BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

September 7, 2007

Mr. Bradford R. Lang
Public Health Analyst
Office of Pharmacy Affairs
Healthcare Systems Bureau
Health Resources and Services Administration
Department of Health and Human Services
5600 Fishers Lane
Parklawn Building, Mail Stop 10C-03
Rockville, MD 20857

Re: Comments on Notice Regarding the 340B Pricing Program; Children's Hospitals

Dear Mr. Lang:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to respond to the Health Resources and Services Administration's July 9, 2007 Notice and Request For Comment on proposed guidelines regarding the addition of children's hospitals to the Section 340B drug pricing program. *See* Notice Regarding the 340B Drug Pricing Program; Children's Hospitals, 72 Fed. Reg. 37,250 (July 9, 2007) (hereinafter the "July 2007 Notice" or the "Notice"). 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.

As a representative for an industry dedicated to developing new therapies and ensuring access to them, BIO supports the stated goals of the 340B program of improving patient access to necessary drug and biological therapies among indigent and vulnerable populations. However, BIO is concerned that the significant expansion of 340B discounts in recent years has not been accompanied by a commensurate increase in oversight to ensure that the benefits of the program reach these targeted patient populations. As you know, while the statute provides for covered entities to purchase covered outpatient drugs at the 340B 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). Thus, the extent to which the 340B program expansion will benefit patients is poorly understood.

BIO also includes in these Comments its view that HRSA lacks the legal authority to issue the guidelines proposed in the July 2007 Notice. By its terms, Section 340B defines the universe of "covered entities" eligible for the drug discounts set forth in that section. The Pharmaceutical Pricing Agreements ("PPAs") between the Secretary and pharmaceutical manufacturers only require the manufacturers to provide drug discounts to "covered entities" as defined in Section 340B. As HRSA acknowledged in its Notice, Congress has not amended Section 340B to include children's hospitals as "covered entities." As a result – and contrary to the assertions in the Notice – the existing PPAs cannot be read to require pharmaceutical manufacturers to extend the Section 340B discounts to children's hospitals. Furthermore, BIO believes that HRSA is not statutorily authorized to require manufacturers to amend their PPAs, or to enter new PPAs, to extend the Section 340B discounts to children's hospitals.

However HRSA ultimately decides to implement this any future changes to the 340B program that would expand eligibility, BIO urges the agency to evaluate first and foremost the impact of such changes on the patients for whom the program was intended by Congress to serve. We welcome the opportunity to work with HRSA to ensure that all of the 340B program's requirements are implemented in a clear, predictable, and efficient manner for all stakeholders so that the important program objectives can be achieved. BIO's specific comments on the Notice are included below.

1. The Secretary Lacks Authority to Require Manufacturers to Extend 340B Pricing To Children's Hospitals.

Under Section 340B of the Public Health Service Act, 42 U.S.C. § 256b, and Section 1927 of the Social Security Act, 42 U.S.C. §1396r-8, pharmaceutical manufacturers are required to provide discounted prices to specified "covered entities" in order for federal funds to be available to pay for the manufacturer's products under Medicaid and Medicare Part B. In Section 6004 of the Deficit Reduction Act of 2005 (the "DRA"), Congress amended the definition of "covered entity" in Section 1927 to include certain children's hospitals. *See* 42 U.S.C. § 1396r-8. Congress did not, however, amend Section 340B to similarly add these children's hospitals to the list of "covered entities" contained in that statute's definition.

HRSA has concluded that under Section 340B and the amended version of Section 1927 pharmaceutical manufacturers now are required to offer the specified children's hospitals discounted drug prices under their current PPAs. July 2007 Notice at 37,251. According to HRSA, "[g]iven the clear congressional intent in [the

DRA] to expand the category of covered entities, the PPAs currently in place effectively require manufacturers to provide 340B discounts to children's hospitals without need for further amendment to currently existing PPAs." *Id.* at 37,251. Under this interpretation of the statutory prerequisites, BIO members will be required to treat children's hospitals as "covered entities" under the Section 340B program.

