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Submitted Electronically Via Federal Rulemaking Portal: www.regulations.gov

Attention: CMS-5528-IFC
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Most Favored Nations (MFN); Interim Final Rule

To Whom It May Concern:

The U.S. Chamber of Commerce ("the Chamber") submits these comments to the Department of Health and Human Services' ("HHS") Center for Medicare and Medicaid Services ("CMS") in response to the Interim Final Rule with comment period on a Most Favored Nations Model ("IFC"). This IFC implements the Most Favored Nation ("MFN") Model, a new Medicare payment model under section 1115A of the Social Security Act ("the Act"). According to the Department, the MFN Model would test whether more closely aligning payment for Medicare Part B drugs and biologicals (hereafter, referred to as ''drugs'') with international prices and removing incentives to use higher-cost drugs can control unsustainable growth in Medicare Part B spending without adversely affecting quality of care for beneficiaries.

I. OVERVIEW

The Interim Final Rule was published in the Federal Register on November 27, 2020 by the Department of Health and Human Services ("HHS" and "the Department").[1] The MFN Model detailed in the IFC focuses on a select cohort of separately payable Medicare Part B drugs that initially includes 50 single source drugs and biologicals (including biosimilar biological products) that encompass a high percentage of Medicare Part B drug spending. The MFN Model would require mandatory participation for hospitals, physician offices, and Ambulatory Surgery Centers. Participants in the MFN Model would include all providers and suppliers that participate in the Medicare program and submit a separately payable claim for an MFN Model drug with limited exceptions.

[1] Interim Final Rule with comment period, 85 Fed. Reg. 7,6180-7,6259. (November 27, 2020) (to be codified at 42 C.F.R. pt. 513) [hereinafter referred to as the "IFC"] https://www.govinfo.gov/content/pkg/FR-2020-11-27/pdf/2020-26037.pdf

According to the Department, the MFN Model detailed in the IFC would:

- Calculate the payment amount for MFN Model drugs based on a price that reflects the lowest per capita gross domestic product-adjusted (GDP adjusted) price of any non-U.S. member country of the Organisation for Economic Co-operation and Development (OECD) with a GDP per capita that is at least sixty percent of the U.S. GDP per capita, based on available data;
- Make an alternative add-on payment for MFN Model drugs that would remove or reduce the financial incentive to prescribe higher-cost drugs more frequently; and
- Reduce beneficiary cost sharing on MFN Model drugs.

The Chamber is committed to working with the Administration and members of Congress to strengthen and further reform our nation's health care system through regulatory and legislative action. The Chamber has long supported efforts to strengthen overall fiscal integrity of public programs such as Medicare including other demonstration projects and payment models put forth by the Center's for Medicare and Medicaid Innovation ("CMMI"). We support the Department's stated goal behind the MFN Model of "reducing Medicare expenditures while improving or maintaining the quality of beneficiaries' care."[2] Although we support the goals detailed in the preamble, the MFN Model will not accomplish them.

Instead, we have policy concerns around the significant detrimental ramifications which would result from the IFC. Additionally, the Chamber has significant operational and procedural concerns around the implementation timeline and regulatory analysis. Finally, we have legal concerns that the MFN Model exceeds the statutory authority given to CMMI to conduct demonstrations. The Chamber believes that the IFC improperly and illegally exceeds the authority given to the Centers for Medicare and Medicaid Innovation to roll out pilot programs with by imposing a mandatory change on an entire class of providers and beneficiaries.

II. POLICY CONCERNS & SIGNIFICANT DETRIMENTAL RAMIFICATIONS

Implementation of the MFN Model contained in the IFC would have significant detrimental ramifications. Specifically, we are concerned that these policy changes would: disrupt patient access; detrimentally impact provider revenue and result in economic ramifications across the country during a global pandemic; and harm the ability of private companies to innovate and develop life-saving medications.

A. DISRUPTION OF PATIENT ACCESS

The preamble to the IFR plainly states that the MFN Model may have serious detrimental impacts on patient access. According to an analysis by CMS, upon implementation on January 1, physicians "will need to decide if the difference between the amount that Medicare will pay and the price they must pay to purchase the drugs would allow them to continue offering the drugs."[3]

[2] IFC at 76,231
[3] IFC at 76,326.

