



CMS Proposes to Resolve 340B Illegal Rate with \$9M Pay-Out for Traditional Medicare; Medicare Advantage to be Negotiated Privately

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In July 2023, the Centers for Medicare and Medicaid Services (“CMS”) proposed a final rule to address illegal traditional Medicare rates paid in the 340B Drug Pricing Program from 2018-2022. CMS’ proposal would see CMS pay 340B providers an estimated \$9 billion dollars in lump sum payments.

Congress created the 340B Program with the intent to reduce the costs related to purchasing drugs for qualifying safety-net hospitals (i.e., hospitals serving a large low-income population). Section 340B of the Public Health Service Act allows qualifying hospitals and other providers to purchase certain covered drugs from manufacturers at discounted prices.

In 2017 rulemaking, the U.S. Department of Health and Human Services (HHS) changed traditional Medicare’s payment methodology for outpatient drugs acquired through the 340B Program. This change resulted in a nearly 30% decrease in 340B provider payments. Litigation quickly ensued, and in 2022, the Supreme Court unanimously ruled that the reduced rate HHS implemented for 340B providers was “unlawful.”

Since this decision, CMS has grappled with how to remedy the five years of illegal rates for traditional Medicare. Ultimately, CMS settled on paying 340B providers the difference between what providers should have received under the lawful 340B rate and what they actually received. The expected payout tops \$9 billion dollars. While the hospital industry has generally responded

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favorably to CMS' lump sum payment proposal, many aspects of the proposal have been questioned and will likely result in legal challenges. For example, to offset the lump sum payments and make the impact "budget neutral" on the agency, CMS proposed a .05% decrease in all outpatient hospital rates (not just for 340B providers) for the next 16 years. In addition, despite the payments coming years late, CMS did not include any interest in its lump sum calculations.

Comments on CMS' proposed rule were due in early September, and we expect CMS to finalize its 340B remedy in the coming month. CMS estimates it will make lump sum payments in December 2023 or January 2024.

Notably, CMS' remedy focuses solely on traditional Medicare. In the context of Medicare Advantage, CMS has acknowledged that the contracts between providers and Medicare Advantage plans govern reimbursement, including for 340B drugs. CMS will not issue lump-sum remedial payments to providers for 340B payments by Medicare Advantage plans. Instead, providers must look to their Medicare Advantage agreements to identify the appropriate remedy. Consequently, many 340B providers are filing arbitration demands and lawsuits related to how Medicare Advantage plans are remedying (or failing to remedy) the 340B illegal rate from 2018-2022. We recommend all 340B providers review their Medicare Advantage agreements and, if necessary, engage legal counsel to assist with recovering 340B payments due.