February 19, 2016

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

BY ELECTRONIC SUBMISSION

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

Dear Captain Pedley:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to submit the following comments in response to the proposed Information Collection Request (ICR), issued by the Health Resources and Services Administration (HRSA) and published in the Federal Register on December 23, 2015, entitled 340B Drug Pricing Program Reporting Requirements [OMB No. 0915-0176] (the "Proposed ICR").

BIO represents an industry devoted to discovering new treatments and ensuring patient access to them. Accordingly, we support the 340B Program as a way to improve access to therapies for indigent patients. We believe that compliance with 340B Program requirements by all parties—including manufacturers—is an important part of ensuring the sustainability of the 340B Program. To these ends, we applaud HRSA’s recent commitment and activities to enforce program oversight and compliance, including to provide further details surrounding manufacturer audits of covered entities authorized under section 340B(a)(5)(C) of the Public Health Service Act (PHSA). That said, while a number of factors make it difficult for us to evaluate HRSA’s estimated manufacturer burden for these activities with precision, we are concerned that HRSA’s Proposed ICR underestimates the time it generally takes manufacturers to complete each of the reporting activities described. Moreover, we continue to have ongoing concerns regarding HRSA’s existing policies and recent proposals on both manufacturer audits and the informal dispute resolution process, which we believe impose undue burdens on manufacturers, particularly given that HRSA has not, to date, enforced any manufacturer audit findings.

I. It is Difficult for Stakeholders to Evaluate the Accuracy of Proposed Burden Estimates with Precision.

As an initial matter, we note that it is difficult for stakeholders evaluate the accuracy of the burden estimates included in the Proposed ICR, in part due to the lack of detail provided regarding the reporting activities described. Specifically, in an email dated January 11, 2016, a HRSA official confirmed that “[t]here are no collection plans, draft instruments, or other information connected with the Federal Register Publication extension request cited.”\(^2\) Instead, the official noted that “[i]ndividuals seeking to utilize the information dispute resolution or audit process must follow the instructions in the final notice in the Federal Register” published on December 12, 1996 (hereinafter “1996 Notice”).\(^3\) While the 1996 Notice does describe HRSA’s policies for manufacturer audits and the informal dispute resolution process, the absence of standardized collection plans and draft instruments makes it more difficult for BIO and others to estimate the average time and effort necessary to conduct reporting activities in accordance with these policies across the industry.

In addition, as noted throughout the remainder of this letter, the time required to pursue the activities described in the Proposed ICR is subject to variation, in some cases due to factors outside manufacturers’ control, including HRSA’s own policies (or lack thereof). For example:

- As indicated in the Proposed ICR, HRSA’s current policy requires manufacturers to establish, in their audit work plans submitted to HRSA, that “reasonable cause exists” for conducting an audit. Not only is this standard unduly high, as described in section III of this letter, it also is subjective, making it difficult for manufacturers to anticipate what evidence HRSA will find necessary to meet this standard. Manufacturers may therefore err on the side of collecting and reviewing more—rather than less—data to demonstrate reasonable cause, adding to the burden of preparing an audit workplan.

- The time taken to complete a number of the reporting activities described in the Proposed ICR (e.g., covered entity notification and good-faith resolution) may depend, at least to some degree, on the responsiveness of the covered entity in question—a factor largely outside of each manufacturers’ control. The associated burden on manufacturers would therefore be lessened to the extent that HRSA strongly encouraged covered entities to be responsive to manufacturers’ requests for the information necessary to resolve disputes in good faith, and provided covered entities with the guidance and tools to enable them to do so.

Finally, we note that the Proposed ICR makes reference to an “expected revision” to HRSA’s guidance on the dispute resolution process, which “includes additional background information on the dispute resolution process and clarifies the need and proposed use of

\(^2\) Email from Julie Zadecky, HRSA Office of Pharmacy Affairs to Erin Estey Hertzog, BIO (Jan. 11, 2016).
\(^3\) Id. (citing 61 Fed. Reg. 65,406 (Dec. 12, 1996)).
information regarding the manufacturer audit guidelines and the informal dispute resolution process." As this "expected revision" has yet to be released, BIO’s comments have been developed without the benefit of knowing how or to what extent HRSA intends to revise the Agency’s existing processes in this area. We do, however, outline some of our concerns with the Agency’s existing informal dispute resolution process, as well as some recommendations as to how this process can be improved, in section IV of this letter.

