 1927(b)(3). See also CMS, Medicaid Drug Rebate Program Data, http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program-Data.html.
[11] Paperwork Reduction Act of 1980, Pub. L. No. 96-511, 94 Stat. 2812 (codified at 44 U.S.C. § 3501(1), (3)). The term "information resources management" is defined as "the process of managing information resources to

requires the director of each federal agency to "certify . . . that each collection of information submitted to the Director [of the Office of Management and Budget [OMB]] for review . . . is not unnecessarily duplicative of information otherwise reasonably accessible to the agency."[12] This requirement does not appear to be met by aspects of HRSA's proposed information collection, particularly given that HRSA recognizes in the Notice that the Agency already has access to CMS's pricing data.[13]

On the other hand, we believe that HRSA could permissibly require manufacturers to report those data points that manufacturers do not report to CMS—namely the ceiling price and URA—without running afoul of Congressional intent or the PRA. Indeed, given that the manufacturer-calculated URA is considered the official URA for purposes of the MDRP, we strongly urge HRSA to rely on this URA—rather than the unofficial URA calculated by CMS—for purposes of verifying manufacturer-calculated ceiling prices under the Agency's statutory mandate.[14] Moreover, there are instances in which CMS's calculation of the URA can be different from manufacturers' (e.g., when manufacturers restate their reported AMP for a specific time period), or when CMS does not calculate a URA at all,[15] further supporting the need for HRSA to rely on manufacturer-reported URAs for this purpose.

In light of the foregoing, we urge HRSA to rely on those pricing data reported to and maintained by CMS (to which HRSA already has access), and instead require that manufacturers report only manufacturer-calculated ceiling prices, URAs, and—in order to identify the drug in question—NDCs to HRSA for purposes of verifying ceiling prices.[16] We also urge HRSA to clearly articulate whether the obligation to report these data points (ceiling price, URA, and NDC) would be optional or mandatory, as well as to outline its proposed processes for reconciling any differences in the ceiling price HRSA derives against that submitted by manufacturers, as neither is currently specified in the Notice.

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accomplish agency missions and to improve agency performance, including through the reduction of information collection burdens on the public." 44 U.S.C. § 3502(7).

[12] 44 C.F.R. § 3506(c)(5). See also 5 C.F.R. § 1320.9(b) (same); 5 C.F.R. § 1320.5(d)(1)(ii) ("[t]o obtain OMB approval of a collection of information, an agency shall demonstrate that it has taken every reasonable step to ensure that the proposed collection of information: . . . [i]s not duplicative of information otherwise accessible to the agency . . . .")

[13] See 79 Fed. Reg. at 58,792 ("HRSA has already developed a system to prospectively calculate 340B ceiling prices from data obtained from [CMS] as well as OPA-identified commercial databases."). Indeed, the PPA requires manufacturers "to permit CMS to share AMP and unit rebate amount submitted under the Medicaid Rebate on covered outpatient drugs with the Secretary or his designee for purposes of carrying out the Agreement . . . ." Pharmaceutical Pricing Agreement § II(f).

[14] CMS uses the quarterly pricing data submitted by manufacturers (i.e., AMP and Best Price) to calculate an unofficial URA, which is submitted as a courtesy to the states. However, manufacturers are ultimately responsible for calculating the official URA. Notably, this official URA is transmitted to the states with the ROSI and payment, but not to CMS. CMS, Unit Rebate Calculation, http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program.html. See also HHS-OIG, Medicaid Drug Rebate Dispute Resolution Could Be Improved, OEI-05-11-00580 (August 2014).

[15] See Medicaid Drug Rebate Data Guide for Labelers at 15 (Last Revised April 25, 2011) ("When labelers do not submit timely or complete pricing data, or their pricing data results in zero URAs, it is the labeler's responsibility to manually calculate the URA and send a rebate payment along with the ROSI.").

[16] We note that manufacturers will likely need to provide package size and, in some instances, the NDC together with ceiling price and URA data reports. We urge HRSA to use the same format used in the MDRP's DDR for reporting these data.

III. The Estimated Burden is Well Below the Time It Would Take Manufacturers to Complete, Review, and Transmit the Requested Data, Let Alone Implement Systems Necessary to Comply with the New Reporting Obligation.

According to the Notice, HRSA has estimated that it would take each manufacturer 30 minutes per quarter to report all of the requested pricing information to HRSA.[17] We do not believe that this is an accurate estimate of the proposed reporting burden. As HRSA outlines in the Notice, under the PRA, the term "burden" is defined as:[18]

> the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency, including: (i) Reviewing instructions; (ii) Developing, acquiring, installing, and utilizing technology and systems for the purpose of collecting, validating, and verifying information;(iii) Developing, acquiring, installing, and utilizing technology and systems for the purpose of processing and maintaining information; (iv) Developing, acquiring, installing, and utilizing technology and systems for the purpose of disclosing and providing information;(v) Adjusting the existing ways to comply with any previously applicable instructions and requirements;(vi) Training personnel to be able to respond to a collection of information;(vii) Searching data sources;(viii) Completing and reviewing the collection of information; and (ix) Transmitting, or otherwise disclosing the information.

We believe that 30 minutes would be sufficient to accomplish only one of these tasks: the actual transmission of the requested information. And even then, it is difficult to confirm the accuracy of that estimate without knowing the process HRSA proposes to require for such data submission (e.g., will it be through a web interface, like the Drug Data Reporting [DDR] system used by CMS for purposes of the MDRP? On a disk? Paper? Other?). In sum, we disagree that "[t]he burden imposed on manufacturers . . . is low because the information requested is readily available[,]"[19] given that: (1) it is not clear that the data submission requirements used by HRSA will be the same as those used by CMS; and (2) manufacturers will need to review HRSA's reporting instructions, update their technology systems, adjust their compliance policies and procedures, train personnel, and take other steps to comply with the new reporting obligation—actions that are clearly not contemplated in the burden estimate outlined in the Notice.

