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BY ELECTRONIC DELIVERY

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

Re: BIO's Comments to Health Resources and Services Administration (HRSA) on Proposed Collection: Drug Pricing Program Reporting Requirements (OMB No. 0915-0176)—Extension

Dear Commander Pedley:

The Biotechnology Industry Organization ("BIO") is pleased to submit the following comments in response to "Proposed Collection: Drug Pricing Program Reporting Requirements (OMB No. 0915-0176)—Extension" (the "Notice") published in the Federal Register by the Office of Pharmacy Affairs ("OPA") within the Health Resources and Services Administration ("HRSA") on October 26, 2012.[1]

BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of health care, agricultural, industrial, and environmental biotechnology products.

As the representative of an industry that is devoted to improving health care through the discovery of new therapies, BIO understands the significance of the 340B drug pricing program in increasing prescription drug access for the low-income uninsured. BIO members include manufacturers that participate in the 340B program, enabling BIO to provide views with respect to HRSA's burden estimates that are based on actual operational experience. BIO believes that information will be useful to OPA in its efforts to ensure the integrity of the 340B program.

As you know, the 340B statutory scheme gives participating manufacturers certain audit rights. BIO and its members place great importance on these oversight rights, but believe such rights only are meaningful if they can be operationalized and actually result in remedial action. With that as context, BIO includes in this letter comments not only on HRSA's burden estimates but also on the audit process more generally and related opportunities for HRSA to make manufacturer audit rights more accessible and effective. We recognize that

[1] 77 Fed. Reg. 65392 (Oct. 26, 2012).

1201 Maryland Avenue SW
Suite 900
Washington DC 20024
202.962.9200 P
202.488.6301 F
bio.org

HRSA may require new or expanded authorities to implement these recommendations and urge you to undertake formal processes (e.g., notice and comment rule-making, a request for congressional action) that meaningfully engage stakeholders to assist you in putting into place a viable audit program. BIO strongly believes that its recommendations set forth below will increase the integrity of the 340B program, thereby ensuring that the 340B program can continue to effectively improve access to vital medications for those patients which the program was originally intended to benefit: the low-income uninsured.

I. HRSA Should Revise its Burden Estimates to Specifically Correspond to Each of the Steps Set Forth in the 1996 Guidelines.

The Notice provides estimates of the burden associated with three items prepared by the manufacturer in connection with a manufacturer audit, namely the "Audit Notification to Entity" (4 hours), the "Audit Workplan" (8 hours) and the "Audit Report" (8 hours). The Notice also lists the estimated burdens associated with the dispute resolution process, namely with respect to the "Mediation Request" (10 hours) and "Rebuttal" (16 hours). The term "burden" is defined as follows in the Notice:

> Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information.[2]

At the outset, we note that manufacturers may only perform a limited number of audit tasks themselves. The final program guidelines concerning manufacturer audit guidelines and the dispute resolution process, which HRSA published in the Federal Register on December 12, 1996 (the "1996 Guidelines")[3] requires manufacturers to hire an independent public accountant to perform the audit. Thus, in addition to the hours manufacturers must expend to develop and oversee the audit process, they must expend significant funds to hire outside consultants to actually perform the audits.

It is also important to note that the distinct tasks enumerated in the Notice do not correspond to the audit steps and dispute resolution process manufacturers are currently expected to follow, which HRSA published in the 1996 Guidelines.[4] BIO believes that these guidelines can be further improved to better ensure program integrity, however, in its current inquiry, HRSA must request burden information in relation to the same steps and tasks that the agency has defined for those processes for the burden assessment to be valid.

For example, with respect to the "Audit Notification to Entity," the 1996 Guidelines provide that "the manufacturer shall notify the covered entity in writing" of the alleged violation of section 340B, followed by "at least 30 days" during which the manufacturer and the covered entity must "attempt in good faith to resolve the matter."[5] The burden estimate of 4 hours

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[2] Id.
[3] 61 Fed. Reg. 65406 (Dec. 12, 1996).
[4] 61 Fed. Reg. 65406 (Dec. 12, 1996).
[5] Id. at 65410.

set forth in the Notice does not account for the fact that this item actually represents a multi-step process rather than a single act. For that reason, the 4 hour estimate is exceedingly low.

