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

Re: Regulatory Information Number (RIN) 0906-AA89 (Proposed Rule, 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation)

Dear Commander Pedley:

This letter is submitted by Novartis Pharmaceutical Corporation ("NPC") on its own behalf and on behalf of Sandoz Inc. ("Sandoz"), and Alcon Laboratories, Inc. ("Alcon"). We refer to NPC, Sandoz, and Alcon collectively herein as "Novartis." We appreciate the opportunity to provide comments in response to the Health Resources and Services Administration ("HRSA") proposed rule regarding the 340B Drug Pricing Program ("340B program") ceiling price and manufacturer civil monetary penalties, which was published in the Federal Register on June 17, 2015 ("Proposed Rule").[1]

NPC researches, develops, manufactures, and markets innovative prescription drugs in the United States, used to treat a number of diseases and conditions, including cardiovascular,

[1] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties, 80 Fed. Reg. 34,583 (June 17, 2015).

dermatological, central nervous system, bone disease, cancer, organ transplantation, psychiatry, infectious disease and respiratory concerns. The company's mission is to improve people's lives by pioneering novel health care solutions.

Sandoz is a leader in generic pharmaceuticals, providing access to a broad portfolio of high-quality, affordable medicines. Sandoz markets generic drugs in the United States across a range of therapeutic areas.

Alcon is a leader in the research, development, manufacturing, and marketing of eyecare products, including ophthalmic pharmaceuticals, surgical devices, and vision care products. Alcon has one mission: to provide innovative products that enhance quality of life by helping people see better.

Novartis is a committed 340B program stakeholder and places great emphasis on compliance with all statutory and regulatory requirements pertaining to government price reporting, including those under the 340B program. We share a common interest in ensuring that the 340B program is administered in a way that allows manufacturers to act in good faith to avoid application of the penalties proposed in the Proposed Rule while serving 340B covered entities as well. Novartis therefore appreciates this opportunity to submit comments with respect to the Proposed Rule. Novartis affirms the majority of comments regarding the Proposed Rule submitted by both the Pharmaceutical Research and Manufacturers of America ("PhRMA") and the Biotechnology Industry Organization ("BIO").

This letter first reviews the background of the 340B program, summarizes statutory requirements related to the Proposed Rule, and explains why certain aspects of the Proposed Rule are premature. It then discusses the ceiling price calculation provisions in the Proposed Rule, explaining that (1) the proposed ceiling price calculation mechanics are unclear because HRSA has not yet implemented the ceiling price verification mechanism and website for covered entities, (2) HRSA may not finalize a ceiling price estimation and refund requirement because the Proposed Rule does not provide relevant details, (3) the penny pricing requirement would be unlawful and therefore may not be finalized, and (4) HRSA does not have rulemaking authority regarding this topic. The letter next addresses the Proposed Rule provisions regarding civil monetary penalties ("CMPs"), noting that (a) the Proposed Rule fails to provide a definition of "knowing and intentional," (b) critical procedural matters related to CMPs are not addressed, (c) the proposed definition of "instance of overcharging" is inconsistent with the 340B statute, (d) manufacturers should be permitted to offset overcharges against undercharges, (e) it is inappropriate to define "instance of overcharging" as a single order, and (f) limited distribution plans should fall within a CMP safe harbor. Finally, the letter explains that any final regulation should apply prospectively only.

I. 340B Program Background and Statutory Requirements

The 340B program was created by enactment of section 602 of the Veterans Health Care Act of 1992 (Public Law No. 102-585), which added Section 340B to the Public Health Service Act ("PHSA").[2] In 2010, the Patient Protection and Affordable Care Act ("ACA")[3] amended the 340B statute to provide for, among other things, the development "and publishing through an appropriate policy or regulatory issuance" of "precisely defined standards and methodology" for the calculation of ceiling prices.[4] The amended 340B statute further provides for sanctions in the form of CMPs to be "assessed according to standards according to standards established in regulations to be promulgated by the Secretary" against manufacturers that "knowingly and intentionally" charge a covered entity a price that exceeds the ceiling price.[5] The Proposed Rule seeks to implement these provisions.

The ACA added other requirements to the 340B statute that the Secretary has not yet implemented, but that are relevant to an assessment of the Proposed Rule. The ACA requires that the Secretary develop "a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers ... and charged to covered entities,"[6] as well as provide access through a website "to the applicable ceiling prices for covered outpatient drugs as calculated and verified by the Secretary."[7] HRSA has published two notices seeking comments under the Paperwork Reduction Act of 1995 on its estimate of the burden imposed on manufacturers by the proposed information collection request related to these requirements.[8] By letter dated May 21, 2015, Novartis submitted comments regarding this proposed information collection request. The two notices provide little detail regarding the mechanism for verifying the accuracy of ceiling prices or the website for publishing ceiling prices to covered entities, and HRSA has not disclosed any additional information since publishing the notices.

The 340B statute, as amended by the ACA, also directs the Secretary to establish "procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturers."[9] HRSA to date has not made any information available regarding this topic.

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[2] Section 340B of the PHSA is codified at 42 U.S.C. § 256b.

[3] ACA, § 7102, Pub. L. No. 111-148 (2010).

[4] PHSA § 340B(d)(1)(B)(i)(I).

[5] *Id.* at § 340B(d)(1)(B)(vi).

[6] *Id.* at § 340B(d)(1)(B)(i).

[7] *Id.* at § 340B(d)(1)(B)(iii).

[8] Agency Information Collection Activities: Proposed Collection: Comment Request, 79 Fed. Reg. 58,791 (Sept. 30, 2014); Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request, 80 Fed. Reg. 22,207 (Apr. 21, 2015).

[9] PHSA § 340B(d)(1)(B)(ii).

II. Certain Aspects of The Proposed Rule Are Premature

As a general matter, Novartis believes that any attempt to codify regulations on certain of the topics included in the Proposed Rule is premature. Put simply, certain aspects of Proposed Rule seek to create a structure for the imposition of CMPs where a manufacturer has failed to comply with program requirements that are not yet in place. It is difficult, if not impossible, for Novartis and other stakeholders to comment meaningfully on these aspects of the Proposed Rule because HRSA has not yet published critical elements of the overall regulatory scheme upon which the Proposed Rule necessarily relies.

