Oncologists Sue to Stop "Dangerous and Unlawful" Most Favored Nation Drug Pricing Scheme

Community Oncology Alliance Seeks Emergency Injunction to Block Experiment that Endangers Seniors

Washington, D.C. – December 11, 2020 – The Trump Administration's gambit to lower drug prices will force seniors with cancer into potentially life-threatening situations: go elsewhere for cancer care than with their existing oncologist or "forgo access" to treatment. That is among the reasons why the Community Oncology Alliance (COA) is seeking immediate legal relief to stop the "dangerous and unlawful gamble with the lives of some of America's sickest patients" by the Centers for Medicare & Medicaid Services (CMS).

COA is asking the United States District Court in Washington D.C. for injunctive relief to stop the Most Favored Nation (MFN) Model interim final rule CMS-5528-IFC ("Interim Final Rule"), which was announced a little more than 30 days from when this nationwide, mandatory experiment on Medicare seniors goes into effect. Should it proceed, the complaint warns that the MFN "exposes the health and safety of cancer patients, and other patients with potentially life-threatening diseases, to real danger."

- Read COA's full complaint to stop the MFN experiment here.

The MFN experiment was announced as a plan to lower the cost of the top 50 physician-administered Medicare Part B drugs, including 38 of the top treatments used by oncologists/hematologists for cancer and blood disorders. These include mainstay breast, lung, and prostate cancer drugs, as well as the latest cutting-edge immunotherapies that have had dramatic results in improving survival rates for millions of Americans. However, a new study shows that the MFN experiment will only lower out-of-pocket drug costs *for less than one percent of Medicare beneficiaries.* Yet, the risk to a substantial number of seniors is potentially life threatening.

CMS estimates that in the first year of the MFN experiment, 20 percent of seniors will be forced to find new oncologists and treatment elsewhere; however, nearly half of those will "forgo" treatment. By 2023, 30 percent of Medicare seniors may be displaced, with an alarming 1 in 5 seniors not getting treated. That's a death sentence for patients with cancer and other serious diseases.

"This Most Favored Nation experiment on seniors uses patients and their providers as hostages in a deeply flawed attempt to force drug companies to lower prices. There are life and death consequences in this vile scheme the government has cooked up, especially as CMS shockingly estimates that 1 in 5 seniors will go without treatment for cancer," says Ted Okon, executive director of COA.

COA alleges in their complaint that the Interim Final Rule violates the Administrative Procedure Act (APA); it was issued without the required notice-and-comment rulemaking procedures, and without the statutorily required "good cause" to dispense with such procedures. CMS issued an Advance Notice of Proposed Rulemaking (ANPRM) in October 2018 aimed at lowering prescription drug spending by tying Medicare rates to the lower international prices for the same drugs, known as the International Price Index. Eight months later, in June 2019, CMS submitted a Notice of Proposed Rulemaking (NPRM) to the Office of Management & Budget (OMB), but that NPRM was never publicly released.

COA's complaint also says that the MFN experiment is an attempt by the Executive Branch to thwart the Constitutional authority of the Legislative Branch in bypassing existing statute, specifically Medicare Part B reimbursement established in the Medicare Modernization Act. In mandating what it calls a "model," CMS relies on Section 1115A of the Affordable Care Act for its authority. But it exceeds that authority by making the model mandatory in scope and affecting a breathtaking 95 percent of all Medicare Part B fee-for-service and nearly 80 percent of Part B drug spending. In its complaint, COA insists that CMS has no statutory authority in this case to waive any requirements of the Medicare law, especially the Part B drug reimbursement provisions.

“This Constitution-bending, lawbreaking experiment is a gross abuse of power that will not lower drug prices but will endanger the lives of seniors and put a dagger in the back of community cancer care – all during a public health emergency when oncologists and other physicians need all the support they can get.” Okon says.

Read COA’s full complaint to stop the MFN experiment at https://communityoncology.org/wp-content/uploads/2020/12/COA-v-HHS-et-al-Complaint-Final.pdf.

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About the Community Oncology Alliance: *The majority of Americans battling cancer receive treatment in the community oncology setting. Keeping patients close to their homes, families, and support networks lessens the impact of this devastating disease. Community oncology practices do this while delivering high-quality, cutting-edge cancer care at a fraction of the cost of the hospital setting. The Community Oncology Alliance (COA) advocates for community oncology and smart public policy that ensures the community cancer care system remains healthy and able to provide all Americans with access to local, quality, affordable cancer care. Learn more at www.CommunityOncology.org.*