II. HRSA’s Has Underestimated the Time It Generally Takes Manufacturers to Complete Each of the Reporting Activities Described in the Proposed Notice.

While the factors described above make it difficult for us to assess the accuracy of HRSA’s burden estimates with precision, we are nonetheless concerned that HRSA has underestimated the number of hours a manufacturer would generally be required to spend pursuing the reporting activities described. In the following subsections, we describe each of the reporting activities described in the Proposed ICR for which a manufacturer reporting obligation was identified, as well as our thoughts on HRSA’s proposed estimate of the time required to complete them.

A. Audit Notification to Entity.

As HRSA notes, under the Agency’s current guidance regarding the manufacturer audit process, a manufacturer must first notify covered entities in writing when the manufacturer believes the covered entity has violated provisions of section 340B. In the Proposed ICR, HRSA has estimated that this reporting requirement would take manufacturers an average of four hours to complete.

We believe that HRSA has underestimated the time it takes for manufacturers to draft and send an audit notification to a covered entity. Indeed, based on the results of a recent BIO member survey, more than half of survey respondents reported spending more than 10 hours on this activity, and no respondent reported spending less than five hours. In fact, some members have identified that the amount of hours required would be over 30 hours. Moreover, HRSA’s burden estimate clearly does not include all of the time necessary to “search data sources” or “to complete and review the collection of information” included in that notification—burdens clearly contemplated by the Paperwork Reduction Act. For

---

5 Id.
6 In January 2016, BIO conducted an anonymous member survey regarding the manufacturer-specific burden estimates included in the Proposed ICR. Survey results are on file at BIO.
7 80 Fed. Reg. at 79,916. (describing the term “burden” to mean: “the time expended by persons to generate, maintain, retain, disclose or provide the information requested during an audit. 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 for both
example, in addition to the time required to draft and send the notification itself, manufacturers may spend several hours identifying the scope of the potential violation, as well as compiling supporting documentation to be sent to covered entities—survey respondents reported spending at least 15 hours and 5 hours on these activities, respectively. In some instances, manufacturers also must notify multiple covered entity sites of the potential violation, further adding to the burden.

In light of the foregoing, BIO urges HRSA to revise its estimated burden for the covered entity audit notification to at least 25 hours—15 hours to identify the scope of the potential violation, five hours to compile supporting documentation, and five hours to draft and send the notification.

B. Audit Workplan.

HRSA then notes that, for those potential violations that cannot be resolved, manufacturers may then submit an audit work plan "describing the audit and evidence in support of the reasonable cause standard" to HRSA for review. Per HRSA’s 1996 guidance, this requires manufacturers to provide: (1) a clear description of why the manufacturer has reasonable cause to believe a violation of the prohibition on duplicate discounts and/or diversion has occurred; (2) sufficient facts and evidence to support a showing of reasonable cause; and (3) copies of documents supporting these claims. Providing this documentation often requires, among other things: requesting documents and data from the covered entity, as well as other covered entity communications; reviewing documents received from the covered entity; reviewing internal documents and data; and consultation with third parties including outside counsel, consultants, and/or auditors. While HRSA has estimated that this reporting activity takes manufacturers an average of only 8 hours to complete, our survey respondents universally reported spending greater than 25 hours, further reporting that the time required may vary based on the type, scope, and complexity of the violation, as well as the responsiveness of the covered entity in question. We therefore urge HRSA to revise its burden estimate upward to at least 25 hours per audit work plan.

