August 17, 2015

VIA EMAIL: 340BCMPNPRM@hrsa.gov

CDR Krista Pedley, Director
Office of Pharmacy Affairs
Healthcare Systems Bureau
Health Resources and Services Administration
5600 Fishers Lane
Mail Stop 08W05A
Rockville, MD 20857

Re: RIN 0906-AA89
Comments on HRSA Proposed Rule—340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation

Dear CDR Pedley:

The undersigned 340B organizations (340B organizations) appreciate the opportunity to comment on the proposed rule, *340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation*. On June 17, 2015, the Health Resources and Services Administration (HRSA) issued a notice of proposed rulemaking related to 340B ceiling prices and the imposition of civil monetary penalties (CMPs) on manufacturers under the 340B Drug Pricing Program (340B program). The proposed rule would implement provisions of the Affordable Care Act (ACA) that require the Secretary of Health and Human Services (HHS) to develop and publish standards for calculating ceiling prices and to impose CMPs on manufacturers that knowingly and intentionally charge covered entities in excess of the ceiling price. The 340B organizations applaud HRSA for proposing to codify the formula for calculating 340B ceiling prices and penny prices and for setting standards for CMPs. These rules are critically important for ensuring that the 340B program provides covered entities with the benefits intended by Congress. The 340B organizations suggest that HRSA clarify and strengthen certain details of the 340B CMP program.

The 340B organizations represent the tens of thousands of safety net providers participating in the 340B program. Accordingly, the 340B organizations are uniquely positioned to present the perspective of 340B covered entities on the proposed rule. As explained more fully below, the 340B organizations' position on the proposed rule is as follows:

- HRSA should ensure that no changes are made that could impede or hamper federal grantees' ability to negotiate sub-340B or non-340B prices with manufacturers individually, or collectively through group purchasing organizations.
- HRSA should clarify that a drug purchased at or below the ceiling price is a 340B drug only when the price is required by a pharmaceutical pricing agreement and that drugs which are discounted outside the 340B program are not included within the definition of "340B drug," even when sold at or below the ceiling price.

- HRSA should state its statutory authority to issue regulations governing 340B ceiling price calculations.
- The 340B organizations support HRSA's 340B ceiling price formula and efforts to develop a 340B ceiling price database but recommends that HRSA clarify the definition of "case package size."
- The 340B organizations support HRSA's codification of the penny pricing policy.
- The 340B organizations generally support HRSA's codification of the new drug pricing policy with technical clarifications. HRSA should require manufacturers to issue refunds for all overcharges, not just overcharges on new drugs.
- The 340B organizations support HRSA's proposal to assess CMPs according to Office of the Inspector General (OIG) procedures but requests that HRSA clarify that key definitions from OIG regulations will be incorporated into the 340B CMP program. Specifically, a manufacturer should be subject to CMPs based on the manufacturer's actual knowledge, deliberate ignorance, or reckless disregard of an overpayment.
- The 340B organizations recommend that HRSA define "instance of overcharging" on a per-unit basis rather than on a per-order basis.
- HRSA should clarify that the obligation of a manufacturer to ensure the availability of 340B pricing applies to a covered entity's contract pharmacy arrangement with a specialty pharmacy in a manufacturer's limited distribution network for a particular drug.
- HRSA should require manufacturers to honor a covered entity's request to reclassify a purchase from non-340B to 340B and to issue a corresponding refund if a covered entity requests such a reclassification within one year of purchase.

Definitions (42 C.F.R. § 10.3)

I. Group Purchasing Organization

The proposed rule deletes the definition of "Group Purchasing Organization" (GPO) from the regulation. It appears that this deletion occurs simply because the proposed rule will not address orphan drug exclusion. Accordingly, the proposed rule's deletion of the definition does not alter the status quo of GPOs in the 340B program. We ask that HRSA ensure that no changes are made that could impede or hamper federal grantees' ability to negotiate sub-340B or non-340B prices with manufacturers individually, or collectively through GPOs.