IV. The Burden of Reporting the Requested Information Would Be Lower to the Extent HRSA Utilized the Same Format and Specified Timing After the Quarterly Price Submission Process Used by CMS.

As noted previously, it is not clear that the reporting requirements imposed by HRSA will be the same as those used by CMS for purposes of the MDRP. To the extent that HRSA uses different data submission requirements, the burden on manufacturers would obviously be higher, given that manufacturers would need to re-format (or, potentially, manually re-enter)

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[17] Id. at 58,793.
[18] 5 C.F.R. § 1320.3(b)(1). See also 44 U.S.C. § 3502(2).
[19] 79 Fed. Reg. at 58,792.

the requested data. Accordingly, to the extent that HRSA moves forward with the proposed information collection, we urge the Agency to use the same file format and utility as what is already being used by manufacturers to upload pricing data into the CMS's DDR system in order to minimize the burden of reporting the requested pricing data to HRSA.

Relatedly, while the Notice does not address when the requested data would be due to HRSA, the burden on manufacturers would be much lower to the extent the data were due sometime after the quarterly submission deadline for pricing data to CMS, so that the new submission burden does not compound the already stressful quarterly submission process. We note that there are 60 days between when the quarterly numbers are calculated and when those numbers go into effect as the 340B price. To ensure that HRSA will have plenty of time to collate and verify these data, while staggering price reporting timelines sufficiently to mitigate the burden of any new reporting obligations on manufacturers, BIO therefore requests that the submission deadline be 45 days after the quarterly submission deadline to CMS. Any additional requirements related to the data reporting obligation should occur on this same schedule to further minimize the burden on manufacturers.

V. HRSA Must Ensure that Its Proposed Internet Platform Provides Appropriate Context And Assures the Security and Protection of Privileged Pricing Data from Unauthorized Disclosure.

The Notice states that HRSA intends to post validated ceiling prices on a secure Internet-accessible platform made available to registered covered entities.[20] This proposal aligns with section 340B(d)(1)(B)(iii), which requires HRSA to provide "access through the Internet website of [HHS] to the applicable ceiling prices for covered outpatient drugs as calculated and verified by the Secretary in accordance with [section 340B]." We urge HRSA to ensure that this information is provided with appropriate context, and that the Agency ensures the security and protection of privileged pricing data from unauthorized disclosure in accordance with the 340B statute.

As to the context, BIO urges HRSA to be clear to communicate to covered entities that the verified ceiling prices on the Internet platform do not include wholesaler mark-ups or sub-ceiling prices so that covered entities do not mistakenly believe they are being charged the wrong price. We are concerned that, without clarification regarding wholesaler mark-ups, covered entities may complain that manufacturers are not charging the ceiling price, when the discrepancy is due to mark-ups charged by wholesalers. Covered entities should similarly be made aware that the verified ceiling prices do not include sub-ceiling prices, as we strongly urge HRSA to refrain from posting sub-ceiling prices on the proposed Internet platform.[21] For commercial and other reasons, manufacturers do not always uniformly offer sub-ceiling prices, or the same sub-ceiling prices, across all of their covered entity customers. Making manufacturer sub-ceiling prices available to all covered entities could potentially have a chilling effect on manufacturer willingness to extend such discounts to some or all covered

[20] 79 Fed. Reg. at 58,792.
[21] In issuing guidance regarding the reporting of ceiling prices under 340B(a)(1), HRSA may nonetheless want to consider adding a field for manufacturers to indicate if additional voluntary (i.e., sub-ceiling) discounts were offered, indicating that the 340B price will be lower than the statutory calculation due to additional discounts offered by the manufacturer for HRSA's own internal purposes.

entities. Providing appropriate context surrounding what the posted prices do and do not represent will eliminate the need for HRSA to respond to these complaints, and may reduce the potential for disputes.

In terms of the security and protection of the information to be posted online, we note that 340B(d)(1)(B)(iii) expressly requires HRSA to post ceiling price information on its website "in a manner (such as through the use of password protection) that limits such access to covered entities and adequately assures security and protection of privileged pricing data from unauthorized re-disclosure." We urge HRSA to ensure the security and protection of pricing data in accordance with this provision. First, and most importantly, the platform should include only the HRSA-verified ceiling price and should not provide information on AMP. As HRSA is likely aware, AMP data are confidential and protected by statute.[22] Accordingly, while these data can permissibly be shared between federal agencies, they should not be released to covered entities or other third parties. To the extent that HRSA wishes to include information regarding AMP on the Internet, we urge the Agency to follow CMS's lead and indicate only whether a manufacturer did or did not report AMP, without providing the reported amount.[23] Second, HRSA should specify that the proposed Internet platform will be password protected or otherwise limited to covered entities. We note that such data should not be made available to contract pharmacies, given that 340B sales are made directly to the covered entities and contract pharmacies are not specifically identified in section 340B(d)(1)(B)(iii) (or anywhere in the 340B statute).[24] Third, HRSA should ensure that the data posted on the website is protected from unauthorized disclosure by covered entities to other third parties. These pricing data are related only to Medicaid and PHS buyers and is not relevant nor supposed to be accessible to commercial buyers or others. To these ends, we also urge HRSA to consider making the data view only (as opposed to printable), to make it more difficult for them to share the data with others. Fourth, we urge HRSA to lay out the penalties that will result to the extent a covered entity violates this confidentiality requirement.