In analyzing the savings that the MFN Model would provide, the Department acknowledges that: "a portion of the savings is attributable to beneficiaries not accessing their drugs through the Medicare benefit, along with the associated lost utilization."[4] This includes elimination of up to 19 percent of Part B drug utilization due to lack of access by 2023.[5]

Additionally, the MFN policy would endanger access to the newest innovative medicines. The White House Council of Economic Advisors (CEA) report examining the impact of the price controls found that capping the price of medicines could result in as many as 100 fewer medicines being introduced in the United States over the next ten years.[6] By decrease access to life-saving medicines, CEA estimates that price controls would reduce the average Americans' life expectancy by four months. At time when Americans eagerly await effective treatments and vaccines for COVID-19, it is critical that the government reject policies which could undermine access at a time when the healthcare system is already under severe duress due to the COVID-19 pandemic.

Furthermore, many of the countries against which the United States would calculate the payment for drugs suffer from considerable delays in access to medicines. For example, while 87 percent of new medicines are available within three months in the U.S., only 63 percent of those medicines are available in Germany and patients suffer a 10-month delay in access.[7] Likewise, only 59 percent of new innovative medicines are available in the United Kingdom, with an 11-month delay in access. At worst, the MFN model could lead the U.S. down the path of New Zealand and Korea where only 20 percent and 35 percent of new medicines are available, and patients suffer access delays between 28 to 30 months. As COVID-19 cases surge across the country, the Chamber believes the MFN model would have detrimental effects on patient's access to life-saving treatments and vaccines in the United States.

B. Detrimentally Impacts Providers and Economies During a Global Pandemic

The Department fails to acknowledge the economic impact on providers and by extension our country, as many of the largest employers in communities are hospitals, which would see a cut in reimbursements by an average of 65 percent when fully phased in.

Additionally, this mandatory, nationwide model is being hastily deployed during the height of a global pandemic when hospitals and the health care system are already stretched beyond capacity. Adding this new model would only add to the unprecedented challenges being faced by health care providers and patients across the country.

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[4] IFC. at 76,327.
[5] IFR at 76,327, Table 11
[6] https://www.whitehouse.gov/articles/house-drug-pricing-bill-keep-100-lifesaving-drugs-american-patients/#:~:text=House%20Drug%20Pricing%20Bill%20Could%20Keep%20100%20Lifesaving%20Drugs%20from%20American%20Patients,-December%203%2C%202019&text=The%20Trump%20Administration%20is%20committed,H.R.&text=CEA%20also%20estimates%20that%20by%20limiting%20access%20to%20lifesaving%20drugs%2C%20H.R.
[7] https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/Comparison-of-Availability---All-New-Meds---112520.pdf

Furthermore, the MFN model would jeopardize the biopharmaceutical industry's contributions to the U.S. economy. The United States biopharmaceutical industry directly employs more than 811,000 individuals.[8] An additional 3.2 million jobs are indirectly supported by biopharmaceutical industry and worker spending. In addition to supporting job creation, the industry drives economic growth by contributing $625 billion to U.S. gross domestic product (GDP) and supporting more than $1.1 trillion in total economic output. The MFN model would endanger the biopharmaceutical industry's support of the U.S. economy at a time when both the U.S. and global economies have been significantly, adversely impacted by the global pandemic.

C. Negatively Impacts the Ability of Private Businesses to Innovate and Develop Life-Saving Medications

The MFN model would implement harmful price controls that would undermine innovative companies' investment in the next generation of treatments and cures. America's leadership in biopharmaceutical innovation is rooted in its system of market-based pricing for medicines and long-standing respect for intellectual property (IP) protections. The U.S. free market system and strong IP framework have enabled the private sector to thrive by creating incentives for innovators to invest in the research and development (R&D) of new medicines in the United States. Data supports the success of the United States model. For example, between 2001 and 2010, firms in the United States accounted for 57% of new medicines approved globally, while Germany and the UK accounted for only 6% and 8%, respectively.[9]

Furthermore, the United States system supports industry's robust investment in clinical research. While the United States represents only 4% of the global population, U.S. citizens accounted for 31% of clinical trial participants.[10] Clinical trials are not only a critical part of the scientific research process, but they provide patients with access to the latest medicines for diseases for which no therapies exist or for which the therapies can be improved. Price control policies would undermine the success of our free-market system and the resulting IP-driven innovation.

