KING & SPALDING

Client Alert

FDA & Life Sciences Practice Group

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HRSA Issues Final Rule on Calculation of 340B Ceiling Prices and Manufacturer Civil Monetary Penalties

Critical 340B Drug Discount Program Strictures Placed on Manufacturers as Obama Team Departs

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Yesterday, the Health Resources and Services Administration ("HRSA") published in the Federal Register a final rule entitled "340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation" ("Final Rule"). *See* 82 Fed. Reg. 1210 (January 5, 2017). A copy of the Final Rule is available here.

The Final Rule revises and amends all subparts of 42 C.F.R. Part 10 (the "340B Program"). A King & Spalding redline of the regulatory changes is available here.

The Final Rule applies to all drug and biologic manufacturers that are required to make discounted drugs available to covered entities under the 340B Program. It sets forth revised regulations governing the calculation of the 340B ceiling price, and establishes rules regarding the imposition of civil monetary penalties ("CMPs") on manufacturers that overcharge covered entities.

The Final Rule is effective **March 6, 2017**. Because the effective date falls in the middle of the first quarter, HRSA indicated that it will begin enforcing the requirements of the Final Rule at the start of the second quarter, on April 1, 2017. HRSA does not believe that the rule should be implemented retroactively (82 Fed. Reg. at 1211), but what that will mean in practice (for instance, regarding prior period overcharges that have yet to be refunded) remains to be seen.

The Obama Administration issued the Final Rule despite a request from the incoming administration that final rules not be issued. It will be interesting to see what action, if any, the Trump administration takes with regard to the requirements in this Final Rule (or to the 340B Program generally).

Key Takeaways

- Drugs reimbursed under bundled payment methodologies are *not* covered outpatient drugs subject to 340B discounting.
- Penny pricing remains the required method to address calculated $0 ceiling prices; other approaches were rejected by HRSA.
- WAC-based formula dictated for pricing of new drugs, but refunds must be paid within 120 days if "actual" prices are lower.
- The finalization of the CMP rules should cause manufacturers to consider anew known reserves for historic overcharges.
- HRSA delegates to OIG almost all responsibility to determine whether to pursue CMPs.
- An "instance of overcharging," subject to a CMP of up to $5,000, is defined as each *order* of a mis-priced drug no matter how many units are included in that order.
- Manufacturers are responsible for ensuring that wholesalers extend the ceiling price correctly, but fees charged directly by wholesalers or other distributors are not part of the ceiling price.

Background

HRSA issued a proposed rule on June 17, 2015, to implement certain 340B provisions of the Affordable Care Act. *See* our Client Alert here. The proposed rule had three principal sections: (1) proposed regulations related to the calculation of 340B ceiling prices, including rules on penny pricing and new drug price estimation and true-up; (2) proposed regulations on the imposition on manufacturers of CMPs for "knowingly" and "intentionally" charging covered entities 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.

On April 18, 2016, HRSA published a notice reopening comment on its June 17, 2015 proposed rule. *See* our Client Alert here. Three specific areas were mentioned in the notice — alternatives to penny pricing, the pricing of newly-launched covered drugs, and the definition of "knowing and intentional" for purposes of levying CMPs on manufacturers. HRSA indicated that comments would be accepted, however, on any aspect of the proposed rule.

The preamble of the Final Rule published today includes HRSA responses to stakeholder comments received in response to both the proposed rule and the notice. While only the final regulations have the force and effect of law, the preamble provides critical insights into HRSA's thinking about the operation of the 340B Program.

Analysis

The key elements of the Final Rule are described below, along with King & Spalding's analysis of the regulations' internal logic, effect, and enforceability. The discussion tracks the organizational structure of the Final Rule.

Definitions

- The definition of "covered outpatient drug" is relatively non-controversially achieved with reference to the Social Security Act's ("SSA") definition of the term. Very important, however, was HRSA's statement that covered outpatient drugs in the 340B context, as in Medicaid, exclude drugs reimbursed under bundled

payment methodologies. That is, all parts of the statutory definition apply in 340B. Covered entities had argued that they should not be subject to the limitation in section 1927(k)(3) that excludes drugs reimbursed as part of a bundled payment (rather than directly). This is a significant win for manufacturers, as it will deny covered entities the ability to demand 340B pricing for products that are reimbursed as a part of a service. Under the Final Rule, attempting to do so would constitute diversion.