II. 340B Drug

The proposed rule defines "340B drug" as "covered outpatient drug … purchased by a covered entity at or below the ceiling price pursuant to a pharmaceutical pricing agreement with the Secretary." HRSA should clarify that a drug purchased at or below the ceiling price is a 340B drug only when the price is required by a pharmaceutical pricing agreement and that drugs which are discounted outside the 340B program are not included within the definition of "340B drug," even when sold at or below the ceiling price.

340B Ceiling Price Calculations (42 C.F.R. § 10.10)

I. HRSA Authority to Regulate 340B Ceiling Price Calculation

HRSA should state that the 340B statute explicitly grants authority to the Secretary of HHS (Secretary) to issue regulations for 340B ceiling price calculations. Specifically, the 340B statute directs HHS to "[d]evelop[] and publish[] through an appropriate policy or regulatory issuance, precisely defined standards and methodology for the calculation of ceiling prices."[1] The Secretary's authority to issue regulations for 340B ceiling price calculations was recently confirmed by the U.S. District Court for the District of Columbia, which stated that 42 U.S.C. § 256b(d)(1)(B)(i)(I) specifically "mention[s] the Secretary's ability to issue regulations" governing the calculation of the 340B ceiling price.[2] HRSA should clarify the statutory basis for its authority. Accordingly, the 340B organizations recommend that HRSA amend the proposed rule at 42 C.F.R. § 10.1 as follows:

> This part implements section 340B of the Public Health Service Act (PHSA) "Limitation on Prices of Drugs Purchased by Covered Entities." Section 340B(d) of the PHSA directs the Secretary to issue regulations defining standards and methodology for the calculation of ceiling prices and for the imposition of civil monetary penalties on manufacturers that knowingly and intentionally charge covered entities a price for purchase of a drug that exceeds the ceiling price.

II. 340B Ceiling Price Formula

The 340B organizations support the formula in the proposed rule for manufacturers to calculate the 340B ceiling price. A ceiling price for a covered outpatient drug is equal to "the Average Manufacturer Price (AMP) for the smallest unit of measure minus the Unit Rebate Amount (URA)" calculated to six decimal places. HRSA will then multiply this figure by the drug's package size and case package size, calculated to two decimal places. The proposed rule also states that HRSA "will publish the 340B ceiling price to two decimal places." This provision appears to be a reference to the 340B ceiling price database that HRSA is developing to give covered entities' access to ceiling price information. The 340B organizations support HRSA's steps towards developing the 340B ceiling price database.

The 340B organizations are concerned, however, about the term "case package size" in the proposed 42 C.F.R. § 10.10(a) because it apparently creates a new, undefined unit of measure. The term "case package size" is not defined in the definition section and is not used elsewhere in the rule. The preamble mentions the term but does not explain its meaning. The 340B organizations request that HRSA clarify the term "case package size" to assist stakeholders in understanding how 340B prices are calculated and to ensure consistency in the methodology used by manufacturers to calculate 340B prices.

---

[1] 42 U.S.C. § 256b(d)(1)(B).

[2] *Pharmaceutical Res. & Manufs. of Am. v. U.S. Dep't of Health & Human Servs.*, 43 F. Supp. 3d 28 (D.D.C. 2014).

III. Penny Pricing

The 340B organizations support HRSA's codification of its penny pricing policy, which should help ensure that covered entities receive equitable pricing on 340B drugs.[3] Section 10.10 notes an exception to the above AMP calculation. When the AMP is equal to the URA, the ceiling price will be set at $0.01 per unit. The proposed rule refers to this as "penny pricing." HRSA states in the preamble that "[m]anufacturers may not use the prior quarter's pricing, wholesale acquisition cost (WAC), or any other non-340B contract price in the place of the penny pricing." The 340B organizations strongly support HRSA's clarification that manufacturers may not use alternative methods to set the 340B price of a drug when the 340B ceiling price calculation results in an amount less than a penny.