Similarly, the burden estimate of 8 hours associated with the "Audit Workplan" is not aligned with the description of the audit workplan process in the 1996 Guidelines. According to the 1996 Guidelines, the manufacturer must set forth in the audit workplan "a clear description of why it has reasonable cause to believe that a violation of section 340B...has occurred." The audit workplan also must include "sufficient facts and evidence in support" of the manufacturer's belief and describe in detail, among other things, the audit objectives and the tests and procedures to be used to assess the covered entity's system of internal controls. After review of the workplan by HRSA, the manufacturer must "incorporate mutually agreed-upon revisions to the plan," implying a possibly lengthy process of working with HRSA to revise the audit workplan. A burden estimate of 8 hours associated with the "Audit Workplan" is not aligned with the related, multi-step requirements set forth in the 1996 Guidelines.[6]

The burden estimate of 8 hours associated with the "Audit Report" also fails to take into account the requirements set forth in the 1996 Guidelines and, to be adequate, must consider the manufacturer resources expended in conducting the actual audit and developing the audit report. The manufacturer's level of effort associated with overseeing the audit and the creation of the audit report is likely to be high, even where a third party is retained to actually perform the audit.

One BIO member has estimated the cost of an entire audit process of a similar scale, though not directly referencing a 340B covered entity audit, to be approximately $100,000. That amount is notable not only for the level of expense involved, but also because that amount, in many cases, may exceed the amount to be recovered from the errant covered entity. Any remedy that is so expensive that it has the potential to not infrequently exceed the amount to be recovered cannot be viewed as a meaningful opportunity for restitution or a reasonable compliance control. This amount is also notable, of course, because it far exceeds, by orders of magnitude, HRSA's burden estimates.

The burden estimates of 10 hours associated with a "Mediation Request" and of 16 hours associated with a "Rebuttal" are similarly incompatible with the requirements of the 1996 Guidelines. The initial request must set forth "specific facts showing that there is a genuine and substantial issue of material fact in dispute." The request for review must include "documentation supporting the party's position." In addition, the manufacturer must "maintain written documentation as evidence of the good faith attempt to resolve the dispute," including "documentation of meetings, letters, or telephone calls" between the disputing parties.[7]

In light of the significant discrepancies between the burden estimates set forth in the Notice and the actual component activities required under HRSA's audit guidelines and dispute resolution process, BIO recommends that HRSA specify in any final burden estimate each of the steps proposed in the 1996 Guidelines. Further, in the many steps and detailed requirements they enumerate, the 1996 Guidelines themselves clearly suggest a significantly greater burden associated with the audit steps and the dispute resolution process than accounted for by the Notice. For example, the 1996 Guidelines enumerate

[6] Id.
[7] Id. at 65412.

eight detailed suggested audit steps, beginning with a review of the covered entity's "policies and procedures regarding the procurement, inventory, distribution, dispensing, and billing for covered outpatient drugs" and concluding with an oral briefing of the audit findings to the covered entity following completion of the audit. [8] BIO believes that it would be possible for HRSA to provide more realistic burden estimates if a separate estimate were provided for each of the steps set forth in the 1996 Guidelines in any final notice.

In the following sections, BIO identifies and recommends several aspects of the audit and dispute resolution process that must be improved to ensure robust program integrity so that the 340B program serves the low-income uninsured patients it was meant to serve. BIO urges HRSA to pursue appropriate rulemaking processes (e.g., notice and comment rulemaking, a request for congressional action) to obtain any new or expanded authorities that may be required to undertake the recommendations made in the subsequent sections.

II. Lack of Clarity on the Definition of an Eligible Patient Increases the Program Integrity Burden of Manufacturers.

The statute permits manufacturers to audit 340B covered entities only for violations of the statutory prohibitions against diversion and duplicate discounts. The determination of when diversion has occurred, therefore, is directly dependent on the clarity of the definition of an eligible 340B patient. There is a dearth of clarity from HRSA on this topic. The absence of guidance affirmatively hinders manufacturers in their determination of when to engage in an audit.

