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January 19, 2021

Honorable Alex Azar
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
P.O. Box 8013
Baltimore, MD 21244-1850

Re: CMS-5528-IFC – Most Favored Nation (MFN) Model
85 Fed. Reg. 76180 (November 27, 2020)

Dear Secretary Azar and Administrator Verma:

The American Cancer Society Cancer Action Network (ACS CAN), appreciates the opportunity to comment on the Most Favored Nation (MFN) Model interim final rule with comment (IFC). ACS CAN, the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change as well as legislative and regulatory solutions that will reduce the cancer burden.

Approximately 1.9 million new cancer cases are expected to be diagnosed in 2021.[1] Age is one of the most important risk factors for cancer, with one half of cancer cases occurring in people over the age of 65.[2] Thus, cancer and the therapies used to fight the disease, have an enormous impact on the Medicare program. In fact, almost half of all Part B spending on prescription drugs is related to cancer care.[3]

Protecting Cancer Patient Access

Cancer patients and survivors in Medicare rely on drug therapies for lifesaving treatments. Therefore, it is paramount that any new Medicare payment model that seeks to reduce spending on prescription drugs not impede beneficiary access to lifesaving treatments.

Unfortunately, we believe that the MFN Model could actually make it harder for cancer patients to access the drugs they need. Under the MFN Model, 50 Medicare Part B drugs with high annual spending during 2019 will be subject to the new payment structure. [4] The vast majority of these drugs are indicated for use in hematology or oncology. Reimbursement for these drugs will be based on the newly

[1] American Cancer Society, *Cancer Facts and Figures 2021*. Atlanta. American Cancer Society; 2021. Available at https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2021/cancer-facts-and-figures-2021.pdf.
[2] National Cancer Institute, *Age and Cancer Risk*, April 29, 2015, https://www.cancer.gov/about-cancer/causesprevention/risk/age.
[3] Office of the Assistant Secretary for Planning and Evaluation (ASPE). (2016 December). Prescription Drugs: Innovation, Spending, and Patient Access. [Report to Congress]. *U.S. Department of Health and Human Services.*
[4] 85 Fed. Reg. at 76194. Table 2.

created Most Favored Nations Price which is set using a formula that includes the lowest prices set by other select nations. Providers will be reimbursed based on the Most Favored Nations Price.

Unfortunately, this process has the potential to significantly limit beneficiary access to cancer drugs. If providers cannot favorably negotiate with manufacturers on the MFN Model drugs, and do not want to risk financial liability, they may decline to administer those particular drugs and cancer patients would no longer have access to these particular treatments.

We note that while prescription drugs may be approved in different countries, the labeled indication may differ depending upon the regulatory pathway under which the sponsor sought approval. A drug's approved indication has a bearing on the price under which the product will be reimbursed. Comparing a drug's reimbursement from one country to another fails to take this into account.

HHS fully acknowledges that there is "significant uncertainty with these potential effects of the MFN Model" as well as the potential beneficiary access problems:

> 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, 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.[5]

With respect to oncology care – which is predominantly impacted by this model – delays in care can negatively impact a beneficiary's overall health and prognosis. Alternative treatments may not be as efficacious. Postponing or forgoing treatment could result in negative health outcomes and even death, for the beneficiary. And transportation issues could be a further barrier to care.

The Office of the Actuary (OACT) also finds potential access issues. In fact, OACT estimates that the $85.5 billion in estimated savings over the seven years of the Model could largely be attributed to lack of beneficiary access to medically appropriate therapies. Indeed, the Regulatory Impact Analysis, states: "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."[6] According to OACT's own estimates, by the year 2023, 19 percent of the Part B prescription drug decrease could be due to the fact that patients wouldn't have access to their drugs.[7]

Finally, HHS acknowledges that while the model may save money on Medicare spending it could create higher costs in other parts of the Medicare program (e.g., Part D). HHS notes the OACT found that "it is possible that manufacturers could increase prices for non-Part B drugs, which would affect both private market and Part D expenditures, although that potential impact has not been quantified for this estimate."[8]

ACS CAN fully supports generating savings for the Medicare program, but we strongly oppose savings being generated by denying cancer patients access to lifesaving prescription drug therapies. We believe

[5] 85 Fed. Reg. at 76224.
[6] 85 Fed. Reg. at 76237 (emphasis added).
[7] 85 Fed. Reg. at 76237. Table 11.
[8] 85 Fed. Reg. at 76240.

the potential access problems associated with the MFN Model are enough to warrant HHS withdrawing the interim final rule.