Equally importantly, the proposed password-protected Internet platform can only be used to disclose those ceiling prices "calculated and verified by the Secretary,"[25] and to verify such ceiling prices, the 340B statute requires HRSA to first develop and publish a "policy or regulatory issuance [with] precisely defined standards and methodology for the calculation of ceiling prices . . . ."[26] The Department of Health and Human Services Office of Inspector General (OIG) has previously emphasized the risks of error associated with calculating ceiling

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[22] SSA § 1927(b)(3)(D) ("Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under [the Medicaid Drug Rebate statute] . . . is confidential and shall not be disclosed by the Secretary . . . or a State agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler, except" under limited circumstances described in the statute.).

[23] See CMS, Medicaid Drug Rebate Program Data: Quarterly Average Manufacturer Price (AMP) Data for Drugs in the Medicaid Drug Rebate Program: Reported or Not Reported, http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program-Data.html.

[24] Per HRSA guidance, covered entities with contract pharmacies must: (1) purchase the drug; (2) maintain title to the drug; and (3) assume responsibility for setting its price. 75 Fed. Reg. 10,272, 10,277 (March 5, 2010).

[25] PHS Act 340B(d)(1)(B)(iii) (emphasis added).

[26] PHS Act 340B(d)(1)(B)(i)(I).

prices without the benefit of detailed written guidance,[27] and we believe that this is an important lesson that must be taken into account in connection with the proposed Internet platform. Only ceiling prices that have been calculated and verified pursuant to a policy or regulatory issuance that spells out precisely the defined standards and methodology to be used for such calculations can provide the level of reliability the law requires of ceiling price data released via this platform.

Finally, we urge HRSA to articulate how many quarters of verified ceiling prices will be available through the platform at a given time, as well as to specify when new quarterly prices would be posted. As to this last point, BIO urges HRSA to ensure that verified ceiling prices are not posted before the first day of a given quarter to avoid the potential that covered entities may time purchases between periods. We note that industry practice is to provide no advance notice of price changes to those entities subject to such prices (e.g., no notice is provided to wholesalers regarding upcoming changes in wholesale acquisition cost [WAC]), and nothing in the 340B statute indicates that manufacturers or HRSA must alter this practice in order to provide covered entities with advanced access to the ceiling price. Rather, the relevant provision merely requires that covered entities have access to ceiling prices to verify the price received.[28] Moreover, providing covered entities with advance notice of ceiling prices would lead to gaming by covered entities (i.e., buy-ins if the next quarter's price is higher or purchase delays if the next quarter's price is lower), resulting in market fluctuations—a result that is clearly not desirable from a market perspective, nor expected by Congress in enacting this provision.

VI. Conclusion

BIO thanks HRSA for this opportunity to comment on the proposed information collection. As noted previously, we are concerned that the proposed information collection request is both unnecessary and unduly burdensome for manufacturers. To the extent that HRSA nonetheless moves forward with its proposal, we urge HRSA to take into account BIO's recommendations to lessen the burden imposed on manufacturers. We also urge HRSA to ensure that the information posted by HRSA is adequately protected and provided with appropriate context. We look forward to continuing to work with the Agency to improve 340B program integrity in a manner that imposes the least burden on program participants. Please contact me at (202)-962-9200 if you have any questions regarding our comments. Thank you for your attention to this important matter and for your consideration of BIO's views.

Respectfully submitted,

/s/

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[27] HHS-OIG, Deficiencies in the Oversight of the 340B Drug Pricing Program, OEI-05-02-00072 at 12 (Oct. 2005) ("lack of detailed procedures for calculating the 340B ceiling price results in unreliable data with which to oversee the 340B Program and could lead to inappropriate enforcement actions.").

[28] See PHS Act § 340B(d)(1)(B)(iii) (requiring the Secretary to provide "access through the Internet website of the Department of Health and Human Services to the applicable ceiling prices for covered outpatient drugs as calculated and verified by the Secretary in accordance with this section, in a manner (such as through the use of password protection) that limits such access to covered entities and adequately assures security and protection of privileged pricing data from unauthorized re-disclosure.").

Laurel L. Todd
Managing Director
Reimbursement & Health Policy

Biotechnology Industry Organization

May 21, 2015

The Honorable Howard A. Shelanski
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

BY ELECTRONIC SUBMISSION

Re: Information Collection Request: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program and Collection of Manufacturer Data to Verify 340B Drug Pricing Program Ceiling Price Calculations [OMB No. 0915-0327—Revision]

Dear Administrator Shelanski:

The Biotechnology Industry Organization (BIO) is pleased to submit the following comments to the Office of Information and Regulatory Affairs (OIRA) in response to the Health Resources and Services Administration's (HRSA's) proposed Information Collection Notice entitled "Proposed Collection Request: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program and Collection of Manufacturer Data to Verify 340B Drug Pricing Program Price Calculations"[1] (the "Notice"). BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations.

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 also agree with HRSA that covered entities should have "confidence that the amounts being charged are in accordance with statutorily-defined ceiling prices."[2] We are concerned, however, that HRSA's proposed information collection request is both unnecessary and potentially unduly burdensome for manufacturers.

The following comments address our concerns with HRSA's burden estimate articulated in the Notice, which we believe is both difficult to verify, given the lack of detail provided in the Notice as to how the proposed information collection would be operationalized, and laughably small. We begin, however, with our concerns that this information collection is not necessary in the first instance. We also note, while that many of these concerns were articulated in BIO's letter to HRSA in response to the Agency's 60-day *Federal Register* Notice

[1] 80 Fed. Reg. 22,207 (Apr. 21, 2015).
[2] Id. at 22,208.

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issued last September,[3] it appears that HRSA has not responded to these comments, contrary to the "Information Collection Request Time Line" that appears on the Department of Health and Human Services' website.[4] Indeed, while the Paperwork Reduction Act (PRA) requires two separate notices, in part, to "consult with members of the public," it appears that the current Notice is a virtual a copy of the 60-day Notice HRSA issued last year.[5]

In light of these concerns, we urge OIRA either to disapprove this proposed collection of information or to instruct HRSA to make the substantive and material changes outlined in this letter pursuant to 5 C.F.R. § 1320.10(b).

