Biotechnology Industry Organization

December 21, 2015

Captain Krista M. Pedley, PharmD, M.S., USPHS, Director
Office of Pharmacy Affairs
Health Resources and Services Administration
Department of Health and Human Services
5600 Fishers Lane, Parklawn Building, Mail Stop 10C-03
Rockville, Maryland 20857

BY ELECTRONIC SUBMISSION

Re: Proposed Information Collection: 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 Captain Pedley:

The Biotechnology Industry Organization ("BIO") appreciates the opportunity to submit the following comments in response to the proposed Information Collection Request ("ICR"), issued by the Health Resources and Services Administration ("HRSA") and published in the *Federal Register* on October 20, 2015, entitled *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] (the "Proposed ICR").[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 indigent 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. Accordingly, we applaud HRSA's recent commitment and activities to enforce program oversight and compliance, as well HRSA's effort to finally implement certain provisions added to the 340B statute by the Affordable Care Act ("ACA") by amending the Pharmaceutical Pricing Agreement ("PPA") via a proposed addendum.

I. Background

As HRSA notes in the Proposed ICR, section 7102(b) of the ACA amended section 340B(a)(1) of the Public Health Service Act ("PHSA") to specify two requirements to be

[1] 80 Fed. Reg. 63,560 (Oct. 20, 2015).

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added to the PPA with such manufacturers. Specifically, each such agreement shall require that the manufacturer:[2]

1) "furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to [under section 340B of the PHSA] as the 'ceiling price')"; and
2) ". . . 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."

As an initial matter, we take issue with HRSA's statement in the Proposed ICR that "a manufacturer who sells covered outpatient drugs to eligible entities must sign a [PPA] with the Secretary of Health and Human Services in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed [the statutory 'ceiling price']."[3] What the statute, in fact, requires is that a manufacturer sign the PPA as a condition of obtaining federal financial participation under the Medicaid program for the manufacturer's drugs.[4] Manufacturers are not, by contrast, required to sign a PPA solely by virtue of selling covered outpatient drugs to covered entities. HRSA should correct this misstatement in future *Federal Register* notices, as well as in the General Instructions for completing the proposed PPA addendum.[5]

In addition we note that, by their terms, these statutory modifications made by the ACA are not self-implementing. It has long been BIO's position that HRSA must issue a new PPA agreement, or appropriately amend existing PPAs that are in force, and manufacturers and HRSA must execute such new PPAs or amendments, in order for these provisions to be binding on manufacturers. While we applaud HRSA's efforts to do so via this Proposed ICR—and believe that this proposal is necessary for the performance of the Agency's functions—we strongly urge the Agency to take the following comments into account prior to adopting the proposed addendum to the PPA, which address: (1) the use of information technology and other mechanisms to improve the quality, utility, and clarity of the information to be collected while minimizing the information collection burden on manufacturers; and (2) the accuracy of the estimated burden. Specifically, BIO urges HRSA to:

- Make certain changes to the "Manufacturer Data Fields for 340B Ceiling Price" information collection form (hereinafter "Ceiling Price Information Collection"),[6] and provide additional detail regarding the underlying ceiling price calculation and the ceiling price verification process, in order to minimize the reporting burden on

[2] 42 U.S.C. § 256b(a)(1).
[3] 80 Fed. Reg. at 63,560.
[4] See SSA §§ 1927(a)(1); (a)(5).
[5] See General Instructions for Completing the 340B Drug Pricing Program Pharmaceutical Pricing Agreement – Addendum (OMB No. 0915-0327).
[6] See http://www.reginfo.gov/public/do/DownloadNOA?requestID=265480 (approved Sept. 28, 2015).

manufacturers while ensuring that the data received are useful to the Agency—prior to requiring manufacturers to report ceiling price data to HRSA; and

- Substantially increase the proposed burden estimate to take into account not only the time to actually sign the proposed addendum to the PPA and transmit it to HRSA, but also the time needed to review the applicable instructions—including the Proposed ICR, the proposed addendum, and relevant provisions of the 340B statute and future guidance to be issued by the Agency—and implement mechanisms to ensure compliance with the terms thereof. As articulated in prior BIO comments,[7] we also believe that the Agency's two earlier *Federal Register* notices related to the Ceiling Price Information Collection grossly underestimated the time and resources necessary to prepare for the reporting of ceiling price data to HRSA and we thus urge the Agency also to take this time into consideration in estimating the burden on manufacturers associated with the Proposed ICR.

