THE COALITION
for Government Procurement

April 19, 2017

CAPT Krista Pedley, Director, Office of Pharmacy Affairs (OPA)
Health Care Systems Bureau
Health Resources and Services Administration
5600 Fishers Lane, Mail Stop 08W05A
Rockville, MD 20857

Subject: ***Revised Comments***- 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation (RIN 0906-AA89) –Interim Final Rule

Dear Captain Pedley:

The Coalition for Government Procurement ("the Coalition") appreciates the opportunity to provide comments in response to an Interim Final Rule of the Health Resources and Services Administration ("HRSA") of the Department of Health and Human Services (82 Fed. Reg. 14332, March 20, 2017) ("Interim Final Rule"), delaying the effective date of the Final Rule published on January 5, 2017 (82 Fed. Reg. 1210) ("Final Rule") to May 22, 2017, and proposing a longer delay of the effective date to October 1, 2017. These revised comments are timely submitted by the April 19, 2017 due date and supersede the previous submission.

The Affordable Care Act ("ACA") required the Secretary of Health and Human Services to develop specific rules for administering the drug discount program authorized by section 340B of the Public Health Service Act, known as the 340B Program. In particular, section 7102 of the ACA amended 42 U.S.C. §256b(d)(1) by directing HRSA to develop: 1) a system for verifying and correcting 340B prices; 2) procedures for manufacturers to issue refunds in the event of an overcharge; 3) internet access to applicable 340B prices; 4) a mechanism for issuing credits and refunds to reflect price concessions provided to non-340B purchasers after a 340B sale if they retroactively impact the ceiling price calculation; 5) audit procedures; and 6) standards for imposition of civil monetary penalties for knowingly and intentionally failing to charge the 340B ceiling price on eligible transactions. On January 5, 2017, HRSA published a Final Rule imposing civil monetary penalties on manufacturers who charge more than the 340B price for a drug, even where applicability of the 340B price to a transaction is in dispute, and including within the scope of sanctioned conduct a manufacturer's failure to retroactively adjust invoiced 340B prices and refund the difference within a specified time after restating pricing data reported under the Medicaid Drug Rebate Program from which the 340B price is derived. By Executive Order 13765, dated January 20, 2017 (82 Fed. Reg. 8351), HRSA was directed to exercise all authority and discretion available to waive, defer, grant exemptions from, or delay any provision or requirement of the Affordable Care Act that would among other things impose a cost, penalty, or regulatory burden on makers of medications. Accordingly, HRSA delayed the effective date of the Final Rule until May 22, 2017, and invited comments as to whether a longer delay until October 1, 2017 is more appropriate.

The Coalition submitted comments on the proposed rule on August 17, 2015, including objections to finalization of a rule imposing penalties for non-compliance before proposed program guidance has been finalized. We reiterate that concern as well as our comments on the proposed guidance, which are attached and incorporated in this submission. The comments below focus on the administrative burdens and unnecessary cost of complying with the Final Rule and suggest less burdensome and costly alternatives to meet the statutory goals.

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 business 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

As noted in our previous comments, the 340B ceiling price is the product of a statutory formula based on pricing information reported on a quarterly basis under the Medicaid Drug Rebate Program administered by the Centers for Medicare and Medicaid Services ("CMS"), a sister agency of HRSA within the Department of Health and Human Services. Reported price values (AMP and Best Price) reflect prices charged certain customers exclusive of covered entities. It is routine for manufacturers to subsequently adjust Medicaid prices from prior reporting periods to reflect calculations generated by more sophisticated algorithms, or new information, such as price concessions associated with reported sales but realized after the reporting period, and they have up to twelve calendar quarters from the date of submission to restate previously reported prices. 42 C.F.R. §447.510(b). These routine adjustments may cause the reported prices to increase or decrease, impacting the Unit Rebate Amount used to calculate rebates paid the States, often for negligible amounts; however, when manufacturers restate their reported prices, they are allowed by CMS to aggregate all refunds due each State for all their drugs and net refunds against credits before paying an additional rebate, which eases the compliance burden on manufacturers.

Restated Medicaid prices also affect prior period 340B ceiling prices derived from them, and the ACA required development of a mechanism by which credits and refunds resulting from lagged price concessions that lower the ceiling price are issued to covered entities. In recognition of the distinction between "overcharges" and routine prior period price adjustments, section 256b(d)(1) of title 42 directed HRSA to develop *separately* procedures for issuing refunds in the event of an overcharge and a mechanism for issuing credits and refunds to reflect discounts and rebates provided to purchasers (other than covered entities) after a 340B sale if they have the effect of lowering the ceiling price calculation for a prior period.