I. The Proposed Information Collection Is Not Necessary for the Proper Performance of HRSA's Functions and Is Inconsistent with the PRA's Prohibition on Duplicative Reporting Obligations.

In the Notice, HRSA cites the new requirement that the Secretary develop a system to verify HRSA-calculated 340B ceiling prices based on data maintained by the Centers for Medicare & Medicaid Services (CMS) by comparing such ceiling prices to the quarterly data submitted by manufacturers to the Medicaid Drug Rebate Program (MDRP).[6] However, rather than rely on the data already reported to and maintained by CMS, the Notice proposes to require participating manufacturers to report all of the following quarterly pricing data to HRSA for each covered outpatient drug:

- Average Manufacturer Price (AMP);
- Unit Rebate Amount (URA);
- Package Sizes;
- National Drug Code (NDC);
- Period of Sale (year and quarter); and
- Manufacturer calculated ceiling price.

The draft reporting format that HRSA provided to OIRA with the request for approval to collect manufacturer ceiling price data would further require the provision of information as to:

- Unit Type;
- Case Pack;
- FDA Product Name;

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[3] This earlier HRSA notice was published in the Federal Register on September 30, 2014. See 79 Fed. Reg. 58,791 (Sept. 30, 2014).

[4] HHS.gov, Information Collection Request Timeline, http://www.hhs.gov/ocio/policy/collection/infocollectiontimeline.html (last visited May 18, 2015) (providing that, with respect to the 60-day Federal Register notice, "[i]f any comments are received, they need to be responded to and the response along with the comments are included with the ICR.").

[5] We obtained a copy of the clearance requests submitted to OIRA for review from HRSA's Information Collection Clearance Officer, as suggested in the Notice. However, notably absent from this submission were both the comments submitted in response to HRSA's earlier notice and HRSA's responses thereto. We later emailed HRSA requesting the comments received, to which HRSA replied that "the comments have been submitted to OMB for review, along with HRSA's response", but that "[w]e are unable to distribute this information externally." It is our position that this last statement is contrary to the applicable regulations, which require that the Agency shall provide, *for public inspection*, those materials provided to OMB—including a "summary of the public comments received [in response to the 60-day Notice], including actions taken by the agency in response to the comments." See 5 C.F.R. §§ 1320.14(a); 1320(a)(1)(iii)(F).

[6] 80 Fed. Reg. at 22,207-08.

- Labeler Name; and
- Wholesale Acquisition Cost (WAC).

As an initial matter, we note our concern that the data elements outlined in the Notice do not align with those included in the draft reporting format, thereby impeding the ability of stakeholders to submit informed comments as to the likely burden that this reporting obligation will impose.

We also are very concerned that this proposed information collection is neither necessary nor permitted. As an initial matter, we note that the statutory requirement to verify ceiling prices does not necessarily require that HRSA obtain all of its quarterly pricing data directly from manufacturers. Instead, the statute requires "the Secretary to verify the accuracy of ceiling prices calculated by manufacturers" by, among other things, "[c]omparing regularly the ceiling prices calculated by the Secretary with the quarterly reporting data that is reported by manufacturers to the Secretary."[7] In all three instances, the term "Secretary" refers to the Secretary of Health and Human Services (HHS)—the Department that includes both HRSA and CMS. This is relevant because manufacturers are already required to report AMP, package size, NDC, unit type, FDA product name, and period of sale on a quarterly basis to the Secretary (i.e., CMS) pursuant to the MDRP statute.[8] It is not likely that Congress intended for manufacturers to report this same pricing data twice to the same individual (the "Secretary").

In short, reading the 340B and Medicaid statutes together, it appears that Congress intended that HRSA would verify the accuracy of manufacturer-calculated ceiling prices, at least in part, by comparing the HRSA-calculated ceiling prices with the quarterly pricing data that is reported by manufacturers to CMS. Furthermore, we note that an alternative interpretation (i.e., that manufacturers must report AMP, package size, NDC, unit type, FDA product name, and period of sale to HHS twice) would be inconsistent with the federal Paperwork Reduction Act (PRA).

The PRA was enacted in order to reduce the total amount of paperwork burden the federal government imposes on private businesses and citizens, including through the coordination and integration of federal information resources management policies and practices.[9] To these ends, the PRA expressly requires the director of each federal agency to "certify . . . that each collection of information submitted to the Director [of the Office of Management and Budget [OMB]] for review . . . is not unnecessarily duplicative of information otherwise reasonably accessible to the agency."[10] This requirement does not appear to be

[7] PHS Act § 340B(d)(1)(B)(i)(II) (emphasis added).
[8] Social Security Act (SSA) § 1927(b)(3). See also CMS, Medicaid Drug Rebate Program Data, http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program-Data.html.
[9] Paperwork Reduction Act of 1980, Pub. L. No. 96-511, 94 Stat. 2812 (codified at 44 U.S.C. § 3501(1), (3)). The term "information resources management" is defined as "the process of managing information resources to accomplish agency missions and to improve agency performance, including through the reduction of information collection burdens on the public." 44 U.S.C. § 3502(7).
[10] 44 C.F.R. § 3506(c)(5). See also 5 C.F.R. § 1320.9(b) (same); 5 C.F.R. § 1320.5(d)(1)(ii) ("[t]o obtain OMB approval of a collection of information, an agency shall demonstrate that it has taken every reasonable step to ensure that the proposed collection of information: . . . [i]s not duplicative of information otherwise accessible to the agency . . . .")

met by aspects of HRSA's proposed information collection, particularly given that HRSA recognizes in the Notice that the Agency already has access to CMS's pricing data.[11]

On the other hand, we believe that HRSA could permissibly require manufacturers to report those data points that manufacturers do not report to CMS—namely the ceiling price and URA—without running afoul of Congressional intent or the PRA. Indeed, given that the manufacturer-calculated URA is considered the official URA for purposes of the MDRP, we strongly urge HRSA to rely on this URA—rather than the unofficial URA calculated by CMS—for purposes of verifying manufacturer-calculated ceiling prices under the Agency's statutory mandate.[12] Moreover, there are instances in which CMS's calculation of the URA can be different from manufacturers' (e.g., when manufacturers restate their reported AMP or Best Price for a specific time period), or when CMS does not calculate a URA at all,[13] further supporting the need for HRSA to rely on manufacturer-reported URAs for this purpose.

