CANCER LEADERSHIP COUNCIL

A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS ADDRESSING PUBLIC POLICY ISSUES IN CANCER

December 22, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

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

Dear Administrator Verma:

The undersigned cancer patient, physician and other cancer care provider, and research organizations are writing to urge immediate action by the Centers for Medicare & Medicaid Services (CMS) to withdraw the interim final rule that implements a most favored nation (MFN) model in Medicare Part B. The most favored nation model would have serious adverse effects on cancer patients' access to quality care, according to CMS. The agency describes the impact on patients by suggesting that there will be avoided utilization. In fact, that means that the model will result in no care for some cancer patients. For that reason alone, the MFN model should be abandoned, and the interim final rule withdrawn.

However, there are other serious flaws with the proposal to implement the MFN model. The way in which CMS has proposed the MFN model is fatally flawed in procedural terms because of the lack of a meaningful public comment period, and the MFN model is at odds with the Medicare statute. CMS justifies the rapid implementation of the MFN model because of the coronavirus pandemic, asserting that the model will provide financial relief during the coronavirus pandemic to Medicare beneficiaries with cancer. In fact, the MFN model will only exacerbate obstacles to quality cancer care access that cancer patients are facing during the pandemic. The MFN model as outlined in the interim final rule would be unwise at any time, but to move forward with it during the pandemic is unconscionable.

The MFN Model Will Have Serious Adverse Effects on Access to Quality Cancer Care

The MFN model changes the reimbursement system for Medicare Part B drugs to a so-called model that is mandatory and applies to almost all Medicare Part B providers. The new payment system, which will apply in the first year to 50 drugs that account for about 75 percent of Medicare Part B expenditures, will include a formula that blends the international price (MFN

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price) for a drug and the average sales price (ASP). In its first year, the formula will blend 25 percent of the MFN price for the drug (the lowest international pricing for countries with a gross domestic product per capita that is at least 60% of the US GDP per capita) and 75 percent of the ASP price, moving to a 50-50 split in the second year, then to a 75 MFN-25 ASP split, ending at the full MFN price in the fourth year of the model and beyond.

The interim final rule, in a candid but cynical move, concedes that Medicare Part B providers may find that the reimbursement available through the model will be inadequate to cover the cost of acquiring the drugs that are included in the model. CMS projects that Part B providers will lose revenues due to the reimbursement changes and will in some cases be unable to obtain the drugs that are best for their patients. The impact obviously does not stop with providers; if providers cannot obtain the drugs their patients need, their patients are seriously harmed. The interim final rule flatly states, "Beneficiaries lacking continued availability of their drugs through their current provider or supplier are assumed to seek access outside the model, to obtain their drugs through 340B providers, or to forgo access."

In fact, CMS estimates that within the first three years of the MFN model, there will be a drop of nearly one-fifth in the availability of covered Medicare Part B drugs.

The MFN model would result in major disruptions in cancer care. Thirty-eight of the 50 drugs that will initially be included in the model are used in cancer treatment. If even a fraction of those drugs cannot be obtained by providers under the new reimbursement system, patients will suffer. As the rule concedes, cancer patients may not receive the drug that is recommended for them, or they may be forced to leave the practice where they are being cared for to obtain the drugs they need, or they may simply forgo treatment. The MFN model is not a drug pricing plan; it is a care-rationing plan, with savings realized by denying cancer patients the care they need.

The MFN Model Will Significantly Disrupt the Cancer Care Delivery System

We have focused above on the immediate effects of the model, but the negative effects will keep coming. The impact of the model on cancer care providers will deepen and worsen, as they lose revenue and are unable to obtain drugs for their patients. We fear that, in addition to the immediate negative effects on the quality of cancer care resulting from the changing economics of cancer care practices, offices will be shuttered, and oncologists will leave the profession. This comes at a time when there is a cancer care manpower shortage, and the baby boomer generation is looking at serious shortcomings in the system.

CMS suggests that the aim of the model is to encourage pharmaceutical manufacturers to lower their prices consistent with the reimbursement rates set in the model. The interim final rule does not include an adequate analysis of the impact of possible price reductions on industry innovation and patient access to new therapies. We discuss below the procedural shortcomings of the interim final rule and will return to this issue. However, we stress that the impact of the MFN model on patients is immediate and will persist and intensify over the years. The loss of cancer care professionals will be felt for many years and cannot be easily rectified.

