October 11, 2016

Captain Krista Pedley, Director, Office of Pharmacy Affairs (OPA)
Health Care Systems Bureau, HRSA
5600 Fishers Lane, Mail Stop 08W05A
Rockville, MD 20857

Re: 340B Drug Pricing Program Administrative Dispute Resolution RIN 0906-AA90

Dear Captain Pedley:

The Coalition for Government Procurement ("the Coalition") appreciates the opportunity to provide comments on the Health Resources and Services Administration ("HRSA") proposed rule establishing the requirements and procedures for the 340B Program's administrative dispute resolution process (81 Fed. Reg. 53381-53388, August 12, 2016) ("Proposed Rule"). These comments are timely submitted by the October 11, 2016 due date.

The Coalition is a non-profit association of firms selling commercial services and products to the Federal Government. Our members include small, medium and large businesses concerns representing many different industries, including both brand and generic pharmaceutical manufacturers, and collectively account for a significant percentage of commercial items purchased annually by the Federal Government. The Coalition is proud to have worked with government officials for more than 35 years towards the mutual goal of common sense acquisition. The Proposed Rule applies to all drug manufacturers and covered entities participating in the 340B program. Therefore, Coalition members who sell pharmaceutical and biological products and have entered into a Pharmaceutical Pricing Agreement ("PPA") with HRSA have an interest in the Proposed Rule.

Comments

Introduction and General Comments

The 340B Drug Pricing Program is a statutorily created drug purchase discount program intended to assist the poor and uninsured obtain needed medication from safety net providers by reducing the price these providers pay for drugs. It is implemented through standardized terms of a contract – the PPA - entered into between HRSA and pharmaceutical manufacturers, including members of the Coalition. Under the statutory scheme set forth in section 340B of the Public Health Service Act, codified in 42 U.S.C. §256b, the terms of the PPA setting forth manufacturers' obligations are specified in the statute, and these terms can only be amended by

statute. In accordance with the statute and PPA, manufacturers must charge no more than the statutorily specified price, referred to as the "340B price," for "covered outpatient drugs" when purchased by those health care providers whom Congress determines should benefit from the agreement, referred to as "covered entities" ("CEs"), and dispensed or administered to patients of the CEs. 42 U.S.C. §256b(a). CEs are not permitted to resell or otherwise transfer drugs purchased under the program to anyone other than a patient of the entity. 42 U.S.C. §256b(a)(5)(B). In addition, when CEs provide 340B drugs to Medicaid beneficiaries, 340B discounts and Medicaid rebates are prohibited on the same units. 42 U.S.C. §256b(a)(5)(A).

The 340B price is derived from Medicaid pricing information submitted to CMS pursuant to the Medicaid Drug Rebate Program ("MDRP"), and is expressed as the Average Manufacturer Price less the Unit Rebate Amount for a drug product multiplied by the number of units in the package size of the product. 42 U.S.C. §256b(a)(1). CMS, not HRSA, is responsible for administering the MDRP, including the Medicaid pricing information that is used to determine the 340B price. HRSA is responsible for administering the third party beneficiary rights of CEs provided under the PPA, and protecting manufacturers from duplicate discounts and diversion of 340B drugs, consistent with the statute and the terms of the PPA.

42 U.S.C. §256b (d)(3)(A) directs HRSA to promulgate regulations to establish and implement an administrative process for resolving claims by CEs that they have been overcharged for drugs purchased under the program and claims by manufacturers, after the conduct of audits as authorized by subsection (a)(5)(C) of the statute, of violations of the prohibitions against diversion and duplicate discounts. Subsection 256b (d)(3)(B) specifies requirements that must be included in the dispute resolution regulation. Pursuant to this authority, the Proposed Rule would establish the decision-making body, and deadlines and procedures for initiating, consolidating, and resolving disputes before that body.

As discussed below, the Coalition is concerned that the Proposed Rule imposes unfair restrictions on manufacturers' ability to invoke the process. Additionally, the Coalition is concerned that the Proposed Rule if implemented could open the floodgates for adjudicating 340B prices charged CEs based on the accuracy of Medicaid pricing information from which the 340B prices are derived, and result in conflicting decisions and significant burdens on manufacturers. Finally, the Coalition is concerned that the Proposed Rule fails to address disputes involving wholesaler actions independent of manufacturers.

1. **Requirements for Filing a Claim – Proposed 42 C.F.R. §10.21(b)**

The Proposed Rule's Time Limitation on Filing of Claims Should Be Extended to Five Years. As proposed, CEs and manufacturers must file a written claim based on the facts available within 3 years of the date of the sale or payment at issue in the alleged violation, and any claim not filed by this deadline shall be time barred. The three year period is based on the agency's expectations with respect to record retention for the 340B Program. The Coalition concurs that there should be a filing deadline to avoid the difficulties of having to respond to

stale claims; however we recommend that the time period for filing claims align with the five year record retention period for both manufacturers and CEs.

