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Client Alert

FDA & Life Sciences Practice Group

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HRSA Publishes Proposed Rule on the Calculation of 340B Ceiling Prices and Manufacturer Civil Monetary Penalties

Comments Due to HRSA by Monday, August 17, 2015

On Wednesday, June 17, 2015, the Health Resources and Services Administration ("HRSA") published in the Federal Register a notice of proposed rulemaking entitled "340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties" ("Proposed Rule"). *See* 80 Fed. Reg. 34,583 (June 17, 2015). A copy of the Proposed Rule is available **here**.

The relatively short Proposed Rule proposes to revise and amend all subparts of 42 C.F.R. Part 10 ("340B Drug Pricing Program"). A King & Spalding redline of the proposed regulatory changes is available **here**.

The Proposed Rule hues closely to previous HRSA policy pronouncements, but this attempt to codify aspects of the 340B Drug Pricing Program ("340B Program") that had previously not been articulated in regulations presents manufacturers and other stakeholders with an opportunity to formally engage with HRSA, and to influence the direction of 340B Program policy. Comments on the Proposed Rule are due to HRSA ***on or before Monday, August 17, 2015***.

The Proposed Rule has three principal sections: (1) proposed regulations related to the calculation of **340B ceiling prices**, including rules on penny pricing and new drug price estimation; (2) proposed rules on the imposition on manufacturers of **civil monetary penalties** for "knowingly" and "intentionally" charging a covered entity more than the 340B ceiling price for a covered outpatient drug, including what constitutes an "instance of overcharging;" and (3) proposed revisions to the **definitions** found at 42 C.F.R. § 10.3, and elimination of regulations regarding the **orphan drug rule**.

340B Ceiling Prices

HRSA reaffirms the basic methodology for the calculation of the ceiling price: Medicaid Average Manufacturer Price ("AMP") minus Medicaid Unit Rebate Amount ("URA") for the smallest unit of measure, calculated to six decimal places. HRSA indicates that when it begins publication of ceiling

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prices–presumably pursuant to the statutory requirement at § 340B(d)(1)(B)(iii) that the Agency will publish ceiling prices for covered outpatient drugs on a password protected website at some point in the future – the Agency will publish them for every package size and case package size, rounded to two decimal places.

HRSA reiterates its somewhat incomprehensible belief that zero pricing when AMP = URA is *unreasonable*, but that one penny per unit when AMP = URA is *reasonable*. Substitution of prior quarter pricing, or WAC, or any other non-340B contract price (perhaps Non-FAMP?), claims HRSA, would nullify the statutory pricing formula. Penny pricing is a significant driver in covered entity overpurchasing, and perhaps even hoarding and diversion. Manufacturers would be well-served by expressing objection to, and proposing palatable alternatives for, to HRSA's penny pricing policy. If the Proposed Rule is made final, HRSA will have the ability to enforce its penny pricing policy, a right not previously or currently held by the Agency.

The penny pricing-related regulations HRSA proposes raise an interesting calculation question in a particular pricing circumstance. Our colleague Alexandra Mooney Bonelli of Ernst & Young points out that products with calculated ceiling prices of less than a penny but greater than zero may, under the terms of the Proposed Rule, be offered at 1 cent per unit. 80 Fed. Reg. at 34,585 ("HHS proposes that a manufacturer charge $0.01 per unit of measure for a drug with a ceiling price below $0.01."). That is, where 1¢ > (AMP – URA) > 0¢, ceiling price = 1¢. Did HRSA intend to permit manufacturers to raise ceiling prices (albeit by a fraction of a penny per unit) in its penny pricing policy?

With regard to new drugs, HRSA doubles down on its insufficiently specific and unclear 1995 guidance. *See* 60 Fed. Reg. 51,488 (October 2, 1995). Under that guidance, as in the Proposed Rule, manufacturers must estimate ceiling prices for a new drug for the launch and subsequent two quarters, apply a calculated ceiling price for the fourth quarter the product is on the market, calculate the "actual" 340B ceiling prices for the first three quarters and retroactively refund "overcharged" covered entities for that period. The Proposed Rule would require that all refunds be paid by the end of the fourth quarter after launch.

There are several problems with HRSA's proposed approach to calculating ceiling prices for new drugs.