In light of the foregoing, believe that HRSA could permissibly rely on those pricing data reported to and maintained by CMS (to which HRSA already has access), and instead require that manufacturers report only manufacturer-calculated ceiling prices, URAs, and—in order to identify the drug and time period in question—NDCs and period of sale to HRSA.[14] We urge OIRA to disapprove the proposed collection of information unless modified accordingly. We also urge OIRA to ensure that any approved collection of information clearly articulates whether the obligation to report these data points (ceiling price, URA, NDC, and period of sale) would be optional or mandatory, as well as to outline its proposed processes for reconciling any differences in the ceiling price HRSA derives against that submitted by manufacturers, as neither is currently specified in the Notice.

II. The Estimated Burden is Well Below the Time It Would Take Manufacturers to Complete, Review, and Transmit the Requested Data, Let Alone Implement Systems Necessary to Comply with the New Reporting Obligation.

According to the Notice, HRSA has estimated that it would take each manufacturer 30 minutes per quarter to report all of the requested pricing information to HRSA.[15] We do not

[11] See 80 Fed. Reg. at 22,208 ("HRSA has already developed a system to prospectively calculate 340B ceiling prices from data obtained from [CMS] as well as OPA-identified commercial databases."). Indeed, the PPA requires manufacturers "to permit CMS to share AMP and unit rebate amount submitted under the Medicaid Rebate on covered outpatient drugs with the Secretary or his designee for purposes of carrying out the Agreement . . . ." Pharmaceutical Pricing Agreement § II(f).

[12] CMS uses the quarterly pricing data submitted by manufacturers (i.e., AMP and Best Price) to calculate an unofficial URA, which is submitted as a courtesy to the states. However, manufacturers are ultimately responsible for calculating the official URA. Notably, this official URA is transmitted to the states with the ROSI and payment, but not to CMS. CMS, Unit Rebate Calculation, http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program.html. See also HHS-OIG, Medicaid Drug Rebate Dispute Resolution Could Be Improved, OEI-05-11-00580 (August 2014).

[13] See Medicaid Drug Rebate Data Guide for Labelers at 15 (Last Revised April 25, 2011) ("When labelers do not submit timely or complete pricing data, or their pricing data results in zero URAs, it is the labeler's responsibility to manually calculate the URA and send a rebate payment along with the ROSI.").

[14] We note that manufacturers will likely need to provide package size, period of sale, and, in some instances, the NDC together with ceiling price and URA data reports. As articulated in section III of this letter, we urge HRSA to use the same format used in the MDRP's DDR for reporting these data.

[15] 80 Fed. Reg. at 22,208.

believe that this is an accurate estimate of the proposed reporting burden. As HRSA outlines in the Notice, under the PRA, the term "burden" is defined as:[16]

> the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency, including: (i) Reviewing instructions; (ii) Developing, acquiring, installing, and utilizing technology and systems for the purpose of collecting, validating, and verifying information; (iii) Developing, acquiring, installing, and utilizing technology and systems for the purpose of processing and maintaining information; (iv) Developing, acquiring, installing, and utilizing technology and systems for the purpose of disclosing and providing information;(v) Adjusting the existing ways to comply with any previously applicable instructions and requirements;(vi) Training personnel to be able to respond to a collection of information; (vii) Searching data sources; (viii) Completing and reviewing the collection of information; and (ix) Transmitting, or otherwise disclosing the information.

We believe that 30 minutes would be sufficient to accomplish only one of these tasks: the actual transmission of the requested information. And even then, it is difficult to confirm the accuracy of that estimate without knowing the process HRSA proposes to require for such data submission (e.g., will it be through a web interface, like the Drug Data Reporting [DDR] system used by CMS for purposes of the MDRP? On a disk? Paper? Other?). In sum, we disagree that "[t]he burden imposed on manufacturers . . . is low because the information requested is readily available[,]"[17] given that: (1) it is not clear that the data submission requirements used by HRSA will be the same as those used by CMS; (2) manufacturers will need to take steps to prepare for the quarterly reporting obligation before it actually goes into effect; and (3) manufacturers will undoubtedly be required to spend time on the back-end resolving disputes with HRSA over disparate ceiling price calculations, particularly if there remain open questions with respect to certain, nuanced aspects of the ceiling price calculations—all factors that will result in manufacturers spending time that was not contemplated by the burden estimate outlined in the Notice. Each of these factors is addressed, in turn.

A. The Burden of Reporting the Requested Information Would Be Lower to the Extent HRSA Utilized the Same Format as, and Specified Timing After, the Quarterly Price Submission Process Used by CMS.

