

**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

Michele Sartori (Bar No. 26829)  
E. Elizabeth Halpern\*\*\*\*  
Susan M. Cook\*\*\*\*  
HOGAN LOVELLS US LLP  
555 Thirteenth Street, NW  
Washington, DC 20004  
(202) 637-5600  
michele.sartori@hoganlovells.com  
elizabeth.halpern@hoganlovells.com  
susan.cook@hoganlovells.com

*Counsel for Plaintiff Association of  
Community Cancer Centers*

Andrew Zimmitti (Bar No. 18539)  
Michael Kolber\*  
Adam Finkelstein\*\*  
MANATT, PHELPS & PHILLIPS LLP  
1050 Connecticut Avenue, NW, Suite 600  
Washington, DC 20036  
(202) 585-6505  
azimmitti@manatt.com  
mkolber@manatt.com

*Counsel for Plaintiff Global Colon Cancer  
Association*

Respectfully submitted,

/s/ John P. Elwood  
John P. Elwood\*  
Jeffrey L. Handwerker\*\*\*  
R. Stanton Jones (Bar No. 20690)  
Allon Kedem\*  
Diana Sterk\*  
ARNOLD & PORTER KATE SCHOLER LLP  
601 Massachusetts Avenue, NW  
Washington, DC 20001  
(202) 942-5000  
john.elwood@arnoldporter.com  
jeffrey.handwerker@arnoldporter.com  
stanton.jones@arnoldporter.com  
allon.kedem@arnoldporter.com  
diana.sterk@arnoldporter.com

*Counsel for Plaintiff Pharmaceutical Research  
and Manufacturers of America*

Timothy Cleveland\*  
Alethea Anne Swift\*  
CLEVELAND | TERRAZAS PLLC  
303 Camp Craft Rd., Suite 325  
Austin, TX 78746  
(512) 689-8698  
tcleveland@clevelandterrazas.com  
aswift@clevelandterrazas.com

Benjamin H. Carney (Bar No. 27984)  
GORDON, WOLF & CARNEY, CHTD.  
100 W. Pennsylvania Avenue, Suite 100  
Towson, MD 21204  
(410) 825-2300  
bcarney@gwcfirm.com

*Counsel for Plaintiff National Infusion Center  
Association*

\* *Pro hac vice*

\*\* *Pro hac vice* application forthcoming

\*\*\* Application for admission forthcoming

\*\*\*\* Application for admission pending