We begin, however, by noting that, as a legal matter, the applicability of the proposed addendum can be prospective only, and that the scope and purpose of the "must offer" language is limited to implementing HRSA's longstanding non-discrimination policy.

II. HRSA Should Expressly Recognize that Application of the Proposed Addendum Would be Prospective Only.

While HRSA has modified the form PPA multiple times since the inception of the 340B Program, to our knowledge, the form PPA has never contained—and certainly the current form PPA does not contain—a provision that automatically incorporates changes to the PPA directed by modifications to the 340B statute into the agreement, or that requires the parties to automatically comply with such directives.[8] Instead, the PPA expressly requires that the agreement may not be altered, except by an amendment "in writing" and "signed by both parties."[9] Thus, while courts have stated that the "PPAs simply incorporate statutory . . . obligations and record the manufacturers' agreement to abide by them,"[10] this approach requires both of these events to occur: (1) the PPA must reflect the obligations; and (2) manufacturers must agree to them. In the absence of a contract clause that requires automatic adherence to PPA modifications directed by statutory

[7] See BIO Comments in Response to *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* (Nov. 14, 2014), https://www.bio.org/sites/default/files/FINAL%20BIO%20Comments%20on%20HRSA%20Notice%2011_14_14.pdf; BIO Comments in Response to *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 Ceiling Price Calculations* (May 21, 2015), https://www.bio.org/sites/default/files/FINAL%20BIO%20Comments%20to%20OIRA%20on%20HRSA%20Notice%205_21_15%20(Combined)_0.pdf.

[8] 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).

[9] 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.").

[10] Astra USA, Inc. v. Santa Clara County, 131 S. Ct. 1342, 1348 (2011).

changes or that permits HRSA to modify an existing PPA without the manufacturer's consent, the two provisions HRSA now proposes to add to the PPA currently are not binding for manufacturers because they have not yet been added to the PPA.[11] Thus, as a legal matter, HRSA must amend the PPA to include these terms (and manufacturers must sign the amended PPA), for the terms to be binding from that point forward.[12] We encourage HRSA to expressly recognize as much in adopting the proposed addendum.

III. HRSA Should Clarify that the Scope and Purpose of the "Must Offer" Provision is Limited to Prohibiting Discrimination.

As noted in section (I) of this letter, the ACA amended the 340B statute to provide 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," language referred to as the "must offer" provision.[13] In addition to the fact that this "must offer" language is not legally operative unless and until it is incorporated into the PPA, we have significant concerns with HRSA's description of this statutory provision in the abstract section of the Proposed ICR. Specifically, this section of the Proposed ICR states, without appropriate qualification, that, "[a] manufacturer subject to a PPA must offer all covered outpatient drugs at no more than the ceiling price to a covered entity listed on the public 340B database."[14]

The statute itself includes additional language that provides an important limitation on this requirement. Specifically, the statute requires that "the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price *if such drug is made available to any other purchaser at any price*."[15] This last phrase, which HRSA omits from the abstract text, is critical because the provision's purpose was to codify in the 340B statute HRSA's longstanding "non-discrimination" policy (i.e., that manufacturers treat 340B providers the same as non-340B providers in distribution systems).[16] Indeed, HRSA recognized the relationship between its non-discrimination policy and the "must offer" provision in its 2012 "Clarification of Non-Discrimination Policy" Program Notice.[17] Moreover, Congress clearly intended for the phrase "*if such drug is made available to any other purchaser at any price"* to have effect for purposes of the 340B Program, as there are examples—including in the statute establishing the Federal Supply Schedule—in which Congress established a "must offer" obligation without similar

