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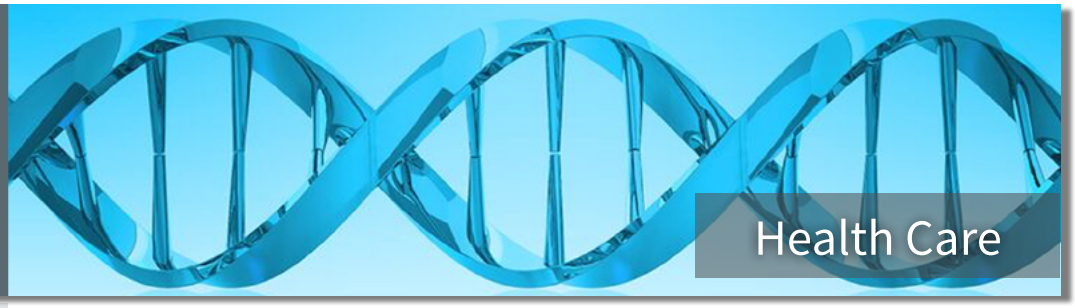

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Drug Manufacturer Pricing Under the Microscope: HRSA's 340B Civil Monetary Penalty and Drug Pricing Final Rule

by Lauren Groebe, Travis Jackson, Emily Shaw and Kyle A. Vasquez

The Health Resources and Services Administration recently surprised the 340B Drug Pricing Program community with the release of its regulations pertaining to drug manufacturer ceiling price calculations and civil monetary penalties.

HRSA's new rule, titled "340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation" (Final Rule), 82 Fed. Reg. 1210 (January 5, 2017), is available here. The Final Rule addresses the calculation of the 340B ceiling price and establishes the rules by which significant CMPs would be imposed on a manufacturer who knowingly and intentionally overcharges a covered entity. It replaces all former HRSA guidance on Penny Pricing and New Drug Pricing, and the Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 New Drug Pricing.

The Final Rule appears to be an attempt by HRSA to balance the scales between covered entities and drug manufacturers. It purports to impose significant penalties on manufacturers that knowingly and intentionally violate the terms of the 340B statute. The timing of the Final Rule is a potential problem in light of the recent election. While HRSA clearly has regulatory authority to issue the Final Rule, its authority originated from the Affordable Care Act (ACA) – the program that is under intense scrutiny by the new Administration. **It is yet to be seen what effect the current political environment and new Administration's threatened repeal of the ACA** will have on the Final Rule (or to the 340B Program), if any.

HRSA has already encountered its first roadblock relative to the Final Rule. On January 20, 2017, President Trump issued an executive branch-wide freeze on all pending regulations. On its face, this regulatory freeze applies to the Final Rule as it was published with a future effective date (February 28, 2017). There is an argument that the Administrative Procedure Act limits President Trump's ability to delay final rules that have already been published in the Federal Register, but HRSA can address this limitation by issuing a notice and comment delaying the Final Rule. Chief of Staff

Priebus's regulatory freeze memorandum can be found here. A discussion regarding the President's ability to impact the effective date of pending regulations can be found here.

Key components of the Final Rule are highlighted below:

- *Effective Date.* The Final Rule is effective February 28, 2017. However, as this is in the middle of a calendar quarter, HRSA plans to begin enforcing the requirements of this Final Rule at the start of the next quarter, which begins April 1, 2017.

- *No Retroactive Application.* HRSA indicated that the Final Rule will not apply to purchases prior to the effective date.

- *340B Ceiling Price Calculation*. Manufacturers must calculate the 340B ceiling pricing for each covered outpatient drug on a quarterly basis. The ceiling price for a covered outpatient drug is equal to the Average Manufacturer Price (AMP) reported from the preceding calendar quarter for the smallest unit of measure minus the Medicaid Unit Rebate Amount (URA). The ceiling price will be calculated using six decimal places, potentially resulting in changes to the way drug manufacturers track and report pricing data relative to 340B.

