August 13, 2015

The Honorable Sylvia M. Burwell, Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Via Electronic Submission: www.regulations.gov

340B Drug Pricing Program: Ceiling Price and Manufacturer Civil Monetary Penalties Regulation [RIN 0906-AA89]

Dear Secretary Burwell:

GlaxoSmithKline ("GSK" or the "Company") appreciates this opportunity to comment to the Department of Health and Human Services ("HHS") on the proposed rule issued by the Health Resources and Services Administration ("HRSA") on June 17, 2015, entitled *340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation* [RIN-0906-AA89] (the "Proposed Rule").[1] GSK is a leading worldwide research-based pharmaceutical company with a mission to improve the quality of human life by enabling people to do more, feel better, and live longer. GSK has been an active participant in the 340B program since the program's inception. GSK understands the importance of the government's role in ensuring access for all patients who need life-saving and sustaining drugs and thanks HHS and HRSA for their ongoing attention to the 340B program.

GSK is a member of the Pharmaceutical Research and Manufacturers of America ("PhRMA") as well as the Biotechnology Industry Organization ("BIO"), and endorses the comments of those two trade groups. GSK nevertheless has identified certain issues of such significance to the company that they warrant separate discussion and explanation. We request that HHS and HRSA consider these comments in formulating any final rule.

GSK applauds HRSA's efforts to implement the new provisions of the Affordable Care Act ("ACA"), including the manufacturer civil monetary penalty ("CMP") provision. Moreover,

[1] 80 Fed. Reg. 34,583 (June 17, 2015).

guidance on the calculation of 340B ceiling prices is sorely needed. We echo BIO's comments, but state more strongly that we feel that HRSA needs to commit to a larger, more holistic effort to providing guidance in this area, to ensure that the various parts of the 340B statute both work as intended and cover all of the necessary points of concern. Nonetheless, in the absence of such larger guidance, we believe that the following issues should be addressed in the Proposed (and resulting Final) Rule.

GSK Recommendations:

- We believe that the quarterly ceiling prices should be reported and calculated in dollars and cents (i.e., to two decimal places as in $XX.XX) to reducing the price-reporting burden, as well as the likelihood of disputes with HRSA;
- We ask HRSA to eliminate the proposal to multiply the ceiling price calculation by "case package size" for simplicity, clarity and to conform to longstanding HRSA policy and practice;
- GSK asks HRSA to permit manufacturers to elect an alternate methodology for estimating the ceiling price when the unit rebate amount ("URA") equals the average manufacturer price ("AMP"), in lieu of the Agency's problematic penny pricing proposal;
- GSK would also like HRSA to articulate a proposed policy with respect to how manufacturers should estimate ceiling prices during the first three quarters that a drug is on the market;
- GSK urges HRSA to provide additional detail and clarification with respect to the calculation of ceiling prices for the first three quarters after pricing data become available, and to incorporate parallel obligations for covered entities with respect to the related refund proposal;
- GSK asks HRSA to revise its proposed definition of an "instance" of overcharging a covered entity to refer solely to actions that are within a manufacturer's control, namely: (1) each incorrectly calculated ceiling price that actually results in an overcharge to a covered entity; and (2) each incorrect determination by a manufacturer that a covered entity is not a covered entity entitled to the ceiling price that actually results in the covered entity purchasing products at prices higher than the ceiling price;
- GSK asks HRSA to eliminate the Agency's proposal that an instance of overcharging may not be offset by other discounts provided on any other NDC or on the same NDC as part of other transactions, orders, or purchases;
- GSK asks HRSA to either eliminate its proposal that an instance of overcharging can occur when subsequent ceiling price recalculations resulting from pricing data submitted to CMS occur, or to expressly recognize that such overcharges cannot be "knowing and intentional" unless and until manufacturers have had the opportunity to identify, investigate, and correct mistakes with respect to quarterly pricing data through the process to be established by HRSA per section 340B(d)(2)(B)(iv);
- GSK asks HRSA to clarify that manufacturers will not be subject to CMPs for refusal to sell to covered entities in the first instance, particularly to the extent that the 340B statute's "must offer" language has not been incorporated into the pharmaceutical pricing agreement ("PPA"), or, at a minimum, to create a safe harbor from the CMP provisions for covered outpatient drugs distributed through limited distribution plans that meet HRSA's standards

for non-discrimination;

- GSK asks HRSA to clarify that manufacturers will not be subject to CMPs for the actions of other parties (e.g., wholesalers) unless causation can be established between a manufacturer's knowing and intentional actions and a wholesaler's or distributor's failure to sell covered outpatient drugs to a covered entity at the 340B ceiling price.