As noted previously, it is not clear that the reporting requirements imposed by HRSA will be the same as those used by CMS for purposes of the MDRP, including with respect to the reportable fields. For example, "Case Pack," which is a proposed field that manufacturers would be required to report to HRSA, is not a standard reportable field under the MDRP. As such, the addition of this data field would produce incremental burden for manufacturers to incorporate into their systems and the file format for HRSA. The same could be said for Wholesale Acquisition Cost (WAC). We have prepared a chart, provided as Appendix A, which compares the text files used in the DDR under the MDRP and HRSA's proposed text file for

[16] 5 C.F.R. § 1320.3(b)(1). See also 44 U.S.C. § 3502(2).
[17] 80 Fed. Reg. at 22,208.

purposes of 340B quarterly price reporting submissions. We also have attached the MDRP text files, as Appendix B, for your reference.[18]

To the extent that HRSA uses different data submission requirements, the burden on manufacturers would obviously be higher, given that manufacturers would need to re-format (or, potentially, manually re-enter) the requested data. For instance, in a survey of BIO members, two-thirds of respondents anticipated spending at least 10 hours responding to HRSA's request, assuming that the Agency did not employ the same reporting format as the MDRP's DDR; the same number anticipated spending fewer than 10 hours were HRSA to employ the same format. Accordingly, to the extent that OIRA permits HRSA to move forward with the proposed information collection, we urge OIRA to ensure that the Agency plans to use the same file format and utility as what already is being used by manufacturers to upload pricing data into the CMS's DDR system in order to minimize the burden of reporting the requested pricing data to HRSA.

On a related note, while the Notice does not address when the requested data would be due to HRSA, the burden on manufacturers would be much lower to the extent the data were due sometime after the quarterly submission deadline for pricing data to CMS, so that the new submission burden does not compound the already stressful quarterly submission process. We note that there are 60 days between when the quarterly numbers are calculated and when those numbers go into effect as the 340B price. To ensure that HRSA will have plenty of time to collate and verify these data, while staggering price reporting timelines sufficiently to mitigate the burden of any new reporting obligations on manufacturers, BIO therefore requests that the submission deadline be 45 days after the quarterly submission deadline to CMS. Any additional requirements related to the data reporting obligation should occur on this same schedule to further minimize the burden on manufacturers. We ask OIRA to take this into account in working with HRSA on this proposed collection of information.

B. Manufacturers Will Need to Take Preparatory Actions Prior to the First Quarterly Report That Were Not Factored into HRSA's Burden Estimate.

Before manufacturers are able to submit ceiling price data to HRSA during the first quarter, they will be required to take certain preparatory measures. For instance, it will be necessary for manufacturers to review HRSA's reporting instructions, create a reporting template, 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 reporting obligation. As noted previously, these are the types of activities that the PRA requires to be incorporated into an agency's burden estimate. Yet, it is clear that HRSA's 30-minute burden estimate does not take this time into account.

In addition, a recent update posted on HRSA's website requests that manufacturers "verify the accuracy and completeness of the information on file for each labeler code in the 340B Drug Pricing Program database."[19] To the extent any updates are necessary with respect to this information, HRSA further directs manufacturers to submit a "manufacturer

[18] We have attached two forms, as not all of the data fields proposed by HRSA are contained on the same DDR File layout.
[19] HRSA, Office of Pharmacy Affairs (OPA) Monthly Update: 340B Ceiling Price Calculation (May 2015).

change request form" to a designated email address. Each of these steps further adds to the preparatory burden.

Finally, HRSA's recent update also adds to the quarterly reporting burden by directing manufacturers to identify an authorizing official who is a "corporate officer or someone who would be otherwise authorized to legally bind the company to the terms of the Pharmaceutical Pricing Agreement (Chief Executive Officer, Chief Financial Officer, Chief Operating Officer, etc.)." We note that this requirement will require the involvement, not only of these C-Suite officers, but of other employees, including technical experts who are familiar with the complex calculations that underlie this reporting obligation. Appropriate evaluation of the burden would require an assessment of the number and level of staff required to comply with the information collection. Similar to the data reporting format document, this additional request for manufacturers to update the database has not been reflected in the information collection request submitted to OIRA, even though it is central to assessing the overall burden of HRSA's information collection efforts.

C. Manufacturers Will Be Required to Spend Time Resolving Disputes with HRSA Over Disparate Ceiling Price Calculations that Was Not Contemplated in HRSA's Burden Estimate.

Another area that may increase the reporting burden on manufacturers relates to the potential for disputes with HRSA over ceiling prices calculations. While both manufacturers and HRSA will be calculating ceiling prices, HRSA has not addressed how it will reconcile any differences between the ceiling prices reported by manufacturers and those calculated by the Agency.[20] Nonetheless, we presume that manufacturers will spend time involved in this reconciliation process with the Agency.

Moreover, there are a significant number of questions as to how manufacturers should go about calculating ceiling prices that are not resolved in the Notice or elsewhere. For example, it is unclear how HRSA intends to address:

- Provisional pricing for newly launched products;
- Sub-ceiling pricing; and
- To the extent that HRSA plans to rely on the CMS-calculated URA,[21] instances in which there is a disparity between a manufacturer's URA and the URA calculated by CMS (e.g., products like line extensions that utilize alternative URAs, NDCs that failed CMS's variance test).

To the extent that these questions remain unresolved, manufacturers may not only spend unnecessary time in providing feedback, but there is an increased likelihood of disconnects between the data a manufacturer submits and HRSA's thoughts as to what the price should be. These disputes would undoubtedly increase the level of burden for both parties.

[20] HRSA's recent update addresses this, but only to note that manufacturers will receive a "system-generated e-mail notification to access the system and resolve the price discrepancies" and that "[i]f a discrepancy is not able to be resolved, HRSA will conduct additional inquiry and work with manufacturers to take corrective action, as necessary." Id. The Notice does not address, or even mention, this reconciliation process at all.

[21] As noted previously, BIO urges HRSA to rely on manufacturer-reported URAs, as opposed to URAs calculated by CMS, for purposes of the Agency's ceiling price verification activities.

