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December 1, 2014

BY EMAIL (paperwork@hrsa.gov)

CDR Krista Pedley
Director, HRSA Office of Pharmacy Affairs
5600 Fishers Lane, Room 8W10
Rockville, Maryland 20857

Re: Information Collection Request Title: 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 CDR Pedley:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to comment on the notice published by the Health Resources and Services Administration (HRSA) regarding its proposed 340B information collection request.[1] PhRMA is a voluntary, non-profit organization representing the nation's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. We have comments on a number of issues raised by the notice, and we look forward to further dialogue with HRSA on these issues. PhRMA and its member companies are committed to ensuring that HRSA has the data it needs to carry out its responsibilities under the 340B law properly and we look forward to working with you to achieve that objective.

* * * *

I. The Proposed Data Collection is Premature Because HRSA Has Not Yet Developed and Issued a Methodology for Calculating Ceiling Prices

HRSA is proposing to collect certain data elements from manufacturers on a quarterly basis (i.e., average manufacturer prices, unit rebate amounts, package sizes, National Drug Codes, and manufacturer-determined ceiling prices) in order to compare HRSA-calculated ceiling prices with those calculated by manufacturers.[2] As a threshold matter, HRSA's data collection proposal is premature, because HRSA has not yet developed a precise methodology for calculating 340B ceiling prices. Manufacturers would need detailed guidance before the ceiling prices were submitted and made available to covered entities via the

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1 79 Fed. Reg. 58791 (Sept. 30, 2014).

2 79 Fed. Reg. at 58792.

password-protected mechanism. The detailed guidance is important and should come before submission and publication of the prices.

The Public Health Service Act (PHSA) requires HRSA to "verify the accuracy of ceiling prices calculated by manufacturers,"[3] and only permits HRSA to disclose to covered entities ceiling prices "calculated and verified by the Secretary."[4] However, HRSA cannot "verify" ceiling prices until it develops -- as required by the 340B statute -- a "policy or regulatory issuance [with] precisely defined standards and methodology for the calculation of ceiling prices."[5] The OIG previously has emphasized the substantial risks of error associated with calculating ceiling prices without the benefit of detailed written guidance.[6]

On its face, the 340B ceiling price calculation looks relatively straightforward; however, in the past, one obstacle hindering HHS' efforts to calculate accurate 340B ceiling prices has been determining the correct package size and unit of measure information to use in converting the per-unit ceiling price to an NDC-11 level ceiling price.[7] Perhaps because the package size information manufacturers report to CMS is not necessarily what HRSA needs to calculate the NDC-11 level 340B ceiling price,[8] HRSA apparently obtains package size data from commercial sources.[9] How HRSA is using this commercial data, whether the data

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3 PHSA § 340B(d)(1)(B)(i).

4 PHSA § 340B(d)(1)(B)(iii) (emphasis added).

5 PHSA § 340B(d)(1)(B)(i)(I).

6 See, e.g., HHS OIG, Deficiencies in the Oversight of the 340B Drug Pricing Program, OEI-05-02-00072 (Oct. 2005) at 12 ("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").

7 HHS OIG, Deficiencies in the Oversight of the 340B Drug Pricing Program at 13 ("Due to the absence of established procedures, the 340B ceiling price was calculated using incorrect package size information.") See also HHS OIG, Review of 340B Prices, OEI-05-02-00073 (July 2006) at 8 (" we discovered disparities between CMS and pharmaceutical industry standards for describing a drug's unit of measure and package size, which led to incorrect HRSA 340B ceiling prices for certain drugs").

8 The data elements reported in Medicaid rebate submissions include "units per package size" (UPPS, the "total number of units in the smallest dispensable amount for the 11-digit NDC"); "package size code" (the last two digits of the 11-digit NDC); and "unit type" (cap, gram, ml, etc.). See Data Definitions for CMS-367a, CMS-367b, and CMS-367c; CMS Record Specification, DDR Quarterly Pricing Data, Text File for Transfer to CMS. The number of units in the NDC-11 (which presumably is what HRSA wants) cannot necessarily be determined from these data elements, because CMS guidance instructs that "[w]here the number of units in the package size is such that the pharmacist is not expected to routinely dispense the entire package to the retail customer (a breakable quantity), the appropriate entry in the UPPS field is '1'"; e.g., if "[t]he unit type is a tablet, the package holds 500 tablets and the usual quantity prescribed by the doctor and dispensed by the pharmacist is fewer than 500 tablets," then "[t]he UPPS entry should be '1.'" Medicaid Rebate Release No. 82 (Nov. 1, 2010) at 2. In this scenario, HRSA could not calculate the 340B ceiling price for the 500-tablet NDC-11 by multiplying the per-unit ceiling price by the UPPS, because the UPPS is 1 whereas the number of units in the NDC-11 is 500.

9 79 Fed. Reg. at 58792; see, e.g., HHS Office of Inspector General (OIG), Review of 340B Prices, OEI-05-02-00073 (July 2006) at 3-4: "To calculate 340B ceiling prices, HRSA receives the AMP and URA from CMS each

[Footnote continued on next page]

is complete, and whether its use consistently yields accurate results will remain unclear until HRSA issues a proposal fully explaining its methodology.[10]

PhRMA believes that HRSA must develop a solution to these challenges before it can calculate and verify 340B ceiling prices. We look forward to providing comments on a proposed ceiling price calculation methodology and we would be glad to provide information on technical issues associated with these calculations at any time if that would be useful.

II. The Pharmaceutical Pricing Agreement Must Be Amended Before Requiring that Manufacturers Furnish Ceiling Prices

Section 340B(a)(1) of the PHSA provides in pertinent part that "each [PPA] shall require that the manufacturer 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 in this section as the 'ceiling price') . . . ." (Emphasis added.) Therefore, the 340B statute requires that manufacturers report ceiling price data to HRSA once the PPA is amended to impose such a requirement, which has not yet occurred. We believe that HRSA must amend the PPA before it may impose this data collection requirement on manufacturers.