In a 2006 report, the HHS OIG sampled 340B purchases and found that the largest overcharges were due to manufacturers' failure to comply with HRSA's penny pricing policy.[4] OIG found that manufacturers overcharged for more than half of drugs subject to penny pricing with incorrect charges ranging "anywhere from $1.65 to $1,931 per purchase over the ceiling price."[5] The 340B organizations are concerned that manufacturers continue to misapply the penny pricing policy and overcharge covered entities. The 340B organizations therefore welcome HRSA's codification of the policy.

The penny pricing policy treats manufacturers equitably because it relieves them from a statutory duty to provide certain drugs at no cost. By incorporating an inflation factor into the URA, Congress structured the ceiling price formula to discourage manufacturers from raising prices faster than inflation. Congress presumably understood and intended that the statutory formula could result in ceiling prices that are extremely low. The plain language of the statute appears to require manufacturers to provide covered outpatient drugs at no cost in those instances where the AMP minus the URA is less than a penny. The penny pricing policy is, therefore, generous to manufacturers because it tempers the statutory pricing calculation while ensuring that covered entities are not charged excessively.

Finally, HRSA's penny pricing policy is easy to administer and enforce. Possible alternatives, such as price reductions in future quarters, would require complex tracking mechanisms by all interested parties. The 340B organizations support penny pricing because it will conserve the resources of the agency, manufacturers, and covered entities.

---

[3] HRSA's current penny pricing policy is stated in Policy Release 2011-2, "Clarification of Penny Pricing Policy." http://www.hrsa.gov/opa/programrequirements/policyreleases/pennypricingclarification112111.pdf.

[4] Dept. of Health and Human Servs., OIG, *Review of 340B Prices* (July 2006), https://oig.hhs.gov/oei/reports/oei-05-02-00073.pdf.

[5] *Id.* at ii.

IV. New Drugs

A. Codification of HRSA's New Drug Pricing Policy

The 340B organizations support HRSA's codification of its new drug pricing policy.[6] Section 10.10 of the proposed rule contains a special provision for new drugs. For a new drug, a manufacturer must estimate the ceiling price for the first three quarters the drug is available for sale. This price estimation operates as the ceiling price for the first three quarters the drug is available for sale. In the fourth quarter, a manufacturer must begin calculating the ceiling price in accordance with the above described formula (AMP – URA). In addition, a manufacturer must calculate "actual ceiling prices" for the first three quarters. If the "actual ceiling prices" are less than the estimated ceiling prices for the first three quarter, the rule requires a manufacturer to provide a refund or credit to covered entities that purchased the drug at the higher estimated prices. Refunds or credits for the first three quarters must be provided to covered entities by the end of the fourth quarter. This rule appropriately ensures that covered entities will be able to obtain 340B pricing when a drug first comes to market.

We believe HRSA should clarify the term "actual ceiling prices" to ensure covered entities receive access to discounted pricing. The 340B organizations presume that the URA and AMP first calculated in the third quarter will be used for the first and second quarters. The use of the word "actual" to describe the ceiling price in the first two quarters might be somewhat misleading, as the AMP used to calculate the URA for those two quarters is only available once the actual sales data from those two quarters is made available to CMS.[7] The 340B organizations suggest that HRSA clarify this issue in the final rule by describing the ceiling price in the first two quarters as the "calculated" ceiling price instead.

