PERSONALIZED MEDICINE COALITION

January 26, 2021

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

Sent electronically

Re: Most Favored Nation (MFN) Model Interim Final Rule with Comment Period (CMS-5528-IFC)

Dear Acting Administrator Richter:

The Personalized Medicine Coalition (PMC), a multi-stakeholder group comprising more than 200 institutions across the health care spectrum, thanks the Centers for Medicare and Medicaid Services (CMS) for the opportunity to comment on the Most Favored Nation (MFN) Model Interim Final Rule (MFN Rule).[i] PMC recognizes that the intent of the MFN Model is to reduce the cost of prescription drugs in the United States by aligning prices for the top 50 Medicare Part B drugs with the lowest available price in economically similar countries. We are concerned that to achieve this goal the MFN Model will reduce patient access to Medicare Part B treatments that are most appropriate for meeting patients' health needs and limit access to health care providers. We therefore urge CMS to withdraw the MFN Rule and instead pursue policies that allow for the more rapid adoption of personalized medicine into the health care system. We believe this approach holds the greatest potential for improving patient outcomes and reducing overall health care costs.

Personalized medicine is an evolving field in which physicians use diagnostic tests to determine which medical treatments will work best for each patient or use medical interventions to alter molecular mechanisms that cause disease. By combining data from diagnostic tests with an individual's medical history, circumstances and values, health care providers can develop targeted treatment and prevention plans with their patients.

Personalized medicine is helping to shift the patient and provider experiences away from trial-and-error care of late-stage disease in favor of more streamlined strategies for disease prevention and treatment. PMC's members are leading the way in personalized medicine and recommend that patients who may benefit from this approach undergo appropriate testing and tailored treatment as soon as possible during their clinical experiences.

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Statement of Neutrality

Many of PMC's members will present their own responses to CMS and will actively advocate for those positions. PMC's comments are designed to provide feedback so that the general concept of personalized medicine can advance and are not intended to impact adversely the ability of individual PMC members, alone or in combination, to pursue separate comments with respect to the MFN Model Interim Final Rule.

Flawed Model Development Process

PMC submitted comments to CMS in 2017 in response to a request for information on "New Directions" for the Center for Medicare and Medicaid Innovation (CMMI).[ii] In our comments, we expressed concern that poorly developed or vetted large-scale payment and service models could negatively impact care delivery. We were encouraged that CMS was looking to establish guiding principles to provide reasonable assurance that CMMI demonstrations would proceed at a more measured pace with an eye toward enhanced transparency and broader stakeholder. PMC is therefore concerned with CMS' decision just three years later to proceed with the MFN Model development through CMMI without a standard notice and comment period for rulemaking. CMS should have offered stakeholders a meaningful opportunity to provide feedback before the model was to go into effect, as required by the Administrative Procedures Act (APA).

The statute that created CMMI states that "the Secretary shall select models to be tested from models where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures."[iii] We believe that imposing a nationwide, mandatory model that has not been through the required notice and comment period exceeds CMMI's authority and it unnecessarily puts many Medicare beneficiaries at risk of losing access to their medications and providers. Given the magnitude of changes to Medicare included in the MFN Rule, the significant negative impact on beneficiary access to care, the nationwide scope of the demonstration, and its duration, we believe the model should be withdrawn.

Reduction in Patient Access to Personalized Medicines

The number of personalized medicines approved by the U.S. Food and Drug Administration has grown from five in 2008 to 286 in 2020.[iv] PMC's annual analyses of new drug approvals also highlight that personalized medicines have accounted for more than 25 percent of newly approved drugs each of the last six years.[v] Some of the advances we have observed that are beginning to transform patient care include novel cell and gene therapies, additional targeted therapies for rare diseases and infectious diseases, and the first tissue agnostic therapies that act on specific biomarkers present in a patient as opposed to a tumor or cancer type.

The first year of the MFN Model will cover 50 Medicare Part B drugs that represent 75 percent of Medicare Part B spending. As currently designed, multiple drugs that are essential to the delivery of personalized medicine are included on the MFN drug list. These drugs include life-saving targeted

treatments and immunotherapies for diseases most commonly experienced by older adults and other vulnerable Medicare beneficiaries. Subjecting these treatments to foreign reference pricing will reduce their availability and make them more difficult for patients to access. This will not only apply to personalized medicines currently on the drug list included in the MFN Rule, but, importantly, also new treatments that may be introduced into the market each year as CMS annually reviews and updates the list.

CMS' Office of the Actuary (OACT) has determined that the MFN Model would contribute to a significant reduction in patient access to medications placed on the MFN drug list. According to the OACT, after one year into the seven-year demonstration, nearly one in 10 Medicare beneficiaries could lose access to MFN listed drugs. By year three, the OACT estimates that nearly one in five beneficiaries could lose all access to their MFN medications.

