340B UPDATE: HRSA FINALIZES 340B PRICING & PENALTIES FOR DRUG MANUFACTURERS

Date: 18 January 2017

Health Care Alert

On January 5, 2017, the U.S. Department of Health and Human Services ("HHS") and the Health Resources and Services Administration ("HRSA") issued a final rule on the calculation of drug ceiling prices under the 340B Drug Pricing Program (the "340B Program") and civil monetary penalties ("CMPs") against manufacturers that "knowingly and intentionally" fail to provide such pricing to 340B covered entities.[1] The final rule follows the release of a proposed rule in June 2015 and HRSA's reopening of the comment period in April 2016 and covers issues that Congress directed the HHS Secretary to address through regulation as part of the Patient Protection and Affordable Care Act ("ACA"). Our alert on the proposed rule is available here.

The final rule comes at a time of great uncertainty for the 340B Program and the ACA more broadly. The 340B Program has come under scrutiny in recent months as drug manufacturers, hospitals, and other stakeholders debate potential changes to the 340B Program, including legislative changes and the policies contained in HRSA's proposed 340B Omnibus Guidance. In addition, the ACA is entering a period of turmoil as the Republican-controlled Congress and President-elect Donald J. Trump vow to repeal and replace the law.

SUMMARY OF FINAL RULE

The final rule retains many provisions of the proposed rule but differs in several notable ways.

Effective Date

First, HRSA clarified that the effective date of the final rule will be March 6, 2017. However, HRSA plans to begin enforcing the requirements at the start of the following calendar quarter, beginning April 1, 2017, since the 340B Program operates on a quarterly registration and participation schedule. The effective date also ensures that HRSA will not apply CMPs retroactively, despite the concerns of some commenters.

Civil Monetary Penalties for Drug Manufacturers

As in the proposed rule, HRSA's final rule imposes CMPs of up to $5,000 per instance on drug manufacturers that "knowingly and intentionally" overcharge covered entities for 340B drugs.[2] Each order by National Drug Code number for a particular drug (i.e., at the package size level but not at the individual product package level) would constitute a single instance of overcharging for purposes of the final rule.

HRSA declined to provide a definition of "knowingly and intentionally" as part of the regulatory text. In this regard, HRSA indicated it will defer to the Office of the Inspector General, which is tasked with enforcing the final rule and

©2005-2026 K&L Gates LLP. All Rights Reserved.

bringing regulatory actions against manufacturers, to review the facts and circumstances in determining whether a manufacturer acted knowingly and intentionally in each case.

Nonetheless, the final rule does provide commentary on what constitutes knowingly and intentionally overcharging. In particular, commentary to the final rule contains a series of examples of what would not constitute knowing and intentional behavior:

- The manufacturer made an isolated inadvertent, unintentional, or unrecognized error in calculating the 340B ceiling price;
- The manufacturer sells a new covered outpatient drug during the period the manufacturer is estimating a price based on the final rule, as long as the manufacturer offers refunds of any overcharges to covered entities within 120 days of determining an overcharge occurred during the estimation period;
- When a covered entity did not initially identify the purchase to the manufacturer as 340B-eligible at the time of purchase; or
- When a covered entity chooses to order non-340B priced drugs and the order is not due to a manufacturer's refusal to sell or make drugs available at the 340B price.[3]

For purposes of the final rule, HRSA removed certain other examples that were initially included (e.g., when a manufacturer "acted on a reasonable interpretation of agency guidance"). HRSA also reiterated its comment from the proposed rule that the knowing and intentional standard does not require a manufacturer to have specifically intended to violate the 340B statute; rather, it only requires that the manufacturer intended to overcharge the covered entity.[4] In addition, HRSA noted that manufacturers are prohibited from unilaterally charging a covered entity a price above the 340B ceiling price in situations where the manufacturer has evidence that the covered entity is out of compliance with 340B Program requirements.[5]

As in the proposed rule, a manufacturer's refusal to refund or issue a credit to a covered entity, if new pricing data and the recalculation of a drug's 340B ceiling price reveals that a manufacturer overcharged a covered entity in the past, could amount to a knowing and intentional overcharge giving rise to CMPs.[6] The final rule also maintains the proposed rule's requirement that drug manufacturers bear the burden of ensuring their distribution partners (e.g., wholesalers and authorized distributors) do not overcharge covered entities for 340B drugs.[7] With that said, the final rule clarifies that fees charged directly by a wholesaler or other distributor are not considered part of the 340B ceiling price. In addition, it clarifies that manufacturers may also continue to develop limited distribution procedures, provided that these arrangements comply with 340B Program requirements, and HHS will consider whether a manufacturer has submitted an alternative allocation plan to HHS when investigating a manufacturer for a possible overcharge.[8] However, manufacturers may not offset potential overcharges with discounts or other price reductions on other transactions.[9]

HRSA indicated it will develop further subregulatory guidance for manufacturers to follow in issuing refunds to covered entities for drug purchases above the 340B ceiling price. Until such guidance is released, HRSA expects that manufacturers and covered entities will work in good faith to resolve refund-related issues in a reasonable manner that is documented by the parties.[10]

Under the final rule, CMPs will be imposed "pursuant to applicable procedures at 42 CFR part 1003."[11] Although some commenters argued that the regulatory text (which was also included in the proposed rule) is not sufficiently

©2005-2026 K&L Gates LLP. All Rights Reserved.

