January 25, 2021

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: 42 CFR Part 513 [CMS–5528–IFC] RIN 0938–AT91 Most Favored Nation (MFN) Model

Introduction

On behalf of the undersigned federal and state-based organizations, we write to express our opposition to the interim final rule to implement the Most Favored Nation (MFN) Model under section 1115A of the Social Security Act. We request you withdraw the rule.

The rule forces physicians, patients, and providers into a mandatory demonstration under the Obamacare Center for Medicare and Medicaid Innovation (CMMI) and ties the prices paid for medicines in Medicare Part B to the prices in foreign countries with socialized health care systems.

The proposal imports foreign price controls into America's healthcare system. This will harm medical innovation and the development of new medicines. It will threaten high-paying American manufacturing jobs and do nothing to stop foreign freeloading. Instead, it will move the United States closer to a system of government-controlled healthcare.

The need for free market policies that promote American medical innovation is clear. Manufacturers have developed several highly effective COVID-19 vaccines at the fastest rate ever. This good news is only possible because the U.S. leads the world when it comes to developing innovative, lifesaving and life enhancing medicines.

The MFN would do nothing to stop foreign freeloading

One of the goals of the MFN is to "end foreign freeloading," where foreign countries benefit from American innovation and the development of cures but do nothing to pay for the extensive investments required for the next generation of cures.

Supporters of the MFN have claimed the concept is a free-market proposal that will incentivize manufacturers to negotiate better deals. However, this theory is based on the flawed assumption that American manufacturers were not fighting as hard as they could against foreign price controls in past years.

Rather than fighting price controls that distort markets and impede innovation, the MFN would surrender to foreign freeloading by setting U.S. prices based on the prices of other countries.

Foreign countries pay less for medicines because they utilize price controls. There is little or no negotiation between foreign government and manufacturers which often forces innovators to accept lower prices in a “take-it-or-leave it” proposition.

While this artificially lowers the cost of prescription drugs overseas, it also results in reduced or restricted access to new medicines and higher prices for medicines when they enter the market.

The MFN would reduce access to new cures

Adopting foreign price controls will create the same problems that foreign healthcare systems suffer from – there will be less medical innovation resulting in fewer new treatments and cures leading to healthcare shortages for American patients.

Developing new medicines requires a substantial investment of time and costs. In all, it costs an average of $2.6 billion to successfully develop, test, and bring a new prescription drug to market, according to a study by Tufts Center for the Study of Drug Development. In addition to being costly, the process of drug development is also risky –just 12 percent of drugs entering clinical development become approved, based on Tufts' analysis of 1,442 experimental drugs.

Patients in many of the countries referenced by the MFN have access to far fewer new medicines than patients in America.

According to a study by the Galen Institute, patients in the U.S. had access to nearly 90 percent of new medical substances launched between 2011 and 2018. By contrast, other developed countries had a fraction of these new cures. Patients in the United Kingdom had 60 percent of new substances, Japan had 50 percent, Canada had 44 percent, and Spain had 14 percent.

The fact is, if the U.S. had the same price controls utilized by foreign countries, we would have many fewer innovative cures available to patients today, as noted in a February 2018 report released by the president's Council of Economic Advisors. As the report stated:

"If the United States had adopted the centralized drug pricing policy in other developed nations twenty years ago, then the world may not have highly valuable treatments for diseases that required significant investment."

The MFN will threaten millions of high-paying jobs

Not only will the MFN harm American patients in the form of fewer treatments and worse health outcomes, it also will threaten America's position as a leader of high-paying pharmaceutical manufacturing jobs.

Medical innovation is a key driver of job creation and the American economy. Every year, manufacturers invest more than $100 billion in the U.S. economy, which directly supported more than 800,000 jobs as of December 2017. When accounting for indirect and induced jobs, this innovation supports more than four million jobs across the country.

This is a substantial contributor to the U.S. economy – creating an estimated $1.1 trillion in annual economic output. For context, national GDP in the U.S. at the end of 2017 was $19.7 trillion, according to the Bureau of Economic Analysis.

Pharmaceutical jobs are also high paying – the average compensation is over $126,000 – more than double the $60,000 average compensation in the U.S.

These high-paying jobs can be found across the country. For instance, in Florida there are an estimated 25,000 pharmaceutical manufacturing jobs and the industry directly and indirectly supports more than 130,000 jobs. In Pennsylvania, there are over 46,000 manufacturing jobs and more than 250,000 jobs directly or indirectly supported by the industry.

Politicians on both sides of the aisle routinely call for the creation of more high-paying manufacturing jobs. We should be pursuing policies that help create more of these jobs, rather than policies that threaten existing jobs.

The MFN will move America one step closer to a government run healthcare system

The MFN would move the U.S. closer towards socialized medicine by placing price controls on Medicare Part B.

Progressives are pushing proposals to expand the power that government has over the healthcare system like "Medicare for All" and the public option. These proposals also heavily rely on price controls on the healthcare system.

Similar policies to the MFN can be found in the proposals pushed by progressives in Congress. For instance, the most favored nation plan can be found in Medicare for All legislation proposed by Vermont Senator Bernie Sanders. A variant of this proposal was also included in House Speaker Nancy Pelosi's H.R. 3, legislation that forced manufacturers to accept government set prices or face a 95 percent excise tax.

If the left had their way, government would control the entire healthcare system, an outcome that would also result in significant tax and spending increases and the loss of existing coverage for millions and millions of Americans.

It would lead to health care rationing, which occurs in other nations that have socialized health care, such as Canada and the United Kingdom. In the UK for instance, there was a shortage of 10,000 doctors and 43,000 nurses in 2019, with 9 in 10 managers in the National Health Service saying that having too few doctors and nurses presents a danger to patients. At any one time, 4.5 million patients were waiting for hospital care.

The MFN Utilizes Obamacare to Circumvent Article I of the Constitution

We are also concerned that the MFN is being proposed through CMMI, an agency created by Obamacare. The agency was created with the goal of increasing efficiency in healthcare programs by conducting demonstrations in new health care delivery and payment for Medicare, Medicaid, and the Children's Health Insurance Program.

The MFN demonstration is mandatory and being conducted across the entire country, so the proposal is a major policy change that is being proposed to circumvent Congress.

As such, CMMI and the MFN violate Article I of the Constitution, which gives Congress, not the executive branch the authority to make law. CMMI is not under the normal appropriations process and automatically receives $10 billion every decade in perpetuity. As a result, Congress is limited in its ability to conduct routine, necessary oversight.

Rather than utilizing CMMI to push broad policy changes on the country, CMS should work with lawmakers to enact long-term policy changes to lower prescription drug costs through competition, innovation and the removal of unnecessary regulatory burdens.

Conclusion

We urge you to withdraw the MFN interim final rule. This proposal would adopt foreign price controls that will harm America's role as a leader in medical innovation. It will imperil the next generation of cures and threaten high-paying manufacturing jobs across the country.

It fails to stop foreign countries freeloading off American R&D and will instead move the U.S. closer to a system of government-controlled healthcare, with the rationing and lack of innovation we see in other countries. The MFN rule also circumvents the Congress' constitutionally delegated role of making laws.

Sincerely,

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