This interpretation ignores the key fact that Congress did not amend Section 340B itself. Given that PPA contractual obligations are tied directly to Section 340B, BIO strongly believes that this congressional omission prevents HRSA from requiring manufacturers to extend 340B pricing to children's hospitals under their existing PPAs. BIO also believes the congressional decision not to amend Section 340B leaves the Secretary of the Department of Health and Human Services without authority to enter into new PPAs that include children's hospitals as covered entities.

A. The Secretary Cannot Amend or Otherwise Interpret Current PPAs To Require Manufacturers To Provide Discounted Prices To A New "Covered Entity" Not Specified In Section 340B.

The question of whether manufacturers are obligated to provide discounted prices to children's hospitals under their *current* PPAs is one of contract law. *See* Section 340B Pharmaceutical Pricing Agreement (2006), at 8; *see also County of Santa Clara v. Astra USA, Inc.*, 2006 WL 1344572 (N.D. Cal. 2006) (A PPA is a contract, the interpretation of which is governed by federal common law). Each manufacturer participating in the Section 340B program enters into a PPA with the Secretary under which the manufacturer agrees to offer discounted prices to covered entities as defined in Section 340B. The most recent version of this form agreement states:

> Pursuant to requirements under section 340B of the Act, the Manufacturer agrees to the following: (a) for single source and innovator multiple source drugs, to charge *covered entities* a price for each unit of the drug that does not exceed an amount equal to the [average manufacturer price less the rebate amount] for the covered outpatient drug . . . .

Section 340B Pharmaceutical Pricing Agreement (2006), at § II (emphasis added). Crucially, the PPA also states that "covered entity" for purposes of the agreement means the same thing as "covered entity" in Section 340B:

> "Covered Entity" means: (1) certain Public Health Service grantees, "look-alike" Federally Qualified Health Centers and disproportionate share hospitals *as described in section 340B(a)(4) of the Act*; and (2) in

> the case of a covered entity that is a distinct part of a hospital, the hospital itself shall not be considered a covered entity unless it meets the requirements of section 340B(a)(4)(L) of the Act, as determined by the Secretary.

Id. at § I(e) (emphasis added).

Manufacturers therefore are not required to charge the discount price to children's hospitals under their current PPAs. The PPA defines "covered entity" as the definition in 340B – and 340B does not include, and never has included, children's hospitals. It is hornbook contract law that "'where the words of a . . . contract[ ] have a plain and obvious meaning, all construction, in hostility with such meaning, is excluded.'" *Norfolk Southern Railway Co. v. Kirby*, 543 U.S. 14, 32 (2004) (quoting *Green v. Biddle*, 8 Wheat. 1, 89-90 (1823)). Accordingly it is incorrect as a matter of law to state that "the PPAs currently in place effectively require manufacturers to provide 340B discounts to children's hospitals without need for further amendment to currently existing PPAs." *See* July 2007 Notice at 37,251.

Furthermore, even if the definition of "covered entity" could be said to have been modified by the amendment to Section 1927, that change cannot be implemented unilaterally. The PPA is a contract. The Secretary is a party to that contract. As a contracting party it is subject to the normal rules governing contractual relationships. See, e.g., *United States v. Winstar Corp.*, 518 U.S. 839, 886 (1996) (applying standard contract principles to government contracting). The Secretary therefore cannot unilaterally change the terms of the contract and increase manufacturers' obligations. When manufacturers entered into their PPAs, they promised to provide the discounted price to the covered entities as defined at the time the PPA was signed. Those entities did not include children's hospitals, and the Secretary cannot amend the contract by fiat. As the PPA itself makes clear, "[e]xcept for changes of addresses, the Agreement will not be altered except by an amendment in writing signed by both parties." See Section 340B Pharmaceutical Pricing Agreement (2006), at § VII(h). The parties have not signed a written amendment to the PPA; therefore, they have not modified the agreement

B. The Secretary Cannot Enter Into New PPAs That Include Additional "Covered Entities."

Nor is the Secretary statutorily authorized to enter into *new* PPAs that would cover children's hospitals. Section 340B – the exclusive source of authority for PPA contracting – directs that "[t]he Secretary shall enter into an agreement with each manufacturer of covered drugs under which the amount required to be paid . . . to the manufacturer for covered drugs . . . *purchased by a covered entity* . . . does not exceed an amount equal to the average manufacturer price for the drug." 42 U.S.C.

