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MEMORANDUM

To:	Clients and Friends of the Powers Law Firm
From:	Bill von Oehsen Barbara Straub Williams Jason Reddish
Date:	January 5, 2017
Subject:	**HRSA Publishes Final Rule Addressing 340B Ceiling Price Calculations and Manufacturer Penalties for Overcharging**

Today HRSA published long-awaited regulations specifying how the 340B ceiling price is calculated for a drug and creating standards for imposing civil monetary penalties (CMPs) on manufacturers that knowingly and intentionally overcharge covered entities.[1] The final rule is a major step forward toward holding drug manufacturers accountable for ensuring that covered entities are offered covered outpatient drugs at a price that does not exceed the 340B ceiling price. HRSA adopted several proposals from the 340B Coalition. The rule generally benefits covered entities, and should make it easier for covered entities to obtain refunds when they are overcharged.

HRSA is required to promulgate these regulations under "Improvements in Program Integrity" changes made to the 340B statute in the Affordable Care Act (ACA). HRSA has only promulgated regulations specifically addressing 340B program requirements once before, relating to the circumstances in which critical access hospitals, rural referral centers, sole community hospitals, and free-standing cancer hospitals may purchase orphan drugs at 340B program pricing, but those regulations were invalidated following litigation initiated by PhRMA. The regulations published today are thus the only effective regulations – rules that carry the force of law – directly addressing the 340B program.[2]

HRSA originally proposed rules addressing both topics in June 2015 and requested additional feedback in April 2016.[3] The final rule mostly adopts the proposed requirements, though there

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[1] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210 (Jan. 5, 2017).

[2] The orphan drug regulations were invalidated because HRSA lacked clear authority from Congress to issue regulations addressing the orphan drug prohibition. HRSA does have clear legislative authority regulate in the areas covered by the final rule. The incoming administration might choose to suspend or roll back the final rule if it wants additional time to review regulations promulgated by the Obama Administration after the November elections. Congress can also roll back any regulations issued between the election and the inauguration of the new President.

[3] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 80 Fed. Reg. 34,583 (June 17, 2015); 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation; Reopening of Comment Period, 81 Fed. Reg. 22,960 (Apr. 19, 2016).

are some notable differences. Below is a summary of the provisions of the final rule. The 340B Coalition commented on the proposed rule, and its positions are reflected in *italics* below.

General

- HRSA is making the final rule effective on March 6, 2017. Because 340B ceiling prices are calculated on a quarterly basis, HRSA will begin enforcing the rule beginning with prices offered April 1, 2017.
    - *The 340B Coalition asked HRSA to clarify that the CMPs could be applied retroactively to HRSA's statutory deadline for establishing guidelines for the CMPs – September 19, 2010. HRSA declined.*
- The final rule is not related to the Omnibus Guidelines – or "Mega-Guidance" – proposed by HRSA in August 2015.[4] HRSA has not finalized the Mega-Guidance and has not addressed its status since the election.
- The final rule does not address the Affordable Care Act requirement that HRSA create an internet-based tool that allows covered entities to verify the 340B ceiling price of a drug. HRSA is addressing that development separately through an Information Collection Request.[5]
- The final rule also does not address the alternative dispute resolution process. HRSA has separately proposed that rule.[6]
- HRSA has finalized some 340B program definitions through the rulemaking.
    - HRSA has finalized the proposed definition of a "covered entity" to mean an entity listed among the eligible types, which meets the diversion and duplicate discount requirements and which is registered and listed in the 340B database. The 340B database is not addressed in the 340B statute, so HRSA is effectively adding a legal requirement to the definition that is not found in the statute.
    - HRSA has finalized the proposed definition of "covered outpatient drug" by reference to the definition in the Social Security Act (SSA). The SSA defines covered outpatient drug broadly, but includes a "limiting definition" that removes many drugs from the broad definition depending on the circumstances in which the drugs are administered and billed.[7] HRSA stated that the limiting definition is

[4] 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52,300 (Aug. 28, 2015).
[5] Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request, 80 Fed. Reg. 22,207 (Apr. 21, 2015).
[6] 340B Drug Pricing Program; Administrative Dispute Resolution, 81 Fed. Reg. 53,381 (Aug. 12, 2016).
[7] SSA § 1927(k)(2) and (3); codified at 42 U.S.C. § 1396r-8(k)(2) and (3).

also applicable to the definition of a covered outpatient drug for 340B program purposes.