III. The Proposed Data Collection Goes Beyond the Statutory Data Collection Requirements

PHSA § 340B(d)(1)(B)(i) requires HRSA to develop a system "to verify the accuracy of ceiling prices calculated by manufacturers under subsection [340B](a)(1) and charged to covered entities," which shall include, among other things, "comparing regularly the ceiling prices calculated by the Secretary with the quarterly pricing data that is reported by manufacturers to the Secretary."[11] In the notice, HRSA states that "to implement Section 340B(d)(1)(B)(i)(II), HRSA has already developed a system to prospectively calculate 340B ceiling prices from data obtained from the Centers for Medicare and Medicaid Services as

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[Footnote continued from previous page]
quarter under the terms of an Intra-Agency Agreement. . . . CMS receives the manufacturers' pricing data for the Medicaid drug rebate program and calculates a URA. Under a separate contract, HRSA obtains the package size information needed to calculate 340B ceiling prices from First DataBank (FDB), a contracted provider of drug product information. HRSA assumed responsibility for calculating the 340B ceiling price in October 2005. Previous to this, CMS had calculated the 340B ceiling price and transmitted it to HRSA.".

[10] HHS OIG, Deficiencies in the Oversight of the 340B Drug Pricing Program, OEI-05-02-00072 (Oct. 2005) at 14 ("Our review of FDA and First Databank package size data, which are both reported by manufacturers, yielded marked discrepancies that raise questions about potential problems with the general consistency and reliability of manufacturers' package size reporting"). See also HHS OIG, Review of 340B Prices, OEI-05-02-00073 (July 2006) at 23 (" the prices are incorrect for certain products for which CMS and NCPDP have divergent standards for defining a unit or package. Until these unit of measure and package size issues are resolved, HRSA will continue to incorrectly calculate the 340B ceiling price for certain drugs").

[11] PHSA § 340B(d)(1)(B)(i) (quoted in 79 Fed. Reg. at 58792) (emphasis added).

well as OPA-identified commercial databases," but "to conduct the comparison, HRSA must require manufacturers to submit the [following] quarterly pricing data": Average Manufacturer Price (AMP), Unit Rebate Amount (URA), Package Sizes, National Drug Code (NDC), and manufacturer-determined ceiling price, for each product subject to a PPA.[12]

As noted above, however, PHSA § 340B(a)(1) provides that the PPA shall require manufacturers to submit ceiling prices; there is no requirement to report AMPs, URAs, or Package Sizes (NDCs are not referenced explicitly in § 340B(a)(1), but presumably would be needed to report the ceiling price "for each covered outpatient drug subject to [the PPA]"). Therefore the proposed data collection would go beyond the statutory data collection provisions, which hinge on amendment of the PPA and only involve the collection of ceiling prices.

IV. The Proposed Data Collection is Unnecessary, Duplicative, and Unduly Burdensome

Pursuant to the Paperwork Reduction Act,[13] prior to approving a proposed collection of information, the Office of Management and Budget (OMB) must determine whether the collection is "necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility"; if OMB determines that an information collection "is unnecessary for any reason, the agency may not engage in the collection of information."[14] Further, the Paperwork Reduction Act and its implementing regulations provide that agencies must certify that each proposed information collection submitted "is not unnecessarily duplicative of information otherwise reasonably accessible to the agency,"[15] and "[r]educes to the extent practicable and appropriate the burden on [respondents]."[16] HRSA's proposed information collection appears to be almost wholly unnecessary and thus to run afoul of these statutory and regulatory requirements.

Assuming that HRSA needs information on AMPs, URAs, or package sizes, (notwithstanding the fact that the 340B law does not authorize HRSA to require that manufacturers submit this information), collection of this information would still be unnecessary, because HRSA could more easily obtain this data from CMS. Moreover, HRSA already may be obtaining AMP and URA data from CMS, since its notice states that HRSA "has already developed a system to prospectively calculate 340B ceiling prices from data obtained from [CMS] as well as OPA identified commercial databases,"[17] and the HHS Office of Inspector General (OIG) has reported that (at least as of 2005-2006) HRSA was receiving AMP and URA data from CMS (and

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12 79 Fed. Reg. at 58792.

13 44 U.S.C. §§ 3501 et seq.

14 44 U.S.C. § 3508.

15 44 U.S.C. § 3506(c)(3)(B); 5 C.F.R. § 1320.9(b) (emphasis added).

16 5 C.F.R. § 1320.9(c).

17 79 Fed. Reg. at 58792.

obtaining package size data from a vendor).[18] While HRSA states that "to conduct the [ceiling price] comparison, HRSA must require manufacturers to submit the [various data elements requested]," PhRMA believes that this statement is incorrect because all HRSA needs to do is compare its calculated ceiling price -- apparently the AMP minus the URA it obtains from CMS (multiplied by validated package size data obtained from commercial databases, to obtain an NDC-11 level ceiling price) -- with a ceiling price reported by the manufacturer.

Therefore, it appears that HRSA already has access to the data it is proposing to collect from manufacturers, with the sole exception of ceiling prices. Accordingly, PhRMA believes that the scope of the proposed collection is unnecessary, and not permissible under the Paperwork Reduction Act.

V. HRSA Should Specify How It Intends to Comply with Applicable Security and Confidentiality Requirements Concerning Ceiling Prices

Any manufacturer pricing data that HRSA obtains from manufacturers or from CMS must be treated as proprietary and all applicable confidentiality requirements observed. According to HRSA's notice, "HRSA has developed a mechanism for secure manufacturer submissions" and "[o]nce any discrepancies between manufacturer and OPA-calculated prices have been resolved, the validated prices will be made available to registered covered entities via a secure Internet-accessible platform as required by [PHSA] Section 340B(d)(1)(B)(iii)."[19] We appreciate HRSA's recognition of the commercially sensitive nature of this pricing information and the confidentiality and security requirements that attach to it. HRSA has not yet provided any specifics concerning the mechanism for secure manufacturer submissions, however, nor has HRSA provided any details explaining how it intends to safeguard the data to ensure that any disclosures of HHS-verified ceiling prices (the one and only data point that potentially can be disclosed by HRSA) made under PHSA § 340B(d)(1)(B)(iii) conform strictly with all of the safeguards set forth in that provision.[20]

In addition, we urge HRSA to specify precisely what information it will make available, and to whom. Specifically, HRSA should clarify that, consistent with the statute, only "ceiling prices . . . as calculated and verified by the Secretary" will be made accessible via the secured website using a method such as

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18 See footnote 9, supra.

