January 31, 2014

BY ELECTRONIC DELIVERY

Jeanette Badrov
General Counsel
Illinois Department of Healthcare and Family Services
201 South Grand Avenue E., 3rd Floor
Springfield, Illinois 62763-0002

RE: 340B Drug Discount Program – Proposed Amendments to 89 Ill. Adm. Code 140

Dear Ms. Badrov:

The Biotechnology Industry Organization (BIO) and the Illinois Biotechnology Industry Organization (iBIO) appreciate this opportunity to comment on the Illinois Department of Healthcare and Family Services (the "Department") proposed rule to amend 89 Ill. Adm. Code 140 regarding the 340B Drug Discount Program (the "Proposed Rule").

BIO is the largest trade association to serve and represent the biotechnology industry in the United States and around the globe. Indeed, BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations. BIO members are involved in the research and development of healthcare, agricultural, industrial, and environmental biotechnology products. In Illinois BIO works in collaboration with iBIO, whose membership includes strong representation from the bio-pharmaceutical sector. This sector accounts for a large portion of the $98 billion in biotech annual economic output and 369,000 directly and indirectly-created jobs in the state.[1]

BIO represents an industry that is 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 have become aware, however, that oversight of the program has been inadequate, including with respect to the federal prohibition on duplicate discounts (i.e., the prohibition on obtaining both a Medicaid rebate and a 340B discount for a covered outpatient prescription drug).[2] For instance, the Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) has found that approximately half of the

[1] For additional information about iBIO, please visit: http://www.ibio.org/.

[2] See 42 U.S.C. § 256b(a)(5)(A) (" . . . [a] covered entity shall not request payment under [the Medicaid program] . . . with respect to a drug that is subject to an agreement under [the 340B program] if the drug is subject to the payment of a rebate to the State under [the Medicaid drug rebate statute].")

states do not yet have systems in place and/or access to the necessary pricing data to ensure that duplicate discounts do not occur.[3]

BIO recognizes the diligent work of the Department to implement the Save Medicaid and Resources Together (SMART) Act (Public Act 097-0689), including provisions pertaining to the intersection between the 340B Program and Illinois Medicaid. However, we believe that the Proposed Rule does little to offer improvement or clarification for the operation of the 340B Program in Illinois and may instead put the Program's integrity at risk.

Specifically, the Department's Notice of Proposed Amendments states that the purpose of the Proposed Rule is to "delay the requirement that contract pharmacies participate in the 340B program" and to exempt contract pharmacies "from the requirement that 340B covered entities bill the Department using 340B inventory and that the covered entities charge the 340B actual acquisition cost."[4] As an initial matter, we are concerned that the existing requirement that covered entities enroll in the 340B Program is not good public policy in that it forecloses their ability to weigh the risks and benefits of participation in the program on a case-by-case basis. In addition, we have three specific concerns regarding the state's current proposal: (1) it seems to assume, incorrectly, that the contract pharmacies themselves, rather than their sponsoring covered entities, are the participants in the 340B program; (2) it is not clear that a covered entity would be found in compliance with the state's "carve in" requirement to the extent their contract pharmacy opted to "carve out" under the proposal; and (3) the actual proposed revisions to the existing regulatory text do not appear to accomplish the intended purpose. Finally, to further the state's efforts to promote and protect the 340B program, we urge Illinois to also issue claims processing regulations aimed at preventing duplicate discounts.

I. The Obligation that Covered Entities Enroll in the 340B Program is Not Good Public Policy

As you are aware, the 340B Program plays an important role in America's healthcare system by supporting needy patient access to outpatient drugs. However, as the Health Resources and Services Administration (HRSA)—the federal agency charged with administering the 340B Program— itself has said, with this important benefit comes "significant responsibility."[5] Covered entities participating in the 340B Program have considerable registration, certification, and recordkeeping requirements to enable compliance with numerous federal program integrity requirements (e.g., prohibitions on duplicate discounts and diversion), and are subject to selective federal audits.[6] Those covered entities found out of compliance with these program requirements may be liable for refunds of discounts received from manufacturers and/or removal from the program.