C. Audit Report.

HRSA then notes that, once an audit is completed, the manufacturer “will submit copies of the audit report to [the Office of Pharmacy Affairs] for review and resolution of the findings, as appropriate,” as well as “an informational copy of the audit report to the HHS Office of Inspector General (OIG).”8 HRSA has estimated that these activities would take manufacturers an average of 8 hours to complete. Our survey results again indicate that this is an underestimate; virtually all respondents reported spending over 15 hours preparing and submitting these reports. We therefore urge the Agency to adjust this estimate upwards to at least 15 hours per audit report.

---

D. Good Faith Resolution.

In the Proposed ICR, HRSA also notes that the Agency has created an informal, voluntary dispute resolution process “because of the potential for disputes involving covered entities and participating drug manufacturers.”\(^9\) HRSA further notes that, prior to filing a request for resolution of a dispute with HRSA through this process, manufacturers and covered entities “should attempt in good faith to resolve a dispute” and “must maintain written documentation as evidence of a good faith attempt to resolve the dispute.”\(^10\) HRSA has estimated that this reporting activity requires, on average, 40 hours to complete. We again disagree. Instead, our survey indicates that over 80 hours are required to compile and submit documentation to HRSA regarding evidence of good faith efforts to resolve a dispute, with half of survey respondents reporting that greater than 120 hours are required to complete this activity. We therefore urge HRSA to revise this burden estimate upwards to at least 80 hours per good faith attempt at dispute resolution.

III. BIO Has Ongoing Concerns Regarding HRSA’s Standards for Manufacturer Audits.

In the Proposed ICR, HRSA references the Agency’s longstanding policy that a manufacturer must demonstrate to HRSA that there is “reasonable cause” for an audit before the Agency will authorize the audit. As we have articulated in prior comments,\(^11\) BIO is concerned about HRSA’s use of a “reasonable cause” standard, which is a very high threshold for a manufacturer to even get into the audit process—really the only remedy provided to manufacturers to address covered entity non-compliance. The 340B statute also does not provide for such a threshold. Moreover, the cost of the audit is borne by the manufacturer per the statute, so that should be adequate deterrence to discourage unfounded audits. Accordingly, we request HRSA to strengthen the ability by manufacturers to perform independent audits of covered entities, such as by allowing manufacturers to conduct a limited number of audits per year without obtaining prior approval from HRSA provided the manufacturers have a reasonable basis for performing such audits.

We also are concerned with HRSA’s recent proposal to continue to require manufacturers to use an independent certified public accountant (CPA) to conduct a covered entity audit. This purported requirement is overly burdensome and without justification. These audits do not require an accounting background or knowledge of generally accepted accounting principles, and therefore do not require a CPA to perform. There are many qualified management consulting auditors that are perfectly qualified to perform this function. Instead, manufacturers should be able to conduct audits of covered entities using an internal consultant, an internal CPA, or external management consultants to the extent

---

\(^9\) Id.

\(^10\) Id.

that this individual follows standard audit protocols, including those outlined in the audit work plan submitted to and approved by HRSA.

In addition, HRSA, to date, has not proposed to impose any requirement on HRSA to act on the audit results generated by a manufacturer’s audit (other than the potential for referral to other federal agencies). This is in contrast to HRSA’s own audits, which HRSA has specified could result in a covered entity’s termination or a requirement that the covered entity submit a corrective action plan.12 If HRSA does not commit to acting on manufacturer audit results, the manufacturer audit option is no remedy at all. HRSA cannot encourage manufacturers to conduct such audits and portray them as an avenue for manufacturer oversight if HRSA does nothing to act on those results. This is particularly the case given that HRSA requires manufacturers to retain an independent CPA to conduct the audits in the first instance.

Manufacturer audits performed by CPAs clearly provide a reasonable basis for HRSA to make determinations of covered entity non-compliance. Indeed, we note that HRSA recently proposed to rely on an independent auditor employed by covered entities to inform a number of official actions and determinations of the Agency (e.g., with respect to eligibility standards for children’s hospitals and their child sites).13 We therefore believe HRSA must similarly respect and take action upon any findings resulting from manufacturer audits conducted by independent CPAs, including relying on such findings to impose corrective actions on covered entities found to be in violation of program requirements. Again, HRSA cannot rely on auditor results only to support covered entity actions but ignore such results when they identify covered entity compliance violations. Such an arbitrary approach is precisely what a government agency cannot condone.