BIO therefore recommends that HRSA provide—through notice and comment rulemaking—updated, specific guidance with respect to key definitional aspects of the 340B program that are much needed in the determination of patient eligibility and whether diversion or claims for duplicate discounts are occurring. A report released in September 2011 by the Government Accountability Office entitled "Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement" supports BIO's recommendation.[9] The report states that "HRSA's guidance on key program requirements often lacks the necessary level of specificity to provide clear direction," which makes it difficult for participants, such as manufacturers, to "monitor others' compliance." The report cites the definition of eligible 340B patient as one example where stakeholders raised concerns that HRSA's too general guidance "will be interpreted too broadly leading to cases of unintended diversion."[10]

BIO previously suggested that HRSA clarify the definition of a "patient" of a covered entity (see the letter from BIO to HRSA dated November 19, 2010 entitled "BIO's comments to Health Resources and Services Administration (HRSA) on dispute resolution authorized in Section 7102 of the Patient Protection and Affordable Care Act"). In connection with HRSA's review of the manufacturers' burden associated with the audit and dispute resolution process, BIO again urges HRSA to issue clarifying guidance through a notice and comment rulemaking process with respect to the definitional aspects of the 340B program that are relevant to the audit and dispute resolution process, thereby reducing the associated burden on manufacturers.

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[8] Id. at 65411.
[9] United States Government Accountability Office, "DRUG PRICING: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement," GAO-11-836, September 2011.
[10] Id. at 22.

III. The Burden on Manufacturers is Increased by Limited or Incomplete Data Available from Covered Entities.

To identify potential diversion or duplicate discounts, manufacturers analyze data from multiple sources and attempt to identify trends and patterns that suggest non-compliant use of the program. For these analytical efforts to be successful, it is critical that the 340B program incorporate data points consistent with other systems so that the data points can be properly aligned and compared. Congress clearly appreciated this need for data clarity when it required the Secretary, under the Patient Protection and Affordable Care Act, to implement several program integrity provisions relating to covered entity data sources and updates to those data sources. The information currently provided by covered entities through the HHS OPA website is too limited to permit manufacturers to effectively monitor the actions of covered entities or, if necessary, to conduct audits of the covered entities. In connection with HRSA's review of the burden associated with the audit process, BIO therefore urges HRSA to make the implementation of the foregoing statutory requirements an immediate priority. Specific instances in which the burden placed on manufacturers could be reduced, thereby increasing the robustness of the overall integrity of the 340B program, are described below.

A. HRSA Should Implement a Mandatory Entity Identifier that is Utilized Across All Types of Data.

Currently, the various data sets available to manufacturers via the OPA website do not employ the same entity identifiers, making it virtually impossible for manufacturers to relate and compare information across various data sets to the same covered entity. Although each covered entity currently is required to maintain a unique 340B identifier, that identifier is utilized only in chargeback data, but not in the other data sets typically available to manufacturers. The lack of a unique entity identifier that is consistent across all types of data greatly increases the burden placed on manufacturers in monitoring the 340B program and increases the likelihood that covered entities can relax their standards without repercussion.

For example, in records relating to expired/returned goods, entities are identified by their Drug Enforcement Administration ("DEA") number. Entities are commonly identified by their DEA number or, alternatively, their Health Industry Number ("HIN") in pharmacy sales data. Records related to outpatient prescription claims utilize yet another identifier, namely an entity's National Provider Identifier ("NPI") number, or the National Council for Prescription Drug Programs ("NCPDP") or National Association of Boards of Pharmacy ("NABP") number or, alternatively, a specific Medicaid ID number. In addition, larger Disproportionate Share Hospitals have access to Group Purchasing Organization ("GPO") contracts, in which case the DEA or HIN number is used to identify GPO chargebacks. However, such organizations frequently "roll up" all of their pharmacy sales data under a single DEA number, serving to essentially anonymize the pharmacy sales data and making it virtually impossible for manufacturers to monitor 340B program activity. The difficulty of connecting covered entity transactions under different identifiers is magnified exponentially for those covered entities that utilize contract pharmacies, as those pharmacies need to be identified and cross-referenced to the covered entity for a manufacturer to effectively monitor diversion and duplicate discounts (discussed in detail below).

B. HRSA Should Require Reporting and Updating of All Entity Identifiers and Include Those Identifiers on the OPA Database.

To date, HRSA, through its recertification efforts, certainly has made efforts to begin the review of the data provided by covered entities via the OPA website. While BIO welcomes those efforts, more oversight is needed. BIO recommends that HRSA introduce additional mandatory data fields that covered entities must provide. BIO recommends that, at a minimum, HRSA require covered entities to provide all of the identifiers discussed above as a condition of registration and then list those identifiers on the OPA database, essentially creating a cross-reference file that can relate these identifiers to an individual covered entity. BIO realizes these efforts may require new or expanded authorities and urge HRSA to engage in formal processes (e.g., notice and comment rulemaking, a request for congressional action) when implementing these recommendations.