Additionally, foreign countries who have implemented harmful price controls predict what would happen to U.S. innovation should the Administration move forward with the MFN policy. In 1990, biopharmaceutical R&D investment in Europe was 45% higher than the investment in the United States.[11] Following two decades of government price controls, biopharmaceutical R&D shifted to the United States, with over 16% more invested in the U.S. than in Europe in 2017. Implementing foreign price controls would cede leadership in biopharmaceutical innovation at a time when U.S. industry is delivering urgently needed solutions to the COVID-19 pandemic. A recent report by NDP Analytics suggests that between 2008-2016 biopharmaceutical investment in Asia grew by 19.3% annually in Asia, compared to only 3.8% per year during the same time period. As markets around the world seek to attract great biopharmaceutical investment and strengthen their domestic biotechnology industry, the United States must reject policies like the MFN model that would erode the United States' leadership in

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[8] : https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/D-F/Economic-Impact-US-Biopharmaceutical-Industry-December-2019.pdf

[9] https://assets1c.milkeninstitute.org/assets/Publication/ResearchReport/PDF/CASMIFullReport.pdf

[10] 2015-2016 Global Participation in Clinical Trials Report (fda.gov)

[11] https://catalyst.phrma.org/learning-from-history-how-government-price-setting-and-other-anti-innovation-policies-negatively-impact-biopharmaceutical-rd

biopharmaceutical innovation and undermine the investment in life-saving treatments during the global pandemic.

III. OPERATIONAL AND PROCEDURAL CONCERNS

Further, the Chamber has significant operational and procedural concerns around the untenable implementation time-table, lack of appropriate stakeholder review and comment, and the lack of meaningful regulatory impact analysis.

A. UNTENABLE TIME-TABLE OF A SIGNIFICANT AND COMPLEX RULE

We continue to urge HHS and other Departments to remain mindful of the importance of public comment and the critical regulatory process formalities that ensure meaningful public input. The scope of the IFC is vast, as the Department itself states:

> "[T]his rulemaking is ''economically significant'' as measured by the $100 million threshold and hence also a major rule under the Congressional Review Act."[12]

The application itself is substantial—nationwide and mandatory. Further, the 60-day comment period deadline closed **after** the effective date of the rule. This is not only insufficient, but it is legally impermissible as multiple courts have now ruled. Stakeholders have hardly been given the time to adequately analyze the impact of this proposal much less prepare for its near immediate implementation during the global pandemic.

While the Department is correct in stating that "section 553(b)(B) of the Administrative Procedure Act and section 1871(b)(2)(C) of the Social Security Act authorize an agency to dispense with normal rulemaking requirements for good cause if the agency makes a finding that the notice and comment process is impracticable, unnecessary, or contrary to the public interest."[13] We disagree with the rational put forth by the Department for why such authority can be utilized in this context, which is based on three assertions:

- High drug prices in the U.S. have serious economic and health consequences for beneficiaries in need of treatment.
- With more than 25 million Medicare beneficiaries living at or below 200 percent of the Federal Poverty Line, 99 high drug prices could lead to improper medication adherence or skipped treatment.
- Furthermore, the COVID–19 pandemic has led to historic levels of unemployment in the U. S., with both the unemployment rate and number of unemployed persons remaining nearly twice their February (pre-pandemic) numbers.[14]

We believe this evaluation fails to consider the tremendous impact the MFN model would have on economies around the country as many of the largest employers in communities are hospitals.

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[12] IFC at 76,235
[13] IFC at 76, 248
[14] IFC at 76, 249

These employers would see a cut in reimbursements as a result of this rule by an average of 65 percent when the MFN model is fully implemented.[15]

Additionally, this mandatory, nationwide model is being hastily deployed during the height of a global pandemic when hospitals and the health care system are already stretched beyond capacity. Adding this new model would only add to the unprecedented challenges being faced by health care providers and patients across the country.

Further, several judges have agreed with plaintiffs filing lawsuits on procedural grounds that the government did not have authority to dispense with normal rulemaking in this instance. As noted above, COVID-19 therapies/vaccines are excluded from the model which shows that the pandemic is not a reason for moving this forward quickly. To be clear, those therapies that are available to combat the pandemic are not even included in the model and for good reason. The Administration has acknowledged that the model will inappropriately limit access to needed therapies.

IV. LEGAL CONCERNS: EXCEEDS THE CMMI'S SCOPE AND STATUTORY AUTHORITY

The Chamber believes that the IFC improperly and illegally exceeds the authority given to the Centers for Medicare and Medicaid Innovation to roll out pilot programs with by imposing a mandatory change on an entire class of providers.

A. EXCEEDS CMMI SCOPE: CIRCUMSTANCES THAT PERMIT NATIONWIDE APPLICATION ARE NOT SATISFIED

The Department sites the authority for issuing the IFR's MFN Model as within the scope of creating a new Medicare payment model under Section 1115A of the Social Security Act. However, the breadth in scope and geography exceed parameters for CMMI's payment model authority for several reasons.