The Final Rule failed to develop a fair and reasonable mechanism for issuing credits and refunds resulting from routinely restated Medicaid prices consistent with section 256(b)(d)(1), and unfairly treats noncompliance with the Rule's aggressive refund payment schedule as knowing and intentional overcharges warranting imposition of civil monetary penalties. In order to alleviate the burden of refunding small amounts to thousands of covered entities, the Coalition previously proposed measures that are consistent with the administration of the Medicaid drug rebate program and the intent of the 340B statute, but are not unduly burdensome and economically wasteful. First, the Coalition recommended establishing a *de minimis* standard for individual exemptions that would equal or exceed the average cost of processing refunds. Not all manufacturers are able to use bill-back procedures and even where such a system is available, there is still a considerable administrative cost. HRSA should survey manufacturers and consider the amount its prime vendor charges for this refund service to determine the minimum requirement. Second, manufacturers need a reasonable time to refund a covered entity after restating Medicaid prices. This compliance burden, and the resulting need to repeatedly issue small refunds for recalculations affecting the same sales – reported prices can be restated more than once - would be reduced if HRSA allowed manufacturers to aggregate refunds and issue them on an annual or bi-annual basis. Third, when restated Medicaid prices change the 340B ceiling prices, manufacturers should be able to net total credits from higher restated ceiling prices against total refunds due a covered entity from lower restated ceiling prices for all their drugs, and refund the difference, just as their Medicaid prior period adjustments net the impact resulting from changes to the Unit Rebate Amount of all their drugs when determining the amount of additional rebates due each State. Such a process would not only be more equitable, it would bring manufacturers' obligations in line with the related Medicaid program.

Instead of implementing measures that would limit needless compliance costs and greatly reduce the administrative burden on drug manufacturers, the Interim Final Rule imposed the most burdensome procedures conceivable. First and foremost, in implementing the ACA, the Rule fails to distinguish between an overcharge and a prior period price adjustment, as contemplated by the statute, treating routine adjustments as overcharges and subjecting manufacturers to civil monetary penalties for "failure or refusal" to issue a refund without any standard for determining "failure or refusal" to issue a refund. Under new 42 C.F.R. §10.11(b)(4), it could be any time after the manufacturer restates the Medicaid rebate percentage. Once the percentage is recalculated, the Rule requires manufacturers to refund any amount in excess of the invoiced 340B price no matter how small, forcing refunds measured in pennies to thousands of covered entities. At the same time, the Rule refuses to permit aggregation of refunds arising from subsequent transactions over a period of time, which would prevent repeated issuance of refunds on the same sales from multiple price adjustments and ease the compliance burden considerably with no appreciable harm to the covered entities. The Final Rule also refuses to allow netting of credits and refunds due individual covered entities resulting from restated Medicaid prices, which is inconsistent with the Medicaid program and greatly increases manufacturers' compliance costs. Finally, the Rule applies the requirement to charge the ceiling price defined in the statute to sales of new drugs before the ceiling price can exist and then subjects manufacturers to penalties for knowingly and intentionally "overcharging" covered entities if they fail to refund amounts resulting from the subsequent price adjustment required by

HRSA within 120 days.[1] In sum, the Final Rule's implementation of the ACA is extraordinarily unfair, unnecessarily burdensome and economically wasteful, and, in the case of new drug sales that pre-exist the 340B ceiling price, exceeds the statutory mandate.

The Coalition urges HRSA to delay the Interim Final Rule and effective date of the Final Rule until at least October 1, 2017, in order to reconsider the basis for imposition of Civil Monetary Penalties, including a clear exemption from the standard of knowingly overcharging a covered entity where applicability of the 340B price to a particular transaction is in dispute. In addition, the Rule should be delayed for further consideration of alternative refund measures that would achieve a better balance between the interests of covered entities in receiving the correct ceiling price and the interests of manufacturers in reducing the cost of processing refunds, and ensure covered entities are impacted by Medicaid price adjustments on par with the States. Finally, the Interim Final Rule should be delayed while HRSA considers deferring the Final Rule's effective date pending finalization of the agency's guidance on program compliance.

Thank you for considering the Coalition's comments concerning the 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation (RIN 0906-AA89) –Interim Final Rule. If there are any questions, please contact me at (202) 331-0975 or rwaldron@thecgp.org.