First, HRSA claims that ceiling prices are based on the pricing data from the immediately preceding quarter. That is simply not true. Ceiling prices are based on the Medicaid *calculations* conducted in the immediately preceding quarter, which relate to pricing data in the quarter before that. 340B pricing operates on a two quarter lag, as evidenced by the fact that only in the fourth quarter after launch will manufacturers be able to compute a ceiling price under the normal rules.

Second, HRSA gives no guidance whatsoever on how to compute an "estimated" ceiling price. To be sure, manufacturers will be able to guess at a ceiling price. But one wonders how manufacturers will balance giving additional unrecoverable discounts, on the one hand, with offering high prices and almost guaranteeing the headache of refunds, on the other. We think a good argument could be made that a reasonable, good faith interim ceiling price should be immune from a recalculation and refund requirement.

Third, what is meant by "actual" ceiling prices in the stump period (*i.e.*, launch date through the end of the launch quarter) and first two full quarters is unexplained. Are manufacturers to abandon the two quarter lag that is a staple of every other ceiling price calculation? Are manufacturers to create "actual" ceiling prices using the AMP and URA of that quarter, including the incomplete launch quarter, and apply it retroactively? Or are manufacturers to calculate some combination of lagged (for second full quarter) and non-lagged (for launch quarter) "actual" 340B prices?

Finally, the Proposed Rule's requirement that all refunds for the first three quarters (however calculated) be made by the end of the fourth quarter is patently unreasonable in a world without a reliable, workable, efficient system for the

payment of refunds. Until HRSA creates such a mechanism (as required by the Affordable Care Act), manufacturers cannot be held to so strict a standard.

Manufacturer Civil Monetary Penalties

Section 7102(a) of the Affordable Care Act amended section 340B(d) of the PHSA to require the Secretary of the Department of Health and Human Services (HHS) to develop and issue regulations for the 340B Program that provide for the imposition of civil monetary penalties on manufacturers that "knowingly" and "intentionally" overcharge a covered entity more than the ceiling price for a covered outpatient drug.

Neither the Affordable Care Act nor the Proposed Rule define "knowingly" and "intentionally." In an Advanced Notice of Proposed Rulemaking published in September 2010, however, HRSA

> contemplate[d] a standard whereby knowing and intentional [could] 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.

75 Fed. Reg. 57,230, 57,232 (September 20, 2010). None of this language, nor any other indication of HRSA's thinking regarding the definitions of "knowingly" and "intentionally," was included in the Proposed Rule.

HHS and HRSA propose to delegate authority to the HHS Office of Inspector General ("HHS OIG") to bring "340B CMP actions" against manufacturers. The Proposed Rule does not explicitly address critical aspects of such a prosecution, including the nature of an impartial tribunal to hear such actions, procedural safeguards for manufacturers, and appeal rights of penalized manufacturers, though it references HHS OIG's "authority to bring 340B CMP actions utilizing the standards applied to other civil monetary penalties under" 42 C.F.R. Parts 1003 and 1005. 80 Fed. Reg. at 34,585 (42 C.F.R. Part 1003 addresses judicial review and other procedural issues; 42 C.F.R. Part 1005 addresses procedural safeguards and appeal rights). Presumably, covered entities may bring accusations against manufacturers before HHS OIG for investigation. Will manufacturers have the right to confront their accusers?

A manufacturer found (by whatever process) to have "knowingly and intentionally" (by whatever definition) overcharged covered entities may be penalized up to $5,000 (plus repayment for the overcharge) for each "instance of overcharging." The Proposed Rule attempts to define an "instance of overcharging:" any order for a covered outpatient drug (by NDC-11) which results in the covered entity paying more than the ceiling price for that drug. 80 Fed. Reg. at 34,585.