- HRSA makes clear in its definition of "quarter" that it understands and accepts the two-quarter lag inherent in the 340B Program. The Agency's understanding of this point was unclear in the proposed rule.

- Several proposed definitions were eliminated in the Final Rule because they were deemed unnecessary or confusing — "340B drug," "package size," "case package size," and "wholesaler."

Calculation of 340B Ceiling Price

- HRSA clarified that the data utilized for the 340B ceiling price calculation should be in the same format as that reported to HRSA by CMS (*i.e.*, average manufacturer price ("AMP") calculated to 6 decimal places, unit rebate amount ("URA") calculated to 4 but padded with zeros to get to 6). HRSA will then round the 340B ceiling price to 2 decimals when the Agency publishes the data in the forthcoming secure 340B ceiling price system.

- HRSA reiterated that the 340B ceiling price is based on quarterly (as opposed to monthly) AMP data.

Ceiling Prices for Drugs Where AMP = URA

- The formula for the calculation of the 340B ceiling price is AMP less URA. Because URA was capped at 100% of AMP by the Affordable Care Act in 2010, the calculated ceiling price cannot be negative, but it can equal $0. Having deemed $0.00 to be an *unreasonable* price, it has been HRSA's policy to require manufacturers to charge one penny per unit when the calculated price equals zero.

- The Final Rule wrote into regulation the penny pricing policy as it has existed, informally, for many years. That is, when the 340B ceiling price calculation results in an amount less than $0.01, a manufacturer must charge a $0.01 per unit.[1] In so doing, HRSA considered and rejected several alternatives proposed by stakeholders. The Agency stated that the policy is "well-established and effective," consistent with HRSA's existing policy, and best effectuates the statutory scheme. HRSA argued that:

    - Setting the price at $0.01 requires a payment and therefore ensures that there is a purchase within the meaning of the statute and, as a practical matter, between the buyer and seller;

    - Setting the price at zero rather than $0.01 would lead to operational challenges (*e.g.*, IT systems not able to generate invoices for any prices less than $0.01);

    - Manufacturers control when a product reaches a zero 340B ceiling price through their own pricing decisions, and, therefore, relief in the form of an alternative (*e.g.*, nominal price, last positive computed price, Federal Ceiling Price) is not warranted. HRSA stated, "The methodologies proposed as alternatives to penny pricing would decrease the effect of the inflationary component of the statutory formula established by Congress (AMP increasing faster than inflation)…. A manufacturer can control AMP [and therefore 340B prices] by adjusting the prices that it charges for drugs." 82 Fed. Reg. at 1215, 1216;

- Few products are affected by the penny pricing policy — for the first quarter of 2016, approximately 1% of all 340B drugs were in penny pricing; and

- The longstanding penny pricing policy has not yet been shown to cause significant risk of stockpiling, diversion, harm to patients, or abuse of controlled substances.

- It is now obvious why HRSA reopened the proposed rule for additional comment. In order to avoid charges that the penny pricing policy is arbitrary and capricious, the Agency wanted to construct and then knock down as many alternatives to the policy as could be proposed.

- In light of the final regulation articulating this policy at §10.10(b), HRSA has, for the first time, formal regulatory power to enforce penny pricing. As noted above, HRSA believes this Final Rule to be applicable prospectively. It is unclear, therefore, if HRSA would, or could, take any action against a manufacturer that ignored the informal penny pricing policy prior to March 6, 2017.

New Drug Pricing

- New drugs must launch with a 340B ceiling price, despite the fact that no historic data is available from which to calculate such a ceiling price. For purposes of the 340B Program, a new covered outpatient drug is any NDC-9 that does not have a previous quarter AMP calculation from which a ceiling price can be derived. New NDC-11s of existing NDC-9s are not new drugs, as an AMP for the new NDC-11 is that of the pre-existing NDC-9.

- Manufacturers are required to establish an estimated 340B ceiling price for a new covered outpatient drug until there is AMP data available to calculate an "actual" ceiling price as set forth in 340B(a)(1). The proposed rule left it to manufacturers to determine an appropriate methodology by which to estimate that ceiling price for new drugs. The Final Rule dictates a specific methodology: WAC less the applicable Medicaid minimum rebate percentage for the type of drug at issue (23.1% for single source and innovator drugs, 17.1% for clotting factors and drugs approved exclusively for pediatric indications, or 13% for generics).