Sincerely,

Roger Waldron
President

[1] The Department of Veterans Affairs administers a ceiling price required by Section 603 of the Veterans Health Care Act distinct from the 340B ceiling price required by Section 602 of that Act. In recognition that the Section 603 ceiling price cannot be calculated when a drug is first introduced to the market, the VA allows a provisional price but does not require retroactive adjustment after the statutory price is calculated and reported.

Attachment
RIN 0906-AA89 Proposed Rule Comments (8/17/2015)

August 17, 2015

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

Subject: ***Revised Comments-*** 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation (RIN 0906-AA89)

Dear Commander Pedley:

The Coalition for Government Procurement ("Coalition") submits the following comments in response to the proposed rule (RIN 0906-AA89) concerning the 340B Drug Pricing Program Ceiling Price and Civil Monetary Penalties ("proposed rule"). The Coalition previously submitted comments on August 11, 2015. These revised comments provide additional information and supersede the previous submission.

The Health Resources and Services Administration ("HRSA") of the Department of Health and Human Services published the proposed rule in the Federal Register on June 17, 2015, indicating that the rule, when finalized, will be codified as a regulation in 42 C.F.R. Part 10. The proposed rule would make intentional overcharging subject to a civil monetary penalty, not to exceed $5,000 per instance of overcharging, and would define an instance of overcharging as any order for a covered drug resulting in a covered entity paying more than the 340B ceiling price, including situations in which the ceiling price is subsequently adjusted due to recalculated Medicaid drug rebate program (MDRP) pricing data from which 340B ceiling prices are derived. Failure to refund the difference, no matter how small, would constitute intentional overcharging. These comments largely echo concerns we initially expressed to HRSA in 2010 regarding the administrative costs and logistics of retroactively adjusting invoiced prices at the 340B price and refunding the difference if the calculated ceiling price is later affected by restated Medicaid pricing.[2]

The Coalition is a non-profit association of commercial firms selling services and products to the Federal Government. Our members collectively account for approximately half the commercial item solutions purchased annually by the Federal Government. Coalition members include small, medium and

[2] 42 U.S.C. §256b(d)(1) required the Secretary of the Department of Health and Human Services to develop a system for verifying and correcting 340B prices, procedures for issuing refunds in the event of an overcharge, and a mechanism for issuing credits and refunds to reflect discounts and rebates provided to purchasers after a 340B sale if they impact the ceiling price calculation. The proposed rule would rely on the pricing information submitted under the Medicaid drug rebate program to verify and correct 340B prices and capture lagged discounts to purchasers.

large businesses concerns and represent many different industries, including both brand and generic pharmaceutical manufacturers. The Coalition is proud to have worked with government officials for more than 35 years towards the mutual goal of common sense acquisition.

Introduction

The 340B Drug Pricing Program is a statutorily created pricing program implemented through the terms of standard contracts entered into between HRSA and pharmaceutical manufacturers that choose to participate in the program. Under the statutory scheme set forth in section 340B of the Public Health Service Act, Congress specifies the terms of the contracts, and HRSA administers the program. In their contracts, manufacturers agree to charge no more than the statutorily specified price for covered outpatient drugs purchased by those health care providers whom Congress determines should benefit from the agreement, referred to as covered entities. The 340B program is largely a derivative of the Medicaid drug rebate program (MDRP). The 340B ceiling price is predicated on Medicaid MDRP pricing information, product and package size information, and the Unit Rebate Amount (URA), 42 U.S.C. §256b(a)(2). For that reason, there should be consistency in the administration of the statutory prices under the 340B pricing and Medicaid pricing programs. More importantly, the proposed rule fails to consider the high cost and compliance burden manufacturers must assume to avoid civil monetary penalties.

Specific Comments on Proposed 42 C.F.R. 10.21

As the proposed rule recognizes, the 340B ceiling price value in a particular quarter is derived from product and pricing information (Average Manufacturer Price ("AMP") and Unit Rebate Amount ("URA")) required under MDRP. Since the inception of MDRP, pricing information has been estimated when first reported based on the sales and discounts data available at the time. Often, due to price concessions provided after the point of sale, the complexity of the MDRP pricing calculations as well as the large amounts of data involved, Medicaid pricing was later restated to reflect actual transactional data. Consequently, in 2007, CMS required Medicaid pricing information to be restated in later periods.[3] Any changes in the original pricing data result in revised rebate rate values, which result in either a credit due the manufacturer or an additional rebate due the state. MDRP pricing and rebate information is calculated out several decimal points to a fraction of a cent, and these adjustments on a unit basis can be very small.

