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340B Update: HRSA Proposes Penalties for Drug Manufacturers that Overcharge Covered Entities

Health Care Alert

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On June 16, 2015, the U.S. Department of Health and Human Services ("HHS") and the Health Resources and Services Administration ("HRSA") released proposed rules on civil monetary penalties and drug ceiling prices under the 340B Drug Pricing Program (the "340B Program").[1] Comments on the proposed rule are due August 17, 2015.

The proposed rules, which Congress required as part of the Patient Protection and Affordable Care Act ("ACA"), are the latest in a series of events that have put a spotlight on the 340B Program, including the recent litigation surrounding HRSA's orphan drug rules, the upcoming release of HRSA's omnibus 340B Program guidance (which is expected to cover topics like contract pharmacy arrangements and the definition of a 340B "patient"), and congressional interest in reforming the program.

Background on the 340B Program

The Veterans Health Care Act of 1992 created Section 340B of the Public Health Service Act ("PHSA"), codified at 42 U.S.C. § 256b and commonly known as the "340B Program." Section 340B instructs HHS to enter into pharmaceutical pricing agreements with drug manufacturers. Under these agreements, the manufacturers agree to charge 340B-participating providers ("covered entities") no more than a defined "ceiling price" for covered outpatient drugs. Covered entities include federally qualified health centers, disproportionate share hospitals, hemophilia treatment centers, and other safety net providers.[2]

Summary of the Proposed Rule

The proposed rules addresses two issues that Congress required the HHS Secretary to address through regulation as part of the ACA: (1) civil monetary penalties for drug manufacturers that overcharge covered entities for 340B drugs, and (2) the calculation of ceiling prices for 340B drugs.

Civil Monetary Penalties for Drug Manufacturers

HRSA's proposed rules impose civil monetary penalties of up to $5,000 per instance on drug manufacturers that "knowingly and intentionally" overcharge covered entities for 340B drugs. Each order for a drug would constitute a single instance of overcharging under the rules, regardless of the number of units the covered entity orders. The HHS Office of the Inspector

[1] *340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation: Notice of Proposed Rulemaking*, 80 Fed. Reg. 34,583 (June 17, 2015).

[2] 42 U.S.C. § 256b.

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General ("OIG") will enforce the 340B Program's civil monetary penalties using the standards it applies to other civil monetary penalties.[3]

In addition to facing civil monetary penalties, drug manufacturers that are found to have overcharged a covered entity must continue to refund the covered entity for the overcharged amount, in accordance with statute. In this regard, the proposed rules also impose a civil monetary penalty for a manufacturer's refusal to refund or issue a credit to a covered entity if new pricing data and the re-calculation of a drug's ceiling price reveals that a manufacturer overcharged a covered entity in the past.[4]

Under the proposed rules, drug manufacturers also bear the burden of ensuring their distribution partners do not overcharge covered entities for 340B drugs. In particular, the rules provide that civil monetary penalties apply to drugs ordered directly from the manufacturer, as well as those ordered through entities like wholesalers, authorized distributors, or agents. With that said, if a covered entity does not identify a drug as eligible for a 340B discount at the time of purchase, the OIG will not pursue civil monetary penalties against the manufacturer for overcharging the covered entity for the drug.[5]

Calculation of Ceiling Prices

The proposed rules also clarify how covered entities should calculate the "ceiling price" of 340B-eligible drugs.

The proposed rules generally codify in regulation certain policies relating to ceiling prices that have previously appeared only in guidance (e.g., the penny pricing policy). To calculate the ceiling price of a drug, manufacturers must subtract the drug's Medicaid "Unit Rebate Amount" from the drug's "Average Manufacturer Price." Drug manufacturers must also provide HRSA with estimated ceiling prices for the first three quarters after a drug is first made available for sale. Beginning with the fourth quarter after a drug is made available for sale, the manufacturer must retroactively calculate the actual ceiling price for the first three quarters the drug was available. If a covered entity paid more than the actual ceiling price for the drug during the first three quarters (e.g., because the estimated ceiling price was higher than the actual ceiling price), the covered entity is entitled to a refund or credit from the manufacturer for those purchases. Manufacturers are required to calculate 340B ceiling prices on a quarterly basis, and HRSA will publish each manufacturer's ceiling prices.[6]

Other Changes in the Proposed Rule

In addition, the proposed rules revise several key definitions under the 340B program, including the definitions of "ceiling price," "covered entity," "covered outpatient drug," and "manufacturer." The rules also add new definitions to the regulations for terms such as "340B drug," "Average Manufacturer Price (AMP)," and "wholesaler."[7]

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[3] 80 Fed. Reg. at 34,588.
[4] *Id.*
[5] *Id.*
[6] *Id.*
[7] 80 Fed. Reg. at 34,587-88.

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Finally, the proposed rules remove the provisions that applied to "orphan drugs." HRSA's 340B orphan drug regulations were struck down in litigation,[8] leading the agency to repackage and re-issue the regulations as an "Interpretive Rule."[9]

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[8] PhRMA v. HHS, No. 13–01501 (D.D.C. May 23, 2014).

[9] HEALTH RESOURCES & SERVS. ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., INTERPRETIVE RULE: IMPLEMENTATION OF THE EXCLUSION OF ORPHAN DRUGS FOR CERTAIN COVERED ENTITIES UNDER THE 340B PROGRAM (2014), http://www.hrsa.gov/opa/programrequirements/interpretiverule/interpretiverule.pdf.