NATIONAL INFUSION CENTER ASSOCIATION

The Nation's Advocacy Voice for In-Office Infusion

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The Centers for Medicare & Medicaid Services ("CMS") recently announced a rule, set to take effect on January 1, 2021, that will cause most outpatient infusion patients on Part B Medicare to face a dangerous choice: transition to less effective medications, forego vital infusion therapy altogether, or seek treatment in costlier and more dangerous environments. Because this rule presents an unreasonable, and unnecessary, risk of harm with no countervailing upside, the National Infusion Center Association (NICA) has joined a lawsuit seeking to stop the rule from taking effect.

Along with the Association of Community Cancer Centers, Global Colon Cancer Association, and Pharmaceutical Research and Manufacturers of America, NICA is asking the United States District Court in Maryland for injunctive relief to stop the Most Favored Nation (MFN) Model interim final rule CMS05528-IFC ("MFN Rule"). CMS first announced the MFN rule in late November 2020, providing no opportunity for official commentary before January 1, 2021—the date on which the Rule is set to become effective across the nation. If allowed to take effect, the complaint warns, the Rule "will result in shortages of drugs and delays in access." Patients will "experience access to care impacts by . . . having to travel to seek care from an excluded provider, receiving an alternative therapy that may have lower efficacy or greater risk, or postponing or foregoing treatment."

[Read NICA's full complaint to stop the MFN Rule here.]

The MFN Rule targets the 50 most heavily prescribed Medicare Part B drugs, including numerous infused biologics, antibiotics, and neurologic agents. These medications are so heavily prescribed because they are so effective, often proving to be patients' last remaining hope in the battle against chronic, debilitating, and demoralizing diseases. Patients around the nation rely on standalone, community-based infusion centers in order to receive these vital therapies, which can be provided more efficiently, more conveniently, and more affordably than equivalent therapies offered in hospital or home-health settings. But outpatient infusion centers will be unable to absorb the cost of administering these essential medications under the reimbursement structure imposed by the MFN Rule.

Under the Rule, CMS will dramatically slash reimbursement rates. Unlike the current market-based Medicare system, which reimburses clinics based on average domestic drug prices, the MFN Rule bases reimbursement rates on the lowest price available in any of almost two dozen foreign countries. As even CMS acknowledges, tethering reimbursement rates to foreign drug prices in this manner will lead to reduced healthcare access for millions of patients who rely on Part B Medicare coverage. This is, in fact, part of CMS's cost-savings plan, which relies on the reality that many outpatient treatment centers will no longer be able to provide infusions to Part B patients. This will lead to losses of such enormity that many centers will be forced to close their doors to Part B Medicare patients, requiring those patients to turn to less effective treatments, more expensive inpatient treatment centers, or worse, no treatment at all.

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Many patients rely on outpatient infusion centers to provide them with some semblance of quality of life. Especially in rural communities, outpatient infusion centers present the only convenient location where patients can obtain infused medications. If these patients are turned away, they will have no choice but to seek inpatient infusions, which are not covered by the MFN Rule, but which are vastly more expensive and not as readily available, or forego treatment altogether. For the population of patients who need these infused therapies—for example, those with multiple sclerosis, severe rheumatic disease, or uncontrolled gastrointestinal disorders—foregoing treatment risks relapse and a severe worsening of symptoms, which ultimately may be irreversible. Although some of these patients could be transitioned onto different treatments, which would not be affected by the MFN Rule, the expediency with which CMS intends to implement the Rule—by January 1—leaves no time for that transition.

The MFN Rule also violates the Administrative Procedure Act and the Constitution. CMS did not follow the required procedures for notice-and-comment, which would have allowed NICA and others to voice their concerns pursuant to formal rulemaking procedures designed to protect the public and our system of government.

CMS also lacks the authority to implement, or effectuate, the MFN Rule. Section 1115 of the Affordable Care Act authorizes CMS to "test innovative payment and service delivery models." But CMS has exceeded any authority under that Act. The MFN Rule is not a "test," but a mandatory, nationwide drug reimbursement system that affects 95 percent of all Medicare Part B fee-for-service visits and nearly 80 percent of funds currently spent on Part B drugs. The Rule runs directly counter to the market-based system Congress has implemented, which CMS has no authority to overturn.

Adding insult to injury, the timing of the MFN Rule is particularly problematic in light of the ongoing COVID-19 pandemic. Most outpatient centers operate facilities that allow patients to be treated in private rooms where social distance may be maintained. Under the MFN Rule, these same patients—many of whom are very immunocompromised—will be forced to seek treatment in hospitals, which currently are overrun with COVID-19 patients. Worse, patients who forego treatment risk relapse or the development of other health conditions, any of which could require surgical intervention or a need for other inpatient treatment. The public health system is already at its breaking point, and now is not the time to be funneling more patients into already overburdened hospitals.