First, Novartis opposes any codification of a CMP regulation applicable to a manufacturer's failure to extend the ceiling price to a covered entity until HRSA has finalized its methodology for verifying and publishing such prices. The Proposed Rule would support the imposition of CMPs on manufacturers that knowingly fail to extend the ceiling price to covered entities. More specifically, the Proposed Rule would do so by evaluating manufacturer compliance against the ceiling price as verified and published by HRSA. As described above, however, HRSA has not yet finalized its proposal for, or details regarding, how it will verify ceiling prices or publish ceiling prices to covered entities. Unless and until HRSA does so, stakeholders, including Novartis, cannot comment meaningfully on a proposed regulation regarding the imposition of CMPs based on such verified and published ceiling prices.

Second, Novartis opposes any codification of a CMP regulation that would penalize a manufacturer's failure to issue a refund to a covered entity for a deemed retroactive overcharge resulting from a resubmission of Medicaid pricing data. As noted above, the ACA specifically directs the Secretary to establish procedures for such refunds, but HRSA has not yet established the mechanism for issuing such refunds. HRSA simply cannot seek to codify a regulation that penalizes manufacturers for failing to comply with a process that does not yet exist due to HRSA's own inaction.

Finally, in this Proposed Rule, HRSA proposes to delegate authority to the Office of the Inspector General of the Department of Health and Human Services ("OIG") to bring CMP actions. That delegation of authority has not yet occurred, and it is unclear how OIG would act pursuant to such a delegation. Stakeholders cannot comment on processes and inter-agency delegations that are critical to the Proposed Rule's function where those processes and relationships do not yet exist.

Each of these three topics are addressed in more detail below, in conjunction with the substantive discussion of these proposals. However, Novartis believes it is important to emphasize at the outset the critical nature of this issue. The notice and comment process for agency rule-making is fundamental to the legitimacy of the resulting final regulations. That process must afford a meaningful opportunity for stakeholders to comment, but it cannot do so when the "notice" component is lacking. That is precisely the case for the above topics because HRSA has not yet

established the regulatory framework that the Proposed Rule seeks to enforce. Novartis strongly believes that the above topics cannot be included in any final regulation for that reason.[10]

III. Ceiling Price Calculation

This section of the letter sets forth Novartis' comments regarding the Proposed Rule provisions that address the calculation of the ceiling price. As described below, Novartis believes that (1) the proposed ceiling price calculation mechanics are unclear because HRSA has not yet implemented the ceiling price verification mechanism and website for covered entities, (2) HRSA may not finalize a ceiling price estimation and refund requirement because the Proposed Rule does not provide relevant details, (3) the penny pricing requirement would be unlawful and therefore may not be finalized, and (4) HRSA does not have rulemaking authority regarding this topic.

A. The Proposed Ceiling Price Calculation Mechanics Are Necessarily Unclear Given that HRSA Has Not Yet Implemented the Ceiling Price Verification Mechanism and Website for Covered Entities

The Proposed Rule provides details with respect to the ceiling price calculation that go beyond the statutory formula. For example, HRSA explains that it would rely on the "case package size" data field to convert the ceiling price from the per-unit value that results from the statutory formula to a price that "is operational in the marketplace."[11] HRSA then would "publish" the ceiling price. Unlike the inputs for the statutory ceiling price calculation—the drug's average manufacturer price ("AMP") and the unit rebate amount ("URA")—the "case package size" is not a data point that HRSA can obtain from the Medicaid drug rebate program. The "case package size" is not currently used by the Medicaid drug rebate program, and therefore also is not a value stored in the Drug Data Reporting for Medicaid (DDR) system—but the Proposed Rule does not explain how HRSA proposes to obtain this information. Indeed the "case package size" concept is foreign not just to the Medicaid drug rebate program, but also is not utilized in other price reporting programs, such as the Veterans Affairs Federal Supply Schedule ("VA/FSS") pricing program. HRSA's two notices under the Paperwork Reduction Act related to the ceiling price website indicate that HRSA would collect this information through the website, but no further detail is available.[12] The "case package size" concept poses operational concerns as well, because drugs may be sold in increments that are smaller than the "case

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[10] *See, e.g., Allina Health Services v. Sebelius*, 746 F.3d 1102 (D.C. Cir. 2014) (vacating a final rule and holding HHS's notice inadequate where the final rule was not a "logical outgrowth" of the proposed rule, and noting that an agency's failure to disclose critical material on which it relies deprives commenters of their § 553 right to "participate in rulemaking").

[11] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties, 80 Fed. Reg. 34,583, 34,585 (June 17, 2015).

[12] Agency Information Collection Activities: Proposed Collection: Comment Request, 79 Fed. Reg. 58,791 (Sept. 30, 2014); Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request, 80 Fed. Reg. 22,207 (Apr. 21, 2015).

package." For example, in Novartis' experience, some customers—particularly 340B covered entities—seek to purchase a drug by the bottle or in smaller packages, rather than as a complete case. Introducing the new "case package size" value therefore may lead to unnecessary confusion and also rounding issues.

The example of the "case package size" concept illustrates that the ceiling price calculation described in the Proposed Rule appears to rely on aspects of the 340B statute that HRSA has not yet implemented, and it therefore is impossible for Novartis to comment on the proposed ceiling price calculation in a meaningful way. Novartis cannot evaluate the Proposed Rule in a vacuum and on a merely hypothetical basis, when its operation and implementation depend on mechanisms and HRSA initiatives that HRSA has not disclosed to stakeholders.
Similarly, the Proposed Rule would calculate the ceiling price at six digits, then multiply that result by the package size and the "case package size," and finally round to two digits. This calculation, however, may cause problems and inaccuracies if there is a discrepancy between the price the manufacturer submits to wholesalers and the price calculated by HRSA. Without any information regarding how HRSA proposes to validate ceiling prices or publish ceiling prices to covered entities, it is impossible for Novartis to meaningfully comment on the ceiling price formula in the Proposed Rule because the implications of the ceiling price formula in the Proposed Rule cannot be ascertained without knowledge of the related, as yet unpublished, aspects of the 340B program. Novartis urges HRSA to publicly release details regarding the ceiling price validation mechanism and covered entity website and then afford stakeholders another opportunity to comment on the proposed ceiling price formula.

