January 26, 2021

Elizabeth Richter
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Most Favored Nation (MFN) Model - (CMS-5528-IFC)

Submitted electronically

Dear Acting Administrator Richter:

Biocom California writes to offer comments on the Centers for Medicare & Medicaid Services' (CMS) interim final rule Most Favored Nation (MFN) Model ("the rule").

Biocom California is the largest, most experienced leader and advocate for California's life science sector, which includes biotechnology, pharmaceutical, medical device, genomics and diagnostics companies of all sizes, as well as research universities and institutes, clinical research organizations, investors and service providers. With more than 1,300 members dedicated to improving health and quality of life, Biocom drives public policy initiatives to positively influence the state's life science community in the research, development, and delivery of innovative products. California's life sciences industry generates $372 billion in annual economic output, boosts the state's total gross product by $212 billion, supports over 1.4 million jobs, and increases labor income by more than $115 billion per year[1].

Biocom California strongly opposes this rule and urges CMS to abandon this flawed and detrimental policy in its entirety. Our comments below describe four main reasons why we believe the rule should be permanently withdrawn: it misuses the authority granted by the Centers for Medicare and Medicaid Innovation (CMMI), violates the Administrative Procedure Act (APA), would harm the research and development of innovative treatments and therapies, and would ultimately limit patient access to such medicines.

[1] Biocom 2020 Economic Impact Report Databook

Misuse of CMMI's Authority

The rule has been set forth under the authority of CMS' CMMI, which was established by the Affordable Care Act (ACA) to test new methods or demonstration models for reimbursing healthcare services with the purported goal of decreasing costs while maintaining or improving health outcomes within Medicare, Medicaid, or the Children's Health Insurance Program. The demonstration models must address a defined population, specific deficits in care, and cannot impede access to medical care[2]. The ACA permits CMMI to implement models in two phases: a test phase and a subsequent expansion phase after engaging stakeholders in model development.

The rule released by CMS fails to meet these statutory requirements. It intends to implement a new reimbursement mechanism for many physician-administered prescription medicines in Medicare Part B that would eliminate the current average sales price (ASP) methodology enacted by Congress on over 80 percent of Medicare Part B utilization and replace it with a payment amount based on the lowest price paid for the same medicine among 22 countries (with gross domestic product adjustments). It would be mandatory for all providers who bill Medicare Part B, with limited exceptions, and apply nationwide for a duration of seven years. Importantly, it also does not contain control groups, which are necessary for the model to be evaluated for comparative effects.

This massive overruling of Congress' authority used here to re-write statutory provisions and set a new reimbursement policy for Medicare Part B drugs and biologics undoubtedly goes against the ACA's intent to test payment models as it would be applied nationwide and to the vast majority of Medicare Part B providers and their patients. Medicare providers and beneficiaries would be blindly forced into this high-risk reform with unknown impacts. Worse, CMS' own estimates show that many beneficiaries would likely have to change where they receive treatment or lose access to their medicines altogether following implementation of the rule.

Violation of the APA

In addition to disregarding the requirements of the CMMI statute under which it was released, the rule also violates the Administrative Procedure Act (APA),[3] which is extremely concerning. The APA established a process for issuing final regulations, which requires issuing a proposed rule, soliciting comments on that proposal, and receiving and considering all received comments prior to finalizing said rule. Instead, the rule was hastily released as an interim final rule and slated to be implemented only five weeks after being released and several weeks before the comment period closes. Indeed, the rule should have gone into effect on January 1, 2021, 35 days after publication and 26 days before the deadline for stakeholders to provide comments on the rule. This comment period is clearly unreasonable as it does not allow for meaningful consideration of the content of the rule by stakeholders and negates the ability to provide any feedback that would result in changes before it is implemented.

In the short amount of time that the rule was released, every court that has considered the propriety of the process used to issue this rule has concurred that CMS failed to provide for adequate notice to stakeholders. On December 28, 2020, the Northern District of California issued a preliminary injunction

[2] 42 USC 1315a
[3] Pub.L. 79–404, 60 Stat. 237

enjoining the Department of Health and Human Services (HHS) from implementing the rule pending completion of the notice and comment procedures required by the APA[4]. This injunction effectively prevented the rule from going into effect and built upon a previous order from the District of Maryland, which issued a 14-day nationwide temporary restraining order[5] on December 23, 2020. On January 6, 2021, the Court extended the temporary restraining order through January 20, 2021. On December 30, 2020, the Southern District of New York issued a preliminary injunction also enjoining HHS from implementing the rule[6].

Lastly, CMS' justification for the rushed timeline and the waiving of the APA requirements, which invokes hardships on patients resulting from the COVID-19 pandemic, can be easily invalided by the fact that the rule specifically exempts vaccines and therapies that prevent and treat COVID-19 from being included in the model, and the pandemic itself does not justify overruling Congressional authority to overhaul Medicare Part B reimbursement. In addition, HHS, under the previous Administration, had already been working on policies to reduce drug prices and make changes to Medicare Part B, well before the beginning of the pandemic. The "American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs"[7] was released in May 2018, followed by an Advanced Notice of Proposed Rulemaking, which proposed a policy similar to the MFN model, in October 2018[8].

Harm to Innovation

The Unites States produces almost two-thirds of the world's new medicines, which can be traced to regulatory policies that support the development and timely approval of innovative products, strong intellectual property protections, and a free-market and competitive reimbursement environment. On the other hand, European-based companies are investing 40 percent less in research and development (R&D) than their American counterparts, while they were leading by 24 percent before European governments started imposing price controls at the end of the 20th century[9]. It would be irresponsible to assume that importing those same price controls to the U.S. wouldn't have a similar chilling effect on American R&D.