- The regulations will be codified at 42 C.F.R. §§ 10.1, 10.2, 10.3, 10.10 and 10.11.

Ceiling Price Calculation

- In the ACA, HRSA was charged with "developing and publishing…precisely defined standards and methodology for the calculation of ceiling prices…"[8]

- The final rule adopts the statutory formula for calculating the 340B ceiling price of a drug – its Average Manufacturer Price (AMP) for the smallest unit of measure (to six decimal places) minus the Unit Rebate Amount (URA). The 340B ceiling price is specific to each 11-digit National Drug Code. The AMP from the prior calendar quarter is used to calculate the 340B ceiling price in a given quarter.

    - *The proposed rule stated that the amount would be multiplied by the drug's "package size" and "case package size." The 340B Coalition expressed concern over these terms as they created some new undefined unit of measurer. HRSA removed the language from the final rule.*

- HRSA finalized its policy for circumstances in which the 340B ceiling price is zero. The 340B ceiling price might be zero if the URA equals the AMP, particularly when the price of a drug increases faster than the rate of inflation. HRSA finalized its proposal and long-standing policy that the 340B ceiling price for such a drug will be set at $0.01.[9] HRSA felt that its "penny-pricing" policy ensured that the drugs were still being "purchased" without rewarding manufacturers for price increase that outpace inflation. Manufacturers have long opposed HRSA's penny-pricing policy.

    - *The 340B Coalition strongly supported the penny-pricing policy.*

- HRSA adopted a new policy for new drug pricing, replacing its 1995 guidance on the same topic.[10]

    - When a new drug is introduced, its AMP will not be known for some time. A new drug's first AMP is calculated within 30 days of the beginning of the second calendar quarter following its introduction. The AMP thus would not be effective until the third calendar quarter, and the 340B ceiling price would not be in place until the fourth calendar quarter. Under the 1995 guidance, manufacturers

[8] 42 U.S.C. § 256b(d)(1)(B)(i).
[9] HRSA, OPA, Clarification of Penny Pricing Policy, 340B Drug Pricing Program Notice Release 2011-2 (Nov. 21, 2011).
[10] Notice Regarding Section 602 of the Veterans Health Care Act of 1992; New Drug Pricing, 60 Fed. Reg. 51,488 (Oct. 2, 1995).

estimated the 340B ceiling price, and covered entities had to pursue refunds in the event that the estimated 340B price was higher than the price calculated once the AMP was available.

- In the final rule, HRSA is establishing that the estimated 340B price is equal to the drug's wholesale acquisition cost (WAC) minus the statutory Medicaid Drug Rebate Program rebate applicable to the drug (23.1% for single-source and innovator drugs, 17.1% for clotting factor and pediatric drugs, and 13% for generic drugs).

- Once the AMP is calculated, if the 340B ceiling price is less than the estimated 340B price (as it often will be because WAC typically exceeds the 340B price of a drug by over 30%), the manufacturer must contact all covered entities that overpaid for the drug and offer them repayment. The manufacturer has 120 days from when the price can be calculated to offer repayment. The manufacturer may not impose *de minimis* (threshold) standards or "net" the overcharge against other purchases unless the covered entity agrees to do so.

  - *The 340B Coalition supported a reasonable threshold, in part because a threshold concept might be helpful for covered entities.*

- If a manufacturer fails to refund new drug overcharges within 120 days, it might be subject to CMPs for knowingly and intentionally overcharging covered entities.

  - *The 340B Coalition strongly supported the notion that manufacturers have an affirmative obligation to offer refunds when the estimated 340B ceiling price exceeds the calculated 340B ceiling price.*

- HRSA declined to address instances in which a covered entity is undercharged for a new drug, finding the circumstance unlikely and noting that the statute only addresses overcharges.

