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# Department of Health and Human Services Delays Effective Date of Final Rule Limiting Retrospective Manufacturer Rebates on Medicare Part D Prescription Drug Prices

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On January 29, 2021, Pharmaceutical Care Management Association ("PCMA"), a national trade association representing pharmacy benefit managers ("PBMs"), secured a one-year stay in a challenge to a new regulation issued by the Department of Human Health and Services Office of Inspector General ("HHS-OIG") that sought to prohibit PBMs and plan sponsors from accepting retrospective manufacturer rebates under Medicare Part D plans. In response to a complaint and a motion for partial summary judgment, together with a request for expedited consideration, filed by Gibson Dunn behalf of PCMA in the United States District Court for the District of Columbia, HHS-OIG offered to delay the effective date of a challenged regulation while it considers whether to withdraw or modify the rule.

PBMs administer prescription drug plans for more than 270 million Americans with health coverage through their employers, the health insurance market, or federal programs including Medicare Part D. Plan sponsors engage PBMs to maximize the value of prescription drug benefits by negotiating price concessions from drug manufacturers and pharmacies, in addition to providing numerous other services. Since the mid-1990s and through the earliest days of Part D, PBMs and manufacturers in both the commercial and Part D contexts have converged around a business model in which manufacturers pay retrospective rebates to PBMs after the product is dispensed to the enrollee, and PBMs pass rebates on to plan sponsors.

On November 30, 2020, HHS-OIG issued the "Rebate Rule," a new regulation that attempted to prohibit PBMs and plan sponsors from accepting retrospective manufacturer rebates under Medicare Part D plans. HHS-OIG issued the rule despite concerns from within the Trump administration that the Rule would weaken PBMs' ability to negotiate price concessions, drive up net drug prices, increase premiums for Medicare Part D enrollees by 25 percent, and increase federal spending by $196 billion over the next decade—concerns confirmed by actuarial analyses from multiple federal agencies and the Department of Health and Human Services' own actuaries. HHS-OIG set the Rebate Rule's provisions eliminating retrospective rebates to take effect January 1, 2022, even though the process of negotiating with drug manufacturers, designing Medicare Part D plans, and submitting bids to the government to provide coverage in 2022 was already well underway, with bids due in June 2021.

The timing of the rule thus interrupted ongoing negotiations and left PBMs and plan sponsors without adequate guidance or regulation from the government about how the new rule would impact bidding and the operation of Medicare Part D for the 2022 contract

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year. PCMA and its member PBMs sought immediate relief because the Rebate Rule had disrupted their work midstream and left them in regulatory limbo without enough time to receive necessary operational guidance and regulations before they submit bids in June.

In response, Gibson Dunn developed a strategy to challenge the rule as arbitrary and capricious under the Administrative Procedure Act and to delay its effective date. After filing a complaint on January 12, 2021, Gibson Dunn then filed a motion for partial summary judgment on January 25, 2021 targeting the Rebate Rule's impending effective date. Gibson Dunn contemporaneously filed a motion asking for an expedited ruling on the effective date's validity within five weeks.

At a status hearing on January 29, 2021 before Judge John D. Bates, the government responded to the motion for partial summary judgment by offering to delay the effective date of the Rebate Rule for a full calendar year, with a new effective date of January 1, 2023. The parties stipulated to that approach, and the court approved the delayed effective date, which restored the status quo and provided plan sponsors and PBMs clarity as they work to submit bids in June 2021 to provide Medicare coverage for millions of Americans, and held the case in abeyance. During the stay, the Biden administration will study the rule adopted by its predecessors and determine whether to repeal or modify it. If HHS-OIG ultimately elects to leave the Rule in place, or fails to make a decision before planning for contract year 2023 begins, Gibson Dunn is prepared to proceed with its remaining challenges to the Rule.

The case is *Pharmaceutical Care Management Association v. U.S. Department of Health and Human Services, et al.*, No. 21-cv-95 (D.D.C.).

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The following Gibson Dunn lawyers assisted in the litigation and in the preparation of this client update: Helgi C. Walker, Matthew Rozen, Brian Richman, Aaron Smith, and Max Schulman.

Gibson Dunn's lawyers are available to assist in addressing any questions you may have regarding these developments. Please contact the Gibson Dunn lawyer with whom you usually work, any member of the firm's Administrative Law and Regulatory Practice Group, or the following authors:

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