19 79 Fed. Reg. at 58792.

20 In addition to the confidentiality and security requirements in PHSA § 340B(d)(1)(B)(iii), other confidentiality provisions apply to this pricing information. The Trade Secrets Act 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. Information protected by the Trade Secrets Act is exempt from disclosure under the Freedom of Information Act (FOIA) under FOIA exemption four. See, e.g., CNA Fin. Corp. v. Donovan, 830 F.2d 1132, 1151-52 (D.C. Cir. 1987) (the Trade Secrets Act is "at least coextensive" with FOIA exemption four). 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).

password protection "that limits such access to covered entities and adequately assures security and protection of privileged pricing data from unauthorized re-disclosure."[21] This means that even under a password-protected system: (1) only verified ceiling prices can be made available to covered entities -- AMP and URA data should not be disclosed to covered entities (or any other entity); and (2) covered entities must be precluded from re-disclosing the ceiling prices (including to the 340B prime vendor, contract pharmacies, third party administrators, or any other entity). It is critically important that HRSA maintain the security and confidentiality of any data collected from manufacturers. We are concerned that if any information beyond ceiling prices is disclosed, or if ceiling price information is disclosed more broadly from what the law permits, the risk increases that someone could reverse engineer manufacturers' best commercial pricing. Exposure of such sensitive data would cause commercial harm to manufacturers and undercut competition.

Given the lack of specifics about these issues in HRSA's notice, PhRMA urges HRSA to release a revised information collection proposal that explains the specific safeguards it plans to adopt in order to assure compliance with the applicable security and confidentiality requirements, and to invite manufacturers to comment on the substantive aspects of the data collection and burden in response to the revised proposal.

VI. The Proposed Data Collection Lacks Sufficient Detail for Manufacturers to Evaluate the Burden

HRSA states that the burden on manufacturers to provide the requested information "is low because the information requested is readily available."[22] However, the proposed information collection notice does not provide enough information to allow manufacturers to evaluate the burden of the proposed collection with reasonable confidence; too many important variables are unknown at this point. For example, the notice does not specify whether manufacturers would submit their data through a web interface like the Drug Data Reporting (DDR) system used for Medicaid rebate reporting, on a disk, on paper, or through another process. In addition, the timing of data submissions -- i.e., when the data from a particular quarter's sales would be due to HRSA -- is another key issue not addressed in the notice that will affect the information collection burden. Only when these and other issues are specified will manufacturers (and HRSA) be able to estimate the burden on manufacturers of submitting the information to HRSA (with additional data elements manufacturers currently do not report to any agency).

VII. Information on Whether the Proposed Information Collection Request Would Be Mandatory or Voluntary After Finalization

Under the Paperwork Reduction Act, agency information collection requests must inform the parties from whom information is being collected "whether responses to the collection of information are voluntary,

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21 PHSA § 340B(d)(1)(B)(iii) (emphasis added.)

22 79 Fed. Reg. at 58792.

required to obtain a benefit, or mandatory."[23] This information was not provided in the proposed information collection, and we ask that HRSA provide its position on this issue.

* * *

PhRMA appreciates HRSA's consideration of our comments. We hope our comments are useful to HRSA, and we look forward to further discussion on these issues. If you have any questions, please contact us.

Sincerely,

Maya J. Bermingham
Vice President, Law and Senior Counsel for Federal Programs

[23] 44 U.S.C. § 3506(c)(1)(B)(iii)(IV).

COMPLIANCE
IMPLEMENTATION
SERVICES

November 26, 2014

VIA ELECTRONIC MAIL

Compliance Implementation Services, LLC
3809 West Chester Pike
Suite 100
Newtown Square, PA 19073

HRSA Information Collection Clearance Officer
5600 Fishers Lane
Parklawn Building, Room 10C-03
Rockville, MD 20857

RE: Agency Information Collection Activities: Proposed Collection: Comment Request

To Whom It May Concern:

Compliance Implementation Services, LLC (CIS) is a life sciences consulting firm that was built upon specialized legal and regulatory knowledge, focusing on implementing strategies addressing those requirements with the greatest impact on industry-specific operations. Our service offering includes a strong focus on assisting pharmaceutical manufacturers with their Government Programs Compliance, including Medicaid and the Public Health Service (PHS) Programs. Our consultative and operational support services include helping manufacturers develop or evaluate Average Manufacturer Price methodologies and calculations, as well as calculating the PHS Ceiling Price. CIS has reviewed the Proposed Information Collection Request (referred to herein as the "ICR") that pertains to the 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 and submits the following comments.

1. **The necessity and utility of the proposed information collection for the proper performance of the agency's functions;**

Section 340B(d)(1)(B)(i) of the PHS Act requires the development of system that can be used by HRSA to validate and verify the accuracy of ceiling prices calculated by manufacturers. In the proposed ICR, HRSA states that it has *"…already developed a system to prospectively calculate 340B ceiling prices from data obtained from the Centers for Medicare and Medicaid Services (CMS) as well as Office of Pharmacy Affairs (OPA)-identified databases.*" To support this system and establish the comparisons, HRSA must require manufacturers to submit

the Average Manufacturer Price (AMP), Unit Rebate Amount (URA), Package Sizes, National Drug Code (NDC) and manufacturer-determined 340B Ceiling Prices for each product subject to the Pharmaceutical Pricing Agreement (PPA). HRSA states that the data will be used to identify discrepancies between the manufacturer-determined and OPA-calculated ceiling prices and provide registered covered entities with the validated prices.

CIS acknowledges the necessity of the proposed ICR to fulfill section 340B(d)(1)(B)(i) of the PHS Act. As noted, the creation of a system that is able to verify ceiling prices calculated by Manufacturers against ceiling prices calculated by HRSA will assure that covered entities will have access to drugs under 340B drug pricing program at the statutorily defined ceiling prices. CIS believes that the systemization, standardization, and verification of price submission for manufacturers, as well as a centralized system for covered entities to access pricing, supports the overall goal of ensuring that covered entities and eligible patients are able to access drugs at accurate prices. However, CIS believes that HRSA must provide additional detail and clarification regarding the on-going operational and administrative burdens of ensuring the system's accuracy, timeliness, and additional on-going administrative burden on all parties involved.