[11] BIO recognizes the fact that the Proposed ICR does not include the following problematic language regarding the "must offer" language that was included by HRSA in other recent *Federal Register* notices: "[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*." See, e.g., 80 Fed. Reg. 52,300, 52,311 (Aug. 28, 2015) (emphasis added). This italicized language ignores that the PPA must be amended, or a new PPA issued, in order for the "must offer" language to be binding on 340B-participating manufacturers. BIO therefore applauds its omission from the instant Proposed ICR.
[12] See Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 208 (1988) ("Retroactivity is not favored in the law.").
[13] 42 U.S.C. §256b(a)(1).
[14] 80 Fed. Reg. at 63,560. We note that similar language appears in the recent proposed Omnibus Guidance. See 80 Fed. Reg. 52,300, 52,311, 52,321 (Aug. 28, 2015).
[15] 42 U.S.C. § 256b(a)(1) (emphasis added).
[16] See HRSA, 340B Drug Pricing Program Notice: Clarification of Non-Discrimination Policy, Release No. 2011-1.1 (May 23, 2012).
[17] Id.

qualifying language.[18] Thus, the absence of this phrase from the abstract text reflects an overbroad and inappropriate interpretation of the 340B statute's "must offer" provision, which has the potential to result not only in confusion, but disputes.

We also note that, while not binding on manufacturers, HRSA's 2012 non-discrimination policy release inherently recognizes that the 340B statute's "must offer" language should be read contextually. Specifically, this release demonstrates that it is HRSA's current policy to read the "must offer" language reasonably to provide that, so long as the manufacturer is treating a 340B covered entity on similar terms as a non-340B provider, the manufacturer satisfies the terms of the "must offer" language. We therefore urge HRSA to align its description of the "must offer" provision in any future notices—as well as in the proposed addendum to the PPA—with the language of the 340B statute itself, and to expressly recognize that, pursuant to this statutory language, manufacturers are expected only to treat 340B and non-340B providers alike.

IV. HRSA Should Modify its Ceiling Price Information Collection to Minimize the Burden on Manufacturers, and Provide Additional Detail Regarding both the Underlying Ceiling Price Calculation and Ceiling Price Verification Process to Ensure that the Data Reported are Useful to the Agency, Before Manufacturers Should be Required to Report Ceiling Price Data to HRSA.

While BIO supports HRSA's proposal to finally take steps to incorporate the ACA's program integrity provisions into the PPA, we believe that the Agency should delay implementation of the requirement to report ceiling price data, in particular, until the Agency has both: (1) made necessary modifications to the Ceiling Price Information Collection in order to minimize the burden on manufacturers; and (2) provided additional detail regarding the ceiling price calculation and ceiling price verification process to ensure that any data reported are useful to the Agency.

A. HRSA Should Modify its Ceiling Price Information Collection to Minimize the Burden on Manufacturers, as Required by the PRA.

In two separate Notices published in the *Federal Register*, HRSA outlined proposed information collection requirements, citing 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").[19] Rather than rely on the data already reported to and maintained by CMS, however, these Notices proposed to require participating manufacturers to report *all* of the following quarterly pricing data to HRSA for each covered outpatient drug:

- Average Manufacturer Price ("AMP");

[18] See Veterans Health Care Act of 1992, Public Law 102-585 § 603 (Nov. 4, 1992) ("beginning January 1, 1993, the manufacturer shall make available for procurement on the Federal Supply Schedule of the General Services Administration each covered drug of the manufacturer").
[19] 80 Fed. Reg. at 22,207-08.

- 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 the Office of Information and Regulatory Affairs ("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;
- Labeler Name; and
- Wholesale Acquisition Cost ("WAC").

Notwithstanding the fact that the proposed information collection request has apparently since been approved by the Office of Management and Budget ("OMB") as the Ceiling Price Information Collection,[20] BIO remains very concerned that this information collection, as proposed and finalized (without modification), 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."[21] 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, 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.[22] 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 are 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").

[20] See http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201504-0915-001.
[21] PHS Act § 340B(d)(1)(B)(i)(II) (emphasis added).
[22] 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.

