April 16, 2007

Jimmy R. Mitchell, 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, MD 20857

Re: Definition of Average Manufacturers Price Used for 340B Ceiling Prices

Dear Director Mitchell:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on your January 30, 2007 Letter to Pharmaceutical Manufacturers regarding the definition of Average Manufacturers Price (AMP) used to calculate 340B ceiling prices (the Letter). 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. One important avenue for patient access is the drug pricing Program established by section 340B of the Public Health Service Act (the 340B Program). As you know, the 340B Program allows certain covered entities to purchase prescription medications at greatly reduced prices. The "ceiling price" that pharmaceutical manufacturers may charge 340B covered entities must not exceed the AMP decreased by the "rebate percentage," which is the same as the Medicaid rebate amount. The Letter contains guidance to manufacturers in calculating AMP for 340B ceiling prices in light of changes to the definition of AMP passed as part of the Deficit Reduction Act of 2005 (DRA). BIO

believes that the guidance contained in the Letter undermines the goals of the 340B program and inappropriately applies the statutory requirements. As the Letter directly impacts manufacturer ceiling price calculations for the third quarter 2007. BIO respectfully requests that HRSA provide a response to this letter with additional guidance to manufacturers no later than May 31, 2007.

I. Does The Letter Support Program Goals?

The Letter represents HRSA's first ever application of section 340B(c) to any change in a provision of the Social Security Act referenced in section 340B. In such application, the Letter is both inconsistent in its treatment of the Social Security Act amendments included in the DRA, and a clear departure from HRSA's prior practice of not applying section 340B(c) to any of the numerous amendments to the Social Security Act provisions referenced in section 340B. Many of those Social Security Act amendments worked to expand the 340B Program, and therefore BIO strongly believes that application of the Letter's interpretation of section 340B(c) would undermine rather than promote the goals of the Program. BIO urges HRSA to withdraw the Letter in order to consider these implications and then to take any future action solely through a *Federal Register* notice that would permit public comment.

Section 340B(c) applies to "[a]ny reference in this section to a provision of the Social Security Act." The provisions of the Social Security Act referenced in the 340B statute have been amended many times since the 340B Program was enacted in 1992, *and the 340B Program has never previously directed manufacturers or covered entities to disregard any of those amendments when determining their rights and obligations under the statute*. Even with regard to the changes imposed by the DRA, the Letter mentions only the prompt payment discount amendment to the definition of AMP and not the other amendments to Social Security Act provisions cited in Section 340B.[1]

II. Does the Letter Interpretation Eliminate the Eligibility for Certain Entities?

Section 340B includes a list of "covered entities" eligible under the Program to purchase drugs at 340B prices. Many of the entities are defined through references to the Social Security Act, including federally-qualified health centers and Disproportionate Share Hospitals (DSHs). Congress has expanded those Social Security Act statutory definitions since November 4, 1992, and HRSA

[1] See Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 6001(d)(2) (Feb. 8, 2006) (amending the definition of Best Price by limiting nominal sales that may be excluded from the calculation); id. § 6003(a) (amending the definition of AMP and Best Price by requiring manufacturers to include sales of authorized generics in the brand drug's AMP and Best Price). These all were prospective changes to the Social Security Act. Id. §§ 6001(g), 6003(c).

has never stated that the subset of entities deemed eligible solely through the amendments were not to be considered "covered entities" eligible for 340B pricing. Specifically, application of the Letter's interpretation of section 340B(c) would adversely affect patient access through:

- Federally-Qualified Health Centers: The definition of federally-qualified health centers in the Social Security Act was amended in 1993. That year, Congress added outpatient health programs or facilities operated by an urban Indian organization receiving funds under the Indian Health Care Improvement Act for the provision of primary health services to the definition of federally-qualified health care centers.[2] These entities would not be considered covered entities and would not be eligible for 340B pricing if the position set forth in the Letter was implemented.

- Disproportionate Share Hospitals (DSHs): The Social Security Act definition of DSHs also has been amended several times, adding certain comprehensive cancer centers and clinical cancer research centers to the definition.[3] It was also amended to allow particular cancer hospitals to retain their DSH status when located in the same building or on the same campus with another hospital.[4] Under the policy set forth in the Letter, these DSHs would not be eligible for 340B prices.

As you know, section 340B defines the ceiling price as AMP minus the "rebate percentage" as defined in Social Security Act section 1927(c), which is the same as the rebate amount. Section 1927(c) defines the rebate amount in the case of innovator products in part based on the definition of Best Price.[5] The statutory definition of Best Price has been amended a number of times since 1992. These amendments exempt prices offered to certain entities from the Best Price calculation, thereby giving manufacturers an incentive to offer lower prices to those entities.[6] The Letter's purported application of section 340B(c) would remove this

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[2] Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, § 13631(f)(2). This was a prospective change to the Social Security Act. Id. § 13631(f)(3).

