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: HRSA Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Definition of Patient

Dear Mr. Lang:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Health Resources and Services Administration's notice regarding definition of patient under the 340B Drug Pricing Program.[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 represents an industry that is devoted to discovering new treatments and ensuring patient access to them. It is in this spirit that we offer comments to the proposed guidance on the definition of patient.

[1] 72 Fed. Reg. 1543 (Jan. 12, 2007).

BIO writes to express its full support for HRSA's effort to provide needed clarifications to the definition of patient. These clarifications work both to provide additional specificity to the existing definition but also to incorporate into that definition related guidance that HRSA previously has expressed in other contexts. In all cases, BIO believes that the HRSA notice provides the clarity needed to implement the statutory prohibition on diversion.

A. Background

As you know, Section 602 of the Veterans Health Care Act of 1992 provides that pharmaceutical manufacturers that want their products to be reimbursed with Federal funds under Medicaid and Medicare Part B are required to participate in the PHS Drug Pricing Program ("340B Program") and sell their covered outpatient drugs to PHS covered entities at deeply discounted prices.[2] The statute mandates that prices offered to covered entities may not exceed a covered outpatient drug's AMP for the preceding quarter, reduced by the unit rebate amount for the same product in that same quarter ("Ceiling Price").[3] Importantly, while the statute provides for covered entities to purchase covered outpatient drugs at the Ceiling Price, it places no limitation on the price at which they can sell the covered drugs to their patients (i.e., the covered entity need not pass the savings on to its patients).

To safeguard against the potential for product diversion, Congress specifically prohibited resale of drugs purchased at the 340B Ceiling Price "to a person who is not a patient of the entity."[4] "Patient" is not defined in the statute and therefore HRSA has defined that term for use in the 340B Program. HRSA first defined this term in final guidance issued on Oct. 24, 1996, entitled, "Patient and Entity Eligibility."[5]

As HRSA is aware, that guidance has not always been successful in preventing product diversion, and diversion has become an acute concern for manufacturers. Diversion results in a real and significant harm to all patients and payers, including 340B patients, and to covered entities. When covered outpatient drugs are provided to those not intended by Congress to be recipients of 340B drug pricing, it causes access problems for all stakeholders. HRSA has now added clarity to the requirements for patient and entity eligibility and reinforced the constraints under which covered entities are entitled to purchase drugs at the 340B Ceiling Price.

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[2] 42 USC 256b; Public Law 102-585.
[3] 42 USC 256b(a)(1).
[4] 42 USC 256b(a)(5)(B).
[5] 61 Fed. Reg. 55156.

BIO supports those clarifications in their entirety, but discusses below certain aspects of the Notice that are of particular importance to BIO and its members.

B. The Proposed Guidance is Consistent with HRSA's Current Guidance Regarding Patient and Entity Eligibility

BIO supports HRSA's effort in the Notice to incorporate in one guidance document those previously-issued directions that relate to patient and entity eligibility. BIO believes that the revised patient definition incorporates guidance that HRSA previously has issued and appropriately:

> (1) reiterates that employees must meet the definition of patient in order to be considered patients of the covered entity;
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> (2) limits the definition of patient to those individuals who receive outpatient health services from the covered entity;
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> (3) focuses on the requirement that an outpatient facility of a Disproportionate Share Hospital ("DSH") be eligible for the 340B Program only if it is an integral part of the DSH, as evidenced by the covered entity's Medicare Cost Report; and,
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> (4) provides more detailed direction regarding the records that a covered entity must maintain relating to an individual's health care.

BIO fully supports these clarifications for the reasons stated below.