- *Penny Pricing.* Keeping with longstanding HRSA policy, the ceiling price will be $0.01 where the ceiling price calculation results in an amount less than $0.01, a policy commonly referred to as "penny pricing." Orphan drugs, to the extent that they are covered outpatient drugs, are not exempt from penny pricing.

- *New Drug Price Estimation.* Manufacturers must estimate the 340B ceiling price for a new covered outpatient drug as of the date the drug is first available for sale. The estimated price will be in effect for the first three quarters due to the reporting timeline for AMP calculation. The new drug ceiling price estimation is the wholesale acquisition cost (WAC) minus the appropriate rebate percentage (generally, 23.1 percent for most single-source and innovator drugs, 17.1 percent for clotting factors and drugs approved exclusively for pediatric indications, and 13 percent for generics). In fourth quarter, the manufacturer must calculate the actual ceiling price based on AMP, as discussed above, and refund any overpayments to the covered entity within 120 days. Refunds can be negotiated. *If a manufacturer refuses to refund a covered entity, this could meet the knowingly and intentionally standard for CMPs.* Undercharges are not addressed in the Final Rule and there will be no offset to manufacturer refunds of overpayments by any perceived underpayments.

- *Manufacturer Civil Monetary Penalties – Generally.* CMPs may be imposed on manufacturers that "knowingly and intentionally" charge a covered entity in excess of the 340B ceiling price. CMPs are capped at $5,000 for each instance of overcharging. HRSA does not define "knowingly and intentionally" and instead defers to the OIG to interpret the terms at their discretion and allow the OIG flexibility to evaluate each instance of overcharge on a case-by-case basis. HRSA did offer some limited guidance in the Final Rule, providing a list of non-exhaustive circumstances where HRSA would assume that a manufacturer did not "knowingly and intentionally" overcharge a covered entity. The Final Rule also solidified HRSA's position regarding the behavior of manufactures in two key areas. First, since manufacturers are responsible for setting appropriate 340B ceiling prices, they are responsible for the conduct of their business partners (i.e., distributors, wholesalers, specialty pharmacies) to ensure the covered

entity receives the correct price. Second, manufacturers cannot condition the sale of a 340B drug at the 340B ceiling price because the manufacturer has concerns or specific evidence of possible non-compliance by a covered entity. HRSA encourages manufacturers that suspect diversion to work in good faith with the covered entity or use HRSA's established audit mechanisms.

- *Manufacturer Civil Monetary Penalties – Instance of Overcharging.* HRSA finalizes the definition of an "instance of overcharging" for the purpose of imposing a CMP in the Final Rule as any order for a certain covered outpatient drug, by NDC-11, which results in a covered entity paying more than the 340B ceiling price. Regardless of number of units of an NDC in an order, only the order for the NDC will constitute a single instance for purposes of calculating an overcharge. HRSA states that an instance of overcharging may not be offset by other discounts provided on any other NDC or discounts provided on the same NDC on other transactions, orders, or purchases. HRSA also explains that an instance of overcharging may occur at the time of initial purchase or at subsequent ceiling price recalculations. HRSA acknowledges in its commentary, with examples, that there may be circumstances where a manufacturer's failure to sell at the 340B ceiling price is not an overcharge. Understanding the Final Rule doesn't include procedural guidance – HRSA has indicated subsequent guidance will be issued to address specific refund processes.

HRSA plans to post FAQs and host a webinar to provide an overview of the Final Rule for all 340B stakeholders. Polsinelli will continue to monitor subsequent guidance from HRSA regarding the implementation of this Final Rule.

For More Information

For questions regarding this alert or to learn more about how it may impact your business, please contact one of the authors, a member of our Health Care practice, or your Polsinelli attorney.

To learn more about our Health Care practice, or to contact a member of our Health Care team, click here or visit our website at polsinelli.com.

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