

### The Most Favored Nation Rule (MFN Rule) Threatens Patient Interests

- The MFN Rule links reimbursement for the top 50 physician-administered medicines—which include many of the most innovative cancer and ophthalmology medicines—to the lowest price available in 22 foreign countries in the Organization for Economic Co-operation and Development (OECD). The OECD countries chosen include countries with per capita GDPs as low as 60% of the U.S. figure. The 50 medicines chosen are those with the highest Medicare Part B allowed charges, after excluding certain drug categories, including COVID-19 treatments, vaccines and reimbursement codes containing generic products.
- The problem with that approach is these foreign countries impose government price setting, have single-payer health care systems or otherwise make value judgments about quality of life that have nothing in common with the U.S. system. What is more, those systems often result in reduced patient access, rationing of care and fewer new lifesaving and life-enhancing medications. For example, one study found that [if OECD countries removed their price controls](#), there would be anywhere between 8 and 13 new medicines introduced annually by 2030.
- Government price setting is detrimental to patient access to innovative medicines. [Nearly 90% of new medicines](#) launched since 2011 are available to patients in the United States, compared to an average of only 49% for some of the countries included in the MFN Rule.
- The MFN Rule acknowledges that [reduced patient access](#) to treatments may be an unintended consequence, stating that “beneficiaries may experience access to care impacts by having to find alternative care providers locally, having to travel to seek care from an excluded provider, receiving an alternative therapy that may have lower efficacy or greater risks, or postponing or forgoing treatment.”
- The MFN Rule also would do little to reduce patient costs at the pharmacy. It would [lower out-of-pocket costs for less than 1% of seniors](#) in Medicare Part B because the vast majority of them already have supplemental coverage or do not rely on the medicines included in the rule.

### The MFN Rule Is Not Authorized

- **Statutory Violation:** The administration claims that Congress empowered it to overhaul the drug pricing system for Medicare Part B through a little-known provision of the Affordable Care Act. But that provision actually gives the administration the power only to “test” new payment “models”—not to rewrite the Medicare Part B program’s pricing rules wholesale on a nationwide, mandatory basis. The administration has no authority to proceed in this manner.
- **Constitutional Violation:** If Congress actually had given the administration the authority it now claims, then that delegation would be unconstitutional. The Constitution requires changes of the magnitude contemplated to be enacted by Congress and signed by the president. Executive agencies are not permitted to override prior-enacted statutes through rulemaking.
- **Procedural Violation:** The administration implemented this rule as an interim final rule, giving it immediate effect without prior public comment. The administration has thus deprived the public of any chance to weigh in before the policy goes into effect. This is an end run around the usual process through which agencies consider stakeholder views of proposed regulations, and by which agencies are held accountable to the public. Interim final rules can be used only when there is “good cause” for implementing a rule without such comment. The administration cites concerns with drug pricing generally and the COVID-19 pandemic specifically as the sole bases for good cause, but has excluded all COVID-19 treatments from the scope of the rule and provides no explanation for waiting over 8 months after the COVID-19 pandemic and the more than 2 years after the advance notice of proposed rulemaking on the international reference pricing index to issue the MFN Rule.