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Health Resources and Services Administration Announces Final Rule on Civil Monetary Penalties for Drug Manufacturers that Overcharge 340B Covered Entities

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A new regulation issued by the ***Health Resources and Services Administration ("HRSA")*** sets forth a process by which civil monetary penalties may be imposed on drug manufacturers that knowingly and intentionally charge 340B covered entities for covered outpatient drugs more than the statutory ceiling price. The regulation addresses the ceiling price calculation for drugs purchased pursuant to the ***340B Drug Pricing Program ("340B Program")***, and provides that drug manufacturers may be subject to a civil monetary penalty of up to $5,000 for each instance of overcharging. The regulation finalizes a proposal dating back to June 2015. The regulation will be enforced beginning on April 1, 2017.

The civil monetary penalties would not be calculated and imposed by HRSA's Office of Pharmacy Affairs, but by the Office of Inspector General ("OIG"). The civil monetary penalties would be in addition to any refunds to covered entities that may be required by the 340B Program. The final rule does not provide a mechanism for covered entities to file a complaint against a drug manufacturer for overcharging for 340B drugs. Once HRSA's 340B administrative dispute resolution rules are finalized and the appropriate system has been established, a covered entity could submit a claim against a manufacturer for an instance of overcharging for administrative dispute resolution.

The new regulation requires drug manufacturers to calculate the 340B ceiling price for each covered outpatient drug, by National Drug Code (NDC), on a quarterly basis. The 340B ceiling price is based on the Average Manufacturer Price (AMP) for the prior quarter, minus a Unit Rebate Amount. For new drugs, manufacturers will need to estimate the 340B ceiling price and then calculate the actual 340B ceiling price once the appropriate data is available. If an overcharge has a occurred as a result of this estimation, drug manufacturers must refund or credit a covered entity the difference between the estimated and actual 340B ceiling price within one hundred and twenty days. Overcharges may also occur if a drug manufacture does not credit or refund a covered entity after subsequent recalculations of the ceiling price by the Centers for Medicare and Medicaid Service ("CMS"). Overcharges are determined on an NDC code basis, and may not be offset by other discounts the manufacturer provides on any other NDC. Drug manufacturers are also required to ensure that 340B discounts are provided through distribution arrangements made by the manufacturer.

The new regulation is based upon a requirement set forth in the Affordable Care Act, and comes at a time when drug prices and the 340B Program are receiving heightened scrutiny by the incoming Congress and administration. We will continue to report on modifications to the 340B Program as they develop.

FOLEY
FOLEY & LARDNER LLP

Article By Claire Marblestone
Anil ShankarFoley & Lardner LLP
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