These additional fields would include some of the identifiers alluded to above, such as DEA number, HIN number, Pharmacy License Number, pharmacy NPI, pharmacy NCPDP/ NABP and Medicaid ID number, among others. In addition, BIO recommends that HRSA implement a mandatory annual review by covered entities of the data they have provided during the preceding year. The introduction of additional mandatory data fields, together with an annual review requirement, would result in improved data quality without creating additional demands on HRSA's limited resources.

BIO urges HRSA to improve the quality of the data provided by covered entities. Such improved data quality would greatly reduce the burden placed on manufacturers in connection with monitoring 340B program activity.

C. HRSA Should Improve Data Clarity to Mitigate the Increased Risk of Diversion Under the Multiple Contract Pharmacy Network Model.

It is particularly difficult for manufacturers to detect diversion and duplicate discounts when covered entities contract with external pharmacies since 340B and commercial supplies may be co-mingled or maintained "virtually". Compounding that difficulty is the fact that there currently is no mandatory data field that identifies when a 340B claim is filled by a contract pharmacy provider using a commercial or a 340B unit. The lack of such a data field makes it impossible for manufacturers to track and monitor 340B program activity that occurs within the contract pharmacy provider network infrastructure. BIO notes that the NCPDP recently adopted new data standards that provide for a data field that would identify when a pharmacy provider used 340B product to fill a prescription. Unfortunately, that field is not mandatory, and currently is not utilized or supported by 340B contract pharmacy providers. This example highlights the importance of adding required data fields to improve data quality, and BIO urges HRSA to give serious consideration to the implementation of these additional mandatory data fields, in particular, as a condition of participation for contract pharmacies.

IV. High Burden on Manufacturers Places Limits on Manufacturer Audits of Covered Entities.

Beyond the data gathering and definitional needs required to improve the current audit process described in the previous section, HRSA should consider longer-term, fundamental reforms to the process to lessen the high burden on manufacturers that conduct audits of 340B covered entities. As discussed above, the 1996 Guidelines indicate that a prerequisite for an audit of a covered entity by a manufacturer is the submission by such manufacturer

of an audit workplan that sets forth a clear description of why the manufacturer has "reasonable cause to believe" that a violation has occurred, together with "sufficient facts and evidence in support" of the belief. Unfortunately, the unavailability of data, discussed above, coupled with delays of information from covered entities after a manufacturer makes exploratory inquiries, places a significant resource burden on manufacturers. As outlined in the 1996 Guidelines, manufacturers may request data and information from covered entities, and covered entities have certain timeframes in which they must respond. In cases where the covered entity does not respond in a timely manner to requests for audit information, BIO urges HRSA to permit manufacturers to withhold the 340B drug discount until the covered entity demonstrates cooperation with audit processes. Without this currently unavailable recourse, manufacturers face tremendous uncertainties related to the length of time it will take to conduct an audit, which in turn, increases the unpredictability of the total burden estimate.

BIO realizes that many of the above recommendations to improve the audit and dispute resolution process, including establishing an intermediate audit process as set forth in the preceding section, may be significant new methods of enforcing the standards of the 340B program and that the specific mechanisms likely will require further development before a final proposal can be formulated. BIO urges HRSA to pursue formal processes that meaningfully engage stakeholders—for instance, through notice and comment rulemaking, or requesting congressional provision of increased authorities—in undertaking these efforts. However, BIO believes that these provisions, including an intermediate audit process that could be instituted after meeting a less onerous threshold than the completion of the full audit process that is currently required, should be further discussed and given consideration as a possible approach to balancing the burden placed on manufacturers and the importance of ensuring the integrity of the 340B program.

V. Conclusion

BIO appreciates the opportunity to comment on the Notice and the proposed estimates of the burden to manufacturers associated with the audit and dispute resolution process under the 340B program. We hope HRSA finds this letter and BIO's comments, including the more general comments related to the audit process and the associated burden placed on manufacturers, helpful in considering the audit process. Please feel free to contact Laurel L. Todd at (202) 962-9220 if you have any questions regarding any of the issues raised in these comments. Thank you to your attention to this very important matter.

Respectfully submitted,

/s/

Laurel L. Todd
Managing Director,
Reimbursement and Health Policy