1. Employees Should Continue To Be Excluded From the Definition of Patient

The proposed guidance puts to rest an apparent misconception by covered entities that their employees can qualify as "patients" either by virtue of being employed by the covered entity or under some lesser standard than that required for non-employees:

> Employees of a covered entity regardless of their health care coverage, are not considered patients of the covered entity for the purpose of the 340B Program unless they receive health care from a provider employed by or under contract with the covered entity. The fact that the person is an employee of the covered entity, or that they receive

> health care benefits from their covered entity-employer is not relevant.[6]

This clear statement reiterates the initial guidance issued by HRSA more than 10 years ago relating to patient definition. That guidance did not create an exception for employees, but rather squarely addressed the issue in response to a comment:

> *Comment*: Employees of covered entities should be either specifically precluded or included as eligible patients to receive discounted drug products.
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> *Response*: Any employee of a covered entity who meets the criteria of the definition of covered entity "patient" would be eligible to access 340B pricing.[7]

To the extent that covered entities have been extending 340B pricing to their non-patient employees, they have been doing so contrary to the long-standing, public declaration by HRSA that employees are not patients of the covered entity unless they meet the three prongs of the patient definition test. The proposed guidance now explicitly incorporates this pre-existing standard into the definition of patient itself and BIO strongly supports this clarification and its importance in order to protect the integrity of the 340B program

HRSA also should make clear that covered entities cannot avoid this prohibition by permitting one of its own employee or contracted prescribers to re-write prescriptions that employees receive from their own health care providers. For the reasons addressed below, such an act would not constitute the provision of outpatient health care services, and BIO requests that HRSA make this clear in its final guidance document.

2. The Patient Definition Appropriately Is Limited to Individuals Receiving Outpatient Health Care Services

The proposed patient definition also includes the statutory requirement that the patient receive "outpatient health care services" that result in the use or prescription of drugs purchased at the 340B Ceiling Price.[8] This clarification serves to explicitly incorporate into the patient definition the 340B Program's long-standing and statutory limitation to the outpatient setting.

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[6] 72 Fed. Reg. at 1546 (Jan. 12, 2007).

[7] 61 Fed. Reg. 55156, 55157 (Oct. 24, 1996).

[8] 72 Fed. Reg. 1544 (Jan. 12, 2007).

The 340B Program requires manufactures to extend discounted pricing to covered entities on covered outpatient drugs.[9] The 340B statute notes that the term "covered outpatient drug" has the meaning given to the term by section 1927(k) of the Social Security Act.[10] The Social Security Act defines covered outpatient drug in detail and then provides for a "limiting definition":

> The term "covered outpatient drug" does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as . . . inpatient hospital services.[11]

Based on this limitation in the statutory definition of covered outpatient drug, HRSA consistently has advised both manufacturers and covered entities that 340B drugs are for use in connection with outpatient services only. On February 25, 1993, HRSA published a letter in which it responded to questions regarding the scope of the 340B Program. Among the questions asked was the propriety of using 340B drugs for individuals being treated in an inpatient setting:

> 12. The Medicaid Rebate Law exempts certain drugs. Does the PHS Act include or exclude such drugs?
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> Answer: Section 340B(b) of the Act refers to section 1927(k) of the Social Security Act for the definition of "covered outpatient drug." The term incorporates both section 1927's general definition, (k)(2), and the limiting definition, (k)([3]), of "covered outpatient drug."
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> * * *
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> 15. Does a manufacturer have to provide discounts to disproportionate share hospitals for "covered outpatient drugs" used by inpatients, or are the discounts limited to drugs utilized by outpatients?
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> Answer: A covered outpatient drug does not include any drug, biological product or insulin provided as part of, or incident to and in the same setting as inpatient services (and for which payment is made as part of payment for the services and not as direct reimbursement for the drug).

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[9] 42 USC 256b(a)(1) and (2).

[10] 42 USC 256b(b). The definition of covered outpatient drug is codified at 42 USC 1396r-8(k)(2) and (3).

[11] 42 USC 1396r-8(k)(3)(A) (1992).

> See section 340B(b) of the Act and section 1927(k)(3) of the Social Security Act.[12]

HRSA reiterated its position with respect to the distinction between inpatient versus outpatient services in a letter to covered entities on March 9, 1993:

> (c) Diversion to excluded services of the covered entity
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> The PHS Act mandates the statutory price only for outpatient drugs. The covered entity must use these discounted drugs only in connection with outpatient services. . . .[13]

Subsequent to issuing these letters to industry, HRSA promulgated a final notice in which it expressly provided, under the subheading of "Entity Guidelines Regarding Drug Diversion," that "the covered entity itself may not use the covered outpatient drug in excluded services (e.g., inpatient services)."[14] Accordingly, covered entities have long known that 340B drugs may be used only with outpatient services.