§ 256b(a)(1) (emphasis added). The statute explicitly defines "covered entity" in Section 340B(a)(4), and that definition does not include children's hospitals. Therefore, a pricing agreement that includes drug sales to children's hospitals would not fall within the Secretary's authority. [1]

It is "axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress." *Bowen v. Georgetown University Hospital*, 488 U.S. 204, 208 (1988); *see also Killip v. Office of Personnel Management*, 991 F.2d 1564, 1569 (Fed. Cir. 1993) ("Any and all authority pursuant to which an agency may act ultimately must be grounded in an express grant from Congress").[2] It follows that "[a] regulation may not serve to amend a statute, nor add to the statute something which is not there." *California Cosmetology Coalition v. Riley*, 110 F.3d 1454, 1460 (9th Cir. 1997) (quotation marks and internal citations omitted). This remains true even if the agency purports to discern congressional suggestions, or policy considerations, that cut in a different direction: "When an agency acts in violation of an express congressional mandate, its motives are irrelevant" and its action must be struck down. *Electric Power Supply Ass'n v. F.E.R.C.*, 391 F.3d 1255, 1266 (D.C. Cir. 2004). Indeed – and particularly relevant here – the federal courts have "categorically reject[ed]" the notion that an agency "possesses plenary authority to act within a given area simply because Congress has endowed it with some authority to act in that area." *Railway Labor Executives' Ass'n v. National Mediation Bd.*, 29 F.3d 655, 670-671 (D.C. Cir. 1994). They have done so on the rationale that "'an agency literally has no power to act . . . unless and until Congress confers power upon it.'" *Id.* at 670-671 (quoting *Louisiana Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986)).

Here, Congress has delegated to the Secretary the authority to enter PPAs that require discounts to a precisely delineated set of private parties – namely, those defined as "covered entities" under Section 340B(4). That subsection carefully describes the 11 types of entities that fall within the statutory definition. *See* 42 U.S.C. § 256b(4)(A)-(L). It follows that the Secretary is without authority to enter into PPAs with entities that fall *outside* of the statutory definition. *See U.S. Telecom Ass'n v. FCC*, 359 F.3d 554, 592 (D.C. Cir. 2004) (holding that an agency

---

[1] Section 1927, the provision where the definition of "covered entities" *has* been altered, does not provide the Secretary with any contracting authority. Neither does it purport to somehow apply its altered definition of "covered entity" to Section 340B; to the contrary, it explicitly states that its definition of that term applies only "[i]n this subsection." 42 U.S.C. § 1396r-8(a)(5)(B).

[2] *See also Nagahi v. Immigration & Naturalization Service*, 219 F.3d 1166, 1169 (10th Cir. 2000) ("[A]n agency cannot create regulations which are beyond the scope of its delegated authority"); *Real v. Simon*, 510 F.2d 557, 564 (5th Cir. 1975) ("Administrative determinations must have a basis in law and must be within the granted authority.") (quoting *Social Security Board v. Nierotko*, 327 U.S. 358 (1946)).

was without power to "exclude from coverage certain items that clearly fall within the plain meaning of a statutory term."). A contrary rule – like the one implicitly endorsed in the July 2007 Notice – would give the Secretary the power to change the law, not implement it. This approach is clearly *ultra vires*: "The power of an administrative officer or board to administer a federal statute and to prescribe rules and regulations to that end is not the power to make law – for no such power can be delegated by Congress – but the power to adopt regulations to carry into effect the will of Congress *as expressed by the statute*." *Iglesias v. United States*, 848 F.2d 352, 366 (2d Cir. 1988) (emphasis added).

Section 340B, in short, has meaning only to the extent that it defines the scope of the program and the Secretary's authority to administer it. The statute's directive is quite specific; it expressly embraces certain entities within its scope and excludes others. BIO believes it is clear that Congress has not authorized the Secretary to enter into drug pricing agreements that include children's hospitals.

C. The Solution to the Statutory Gap Is For Congress To Amend Section 340B – Not For HRSA To Endorse A Legally Problematic Interpretation of the Statute.