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[3] HHS Office of the Inspector General. 2011. *State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs*. Washington, DC: HHS/OIG, http://www.hrsa.gov/opa/programrequirements/reports/medicaidpoliciesandoversities062011.pdf.

[4] See Illinois Register Vol. 37, Issue 51 (19971-19972, 19994-19997), issued December 20, 2013.

[5] HRSA, Program Requirements, http://www.hrsa.gov/opa/programrequirements/ (last accessed Jan. 29, 2014).

[6] HRSA, Program Integrity, http://www.hrsa.gov/opa/programintegrity/index.html (last accessed Jan. 29, 2014).

As these risks and responsibilities are associated with real costs for covered entities, we believe that each entity should be able to evaluate whether such costs are outweighed by the potential benefits on a case-by-case basis. Moreover, as this cost-benefit analysis will vary entity-by-entity, we believe it is inappropriate for the state to universally mandate that all potentially eligible entities participate in the 340B Program. We therefore strongly urge Illinois to repeal the enrollment requirement outlined in subsection 140.12(m) and instead trust that the state's healthcare providers will make informed and responsible decisions about participation in the 340B Program.

II. Contract Pharmacies Are Not 340B Covered Entities

Assuming that Illinois retains its obligation to enroll in the 340B program, we believe the applicable regulatory provision requires clarification to eliminate any misconception that contract pharmacies are themselves 340B covered entities. Under federal law, contract pharmacies are not covered entities and have no independent responsibilities or rights under the 340B Program. Rather, covered entities are defined by federal statute to include certain specified healthcare providers (e.g., federally qualified health centers and certain types of hospitals).[7] Many of these 340B covered entities elect, in turn, to dispense 340B drugs to patients through contract pharmacy services—an arrangement under which the 340B covered entity signs a contract with a pharmacy to provide pharmacy services.[8] This contracting arrangement does not, however, render contract pharmacies "covered entities" for purposes of the 340B Program. Thus, rather than "delaying" the requirement that contract pharmacies enroll in 340B, we urge the Department to amend the applicable regulation to clarify the relationship between contract pharmacies and 340B covered entities. Specifically, we urge the Department to add language to the end of subsection 140.12(m) clarifying that contract pharmacies are not eligible to participate in the 340B Program and are thus not subject to the enrollment requirement outlined in this provision.

Related to the fact that contract pharmacies have no independent rights or responsibilities under the 340B Program, HRSA has made clear that covered entities that enter into arrangements with contract pharmacies ultimately bear the responsibility for compliance with all 340B Program requirements. Indeed, per HRSA's guidance, "[t]he covered entity is responsible for compliance of their contract pharmacy arrangement(s) and must maintain ownership of the 340B drugs at all times."[9] Accordingly, we urge Illinois to revise the applicable regulatory text to clearly impose any and all obligations on the covered entity itself. Specifically, we urge the state to revise the text of paragraph 140.440(b)(5) to clarify that the billing requirements for 340B-purchased drugs apply to covered entities rather than merely "a pharmacy."

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[7] See 42 U.S.C. § 256b(a)(4).

[8] In 1996, the Health Resources and Services Administration (HRSA) issued guidelines that permitted covered entities participating in the 340B Drug Pricing Program to contract with a pharmacy to provide services to the covered entity's patients. See 61 Fed. Reg. 43,549 (Aug. 23, 1996). In 2010, this notice was amended to allow for more than one contract pharmacy to operate on behalf of a covered entity. See 75 Fed. Reg. 10,272, 10,278 (March 5, 2010).

[9] Health Resources and Services Administration (HRSA), Contract Pharmacy Services, http://www.hrsa.gov/opa/implementation/contract/ (last visited Jan. 27, 2014) (emphasis added).