BIO notes that it is precisely because the 340B Program does not include inpatient drugs that Congress amended the statutory definition of Best Price in the Medicare Modernization Act, to exclude "inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the Public Health Service Act."[15] This added exception from Best Price would not have been required had the pre-existing exception for 340B covered entities included inpatient drugs. As Congress itself recognized, however, the 340B Program does not include inpatient drugs, and therefore the added exception to Best Price was needed if prices on drugs used in the inpatient setting were to be excluded from the calculation of Best Price. The proposed guidance now explicitly and appropriately incorporates this longstanding statutory limitation into the definition of patient.

Finally, although it is clear that 340B drugs may be used only with outpatient services, ambiguity does exist regarding whether certain services are considered inpatient or outpatient. BIO is concerned that some entities may consider services provided in their emergency room to be outpatient services, even where the

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[12] Letter from M. Alvarez to J. Bobula, Feb. 25, 1993 at page 4.

[13] *See also* Dear Covered Entity Letter, Mar. 3, 1993, Enclosure B, III; Dear Manufacturer Letter, Arp. 15, 1993 at 4-5 (noting that the limiting definition of 42 USC 1927(k) applies to the 340B Program.

[14] 59 Fed. Reg. 25110, 25113 (May 13, 1994). *But see* explanation of covered outpatient drug, in which HRSA explained that for certain limitations on the definition relating to outpatient services (e.g. emergency room, hospice, dental, physician, nursing facilities, x-ray, lab, and renal dialysis), if a covered drug is included in the per diem rate, it will not be included in the 340B Program. But if the covered drug is billed and paid for as a separate line item as an outpatient drug in a cost basis billing system, the drug will be included in the program. 59 Fed. Reg. 25110, 25113.

[15] Medicare Modernization Act, Pub. L. No. 108-173 § 1002 (Dec. 8, 2003).

patient is to be admitted. HRSA should provide clear guidance to manufacturers and covered entities where such ambiguity exists, specifically with regard to the emergency room setting. If it appears that covered entities are improperly characterizing services as outpatient to obtain 340B prices (e.g., treating individuals in the emergency room to qualify for 340B prices with the knowledge that the individual will be admitted), such entities should be held accountable.

3. The Patient Definition Requirement for Provider-Based Designation for DSH Locations Is Consistent with Prior Guidance

In response to a growing number of requests by DSHs to include related clinic locations as "eligible" facilities, the Notice also includes a requirement that DSHs demonstrate the provider-based status of such locations through their Medicare Cost Report.[16] In so doing, HRSA incorporates into its definition of "patient" the same guidance it previously has issued on this topic in other Federal Register Notices:

> Set forth below are the final guidelines regarding the inclusion of DSH outpatient facilities: the outpatient facility is considered an integral part of the "hospital" and therefore eligible for section 340B discounts if it is a reimbursable facility included on the hospital's Medicare cost report. . . . However, free-standing clinics of the hospital that submit their own cost reports using different Medicare numbers (not under the single hospital Medicare provider number) would not be eligible for this benefit.[17]

BIO supports the inclusion of this pre-existing requirement in the third prong of patient definition and the inclusion of Example 3 in the notice. The proposed guidance once again reinforces to covered entities that in order to meet the patient definition, the individual must be a patient of an eligible entity.

4. The Proposed Guidance Does Not Substantively Change the Covered Entities' Obligations Regarding Patient Records

HRSA's original guidance relating to the "patient" definition set forth as its first prong, that "[t]he covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care."[18] HRSA further explained that "[t]he entity will document in the record the

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[16] 72 Fed. Reg. at 1546, Example 3 (Jan. 12, 2007).

[17] 59 Fed. Reg. 47884, 47886 (Sept. 19, 1994).

[18] 61 Fed. Reg. 55156, 55157 (Oct. 24, 1996).

care provided and, when appropriate, the prescriptions written."[19] This explanation is almost identical to the language in the current notice stating that the covered entity must maintain "records that appropriately document health care services that result in the use of, or prescription for, 340B drugs."[20] BIO strongly supports this clarification as it believes a covered entity must maintain such a level of documentation in order to be able to demonstrate that it dispensed 340B drugs to individuals who were patients of the entity. To this end, HRSA should specifically exclude from the definition records maintained for administrative purposes only, such as health screening or drug interaction reports.