[3] Balanced Budget Act of 1997, Pub. L. No. 105-33, §§ 4417(b)(1), 4418(a)(1) (Aug. 5, 1997); Consolidated Appropriations Act, 2001, Pub. L. No. 106-554, Appendix D, Division B, Title 1, § 152(a) (Dec. 21, 2000). One of these amendments was made retroactive to cost reporting periods beginning on or after January 1, 1991 while the other two were prospective in application. Pub. L. No. 105-33, §§ 4417(b)(2), 4418(b)(1); Pub. L. No. 106-554, Appendix D, Division B, Title 1, § 152(c)(1).

[4] Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4417(a)(1). This amendment was prospective in application. Pub. L. No. 105-33, § 4417(a)(2).

[5] Social Security Act § 1927(c), 42 U.S.C. § 1396r-8(c).

[6] These amendments include the retroactive exclusion from Best Price of depot and single award contract prices, Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, § 13602(a)(1), (d)(1); the exclusion of prices negotiated from drug manufacturers for covered discount card drugs under an

incentive, by requiring these prices' inclusion in the determination of Best Price used for ceiling price purposes.

The most significant of these amendments to the 340B Program was that which excluded 340B prices offered to DSHs for drugs used in the inpatient setting.[7] This amendment was intended to create an incentive for manufacturers, already required to offer outpatient drugs to DSHs at 340B prices, to give DSHs the same discount on inpatient drugs. This incentive will disappear if manufacturers are required to include 340B prices offered to DSHs for inpatient drugs in the Best Price used to calculate 340B ceiling prices, to the detriment of the 340B covered entities.

III. Does Applying the Policy Set Forth in the Letter Undermine Efforts to Make the 340B Program More Transparent?

The 340B Program has been criticized for the lack of transparency as to manufacturer calculation of ceiling prices.[8] In its report *Deficiencies in the Oversight of the 340B Drug Pricing Program*, the Office of the Inspector General (OIG) recommended that the Health Resources and Services Administration (HRSA) "institute oversight mechanisms to validate its 340B price calculations."[9]

Currently HRSA can validate the 340B ceiling prices manufacturers charge covered entities. Manufacturers use the same data to calculate the AMP and Best Price figures they are required to submit to CMS under the Medicaid Drug Rebate Program and to calculate 340B ceiling prices. HRSA can access the AMP reported to CMS and the Medicaid rebate amounts CMS calculates from the reported pricing data to validate the 340B ceiling prices. If the policy in the Letter is implemented, this method of verification will become unavailable. The pricing information submitted by manufacturers to CMS to calculate Medicaid rebates will not be the same pricing data used to calculate 340B ceiling prices so that HRSA will not be able to use the information reported to CMS to verify the 340B prices. It is unclear whether HRSA has the staff or budgetary resources available to validate ceiling prices even when those prices are derived from reported Medicaid figures.

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endorsed discount card program created pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 103(e) (Dec. 8, 2003); and the prospective exclusion of prices charged which are negotiated by a prescription drug plan or qualified retiree plan for Medicare, id.

[7] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1002. The provision became effective upon enactment.

[8] Statement of John E. Dicken, Director of Health Care, Government Accountability Office Before the H. Comm. on Oversight and Government Reform, *available at* http://seaching.gao.gov/query.html?qt=+GAO-07-481T&charset=iso-8859-1&ql=; Office of the Inspector General, *Deficiencies in the Oversight of the 340B Drug Pricing Program*, Report OEI-05-02-00072 (Oct. 2005).

[9] Office of the Inspector General, *Deficiencies in the Oversight of the 340B Drug Pricing Program*, Report OEI-05-02-00072 at 21 (Oct. 2005).

Such validation will certainly become untenable from a resource perspective when ceiling prices cannot be validated from such readily-available data. Again, BIO expresses its deep concern that the application would appear to undermine rather than promote current Program priorities.

IV. Does the Letter's Policy Create an Excessive and Unnecessary Burden on Manufacturers.

BIO also wishes to emphasize the excessive burden that would result from the implementation of the policy set forth in the Letter. Each quarter manufacturers would have to calculate two separate AMP and rebate amount figures for each product, increasing the number of AMP calculations per year from 16 to 20 and the number of Best Price calculations per year from four to eight. For new products launched in or after 2007, manufacturers also would have to maintain two separate base date AMPs. The calculation of separate "340B" AMPs and rebate amounts will increase manufacturer compliance burdens and certainly will require manufacturers to hire and train additional personnel. The Letter has a stated goal of minimizing the burden on manufacturers in "submitting the required data," with regard to including customary prompt pay discounts in AMP for ceiling prices. As described above, the policy set forth in the Letter has much more far reaching implications. BIO does not believe that the 340B Program intended to impose the consequent burdens on manufacturers and therefore urges HRSA to withdraw its Letter on this basis as well.