Imposing price controls on the most innovative drugs and reducing biopharmaceutical companies' revenue as a result would discourage investors from funding future R&D projects while also limiting the amount of funding such companies can invest in the innovation ecosystem, including investing in small biotechnology companies. Risk-averse investors would most likely leave the market as a response to dramatically lower returns on investments, which would impair the ability of companies to obtain financing and disproportionally affect small companies. In addition, it would effectively reduce the clinical pipeline and some medicines would never be developed.

[4] Biotechnology Innovation Organization v. Azar, No. 3:20-cv-08603
[5] Association of Community Cancer Centers v. Azar, No. 1:20-cv-03531
[6] Regeneron Pharmaceuticals v. United States Department of Health and Human Services, No. 7:20-cv-10488
[7] HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, 83 FR 22692, May 16, 2018
[8] International Pricing Index Model for Medicare Part B Drugs, 83 FR 54546. October 30, 2018
[9] https://www.nber.org/system/files/working_papers/w12676/w12676.pdf

Economists have found that H.R. 3, the Lower Drug Costs Now Act, legislation that passed in the House of Representatives in December 2019, and would establish a reference pricing mechanism (although different than the one used for this rule and including the Medicare Part D program) would fundamentally disrupt our nationwide life sciences ecosystem and uniquely harm California's companies, which lead the world in the development of life-saving treatments and cures. The study shows that importing foreign price controls into Medicare Part D would cause a 58 percent reduction in industry revenue, significantly reducing the investment capital available for partnerships and licensing agreements with emerging companies, and therefore leading to an 88 percent reduction in new medicines developed by small U.S. biotech companies. It also found that if H.R. 3 had been in effect from 2009 to 2019, California's emerging companies would have brought just three new drugs to market, instead of 25.[10]

The same economists have released preliminary data on the impact the MFN rule would have on innovation and found that if fully implemented, the rule would reduce the U.S. biopharmaceutical industry's commercial revenue from $1.09 trillion to $525 billion, a 52 percent reduction, and lead to a loss of 100,000 industry jobs. Several manufacturers would see revenue reductions larger than their current annual earnings (EBIT). This reduction of approximately $70 billion a year in revenue is 2.5 times the annual $29 billion a year invested in partnerships with biotechnology companies. According to the study, if the rule had been in effect from 2009 to 2019, only 7 new drugs would have been brought to market, instead of 43. California, which alone accounted for 33 percent of investment partnerships and produced 14 of the 43 drugs (28 percent), would be disproportionally affected by this model[11]. In addition, higher risk therapeutic areas would suffer the most because of the high investments necessary and the uncertain economic returns on areas where patient populations are limited and/or the science is less advanced.

Negative Impact on Patient Access to Innovative Medicines

The rule would harm patients in many ways. Not only would it prevent new life-saving drugs from coming to market as explained above, but it would also limit patient access to existing medicines. The reduced payments to physicians that this rule establishes would likely cause financial hardship for providers administrating MFN therapies, which may force them to stop offering such medicines to patients. As a result, patients may be placed on alternative treatments that may not be the most appropriate for them (including lower efficacy, higher risks and higher costs), have to find alternative providers, or may postpone or forgo treatment altogether. CMS' own estimates show that, within three years, nearly one in five Medicare Part B beneficiaries may have no access to drugs covered by the rule, and half of the projected savings to Medicare would be due to lost utilization of these drugs.

Unfortunately, reduced access to medicines available here in the U.S. is very common among the 22 countries that are part of the MFN model. Nearly 90 percent of all new medicines launched since 2011 are available in the U.S., compared to just 50 percent in France, 48 percent in Switzerland, and 46

[10] H.R. 3 – Medicare D Reform Calculating the Impact of International Reference Pricing on California's Biopharmaceutical Innovation Ecosystem, Vital Transformation, Oct. 2019

[11] "MFN – Medicare B Reference Pricing; Calculating the impact of most favored nations on Medicare Part B innovation, as well as the ecosystem impacts on the US and California's biopharmaceutical sector, Vital Transformation, LLC, 2021"

percent in Canada.[12] Price controls also affect how long it takes for medicines to become available to patients once they are approved. Patients in the U.S. can access 96 percent of all new oncology products within two months of launch, while patients in Greece, Ireland, and Italy wait an average of 41, 23, and 21 months, respectively.[13] This is not a model that we want to see replicated here in the U.S.

Biocom is dedicated to supporting biotechnology innovation in California and improving patient access to innovative technologies. Not only would the rule harm both of those missions but it also clearly misuses the authority granted to the federal government to test demonstration models under CMMI and violates the rulemaking process requirements set forth by the APA, as repeatedly stated by judicial courts in the short time the rule was released. Therefore, we ask CMS to permanently withdraw this policy.

However, we will always remain available for open and collaborative conversations with CMS to establish meaningful policies that reduce patient out-of-pocket costs, while supporting the biotechnology innovation that continues to improve and save lives. If you have any questions about these comments, please contact Laure Fabrega, Biocom's Director of Federal Policy and Government Affairs at lfabrega@biocom.org.

Sincerely,

Joe Panetta
President and CEO
Biocom California

[12] PhRMA setting the record on international reference pricing
[13] PhRMA comparison of availability cancer meds