I. Implementation of the ACA's 340B Program Integrity Requirements Should be Comprehensive and Coordinated

The 340B statute, as amended by the ACA, charges HRSA with establishing eleven (11) discernible systems and/or processes, as a means to improve the functioning of the Program. The 11 proposed and enumerated systems were intended to aid compliance by both manufacturers and covered entities with the 340B program requirements.[2] As drafted and codified, those 11 elements were contemplated as interrelated parts to improve the current system, each essential to the goal of making the 340B program better.

In the current Proposed Rule, HRSA seeks to implement only one of the 11 program integrity improvements: the imposition of CMPs on manufacturers for knowing and intentional overcharges of covered entities pursuant to section 340B(d)(1)(B)(vi).[3] Given the many areas implicated by the 11 program improvements, it is unclear how HRSA's attention to one will effectuate the aims of the whole program. In fact, GSK believes that success of the 340B program depends on a global approach, not the limited focus applied here.

As noted by other commenters, each of the 11 provisions is not only interrelated, but interdependent. In order for stakeholders like GSK to comment in a meaningful way, it is

[2] These include: (1) the development of a system to verify the accuracy of ceiling prices calculated by manufacturers and charged to covered entities (42 U.S.C. § 256b(d)(1)(B)(i)); (2) the establishment of procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturers (42 U.S.C. § 256b(d)(1)(B)(ii)); (3) the provision of secure access by covered entities to the applicable ceiling prices for covered outpatient drugs as calculated and verified by HRSA (42 U.S.C. § 256b(d)(1)(B)(iii)); (4) the development of a mechanism by which rebates and other discounts provided by manufacturers to other purchasers subsequent to the sale of covered outpatient drugs to covered entities are reported to HRSA, and appropriate credits and refunds are issued to covered entities if such discounts or rebates have the effect of lowering the applicable ceiling price for the relevant quarter for the drugs involved (42 U.S.C. § 256b(d)(1)(B)(iv)); (5) selective auditing of manufacturers and wholesalers to ensure program integrity (42 U.S.C. § 256b(d)(1)(B)(v)); (6) the imposition of sanctions on manufacturers in the form of civil monetary penalties for each instance of knowing and intentionally overcharging a covered entity (42 U.S.C. § 256b(d)(1)(B)(vi)); (7) the development of procedures to enable and require covered entities to regularly update (at least annually) the information on the HRSA's 340B database (42 U.S.C. § 256b(d)(2)(B)(i)); (8) the development of a system for HRSA to verify the accuracy of information regarding covered entities that is listed on such database (42 U.S.C. § 256b(d)(2)(B)(ii)); (9) the development of more detailed guidance describing methodologies and options available to covered entities for billing covered outpatient drugs to State Medicaid agencies in a manner that avoids duplicate discounts (42 U.S.C. § 256b(d)(2)(B)(iii)); (10) the establishment of a single, universal, and standardized identification system by which each covered entity site can be identified by manufacturers, distributors, covered entities, and HRSA for purposes of facilitating the ordering, purchasing, and delivery of covered outpatient drugs under the 340B program (42 U.S.C. § 256b(d)(2)(B)(iv)); and (11) the imposition of sanctions on covered entities, in appropriate cases as determined by the Secretary (42 U.S.C. § 256b(d)(2)(B)(v)).

[3] HRSA also proposes to provide certain, limited guidance, regarding the calculation of 340B ceiling prices, but it does not appear that it is intended to be an exhaustive guidance on this point.

necessary to understand how HRSA proposes to implement all 11 provisions. Accordingly, we urge HRSA to propose a comprehensive Rule to implement *all* of the ACA's 340B program integrity improvements and to seek comments, at one time, on the entire proposed Rule.

II. Ceiling Price Calculation

The Proposed Rule purports to explain how each manufacturer is to calculate the ceiling price for each of its 340B drugs. It is not, however, a model of clarity or consistency. As detailed below, an area presumably as straightforward as price calculation can be confusing when not grounded in practical considerations or part of a uniform approach.