The Proposed Rule Should Relax Restrictions on Manufacturers' Audit Rights. The Coalition agrees that manufacturers must include with their claims documents sufficient to demonstrate diversion and/or duplicate discounts, but is concerned with certain aspects of the proposed requirement for manufacturer audits. Specifically, the Proposed Rule unfairly restricts a manufacturer's ability to initiate a dispute authorized by section (d)(3) of the statute by overly restricting the manufacturer's right to audit a CE. Subsection (d)(3)(A) of the statute directs that a process be available to resolve manufacturer claims of diversion and duplicate discounts, "after the conduct of audits as authorized by subsection (a)(5)(C)." Subsection (a)(5)(C) authorizes a manufacturer of a covered outpatient drug that is subject to a PPA to audit, at the manufacturer's expense, the records of a CE that pertain to compliance with the prohibitions against diversion and duplicate discounts. The only limitation on this audit right is that the audit must be conducted in accordance with procedures established by HRSA "relating to the number, duration and scope of audits." The statute does not authorize HRSA to require manufacturers to conduct audits through outside firms, which increases the audit costs manufacturers must absorb. Nor does the statute authorize HRSA to condition a manufacturer's right to audit records on the manufacturer providing HRSA with evidence of diversion or duplicate discounts. Yet, HRSA's proposed omnibus guidance imposes these requirements as threshold criteria on manufacturers' right to audit.

By incorporating HRSA's non-binding guidance into the Proposed Rule, HRSA would, by regulation, establish significant hurdles to manufacturers' access to CE records, and thus severely limit their ability to dispute occurrences of diversion and duplicate discounts. The Coalition is particularly concerned with the high cost of manufacturer audits when outside firms must be used – up to $80,000 per covered entity. A regulatory prohibition against manufacturers' conducting audits with their own resources will, as a practical matter, continue to deter manufacturers from auditing suspected noncompliance and prevent them from resolving their claims through the disputes process. As a result, manufacturers will likely be unable to justify the cost of an audit needed to assert a claim for payment if the cost exceeds the recoverable amount. The Coalition urges HRSA to rescind prior guidance requiring use of outside auditors and relax the audit requirement to permit manufacturers to conduct audits of CE records with their own internal resources, which would lessen their financial burden, provided the manufacturer submits its audit plan to HRSA in advance of conducting an audit with internal resources.

The Proposed Rule also creates a double standard in which CEs are permitted to band together to allege noncompliance and use the resources of their trade association to engage in extensive discovery to support their allegations, thereby easing the financial burden of identifying and reviewing relevant data, while manufacturers are denied the right to raise allegations of diversion or duplicate discounts (individually or collectively) if they have not first

demonstrated cause to HRSA's satisfaction and incurred the significant prerequisite costs of an outside audit. Even if manufacturers are permitted to consolidate claims against a CE, they still must individually incur the cost of an outside audit before they can pursue a joint claim. This is of particular concern for smaller pharmaceutical companies least able to expend the resources needed to protect their interests. Additionally, the one-sidedness of the dispute process, and especially the incorporation of the need to show cause as a condition of audit, raises concerns where drugs are dispensed by contract pharmacies. Manufacturers lack visibility into pharmacy transactions – either the pharmacy's claim for prescription reimbursement submitted to a CE patient's health plan or the pharmacy's post-adjudication remittance to the CE - that would enable manufacturers to question pharmacy compliance. At a minimum, the necessity to show cause before auditing should not apply to 340B drugs dispensed by contract pharmacies.

2. Deadlines and Procedures for Filing a Claim – Proposed 42 C.F.R. §10.21(d)

Additional Requirements Would Improve Claim Procedures. First, the Coalition concurs in the Proposed Rule's requirement that a party filing a claim send written notice and a summary of documents to the opposing party within three days of submitting the claim, and that the opposing party send confirmation of receipt within three days; however, we recommend that such communications and any additional communications regarding the claim be sent by a party to the Point of Contact for the opposing party identified on the HRSA website, with certified receipt. Second, the Proposed Rule should clarify the type of information that should be included in the summary of documents submitted as part of the claim, specifically, what the description of each document listed in the summary should include. Third, there should be a mechanism for a party to request an extension to the 20-day time period for requesting additional information or for the opposing party to submit a written response, as appropriate, as 20 days may be inadequate under certain circumstances.

