FEDERAL COURTS BLOCK IMPLEMENTATION OF MOST FAVORED NATION DRUG PRICING RULE

Date: 29 December 2020

U.S. Health Care Alert

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On 23 December 2020, Judge Catherine Blake of the U.S. District Court for the District of Maryland granted the Pharmaceutical Research and Manufacturers of America (PhRMA) a 14-day nationwide temporary restraining order, preventing the Centers for Medicare and Medicaid Services (CMS) from implementing and enforcing its Most Favored Nation (MFN) interim final rule (MFN Rule) scheduled to take effect on 1 January 2021.[1]

On 28 December 2020, in a parallel case and specifically adopting the reasoning in Judge Blake's order, Judge Vince Chhabria of the U.S. District Court for the Northern District of California granted California Life Sciences Association (CSLA) a preliminary injunction prohibiting CMS from implementing the MFN Rule based on a failure to follow notice and comment procedures under Administrative Procedure Act (APA). Most notably, Judge Chhabria's order vacates the MFN Rule in its entirety pending completion of the notice and comment process under the APA.[2]

As we outlined in our previous client alert here, CMS issued the MFN Rule on 27 November 2020, which revised Medicare Part B reimbursement methodology for certain drugs to align with the lowest international price among a group of countries. This new reimbursement model was promulgated as a Center for Medicare and Medicaid Innovation new payment model pursuant to 42 USC 1315a, which permits CMS to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to government program beneficiaries.

On 4 December 2020, PhRMA, along with the Association of Community Cancer Centers, the Global Colon Cancer Association, and the National Infusion Center Association, filed a complaint in the U.S. District Court for the District of Maryland seeking to enjoin enforcement of the MFN Rule, arguing, among other things, that the MFN Rule exceeds CMS' demonstration authority and that the rule violates the Administrative Procedure Act (APA) by failing to provide notice or opportunity for public comment.[3]

On 10 December 2020, the plaintiffs moved for a temporary restraining order and a preliminary injunction pending resolution of their claims on the merits.[4] The court found that the plaintiffs had demonstrated a likelihood of success on the merits of their APA claim. Judge Blake found that, while the court is not unsympathetic to CMS' desire to test a new model to rein in Medicare Part B drug costs, “an agency may not dispense with notice and comment procedures merely because it wishes to implement what it sees as a beneficial regulation immediately.”[5] The court also found that the plaintiffs demonstrated a likelihood that they would suffer irreparable harm absent judicial relief, noting that the rule in its first year would reduce Medicare drug expenditures by nearly US$5 billion.[6]

In concluding that the balance of the equities and public interest favor granting the temporary restraining order, Judge Blake noted the MFN Final Rule was promulgated without adequate procedure, “depriving the plaintiffs of

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an opportunity to comment on a potentially drastic revision to an important regulatory system with far-reaching consequences." She said that the MFN Rule "threatens not just to harm the livelihoods of healthcare providers, but also to shutter community-based healthcare facilities, without which many patients may have to travel long distances to obtain medical care," adding that the rule may cause some patients to choose between accepting inferior treatment, going elsewhere for treatment, or forgoing treatment.[7]

As noted above, on 4 December 2020, CLSA, along with Biocom California and Biotechnology Innovation Organization filed a parallel case in the District Court of the North District of California requesting a preliminary and permanent injunction prohibiting CMS from implementing the MFN Rule on similar grounds as the PhRMA case.[8] In contrast to Judge Blake's 14-day temporary restraining order, Judge Chhabria's order vacates the MFN Rule until CMS completes the notice and comment process under the APA.[9] Accordingly, President-Elect Biden's administration will have an opportunity to review and respond to both the MFN Rule and the pending litigation.

These orders provide at least temporary reprieve as institutional providers, practices and practitioners have scrambled to implement the administrative and billing system changes necessary to comply with the MFN Rule without further additional billing and claims processing guidance from CMS, as was initially contemplated. Additionally, it is no longer necessary for manufacturers and providers to enter into new, drastically different sales agreements to make sure that providers are not upside down.

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K&L Gates' Health Care practice and Public Policy and Law practices routinely assists stakeholders with legal advice regarding hospital, 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] Order, Assoc. Comm. Cancer Ctrs. v. Azar, No. 20-cv-03531 (D. Md. Dec. 23 2020)

[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) [hereinafter, Preliminary Injunction Order]

[3] Compl., Assoc. Comm. Cancer Ctrs. v. Azar, No. 20-cv-03531 (D. Md. Dec. 4 2020)

[4] Mem., Assoc. Comm. Cancer Ctrs. v. Azar, No. 20-cv-03531 (D. Md. Dec. 23 2020)

[5] Id. at 19.

[6] Id. at 20.

[7] Id. at 24.

[8] Compl.,Biotechnology Innovation Org. v. Azar, No. 20-cv-03531 (N.D. Cal. Dec. 28 2020).

[9] Preliminary Injunction Order, at 4.

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