Each order is proposed to be a single instance, whether placed directly to a manufacturer or through an intermediary such as a wholesaler. Each discrete order would qualify as a single instance, no matter how many units of that particular NDC were requested in the order. An "instance" can occur both (a) at the time of initial purchase, and (b) when ceiling prices are retroactively recalculated and the manufacturer refuses to refund or credit a covered entity. This second category is particularly important to manufacturers that have made retroactive changes to ceiling prices, but have been waiting to offer refunds for overcharges until HRSA creates a mechanism for doing so. Moreover, HRSA does not

indicate in the Proposed Rule whether this requirement, if finalized, would apply retroactively to a particular date. The covered entity must request the 340B price, and be refused it by the manufacturer, to constitute an instance of overcharging. Manufacturers that utilize intermediaries to sell drugs to covered entities, such as wholesalers or specialty distributors, must, according to the Proposed Rule, police the intermediaries, third parties operating in many respects independent of manufacturer control, to ensure that covered entities are not overcharged. Manufacturers that fail to ensure that covered entities obtain the ceiling price from wholesalers or specialty distributors may be subject to these civil monetary penalties.

The Proposed Rule suggests that the use of these penalties "would probably be rare." We would agree, if we had a better idea of what HHS OIG considers to be a "knowing and intentional" act, the antecedent to imposition of CMPs. How much time may pass, for example, between CMS acceptance of restated AMPs and/or URAs and a refund being paid to an overcharged covered entity, before that failure to pay becomes a "knowing and intentional" overcharge? What wholesaler or distributor fees (for expedited delivery, for example) may be ignored in determining if covered entities obtained the calculated ceiling prices or were "overcharged"?

What is clear from the Proposed Rule is that $5,000 per order per NDC-11 can add up very, very quickly for manufacturers thought by HHS OIG to have intentionally overcharged covered entities. Though reference is made to the CMP regulations, no 340B Program-specific procedural safeguards for targeted manufacturers are articulated in the Proposed Rule. If finalized, these sparse regulations would seem to invite government and/or covered entity abuse.

Definitions and Orphan Drugs

The majority of the proposed changes to the definitions found at 42 C.F.R. § 10.3 are ministerial and non-substantive. Three proposed amendments are worth noting, however.

- The proposed definition of "covered entity" adds the requirements that the entity not only be qualified and one of a type listed in the statute (§§ 340B(a)(5) and 340B(a)(4), respectively), but that the entity be registered and listed in the 340B database. These requirements have long been understood to be part of what it means to be a legitimate 340B covered entity, but the explicit addition of the registration and listing requirements is a welcome amendment to the regulations.

- HRSA proposes to define "340B drug" to be a covered outpatient drug "purchased by a covered entity at or below the ceiling price." Covered entities regularly purchase drugs at prices higher than the ceiling price (*e.g.*, Medicaid carve-out, units to be dispensed to non-patients). Defining "340B drug" to be only those purchased at or below the ceiling price may be too restrictive, particularly in light of the fact that the Medicaid statute exempts from Best Price *any* prices charged to covered entities. 42 U.S.C. § 1396r-8(c)(1)(C)(i)(I). HRSA's narrow definition may be in service of an attempt by the Centers for Medicare and Medicaid Services ("CMS") to distinguish between discounted drugs sold to covered entities and non-discounted drugs sold to covered entities for Best Price purposes, arguably in violation of the Medicaid statute.

- HRSA proposes to delete both the definition of "orphan drug" and sections 10.20 ("Drugs eligible for purchase under 340B") and 10.21 ("Exclusion of orphan drugs for certain covered entities") from the current regulations. We believe this to be HRSA's formal recognition that its attempts to promulgate regulations regarding the orphan drug rule (§ 340B(e)) were rejected by the courts. It is possible that we will see references to the treatment of orphan drugs in the Agency's "Mega Guidance" expected later this year. In any event, the removal of these regulatory provisions strikes us as a good and proper thing.

The 340B Program integrity matters addressed in the Proposed Rule may be highly significant to your company, and to its rights and obligations under the Program. We urge you to read the Proposed Rule closely with an eye toward drafting and submitting comments (***due on or before August 17, 2015***), both to influence policymaking and to reserve your right to take legal action should a final rule ignore or reject your comments.

The K&S Government Pricing Team is ready to assist you in the preparation of comments to this Proposed Rule at every stage – evaluation, consideration and articulation. Please keep us in mind if there is any way we can help. We have extensive experience interpreting Proposed Rules and in drafting agency comments. We would be very happy to help you create effective, thoughtful, coherent and persuasive comments on any and all government pricing issues, including those presented in this Proposed Rule. For more information, please see www.kslaw.com/practice_areas/pags/PharmaGovPricingCompliance.pdf.