Finally, while we appreciate that the Agency has provided some guidance as to the ceiling price calculation, we believe that some of this guidance also has the potential to create disputes. For instance, in HRSA's proposed file layout, the ceiling price would be calculated to six decimals, truncated to four, and then positions five and six would be padded with zeros. We suggest that the quarterly ceiling prices be reported in dollars and cents (i.e., 99999.99).[22] The requirement for additional decimal places, beyond two, will likely increase the burden due to any disputes that could arise with HRSA.

III. Conclusion

BIO thanks OIRA for this opportunity to comment on the Notice. As noted previously, we are concerned that the proposed information collection request is both unnecessary and unduly burdensome for manufacturers. We therefore urge HRSA to disapprove the proposed information collection request. To the extent that OIRA nonetheless permits HRSA to move forward with its proposal, we urge OIRA to instruct HRSA to take into account BIO's recommendations to lessen the burden imposed on manufacturers. Please contact me at (202) 449-6384 if you have any questions regarding our comments. Thank you for your attention to this important matter and for your consideration of BIO's views.

Respectfully submitted,

/s/

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

[22] Wholesaler Acquisition Cost (WAC) is another field in HRSA's proposed file layout that should be reported in dollars and cents. HRSA also should clarify at what date WAC should be reported (i.e., beginning or end of quarter) in the file layout.

Appendix A: Comparison of Draft HRSA 340B Quarterly Pricing Data File to CMS MDRP DDR Data Text Files

HRSA 340B Quarterly Pricing Data Text File	Remarks	Compare to CMS MDRP DDR Data Text Files
Labeler Code	NDC#1	These data fields appear in the DDR Quarterly Pricing Data Text File
Product Code	NDC#2	
Package Size Code	NDC#3	
Period Covered	QYYYY	
Average Manufacturer Price	99999.999999	
Unit Rebate Amount	99999.999999	NEW
Package Size	9999999.999	This data field appears on the DDR Drug Product Data Text File as "Units Per Pkg Size"
Unit Type	e.g., CAP, TAB, ML	This data field appears on the DDR Drug Product Data Text File
Case Pack	9999999.999	NEW
340B Price		NEW
FDA Product Name		This data field appears on the DDR Drug Product Data Text File
Labeler Name		NEW
Wholesale Acquisition Cost	99999.999999	NEW

Appendix B:

CMS Record Specification DDR Data Text Files

CMS RECORD SPECIFICATION
DDR QUARTERLY PRICING DATA
TEXT FILE FOR TRANSFER TO CMS
Effective: January 1, 2008

Source: Drug Manufacturers
Target: CMS

Field	Size	Position	Remarks
Record ID	1	1 - 1	Constant of "Q"
Labeler Code	5	2 - 6	NDC #1
Product Code	4	7 - 10	NDC #2
Package Size	2	11 – 12	NDC #3
Period Covered	5	13 – 17	QYYYY (Qtr/Yr)
Average Mfr Price	12	18 – 29	99999.999999
Best Price	12	30 – 41	99999.999999
Nominal Price	9	42 – 50	999999999
Customary Prompt Pay Disc.	9	51 – 59	999999999

QUARTERLY PRICING DATA FIELDS

Labeler Code: First segment of National Drug Code that identifies the labeler. Numeric values only, 5-digit field, right-justified and zero-filled for 4-digit labeler codes.

Product Code: Second segment of National Drug Code. Alpha-numeric values, 4-digit field, right-justified, zero-filled for 3-digit product codes.

Package Size Code: Third segment of National Drug Code. Alpha-numeric values, 2-digit field, right-justified, zero-filled for 1-digit package size codes.

Period Covered: Calendar quarter and year covered by data submission. Numeric 5-digit field, QYYYY.

Valid values for Q:
1 = January 1 - March 31
2 = April 1 - June 30
3 = July 1 - September 30
4 = October 1 - December 31

Valid values for YYYY:
4-digit valid calendar year.

Average Manufacturer's Price (AMP): The AMP per unit per product code for the period covered. If a drug is distributed in multiple package sizes, there will be one "weighted" AMP for the product, which is the same for all package sizes. Compute to 7 decimal places, and round to 6 decimal places. Numeric values, 12-digit field: 5 whole numbers, the decimal place ('.') and 6 decimal places; right-justified, zero-filled.

Best Price: Per the statute and rebate agreement, the lowest price available per product code, regardless of package size. Compute to 7 decimal places and round to 6 decimal places. Zero-fill for Non-Innovator Multiple Source drugs. Numeric values, 12-digit field: 5 whole numbers, the decimal ('.') and 6 decimal places; right-justified, zero-filled.

Nominal Price (NP): Sales that meet the statutory/regulatory definition of NP. Total dollar figure per 11-digit NDC, rounded to nearest dollar. 9-digit field; 9 whole numbers; right-justified, 0-filled. If no sales for a package size, fill with all zeroes.

Customary Prompt Pay Discount (CPP): Total dollar figure per 11-digit NDC, rounded to nearest dollar. 9-digit field; 9 whole numbers; right-justified, 0-filled. If no discount for a package size, fill with all zeroes.