V. Is The Letter Consistent With Prior HRSA Actions?

HRSA's decision to apply section 340B(c) solely and for the first time to the DRA's exclusion of prompt payment discounts from the definition of AMP is a clear and marked departure from HRSA's prior interpretations and directions regarding the 340B statute. That guidance has included a document published in the *Federal Register* that directed manufacturers to use the data reported to the Centers for Medicare and Medicaid Services (CMS) when calculating the ceiling price.[10] The Letter's current direction contradicts that guidance document, as the AMP and rebate percentage to be used post-DRA will not match those figures reported to CMS. Such a change in interpretation, particularly one that would adversely impact covered entity eligibility and manufacturer discount incentives,

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[10] Notice Regarding Section 602 of the Veteran's Health Care Act of 1992; New Drug Pricing, 60 Fed. Reg. 51488, 51488 (Oct. 2, 1995) ("Calculation of the current quarter PHS ceiling price for each covered outpatient drug, as provided in section 340B(a)(1) of the PHS Act, is based upon data supplied to the Medicaid Drug Rebate Program (i.e., AMP, baseline AMP, and BP). The manufacturer calculates pricing information for all of its covered outpatient drugs and sends this pricing data to HCFA within 30 days . . . .") (emphasis added).

also should take the form of a *Federal Register* notice and be subject to public comment.[11] BIO urges HRSA to withdraw the Letter for these reasons.

VI. Is The Letter Consistent with the Statutory Requirements?

BIO also believes that another reasonable interpretation can be found in Section 340B(c) of the Public Health Services Act (PHSA) which states that "[a]ny reference in this section to a provision of the Social Security Act shall be deemed to be a reference to the provision as in effect on [November 4, 1992]."[12] The purpose of this statutory requirement presumably is to limit those aspects of the 340B program that are based in the Social Security Act to the contours of the Social Security Act as in effect when the 340B program itself was created. However, BIO believes that the agency is improperly relying on this language as the Letter directs manufacturers to continue to include customary prompt pay discounts in AMP when calculating 340B ceiling prices and disregard the DRA's 2006 amendment to the AMP definition that now requires exclusion of those discounts from AMP.

The basis for this direction is the Health Resources and Services Administration's (HRSA's) assumption that the statutory definition of AMP in effect on November 4, 1992 included prompt pay discounts, so that such discounts should remain in the AMP used to calculate ceiling prices post-DRA. **This assumption is incorrect**. The reference to customary prompt pay discounts in the statutory definition of AMP was enacted as part of a **1993** amendment to the Social Security Act.[13] A correct application of section 340B(c) would direct manufacturers to continue to exclude customary prompt pay discounts from the calculation of AMP when determining 340B ceiling prices. BIO therefore urges that the Letter be withdrawn immediately and that HRSA provide this guidance no later than May 31, 2007, so that manufacturers have sufficient notice to apply the guidance to their ceiling price calculation for the third quarter.

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In sum, the Letter is inconsistent in its application of the cited provision of section 340B to other changes to the Social Security Act, including those in the DRA itself, as well as numerous prior amendments. In addition, such changes should not be effectuated through a letter but rather through a *Federal Register* notice that is

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[11] Any change in interpretation to a guidance document issued through a notice-and-comment process also should be subject to that same process. Cf. Alaska Professional Hunters Ass'n v. FAA, 177 F.3d 1030 (D.C. Cir. 1999).

[12] Public Health Services Act § 340B(c), 42 U.S.C. § 256b(c).

[13] Omnibus Budget Reconciliation Act of 1993, Pub. Law No. 103-66, § 13602(a)(2)(B)(i)(II), 107 Stat. 312, 618-19 (Aug. 10, 1993). The amendment was retroactive to the 1990 enactment of the Medicaid Rebate Statute, presumably to permit recalculations of AMP inclusive of such discounts, but clearly was not "in effect" on "the date of enactment of" the 340B Program.

subject to public comment. BIO also believes that the Letter's policy would limit rather than expand patient access and undermine any effort at the greater transparency that has been the focus of recent oversight efforts. Finally, BIO notes the excessive burden that implementing the Letter's policy would have on manufacturers. Thus, BIO urges HRSA to withdraw the Letter and provide any further guidance to manufacturers on these issues through a notice-and-comment rulemaking.

BIO greatly appreciates the opportunity to comment on the important issues raised by the Letter. We look forward to working with HRSA and the 340B Program to ensure the 340B Program's requirements are implemented effectively and efficiently. We sincerely hope that you will give thoughtful consideration to our comments. Please feel free to contact Jayson Slotnik 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 &
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cc: James Stansel, Deputy General Counsel, Office of the General Counsel, Department of Health and Human Services
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