The Secretary does not currently have the authority under 340B to enter into PPAs that include children's hospitals. If Congress wishes to amend that provision to direct manufacturers to provide discounted prices to children's hospitals, then it may do so. There may well be a "clear congressional intent in Section 6004 to expand the category of covered entities," as HRSA observes. Notice, *supra* at 37,251. But that "clear . . . intent" appears only in Section 6004. Section 340B on its face speaks with no such clarity. It is not permissible, as a basic matter of statutory interpretation, simply to tack "children's hospitals" on to a statute that has not been amended through the usual processes.

The mischief that could be wrought if this were an acceptable form of regulatory practice and statutory interpretation is manifold; Congress could amend one statute, and a federal agency – or a federal court – could invoke that amended provision in service of a different statutory interpretation, to reach a result quite different from that directed on the plain face of the statute. This is not just a mere housekeeping exercise in semantics; it is a strain on the statute to interpret it as HRSA suggests. There are processes that must be followed--as a legislative matter and a regulatory one--before the changes HRSA has proposed may be made. HRSA and Congress should pursue those processes before forcing these changes.

2. The Secretary Should Impose Adequate Controls and Audit Requirements on the Participation of Children's Hospitals in the 340B Program and Address the Impact of Retroactive Discounts on Federal Price Reporting Obligations.

Should the Secretary proceed with its stated intent to require manufacturers to extend 340B pricing to qualifying children's hospitals, BIO believes that a number of controls and safeguards should be put in place to ensure compliance with statutory requirements. As the Notice also provides for the retroactive provision of discounts to children's hospitals, BIO also urges HRSA to provide specific guidance, after consultation with the Centers for Medicare and Medicaid Services ("CMS") regarding the impact of such discounts on previously reported Average Manufacturer Price ("AMP") and Average Sales Price ("ASP") figures.

A. Children's Hospitals Must Comply with all Aspects of the 340B Program as a Covered Entity.

Should HRSA proceed with requiring manufacturers to provide 340B discounts to children's hospitals, BIO urges HRSA to finalize its proposal that children's hospitals must comply with current enrollment processes and certification requirements. The July 2007 Notice states that children's hospitals "must wait to enter or withdraw from the program until the next official updating of the 340B covered entity database" and that they "must comply with all program guidelines for covered entities until the date they are removed from the 340B covered entity database." Notice, *supra* at 37,251. Although BIO has serious legal concerns regarding classifying children's hospitals as a type of covered entity, we urge HRSA's to require children's hospitals to comply with current enrollment processes and ask that HRSA finalize this proposal.

BIO also agrees with HRSA's statement that "[u]nless children's hospitals are subject to all of the same rules as other covered entities, the inclusion of children's hospitals in the 340B Program would be difficult." *Id.* The July 2007 Notice also details the statutory certification requirements required of all covered entities that wish to participate voluntarily in the 340B program. *Id.* BIO agrees that children's hospitals must satisfy all of the same certification requirements as other covered entities and asks that HRSA finalize this position.

Finally, HRSA seeks comment as "to whether it would be appropriate to require a statement from an independent auditor certifying that a children's hospital meets the requirements of section 340B(a)(4)(L)(ii)" of the statute. *Id.* This statutory provision states that hospitals must meet the eligibility requirements of a disproportionate share hospital ("DSH") in order to be considered a covered entity. There are two methods for a hospital to qualify for additional payments as a

Medicare DSH. SSA § 1886(d)(5)(F). The primary method is for a hospital to qualify based on a complex statutory formula that results in the DSH patient percentage.[3] *Id*. The alternate special exception method is for large urban hospitals that can demonstrate that more than 30 percent of their total net inpatient care revenues come from State and local governments for indigent care (other than Medicare or Medicaid). *Id*. Given the complexity of these requirements and their newfound application to this distinct hospital category, BIO urges HRSA to require that an independent auditor verify DSH eligibility. BIO believes that HRSA should require an independent assessment and verification of DSH eligibility to ensure that the individual hospital is truly eligible to participate in the 340B program. BIO believes that an independent auditor will help children's hospitals comply with the many requirements of the 340B program and also ensure that only truly eligible entities receive 340B pricing.