A. Mechanics of the 340B Ceiling Price Calculation

1) Applicable Average Manufacturer Price

The Proposed Rule provides that "[t]he 340B 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)."[4] It is not clear from this language or from the definitions section whether this proposal refers to monthly or quarterly AMP. Because the 340B ceiling price is to be calculated on a quarterly basis, we urge HRSA to clarify, in issuing the Final Rule that this calculation is based on the *quarterly* AMP.

2) Decimal Places

HRSA proposes to calculate the ceiling price to six decimal places.[5] HRSA would then publish these ceiling prices, after rounding to two decimal places, on a secure site available to covered entities.[6] We do not see the benefit of this added complexity and suggest that the quarterly ceiling prices be reported and calculated in dollars and cents only, to two decimal places (i.e., $99999.99). As this is how prices are to be reported and how entities are paid, we see no benefit to the false accuracy suggested by going beyond two decimal places.

3) Case Package Size

In the Proposed Rule, HRSA further suggests that, in order "to ensure the final price is operational in the marketplace," the 340B ceiling price would be multiplied "by the drug's package size and case package size."[7] We note that HRSA's longstanding policy has been to multiply the 340B ceiling price solely by the package size.[8] We believe that the introduction of this new variable, "case package size," would result in substantial

[4] 42 C.F.R. § 10.10(a) (proposed). We note that this proposal is somewhat different from the language in the Agency's 340B Quarterly Pricing Data Text File for Transfer to HRSA, which provides in the section on "Data Field Definitions" that the "340B Price" should be "[c]alculate[d] to 6 decimal places and truncate[d] to 4 decimal places, pad positions 5 and 6 with zeros."
[5] 42 C.F.R. § 10.10(a) (proposed).
[6] 80 Fed. Reg. at 34,585.
[7] 42 C.F.R. § 10.10(a) (proposed).
[8] See, e.g., HRSA, Clarification of Penny Pricing Policy, Release No. 2011-2 (Nov. 21, 2011) ("The following formula is used for calculating 340B ceiling prices: 340B Ceiling Price = [(AMP) – (URA)] * Drug Package Size").

confusion for manufacturers, covered entities, and HRSA. As it is not necessary, we ask that this proposed language be deleted.

The proposed "case package size" is not a metric tabulated or reported anywhere else in the price reporting world (including, but not limited to the Medicaid Drug Rebate Program). Requiring this new data point would increase the burden on manufacturers of both calculating the ceiling price and of reporting ceiling price data to HRSA for purposes of the Agency's ceiling price verification activities. GSK does not see the benefit of introducing a new metric/calculation that would require additional work but does not reduce the burdens, simplify, streamline or clarify existing procedures. In light of the foregoing, GSK asks HRSA to refrain from introducing this new variable without analysis and an understanding of the overall ceiling price calculation.

B. Penny Pricing

HRSA proposes that a manufacturer charge $0.01 per unit of measure for a drug with a ceiling price below $0.01.[9] While this proposal is consistent with the Agency's statement of its "penny pricing" policy issued in 2011, we have serious concerns with respect to this approach.

To date, the penny pricing policy has led to some problematic consequences, including apparent violations of the 340B statute. HRSA expressly acknowledges this in its own policy release on this topic, "[w]hen a 340B price drops to a penny price, a manufacturer may anticipate challenges with equitable market distribution of the drug . . . ." due to the potential for drug shortages.[10] Our experience confirms this – when the prices of our products have dropped to a penny, GSK has noted actual and extreme purchasing behavior, not in line with the intent of the program. GSK is harmed by this behavior, but so are patients who need our products but cannot get them. We welcome the chance to bring attention to this issue through the Proposed Rule and hope that HRSA will take the steps needed to remedy this conduct.

There are so many conflicting and contradictory parts of the policy; for example, the existence of the penny pricing policy in conjunction with the 340B statute's "must offer" requirement.[11] Together, they have a particularly high potential to result in drug shortages. Although HRSA has articulated its policy that manufacturers can adopt alternate allocation procedures in this context,[12] we do not believe the burden to design lawful policies should be left to individual manufacturers, especially when global guidance is possible and needed and where a uniform approach would benefit all.

