November 14, 2014

***BY ELECTRONIC DELIVERY***

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

**Re: 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.

1201 Maryland Avenue SW
Suite 900
Washington DC 20024
202.962.9200 P
202.488.6306 F
bio.org

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.

---

[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

---

[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.

---

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)

---

[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

---

[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/

---

[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