3. Covered Entity Information Requests – Proposed 42 C.F.R. §10.22

The Proposed Rule Should Exclude Disputes Over Prices Charged CEs by Wholesalers and Distributors Acting Independently of Manufacturers. The overwhelming majority of orders by CEs are placed with wholesalers that invoice the CEs at the statutory price provided to HRSA and are made whole by manufacturers for which the wholesalers act as distribution agents. We are concerned that manufacturers are being asked to supply information obtained from wholesalers who are not parties to the proceeding. Manufacturers do not control the availability and credibility of data that must be obtained from third parties. Therefore, we urge HRSA to allow additional time to respond to requests for third party data and limit the consequences for manufacturers that must rely on third parties to produce the requested information. In addition, if manufacturers provide the correct price to HRSA and wholesalers, but CEs are charged the wrong price due to wholesaler error, the wholesalers chargeback claim may be corrected and an additional credit provided by the manufacturer for the correct amount. Alternatively, a wholesaler may charge a higher price to cover its

distribution services while submitting a correct chargeback claim. In either case, the manufacturer has been paid the 340B price. It would be unfair to force manufacturers to defend disputes between CEs and their distributors when the manufacturer did not cause the alleged overcharge. Finally, a manufacturer may sell through a restricted network of distributors, but a CE may obtain product from an unauthorized distributor at a price that exceeds the statutory price. In that case, the seller is acting independently, not as a distribution agent of the manufacturer. Manufacturers should not be liable for prices charged in sales transactions over which the manufacturers have no contractual control. The Coalition requests that HRSA clarify in the Proposed Rule that a CE provide evidence that the wholesaler or distributor from which it purchased was acting on behalf of the manufacturer when it overcharged the CE, and that a manufacturer representation or omission be the proximate cause of the amount invoiced by a wholesalers or distributor.

The Proposed Rule Should Exclude Adjudication of Medicaid Pricing from the Scope of the 340B Program Administrative Dispute Resolution Process. As HRSA acknowledged in its proposed rule on civil monetary penalties and omnibus guidance, the 340B statutory price is derived from pricing information specified in a different statute, 42 USC §1396r-8, and regulations promulgated by CMS. CMS is responsible for interpretation of the Medicaid statute and its own regulations. Therefore, HRSA should only determine through the dispute resolution process whether a 340B price is calculated in accordance with reported Medicaid values, and should defer to CMS with respect to the accuracy of the Medicaid pricing underlying the 340B price. Otherwise, CMS and HRSA could reach conflicting conclusions, which would create enormous compliance problems for manufacturers. This potential problem is exacerbated by the conflicting interests that CMS and CEs have in the Medicaid rebate calculation. If manufacturers do not restate AMP to downwardly adjust a calculation that caused higher rebate payments to the states and the Medicaid program, CMS may have little interest in seeking a correction that would result in offsetting credits to the states based on Medicaid utilization. By contrast, CEs may be motivated to challenge AMP calculations and seek decisions from HRSA interpreting the AMP regulation in order to lower the value, as that could lower the price CEs pay. The Coalition urges HRSA to exclude CE challenges to the calculation of Medicaid pricing information from the dispute process.

In addition, manufacturers are required and routinely do adjust prior period prices reported to CMS as better data becomes available and estimates of Best Price are revised; however, the 340B law requires HRSA to "develop procedures for manufacturers to issue refunds to covered entities in the event there is an overcharge by the manufacturers," including oversight to ensure that refunds are issued accurately and in a reasonable period of time both in routine instances of retroactive adjustment to relevant pricing data and in exceptional circumstances. HRSA has yet to develop or even propose those refund procedures. Challenging Medicaid prices used to calculate 340B prices before manufacturers are able to revise and restate them is premature, and allowing such challenges would disrupt

the normal process and enable CEs to pursue unsubstantiated and unverified claims of overcharges.

For all these reasons, the Coalition strongly urges HRSA to clarify that CEs should be barred from disputing the 340B price charged on the grounds that the reported Medicaid pricing information on which the 340B price was based was not correct. Such a limitation would not preclude a claim that a manufacturer failed to adjust the 340B price after a Medicaid price was restated with CMS.

4. **Final Agency Decision – Proposed 42 C.F.R. §10.23**

ADR Procedures and the Final Agency Decisions Should Protect Confidential Information. The Coalition is concerned that the ADR proceedings remain confidential until the process has concluded, and that confidential information not be posted on HRSA's website. We urge HRSA to adopt provisions for protection of confidential information provided during the ADR proceeding, and, in particular, that HRSA prepare and release a redacted public version of the final decision that does not identify the parties or any confidential information.

The Coalition appreciates the opportunity to submit comments on the Proposed Rule for consideration in the agency's decision-making process. If there are any questions, please contact me at rwaldron@thecgp.org or (202) 331-0975.

Regards,

Roger Waldron
President