III. The Department Should Clarify that the Option for Contract Pharmacies to "Opt Out" is an Exception to the Requirement that Covered Entities "Carve in"

As noted previously, BIO strongly supports the state's efforts to promote the integrity of the 340B Program, including by reducing the risk of duplicate discounts. Like HRSA, we believe that the need to implement such preventive measures is particularly pronounced where covered entities and their contract pharmacies employ "carve in" (i.e., the use of 340B product to treat Medicaid patients).[10] For this reason, we support Illinois' proposal to allow contract pharmacies to "carve out" (i.e., to refrain from using 340B products to treat Medicaid patients such that the state may seek Medicaid rebates on the drugs instead).

We are concerned, however, that, without further clarification, this proposal could result in covered entities being found out of compliance with the state's carve-in requirement. As noted above, under guidance issued by HRSA "[t]he covered entity is responsible for compliance of their contract pharmacy arrangement(s) and must maintain ownership of the 340B drugs at all times."[11] Yet, while Illinois law requires covered entities to "carve in," the Department is proposing to allow their contract pharmacies to "carve out."[12] We therefore urge the Department to clarify that covered entities may enter into arrangements with contract pharmacies that "carve out" without running afoul of the otherwise-applicable "carve in" requirement.

IV. The Proposed Amendments to the Existing Regulatory Text do not Appear to Accomplish the Intended Purpose

Importantly, we note that the proposed amendments published in the Register appear to reflect only technical changes pertaining to requirements for Hemophilia Treatment Centers, rather than the proposed changes regarding contract pharmacies. We therefore urge the state to re-issue the Proposed Rule—including the revised regulatory text—with the clarifications described above for review and public comment.

V. Illinois Should Promulgate Claims-Processing Regulations to Prevent Duplicate Discounts

To further the state's efforts to promote and protect the 340B program, we urge Illinois to issue claims processing regulations aimed at preventing duplicate discounts. As noted previously, the risk for duplicate discounts is particularly acute to the extent covered entities use 340B drugs for

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[10] See 75 Fed. Reg. at 10,278 (HRSA guidance requires that neither covered entities nor contract pharmacies "will use drugs purchased under section 340B to dispense Medicaid prescriptions, unless the covered entity, the contract pharmacy and the State Medicaid agency have established an arrangement to prevent duplicate discounts" and that "[a]ny such arrangement shall be reported to the Office of Pharmacy Affairs (OPA), HRSA, by the covered entity.").

[11] Health Resources and Services Administration (HRSA), Contract Pharmacy Services, http://www.hrsa.gov/opa/implementation/contract/ (last visited Jan. 27, 2014) (emphasis added).

[12] Specifically, Illinois proposes to exclude contract pharmacies "from the requirement that 340B covered entities bill the Department using 340B inventory and that the covered entities charge the 340B actual acquisition cost," and instead proposes that "[t]he contract pharmacies can continue to bill non-340B drugs for Medicaid patients." See Illinois Register Vol. 37, Issue 51 (19971-19972, 19994-19997), issued December 20, 2013.

Medicaid patients (i.e., "carve in"). Thus, it is critical that Illinois create a mechanism to identify these claims to ensure that the state does not also seek Medicaid rebates for these products. While we understand that the state has issued guidance requiring providers to include a modifier on their claims forms to indicate where 340B product was supplied,[13] we believe that this particular claims-processing issue should be addressed via regulation to ensure that the state has the information it needs to comply with the federal duplicate discount prohibition and to ensure that the state is able to identify product subject to the lower 340B reimbursement rate. We therefore urge the state to codify these guidelines in regulation, together with a mechanism to ensure compliance with these requirements.

VI. Conclusion

BIO appreciates the opportunity to comment on the Department's Proposed Rule regarding the 340B Drug Discount Program. While we support the state's effort to provide robust guidance to covered entities, we hope that our comments will be a useful tool as the agency refines its proposed regulations. Please feel free to contact me at (202) 962-9200 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

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BIO

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[13] See Illinois Department of Healthcare and Family Services, Informational Notice Re: Clarification Regarding Billing for 340B Purchased Drugs (May 30, 2012), available at: http://www.hfs.illinois.gov/html/053012n.html.