- Once an "actual" 340B ceiling price can be determined, manufacturers will be obligated to refund any difference between the estimated 340B price and the "actual" 340B ceiling price.[2] Two price points are necessary for the calculation of an "actual" ceiling price: AMP and URA. Once an AMP and a URA are calculable for a new NDC-9, the resulting ceiling price is to be compared *retroactively* to the periods in which an estimated ceiling price was in place. Note how different this approach is from the normal operation of the 340B Program specifically articulated in the 340B statute, in which ceiling prices are applied *prospectively* after a two-quarter lag. This is why we use "actuals" in quotes. HRSA did not specifically recognize this difference.

- Our best guess at how this new drug process would work follows this example:

  Assume a new innovator NDC-9 (that is not a clotting factor or a pediatric drug) is launched on March 7. From March 7 to June 30, the ceiling price for the drug will be WAC less 23.1%. At some point in the last two months of 2Q, the manufacturer will subtract 1Q URA from 1Q AMP (derived from sales in the last 24 days of March), and determine the "actual" ceiling price for 1Q.[3] That amount will be compared to the estimated price (WAC – 23.1%). If it is lower than the estimated price, the covered entities will be due a refund. The 3Q ceiling price will follow the normal rules and

be set at 1Q AMP less 1Q URA. At some point after the 2Q AMP and URA are calculated in July, a ceiling price will be calculated by subtracting the latter from the former. That ceiling price will also serve two purposes: (a) it will be compared to the estimated price available in 2Q (WAC – 23.1%) and potential overcharges will be identified, and (b) it will be used in the normal course as the ceiling price for 4Q.

- Manufacturers that fail to refund covered entities within 120 days after a new drug "overcharge" has been identified may be subject to CMPs (see §10.11). HRSA specifically made clear that such a failure could satisfy the "knowing and intentional" standard for the imposition of CMPs, making it very important that manufacturers act quickly to prepare refunds in those 120 days. HRSA clarified that the 120-day refund requirement set forth in the Final Rule applies only to new drug price estimations, and that refunds in other contexts are outside the scope of the Final Rule and would be addressed in future guidance.

- HRSA refused to establish a materiality threshold for new drug refunds in the Final Rule, but stated that "to the extent that a manufacturer and covered entity agree that a de minimis threshold for refunds should be established, such a threshold can be established through mutual agreement between the manufacturer and covered entity." 82 Fed. Reg. at 1220; *see also* 82 Fed. Reg. at 1225. Similarly, netting, crediting, and other accommodations could be applied if the manufacturer and the covered entity agree together to permit them. This suggestion — thoughtful on its face — strikes us as completely impractical and slightly preposterous. If an "actual" price turns out to be less than an estimated price, an overcharge will have been generated on every sale to every covered entity that purchased the drug in the estimation period. That a manufacturer could reach agreement as to materiality or netting or otherwise with the tens of thousands of affected covered entities, or even to contact them seeking such an agreement, strikes us as impossible. Unless a single covered entity or a manageable set of covered entities were disproportionately affected, making individual negotiation worthwhile, we suspect that no manufacturers will be able to avail themselves of any of these accommodations. If HRSA sticks to this approach — the requirement for specific agreement with each affected covered entity — when finalizing its guidance as to much more common instances of overcharging (as we unfortunately expect it will), there will be no netting, no de minimis exclusions, no crediting, or any other pathways to efficient and reasonable refund issuances.

- Once again, HRSA maintains that a mechanism for the issuance of refunds need not be in place before rules requiring refunds become effective. 82 Fed. Reg. at 1225-26. HRSA is required under the 2010 amendments to the 340B statute to develop such a mechanism, but it has not done so. We continue to believe that the formal establishment of a mechanism to operationalize the refund process (*e.g.*, the Drug Data Reporting system in Medicaid) is critical to the 340B Program, and that to insist upon manufacturer refunds in the absence of an efficient mechanism is misplaced and an abdication of the Agency's responsibilities.

<u>Manufacturer CMPs: General</u>

- The amended 340B statute provides for the imposition of CMPs on manufacturers that "knowingly and intentionally" overcharge covered entities (not to exceed $5,000 for each instance of overcharging).

