KING & SPALDING

Client Alert

FDA & Life Sciences Practice Group

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340B Proposed Pricing Rule Reopened for Comment:

Penny Pricing, New Drug Pricing and Definition of "Knowing and Intentional" Back In Play

On Monday, April 18, the Health Resources and Services Administration ("HRSA") published a Notice reopening comment on its June 17, 2015 Proposed Rule regarding 340B pricing and manufacturer civil monetary penalties.

Three specific areas are 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 civil monetary penalties ("CMPs") on manufacturers. Comments will be accepted, however, on *any aspect* of the Proposed Rule. From a manufacturer's perspective, this re-opening of the Proposed Rule is a very welcome event, as it suggests that HRSA is contemplating changes to the 340B program that would make it more fair, easier to implement and more transparent.

Stakeholder comments will be due **30 days** after publication of the Notice in the Federal Register, which we expect in the next few days. We at King & Spalding stand ready to assist you in drafting and submitting your comments to HRSA by mid-May.

Penny Pricing

HRSA acknowledged that many comments to the Proposed Rule expressed dissatisfaction with its longstanding – if arguably not legally binding – penny pricing policy. Under that policy, manufacturers whose Average Manufacturer Prices equal their Unit Rebate Amounts, leading to $0 calculated 340B ceiling prices, must charge covered entities 1 penny per unit. The manufacturing community has consistently opposed the penny pricing policy as unreasonable and designed to induce inappropriate overpurchasing by 340B covered entities.

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A number of alternatives to penny pricing were suggested to HRSA, including defaulting to the FSS federal ceiling price, the most recently reported ceiling price greater than zero, and MDRP-based nominal pricing. HRSA is considering these and any other alternatives to penny pricing, and wants to hear again from stakeholders as it makes its decision.

New Drug Pricing

The Proposed Rule reiterated HRSA's convoluted and inexact process for determining the 340B ceiling price of newly launched covered drugs. Under the regime as currently proposed, 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.

Today, HRSA asks stakeholders to comment on a specific proposal that would greatly simplify the process for introducing new drugs to the 340B program. Namely, setting the ceiling price for new drugs at WAC less the applicable minimum rebate percentage (23.1%, 17.1% or 13% depending on the type of drug at issue).

Definition of "Knowing and Intentional"

The Public Health Service Act permits the Secretary of HHS to levy CMPs on manufacturers that have "knowingly and intentionally" overcharged covered entities. 42 U.S.C. §256b(d)(1)(B)(vi). Manufacturers can be assessed up to $5,000 for each "instance" of overcharging under the statute.

The Proposed Rule interpreting this provision did not, however, specifically define "knowingly and intentionally." Commenters in 2015 suggested defining "knowingly and intentionally" to mean, among other things, "actual knowledge," "willful or purposeful acts," "acting consciously and with awareness," and "acting with a conscious desire or purpose" to overcharge.

Hopefully, no manufacturer will ever be charged with "knowingly and intentionally" overcharging covered entities under any standard. In the interest of program integrity, however, and to ensure that the standard is clearly defined in the event HRSA does attempt to impose CMPs, manufacturers should take this opportunity to assist HRSA in carefully crafting a reasonable definition.

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Drug and biologics manufacturers should give serious consideration to drafting and submitting comments on these three issues that are of significant importance to their participation in the 340B program. We take it as a very good sign that HRSA would reopen comment on these issues, and urge drugmakers to submit thoughtful and persuasive letters during the comment period. There are also a number of other matters addressed in the Proposed Rule that would, in our opinion, bear comment, for instance, what qualifies as an "instance" of overcharging subject to CMPs.

The King & Spalding Government Pricing Compliance Team is ready to assist you in evaluating the matters raised in the Notice and in drafting responsive comments. 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.