CMS RECORD SPECIFICATION
DDR DRUG PRODUCT DATA
TEXT FILE FOR TRANFER TO CMS

Source: Drug Manufacturers

Target: CMS

Field	Size	Position	Remarks
Record ID	1	1 – 1	Constant of "P"
Labeler Code	5	2 – 6	NDC #1
Product Code	4	7 – 10	NDC #2
Package Size Code	2	11 - 12	NDC #3
Drug Category	1	13 - 13	See Data Element Definitions
Unit Type	3	14 - 16	See Data Element Definitions
FDA Approval Date	8	17 - 24	MMDDYYYY
FDA Thera. Eq. Code	2	25 - 26	See Data Element Definitions
Market Date	8	27 - 34	MMDDYYYY
Termination Date	8	35 - 42	MMDDYYYY
DESI Indicator	1	43 - 43	See Data Element Definitions
Drug Type Indicator	1	44 - 44	See Data Element Definitions
Baseline AMP	12	45 - 56	99999.999999
Units Per Pkg Size	11	57 - 67	9999999.999
FDA Product Name	63	68 – 130	FDA Drug Listing Name
DRA Base AMP	12	131-142	99999.999999
Package Size Intro. Date	8	143-150	MMDDYYYY
Purchase Product Date	8	151-158	MMDDYYYY
Filler	17	159-175	spaces

DRUG PRODUCT DATA FIELDS

Labeler Code: First segment of National Drug Code that identifies the labeler. Numeric values only, 5-digit field, right-justified and zero-filled for 4-digit labeler codes.

Product Code: Second segment of National Drug Code. Alpha-numeric values, 4-digit field, right-justified, zero-filled for 3-digit product codes.

Package Size Code: Third segment of National Drug Code. ~~Alpha-~~numeric values, 2-digit field, right-justified, zero-filled for 1-digit package size codes.

Drug Category: Alpha-numeric values, 1 character.

Valid values:
- S = Single source
- I = Innovator multiple source
- N = Non-innovator multiple source

Unit Type: One of the 8 unit types by which the drug can be dispensed. Alpha-numeric values, 3-character field, left-justified.

Valid values:
- AHF = Injectable Anti-Hemophilic Factor
- CAP = Capsule
- SUP = Suppository
- GM = Gram
- ML = Milliliter
- TAB = Tablet
- TDP = Transdermal Patch
- EA = Each

FDA Approval Date: NDA or monograph approval date. If the drug was approved prior to the start of the Medicaid Drug Rebate Program (i.e., 10/1/1990), use 9/30/1990 as the FDA Approval Date. For covered outpatient drugs for which the FDA does not require approval, use 9/30/1990 or the actual date marketed if the drug was marketed after 9/30/1990. Numeric values, 8-digit field; format: MMDDYYYY

TEC: FDA-assigned Therapeutic Equivalence Codes. Alpha-numeric values, 2-character field.

Valid values:

AA	BC	BS
AB	BD	BT
AN	BE	BX
AO	BN	NR - Not rated
AP	BP	A1 thru A9 = AB value
AT	BR	

Market Date: For S and I drugs, the date the drug was first marketed by the original manufacturer (e.g., NDA holder). For N drugs, the date the drug was first marketed under the manufacturer's rebate agreement. If a Market Date falls on a date that is earlier than 9/30/1990, CMS will change it to 9/30/1990 in both the Medicaid Drug Rebate (MDR) system and the Drug Data Reporting for Medicaid (DDR) system since dates earlier than the start of the Drug Rebate Program have no bearing on this aspect of the program. Numeric values, 8-digit field, format: MMDDYYYY

Termination Date: The date a drug is withdrawn from market or the drug's last lot expiration date. Zero or blank fill if not present. Numeric values, 8-digit field, format: MMDDYYYY

DESI Indicator: Drug Efficacy Study Implementation code. Numeric value, 1 digit.

Valid values:
- 2 = Safe and effective or DESI Drug Pending FDA Review
- 3 = Drug under review (no NOOH issued)
- 4 = LTE/IRS drug for some indications
- 5 = LTE/IRS drug for all indications
- 6 = LTE/IRS drug withdrawn from market

Drug Type Indicator: Identifies a drug as prescription (Rx) or over-the-counter (OTC). Numeric values, 1-digit field.

Valid values:
- 1 = Rx
- 2 = OTC

OBRA '90 Baseline AMP: The AMP per unit for the period that establishes the OBRA '90 Baseline AMP for innovator drugs. There will be one weighted baseline AMP for the product, which will be the same for all package sizes. Compute to 7 decimal places and round to 6 decimal places. Numeric values, 12-digit field: 5 whole numbers, the decimal ('.') and 6 decimal places; right-justified, zero-filled for innovator drugs (i.e, S or I drugs) with a Market Date of 10/1/1993 or greater and for all non-innovator drugs.

Units Per Package Size: Total 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.

FDA Drug Listing Name: Drug name as it appears on FDA listing form. Alpha-numeric values, 63 characters, left-justified.

DRA Baseline AMP: For active innovator drugs with a Market Date less than July 1, 2007, the OBRA '90 or OBRA '93 Baseline AMP revised, at labeler option, in accordance with relevant regulations and program guidance. There will be one weighted DRA Baseline AMP for the product, which will be the same for all package sizes. Per CMS-2238-FC, labelers will have four quarters (i.e., January 2, 2008-October 30, 2008) to report this optional field. Numeric values, 12-digit field; 5 whole numbers, the decimal ('.') and 6 decimal places, right-justified, zero-

filled. Compute to 7 decimal places and round to 6 decimal places. PLEASE NOTE: This field is now closed as the deadline for reporting (i.e, 10/30/2008) has passed; therefore, no additional DRA Baseline AMP submissions will be allowed.

Package Size Introduction Date: The date the package size is first available on the market. If the product was purchased from another company, the Package Size Introduction Date should equal the date the package size is first available on the market under the labeler code of the company currently holding legal title to the NDC. Numeric values, 8-digit field, format: MMDDYYYY

Purchased Product Date: The date on which the company currently holding legal title to the NDC first markets the drug under this NDC (this date can result, for example, from the purchase of an NDC from one company by another company, the re-designation of an NDC from one of a company's labeler codes to another of that same company's labeler codes, cross-licensing arrangements, etc…). Zero or blank fill if not present. Numeric values, 8-digit field, format: MMDDYYYY

Filler: Spaces