B. Refund Policy for 340B Overcharges

Importantly, in a positive shift from current policy, a manufacturer's obligation to issue a refund or credit does not appear to be conditioned on a covered entity requesting the refund or credit. The 340B organizations support HRSA's requirement that covered entities do not have to contact manufacturers in order to receive refunds or credits for overcharges on new drugs.[8] Furthermore, it is appropriate to assign responsibility to manufacturers to issue refunds without being requested to do so because manufacturers have ready access to pricing information and are best positioned to identify overcharges. Covered entities, as safety net providers, often lack resources to track changes in new drug prices and to submit refund requests. The 340B organizations suggest that HRSA revise the rule to establish more clearly that manufacturers have an affirmative obligation to contact affected covered entities to coordinate the refund of the overpayment within a reasonable period of time after discovering an overcharge. The 340B organizations support HRSA's proposed rule to set a deadline for issuing refunds or credits by the end of the fourth quarter. Accordingly, the 340B organizations request that HRSA add the

[6] HRSA's current pricing policy for new drugs is stated at 60 Fed. Reg. 51,488 (Oct. 2, 1995). *Available at* http://www.hrsa.gov/opa/programrequirements/federalregisternotices/newdrugpricing100295.pdf.
[7] *See* 80 Fed. Reg. at 34,585, 34,588.
[8] *See* 42 U.S.C. § 256b(d)(1)(B)(ii)(II).

following to the end of the proposed 42 C.F.R. § 10.10(c): "A covered entity is not required to request such refunds or credits."

The 340B organizations request that HRSA clarify that this refund policy applies to all overcharges, not just overcharges on new drugs. Specifically, covered entities should not have to request refunds following AMP "true-ups," which occur when manufacturers restate the reported AMP for a particular period and are supposed to refund any difference to covered entities that were overcharged. The 340B organizations are concerned that manufacturers regularly do not issue refunds when the AMP is restated and should be required to do so without putting the onus on covered entities to request the refund. Indeed, the 340B statute mandates that manufacturers issue refunds "accurately and within a reasonable period of time, both in routine instances of retroactive adjustment to relevant pricing data and exceptional circumstances such as erroneous or intentional overcharging for covered outpatient drugs."[9] The statute does not condition refunds on requests by a covered entity. Accordingly, the 340B organizations request that HRSA add a new subsection (d) to the proposed 42 C.F.R. § 10.10:

> (d) *Manufacturer Refunds*. (1) With respect to any covered outpatient drug, as identified by its NDC, if a manufacturer retrospectively recalculates, restates, or otherwise changes any variable (such as AMP or best price) with respect to a prior calendar quarter or prior calendar quarters that results in the recalculation of a lower 340B ceiling price than that charged to covered entities during the affected quarter(s), the manufacturer must issue a refund to each affected covered entity for the aggregated amounts paid by the covered entity in excess of the recalculated 340B ceiling price for 340B drugs purchased by the covered entity during the affected quarter(s). The refund must be made within three months of the recalculation. A manufacturer that fails to issue such refunds in a timely manner will be deemed to have knowingly and intentionally overcharged affected covered entities.

The 340B organizations would support a reasonable threshold below which manufacturers would not be required to issue refunds if the manufacturer did not knowingly and intentionally overcharge for the drug. The 340B organizations would also support establishing a reasonable time frame after which a manufacturer would not be required to provide a refund if the manufacturer did not knowingly and intentionally overcharge for the drug. Any minimum threshold and time frame should apply both to amounts owed by manufacturers to covered entities and to any repayment amounts owed by covered entities to manufacturers.

The 340B organizations are aware that refund processing can be challenging for both drug manufacturers and covered entities. Solutions, including a manufacturer refund service being developed by the 340B program's prime vendor, Apexus, Inc., are eroding this barrier for manufacturers. Perceived logistical challenges should not excuse manufacturers from their statutory obligation to refund overpayments in a timely manner.[10]

[9] 42 U.S.C. § 256b(d)(1)(B)(ii)(II).
[10] *Id.*

Civil Monetary Penalties (42 C.F.R. § 10.11)

The 340B organizations generally agree with HRSA's proposed CMP rule. However, we have identified several changes that HRSA should make to ensure that the rule effectively safeguards the 340B program. HRSA should expressly delegate authority to the OIG to enforce the CMP rule. HRSA should define "knowingly and intentionally." A portion of CMP penalties should be used to support the 340B program. HRSA should revise the definition of "instance of overcharging" to a per-unit basis. HRSA should also revise the timing of penalties, as specified below.