First, while it is true that the Secretary has the authority to test a model nationwide, certain qualifications and conditions must be met. These qualifications and conditions are indicated in two separate places on the Department's website:

> While Congress has provided the Secretary of Health & Human Services (HHS) the authority to expand the scope and duration of a model through rulemaking, including the ***option to test a model nationwide. To exercise this authority***, the Secretary and CMS actuaries must review the CMS evaluations and determine that a ***model must either reduce spending without reducing the quality of care***, or improve the quality of care without increasing spending, and ***must not deny or limit the coverage or provision of any benefits.***[16] [emphasis added]
>
> Section 1115A of the Social Security Act established CMMI within CMS to test innovative payment techniques and service delivery models. For successful models, the law states that "the Secretary may, through rulemaking, expand (including

[15] https://www.aha.org/press-releases/2020-11-20-aha-statement-most-favored-nation-model-interim-final-rule
[16] https://innovation.cms.gov/about

implementation on a nationwide basis) the duration and the scope of a model that is being tested…***to the extent*** determined appropriate by the Secretary, if—

1. The Secretary determines ***that such expansion*** is expected to—
   (A) reduce spending under the applicable title without reducing the quality of care; or
   (B) ***improve the quality of patient care*** without increasing spending;
2. The Chief Actuary of the Centers for Medicare & Medicaid Services certifies that such expansion would reduce (or would not result in any increase in) net program spending under the applicable titles; and
3. The Secretary determines that such expansion would ***not deny or limit the coverage or provision of benefits*** under the applicable title for applicable individuals."[17] [emphasis added]

While the IFC indicates that the CMS Office of the Actuary (OACT) estimates savings, it further qualifies those assertions: "We note that there is much uncertainty around the assumptions for both the OACT and the Assistant Secretary for Planning and Evaluation estimates and refer readers to section VI of this IFC for a more complete discussion of potential impacts of the MFN Model." Looking more closely at Section VI, caveats seem to abound. Furthermore, many of these caveats indicate a reduction in utilization, which contradicts the required determination that the expansion improve the quality of care and not deny or limit the provision of benefits.

> While there are significant savings as a result of this model, a portion of the savings is attributable to beneficiaries ***not accessing their drugs*** through the Medicare benefit, along with the associated ***lost utilization***.[18]
>
> To cover the spectrum of possible outcomes, the impact of a greater behavioral response from manufacturers and MFN participants was also considered. Under this scenario, … the overall impact of the model would be a substantial savings to Medicare of $286.3 billion, but ***nearly half of that impact would be due to lost utilization***.[19]
>
> The behavioral responses of manufacturers, providers, suppliers, and beneficiaries to the MFN Model are critical to estimating its impact on key outcomes. Lack of direct experience with policies such as the MFN Model, however, results in ***great uncertainty*** for making these behavioral assumptions.[20] [emphasis added]

This hardly qualifies as the Secretary's determination "that the expansion will not reduce the quality of care and not deny or limit the coverage or provision of benefits."

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[17] https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/CMMI-Model-Certifications
[18] IFC, 76,237
[19] IFC at 76, 239
[20] IFC at 76,240

B. MANDATORY APPLICATION IS IMPROPER

Not only does the Chamber dispute the IFC's satisfaction of qualifiers and criteria for applying a pilot or model nationally,[21] we also dispute the mandatory application of the model.

> CMS believes that the MFN Model cannot realize its full potential in spending reductions for Medicare and its beneficiaries and improvement in quality of care without ***broad*** participation of Medicare participating providers and suppliers through a nationwide scope.

Broad participation is hardly the same as mandatory nationwide participation. A mandatory nationwide reimbursement revision far exceeds the scope of a demonstration project.

V. CONCLUSION

We urge HHS, CMS and CMMI to withdraw this model immediately to avoid the significant harm that would come to providers, patients, and future innovative therapies. The agencies should continue to work carefully, pragmatically and cooperatively with the numerous stakeholders to minimize unnecessary costs for, and burdens on, employers and provide flexibility as employers work to comply with the law. To that end, we urge the HHS to rescind the IFC and explore other policy options to improve access to medications and treatments. We look forward to continuing to work together in the future.

Sincerely,

Katie Mahoney

Katie Mahoney
Vice President, Health Policy
U.S. Chamber of Commerce

[21] "Section 1115A(b) of the Act gives the Secretary discretion in the design of models, including the scope of models. Section 1115A(a)(5) of the Act states that the Secretary may elect to limit testing of a model to certain geographic areas. It follows that the Secretary could similarly elect not to limit testing to certain geographic areas, and instead test a nationwide model."