

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

ASSOCIATION OF COMMUNITY CANCER
CENTERS, *et al.*,

Plaintiffs,

v.

ALEX M. AZAR II, in his official capacity as
Secretary of the U.S. Department of Health and
Human Services, *et al.*,

Defendants.

Civil Action No. 1:20-cv-03531-CCB

ORAL ARGUMENT REQUESTED

**MOTION FOR A TEMPORARY RESTRAINING ORDER
AND PRELIMINARY INJUNCTION**

On November 27, 2020, the Trump administration published an interim final rule (MFN Rule) that will completely overhaul the Medicare Part B reimbursement system for physician-administered innovative medicines as of January 1, 2021. The MFN Rule seeks to replace the current primarily market-based approach to reimbursement for Part B products with a totally new system that ties reimbursement to the lowest price available in almost two dozen other countries—regardless of how those countries structure their healthcare systems, the (dis)incentives they provide for innovation, or the limitations they place on patients’ ability to access medications. But instead of adopting this sea-change to the Medicare program through proper legislative channels, the Trump Administration implemented the nationwide, mandatory MFN Rule in the guise of its narrow authority under Section 1115A of the Social Security Act to “test” a payment “model.” Worse still, the Administration took these steps without going through statutorily required notice-and-comment procedures.

As the accompanying Memorandum of Law explains, the MFN Rule is unlawful on several procedural and substantive grounds, both statutory and constitutional. It will immediately and irreparably harm Medicare patients, healthcare providers, and pharmaceutical manufacturers. And the balance of equities and the public interest weigh heavily against implementation of the Rule. Plaintiffs accordingly seek a temporary restraining order and preliminary injunction, pursuant to Federal Rule of Civil Procedure 65, to enjoin implementation of the MFN Rule.

Time is of the essence. Under the MFN Rule, massive changes to Medicare reimbursement will begin to operate on January 1, 2021. At that point, the Rule will begin to inflict multiple forms of irreparable harm on Plaintiffs and their members, as well as on the general public. Despite waiting years to propose and implement the MFN Rule, the Trump Administration picked an implementation date only one month away from the date of publication. An entire industry—patients, providers, group purchasing organizations, and pharmaceutical manufacturers—cannot reasonably be expected to upend their treatment plans, practices, contracts, pricing systems, and business plans within a single month. Not only is the Rule’s timeline plainly infeasible, but implementation will immediately undermine access to healthcare and life-saving medications for patients who are in most critical need; and it will cause healthcare providers and other businesses to shutter, while inflicting billions of dollars in losses on the industry. The Rule will also increase burdens on a fragile medical system already overtaxed by the COVID-19 pandemic, further jeopardizing the health of millions at a time when access to quality care is of the utmost importance.

Plaintiffs have proceeded with diligence. The MFN Rule was published in the Federal Register on November 27, 2020. Plaintiffs filed their Complaint in this action on December 4, only one week later. Plaintiffs asked Defendants to delay implementation of the Rule pending litigation

of a motion for preliminary injunction, but Defendants declined. Plaintiffs now file this Motion for temporary and preliminary injunctive relief on December 10, less than one week after filing their Complaint.

For these reasons, and those set forth more fully in Plaintiffs' accompanying Memorandum of Law, Plaintiffs' Motion for a Temporary Restraining Order and Preliminary Injunction should be granted, and the MFN Rule should be preliminarily enjoined during the pendency of this litigation. At a minimum, Plaintiffs request that the Court enter an order temporarily enjoining the interim final rulemaking from going into effect until Defendants have complied with notice-and-comment requirements. With massive upheaval of the Medicare program less than three weeks away, Plaintiffs also request expedited briefing and oral argument on this Motion. Plaintiffs discussed a briefing schedule with Defendants, but the parties were unable to agree on a schedule that gave both sides what they considered sufficient time to brief the issues and that provided the Court with sufficient time to resolve the issues in advance of the January 1 deadline, particularly in light of the upcoming holidays.

DATED: December 10, 2020

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Respectfully submitted,

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