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.[23] The Congressionally specified purposes of the PRA also speak of "minimiz[ing] paperwork burden," "maximiz[ing] the utility of information . . . collected," and "minimiz[ing] the cost to the Federal government of the . . . collection . . . of information."[24] 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 OMB] for review . . . is not unnecessarily duplicative of information otherwise reasonably accessible to the agency."[25] This requirement does not appear to be met by aspects of HRSA's Ceiling Price Information Collection, particularly given that HRSA recognized in the associated *Federal Register* notices that the Agency already has access to CMS's pricing data.[26]

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.[27] 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,[28] further supporting the need for HRSA to rely on manufacturer-reported URAs for this purpose.

Given that manufacturers report many of the data elements necessary for the ceiling price verification system envisioned in the 340B statute to CMS under the MDRP, we believe that HRSA could permissibly require manufacturers to report only those data points that manufacturers do not report to CMS, namely the manufacturer-calculated

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[23] 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).

[24] 44 U.S.C. § 3501.

[25] 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 . . . .").

[26] See, e.g., 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).

[27] 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).

[28] 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.").

ceiling price, the URA, and—in order to identify the drug and time period in question—the NDCs and period of sale. HRSA therefore should modify its Ceiling Price Information Collection accordingly, in order to minimize the burden imposed on manufacturers.

BIO also continues to be concerned by the two data elements included in the Ceiling Price Information Collection that are not utilized in the context of the MDRP. These include "case pack" and WAC. As these are not standard reportable data fields under the MDRP, the use of these data fields would produce incremental additional burdens for manufacturers to incorporate into their systems and the file format for HRSA. Yet HRSA has yet to articulate precisely how these data elements will be utilized, or why they are necessary to calculate the ceiling price and/or to verify ceiling price data submitted by manufacturers. We therefore strongly urge HRSA to eliminate these data fields from the Ceiling Price Information Collection. We also continue to urge HRSA to require that the ceiling price be reported in dollars and cents (i.e., 99999.99)—as opposed to six decimals, truncated to four, with positions five and six padded with zeros, as outlined in the Ceiling Price Information Collection and recent proposed rule related to the ceiling price calculation[29]—to lower the risk of disputes with HRSA regarding the underlying ceiling price calculations.

We strongly urge HRSA to make all of these revisions to the Ceiling Price Information Collection prior to implementing the requirement that manufacturers report ceiling price data to HRSA.

Relatedly, we also urge HRSA to make certain modifications to the ceiling price reporting system currently under development by the Agency to minimize the burden for manufacturers. For instance, the current system offers only two contacts—the Authorizing Official (AO) and Primary Contact (PC)—for purposes of fulfilling a company's price reporting obligations. The system essentially requires the AO (typically a CFO or CEO) to act in dual capacity as both a certifier and as a system administrator to assign users. This approach is not realistic. We therefore urge HRSA to adopt the approach taken in the MDRP's DDR, under which the higher ranking officer attests to the results, while a separate technical contact performs the associated administrative duties.

B. HRSA Should Provide Additional Guidance Regarding both the Ceiling Price Calculation and Ceiling Price Verification Process to Ensure that the Data Received are Useful to the Agency.

In addition to the fact that HRSA has not yet finalized its recent proposed rule regarding the ceiling price calculation itself, causing some uncertainty regarding the Agency's policies as to this underlying calculation, there remain a number of open questions with respect to the process by which HRSA will verify manufacturer-calculated ceiling prices that must be resolved before manufacturers should be required to report pricing data to HRSA pursuant to the proposed addendum. These include, among others, the need to define:

[29] 80 Fed. Reg. 34,584, 34,585 (June 17, 2015) (Proposed 42 C.F.R. § 10.10(a)).