The Need for Monitoring

The rule indicates that "CMS will carefully monitor for evidence of these potential effects and conduct beneficiary surveys to assess impacts of the MFN model on beneficiaries. … Given the uncertainty of these impacts, we are unable to quantify these potential effects on the Model."[9] We are disappointed that despite HHS' own recognition of the serious, and potentially deadly, possible outcomes as a result of the enactment of this Model, that HHS chooses not to conduct further analysis before commencing the program to determine what, if any, solutions could prevent or at the very least mitigate these serious outcomes. We do not believe that monitoring and beneficiary surveys provide sufficient beneficiary protection.

If HHS proceeds with the MFN Model, we strongly urge the Department devote significant resources to utilize real-time claims data to ensure that beneficiaries' access to oncology medications is not hindered – including monitoring the extent to which beneficiaries are unable to access their oncology services in a timely manner. HHS should also develop a contingency plan to be triggered in the event that the real-time evaluation reveals beneficiary access problems. Such a plan must clearly identify the action steps HHS will implement in the event that access problems are identified. In developing this plan, HHS should solicit stakeholder comments through an open and transparent comment process. We strongly urge HHS not to proceed with the implementation of the MFN Model until such a contingency plan is developed.

We appreciate HHS' intent to coordinate with the Medicare Beneficiary Ombudsman to ensure that any MFN Model-related beneficiary complaints would be responded to in a timely manner. While we support the Medicare Ombudsman's role, simply coordinating with that office will serve as insufficient beneficiary protection, particularly given the Ombudsman's existing charges and limited resources. New payment models often bring unintended consequences, and while these consequences are not always known, HHS should expect that issues may arise and plan accordingly. If HHS intends to utilize the Medicare Ombudsman as the point of contact for managing complaints, the office will need significantly more resources to respond to beneficiaries in a timely manner.

We are disappointed that the MFN Model does not contain information regarding any beneficiary education and outreach regarding the existence of the MFN Model and potential beneficiary implications. We strongly urge that if HHS decides to proceed with this Model, that it devotes significant resources in the development and implementation of beneficiary educational materials. Given the complexity of the issues, we urge that any communication to beneficiaries be field tested – both with beneficiaries as well as beneficiary advocate groups – to determine the most appropriate way to communicate information to beneficiaries, with particular attention to language and accessibility considerations.

[9] 85 Fed. Reg. at 76244.

Lack of Meaningful Stakeholder Input

Finally, we would be remiss if we did not comment on the fact that the interim final rule has gone into effect before the end of the comment period. Critical to a transparent regulatory process is the ability for stakeholders to provide comment on changes being proposed by the Department. Unfortunately, in the case of the MFN proposal HHS chose to issue an interim final rule instead of a proposed rule. Further, the interim rule went into effect on January 1 – before the end of the comment period – thereby precluding stakeholders from providing meaningful comments or influencing the final rule before it was implemented. We urge HHS to ensure that, in the future, stakeholder input is collected before an interim final rule is published.

Conclusion

On behalf of the American Cancer Society Cancer Action Network we thank you for the opportunity to comment on the Most Favored Nation (MFN) Model. As noted above, we have significant concerns about the Interim Final Rule with Comment period and urge HHS to withdraw the rule. If you have any questions, please feel free to contact me or have your staff contact Anna Schwamlein Howard, Policy Principal, Access and Quality of Care at Anna.Howard@cancer.org or 202-585-3261.

Sincerely,

Lisa A. Lacasse, MBA
President
American Cancer Society Cancer Action Network