- The Final Rule does not affirmatively define a "knowing and intentional overcharge," preferring to defer such interpretations to HHS OIG "to allow the OIG the necessary flexibility to evaluate each instance of overcharge on a case-by-case basis." 82 Fed. Reg. 1221. HRSA has essentially punted on much of the substantive enforcement framework, aside from certain specific safe harbors noted in the preamble to the Final Rule.[4] The terms "knowingly" and "intentionally" are used frequently in other parts of federal law and their interpretation is therefore reasonably settled. Nonetheless, there is still room for interpretation, and

HRSA's refusal to provide clear definitions of statutory and regulatory terms provides OIG with largely unbridled discretion. As we have seen in the off-label enforcement context, this has the potential to lead to overly broad enforcement action.

- The Final Rule notes that specific intent to violate the 340B statute is not required to be shown to warrant an application of the penalty provision. 82 Fed. Reg. at 1222.

- HRSA indicated that the applicable provisions of 42 CFR parts 1003 and 1005 will be followed in matters involving the imposition of CMPs and any appeals therefrom. In our experience, these provisions do not provide much prescriptive guidance on dispute resolution. HHS administrative proceedings are often viewed as partial to the Agency. As a result, manufacturers may face pressure to negotiate directly with OIG regarding the exercise of enforcement discretion in order to avoid proceeding through the administrative review process.

- Consistent with previous guidance, HRSA did not exempt overcharging based on manufacturer suspicion of covered entity noncompliance from referral to OIG. "HHS does not believe that unilaterally overcharging a covered entity based upon suspicion of diversion is warranted under the statutory language. Manufacturers cannot condition the sale of a 340B drug at the 340B ceiling price because they have concerns or specific evidence of possible non-compliance by a covered entity. Manufacturers that suspect diversion are encouraged to work in good faith with the covered entity, conduct an audit per the current audit guidelines, or contact HHS directly." 82 Fed Reg at 1223.

- The Final Rule is prospective in application. Nevertheless, OIG, HRSA, or a covered entity may argue that post-effective date imposition of CMPs for overcharges relating to *pre-effective date periods* is appropriate. Such an argument could even be raised when both the purchase and the event giving rise to the overcharge (*e.g.*, the restatement of AMP) occurred in the past. For these reasons, we strongly encourage manufacturers to review again known existing 340B overcharge liabilities in light of this Final Rule, and consider appropriate steps to reduce exposure.

<u>Manufacturer CMPs: Instance of Overcharging</u>

- Consistent with the proposed rule, HRSA defined an "instance of overcharging" in the Final Rule as any order for a covered outpatient drug, by NDC-11, which results in a covered entity paying more than the 340B ceiling price. Each order for an NDC will constitute a single instance, regardless of the number of units of each NDC in that order, and whether the order was placed directly to a manufacturer or through an intermediary (*e.g.*, a wholesaler, authorized distributor, or agent). HRSA further stated 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.

- Covered entities had sought a definition that would have set an "instance of overcharging" at each *unit* purchased. At liability of up to $5,000 per instance, such a rule would have greatly increased manufacturers' potential exposure. (HRSA also rejected manufacturer suggestions that an instance be defined as the setting of an improper price.)

- HRSA noted that 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. HRSA indicated in the Final Rule that this requirement does not apply retroactively, leaving open the question of how to handle refunds for overcharges in prior periods. The Final Rule establishes the requirement to refund if there is an overcharge, but does not provide specific refund procedures. HRSA indicated that refund procedures will be addressed in a separate guidance, but did not provide any timeline for issuance of such guidance. Moreover, HRSA suggested that until such guidance is issued, "manufacturers and covered entities should work in good faith and refund in a reasonable manner that is documented by the parties involved." It seems that, for the foreseeable future, the lack of a standardized refund process will continue to present operational challenges for manufacturers.

- The Final Rule makes clear that manufacturers are ultimately responsible for ensuring that covered entities are able to purchase drugs at or below the 340B ceiling price. This obligation falls squarely on manufacturers, even if third parties (*e.g.*, wholesalers, distributors) have a role in ensuring the covered entity receives a drug at the correct price. According to HRSA, manufacturers have control over the distribution of covered outpatient drugs, including those distributed by wholesalers, distributers, and agents, "wherein the terms and conditions of the sales set through these distribution arrangements are set by the manufacturer via a contract agreed to and between the manufacturer and the distributors." 82 Fed. Reg. at 1224. Manufacturers may want to revisit the terms of their agreements with intermediaries that deliver their products to 340B covered entities to ensure that compliance with the requirements of the Final Rule are well articulated. Manufacturers that fail to ensure that covered entities obtain the ceiling price from their utilized intermediaries may be subject to a CMP. Nevertheless, and very important to manufacturers, fees charged directly by wholesalers or other distributors are *not* considered part of the 340B ceiling price, and would not be considered in assessing an instance of an overcharge.

