March 13, 2007

Mr. Bradford R. Lang
Public Health Analyst
Office of Pharmacy Affairs (OPA)
Healthcare Systems Bureau (HSB)
Health Resources and Services Administration
5600 Fishers Lane
Parklawn Building
Room 10C-03
Rockville, MD 20857

Re: Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services

Dear Mr. Lang:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Health Resources and Services Administration (HRSA) notice on proposed guidelines to allow covered entities to utilize the same contract pharmacy services arrangements previously limited to the Alternative Methods Demonstration Project (AMDP) program (the Notice).[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.

BIO recognizes the importance of ensuring that 340B patients have access to 340B discounted drugs and appreciates that allowing covered entities to utilize the same alternative pharmacy contracting models available to AMDPs may permit expansion of pharmacy services and improve patient access. It is critically important, however, that if HRSA expands the availability of the complex contracting arrangements available under the AMDP program, that it

[1] 72 Fed. Reg. 1540 (Jan. 12, 2007).

also expand the necessary safeguards for deterring drug diversion and duplicate discounts. Accordingly, BIO recommends that HRSA extend the AMDP audit requirement to the proposed expansion of contract pharmacy services and also provide manufacturers with the right to audit covered entities that use multiple pharmacy contracting without requiring that the manufacturer provide documentation of reasonable cause. BIO also urges HRSA to reduce the operational burden on manufacturers of verifying whether discounted pricing offered to multiple contracting pharmacies is excludable from Best Price calculations, by clearly addressing the mechanism to be used to confirm contract pharmacy eligibility and participation status.

I. HRSA Should Retain the Independent, Annual Audit Requirement and Provide Direct Manufacturer Audit Rights Where a Covered Entity Uses Multiple Pharmacy Contracting

As HRSA explains in the Notice, under previous guidelines, a covered entity could contract with only one pharmacy to provide all pharmacy services for any particular site of the covered entity. If the contract pharmacy had multiple locations, the covered entity site had to choose one contract pharmacy location for the provision of services. Under HRSA's proposed guidelines, covered entities will be able to utilize certain alternative pharmacy services arrangements which are currently limited to AMDPs. Specifically, covered entities will be permitted to use multiple contract pharmacy service sites and to utilize contract pharmacies to supplement in-house pharmacy services. BIO agrees with HRSA that, in proposing the expansion of these arrangements, it is "of particular importance" that "appropriate procedures be in place to prevent diversion of 340B drugs or a duplicative 340B drug discount and a Medicaid rebate on the same drug, which are prohibited under the statute."[2] Accordingly, we recommend that HRSA provide manufacturers with a direct audit right to address the increased risk of diversion and duplicate discounts when covered entities use multiple pharmacy contracting.

HRSA explains in the Notice that covered entities that wish to utilize contract pharmacy arrangements must have a written contract in place with each pharmacy, and that it is the responsibility of the covered entity to (1) ensure against illegal diversion and duplicate discounts; (2) maintain readily auditable records; and (3) meet all other 340B Drug Pricing Program requirements.[3] HRSA provides a model agreement format, which includes provisions requiring that the contract pharmacy establish and maintain a tracking system to prevent diversion of 340B drugs to individuals who are not patients of the covered entity, and that both parties agree that they will not resell or transfer a drug to an individual who is not a patient of the covered entity.[4] Although the covered entity must submit a certification to the Office of

[2] *Id.* at 1540.

[3] *Id.* at 1541.

[4] *Id.* at 1541-42.

Pharmacy Affairs (OPA) that is has signed an agreement with the contract pharmacies that includes the provisions set forth in the Notice, the entity instead may choose to submit an agreement with different provision to OPA for review.

BIO appreciates that HRSA has sought to address the risk of diversion of 340B drugs to non-340B patients, but it is concerned that without additional safeguards, such those required for AMDP approval, there remains a heightened risk of diversion where there is an expansion of contract pharmacy services. One of the conditions for AMDP approval is that the demonstration project be audited annually by an independent outside auditor for drug diversion and duplicative discounts under Medicaid, with the results of the audit reported to OPA.[5]

HRSA is proposing to expand availability of the complex contracting arrangements available under AMDPs, but it has not proposed to expand the same safeguards against diversion that are applicable under that program. Although HRSA notes that "[t]o date, there has been no evidence of drug diversion or duplicate manufacturer's discounts on 340B drugs in the AMDP program,"[6] BIO believes that this is evidence that the AMDP audit requirements have served as an effective deterrent to such practices. The expansion of the program does not eliminate the need for this audit requirement, but instead justifies its continued application. BIO strongly urges HRSA to continue to require any covered entity that uses multiple contract pharmacies to conduct these annual audits.

Under HRSA's current audit guidelines, manufacturers may audit the records of a covered entity only where the manufacturer has documentation that indicates there is reasonable cause to believe there has been a violation of the statutory prohibition on duplicate discounts or resale of drugs to ineligible patients. This documentation requirement likely discourages manufacturers from pursuing an audit of a covered entity. BIO believes that permitting manufacturers a direct audit right, without requiring documentation of reasonable cause, would better serve HRSA's goal of limiting the risk of diversion and duplicate discounts. In the alternative, HRSA could retain the reasonable cause requirement but make all contract pharmacy annual audits available to manufacturers so as to provide manufacturers with a basis for determining whether reasonable cause exists.

In summary, BIO urges HRSA to retain the annual audit requirement of the ADMP should HRSA finalize its proposed expansion of the contract pharmacy program. Given the increased risk for diversion under the proposed expansion, BIO also requests that manufacturers be permitted to audit covered entities that utilize contract pharmacies without first having to show reasonable cause for doing so. At a minimum, HRSA should make the contract

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[5] *Id*. at 1540.

[6] *Id*.

pharmacy annual audits available for manufacturer review, to provide manufacturers with a basis for determining whether reasonable cause exists for a manufacturer-initiated audit. We urge HRSA to include these provisions in its finalized guidance.

II. HRSA Should Provide Additional Guidance to Reduce Administrative Burdens on Manufacturers

Sales to contract pharmacies often require special treatment by manufacturers because these pharmacies may also purchase drugs at non-340B prices for non-340B eligible patients. Manufacturers typically utilize the OPA online database to confirm that the contract pharmacy is eligible to receive 340B pricing and is linked to an eligible covered entity, and that both the contract pharmacy and the covered entity are listed as "participating" in the 340B program during the quarter, in order to determine whether the prices are excluded from the manufacturers Medicaid Best Price calculations.

BIO is concerned that, without additional guidance from HRSA, manufacturers may have difficulty confirming eligibility and participation status where a covered entity has contracted with multiple pharmacy sites. We ask that HRSA specifically address in its finalized guidance how the contract pharmacies will be linked to the covered entities in the OPA database, and how manufacturers will be able to confirm that both the contract pharmacy and the covered entity were participating in the quarter.

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BIO greatly appreciates the opportunity to comment on the important issues raised by the Notice, and we look forward to working with HRSA to ensure that 340B patients continue to have access to critical drug and biological therapies. We sincerely hope that HRSA will give thoughtful consideration to our comments and will incorporate our suggestions into its final notice. Please feel free to contact me at (202) 312-9273 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

Jayson Slotnik
Director, Medicare Reimbursement
& Economic Policy
Biotechnology Industry Organization