- Submission deadlines for ceiling price data (to minimize the burden on manufacturers, BIO continues to advocate that the submission deadline be after the quarterly submission deadline of MDRP data to CMS, ideally 45 days later,[30] and that any additional reporting requirements related to the data reporting obligation should occur on this same schedule).
- The submission deadline of ceiling prices for new NDCs, and whether manufacturers will have access to make changes to the system on an off-quarter cycle (e.g., for terminated NDCs, new product launches, new NDCs).
- The format for the reporting of ceiling price data (to minimize the burden on manufacturers, BIO continues to advocate for the use of data elements and submission formats that mirror those used in the MDRP context[31]).
- Whether "AMP" refers to quarterly or monthly AMP (BIO continues to urge HRSA to clarify that it refers to quarterly AMP).
- How manufacturers and HRSA will handle sub-ceiling pricing.
- Proposed processes for reconciling any differences in the ceiling price HRSA derives against that submitted by manufacturers.
- How the original and restated ceiling price/URA will be recorded.
- To the extent that HRSA relies, to any extent, on the CMS-calculated URA—which we continue to note is not the official URA for purposes of the MDRP—how HRSA will address 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).
- How HRSA will ensure the confidentiality of the highly sensitive and proprietary pricing data reported by manufacturers to HRSA, and ensure that any confidential disclosures of ceiling prices conform strictly to all of the safeguards set forth in the 340B statute and other applicable law (BIO strongly urges HRSA to review BIO's comments, submitted to the Agency on November 14, 2014, which outline critical recommendations in this regard[32]).
- How HRSA will ensure that the ceiling price data are available only to covered entities currently enrolled in the program and will be protected from unauthorized re-disclosure. Terminated covered entities should not have access to these data once terminated from the program.

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[30] We note that there are 60 days between when the MDRP quarterly numbers are calculated and when those numbers go into effect as the 340B "ceiling 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.

[31] 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 ten 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 ten hours were HRSA to employ the same format.

[32] See BIO Comments in Response to *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* (Nov. 14, 2014), https://www.bio.org/sites/default/files/FINAL%20BIO%20Comments%20on%20HRSA%20Notice%2011_14_14.pdf.

- Which quarters of ceiling price data will be made available and when (BIO continues to urge HRSA to ensure that covered entities only have access to these data for the quarters and years in which they are participating in the program).
- How HRSA will provide appropriate context with respect to the ceiling price data shared with covered entities (e.g., to make clear that the prices do not reflect wholesaler markups) in order to minimize the potential for disputes. Along these lines, we urge HRSA to incorporate a new data element regarding "orphan" status, as well as a disclaimer that manufacturers are not required to extend 340B ceiling prices on such orphan drugs to the eligibility categories added by the ACA.
- The applicable record retention period (BIO supports the five-year record-retention period for manufacturers proposed in HRSA's recent "340B Drug Pricing Program Omnibus Guidance" proposed Notice,[33] but continues to urge the Agency to implement this requirement by amending the PPA).

We therefore strongly urge HRSA to delay the implementation of the requirement to report ceiling price data to HRSA until guidance is issued in each of these areas. In issuing such guidance, we strongly urge HRSA to take steps to ensure that the guidance imposes as little burden as possible on manufacturers and other 340B Program participants. We also urge the Agency to provide ample public notice and opportunity to comment before implementing any such guidance.

V. HRSA Should Substantially Increase Its Proposed Burden Estimate, Which Does Not Take Into Account Activities Clearly Identified in the PRA's Definition of "Burden."

In the Proposed ICR, HRSA claims that "[t]he burden imposed on manufacturers by the proposed requirement of the PPA is minimal because the addendum does not impose requirements beyond review and a signature by the manufacturer."[34] We disagree.

As noted in prior BIO comments,[35] as well as earlier in this letter, the two provisions of the 340B statute that HRSA proposes adding to the PPA are currently not binding on manufacturers. While we agree that the actual signature of the proposed addendum and its transmission to HRSA might impose a burden as low as 30 minutes per manufacturer, for purposes of the PRA, an estimated "burden" must reflect all of the activities associated not only with "complet[ing] and review[ing] the collection of information" and "transmit[ing] or otherwise disclos[ing] the information," but also the time needed to