2. The accuracy of the estimated burden;

In the proposed ICR, HRSA proposes an annual burden of 2,400 hours across 600 manufacturers for the submission of data to HRSA's system. The total annual burden translates to two (2) burden hours per manufacturer for four (4) responses per respondent or, if reporting is required quarterly, 0.50 hours per quarter per submission.

HRSA further qualifies the annual burden expended by the manufacturer to include *"…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."* HRSA further states that burden imposed on manufacturers is low as the information requested is readily available and already being reported by manufacturers to CMS.

- **CIS requests HRSA to clarify the methodology and scope of the estimated Annual Burden**

CIS requests HRSA to further expand on the methodology used to estimate the annual burden. Based on industry experience, CIS believes that the annual burden of two (2) hours will not be sufficient to cover all the common procedures a manufacturer performs to accurately satisfy the reporting requirements.

In particular, CIS notes that this burden is insufficient for the implementation year of the additional reporting requirement. If a manufacturer's current reporting system is not able to meet the HRSA-defined data

format for reporting, the estimated annual burden will not cover the resource time associated with the acquisition and implementation of an additional system. For manufacturers with an implemented reporting system, the estimated burden will not cover the resource time associated with system upgrades or development of additional reports, as well as the validation of initial results, user-acceptance testing, and training. Furthermore, the resource time will not be sufficient for updating and documenting processes and procedures associated with the reporting requirement. The burden will not be sufficient to provide the necessary training to personnel on HRSA's system of reporting.

CIS notes that the burden is insufficient to cover the resource time for the subsequent years (post implementation year) associated with potential pricing restatements due to routine administrative and operational processes. Pricing restatements are fairly routine and can be driven by a number of factors such as administrative updates due to class of trade assignments, reconciliation of lagged transactions, and methodology changes for any given time period in a year.

Any type of administrative update, methodology change, or consideration of lagged data that results in a material effect on a manufacturer's reported AMP and/or URA will force a manufacturer with the need to restate previously reported pricing. As the ceiling price is dependent on a manufacturer's AMP and URA, resource time associated to the communication of these updates and restatements must be captured in the scope of the estimated annual burden.

3. Ways to enhance the quality, utility, and clarity of the information to be collected; and

CIS requests HRSA to further provide further clarification on prospective reporting requirements such as the timing expectations of submissions. If manufacturers are required to provide pricing to CMS on a quarterly basis, CIS requests HRSA to clarify the expectations regarding manufacturer submissions as well as guidelines on potential restatements.

- **Clarification on prospective reporting requirements and potential restatements**

Currently, a product's AMP, BP, and URA are calculated using the pricing data for the calculation calendar quarter. However, the resulting pricing elements will be used to calculate the ceiling price that will be in effect two calendar quarters following the calculation quarter calendar close (i.e. ceiling price calculated in 2014Q4 will be in effect for 2015Q2). In light of this lag between the calculation quarter and the effective quarter, HRSA must clarify the timing expectations of quarterly submissions. If a manufacturer is expected to report pricing data in the same manner it reports to CMS (based on the calculation quarter), HRSA must provide further reasonable assumptions regarding consequences associated with late submissions, non-reporting, or potential restatements prior to the quarter the ceiling price becomes effective.

CIS request HRSA to define the guidelines regarding restatements and historical edits of prior period submitted pricing. As mentioned in earlier sections, a manufacturer may need to restate reported pricing due, but not limited to, administrative updates, reconciliation of lagged transactions (which could result in a Medicaid Best Price "true up), and methodology changes that may trigger a material change to a manufacturer's historically reported URA and/or AMP. As the ceiling price is dependent on a manufacturer's AMP and URA, HRSA must provide guidance, such as limitations and restrictions, on the process and expectations for manufacturers to report restated pricing through an automated system.

HRSA has stated that the system will also be used to provide validated pricing to covered entities via a secure Internet-accessible platform. Currently, manufacturers provide ceiling prices to wholesalers prior to a product ceiling price's effective quarter so that covered entities are able to make purchases using the effective ceiling price. However, as these prices will now be made available to covered entities using the internet-accessible platform, HRSA must provide additional guidance on the necessity of a manufacturer providing a product's ceiling prices to wholesalers on a quarterly basis. If HRSA deems this activity still a necessity moving forward, it must provide additional guidance on the timing of submissions to ensure that ceiling prices that covered entities access through the HRSA site are consistent with the prices a manufacturer provides to wholesalers. CIS notes that communication and submission guidelines must be made clear as a variance between the manufacturers' ceiling prices made available to covered entities through the HRSA platform and the ceiling prices made available to covered entities through wholesalers may cause purchases at an inaccurate price.

HRSA must also provide additional guidance on how a manufacturer should report a provisional ceiling price for a new-to-market product. Currently, a manufacturer may estimate a ceiling price using an estimated AMP, BP, and URA that factors weighted discounts and concessions extended in the initial quarter a product is made available to the market. The manufacturer provides this estimated provisional price to wholesalers and HRSA so that the product is available to covered entities at an estimated ceiling price. After the close of the quarter, a manufacturer performs a true-up of the estimated price using actual sales data and communicates the price to covered entities. HRSA must provide guidance on how this process will need to be updated based on the additional reporting requirement and the systemization of submissions.

4. The use of automated collection techniques or other forms of information technology to minimize the information collection burden.

- **Clarification on system access, certification, and designation of submissions**

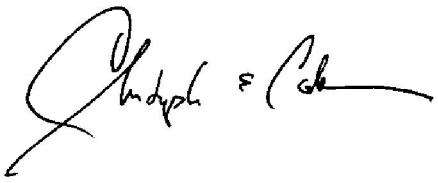
CIS requests HRSA to provide additional guidance on the prospective system controls and parameters regarding designation of submission and system access. If a manufacturer currently outsources government

pricing calculations and submissions, it must be able to provide the same designation and access to the HRSA system. If additional certification of pricing data will be required for pricing, guidelines must be provided regarding who is expected to certify from a manufacturer's perspective.