I. Codify Delegation of Authority to OIG

The 340B organizations agree with the provision in the proposed rule that penalties will be assessed according to the OIG's procedures used to impose CMPs under 42 C.F.R. Part 1003 and that OIG will have authority to bring 340B CMP actions. The delegation of authority to OIG should be explicitly stated in the regulation, and not just mentioned in the preamble. The 340B organizations disagree with HRSA's characterization that an instance of overcharging will "occur very rarely if at all," and the 340B organizations believe that enforcement by OIG will appropriately safeguard the integrity of the 340B program while ensuring due process for manufacturers subject to CMPs. This function falls well within OIG's mission, and OIG's expertise will enhance the efficiency, speed, and fairness of implementing the new CMP structure. Accordingly, the 340B organizations request that HRSA add the following sentence between the second and third sentences of the proposed 42 C.F.R. § 10.11(a): "The Department of Health and Human Services Office of Inspector General is responsible for bringing 340B civil monetary penalty actions utilizing the standards applied to other civil monetary penalties under parts 1003 and 1005."

II. Define Knowingly and Intentionally

The 340B organizations recommend that HRSA clarify that definitions tied to OIG procedures will be used for purposes of the 340B CMP program. Specifically, the proposed rule states that manufacturers will be held liable for civil monetary penalties if the manufacturer "knowingly and intentionally charges a covered entity more than the ceiling price" as defined above. However, the rule does not define "knowingly or intentionally." Therefore, it is unclear what type of actions would cause the imposition of a penalty.

HRSA should incorporate key definitions from the OIG's CMP regulations. OIG regulations impose civil monetary penalties on entities that "knowingly" present certain improper claims.[11] An entity "knowingly" submits an improper claim if it had actual knowledge that the claim was improper, acted in deliberate ignorance of the truth or falsity of the information presented, or acted in reckless disregard of the truth or falsity of the information presented.[12] The 340B organizations recommend that HRSA apply these standards for imposing 340B CMPs. Specifically, a manufacturer should be subject to CMPs based on the

[11] 42 C.F.R. § 1003.102.
[12] *See id.* § 1003.101-.102.

manufacturer's actual knowledge, deliberate ignorance, or reckless disregard of an overpayment. Accordingly, the 340B organizations request that HRSA add the following definition to the proposed 42 C.F.R. § 10.3: "*Knowingly* has the meaning set forth in 42 CFR 1003.102."

The 340B organizations are not aware of an analogous definition for the term "intentionally", as it is used in the proposed regulations. The 340B organizations request that HRSA add the following definition to the proposed 42 C.F.R. § 10.3: "*Intentionally* means not due to a mathematical miscalculation, clerical oversight or similar inadvertent error."

III. Prescribe Use of Collected Penalties to Support Program

The proposed rule does not specify how funds collected from CMPs will be used. The 340B organizations believe that it would be appropriate, and conducive to enhancement of 340B program compliance, if a portion of funds collected from manufacturer CMPs were directed to the HRSA Office of Pharmacy Affairs to support its 340B program responsibilities. The 340B organizations also believe that it would be appropriate to allocate a portion of funds collected from manufacturer CMPs to the OIG to support its enforcement of the 340B CMP program. We also recommend that HRSA direct a portion of the CMP funds towards the creation, operation, and maintenance of the 340B ceiling price database.