Furthermore, the MFN Rule does not highlight the anticipated shifts in drug development that could result from implementation. In their analysis of one legislative proposal aimed at reducing drug costs, the Congressional Budget Office (CBO) wrote that due in part to international reference pricing they would expect to see a $0.5 trillion to $1 trillion reduction in drug maker revenues, leading to 8 to 15 fewer drugs reaching the market in the coming decade.[vi] CBO stated that it is difficult to know in advance the nature of the drugs or to quantify the effect of foregone innovation on health; however a subsequent study examining the impact of the same legislative proposal on a wider range of firms involved in drug development implied that the reductions in drugs would occur in hard-to-test conditions requiring long outcomes trials, like Alzheimer's disease, cardiovascular disease and rare diseases.[vii]

The OACT further states that beneficiaries may "experience access to care impacts" by being forced to use an "alternative therapy that may have lower efficacy or greater risks, or postponing or forgoing treatment." PMC is concerned that this will worsen patient health, result in preventable hospitalizations and even increase mortality rates. Instead of implementing the MFN Model, we believe that personalized medicine can help CMS deliver affordable and efficient health care that puts patients first. This can only happen, however, if models of care allow providers to have the treatments that will be most effective for their patients and provide them with the flexibility required to maximize individual patient outcomes by tailoring care to a patient's genetics and other unique factors.

Limited Reimbursement to Providers

Reimbursement for providers on drugs included in the MFN Model would no longer be based on average sales price (ASP) but, instead, on MFN pricing that would blend ASP and GDP-adjusted international prices in the first years of the model. The MFN price may vary from quarter to quarter based on international prices and which country may have the lowest price. This will make Medicare Part B reimbursement unpredictable and difficult for providers to acquire MFN medications at a price below or equal to what they will be reimbursed.

The MFN Model also changes the reimbursement structure for Medicare Part B drugs by replacing the current ASP+ 6 percent rate with the MFN drug price plus a flat add-on payment of $148.73. This add-on payment is intended to cover administrative costs such as purchasing, storage, and stocking of

medications. CMS acknowledges that the new flat add-on will have uneven results, and that some provider specialties will see significant reductions in revenue from the add-on fee for Part B drugs on the MFN drug list. For example, neurologists will see an average reduction of 21 percent, medical oncologists will see an average reduction of 13 percent, hematologist/oncologists will see an average reduction of 8 percent, and infectious disease physicians will see an average reduction of 10 percent. Many of these specialties employ personalized medicine strategies routinely in their patient care plans.

According to the OACT, if the MFN Model were to go into effect, when reimbursement for the 50 drugs included in the MFN drug pricing list is artificially reduced on the model implementation date, 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." The MFN Rule also acknowledges the burden this shifts onto patients when it states that "If MFN participants choose not to provide MFN Model drugs or prescribe alternative therapies instead, beneficiaries may experience access to care impacts by having to find alternative care providers locally," or "having to travel to seek care from an excluded provider." The reimbursement restrictions placed on providers and patients by the new MFN Model may thereby discourage the use of personalized medicine and will likely adversely affect the ability of providers to deliver high quality care to their patients.

Finally, CMS specifically requests feedback in the MFN Rule on whether certain cell and gene therapies should be excluded from the MFN Model. As stated above, PMC opposes the implementation of the MFN Model, including for any cell and gene therapies. These evolving treatment modalities include CAR T-cell therapies, a new type of therapy with an emerging potential for outpatient treatment. While outpatient administration of CAR T-cell therapies can be less costly than inpatient administration, the MFN Model would inhibit the ability of providers to deliver these highly specialized medicines and drive patients to the more expensive inpatient setting.

Conclusion

Thank you for considering our views. We urge CMS to withdraw the MFN Rule. PMC welcomes the opportunity to serve as a resource for you to assist in shaping policies that improve beneficiary access to personalized medicine tests and treatments so that they achieve the goal the Coalition shares with CMS of delivering appropriate, efficient, and accessible health care to patients. If you have any questions about the content of this letter, please contact me at 202-499-0986 or cbens@personalizedmedicinecoalition.org.

Sincerely yours,

Cynthia A. Bens
Senior Vice President, Public Policy

[i] Centers for Medicare & Medicaid Services. *Most Favored Nation (MFN) Model.* November 27, 2020. https://www.federalregister.gov/documents/2020/11/27/2020-26037/most-favored-nation-mfn-model?_cldee=Y2JlbnNAcGVyc29uYWxpemVkbWVkaWNpbmVjb2FsaXRpb24ub3Jn&recipientid=contact-11b930a79e5a48a98a8ee0b217e795da-be91c775cbe147f682f140d181705690&esid=8d801d48-985a-eb11-a2de-000c2959e3d7.

[ii] Personalized Medicine Coalition. *Comments on CMMI New Directions Request for Information*. November 20, 2017. http://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PMC_comments_CMS-CMMI_New_Directions.pdf.

[iii] 42 U.S.C. §1315a.

[iv] Personalized Medicine Coalition. *2020 Personalized Medicine Report: Opportunities, Challenges, and the Future.* http://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PMC_The_Personalized_Medicine_Report_Opportunity_Challenges_and_the_Future.pdf.

[v] Personalized Medicine Coalition. *Personalized Medicine at FDA: The Scope & Significance of Progress in 2019.* http://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PM_at_FDA_The_Scope_and_Significance_of_Progress_in_2019.pdf.

[vi]Congressional Budget Office. *Effects of Drug Price Negotiation Stemming From Title 1 of H.R. 3, the Lower Drug Costs Now Act of 2019, on Spending and Revenues Related to Part D of Medicare.* October 11, 2019. https://www.cbo.gov/system/files/2019-10/hr3ltr.pdf

[vii] Vital Transformations. *H.R. 3 – Medicare D Reform Calculating the Impact of International Reference Pricing on California's Biopharmaceutical Innovation Ecosystem*. October 30, 2019. https://califesciences.org/wp-content/uploads/2019/10/FINAL-Vital-Transformation-HR-3-Analysis-for-CLSA-10.30.19.pdf