B. HRSA May Not Finalize a Ceiling Price Estimation and Refund Requirement Without Issuing a Proposal That Provides Stakeholders with a Meaningful Opportunity to Comment

The Proposed Rule would require that manufacturers estimate the ceiling price for new drugs, but it does not provide any detail regarding how to perform the estimation. The absence of such vital information amounts to a lack of notice and meaningful opportunity to comment on this topic. The Proposed Rule merely observes that the inputs for the statutory ceiling price calculation, a drug's AMP, URA, and, in the case of innovator products, Best Price, are unavailable for a period following the launch of a new drug, and states that the manufacturer "must estimate the ceiling price" for that period. The Proposed Rule is silent as to how the estimation should be performed. Estimating the ceiling price presumably would require the manufacturer to estimate the AMP, Best Price, and URA, and such estimates could be performed on the basis of any number of assumptions, but HRSA does not share what it expects when it requires manufactures to estimate the ceiling price. In an attempt to fill this void, the preamble to the Proposed Rule points to a Federal Register notice from 1995 in which HRSA first addressed the ceiling price requirement for new drugs.[13] The 1995 guidance, however, also does

[13] Notice Regarding Section 602 of the Veterans Health Care Act of 1992; New Drug Pricing, 60 Fed. Reg. 51,488 (Oct. 2, 1995).

not describe how to estimate the ceiling price. It, too, simply recites the mechanical aspects of the statutory ceiling price calculation.

In addition, under the Proposed Rule, manufacturers would be required to estimate the ceiling price for the first three quarters following the launch of a new drug, and would then have to refund covered entities for overcharges if the estimated ceiling price exceeded the actual ceiling price for that period. HRSA, however, has not put a mechanism in place for manufacturers to issue these refunds, even though, as discussed above, the ACA amended the 340B statute in 2010 to require such a mechanism.

Despite the absence of these predicates, it appears that, under the Proposed Rule, CMPs may apply if a manufacturer fails to refund covered entities for overcharges resulting from estimated ceiling prices. The Proposed Rule would define an "instance of overcharging" as any order for a covered outpatient drug "which results in a covered entity paying more than the ceiling price," and that definition appears to be broad enough to sweep in instances where estimated ceiling prices were too high and the manufacturer did not issue refunds to covered entities in the time proposed to be allotted by the Proposed Rule. It would be inappropriate to apply CMPs when HRSA has not defined in any way the estimation or true-up calculation. The application of CMPs to trued-up ceiling prices would also be inappropriate because HRSA has not established a process for issuing refunds to covered entities, as it is required to do by the 340B statute. HRSA is unfairly creating compliance obligations for manufacturers while, at the same time, failing to provide the very policies and mechanisms that manufacturers would need to comply. Notably, HRSA may not define or establish these concepts for the first time in a final rule because stakeholders would not have had an opportunity to comment on any proposals. In order for stakeholders to be able to meaningfully comment on a ceiling price estimation and refund requirement, HRSA must first provide details regarding the statutorily-mandated mechanism for issuing refunds as well as the estimation and true-up calculations.

Exacerbating the lack of clarity in the proposal, the proposed requirement for manufacturers to issue refunds in the new drug context departs from the 1995 guidance that HRSA itself invokes in the preamble to the Proposed Rule. Under the 1995 guidance, covered entities rather than manufacturers bear the burden of initiating the refund process, in "an attempt to evenly split the administrative burden of the process between the manufacturer and the entity."[14] In addition to more equitably allocating the burden of issuing refunds, this approach helps ensure that covered entities request refunds only when the amounts involved are material, which the 1995 guidance acknowledges.[15] Not only would the Proposed Rule unfairly shift the burden entirely to manufacturers, but it would force manufacturers to issue refunds for minimal amounts, imposing a potentially high administrative cost without sufficient justification. The allocation of the administrative burden in the 1995 guidance should be retained, and, in addition, HRSA should

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[14] *Id.*
[15] *Id.*

specify a materiality threshold to avoid the disproportionately high administrative burden associated with refunds for minimal amounts.

The Proposed Rule also would provide that, in issuing refunds, manufacturers may not offset overcharges against undercharges. Novartis opposes this aspect of the Proposed Rule, as discussed in more detail below. The prohibition against offsetting would be particularly unfair where HRSA would require manufacturers to first estimate a ceiling price and then require manufactures to issue refunds for estimated ceiling prices that are higher than the actual ceiling price, while permitting covered entities to retain the benefit of an estimated ceiling price that is lower than the actual ceiling price. Take, for example, a situation in which the estimated ceiling price is too low in the first two quarters after product launch and too high in the third quarter. In this situation, the covered entity would retain the benefit of sub-ceiling pricing for the first two quarters, while the manufacturer, if unable to offset against the sub-ceiling pricing, would be required to refund the overcharge from the third quarter in its entirety.[16] In keeping with the equitable allocation of the burden associated with issuing refunds set forth in the 1995 guidance, manufacturers should be permitted to offset overcharges resulting from estimated ceiling prices.

C. The Proposed Penny Pricing Requirement Would Be Unlawful and Therefore May Not Be Finalized

HRSA's penny pricing policy, currently set forth in Release No. 2011-2,[17] is unreasonable and not binding (which HRSA itself acknowledges in the Proposed Rule[18]) and should not be codified in regulation for a number of reasons. As described below, HRSA does not have rulemaking authority to issue a binding ceiling price regulation, and, thus, the ceiling price calculation provisions of the Proposed Rule would not be binding even if finalized. Further, even if HRSA were to have rulemaking authority in this area (which it does not, as discussed below), the penny pricing policy still could not be made enforceable because it is arbitrary and capricious and otherwise unlawful.

The penny pricing policy purports to address a gap in the 340B statute—when a ceiling price rounds or calculates to zero—a gap that HRSA necessarily acknowledges by virtue of the penny pricing policy itself. The 340B statute and its legislative history contemplate a positive ceiling price in all cases. For example, the statute authorizes manufacturers to charge "a price for a drug that is lower than" the ceiling price and refers to "the amount required to be paid" to the

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[16] It is possible that such a sub-ceiling price would impact the prices reported and charged under other federal price reporting and contracting programs, such as the VA/FSS pricing program. In that program, subject to only limited exceptions, 340B sub-ceiling prices are required to be factored into the calculation of the Federal Ceiling Price, which is the price charged the Department of Veterans Affairs, Department of Defense, and certain other federal agencies when they buy innovator drugs and biologics under the VA/FSS pricing program.

[17] Health Resources & Servs. Admin., Dep't of Health & Human Servs., Clarification of Penny Pricing Policy, Policy Release No. 2011-2 (Nov. 21, 2011).

[18] *See* 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties, 80 Fed. Reg. 34,583, 34,585 (June 17, 2015).

manufacturer.[19] Both phrases suggest a positive, non-zero price. The original legislative history likewise indicates that the 340B statute was intended to secure "favorable prices" for covered health care providers.[20] To illustrate the contemplated discount, the committee report gives an example of a drug discounted from $1.00 per unit to $0.80 per unit.[21] HRSA agrees that a positive, non-zero price is required. Indeed, the Proposed Rule itself states that "it is not reasonable for a manufacturer to set a 340B ceiling price to $0.00 per unit of measure."[22]

But the Proposed Rule, like release 2011-2 before it, provides no rationale whatsoever for why mandating $0.01 per unit, instead of $0.00 per unit, transforms the result from inherently unreasonable to not only reasonable but required, rendering the penny pricing policy arbitrary and capricious. Indeed, as discussed below, mandating a positive, non-zero price of one penny would be patently unreasonable. HRSA may not seek to compel manufacturers to adhere to penny pricing through the threat of CMPs[23] because a penny pricing mandate would be unlawful.

Most fundamentally, the penny pricing policy is inconsistent with the statutory scheme. When issuing the penny pricing policy, HRSA entirely failed to consider a critical consequence of the policy, namely the heightened risk of improper diversion of controlled substances. The 340B statutory scheme itself reflects the clear intent of Congress to avoid the improper diversion of drugs purchased at the 340B ceiling price.[24] The concern regarding improper diversion is only magnified with respect to controlled substances. The risks of abuse and diversion created by penny pricing with respect to controlled substances are simply too great for Novartis, or HRSA, to ignore.[25] The penny pricing policy, and now the Proposed Rule, completely fails to consider, let alone account for, the troubling risks of abuse and diversion presented by such drugs. Especially given the absence of any attempt to articulate a rationale that reconciles these concerns with express Congressional intent, HRSA's interpretation of the statute, as embodied in the penny pricing policy, is inconsistent with the statutory scheme. The penny pricing policy therefore cannot be a reasonable interpretation of the 340B statute and could not be made enforceable.

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[19] PHSA §§ 340B(a)(1), (a)(10).

[20] H.R. Rep. No. 102-384(II), at 16 (1992).

[21] *Id.* at 15.

[22] 80 Fed. Reg. at 34,585.

[23] 80 Fed. Reg. at 34,587.

[24] PHSA § 340B(d)(2)(A).

[25] *See* U.S. Gov't Accountability Office, GAO-11-836, Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement 21-27 (Sept. 2011) (observing that gaps in the 340B program create a risk of diversion) and U.S. Gov't Accountability Office, GAO-15-442, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals (June 2015) (observing that per beneficiary Medicare Part B drug spending was substantially higher at 340B DSH hospitals than at non-340B hospitals, indicating that, on average, beneficiaries at 340B DSH hospitals were either prescribed more drugs or more expensive drugs).

A venerable canon of statutory construction, the absurdity doctrine, points in the same direction. Requiring pharmaceutical manufacturers to give away unlimited quantities of powerful drugs virtually for free can fairly be characterized as an absurd result, which itself can justify disregard of any statutory language that could be read to counsel such a result. Courts have held that, "'[w]here the result of a literal interpretation of statutory language is absurd, or where the obvious purpose of the statute is thwarted by such slavish adherence to its terms, we may look beyond the plain language.'"[26]

A ceiling price effectively equal to zero also may be unconstitutional. The Constitution generally forbids "arbitrary" or "confiscatory" price controls.[27] As the U.S. Court of Appeals for the Eighth Circuit has explained, "the heart of any confiscatory-rate claim is the ability to show that the government has set a maximum price for a good or service and that the rate is below the cost of production (factoring in a reasonable rate of return)."[28] A ceiling price of effectively zero likely would fail to pass constitutional muster under that test.

Mandating a price of one penny would be especially unreasonable in light of the so-called "must offer" requirement. The 340B statute provides that the pharmaceutical pricing agreement ("PPA"), pursuant to which manufacturers participate in the 340B program, "shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."[29] This "must offer" requirement currently is not binding because HRSA has not implemented this statutory provision through the issuance of a new form PPA or through amendments of existing PPAs. HRSA, however, has asserted that the "must offer" requirement is binding nevertheless. In combination with mandatory penny prices, these two policies work to require manufacturers to supply unlimited quantities of products at a penny a unit, regardless of whether that is a sub-cost price and regardless of any diversion risk. Such a result amply demonstrates the unreasonableness of this aspect of the Proposed Rule.

In the absence of any statutory direction or other binding guidance, manufacturers are left to reasonably determine how to proceed when the ceiling price rounds or calculates to zero. This approach is analogous to that of the Medicaid drug rebate program.[30] There are many linkages between the Medicaid drug rebate program and the 340B program (for example, the statutory ceiling price formula is based on inputs from the Medicaid drug rebate program), supporting the

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[26] *See, e.g., Local Union 36, Int'l Brotherhood of Elec. Workers, AFL-CIO v. NLRB*, 631 F.3d 23, 27 (2d Cir. 2010) (citation omitted).

[27] *Duquesne Light Co. v. Barasch*, 488 U.S. 299, 307 (1989); *Pennell v. City of San Jose*, 485 U.S. 1, 11 (1988).

[28] *TCF Nat'l Bank v. Bernanke*, 643 F.3d 1158, 1164 (8th Cir. 2011).

[29] PHSA § 340B(a)(1).

[30] The Medicaid Rebate Agreement directs that, "[i]n the absence of specific guidance in section 1927 of the Act, Federal regulations and the terms of this agreement, the Manufacturer may make reasonable assumptions in its calculations of AMP and Best Price, consistent with the intent of section 1927 of the Act, Federal regulations and the terms of this agreement." 56 Fed. Reg. 7049, 7052 (Feb. 21, 1991); Medicaid Rebate Agreement at § II(i).

application of precepts from the Medicaid drug rebate program in the 340B context. Manufacturers must be permitted to select among reasonable alternative approaches to penny pricing when a ceiling price rounds or calculates to zero, which HRSA indicates some manufacturers already have done.[31] Novartis believes an alternative approach to penny pricing would be reasonable if it results in pricing data that (1) are readily and objectively verifiable by a third party, i.e., the data are not determined on the basis of costs, profit margins, or other metrics proprietary to the manufacturer, (2) are the same as or related to pricing data calculated for purposes of another government program that is reasonably related to the 340B program, and (3) represent a significant discount that is in all cases lower than AMP minus the basic rebate.

One reasonable approach would be to carry forward the most recent non-zero ceiling price, which the Proposed Rule itself alludes to.[32] That approach meets the criteria Novartis proposes, and is analogous to that in the Medicaid drug rebate program, which as discussed above is closely related to the 340B program. In the Medicaid drug rebate program, manufacturers are required to report the most recent positive AMP if monthly AMP is equal to zero.[33]

Another reasonable alternative approach would be to charge the most recent Federal Ceiling Price where the 340B ceiling price rounds or calculates to zero. The Federal Ceiling Price is calculated for purposes of the VA/FSS pricing program. Under that program, the manufacturer is obligated to make its drugs available for procurement on a Federal Supply Schedule contract and to charge four federal agencies—the U.S. Department of Veterans Affairs, the U.S. Department of Defense, the Public Health Service, and the Coast Guard—a price that is no higher than the Federal Ceiling Price.[34] Like the 340B ceiling price, the Federal Ceiling Price is calculated on the basis of a statutory formula and relies on components that are similar to the URA component of the 340B ceiling price calculation. The 340B program and the VA/FSS pricing program are closely related in other ways as well, as both programs were enacted at the same time through the same legislation.

These examples—which by no means constitute an exhaustive list—illustrate that reasonable alternatives to penny pricing are available when the ceiling price rounds or calculates to zero. Manufacturers should be permitted to apply such reasonable alternatives to avoid the unreasonable and risky outcomes generated by the penny pricing policy.

D. HRSA Has No Rulemaking Authority Regarding the Ceiling Price Calculation

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[31] 80 Fed. Reg. at 34,586.

[32] *Id.* at 34.585.

[33] CMS Release 91; DRA Policy Questions (Jan. 23, 2008), AMP – Reporting, *available at* http://www.cms.gov/Regulations-and-Guidance/Legislation/DeficitReductionAct/downloads/DRAPolicyInquiries.pdf.

[34] See 42 U.S.C. § 8126(a) and Master Agreement (MA) § I.

HRSA does not have rulemaking authority to issue a binding ceiling price regulation, and, therefore, the proposed ceiling price proposals could not be binding, even if they were finalized. HRSA does not have broad rulemaking authority with respect to the 340B program.[35] Instead, HRSA must rely on specific grants of authority in the 340B statute itself. Congress plainly gave HRSA authority to issue regulations regarding the 340B statute's manufacturer CMP provisions, directing that the CMP provisions be implemented through "regulations to be promulgated by the Secretary."[36] When it came to calculating the ceiling price, however, Congress took a different tack. It directed HRSA to establish "precisely defined standards and methodology for the calculation of ceiling prices" via "an appropriate policy or regulatory issuance."[37]

In choosing different words to describe HRSA's powers with regard to ceiling price calculations, Congress must have intended to give HRSA different authority with respect to the ceiling price calculations than CMPs. Courts "refrain from concluding" that "differing language in . . . two subsections has the same meaning in each."[38] Moreover, the different language between the ceiling price calculation and CMP provisions cannot be explained away as a difference in phrasing. As the D.C. Circuit has explained in rejecting a similar argument, "it is through the 'dint of . . . phrasing' that Congress speaks, and where it uses different language in different provisions of the same statute, [a court] must give effect to those differences."[39] After all, if Congress intended HRSA to have authority to issue binding regulations regarding ceiling price calculations, it "knew how to" do so—it could have used the same "regulations to be promulgated by the Secretary" language it used in the CMP provision.[40]

The most logical explanation for the different language in the 340B statute's CMP and ceiling price calculation provisions is that Congress intended HRSA's ceiling price calculation guidance to be nonbinding. Agencies often speak through such nonbinding guidance, which are alternatively labeled "interpretive rules" or "policy statements."[41] Indeed, HRSA has done so itself.[42] It therefore is appropriate for Congress to have directed that HRSA clarify its position on how to calculate the ceiling price through "an appropriate policy or regulatory issuance" while at the same time withholding from HRSA the power to issue a binding legislative rule on the topic.

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[35] *See Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 43 F. Supp. 3d 28, 40-45 (D.D.C. 2014). The opinion lists the ceiling price calculation as one area where HRSA has rulemaking authority, but does so in dictum only.

[36] PHSA § 340B(d)(1)(B)(vi).

[37] *Id.* at § 340B(d)(1)(B)(i)(I).

[38] *Russello v. United States*, 464 U.S. 16, 23 (1983).

[39] *Ford v. Mabus*, 629 F.3d 198, 206 (D.C. Cir. 2010) (ellipses in original).

[40] *Central Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 176 (1994).

[41] *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1322 n.3 (D.C. Cir. 1988).

[42] *See* Availability of Interpretive Rule: Implementation of the Exclusion of Orphan Drugs for Certain Covered Entities Under the 340B Program, 79 Fed. Reg. 42,801 (July 23, 2014).

Accordingly, while Novartis appreciates HRSA's efforts to provide some degree of clarity regarding the calculation of ceiling prices, we do not believe that the ceiling price guidance articulated in the Proposed Rule would be binding, if finalized.

IV. Civil Monetary Penalties

As recently as March 24 of this year, OIG agreed that "a lack of transparency in both 340B ceiling prices and Medicaid claims for 340B-purchased drugs has negatively affected 340B providers, State Medicaid programs, and drug manufacturers."[43] We strongly urge HRSA to finalize the Proposed Rule in a way that provides meaningful guidance to manufacturers that participate in the 340B program, especially in light of the potential for penalties. In particular, as described below, Novartis believes that (1) the Proposed Rule fails to provide a definition of "knowing and intentional," (2) critical procedural matters related to CMPs are not addressed by the Proposed Rule, (3) the proposed definition of "instance of overcharging" is inconsistent with the 340B statute, (4) manufacturers should be permitted to offset overcharges against undercharges, (5) it is inappropriate to define "instance of overcharging" as a single order, and (6) limited distribution plans should fall within a CMP safe harbor.

A. The Proposed Rule Would Provide No Definition of "Knowing and Intentional"

In the Proposed Rule, HRSA explained that "a manufacturer would only be subject to [the penalties described in the statute and this rule] when the overcharge was a result of a knowing and intentional act." HRSA noted that "anecdotal information received from covered entities" indicated "this would occur very rarely if at all." But the Proposed Rule provides no guidance whatsoever to manufacturers about when an overcharge will be considered knowing and intentional. This is an essential threshold that the statute requires before CMPs can apply, and HRSA therefore cannot codify its CMP proposals in a final rule until HRSA (1) proposes an explicit definition of this important scienter standard and (2) provides a meaningful opportunity for public comment on HRSA's proposed definition of "knowing and intentional." A final rule cannot be the first time HRSA defines "knowing and intentional." This topic also is of heightened importance because the advance notice of proposed rulemaking related to the imposition of CMPs ("ANPRM"), issued on September 20, 2010, suggested that HRSA interprets "knowingly and intentionally" to be far broader than a manufacturer might reasonably expect.[44]

In the ANPRM, HRSA stated that

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[43] *Examining the 340B Drug Pricing Program: Hearing Before the Subcomm. on Health of the H. Comm. On Energy and Commerce*, 114th Cong. __ (2015) (statement of Ann Maxwell, Assistant Inspector General, Office of the Inspector General, Department of Health and Human Services).

[44] 340B Drug Pricing Program Manufacturer Civil Monetary Penalties, 75 Fed. Reg. 57,230 (Sept. 20, 2010).

> knowing and intentional can be inferred from the circumstances. For example, the knowledge and intent of employees or agents of a manufacturer may be attributed to the company as a whole. In cases where the ceiling price is known by the manufacturer, the manufacturer knows that a purchaser is a covered entity, and the covered entity is knowingly charged a price in excess of the ceiling price, a finder of fact would be able to infer intentionality of the violation even in cases where no single individual had knowledge of all of these elements. HRSA anticipates there may be circumstances where repeated violations could be considered to be knowingly and intentional if, for example, a manufacturer repeatedly miscalculates a ceiling price or otherwise establishes a system where overcharges are a highly probable consequence.[45]

These statements suggest that HRSA views it as permissible to infer knowing and intentional violations from circumstances in which (1) a single employee or agent of a manufacturer knows a customer is a covered entity and, separately, another employee or agent knows that customer is being charged more than the ceiling price, or (2) a manufacturer calculates a ceiling price incorrectly on multiple occasions or in a way that renders overcharges "highly probable" (whatever that ambiguous phrase encompasses).

That interpretation presents several problems and underscores why a properly established definition of "knowing and intentional" is critical. A threshold problem with the view espoused in the ANPRM is that HRSA has not specified what entities under what circumstances would be considered "agents" of a manufacturer. For example, are wholesalers agents? Are software vendors? Are third-party auditors? Neither the knowledge nor the intent of "agents" or individual employees should have any bearing on whether the statutory standard is met. The standard should instead look to whether an employee of the manufacturer with decision-making authority in the 340B program has both the requisite knowledge (i.e., that a purchaser is a covered entity and that the covered entity is being charged a price in excess of the ceiling price) and intent.

The ANPRM seems to suggest that HRSA may be seeking to impermissibly redefine "knowingly and intentionally," words specifically chosen by Congress, into a lower standard that does not include the higher, more exacting state of mind that Congress intended. While Congress has at times defined "knowing" to require something less than actual knowledge, including "reckless disregard" or "deliberate ignorance"—for example, in the federal civil False Claims Act[46]—here, the statute plainly requires more by referring only to conduct that is both knowing and intentional. In contrast, the False Claims Act disclaims any intentionality requirement.[47] Taken together, "knowingly and intentionally" should be defined to include only conduct undertaken

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[45] *Id.* at 57,232.

[46] 31 U.S.C. § 3729(b)(1)(A).

[47] *Id.* at § 3729(b)(1)(B) (term "knowingly" "require[s] no proof of specific intent to defraud").

with the specific intent to overcharge a customer that the manufacturer actually knows is a covered entity. The phrase cannot include:

- inadvertent, accidental, or negligent conduct,
- unrecognized error in computing the ceiling price,
- 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 a deliberate effort to disobey the law with regard to the 340B program.

As just one example of the difficulties a manufacturer would face under the regulation as currently drafted, consider the following. As the Proposed Rule itself recognizes, "[m]anufacturers commonly use wholesalers to distribute drugs on their behalf"[48] and wholesale distributors are entitled to charge a distribution fee.[49] But the Proposed Rule never addresses if, or when, actions of a wholesaler could be attributable to a manufacturer for purposes of assessing a CMP, or whether a distribution fee could cause an "overcharge." But a manufacturer is left to believe that is possible: "A manufacturer's failure to ensure that covered entities receive the appropriate 340B discount through its distribution arrangements may be grounds for the assessment of civil monetary penalties under this regulation."[50] CMPs should not apply where an overcharge results from an act of a third party, such as a wholesaler or distributor error. If, for example, a manufacturer provides the correct ceiling price to a third party, which then charges a covered entity a higher price than the ceiling price, the manufacturer should not be liable for a "knowing and intentional" overcharge of the covered entity, and CMPs should not apply to the manufacturer.

Other regulations define the actionable mental state relevant to their statutory schemes. For example, in 42 C.F.R. §1003, referenced in the Proposed Rule, the terms "should know" and "should have known" are defined in the regulation's "definitions" section.[51] A clear definition of what constitutes "knowing and intentional" conduct here would allow manufacturers to put the appropriate compliance systems in place and would avoid litigation over what those terms mean in the context of 340B overcharges.

B. Critical Procedural Matters Are Not Addressed

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[48] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties, 80 Fed. Reg. 34,583, 34,586 (June 17, 2015).

[49] *See* HHS OIG, *Deficiencies in Oversight of the 340B Drug Pricing Program* (October 2005) (OEI-05-02-00072).

[50] 80 Fed. Reg. at 34,586.

[51] 42 C.F.R. § 1003.101.

The Proposed Rule does not itself address procedural matters related to imposing CMPs and refers to a delegation of authority to OIG to bring CMP actions. However, that delegation of authority has not yet occurred, and Novartis therefore cannot comment with respect to whether the delegation of authority to OIG would be appropriate or not. Novartis is more concerned with the lack of clarity related to the standards that OIG would apply in connection with CMP actions—a lack of clarity that renders it impossible to meaningfully comment on the proposal.

The Proposed Rule explains that "the HHS Office of Inspector General (OIG) will have the authority to bring 340B CMP actions utilizing the standards applied to other civil monetary penalties under 42 CFR parts 1003 and 1005."[52] However, the Proposed Rule provides no explanation as to what the "standards" are that are being imported from these other sections, and it does not propose amending any aspect of those regulations to make them applicable to the 340B context. For example, 42 C.F.R. § 1003.102 lists the bases on which OIG will purport to impose a CMP—but none of them fits a knowing and intentional overcharge to a 340B entity.

The approach in the Proposed Rule is problematic because the provisions in 42 C.F.R. parts 1003 and 1005 are inapt in this context, for several reasons.

First, 42 C.F.R. §§ 1003.103 and 1003.106 contain elaborate schedules for calculating the amount of the penalty, but the 340B statute, as amended by the ACA, expressly limits CMPs in the 340B context to $5,000 per instance of overcharge.

Second, 42 C.F.R. § 1003.102 does not provide OIG with authority to impose a penalty for a "knowing and intentional" overcharge, but the section does contain several other actionable mental states.[53] No explanation is given as to how these mental states apply and interact here, and no 340B-specific definition of "knowing and intentional" is provided.

Third, numerous provisions of Part 1003 discuss exclusion from participation in Medicare, Medicaid, and all other federal health care programs in lieu of or in addition to a CMP.[54] But only a CMP—not exclusion—is authorized by the 340B statute.[55] The Proposed Rule should clarify that the "standards" from 1003 and 1005 that are to be imported into the 340B CMP process do not include anything related to exclusion.

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[52] 80 Fed. Reg. at 34,585.

[53] *See, e.g.*, § 1003.102(a)(1) ("knew or should have known"); § 1003.102(b)(15) ("knowingly and willfully"); § 1003.102(c)(1)(i)(A) ("knowingly"); § 1003.102(c)(1)(i)(B) ("negligently"); § 1003.102(c)(1)(ii)(D)(2) ("knowingly" defined as "recklessly disregards," "deliberately ignores"); § 1003.102(e) ("knowingly" defined as "has actual knowledge of information, acts in deliberate ignorance of the truth or falsity of the information, or acts in reckless disregard of the truth or falsity of the information, and that no proof of specific intent to defraud is required").

[54] *See, e.g.*, §§ 1003.105, 1003.107, 1003.134-135.

[55] PHSA § 340B(d)(1)(B)(vi).

Fourth, the factors enumerated in § 1003.106 do not account for considerations specific to 340B CMPs that should be taken into account, including (a) the nature and reason for the "overcharge;" (b) whether the manufacturer could readily identify the purchaser as a covered entity given the lack of an accurate database or identification system for identifying entities eligible for the discount program; (c) whether the purported "overcharge" resulted from a lack of developed and published standards and methodologies for calculating ceiling prices; (d) whether the purported "overcharge" resulted from restated pricing data that simultaneously resulted in undercharges that would have been trued up if there were a mechanism for doing so; and (e) whether the purported "overcharge" was de minimus, which should result in a nominal (or no) CMP. This section appears to be the most likely candidate for the "standards" that the Proposed Rule is referencing, but the factors that OIG is directed to take into account in § 1003.106 vary depending on which provision of § 1003.102 is at issue. Because no provision of § 1003.102 will be at issue in a 340B CMP proceeding (as explained above in the "second" point), the Proposed Rule fails to provide any appropriate direction as to what factors should be taken into account in setting the amount of any CMP.

Fifth, § 1003.133 embraces statistical sampling in connection with imposing CMPs. Statistical sampling is inconsistent with the "knowing and intentional" scienter requirement for CMPs within the 340B program, so the final rule should make clear that this provision is inapplicable to 340B CMP proceedings.

Sixth, § 1005.7 permits discovery only between the parties to the CMP proceeding—i.e., the manufacturer and OIG. That may make sense for other CMP proceedings under that part of the CFR, but it does not make sense for proceedings involving 340B covered entities. Given that covered entities are likely to possess information relevant to a manufacturer's defense of itself against a charge of knowing and intentional overcharges, the final rule should embrace third-party discovery from any purportedly overcharged 340B covered entity.

Rather than attempt to indiscriminately import regulatory schemes that do not fit squarely in the context of what the 340B statute authorizes and what the Proposed Rule provides, Novartis urges HRSA to enumerate the "standards" applicable to CMPs in the 340B context within a proposed rule itself, to provide manufacturers with meaningful opportunity to comment, and to avoid future litigation over which of the "standards" from other contexts are fairly encompassed within the 340B program.

C. The Definition of "Instance of Overcharging" Would Be Inconsistent with the Statute

The Proposed Rule would define as an "instance of overcharging" a manufacturer's failure to issue a refund "when subsequent ceiling price recalculations resulting from pricing data submitted to CMS occur."[56] Even assuming that refunds are due in such a circumstance, which

[56] 80 Fed. Reg. at 34,586.

Novartis believes is not the case, as discussed in more detail below, addressing the failure to issue such a refund is not within HRSA's statutory authority for this rule-making.

The 340B statutory authority for CMPs limits CMPs to situations in which a manufacturer "knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the [ceiling price]."[57] That standard necessarily evaluates the manufacturer's actions at the time of the sale. A retroactive restatement of a ceiling price due to a resubmission of Medicaid pricing data by definition changes the ceiling price after the fact. The initial charge to a 340B entity cannot have been a "knowing and intentional" charge above the ceiling price. Put simply, the statutory language does not support treating a failure to true-up and refund as an overcharge. Indeed the 340B statute limits the imposition of CMPs to instances where a manufacturer charges a price in excess of the ceiling price, and addresses refunds for overcharges in a separate statutory provision and in the context of establishing a mechanism for such refunds. Congress knows how to grant that authority when it intends to do so. For example, the civil False Claims Act was amended in 2009 to permit liability in some circumstances for "the retention of an overpayment."[58] When Congress enacted the ACA in 2010, it did not include any comparable language or statutory authority with respect to 340B CMPs.

Even assuming that HRSA's limited CMP authority could somehow sweep in failures to issue refunds, HRSA must first establish a ceiling price true-up and refund process before it could plausibly consider assessing CMPs for "knowing and intentional" failure to issue a refund once the necessity for a refund is discovered. HRSA must provide written agency standards that govern how to "true up" all disparities between the price that originally was charged and the recalculated price. Unless and until there is a clear procedure for a manufacturer to issue credits or refunds, as circumstances warrant, HRSA should not seek to assess a CMP against a manufacturer for failing to use currently non-existent mechanisms to true-up prices paid by covered entities. Standardization of this process is an important step, given the high volume of true-ups and refunds that are likely to occur based on price changes flowing from routine restatements of AMP and Best Price (which are calculated to seven decimal places and rounded to six), as well as the volume of products, covered entities, and manufacturers participating in the 340B program. As it currently stands, a manufacturer could face CMP liability even though there is no agency-established mechanism for issuing refunds and credits. That logically cannot stand.

It is also important to note that the Proposed Rule departs from prior HRSA policy. In February 1993, soon after the 340B program was established, the Pharmaceutical Manufacturer's Association submitted the following question to HRSA: "What is to be done when the Medicaid basic rebate amount changes a few quarters after the 'covered entities' price has been determined

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[57] PHSA § 340B(d)(1)(B)(vi)(III).

[58] 31 U.S.C. § 3729(a)(1)(G), (b)(3) (authorizing liability for any person who "knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government," and defining "obligation" as including "the retention of an overpayment").

and purchases made? Do adjustments need to be made to those units purchased by 'covered entities?'"[59] In response, HRSA stated, "[p]urchases made when a new quarterly price is in effect are governed by the new price."[60] This answer suggests that any revised ceiling price that would result from a routine restatement of quarterly pricing figures must be implemented on a prospective basis only, i.e., only when the revision to the underlying pricing figures occurs before or during the same quarter in which the ceiling price derived from those figures is in effect. Put another way, where a manufacturer engages in a routine restatement of its pricing figures in time to affect a *current or future* ceiling price, the manufacturer must revise that ceiling price and apply it to all subsequent purchases. Significantly, HRSA's response did not impose on manufacturers an obligation to retrospectively revise a ceiling price in response to routine restatements of pricing figures, or to identify and reconcile any resulting overpayments. The Proposed Rule would mark a significant departure from this position.

D. Offsetting Should Be Permitted

The Proposed Rule would prohibit manufacturers from offsetting any overcharges against other discounts provided on any other NDC or discounts provided on the same NDC on other transactions, orders, or purchases.[61] A manufacturer would ordinarily use offsetting if, for example, it were to file revised Best Price data that result in a revised ceiling price that is lower than the original ceiling price in one quarter, but higher than the original ceiling price in the next quarter. The Proposed Rule would require the manufacturer to issue a refund to the covered entity for sales in the second quarter, without taking into account the undercharge that occurred in the first quarter. Offsetting would permit the manufacturer to subtract the amount of the undercharge from the overcharge, thereby reducing or even eliminating the refund to the covered entity.

Under the Proposed Rule, the prohibition on offsetting would make it impossible for manufacturers to recoup inadvertent undercharges to covered entities. Prohibiting offsets where a manufacturer has inadvertently undercharged a covered entity would have the effect of mandating a sub-ceiling price, which HRSA is not authorized to do.

The proposed prohibition against offsetting is particularly misguided in light of HRSA's failure to provide a mechanism for issuing refunds and credits to address prior overcharges, which means that offsetting is the only approach to overcharges in historic periods available to manufacturers today. The use of offsets also is completely consistent with, if not required by, the 340B program's "nondiscrimination" policy, which states that manufacturers may not single

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[59] *See* Letter from Marsha Alvarez, Director, Office of Drug Pricing Program [previous name of Office of Pharmacy Affairs], to Joel Bobula, Manager, Public Studies, Pharm. Mfr.'s Ass'n (Feb. 25, 1993).
[60] *Id.*
[61] 80 Fed. Reg. at 34,588.

out covered entities from their other customers for restrictive conditions.[62] Novartis' approach for all purchasers is to use offsetting, a common approach in the pharmaceutical industry and the commercial arena more generally.[63] The Proposed Rule would prevent Novartis from treating its covered entity customers in the same fashion as its commercial customers. Moreover, offsetting is supported by various legal standards, including restitution principles and case law.

E. The Proposed Definition of "Instance of Overcharging" as a Single Order Is Inappropriate

The Proposed Rule would define an "instance of overcharging" as "an order for a covered outpatient drug, by NDC."[64] It would be more in keeping with commercial practice and the actual operation of the 340B program to instead define "instance" by reference to a price, rather than to an order. For example, if a manufacturer transmits the wrong ceiling price for a particular drug to a wholesaler and covered entities purchase the drug at the erroneous price, all orders at that price should be a single "instance" of overcharging, rather than each separate order by each covered entity being a distinct "instance." Novartis does, however, support HRSA's position that an overcharge has not occurred where a covered entity fails to request the ceiling price and the manufacturer charges a different price.

F. Limited Distribution Plans Should Fall Within a CMP Safe Harbor

The Proposed Rule fails to address how CMPs would apply in the context of limited distribution plans. HRSA policy permits manufacturers to develop alternate allocation procedures "during situations when the available supply of a covered drug is not adequate to meet market demands."[65] The Proposed Rule, however, would provide that CMPs may apply when "the manufacturer's refusal to sell or make drugs available at the 340B price resulted in the covered entity purchasing at the non-340B price."[66] That provision on its face appears to sweep in even sales by the manufacturer when a limited distribution plan is in place. Novartis urges HRSA to provide a CMP safe harbor in instances where a manufacturer has an approved limited distribution plan in place and acts in accordance with that plan.

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[62] Health Resources & Servs. Admin., Dep't of Health & Human Servs., Clarification of Non-Discrimination Policy, Policy Release No. 2011-1.1 (May 23, 2012).

[63] The Medicaid drug rebate program also permits offsetting when pricing revisions change a manufacturer's rebate liability for prior periods. *See* Manufacturer Release 80 (Jan. 5, 2010).

[64] 80 Fed. Reg. at 34,588.

[65] Health Resources & Servs. Admin., Dep't of Health & Human Servs., Clarification of Non-Discrimination Policy, Policy Release No. 2011-1.1 (May 23, 2012).

[66] 80 Fed. Reg. at 34,588.

V. Prospective Application

The Proposed Rule does not indicate that HRSA would apply any final rule prospectively only. Any retrospective application would be unlawful under basic principles of administrative law. In any final rule, HRSA should include a clear statement that it applies only prospectively.

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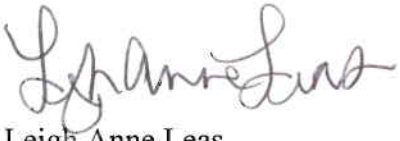
Novartis greatly appreciates HRSA's consideration of these comments. We would be happy to discuss them at greater length; if you have any questions, please do not hesitate to contact me at 862 778 3284.

Sincerely,



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