[9] 42 C.F.R. § 10.10(b) (proposed).
[10] Id.
[11] While we continue to emphasize that this "must offer" language is not operational unless and until it has been incorporated into the PPA, as described in greater detail below, we note that it is HRSA's current position that manufacturers "must offer" their products to covered entities at the ceiling price.
[12] HRSA, Clarification of Non-Discrimination Policy, Release No. 2011-1.1 (May 23, 2012).

In light of the approach taken in the Proposed Rule and for the reasons articulated above, GSK believes the Agency should consider alternative approaches (e.g., nominal pricing, FCP pricing, or non-penny pricing based on a prior period's price) and permit manufacturers to calculate an appropriate ceiling price for quarters in which AMP equals the URA, in accordance with their duty of good faith under the PPA.

C. Pricing Adjustments

GSK believes that HRSA would be well-served in outlining a global policy in the area of price adjustments. Here, HRSA proposes that "[a] manufacturer must calculate the actual 340B ceiling price for the first three quarters the drug [is] available for sale and refund or credit covered entities that purchased the covered outpatient drug above the calculated 340B ceiling price no later than the end of the fourth quarter after the drug is available for sale."[13] While it is a first step and makes sense on a local level, it does not address the larger issues implicated by pricing adjustments.

Here, we concerned that the Proposed Rule discusses only credits and refunds to covered entities when estimated ceiling prices are too high, but not the reciprocal credits and refunds due to GSK or other manufacturers when estimated ceiling prices are too low. The interests of fairness and efficiency require both to be addressed at the same time and in the same policy. We ask HRSA to do so here.

Finally, we ask for the necessary basic details such as timing and procedure to effectuate the price adjustment policy. That level of detail is not present in the current Proposed Rule. Instead of allowing manufacturers to create their own reasonable assumptions of what this means, it is incumbent on HRSA to craft a uniform policy to show how the price adjustments should be done.

III. Manufacturer Civil Monetary Penalties

Without further guidance, GSK also has serious misgivings about the CMP provisions of the Proposed Rule. Again, this is an example of where a uniform and holistic approach would be beneficial. Instead, this section of the Proposed Rule would impose penalties (and in some cases, drastic ones) without the ability of any manufacturer to conform their behavior to intended standard. Certain sections of the Proposed Rule use language and standards that have not been used previously in this context and require further explanation.

As HRSA notes in the Proposed Rule, pursuant to provisions of the 340B statute added by the ACA, any manufacturer with a PPA that knowingly and intentionally charges a covered entity more than the ceiling price for a covered outpatient drug may be subject to a CMP not to exceed $5,000 for each instance of overcharging.

[13] 42 C.F.R. § 10.10(c).

GSK notes that some of the standards of 42 C.F.R. part 1003 are not applicable, or even appropriate, for the imposition of manufacturer CMPs under the 340B statute. For example, some of these provisions, as currently written, establish definitions, penalty or assessment amounts, exclusion authorities, collection of penalty and assessment amounts, and other standards that are inconsistent with, inapplicable to, or not appropriately tailored for, the standards outlined in the 340B statute. These sections need to be clarified and explained.

From an operational perspective a definition for the term "knowingly and intentionally" would need to be added to section 1003.101. HRSA has not proposed a definition for this term, which also is not currently defined in parts 1003 or 1005.[14] As this term is critical to the application of manufacturer CMPs under the 340B statute, it must be defined before such CMPs may be imposed. We note that certain proposals made in the Proposed Rule, discussed in greater detail below, suggest that HRSA may be seeking to impermissibly redefine "knowingly and intentionally"—words specifically chosen by Congress.[15]

Many civil fraud statutes use the term "knowingly" by itself, and most criminal statutes use "knowingly and willfully." However, here, Congress chose an even higher, more exacting state-of-mind requirement, which clearly indicates that Congress intended this CMP remedy to be used only for very serious offenses. HRSA is not permitted to redefine these terms to capture lesser forms of misconduct. Taken together, "knowing and intentionally" should be defined to include only conduct undertaken with the specific intent to overcharge a customer that the manufacturer actually knows is a covered entity. This phrase cannot include, therefore, inadvertent, accidental, or negligent conduct, unrecognized error in computing the ceiling prices, conduct undertaken with the honest belief that the facts were otherwise, situations where there is a reasonable disagreement and no established law or agency guidance on point, or any other situation not presenting circumstances of deliberate misconduct.