clear that the term “procedures” encompasses all the definitions and standards for CMPs otherwise outlined in 42 C.F.R. § 1003, HHS responded that revisions to the text were not necessary. However, HHS will “monitor activities relating to the evaluation and pursuit of CMPs and, if necessary, will consider issuing additional guidance about procedures applicable to such actions.”[12]

Calculation of Ceiling Prices

The final rule maintains the proposed rule's basic formula for manufacturers to calculate the ceiling price of a 340B drug, namely by subtracting the drug's Medicaid “Unit Rebate Amount” from the drug's “Average Manufacturer Price” (“AMP”).[13]

With respect to a new covered outpatient drug, manufacturers are directed to estimate the 340B ceiling price as of the date the drug is first available for sale by subtracting the appropriate rebate percentage from the drug's wholesale acquisition cost. However, once AMP data is available (which should occur no later than the fourth quarter that the drug is available for sale), manufacturers must retroactively calculate the actual 340B ceiling price from the time the drug was first available and use the actual 340B ceiling price moving forward. By contrast, the proposed rule would have required manufacturers to provide estimated ceiling prices for the first three quarters after the drug was available, regardless of the availability of AMP data to calculate the actual 340B ceiling price.

If a covered entity paid more than the actual 340B ceiling price for the drug during the period when the estimated price was used, the covered entity is entitled to a refund or credit from the manufacturer for those purchases within 120 days of the determination by the manufacturer that an overcharge occurred.[14] This represents an extension of time from the proposed rule, which would have required refunds or credits for the first three quarters in which the estimated ceiling price was used by the end of the fourth quarter in which the drug was available.[15] HRSA also notes in the preamble to the final rule that a covered entity and manufacturer may determine that a given overcharge is not significant or agree to other payment options such as netting or crediting.[16] In these instances, both parties are free to pursue mutually agreed-upon alternative refund arrangements.[17] HRSA also rejected the creation of a materiality standard for purposes of determining whether a refund resulting from differences between initial ceiling price estimates and the retroactive actual ceiling price after a new drug becomes available is necessary.[18] HRSA also noted that it plans to issue guidance on operational elements of the 340B ceiling price calculation in future guidance associated with the 340B Program ceiling price reporting system.

As part of the final rule, HRSA also finalized the penny pricing policy as initially proposed, despite objections from many commenters that alternative policies should apply.[19] In particular, alternatives proposed by commenters included the federal ceiling price, the most recent positive 340B ceiling price from previous quarters, a nominal price, and allowing manufacturers to utilize any reasonable pricing methodology they choose. HRSA concluded that the alternatives proposed by commenters were inconsistent with the 340B ceiling price formula established in the Public Health Service Act and the overall 340B statutory scheme.[20] Finally, HRSA removed certain definitions from the final rule after determining that they were either unnecessary or confusing. In particular, HRSA removed the definitions of “340B drug,” “wholesaler,” “package size,” and “case package size” from the final rule.[21]

CONCLUSION

©2005-2026 K&L Gates LLP. All Rights Reserved.

As with the proposed rule, the final rule would impose penalties on conduct that is already prohibited by manufacturers. That said, the final rule is likely to garner significant interest as manufacturers, 340B covered entities, and others monitor HRSA's enforcement activity in this area, particularly given the political climate surrounding the 340B Program. Accordingly, all 340B stakeholders should become familiar with the final rule as part of their overall 340B Program compliance efforts.

Notes:

[1] HRSA, 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210 (Jan. 5, 2017), https://www.gpo.gov/fdsys/pkg/FR-2017-01-05/pdf/2016-31935.pdf.

[2] *Id.* at 1,229-30 (to be codified at 42 C.F.R. § 10.11(a)).

[3] *Id.* at 1,221.

[4] *Id.* at 1,222.

[5] *Id.* at 1,223.

[6] *Id.* at 1,230 (to be codified at 42 C.F.R. § 10.11(b)(4)).

[7] *Id.* (to be codified at 42 C.F.R. § 10.11(b)(1)).

[8] *Id.* at 1,225.

[9] *Id.* (to be codified at 42 C.F.R. § 10.11(b)(3)).

[10] *Id* at 1,226.

[11] *Id.* (to be codified at 42 C.F.R. § 10.11(a)).

[12] *Id.* at 1,227.

[13] *Id.* at 1,229 (to be codified at 42 C.F.R. § 10.10(a)).

[14] *Id.* (to be codified at 42 C.F.R. § 10.10(c)). By contrast, a covered entity is not obligated to refund a manufacturer if the covered entity underpaid for a drug during the period in which an estimated 340B ceiling price was used. *Id.* at 1,220.

[15] *See* 80 Fed. Reg. 34,588 (June 17, 2015), https://www.gpo.gov/fdsys/pkg/FR-2015-06-17/pdf/2015-14648.pdf ("The refunds or credit for the first three quarters must be provided to covered entities by the end of the fourth quarter.").

[16] 82 Fed. Reg. at 1,218.

[17] *Id.*

[18] *Id.* at 1,220.

[19] *Id.* at 1,229 (to be codified at 42 C.F.R. § 10.10(b)).

[20] *Id.* at 1,215.

[21] *See id.* at 1,229 (to be codified at 42 C.F.R. § 10.3).

©2005-2026 K&L Gates LLP. All Rights Reserved.

This publication/newsletter is for informational purposes and does not contain or convey legal advice. The information herein should not be used or relied upon in regard to any particular facts or circumstances without first consulting a lawyer. Any views expressed herein are those of the author(s) and not necessarily those of the law firm's clients.

©2005-2026 K&L Gates LLP. All Rights Reserved.