Accordingly, we continue to urge HRSA to review manufacturer audits within 60 days and enforce such findings, including by requiring covered entities to make any applicable repayments to manufacturers, with 120 days. If HRSA is unable to meet these timelines, the Agency should permit affected manufacturers to withhold future discounts until HRSA, the manufacturer, and the covered entity have resolved the findings noted in the manufacturer’s audits. Requiring speedy resolution of audit findings is critical for all parties, and most importantly manufacturers to mitigate losses during the pendency of HRSA’s review and actions.

Finally, BIO also has concerns that HRSA’s practice of barring manufacturers from auditing a covered entity while HRSA also audits that entity inappropriately forecloses the only statutory remedy manufacturers have to address 340B program violations. What’s more, because HRSA’s covered entity audits are often “targeted,” this policy often renders the very entities most likely to have committed program violations inaccessible for manufacturer audits, which remains the case throughout the entire duration of a HRSA’s audit.

---

13 Id. at 52,301-03; 52,317.
audit. We can find no statutory basis for this condition. Moreover, while we appreciate the need to ensure that covered entities are not subject to undue burden, we believe that HRSA can and should adopt a more targeted approach to minimizing covered entity burden while still affording manufacturers their statutory right to conduct audits of covered entities suspected of program violations. At a minimum, HRSA should publish a list of the ongoing audits and limit the hold on manufacturer audits to no more than six months.

IV. To Address Ongoing Concerns with the Current Dispute Resolution Policy, BIO Urges HRSA to Recalibrate this Process, Adopting Certain Standards to Protect the Interests of All Parties.

BIO has concerns regarding the existing dispute resolution process, which must be substantially recalibrated to be useful. However, as an initial matter, we question why no manufacturer reporting obligations were identified in the Proposed ICR for dispute requests or rebuttals. While the 1996 voluntary, informal dispute resolution guidelines contemplate that the manufacturer, not just the covered entity, can initiate the dispute resolution process, the burden estimate in Proposed ICR does not flag the “dispute request” as being prepared by the manufacturer. Interestingly, HRSA similarly did not identify the “rebuttal” as being prepared by the manufacturer. When HRSA releases its 30-day Federal Register notice on this topic, we urge the Agency to either identify a burden for manufacturers with respect to one or both of these activities, or clarify why no such burden estimate is necessary.

We also remain concerned that the existing dispute resolution process does not serve as a good model for dispute resolution for the 340B program. We noted in our 2010 ANPRM comments that it was our understanding that no disputes had ever been resolved through this process. This remains the case today. The reasons for this are many, including the voluntary nature of the program and the onerous standards, described above, for initiating and conducting a covered entity audit—which must be performed before dispute resolution may be initiated.

However, an additional issue with the existing process is that it lacks clear standards to protect the interest of all parties. BIO therefore urges HRSA to include in its revised process the following key elements:

- An evidentiary standard (e.g., preponderance of the evidence);
- Right to discovery and discovery procedures; and
- Confidentiality of the proceedings and the resolution.

In issuing this new standards, we further urge HRSA to specify the available remedies, if any, beyond those specified in statute, and to take into account BIO’s recommendations for establishing the dispute resolution process envisioned by the Affordable Care Act described in the enclosed comment letter, which was originally submitted in response to HRSA’s 2010 Advance Notice of Proposed Rulemaking (ANPRM) on this topic.
V. Conclusion

BIO appreciates the opportunity to comment on the Proposed ICR. We hope that the Agency finds this letter to be constructive in the process of updating the information collection requirements described. Please feel free to contact us at 202-962-9200 if you have any questions regarding any of the issues raised in these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/
Laurel L. Todd
Vice President
Healthcare Policy and Research

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

Enclosure: