

## ALERTS

## Client Alert: Two lawsuits challenge MFN drug-pricing model

12.2020

On December 4, 2020, separate lawsuits filed in federal courts in Maryland and California allege that the new Medicare drug-pricing regulation released by the Centers for Medicare and Medicaid Services (CMS) on November 20, 2020, known as the Most Favored Nation Rule (MFN Rule), violates federal law, including the United States Constitution.[1] Each of the suits asks the court to (i) declare the MFN Rule invalid; (ii) set aside and vacate the MFN Rule; and (iii) prevent CMS from implementing and enforcing the MFN Rule, which is scheduled to become effective January 1, 2021.

Trade associations for cancer programs, cancer patients, infusion providers and research-based pharmaceutical companies filed the lawsuit in Maryland, and trade associations for biotechnology and life sciences companies filed the suit in California. The specific injuries alleged by the plaintiffs, although not identical, focused on irreparable damage by (i) forcing providers to cease delivery of these drugs or close altogether, which in turn would decrease access to drugs for patients; and (ii) destruction of the funding for research for innovative pharmaceuticals.

Both suits included similar arguments for vacating the MFN Rule. Specifically, plaintiffs argue (i) that the United States Department of Health and Human Services (HHS) violated the federal Administrative Procedures Act by failing to follow the requisite notice-and-comment rulemaking processes; (ii) that the HHS Secretary lacked authority under the Patient Protection and Affordable Care Act to issue the rule as a “test” model because it applies nationally and will not preserve or enhance the quality of care furnished to individuals; and (iii) that the MFN Rule violates the separation of powers doctrine and presentment clause of the Constitution.

Moore & Van Allen will be monitoring both lawsuits together with additional litigation related to the MFN Rule and will provide updates as important developments occur. In the meantime, please contact one of the MVA health law practice team members listed below with questions about the MFN Rule or this litigation.

[1] The MFN Rule, effective January 1, 2021, “will lower prescription drug costs by paying no more for high-cost Medicare Part B drugs and biologicals than the lowest price that drug manufacturers receive in other similar countries.” See CMS Press Release at <https://www.cms.gov/newsroom/fact-sheets/fact-sheet-most-favored-nation-model-medicare-part-b-drugs-and-biologicals-interim-final-rule>.

Carol Bowen  
Member  
[carolbowen@mvalaw.com](mailto:carolbowen@mvalaw.com)

## CLIENT ALERT: TWO LAWSUITS CHALLENGE MFN DRUG-PRICING MODEL

---

Kimberly Kirk  
Senior Counsel  
[kimberlykirk@mvalaw.com](mailto:kimberlykirk@mvalaw.com)

Keith Smith  
Member  
[keithsmith@mvalaw.com](mailto:keithsmith@mvalaw.com)