CIS requests HRSA to provide guidance on the prospective data format requirements and limitations regarding submissions. CIS notes that a system that HRSA uses for submissions must be standardized to accept common data formats and large submissions. Standard data formats is key in ensuring that manufacturers with large product portfolios are able to submit the required pricing data with comparable ease and resource time as manufacturers with significantly smaller product portfolios.

Thank you for the opportunity to comment on the Proposed ICR. If there are questions regarding these comments please contact Chris Cobourn or Jake Keenan by telephone at 919.463.1990 or via email at chriscobourn@cis-partners.com or jakekeenan@cis-partners.com.

Sincerely,



Chris Cobourn
CIS
SVP, Commercial Compliance

Jake Keenan
CIS
Director, Government Programs Consulting

Baskin, Leah (HRSA)

From: HRSA Paperwork
Sent: Monday, December 01, 2014 5:21 PM
To: Momodu, Lawrence (HRSA)
Cc: Lew, Terrence (HRSA)
Subject: FW: Further Information Request

Within one week, please respond to the request below and copy this mailbox on your reply. Thanks.

From: Jeff Davis [Jeff.Davis@snhpa.org]
Sent: Wednesday, November 26, 2014 2:33 PM
To: HRSA Paperwork
Subject: Further Information Request

I would like to obtain a copy of the data collection plans/draft instrument related to the notice of a proposed information collection published by the Health Resources and Services Administration (HRSA) in the September 30, 2014, Federal Register. The notice was titled, "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." An OMB No. of 0915-0327 is listed.

Thank you very much.

Jeff Davis
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SNHPA
Safety Net Hospitals for Pharmaceutical Access

November 26, 2014

Via Email to paperwork@hrsa.gov and First Class Mail

HRSA Information Collection Clearance Officer
Room 10C–03, Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

Re: Comments on Proposed 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), 79 Fed. Reg. 58791 (Sept. 30, 2014)

To Whom It May Concern:

We are submitting comments on behalf of Safety Net Hospitals for Pharmaceutical Access (SNHPA) in response to the notice published in the Federal Register on September 30, 2014 by the Health Resources and Services Administration (HRSA).[1] SNHPA represents more than 1,000 safety net hospitals that participate in the 340B drug discount program by virtue of serving a disproportionate share of low-income and otherwise vulnerable Americans.

The notice relates to HRSA's plans to implement two program integrity sections of the 340B statute that require HRSA to compare 340B ceiling prices calculated by HRSA to manufacturer-calculated prices and to make validated 340B prices available to covered entities via an Internet website. SNHPA strongly supports HRSA's proposed information collection and applauds HRSA for starting the process of implementing these statutory requirements to help ensure that covered entities are not overcharged for 340B drugs.

We agree with HRSA that it is vital that covered entities be able to confirm that manufacturers are charging the correct 340B prices, given prior evidence of overcharges reported by the HHS Office of the Inspector General (OIG) and the Government Accountability Office (GAO). In 2006, the OIG found that 14 percent of the 340B purchases sampled resulted in overcharges.[2] In

[1] Notice, Agency Information Collection Activities: Proposed Collection: Comment Request, 79 Fed. Reg. 58971 (Sept. 30, 2014).
[2] Department of Health and Human Services OIG, Review of 340B Prices, 11 (July 2006), *available at:* http://oig.hhs.gov/oei/reports/oei-05-02-00073.pdf (last visited Nov. 18, 2014).

addition, a 2011 GAO report noted that potential manufacturer overcharges may be limiting the benefit of the program.[3] Implementation of manufacturer pricing program integrity provisions will help combat this overcharge problem. We submit the following comments to support the proposed information collection and to share our thoughts on how HRSA can implement these provisions effectively and efficiently.

A. SNHPA supports HRSA's proposed collection of drug pricing information

Section (d)(1)(B)(i)(II) of the 340B statute requires the creation of a system to verify the accuracy of 340B ceiling prices that manufacturers calculate and charge to program participants.[4] This includes "comparing regularly the ceiling prices calculated by the Secretary with the quarterly pricing data that is reported by manufacturers to the Secretary."[5] HRSA has proposed collecting the following pricing elements from drug manufacturers: average manufacturer price (AMP), unit rebate amount (URA), package sizes, national drug codes and 340B ceiling prices as calculated by manufacturers.[6] Although manufacturers may already submit some of this data to CMS, a direct collection of this information by HRSA would reduce errors and ensure timely calculations.

HRSA should collect data directly from manufacturers and not rely on CMS data because the OIG has highlighted errors in the data CMS provides to HRSA that prevents HRSA from being able to properly calculate 340B ceiling prices. In 2005, the OIG noted that the pricing information HRSA received from CMS to calculate 340B prices was lacking information for a number of drugs, including the AMP data, which is necessary to calculate a 340B price.[7] The OIG also found that manufacturers may make errors or misrepresent their data.[8] HRSA could ensure it has the information necessary to accurately calculate 340B prices by collecting pricing data directly from manufacturers and enforcing its own reporting requirements.

Also, HRSA should not rely on CMS data because doing so could prevent HRSA from being able to calculate 340B prices in a timely manner. CMS collects manufacturer pricing information for purposes of the Medicaid Drug Rebate Program (MDRP), not the 340B program, and the two programs require information for different reasons. The MDRP involves rebates that are given several weeks or months after a drug's sale. In contrast, the 340B program involves an upfront discount at a drug's point of sale. The OIG noted that for MDRP purposes, late submissions of manufacturer data may not prevent a rebate collection, but they do prevent HRSA from being

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[3] GAO, Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement (Sept.2011) 27, *available at:* http://www.gao.gov/assets/330/323702.pdf (last visited Nov. 18, 2014).
[4] 42 U.S.C. 256b(d)(1)(B)(i)
[5] 42 U.S.C. 256b(d)(1)(B)(i)(II).
[6] 79 Fed. Reg. at 58792.
[7] Deficiencies in the Oversight of the 340B Drug Pricing Program, OIG (Oct. 2005), *available at:* http://oig.hhs.gov/oei/reports/oei-05-02-00072.pdf at 10 (last visited Nov. 26, 2014).
[8] Testimony of Stuart Wright, Deputy Inspector General for Evaluation and Inspections, HHS OIG, House Committee on Energy and Commerce Subcommittee on Oversight and Investigations Hearing at 4 (Dec. 15, 2005), *available at:* https://oig.hhs.gov/testimony/docs/2005/340bHouseE&C12-05.pdf (last visited Nov. 25, 2014).

able to calculate a 340B price in a timely manner.[9] HRSA could ensure the timely calculation of 340B prices by collecting pricing data directly from manufacturers and enforcing timely reporting requirements.