Moreover, the "knowing and intentional" language should not implicate conduct or penalize a manufacturer when dealing with non-customers or non covered entities. With the proliferation of alternate handling arrangements and corporate structures, a manufacturer should not be subject to CMPs where it refuses to sell at ceiling price when it cannot identify an entity as a legitimate covered entity or it is unable to discern a valid and enforceable relationship between an entity (e.g., contract pharmacy, depot, etc.) and a valid covered entity. We ask HRSA to make it clear that the CMPs are only available for those rare instances where the covered entity itself has been overcharged, not some entity purportedly acting on its behalf.

[14] 42 C.F.R. 1003.102(e) does define the term "knowingly." However, the term "knowingly and intentionally" imposes a higher intent standard than mere knowledge and is not defined.

[15] We note that HRSA does recognize in the Regulatory Impact Analysis included with the Proposed Rule that "For the penalties to be used as defined in the statute and in this rule, a manufacturer would only be subject to those penalties when the overcharge was the result of a knowing and intentional act. Based on anecdotal information received from covered entities, HHS anticipates that this would occur very rarely, if at all." 80 Fed. Reg. at 34,586. We appreciate this statement, but encourage HHS to incorporate more formal recognition of the knowing and intentional standard into the rule itself.

In addition, knowing and intentional overcharges to 340B covered entities would have to be listed as a basis for the imposition of CMPs under 42 C.F.R. §§ 1003.100 and 102, the amount of the penalty ($5,000 per instance) would have to be added to section 1003.103, and appropriately tailored standards for the imposition of these penalties also would need to be added to section 1003.106.

GSK strongly believes that HRSA should not institute a CMP proceeding where the alleged overcharge involves circumstances not addressed by written (and, as appropriate, binding) Agency standards. In situations outside of those addressed through Agency guidance or regulation, there can be no basis for HRSA (or OIG) to allege in a CMP proceeding that a manufacturer has engaged in a knowing and intentional overcharge—and only knowing and intentional overcharges permit the exercise of this CMP authority, as described above.

Finally, section 1003.128 would need to be amended to provide for the collection of 340B manufacturer CMPs by either OIG or HRSA (as opposed to CMS). We think that HRSA, at a minimum, would have to specify that the Agency will not pursue a civil action to recover amounts due, if at all, until manufacturers have had at least 60 days from the ultimate conclusion of any appeal or judicial review. In addition, to the extent any interest is charged on penalties, we urge HRSA to impose any such interest as of the date of a filing of a notice of intent to assess a CMP, not from the overcharge itself. Given the routine restatements of AMP that are permitted and regularly occur during the three years following a manufacturer's initial AMP statement, it makes sense that interest should not be calculated until the ceiling price is finally adjusted and a CMP proceeding asserts that an overcharge occurred.

Please note that manufacturers have three years to restate a drug's AMP, and its BP in the case of an innovator product, during which time the ceiling price can correspondingly move upwards or downwards.[16] We do not believe that routine (and customary) restatements of AMP and BP meet the "knowingly and intentionally" standard that is required under the statute for imposition of a CMP and we believe that HRSA should clarify that simple and periodic restatements such as these do not implicate the CMP authority.

A. Instance of Overcharging

1) Definition of "Instance"

As articulated in the 340B statute, CMPs are to apply to each "instance" of overcharging a covered entity. In order to implement this requirement, HRSA proposes to define "an instance of overcharging" as "any order for a certain covered outpatient drug, which results in a covered entity paying more than the ceiling price . . . for a covered outpatient drug."[17] HRSA further proposes that "[e]ach order for an NDC will constitute a single instance, regardless of the number of units of each NDC in that order" and that

[16] See 42 C.F.R. § 447.510(b)(1).
[17] 42 C.F.R. § 10.11(b).

"[t]his includes any order placed directly with a manufacturer or through a wholesaler, authorized distributor or agent."[18]

HRSA has similarly clarified that "[c]overed entity orders of non-340B priced drugs will not subsequently be considered an instance of overcharging unless the manufacturer's documented refusal to sell or make drugs available at the 340B price resulted in the covered entity purchasing at the non-340B price."[19] We also support this proposal, as there are a number of reasons that a 340B covered entity would purchase a product at a non-340B price, such as when they elect to "carve out" (i.e., dispense non-340B drugs to Medicaid patients) pursuant to HRSA's longstanding guidance on the prevention of duplicate discounts.[20] It is important that manufacturers are not assessed CMPs for selling such non-340B-priced drugs to covered entities in such instances.

