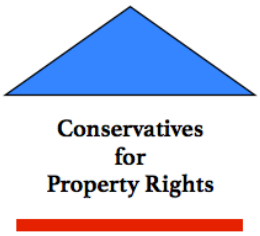

January 25, 2021

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5528-IFC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

To whom it may concern:

Conservatives for Property Rights (CPR), a coalition of policy organizations representing thousand and thousands of Americans on private property rights issues, herein comments on the Interim Final Rule implementing a "Most Favored Nation (MFN) Model" for importing foreign price controls for certain Medicare Part B drugs (CMS-5528-IFC).

The MFN model CMS implements raises very serious concerns from a property rights perspective. The chief of those concerns is that the MFN model imposes government price controls, which are certain to cause harm and adverse consequences for millions of private U.S. citizens and important American entities. It is not overstating the truth that the MFN model rule will ultimately cost many Americans their lives, their health, and their livelihoods.

While CPR's grave concerns over — and reasons for strongly opposing — the MFN model are many, we focus our comments on the unacceptable process that deprives procedural property rights, the deleterious effects on Medicare patients, and the damage it inflicts on health care providers. We connect these specific comments to property rights at issue therein.

1) **The process employed to develop and implement this policy change is an abuse of power.** The rule forcing the model into effect denies due process, exceeds its authority for model testing, and totally disregards the easily foreseeable harms that will result.

The Center for Medicare & Medicaid Innovation (CMMI) has designed a price-control model that imports the worst artificially submarket price a foreign government-controlled health system has dictated to American biopharmaceutical innovators on a take-it-or-leave-it or on a take-it-or-we'll-expropriate-your-intellectual-property basis. Applying those foreign prices to Medicare Part B for certain medicines purchased and administered under this program not only harms patients and doctors, it imports the underlying socialist policies that directly harm the patients, doctors, and health systems from which the price control rates come.

CMMI denies due process by pushing through a model even starker and more cynical than the previously floated international price index (IPI) model. The effective date of the MFN model rule (January 1, 2021) doesn't wait for the end of the public comment period (January 26). The rule neglects to take time to weigh input from public comments and to adjust the model accordingly. The exercise amounts to a sham. It lacks good faith as the rule-making process

fails to accord with the principles of the Administrative Procedure Act and the Regulatory Bill of Rights. Due process is a property right, making this rule an abrogation of property rights.

Further, CMMI exceeds its authority by requiring virtually all Part B medical providers, outpatient facilities, Part B beneficiaries, and suppliers to participate in the MFN model test. The scope of the model is nationwide. Participation is mandatory. The 50 initial drugs subject to imported price controls will increase each additional year of the "demonstration." The "model" is "tested" for seven years.

Thus, this rulemaking amounts to legislating by other means. It effects wholesale policy change while circumventing Congress and congressional intent. It is not in keeping with the constructive demonstrations that honest model pilots might achieve. Further, the model violates the consensus principles of the Healthcare Leaders for Accountable Innovation in Medicare coalition. Thus, the MFN model steadily stifles access for patients, income for struggling physician practices and clinics, and research funds for the biopharmaceutical innovators responsible for discovering and developing new treatments, diagnostics, vaccines, and cures.

CMMI has all too frequently exceeded the limitations of real pilot programs. Mandatory participation, wide application, and broad geographic reach that constitute effecting policy change has caused significant concern. Moreover, MFN backtracks on a short-lived change of direction indicated in CMMI's "New Direction" RFI. There, CMMI admitted that mandatory CMMI models cause disruption. This RFI pledged that CMMI would "focus on voluntary models . . . and reduce burdensome requirements and unnecessary regulations to allow physicians and other providers to focus on providing high-quality healthcare to their patients." It didn't last.

CMMI had already prompted a bipartisan bill in Congress: H.R. 5741, the Strengthening Innovation in Medicare and Medicaid Act. CMMI's abuses have generated sufficient concern that more than 300 organizations from around the nation have signed a letter voicing support for H.R. 5741. With its backsliding on the MFN model's overreach, CMMI rekindles concerns about its unbridled inclinations and the need for legislation to rein it in.