- HRSA reiterated its position that a manufacturer's failure to sell at the 340B ceiling price is *not* considered an overcharge if the covered entity did not identify the purchase as 340B eligible at the time of purchase. In language that would have been useful several years ago at the time of the AIDS Healthcare Foundation lawsuits, HRSA said: "HHS does not authorize covered entities to reclassify a purchase as 340B eligible after the fact. Therefore, HHS has removed this example from the final regulation and instead includes it as an example of what would not be considered an instance of overcharging in the preamble to this rule. Covered entities participating in the 340B Program are responsible for requesting 340B pricing at the time of the original purchase." 82 Fed. Reg. at 1226.

- HRSA also confirmed that covered entity orders of non-340B priced drugs will not subsequently be considered an instance of overcharging unless the manufacturer's documented refusal to sell or make drugs available at the 340B price resulted in the covered entity purchasing at the non-340B price. When a manufacturer's documented refusal to sell or make drugs available at the 340B ceiling price results in the covered entity purchasing at the non-340B price, a manufacturer's sale at the non-340B price could be considered an instance of overcharging. An example of "documented refusal" would include any type of manufacturers' written communication related to reasons a manufacturer is not providing 340B ceiling prices to either a single covered entity or group of covered entities. Manufacturers will want to revisit their 340B Program policies and procedures to assess whether adequate processes are described to handle refusals to sell or make drugs available at the 340B price to covered entities, specifically, the circumstances under which such refusals are permitted, a related internal approval process, and guidelines for standardized company communications with covered entities.

- In what might be an important passage for manufacturers of specialty products that are sold through specialty pharmacies, HRSA wrote: "All requirements as set forth in this final rule for offering the 340B ceiling price to covered entities apply regardless of the distribution system. If a manufacturer is using a specialty pharmacy to distribute covered outpatient drugs, it must ensure the covered entity is not overcharged if drugs are accessed through that pharmacy." 82 Fed. Reg. at 1225. Although we are not entirely sure what is meant by "accessed" through the specialty pharmacy, this language could be read to support a requirement that manufacturers offer the 340B ceiling price to covered entities even if the specialty pharmacy ships product directly to the patient, and the specialty pharmacy is not a contract pharmacy to the covered entity. Recent published limited distribution plans seem to support this interpretation.

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The King & Spalding Government Pricing Compliance Team is ready to assist you in evaluating the matters raised in the Final Rule. For more information, please contact any of the team members on the first page of this Client Alert, or see our Practice at a Glance.

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[1] This appears to put to rest a question posed by our colleague Alixe Bonelli of Ernst & Young in our June 17, 2015 Client Alert. Any ceiling prices calculated to be less than $0.01 but greater than $0.00 are to be priced at 1¢ per unit. This means that in some situations, the ceiling price will actually be higher than the calculated amount (albeit only by a fraction of a cent).

[2] The Final Rule replaces the 1995 HRSA guidance addressing refunds in its entirety (under the guidance, covered entities were responsible for initiating the refund process, and were required to do so without a third-party intermediary; the guidance also required that refund requests be made by the end of the fourth full quarter after a new drug comes to market).

[3] HRSA suggests that AMPs for new covered outpatient drugs "may be established after one full quarter has elapsed." 82 Fed. Reg. at 1219. We disagree. Quarterly AMPs do not require a full quarter of transaction data: they can be calculated using whatever part of a quarter remains after launch.

[4] Specifically, where "the manufacturer made an isolated inadvertent, unintentional, or unrecognized error in calculating the 340B ceiling price," or where "the manufacturer sells a new covered outpatient drug during the period the manufacturer is estimating a price based on this 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." 82 Fed. Reg. at 1221. Other "safe harbors" were suggested in comments (82 Fed. Reg. at 1223) but HRSA deferred consideration of them to OIG.