[33] 80 Fed. Reg. 52,300, 52,311 (Aug. 28, 2015).
[34] 80 Fed. Reg. at 63,560.
[35] See BIO Comments in Response to *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* (Nov. 14, 2014), https://www.bio.org/sites/default/files/FINAL%20BIO%20Comments%20on%20HRSA%20Notice%2011_14_14.pdf; BIO comments in response to *340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation* [RIN 0906-AA89] Proposed Rule (Aug. 17, 2015), https://www.bio.org/sites/default/files/FINAL%20BIO%20Comments%20on%20CMP%20&%20Ceiling%20Price%20Rule%208_17_15_0.pdf; BIO Comments in Response to *340B Drug Pricing Program Omnibus Guidance* [RIN-9096-AB08] (Oct. 28, 2015), https://www.bio.org/advocacy/letters/bio-submits-comments-re-340b-mega-guidance.

review instructions and implement mechanisms to ensure compliance with any new requirements.

Specifically, as HRSA recognizes in the Proposed ICR, under the PRA, the term "burden" is defined as:[36]

> the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information.

The time it will take manufacturers to undertake steps—including to ensure that technology systems, company training programs, and data sources are compliant with the two new requirements—clearly is not reflected in the mere 30-minute estimate outlined in the Proposed ICR.

To illustrate, as articulated in prior BIO comments,[37] manufacturers will need to take preparatory actions prior to the first quarterly report of ceiling price data, and likely would not sign an agreement requiring them to report these data prior to implementing these steps. For instance, it will be necessary for manufacturers to review the new requirements (e.g., the Proposed ICR, the proposed addendum, the applicable provisions of the 340B statute, HRSA's existing and yet-to-be-issued 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. These burdens would be greater to the extent that the reporting format does not align with that used for purposes of the Medicaid Drug Rebate DDR, which would necessitate all manufacturers to invest in modifying their current system to comply with the reporting requirements. These are the types of activities that the PRA requires to be incorporated into an agency's burden estimate, as noted above. Yet, it is clear that HRSA's 30-minute burden estimate does not take this time into account. These burdens similarly were grossly underestimated in

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[36] 80 Fed. Reg. at 63,560. See also 5 C.F.R. § 1320.3(b)(1); 44 U.S.C. § 3502(2).

[37] See BIO Comments in Response to *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* (Nov. 14, 2014), https://www.bio.org/sites/default/files/FINAL%20BIO%20Comments%20on%20HRSA%20Notice%2011_14_14.pdf; BIO Comments in Response to *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 Ceiling Price Calculations* (May 21, 2015), https://www.bio.org/sites/default/files/FINAL%20BIO%20Comments%20to%20OIRA%20on%20HRSA%20Notice%205_21_15%20(Combined).pdf; BIO comments in response to *340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation* [RIN 0906-AA89] Proposed Rule (Aug. 17, 2015), https://www.bio.org/sites/default/files/FINAL%20BIO%20Comments%20on%20CMP%20&%20Ceiling%20Price%20Rule%208_17_15_0.pdf.

calculating the burden estimates outlined in the two *Federal Register* notices related to the Ceiling Price Information Collection.

We further note that this burden would be increased to the extent that manufacturers were required to implement these processes while there remain unresolved questions regarding the underlying ceiling price calculation and ceiling price verification process, some of which are outlined in section (IV), above. Specifically, if these questions remain unresolved, manufacturers may not only spend unnecessary time in both preparing to provide and actually providing the required data (e.g., unnecessarily accounting for multiple possibilities and/or wasted time on false starts), but there also is an increased likelihood of disconnects between the ceiling price data a manufacturer submits and HRSA's thoughts as to what the price should be, which will lead to disputes. These disputes will undoubtedly increase the level of burden for both parties, and similarly are not reflected in the 30-minute estimate outlined in the Proposed ICR.

In light of the foregoing, we strongly urge HRSA to substantially increase the estimated burden of compliance with the Proposed ICR, to include the time it will take manufacturers to prepare for their new price reporting obligations, which are new requirements that heretofore have not been recognized in any burden estimates released by the Agency.

VI. Conclusion

BIO appreciates the opportunity to comment on the Proposed ICR. We hope that the Agency finds this letter to be constructive in the process of amending the PPA to implement changes directed by the ACA. 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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