HRSA does note in the preamble text, however, that "[w]hen a manufacturer's documented refusal to sell or make drugs available at the 340B price results in the covered entity purchasing at the non-340B price, a manufacturer's sale at the non-340B price could be considered an instance of overcharging."[21] We urge HRSA to provide more guidance as to what constitutes a "documented refusal" for this purpose. Specifically, we ask HRSA to clarify that communications between a manufacturer (or wholesaler) and covered entity verifying eligibility for 340B prices prior to a sale should not be considered a "refusal" for this purpose.

2) Offsets

HRSA further proposes that "[a]n instance of overcharging is considered at the NDC level and may not be offset by other discounts provided on any other NDC or discounts provided in the same NDC on other transactions, orders, or purchases."[22] We strongly disagree with this proposed approach. To the extent that manufacturers restate their pricing data, they do so across NDCs, which can result in increased ceiling prices for some NDCs and decreased ceiling prices for others. For purposes of efficiency, manufacturers often correct for these changes by offsetting prices across NDCs. Given that manufacturers generally employ this practice uniformly across all customer types, we note that prohibiting this practice in the context of the 340B program would be contrary to HRSA's non-discrimination policy, as manufacturers would be directed to treat their 340B customers in a manner distinct from commercial and other customers. For these reasons, we urge HRSA to eliminate this language from the Proposed Rule.

3) Overcharges Based on Subsequent Ceiling Price Recalculations

HRSA further proposes that an instance of overcharging can occur: (1) at time of initial purchase; or (2) when subsequent ceiling price recalculations resulting from pricing data

[18] 42 C.F.R. § 10.11(b)(1).
[19] 42 C.F.R. § 10.11(b)(5) (proposed).
[20] See HRSA, Clarification on Use of the Medicaid Exclusion File, Release No. 2013-2 (Feb. 7, 2013).
[21] 80 Fed. Reg. at 34,586.
[22] 42 C.F.R. § 10.11(b)(3) (proposed).

submitted to CMS occur and the manufacturer refuses to refund or issue a credit to a covered entity.[23] GSK has serious concerns with respect to this proposal.

First, we note that there likely will be a high volume of true-ups and refunds based on price changes flowing from routine restatements of Average Manufacturer Price (AMP) and best price (BP), which are calculated to seven decimal places and rounded to six, as well as the rising volume of products, covered entities, and manufacturers participating in the 340B program. However, as noted previously, HRSA has yet to establish a process to restate and reconcile ceiling price numbers, as required under 340B(d)(1)(B)(iv). At a minimum, we believe that HRSA should not impose CMPs based on recalculations until this process has been established. This process should define, among other things, a reasonable timeframe for manufacturers to correct mistakes with respect to quarterly pricing data.

Second and perhaps more troublingly, we note that a manufacturer's failure to restate pricing calculations from prior quarters is not a "knowing and intentional" overcharge for purposes of the 340B statute's CMP provision. We have concerns that subsequent ceiling price recalculations would necessarily result in a "knowing and intentional" overcharge to a covered entity. For example, manufacturers typically use estimates for some price concessions to report initial Best Prices to CMS within thirty (30) days after a calendar quarter end and perform recalculations to incorporate lagged data (e.g., chargebacks, rebates, etc.) for recalculation(s) subsequent to the initial calculation. Also, inadvertent technical mistakes happen with respect to drug pricing data, and drug pricing data may need to be restated to account for pricing adjustments, often due to factors outside the control of a given manufacturer. Indeed, the routine nature of these adjustments is recognized in the 340B statute itself, which expressly directs HRSA to develop a mechanism whereby the resulting refunds and credits would be issued to covered entities.[24] Unless and until manufacturers have had a reasonable timeframe to identify, investigate, and rectify these errors and restatements, and then purposefully decided not to issue an appropriate refund or credit, the manufacturer cannot be considered "knowing and intentional" and should not give rise to manufacturer CMPs.