- Manufacturers may not refuse to sell a drug to a covered entity at or below the 340B ceiling price on the grounds that the manufacturer believes the covered entity is diverting 340B drugs or subjecting the manufacturer to duplicate discounts.

Manufacturer CMPs

- In the ACA, HRSA was charged with developing CMPs not to exceed $5,000 for each instance of knowingly and intentionally charging a covered entity a price higher than the 340B ceiling price of a drug.[11]

[11] 42 U.S.C. § 256b(d)(1)(A)(vi).

- HRSA declined to define "knowingly and intentionally", instead vesting the HHS Office of the Inspector General (OIG) with the authority to determine on a case-by-case basis whether an overcharge was knowing and intentional.
    - *The 340B Coalition proposed clear definitions for "knowingly and intentionally." The commenters suggested that the definition of "knowingly" could be adopted from the OIG's definition at 42 C.F.R. § 1003.102. The 340B Coalition proposed that "intentionally" means "not due to a mathematical miscalculation, clerical oversight or similar inadvertent error."*
- In the explanatory preamble to the rule, HRSA explained that the following are examples of overcharges that would not meet the threshold:
    - Isolated inadvertent, unintentional, or unrecognized errors in calculating the 340B ceiling price; and
    - Sales during a new drug price estimation period at a price higher than the eventually calculated 340B ceiling price (unless the manufacturer fails to issue refunds).
- HRSA also provided two examples that would not be considered instances of overcharging:
    - Sales made to a covered entity that did not identify the purchase as 340B-eligible at the time of purchase; and
    - Sales made to a covered entity on a non-340B account when the covered entity chooses to order non-340B drugs and the order is not due to the manufacturer's refusal to sell or make available 340B drugs.
    - HRSA declined to provide additional examples, instead stating that the OIG could decide on a case-by-case basis whether a knowing and intentional overcharge has occurred.
- HRSA allowed that a knowing and intentional overcharge might occur if the manufacturer fails to issue a new price estimate refund within 120 days, or if AMP for a prior period is restated, resulting in the lower 340B ceiling price, and the manufacturer fails to issue refunds.
    - *The 340B Coalition supported this concept. The Coalition suggested that such a failure should be deemed knowing and intentional. HRSA did not go quite so far, instead saying that the failure "could meet the knowingly and intentionally standard to apply a CMP."*

- HRSA stated in the preamble that the CMP can be applied even if the manufacturer did not specifically intend to violate the 340B statute.

- The final rule confirms HRSA's proposal that an instance of overcharging is a single order for an NDC at an excessive price, regardless of how many packages of that NDC were ordered.

    - *The 340B Coalition proposed that each unit of an NDC would be an instance of overcharging.*

- HRSA declined to permit manufacturers to "net" instances of overcharging using discounts on the same or other NDCs unless the affected covered entity agrees to the process.

    - *The 340B Coalition opposed offsets.*

- Under the final rule, a covered entity purchase of a non-340B drug will not be deemed an overcharge unless the covered entity can provide a documented refusal by the manufacturer to sell the drug at 340B pricing.

    - *The 340B Coalition asked HRSA to require manufacturers to issue a refund to a covered entity that asks the manufacturer to reclassify a non-340B purchase as a 340B purchase within one year of the initial purchase. HRSA declined to do so, stating that it "does not authorize covered entities to reclassify a purchase as 340B eligible after the fact."*

- HRSA clarified that manufacturers are responsible for 340B overcharges when the drugs are sold through a third party (*e.g.*, a wholesaler or limited distribution network).

    - *The 340B Coalition strongly supported this proposal.*

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For more information about the new 340B program regulations, or for assistance with any 340B program or drug pricing inquiries, please contact Bill von Oehsen at 202-872-6765, Barbara Straub Williams at 202-872-6733, Jason Reddish at 202-872-6764, or the Powers attorney with whom you work regularly.