Therefore, CPR considers the process used to push the MFN model to lack legitimacy and an affront to critically important property rights. The MFN model rule should be withdrawn.

2) **The MFN model exposes Medicare beneficiaries, who have equities by duly qualifing for this health care program over their working years, to reduced access to needed medication and associated medical care, resulting in worse clinical outcomes.**

CMS admits that the MFN model imports the rationing of medical care. The rule states 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*." Such disruptions to seniors' access to care and to the most appropriate drugs in their circumstances reeks of the worst aspects of government-controlled health systems. Further, CMS "assumes that *utilization of MFN medicines may decrease* from 9 percent to 19 percent over the course of the demonstration." (emphasis added).

It is a safe assumption that CMS's use of "may" above actually means "will." MFN will reduce not only access to vital medicines, it will reduce pharmaceutical innovation, i.e., new and

improved medicines. The government-controlled health systems of the MFN model's 22 OECD countries deny patients access to new, better medicines. In the United States, 87 percent of new medicines have been available to patients, in contrast with 20 percent in New Zealand and 35 percent in South Korea. Rationed access to care and therapies produces worse patient outcomes. The U.S. 5-year survival rate for all cancers is 42 percent higher for men and 15 percent higher for women than in Europe. MFN will likely reduce the beneficial U.S. outcomes.

Beneficiaries for whom medication is administered in a doctor's office or outpatient facility tend to have more serious, complex medical cases, which in seniors may be accompanied by comorbidities. Illnesses include cancers and rheumatoid arthritis. The mode of drug delivery is infusion, injection, or another means requiring expertise. MFN may arbitrarily and capriciously trim drug spending in Part B in the short-term, but the harms it causes will cost patients, our health system, and the welfare of the American people more over the long-term.

Patient advocates decry the MFN model as a means of reducing patient access and quality of care, most adversely affecting the neediest American patients. "Health outcomes for cancer patients are substantially worse in other countries because their health systems use standards that discriminate to value treatments," CancerCare's Patricia Goldsmith said. "The result is restricted and delayed access to cancer treatment. Yet, the White House is proposing to import those standards to the United States in the middle of a pandemic." The growing number of affected patients as Baby Boomers enter Medicare, coupled with the medical expertise required to administer these medications and diminished access to needed medicines, translates into rationed care and worse outcomes — hallmarks of socialized medical systems.

From a property rights perspective, the Medicare program represents a part of seniors' deferred enjoyment of a portion of the fruits of their labor. Medicare is not welfare. Rather, Medicare is a social contract with those who worked the requisite number of years to qualify for the program's benefits upon reaching age 65. Had they not been required to pay taxes toward Medicare, beneficiaries would have received extra earnings at the time they were in the workforce. At this stage in seniors' lives, they do not have many options or out-years to make up for the income and earnings lost to Medicare taxes throughout those years. They are forced to rely on the government to keep its pledge for their health care at this stage, on which the MFN model rule reneges. Thus, MFN is tantamount to the taking of property (a deferred benefit) without just compensation.

To CMS, this may merely be budgetary slicing and dicing — trimming how much Part B spends on a group of medical commodities. But the medications administered through Part B are hardly commodities, despite the fact CMS may lost sight of the real human beings whose lives are affected by its decisions. Part B drugs, just like Part D drugs or any other medical product brought to bear in Part A, Part C, or any other health care program, are an important component of the provision of a course of medical care in the diagnosis, treatment, and cure of a specific medical condition. And the consequences of cold, bureaucratic legerdemain that place penny-pinching over patient care play out in real people's lives in the real world.

Further, the MFN model radically changes the rules of the game for beneficiaries who are stuck with the government health program. MFN deprives affected seniors of their property rights by government denying them access to medication options that may be best for them, that they and their doctors would otherwise choose, but Medicare's importation of foreign price controls renders unavailable or nonexistent. This risks the earliest availability of new medicines

much earlier in America than in countries with government-run health systems and price controls. The MFN model assaults beneficiaries' property rights and should be dumped.