The Affordable Care Act required HRSA to develop a process for manufacturers to refund amounts to covered entities in excess of the invoiced amount in the event there is an overcharge resulting from retroactive adjustment to Medicaid pricing. 42 U.S.C. §256b(d)(1)(B)(ii). However, in specifying when an overcharge occurs, the proposed rule implements this requirement in a manner that lacks any specificity for the complex implementation processes; it is inequitable, burdensome and economically wasteful. The Medicaid Drug Rebate Program similarly adjusts prior transaction amounts affected by a

[3] 42 U.S.C. § 447.510(b). "(b) Reporting revised quarterly AMP, best price, customary prompt pay discounts, or nominal prices. (1) A manufacturer must report to CMS revisions to AMP, best price, customary prompt pay discounts, or nominal prices for a period not to exceed 12 quarters from the quarter in which the data were due."

change in pricing for each customer (state), but there are only 50 states. Further, manufacturers deal directly with the states and aggregate the net amount due over the restatement period, making credits and refunds logistically practicable. By contrast, there are approximately thirty thousand covered entities, some of which purchase few units in a given quarter. Further, manufacturers in general do not sell to covered entities directly, and thus cannot apply credits against amounts due.[4] Under the proposed rule, failure to provide refunds resulting from restated Medicaid pricing, without exception, would be subject to civil monetary sanctions.

We recommend HRSA adopt procedures to reduce the regulatory burden on manufacturers, including creating an exemption for *de minimis* refund amounts, permitting manufacturers to aggregate credits and refunds in determining overcharges, and applying a provisional price to new drugs that need not be retroactively adjusted after the first ceiling price is calculated.

1. The rule is premature, penalizing failure to follow a refund mechanism before it is established. The 340B statute requires HRSA to develop a mechanism and procedures for refunding amounts in excess of the statutory price. The proposed rule however would penalize failure to follow refund procedures that have not been established. It is premature and irrational to sanction conduct that has not been proscribed. For example, there should be an exemption for de minimus refund amounts.

As discussed, there are tens of thousands of individual covered entities. Many of these entities are small and could have few purchases in a given quarter and most do not buy directly from manufacturers, which means manufacturers cannot provide a credit on account against future purchases – they must affirmatively pay covered entities. In 1995, HRSA recognized that retroactive adjustment of invoiced prices for new drugs could result in a large number of small credits being issued by manufacturers and attempted to balance the administrative burden. 60 Fed. Reg. 51488 (Oct. 2, 1995). Indeed, if the 340B package unit price is altered by just a few cents, the refund processing costs could easily exceed the refund due by an order of magnitude. For example, if the calculated ceiling price for a dispensed unit is $.01 lower, and there are 100 units in a package, the amount due for the package would be $1. Yet, the cost of processing the refund could be $50. If a covered entity bought one package, the administrative cost of complying with the rule would significantly outweigh the minimal benefit to the purchaser. Yet, if manufacturers fail to incur the costs to pay the $1, they risk much greater sanctions.

We reiterate our prior recommendation that routine adjustments to pricing data should only trigger the administrative burden of adjusting invoiced sales prices to covered entities if the adjustment exceeds 1% of the invoiced price for that product (identified by its National Drug Code package size NDC11). Absent such a standard, the rule is economically wasteful and punitive. Spending $50 to refund $1 completely lacks common sense and is a textbook example of why regulations are so costly.

2. The rule should allow manufacturers to net credits and refunds for purchases by the same entity over the period covered by the restated prices to determine net overcharges, in the same way that CMS nets rebate credits against additional rebates due the states. CMS adjusts manufacturers'

[4] Most covered entities purchase from wholesalers. Wholesalers charge the CE the 340B price and then submit chargebacks for the difference between the 340B ceiling price and their acquisition cost (e.g., Wholesale Acquisition Cost "WAC") for reimbursement by manufacturers.

statutory pricing obligations in prior periods based on prices that may be restated within 12 quarters from the quarter in which the data were due, regardless of who benefits from the restatement, and permits manufacturers to aggregate the impact of restated prices on each state to determine the net amount due. States are not permitted to retain excess rebate amounts paid upon recalculation of statutory prices. As these related programs are closely intertwined, they should be consistently administered. There is no sound reason not to apply the same equitable policy for restated Medicaid prices to derivative 340B prices, or to ignore all undercharges enjoyed by covered entities in determining the existence of an overcharge for a given period. In short, because manufacturers' 340B obligations are based on a statutory formula, fairness requires they be permitted to realize both upward and downward adjustments when applying the formula using more accurate data, particularly in the context of determining overcharges subject to penalties. Moreover, as discussed below, the administrative and financial burden of refunding negligible amounts to tens of thousands of covered entities is enormous, and offsetting amounts from undercharged prices would help reduce that burden.