IV. Revise Instance of Overcharging to a Per-Unit Basis

The 340B organizations recommend that HRSA revise its definition of an "instance of overcharging." The proposed rule defines an "instance of overcharging" in § 10.11(b) as "any order for a covered outpatient drug, by NDC, which results in the covered entity paying more than the ceiling price." The term "order" is key. Section 10.11(b)(1) provides that penalties are levied by order, regardless of the number of units within the order. For example, under the proposed rule, a manufacturer could face a single $5,000 penalty for an order that contained ten units, or could face a $50,000 penalty if it overcharged ten orders, each containing one unit. The 340B organizations believe that it would be more appropriate to define an "instance" on a per-unit basis. Thus, if a covered entity is overcharged for 100 units of a covered outpatient drug in single transaction, this should be considered 100 instances of overcharging subject to a CMP. Because the statutory CMP authority provides for imposition of penalties *up* to $5,000 per instance, a decision maker will have adequate discretion to adjust the penalty amounts, so that the total CMP imposed is not excessive when measured against the factors described in the advanced notice of proposed rulemaking pertaining to penalty computation. The definition in the proposed rule would have the perverse effect of imposing a relatively lower per-unit penalty on manufacturers that overcharge for large orders containing multiple units. Accordingly, the 340B organizations request that HRSA revise the proposed 42 C.F.R. § 10.11(b) as follows, strike subsection (b)(1), and renumber subsections (b)(2) through (b)(5) accordingly:

> (b) *Instance of overcharging*. An instance of overcharging is the sale of any unit of a covered outpatient drug, identified by NDC, which results in a covered entity paying more than the ceiling price, as defined in § 10.10, for that covered outpatient drug.

V. Manufacturers Should Not Offset Overcharges with Discounts

The 340B organizations support HRSA's position that a manufacturer may not offset an instance of overcharging with discounts provided on other NDCs or on the same NDC on other transactions, orders, or purchases. HRSA's policy not to permit such offsets will encourage manufacturers to develop systems for accurately assessing 340B prices and will promote manufacturer self-monitoring and compliance programs. It also avoids the need to establish complex tracking systems to ensure that the offsets are accurate and timely.

VI. CMPs Should Be Applied to Manufacturers When Covered Entities Are Overcharged on Orders Through Third Parties

The 340B organizations also support applying CMPs to manufacturers when covered entities are overcharged on orders placed through third parties. Section 10.11(b)(1) provides that manufacturers are liable for penalties even when orders are placed through a wholesaler or distributor. HRSA appropriately suggests that manufacturers work with wholesalers to ensure compliance with ceiling prices. In addition, HRSA should clarify that the obligation of a manufacturer to ensure the availability of 340B pricing applies to a covered entity's contract pharmacy arrangement with a specialty pharmacy in a manufacturer's limited distribution network for a particular drug, unless such purchases are prohibited under other laws. Covered entities have serious concerns about the availability of 340B pricing for drugs in limited supply or sold through limited distribution networks. Covered entities report that they have faced 340B pricing challenges when contracting with a pharmacy in a manufacturer's specialty pharmacy network. HRSA should clarify that a manufacturer will be subject to CMPs if a pharmacy in the manufacturer's network overcharges for 340B drugs. Accordingly, the 340B organizations request that HRSA revise the proposed 42 C.F.R. § 10.11(b)(2) as follows:

> (2) Manufacturers have an obligation to ensure that the 340B discount is provided through distribution arrangements made by the manufacturer, including arrangements with wholesalers, distributors, or pharmacies within the manufacturer's limited distribution network(s).[13]

VII. HRSA Should Revise the Timing of Penalties

HRSA should revise its proposed timing of penalties. The proposed rule states that a manufacturer may overcharge on two occasions: (1) at the time of the initial purchase of the drug or (2) when the manufacturer retroactively recalculates the ceiling price and refuses to refund the difference to the covered entity. However, if the covered entity did not identify the purchase to the manufacturer as 340B-eligible at the time of purchase, then the manufacturer is neither liable for a monetary penalty nor required to issue a refund to the covered entity. This provision would relieve manufacturers of the obligation to provide 340B pricing when a covered entity mistakenly purchases a 340B-eligible drug at a non-340B price. The 340B organizations agree that manufacturers should not be subject to CMPs as a result of a covered entity's mistake, but