3) **MFN places doctors and providers in an untenable position, punishing them through deep cuts in Part B while risking the viability of their medical practices.** This drug price control scheme will drive market consolidation, cause some physicians to leave medicine, deprive patients of access to doctors' care, risk making Medicare as unattractive as Medicaid in which to practice medicine, and put rural America in an even tougher bind.

The MFN rule changes the Part B add-on payment from one calculated as 6 percent of average sales price to a flat fee per dose, calculated across all medicines in the model. That is insane! CMS acknowledges that this change will mean reductions in add-on revenue for some specialties. For instance, neurologists face an average reduction of 21 percent. Medical oncologists stand to see an average reduction of 13 percent. Infectious disease doctors are estimated to experience an average reduction of 10 percent. (A better way to save Medicare money would be to begin with a 10-21 percent cut in CMS's personnel baseline budget.)

The MFN model dramatically hurts doctors, particularly those in small or rural practices, and other Part B providers. Physicians' practices face many demands and constraints in the pursuit of providing their expertise to people in need. It has been an ongoing challenge for rural America to recruit physicians to set up medical practices in the hinterlands. CMS acknowledges that, under MFN, "These rural entities will experience drug payment reductions and overall payment reductions . . . ." In other words, MFN makes rural areas' and rural Medicare patients' lots worse off by reducing the supply of rural providers.

The physician-practice and rural challenges have been exacerbated by the COVID-19 pandemic. A recent American Medical Association survey reported that COVID-19 has caused physician practice revenues to fall 32 percent, on average, since February 2020. Other research has found that utilization of oncology drugs in May 2020 stood at 50 percent below May 2019 levels. The MFN reference pricing model only makes these unsustainable figures worse — and puts many doctors at risk of bankruptcy or facing little choice but to join a large health care conglomerate. Thus, MFN should be anticipated to drive market consolidation, which reduces beneficiaries' choice and diminishes competition.

Providers face not only deep reimbursement cuts under MFN. MFN is likely to impose greater administrative burdens on providers. One example is the likely requirement that providers renegotiate contracts and ensure data on drugs administered to Medicare Part B patients are accurately conveyed to manufacturers or wholesalers for CMS reporting purposes. This piling on of heavier regulatory burdens and overhead costs runs counter to recent CMS actions giving more flexibility under existing CMMI payment models. In June 2020, CMS embraced "delaying certain model reporting requirements so that providers can focus on patients instead of paperwork." Unfortunately, MFN turns back the clock to bureaucratic overregulation and arbitrary peanut counting.

Reducing U.S physicians' incomes from their administering sophisticated medicines to patients with complicated medical situations directly deprives these learned intermediaries a significant portion of the fruits of their labor. Therefore, the MFN model should be revoked.

* * * * *

In summary, government-run and price-controlled health systems may "spend less" than the United States on health costs. However, they do so by depriving the sacred rights of private property and free enterprise. They thereby deny their citizens, patients, medical providers, and would-be innovators the many benefits derived from property rights and free enterprise.

Importing socialized health systems' drug price controls for Medicare Part B, as the MFN model does, is foolhardy. MFN sets a terrible, horrific precedent. It surely will harm Medicare beneficiaries, medical providers, pharmaceutical innovators, and the U.S. innovation ecosystem. The U.S. economy will suffer, as will our health care system. Notably, the MFN model does little to curb foreign freeloading and to force them to start paying their fair share for the medical innovation in which America's private sector invests.

Conservatives for Property Rights strongly urges CMS to withdraw the MFN model.

Respectfully,

James Edwards
Executive Director
Conservatives for Property Rights

Ryan Ellis
President
Center for a Free Economy

C. Preston Noell III
President
Tradition, Family, Property, Inc.

Seton Motley
President
Less Government

Kevin L. Kearns
President
U.S. Business & Industry Council

Ashley Baker
Director of Public Policy
The Committee for Justice

Daniel Schneider
Executive Director
American Conservative Union

Jeffrey Mazzella
President
Center for Individual Freedom

Matthew Kandrach
President
Consumer Action for a Strong Economy

Rick Manning
President
Americans for Limited Government

James L. Martin
Founder/Chairman
60 Plus Association

Saulius "Saul" Anuzis
President
60 Plus Association