B. SNHPA supports HRSA's efforts to verify 340B ceiling prices and make them available online and offers implementation suggestions

Our members are especially appreciative of HRSA's efforts to implement a 340B price list for covered entities. We often hear from members asking how they can verify whether they are receiving the correct 340B price from a manufacturer. Currently, hospitals have few, if any, resources available to make this determination. An online 340B price list would help these hospitals ensure they are receiving the correct prices. As HRSA works to implement a 340B price list, we ask that HRSA develop a user-friendly system that can be easily accessed by hospital pharmacy directors and their staffs. For example, any 340B price list should be searchable and should include for each drug a National Drug Code, description, name, trade name, generic name, company name, 340B ceiling price, and the time period for which the price applies.

HRSA should also make prices available in real time. This is especially important for new drugs. Covered entities may request refunds from manufacturers if a manufacturer incorrectly estimates the 340B price of a new drug during its first three quarters on the market, but entities must have access to current pricing data to know if the estimated price was incorrect. All refunds must be completed by the end of a new drug's fourth quarter on the market, so a lag time in the price file data could interfere with an entity's ability to request a refund.[10]

* * * *

Thank you for considering our comments. Should you have any questions, please feel free to contact Maureen Testoni at 202-552-5851 or maureen.testoni@snhpa.org or Jeff Davis at 202-552-5867 or jeff.davis@snhpa.org.

Sincerely,

Maureen Testoni
Senior Vice President and General Counsel

Jeff Davis
Counsel, Legal and Policy Affairs

[9] Deficiencies in the Oversight of the 340B Drug Pricing Program, OIG (Oct. 2005), *available at:* http://oig.hhs.gov/oei/reports/oei-05-02-00072.pdf at 10 (last visited Nov. 26, 2014).
[10] Final Notice, Notice Regarding Section 602 of the Veterans Health Care Act of 1992; New Drug Pricing, 60 Fed. Reg. 51488, 51489 (Oct. 2, 1995).

Baskin, Leah (HRSA)

From: HRSA Paperwork
Sent: Monday, December 01, 2014 5:18 PM
To: Momodu, Lawrence (HRSA)
Cc: Lew, Terrence (HRSA)
Subject: FW: Information Collection Request Title: 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

Within one week, please respond to the comment below and copy this mailbox (paperwork@hrsa.gov) on your response. Thanks.

From: Ron.Ritter@cslbehring.com [Ron.Ritter@cslbehring.com]
Sent: Monday, December 01, 2014 11:47 AM
To: HRSA Paperwork
Cc: Frances.Richardson@cslbehring.com
Subject: Information Collection Request Title: 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

Good Morning,

The proposed information collection, while necessary for the agency's functions, can be best collected and utilized from CMS' DDR system. DDR is the system of record for all manufacturer submissions of AMP, Unit Rebate Amount (URA), Package Sizes and National Drug Codes. Because both the industry and HRSA are already familiar with or receive information from DDR, the collection of manufacturer calculated 340b ceiling prices should be incorporated as a function within DDR. This will provide access by HRSA to all data necessary to perform its functions, and one source of manufacturer supplied information.

The burden estimate would be more accurate to reflect two hours per manufacturer administrative change and two hours per manufacturer price submission. The burden estimate should be increased to allow for system access, training, process changes, file formatting, file upload, file upload verification, and certification of prices.

The way to enhance the quality, utility, and clarity of the information to be collected is to rely on the DDR system to continue calculating the URA and collecting AMP, Package Sizes, and National Drug Codes. Additionally, the collection of manufacturer calculated 340b ceiling prices can be enhanced by incorporating functionality within DDR to receive this data.

HRSA should leverage the automated collection techniques and other forms of information technology existing within the DDR system to minimize the information collection burden on manufacturers. The DDR system has the most current information available from manufacturers for AMP, URA, Package Sizes and National Drug Codes. Because manufacturers and HRSA are familiar with DDR and it storing and calculating the most current information, it is to HRSA's advantage to enhance DDR and utilize it as the platform for collecting the manufacturer calculated 340b ceiling prices and other necessary data to perform its functions. Utilizing DDR in this way provides one source for manufacturer supplied data, enhancing the quality utility, and clarity of information and reduces the burden of the information proposed for collection.

Sincerely,

Ron Ritter
Sr. Manager, Government Reporting
CSL Behring Biotherapies for Life™

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November 26, 2014

HRSA Information Collection Clearance Office
Room 10C-03 Parklawn Building
5600 Fishers Lane
Rockville, MD 20857
Delivered Electronically
paperwork@hrsa.gov

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

To whom it may concern:

Novo Nordisk Inc. ("Novo Nordisk") is pleased to submit comments on the Information Collection Request (ICR) *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*. Headquartered in Demark, and with almost 5,000 employees in the U.S., Novo Nordisk is a global health care company with over 90 years of innovation and leadership in diabetes, haemophilia, and growth disorders.

Novo Nordisk is pleased that Health Resources and Services Administration (HRSA) is seeking public comment on: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden; however we believe the proposed reporting will be largely duplicative of existing required reporting to the Centers for Medicare and Medicaid Services (CMS) and that HRSA significantly underestimated the reporting burden posed to manufacturers. Further, we urge HRSA to exercise caution in making verified ceiling prices available to covered entities to ensure that access is limited to appropriate program participants and that no privileged and confidential information, such as average manufacturer price (AMP) is disclosed.

1. Necessity and Utility of the Proposed Information Collection

HRSA proposes collecting Average Manufacturer Price (AMP), Unit Rebate Amount (URA), package sizes, National Drug Code (NDC), and manufacturer-calculated 340B price. Since CMS currently maintains the required data subject of the collection request, the HRSA reporting requirements will result in duplicative reporting for manufacturers, including Novo Nordisk, which already report the required data for covered outpatient drugs to CMS quarterly.