B. HRSA Must Establish a Method to Verify Retroactive Eligibility.

The July 2007 Notice also proposes to permit children's hospitals to access 340B pricing as of the date of enactment of the Act because that is the stated effective date of the children's hospital provision. As the DRA was enacted on February 8, 2006, the Notice would permit children's hospitals to be eligible for retroactive discounts back to that date. BIO believes that HRSA must be required to document the eligibility and compliance of these new entities with the 340B program requirements for any time period of eligibility, including retroactive periods.

HRSA states that in order to receive the 340B discount retroactive to February 8, 2006, the entity must have been eligible for the discount as of that date. BIO fully supports this provision but urges HRSA to establish a mechanism and documentation requirements for verifying eligibility back to February 8, 2006. Once completed, BIO asks that HRSA publish on its website the date on which each children's hospital became eligible for the 340B program, including retroactive periods. Additionally, BIO believes that HRSA should create an audit or certification process to determine the actual date that the facility met all the requirements to become eligible either for the 340B program and/or 340B discounts. Similarly, children's hospitals must be able to verify that the drug for which they are seeking a retroactive discount was actually an outpatient drug provided to a patient as both terms are defined in regulation. BIO also believes that manufacturers should have the right to audit the processes and documentation that

---

[3] The DSH patient percentage is equal to the sum of the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income (SSI), and the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A. SSA § 1886(d)(5)(F).

HRSA establishes before the manufacturers are obligated to provide the retroactive discount, and that there should be some type of dispute resolution process if a manufacturer has reason to believe that HRSA's determination is incorrect.

Lastly, BIO asks that HRSA specify that when a children's hospital voluntarily agrees to participate in the 340B program that it must be required to explicitly request retroactive discounts; that HRSA require that any such request be made within 120 days of publication of a final notice; and that such a request specify how the children's hospital can comply with the duplicate discount prohibition contained in the statute on a retroactive basis. The 340B statute prohibits covered entities from seeking 340B discounts on drugs that are included by a state in its Medicaid rebate claim, and where such discounts are sought on a retroactive basis, BIO is concerned that such an exclusion is impossible. Compliance with this prohibition must be specifically addressed in any request for and approval of retroactive discounts.

Manufacturers must comply with many different pricing requirements for a variety of federal pricing programs. Our members therefore need certainty and predictability in pricing programs to help ensure compliance. Clear timelines and an explicit request by the children's hospital that verifies eligibility for an appropriate discount would greatly reduce the administrative burdens on manufacturers when complying with the 340B program.

C. HRSA Should Urge CMS to Provide Guidance Stating that the Retroactive Discounts are Excluded From the AMP and ASP Calculations.

As you know, sales to 340B covered entities are exempt from the calculation of AMP and ASP. A requirement to provide a retroactive discount raises the important question of how such discounts will impact the previously calculated and submitted monthly AMP and quarterly ASP figures for the periods impacted by the retroactive discounts. BIO urges HRSA to work with CMS to issue specific guidance indicating that manufacturers can ignore the impact of these retroactive discounts on the ASP and AMP figures previously calculated for any impacted prior periods. Accordingly, manufacturers would not need to restate any previously submitted monthly AMP and quarterly ASP figures to account for those transactions, because these transactions did not exist at the time the figures originally were calculated and submitted.

D. HRSA Should Further Define the Term Children's Hospital.

The DRA, when amending the Social Security Act ("SSA") to add children's hospitals, references section 1886(d)(1)(B)(iii), which states that children's hospitals

are hospitals "whose inpatients are predominantly individuals under 18 years of age." SSA § 1886(d)(1)(B)(iii). BIO urges HRSA to specifically define "predominantly" to mean that in any fiscal or calendar year no less than 80 percent of patient days involve patients under 18 years of age. By providing this clarity, HRSA will effectuate congressional intent and ensure that only those hospitals that predominantly serve children will access 340B pricing.

* * *

BIO greatly appreciates the opportunity to comment on the important issues raised by the July 2007 Notice. We look forward to working with HRSA and the Section 340B Program to ensure that its requirements are implemented effectively, efficiently, and in keeping with the governing statutes. We sincerely hope that you will give thoughtful consideration to our comments. Please feel free to contact me at 202-962-6673, or John Siracusa at 202-312-9281, if you have any questions regarding these comments.

Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

Sandra J.P. Dennis
Deputy General Counsel
Healthcare Regulatory Affairs