

CMS PROPOSES TO RESCIND MOST FAVORED NATION DRUG PRICING RULE

Date: 10 August 2021

Health Care and FDA Alert

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The Centers for Medicare & Medicaid Services (CMS) published a proposed rule (Proposed Rule) on 10 August 2021 that rescinds the Most Favored Nation (MFN) Model interim final rule, which was issued on 27 November 2020 (the November Rule).¹ As explained in our prior alerts [here](#) and [here](#), the November Rule would have revised Medicare Part B reimbursement methodology for certain drugs, in an effort to align drug prices in the United States with those of economically similar countries.

If the November Rule had taken effect 1 January 2021 as contemplated, it would have dramatically reduced Medicare Part B drug reimbursement. On 28 December 2020, the U.S. District Court for the Northern District of California issued a nationwide preliminary injunction, preventing the Department of Health and Human Services (HHS) from implementing the MFN Model and the November Rule due to failure to follow notice and comment procedures under the Administrative Procedure Act.²

In the Proposed Rule issued this week, CMS indicates that rescinding the November Rule would address procedural deficiencies identified by the courts and allow additional time for the agency to consider the issues raised by comments to the November Rule.

The Proposed Rule also reiterates that President Biden's 9 July 2021 Executive Order on Promoting Competition in the American Economy, in part, directs the secretary of HHS to take steps to lower the prices of and improve access to prescription drugs and biologicals.³ The proposed rule indicates that HHS is exploring opportunities to promote value-based care; to address the high cost of Medicare Part B drugs, manufacturers' pricing, and the resulting growth in Medicare Part B drug spending; and to modernize the Medicare program to improve the quality and cost of care.

Comments regarding the Proposed Rule must be submitted by 12 October 2021. Although arguably only comments regarding the November Rule's withdrawal are in scope, affected parties may nevertheless deem it prudent to also submit comments regarding the lack of wisdom of any new rule that substantially reduces reimbursement for Part B drugs, which could hinder access to life saving treatments.

Our health care practice and public policy and law practice routinely assists stakeholders with legal advice regarding pharmacy, drug pricing, and 340B Program matters, including with the submission of public comments. We can advise and engage with Congress and the administration on these matters.

FOOTNOTES

¹ 86 Fed. Reg. 43,618 (Aug. 10, 2021).

² Order Granting Motion for Preliminary Injunction, Cal. Life Sciences Ass'n v. Azar, No. 20-cv-08603-VC (N.D. Cal. Dec. 28, 2020).

³ Exec. Order No. 14,036, 86 Fed. Reg. 36987 (July 9, 2021), <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/>.

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