[13] This subsection should be redesignated as subsection (b)(1) because, as explained above, the 340B organizations request that HRSA strike the current subsection (b)(1).

manufacturers should still honor their 340B obligations even when errors occur. HRSA should require manufacturers to honor a covered entity's request to reclassify a purchase from non-340B to 340B and to issue a corresponding refund if a covered entity requests such a reclassification within 365 days of purchase. Accordingly, the 340B organizations request that HRSA revise the proposed 42 C.F.R. § 10.11(b)(4)-(5) as follows:

> (4) An instance of overcharging may occur at the time of the initial purchase; when subsequent ceiling price recalculations due to pricing data submitted to CMS result in a covered entity paying more than the ceiling price due to failure or refusal to refund or credit a covered entity; or when a manufacturer fails to reclassify a prior purchase of a covered outpatient drug from a non-340B price to the 340B ceiling price if such a reclassification is requested by a covered entity within one year of purchase.
>
> (5) A manufacturer's failure to provide the 340B ceiling price is not considered an instance of overcharging when a covered entity did not initially identify the purchase to the manufacturer as 340B-eligible at the time of purchase, unless the covered entity requests reclassification of the purchase within one year.[14]

VIII. CMPs Should Be Imposed for Overcharges on or after September 19, 2010

Furthermore, HRSA should revise the proposed rule to state that CMPs may be imposed for overcharges that occurred prior to the effective date of the final regulation as intended by Congress. Congress believed that manufacturer overcharges were a severe problem that warranted imposing CMPs shortly after the enactment of the ACA. The ACA mandated that HHS promulgate regulations for manufacturer CMPs within 180 days after March 23, 2010.[15] That deadline was on September 19, 2010. The CMP rules are now nearly five years overdue, and manufacturers should be subject to liability for overcharges occurring at any time after September 19, 2010 as required by Congress. We believe that covered entities have continued to face overcharges in the five years since enactment of the ACA. Accordingly, the 340B organizations request that HRSA add the following new subsection (c) to the proposed 42 C.F.R. § 10.11: "(c) These provisions apply to purchases made on or after September 19, 2010."

[14] These subsection should be redesignated as subsections (b)(3) and (b)(4), respectively, because, as explained above, the 340B organizations request that HRSA strike the current subsection (b)(1).
[15] 42 U.S.C. § 256b(d)(1)(B)(vi)(I).

Conclusion

The 340B organizations believe that the proposed rule is a positive step toward ensuring manufacturer compliance with 340B program requirements and encourages HRSA to improve the rule as described above. The 340B organizations thank HRSA for the opportunity to comment on the proposed rule. If you have any questions, please feel free to reach out to any of the attached contacts.

Sincerely,

National Association of Community Health Centers
The Hemophilia Alliance
Planned Parenthood Federation of America, Inc.
National Health Care for the Homeless Council
America's Essential Hospitals
Children's Hospital Association
Ryan White Clinics for 340B Access
340B Health

Organizational Contacts

Colleen P. Meiman
Director of Regulatory Affairs
National Association of Community Health Centers
202-296-0158
cmeiman@nachc.org

Joe Pugliese
President
The Hemophilia Alliance
215-439-7173
joe@hemoalliance.org

Amy Yenyo
Senior Policy Counsel
Planned Parenthood Federation of America, Inc.
202-973-4870
amy.yenyo@ppfa.org

Beth Feldpush, DrPH
Senior Vice President, Advocacy and Policy
America's Essential Hospitals
202-585-0111
bfeldpush@essentialhospitals.org

Liz Parry
Manager
Children's Hospital Association
202-753-5392
liz.parry@childrenshospitals.org

Dr. Howell Strauss
President
Ryan White Clinics for 340B Access
610-389-2301
howellstrauss@aidscaregroup.org

Maureen Testoni
Senior Vice President & General Counsel
340B Health
202-552-5851
maureen.testoni@340bhealth.org