3. HRSA should follow the VA policy for pricing new drugs and establish a voluntary, provisional, non-retroactive price for sales preceding the existence of a statutory price. The proposed rule would require manufacturers to sell new drugs under the program before it is possible to calculate the statutory price, then retroactively adjust purchase prices based on later calculated 340B prices, and refund the difference. Because the statute incorporates a 2-month lag between commercial prices charged and 340B prices, imposing a retroactive adjustment based on these same commercial prices impermissibly extends the period to which they apply by a full quarter.

Further, as discussed, most manufacturers sell indirectly and no mechanisms have been established for issuing timely refunds for often very small amounts to tens of thousands of entities. We urge HRSA to revisit this requirement and adopt the policy followed by the Veterans Administration ("VA") for three reasons. First, the 340B ceiling price was established by the same law that established the ceiling price administered by the VA, the Veterans Health Care Act ("VHCA"), and, like the ceiling price specified in section 603 of the VHCA, there is no statutory mandate for manufacturers to sell at the ceiling price specified in section 602 until that price can be calculated. Second, manufacturers lack sales data on which to base 340B prices for new drugs, and must estimate a ceiling price. As HRSA recognized in its 1995 policy, retroactively adjusting estimated prices is an enormous administrative burden that should be shared.[5] Third, the proposed rule is contrary to the longstanding approach to VHCA ceiling prices the VA has implemented for new drugs, *i.e.*, when a manufacturer chooses to add a new covered drug to its contract before the statutory price can be calculated, a provisional price consisting of the mandatory discount off WAC is established until the statutory price can be calculated from available sales data, at which point the statutory price applies prospectively.[6]

[5] HRSA concluded that identifying and refunding the difference between invoiced prices based on estimates and later calculated ceiling prices is a very burdensome and costly exercise for manufacturers that sell covered drugs through wholesalers. Accordingly, HRSA alleviated some of the administrative burden on manufacturers by requiring covered entities to request refunds and document their requests, which it hoped would reduce the number of small requests. 60 Fed. Reg. 51488 (Oct. 2, 1995).

[6] See, e.g., DVA "Dear Manufacturer" guidance letters from the Office of General Counsel dated October 19, 2001, October 19, 2010 and November 2, 2011. http://www/va.gov/oal/business/fss/publicLaw.asp#three.

We believe it would be much fairer, less costly and less burdensome for manufacturers and covered entities if HRSA followed the VA's policy and reduced WAC by the statutory rebate percentages as a provisional ceiling price for the brief period in which it would apply.

4. The proposed rule for new drugs conflicts with the statute and provides an inadequate period in which to comply with a refund requirement. As noted, 340B prices are not required before the prices can be calculated, and thus mandating estimates and retroactive adjustment for this period conflicts with the statute. If the proposed rule conformed to the statute, there would be no need for a four-quarter period in which to adjust prices charged for new drugs. Moreover, even if such a refund requirement were permissible, the proposed rule provides an inadequate period.

After estimating a 340B price for three quarters, manufacturers would have one additional quarter in which to determine what they owe to the thousands of covered entities that purchased the new drug directly and indirectly from wholesalers during the initial three quarters and refund the difference – regardless of how small the amount. Ninety days is insufficient time to obtain indirect sales data from wholesalers for the entire period, particularly the preceding quarter, identify all the covered entities that purchased indirectly from chargeback data, calculate the potential refund amounts, and process refunds. Ninety days is also insufficient time to permit restatement of Medicaid Pricing data. Therefore the proposed rule has the potential for requiring two refunds, one at the end of the first year after a new product launch and one as a result of the 36 month Medicaid pricing restatement requirements. A fairer refund procedure – if the VA provisional price model is not adopted for new drugs - would defer refunds on all product purchases consistent with the timeline for routine Medicaid pricing restatement and refund processes.

In conclusion, we urge you to consider the fairness and reasonableness of the rule that would subject manufacturers to penalties for nominal overcharges resulting from updated pricing information, particularly when the number of transactions affected by a fractional change in price can be enormous and the administrative cost of processing a refund can greatly outweigh the refund amount. Thank you for considering our comments. If there are any questions, I may be reached at (202) 315-0975 or rwaldron@thecgp.org.

Sincerely,

Roger Waldron
President