Novo Nordisk appreciates HRSA's need for accurate, timely reporting of key data to verify 340B ceiling price, but questions the need to establish an additional process and distinct collection instruments from those used by CMS. As such, the proposed information collection is 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 citizen. By adding an additional process to report data collected by another agency within the Department of Health and Human Services (HHS) increases paperwork without a commensurate increase in data or information supplied to key agencies and programs.

To simultaneously meet the requirements of the PRA and HRSA's need for timely, accurate data on products subject to a Pharmaceutical Pricing Agreement (PPA), Novo Nordisk suggests that HRSA and CMS use a uniform and unified process for reporting AMP, URA, NDC, package size, and 340B ceiling price.

2. The Accuracy of the Estimated Burden

HRSA has estimated that it would take manufacturers 30 minutes per product per quarter to report the requested pricing information. We believe the suggested 30 minutes is underestimated and not sufficient to accomplish the task due to the calculation, validation, submission and possible reconciliation activities as discussed further below.

The degree to which the HRSA reporting process overlaps or differs from the established CMS Drug Data Reporting (DDR) system will be the main determinate of actual reporting burden. Different submission formats require different preparation and submission times as well as system requirements. For example, the burden to prepare and submit Average Sales Prices (ASP) to CMS vis-à-vis the burden to submit AMPs are different given that the former is through a standard Excel template vs. the latter which is in a "txt" file format that requires further formatting and submitted and certified online via the DDR.

Should HRSA's requirements and format match that already used by CMS, the burden will likely be moderate to low, but the 30 minute per product per quarter estimate does not account for the time of multiple Novo Nordisk employees who will be involved in the process to cross-check and verify data. If there is significant divergence between the established CMS DDR and HRSA's system, Novo Nordisk will need to review HRSA's reporting instructions, update technology systems, incur additional costs associated with implementing and updating reporting systems, update compliance policies and procedures, train personnel, and take other steps to comply with the new reporting obligation, including implementing updates to the submission system if necessary, all of which would significantly increase the time required to fulfil HRSA's reporting requirements. In addition, the process by which HRSA intends to verify 340B ceiling prices and resolve any discrepancies with manufacturers will also increase reporting burden, likely well beyond the estimated 30 minutes as it does not take into account reconciliation activities Novo Nordisk would have to undertake in the event HRSA's ceiling price calculations do not match submitted prices.

3. Ways to Enhance the Quality, Utility, and Clarity of the Information to be Collected

As noted above, Novo Nordisk urges HRSA to implement their data collection process in a way that is consistent with the existing DDR reporting to CMS. As such, we suggest that the deadline for submissions be no earlier than the quarterly AMP reporting deadline. To the extent that the process diverges from that of CMS or additional information is required of manufacturers, Novo Nordisk suggests implementing a due date for submissions no earlier than 15 days after the quarterly AMP reporting deadline to allow sufficient time to prepare and verify data submissions.

In cases that fall outside of normal quarterly reporting for established products such as 340B pricing restatements and submission of Provisional 340B pricing, a different timeline may be necessary. Specifically, the 340B ceiling price is set by the AMP and URA based on a two quarter lag. For example, calculation of the third quarter 340B pricing uses AMP and URA values that were calculated in the first quarter. However, the timing for Provisional Pricing is different (usually submitted and communicated right before product launch) and is based on "estimated" AMP and URA. The notice does not address the process or timing of the submission of Provisional Pricing for new products.

4. Use of Automated Collection Techniques

The notice states that HRSA intends to post validated ceiling prices on a secure Internet-accessible platform made available to registered PHS covered entities. The notice though does not address the handling of sub-ceiling prices through the Prime Vendor (i.e. Apexus). Novo Nordisk recommends that HRSA make available only verified 340B ceiling price information and refrain from including sub-ceiling prices available to covered entities participating in the Prime Vendor Program (PVP).

In terms of the security and protection of the information to be posted online, we emphasize that HRSA is required 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."[1] Novo Nordisk recommends that HRSA ensure the security and protection of pricing data through appropriate safeguards and data integrity protocols. The platform should include only the HRSA-verified ceiling price and not provide information on AMP, which is privileged and confidential as required by law.

Once again, Novo Nordisk appreciates the opportunity to provide input on HRSA's Information Collection Request. We appreciate HRSA's need to have timely, accurate pricing data to facilitate the 340B program. We stress the need to coordinate with CMS to establish a unified, uniform process for collecting the data needed by both agencies. Further, we urge HRSA to coordinate timelines for data submission with those established by CMS to minimize the reporting burden on manufacturers and to ensure the security and integrity of 340B ceiling price data shared with covered entities. If you have questions or need further information related to our comments, please contact Tracy Zvenyach at 202-626-5632 or TRLZ@novonordisk.com

Sincerely,

Farruq Jafery

Farruq Jafery
Vice President - Pricing, Contracts, Operations & Rebates
Novo Nordisk, Inc.

[1] Section 340B(d)(1)(B)(iii), Public Health Service Act

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Johnson & Johnson HEALTH CARE SYSTEMS INC.

December 1, 2014

HRSA Information Collection Clearance Officer,
Room 10C-03, Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

Re: 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 Commander Pedley:

Johnson & Johnson Health Care System, Inc., on behalf of Johnson & Johnson ("J&J"), is pleased to have the opportunity to submit the following consideration in response to the Health Resources and Services Administration's (HRSA's) proposed Information Collection Notice (Notice) entitled "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" notice of the proposed rule with request for comments dated September 23, 2014. HRSA currently proposes collecting Average Manufacturer Price (AMP), Unit Rebate Amount (URA) Packages Sizes, National Drug Code (NDC) and manufacturer's determined 340B ceiling price for each product subject to a Pharmaceutical Pricing Agreement.

The Notice specifically request comments on: 1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions, 2) the accuracy of the estimated burden, 3) ways to enhance the quality, utility, and clarity of the information to be collected, and 4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden. J&J's comments are organized accordingly.

