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ADVISORY

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CMS ISSUES FINAL RULE REMEDYING THE 340B ACQUIRED DRUG PAYMENT POLICY FOR 2018-2022

On November 2, 2023, the Centers for Medicare & Medicaid Services (CMS) and the Department of Health and Human Services (HHS) published a **final rule (CMS 1793-F)** giving providers participating in the 340B Drug Pricing Program (340B Program) approximately $9 billion as compensation for unlawful payment reductions between 2018 and 2020.

The 340B Program requires pharmaceutical manufacturers who participate in Medicaid to provide discounts on outpatient prescription drugs to hospitals and other providers that treat a high volume of uninsured and low-income patients. Beginning in 2018, Medicare cut pharmaceutical payment rates to hospitals receiving the 340B discounts on the theory that these providers had a lower acquisition cost. Following the 340B payment reductions, the American Hospital Association and other organizations challenged the cuts in federal court, leading to the Supreme Court's unanimous decision last year in *American Hospital Assoc. et. al. v. Becerra, et. al.* deeming the 340B payment reductions from 2018-2022 invalid and ordering CMS to make 340B providers whole. 142 S. Ct. 1896 (2022).

Under the final rule, CMS will pay approximately 1,600 eligible 340B hospitals a single lump sum payment of the calculated amount owed. This comes as a welcome relief for hospitals after years of litigation. However, CMS has taken the position that these payments must be "budget neutral." As a result, under the final rule, CMS will reduce outpatient payment rates for other services going forward until it recoups the entire amount of the lump sum payments. CMS will begin the offset in 2026 by adjusting the outpatient prospective payment system conversion factor by minus 0.5% until the full amount of the 340B lump sum payments are offset, estimated to be 16 years.

Notably, the final rule addresses the concern reflected in comments to the proposed rule that Medicare Advantage Organizations (MAOs) could experience a windfall if they are not required to make refunds to hospitals and then benefit from the budget neutral reductions in future rates. CMS responded to this concern by stating that "these comments are out of the scope of the final rule," pointing out that "CMS cannot interfere in the payment rates that MAOs set in contracts with providers and facilities."

While CMS's response is unfortunate given that CMS does have regulatory authority over MAOs, many MAO contracts adopt original Medicare outpatient payment rates and therefore it may be possible to pursue contractual claims against MAOs that refuse to make retroactive payments to hospitals in line with CMS's approach for original Medicare under the final rule.

Please feel free to reach out to us if you have any questions about the 340 Program final rule, or if you would like to discuss options for recovery from MAOs.

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