GSK asks HRSA to either eliminate its proposal that an instance of overcharging can occur when subsequent ceiling price recalculations resulting from pricing data submitted to CMS occur, or to expressly recognize that such overcharges cannot be "knowing and intentional" unless and until manufacturers have had the opportunity to identify, investigate, and correct mistakes with respect to quarterly pricing data through the process to be established by HRSA per section 340B(d)(2)(B)(iv).

4) Overcharges Through Distribution Arrangements

[23] 42 C.F.R. § 10.11(b)(4) (proposed).
[24] 42 U.S.C. § 256b(d)(1)(B)(iv).

HRSA also proposes that "[m]anufacturers have an obligation to ensure that the 340B discount is provided through distribution arrangements made by the manufacturer."[25] In the preamble, HRSA further states that "[a]ll requirements for offering the 340B ceiling price apply regardless of distribution system" and that "specialty distribution, regardless of justification, must ensure 340B covered entities purchase covered outpatient drugs at or below the ceiling price."[26]

As an initial matter, we note our concern that this proposed regulatory text, together with the cited preamble language, suggests that HRSA believes it would be authorized to treat a refusal to sell a covered outpatient drug as potentially actionable through the CMP process. We disagree.

First, under the 340B statute, manufacturer CMPs are restricted to situations involving an actual overcharge. A refusal to sell is not an overcharge and there are many legitimate reasons why a manufacturer elects not to (or is unable to) sell in a given instance (e.g., improper credentialing, product shortages, recalls, etc.). Moreover, even if a refusal to offer the ceiling price were considered to be an overcharge, a manufacturer will not have an obligation to offer covered outpatient drugs at the ceiling price until HRSA issues a new PPA and manufacturers obligate themselves to offer the ceiling price to covered entities by signing it. The PPA currently in effect only governs the price that manufacturers can charge covered entities for covered outpatient drugs. While Section 7102(b) of the ACA amended the 340B statute to add a must-offer obligation as a new term to the PPA, there certainly can be no CMP proceeding based on this new "must offer" provision unless and until it is implemented through a new PPA or an amendment to manufacturers' existing PPA.

We also are concerned that this statement may be a departure from HRSA's current non-discrimination policy, which permits manufacturers to establish "alternate allocation procedures," based on the recognition that there may be instances in which "available supply of a covered outpatient drug is not adequate to meet market demands."[27] At a minimum, we believe that HRSA should establish a safe harbor from the CMP provisions for covered outpatient drugs distributed through limited distribution plans that meet HRSA's standards for non-discrimination.

Second, we also note our serious concern that this proposal, as applied, would constitute an impermissible departure from the 340B statute's "knowing and intentional" standard for purposes of manufacturer CMPs. Specifically, in the preamble text regarding this proposal, HRSA notes that "[t]his regulation and associated penalties applies solely to manufacturers, even though other parties, such as wholesalers, have a role in ultimately ensuring the covered entity receives a 340B price at or below the ceiling prices" and that "[a] manufacturer's failure to ensure that covered entities

[25] 42 C.F.R. § 10.11(b)(2) (proposed).
[26] 80 Fed. Reg. at 34,586.
[27] HRSA, Clarification of Non-Discrimination Policy, Release No. 2011-1.1 (May 23, 2012).

receive the appropriate 340B discount through its distribution arrangements may be grounds for the assessment of civil monetary penalties under this regulation."[28] While we agree that the 340B statute makes manufacturers ultimately responsible for program compliance, in order to impose CMPs for manufacturer non-compliance in this instance, there is a need to establish causation between a manufacturer's knowing and intentional actions and a wholesaler or distributor's failure to provide a covered outpatient drug to a covered entity at the 340B ceiling price. As noted throughout this letter, we urge HRSA to clarify that manufacturers will not be subject to civil monetary penalties for any actions that do not meet this standard.

GSK thanks HRSA and HHS for the opportunity to comment on the Proposed Rule. We appreciate the effort that HRSA has taken in implementing the changes made to the 340B program in the ACA but believe that more is needed. We are willing and able to assist in any way possible to further the legitimate aims of the program. If you have any questions related to our comments, please do not hesitate to contact me at 919-483-2353.

Respectfully submitted,

/S/
John Boone
Vice-President
Contract Management and Operations
GlaxoSmithKline

[28] 80 Fed. Reg. at 34,586.