NECESSITY AND UTILITY OF THE PROPOSED INFORMATION COLLECTION FOR THE PROPER PERFORMANCE OF THE AGENCY'S FUNCTIONS

AMP – While we recognize that AMP is a necessary component of the 340B ceiling price calculation, we do not believe it is necessary for HRSA to obtain this data from manufacturers. Manufacturers currently submit and certify monthly and quarterly AMP to the Centers for Medicaid and Medicare Services (CMS) through the Drug Data Reporting System (DDR) system. As this data point is already submitted to the Secretary of Health and Human Services, we do not believe the 340B statute permits HRSA to require a duplicative reporting to the Secretary for purposes of HRSA's 340B ceiling price calculation. Therefore, we would encourage HRSA to obtain the AMP values directly from CMS.

URA - In order to accurately calculate the 340B Ceiling Price, the HRSA will need to obtain URAs directly from the manufacturers. "In accordance with the national rebate agreement, labelers are responsible for calculating URAs. However, Center for Medicaid and Medicare Services (CMS) usually provides States with calculated URAs for use on rebate invoices so that States can verify these URAs with any labeler-adjusted URAs that States may receive."[1] In addition, CMS does not have the ability to accurately calculate URAs for Single Source and Innovator Multi-Source Line Extension (i.e., New Formulations) Drugs in Oral Solid Dosage Forms. Also, in some instances CMS does not calculate all URAs for a given quarter. CMS's DDR System has an edit check that will not calculate URAs if a drug's URA was either 400% higher or lower than the previous quarter's URA (i.e. 400/400 check). For instances where the 400/400 check applies, the DDR System will report a zero URA for the applicable quarter and wait until the next quarter to calculate a URA. For these reasons, it is imperative that HRSA rely on the URAs calculated by the manufacturer.

Package Size – In order to accurately convert Medicaid Unit Pricing to a 340B Ceiling Price at the package level, HRSA will need to obtain package size amounts directly from manufacturers.

NDC – To facilitate the collection and alignment of AMP, URA, and 340B Ceiling Price values, HRSA would need to rely on an NDC list provided by manufacturers. It is important to note that for Medicaid purposes AMP and URA values are reported beyond the last lot expiration but would not necessarily generate a corresponding 340B Ceiling Price.

340B Ceiling Price – We agree with the proposal to submit 340B Ceiling Prices in order to validate manufacturer calculated ceiling prices against HRSA derived prices. We recommend that HRSA specify that reported Ceiling Prices reflect those calculated by manufacturers.

The Notice does not address when the requesting information would be due to HRSA. J&J would recommend the requested data be due 45 days after the CMS quarterly deadline. Forty-five days after the CMS quarterly deadline would enable J&J to calculate URAs, calculate and review 340B Ceiling Pricing, extract the data from the appropriate internal systems, validate the data, format the data, review and approve the data and submit the data to HRSA.

ACCURACY OF THE ESTIMATED BURDEN

According to the Notice, HRSA has estimated that it would take a manufacturer 30 minutes per quarter to report the requested information. The "Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time 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."[2] The burden for the proposed process is directly related to the system / process that is ultimately developed and the level of automation included. With that said, the estimated burden would be in the range of 40 to 80 hours depending on the extent of automation built into the process.

1) CMS Release No. 81, Dated August 11, 2010
2) 2) 79 Fed. Reg. 58,791 (Sept. 30, 2014)

In addition, the Notice does not discuss the reconciliation process back to manufacturers when HRSA's 340B Ceiling Price Calculation does not match the manufacturer's reported 340B Ceiling Price. This reconciliation process has the potential to add significant hours to the manufacturer's process. Given the lack of discussion regarding the reconciliation process, the hours added to the estimated burden are difficult to estimate. Therefore, the hours associated with the reconciliation process are not included in the following estimate.

J&J estimates the total annual burden for the quarterly price submissions to be from 160+ hours to 320+ hours and reflects the volume of J&J NDCs eligible for 340B Ceiling Price reporting. The ICR does not address the burden hours associated with any back-end reconciliation process in the event HRSA's ceiling price calculation does not match the manufacturer's calculation. This process has the potential to add to the total burden hours and is not reflected in the estimate provided.

WAYS TO ENHANCE THE QUALITY, UTILITY AND CLARITY OF THE INFORMATION TO BE COLLECTED

In order to accurately capture the required information and minimize potential timing issues, we recommend incorporating some additional data fields; the applicable reporting period for AMP, the applicable reporting period for URA, the effective date of the 340B Ceiling Price and the Last Lot Expiration Date. For Medicaid reporting purposes CMS requires AMP and URA values to be reported beyond the last lot expiration date; but since the product is not saleable beyond that date the 340B Ceiling Price is not applicable. In addition, the HRSA system needs to have the ability to accept 340B Ceiling Prices for new products. Due to the timing of Medicaid price reporting manufacturers load NDCs on the 340B Contract prior to the calculation of AMP and URA using a provisional ceiling price which would need to be captured by the HRSA System.

In certain situations manufacturers may choose to offer sub-ceiling 340B pricing. To avoid potential confusion in the marketplace we recommend the HRSA website clearly state that the prices published by HRSA reflect statutory 340B Ceiling Prices. In addition, the Notice also does not address when the 340B Ceiling Prices would be available on the HRSA website. J&J recommends that the data not be published until the effective date of the pricing.

THE USE OF AUTOMATED COLLECTION TECHNIQUES OR OTHER FORMS OF INFORMATION TECHNOLOGY TO MINIMIZE THE INFORMATION COLLECTION BURDEN

CMS's DDR System has strict security protocols in place and a rigorous application process, which includes collecting a user's Social Security Number. This not only limits the access to the site, but also ensures only authorized users have access to the confidential data contained within the DDR System. Given the sensitive nature of the data J&J recommends that HRSA develop rigorous standards and security protocols using the CMS DDR system as a model.

J&J appreciates the opportunity to comment on the proposed Notice and appreciate your attention to these issues. Please feel free to contact us if you have any questions.

Sincerely,

Kenneth H. Nelson
Director, Government Pricing Analytics

cc: Perry Knight, J&J Law Department

November 14, 2014

BY ELECTRONIC DELIVERY

CDR Krista M. Pedley, PharmD, MS, USPHS
Director
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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.

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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.").

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