By explaining that the covered entity must maintain "ownership, control, maintenance, and possession of" the records of individual's health care, the current notice makes explicit HRSA's understanding of what constitutes the maintenance of records. This is very important because HRSA is proposing to "mandate" that the covered entity have to establish "responsibility" for the outpatient health services it may provide to a patient, and not just a "relationship." Recent incidents of diversion exposed the fact that covered entities were inappropriately interpreting the term "maintain" to require lesser amounts documentation or control. The proposed guidance clarifies that maintenance of health care records necessarily includes ownership, possession, and control of the records. This will help curb potential abuse by certain covered entities without necessarily creating heavy burdens to the entity's normal and legitimate activities.

BIO does request, however, that HRSA clarify this component of the definition to address covered entity concerns regarding whether they must possess paper records on-site at all times, and address how this requirement applies to electronic health records. HRSA's original patient definition stated that covered entities were not required to maintain records in a centralized, on-site location, and BIO believes that this clarification should be stated again in relation to the revised definition to address any covered entity concerns.[21] Similarly, where a DSH is part of a state system such that the DSH itself cannot maintain legal title (i.e., ownership) of a record, BIO believes it should be sufficient that the state own the record. In both cases, however, BIO believes it is imperative that the covered entity have control and responsibility for maintenance of the record beyond a mere right to access it, as access alone is insufficient to demonstrate that a patient relationship exists.

C. The Proposed Guidance Properly Requires a Connection Between the Services Provided By the Covered Entity and the Prescription For the 340B Drug

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[19] *Id.*, response to comment.

[20] 72 Fed. Reg. at 1544 (Jan. 12, 2007). Similarly, the proposed guidance explains that "[t]he covered entity will document in the individual's health care records the health care service provided and the drugs prescribed or used in the covered entity for this individual."

[21] *See* 61 Fed. Reg. at 55157, response to comment.

A fundamental clarification included in the proposed patient definition is the requirement that the covered entity provide "health care services that result in the use of, or prescription for, 340B drugs as part of the diagnosis and treatment from a health care provider" who has the capacity and authority to issue the prescription for the 340B drug.[22] BIO supports this component of the definition as it ensures that the recipient of the 340B drugs is receiving outpatient health services from the covered entity itself, and therefore is appropriately considered a patient of the entity. In the absence of outpatient health services, the individual is more properly considered a "client" or "customer" of the covered entity pharmacy, and not a "patient" of the entity itself. HRSA already has specified in its original definition that an individual is not a patient of a covered entity for purposes of the 340B program if the only service provided to the individual is the dispensing of drugs.[23] This component of the definition serves only to make explicit the pre-existing requirement that the individual be a patient of the entity itself and not just a customer of the entity's pharmacy.

The proposed guidance also clarifies the necessary relationship between the covered entity and the prescribing physician. Previously HRSA provided that an individual was a patient of the covered entity if he received "health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements . . . ."24 The proposed guidelines are more specific, eliminating the ambiguous "other arrangements" language and clarifying that the contract between a treating physician and covered entity must be "valid, binding, and enforceable."25 These clarifications are intended to prevent diversion to individuals based on the "[m]ere acceptance pro forma or rubberstamping of an outside health care provider's diagnosis or medical opinion." BIO appreciates the clarification but notes that the fact that a physician has a valid, binding, and enforceable contract with a covered entity does not necessarily mean that the individuals treated by the physician are patients of the covered entity. BIO asks HRSA to clarify that the contracted providers fulfill this definitional requirement only where the contract with the covered entity obligates the contracted provider to provide outpatient health care services to patients of the entity, as those terms are defined in the notice.

D. Conclusion

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 PHS covered entities continue to have access to critical drug and biological

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[22] 72 Fed. Reg. 1543, 1544, 1545 (Jan. 12, 2007).

[23] 61 Fed. Reg. at 55158 (Oct. 24, 1996).

[24] Id. at 55157.

[25] 72 Fed. Reg. at 1544.

therapies. We sincerely hope that HRSA will give thoughtful consideration to our comments and will find them helpful. 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
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