As we urge above and will repeat, the MFN model is at odds with the needs of cancer patients. The interim final rule should be withdrawn.

CMS Proposed the MFN Model Through a Seriously Flawed Process

The agency has proposed and implemented the MFN model through a process that has denied the public a meaningful opportunity to review the proposal and comment on it, a process that is at odds with the standards of the Administrative Procedure Act (APA). According to the APA, agencies must "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments."[1]

The Trump Administration has over some years suggested that it will proceed with some sort of international pricing model in the Medicare program. The Administration published an advance notice of proposed rulemaking regarding an international pricing index plan and has utilized Executive Orders to advance concepts related to international pricing plans. The Trump Administration did not respond to input received on the advance notice of proposed rulemaking and has entertained no meaningful input from the public related to its Executive Orders. Now, 60 days from the end of the Trump Administration, there is a rush to finalize an international drug pricing plan, and that rush has eliminated any meaningful public participation in rulemaking. We are obviously submitting these comments on the interim final rule, but the rule is in effect already and the MFN model will be in place on January 1, 2021. This is not the opportunity to participate in rulemaking that the APA anticipates.

The implications of the MFN model for cancer care are significant, and the model should not be implemented on the basis of the current flawed rulemaking process. The process cannot be fixed before the January 1, 2021, launch of the MFN program. The interim final rule should be withdrawn.

The MFN Model is not A Test; It is a Mandatory New System of Payment

CMS claims that it is testing a new model for Part B drug reimbursement and that the agency is relying on the authority of Section 1115A of the Social Security Act, as added by the Affordable Care Act, to test the model. However, Section 1115A permits the Center for Medicare & Medicaid Innovation (CMMI) at CMS to test payment and service delivery models to determine the effect of the models on program expenditures and the quality of care received by beneficiaries. The statute also requires that CMMI evaluate the models that it tests before expanding the scope of the models.

The interim final rule on the MFN model flouts the requirements of Section 1115A. The MFN model is not a test; it is a mandatory program with sweeping reach. There is no plan to evaluate the MFN model before expansion because expansion is not necessary beyond the original scope of the plan. Also, the agency has already conceded the impact of the model – a reduction in patient access to critical medications – in proposing the MFN model. CMS is not testing the impact of the MFN model on the quality of care received by beneficiaries; the agency admits that it already understands that impact.

[1] 5 U.S.C. § 553(c).

CMS and CMMI do not adhere to the standards of Section 1115A in proposing and launching the MFN model. The interim final rule on the MFN model should be withdrawn.

The MFN Model is at Odds with the Medicare Statute

Under the Medicare statute, reimbursement for prescription drugs covered under the Medicare Part B program is based on average sales prices (ASP) paid for drugs domestically. The ASP reimbursement system was enacted by Congress as part of the Medicare Modernization Act. As we have discussed above, the MFN model is not properly proposed and constructed as a payment and service delivery test under Section 1115A. Instead, CMS is simply substituting a new formula for reimbursement of Part B drugs for the ASP system that is in statute. CMS does not have the Constitutional authority to use an interim final rule to mandate a change to the ASP formula.

The MFN Model will Exacerbate Rather Than Address the Effects of the Pandemic on Cancer Care

Cancer patients, physicians, nurses, pharmacists, other health professionals, and researchers have felt the intense dislocations, strains, and stresses caused by the coronavirus pandemic. Early in the pandemic, cancer patients suffered interruptions in care, cancer screening was nearly halted, and cancer research, from basic to clinical, was slowed or halted. Providers responded promptly by offering as many services as possible through telehealth, and patients responded positively to this change. Through aggressive, persistent, and even creative efforts, providers have retooled their processes and procedures for seeing patients in person, proceeding with treatment, and keeping cancer screening appointments "back on the books." Research efforts, including cancer clinical trials, are resuming and making up lost time.

However, the effects of the pandemic on cancer care and research have not been entirely resolved and will never be entirely eliminated. National Cancer Institute Director Norman Sharpless has detailed the lasting impact of the pandemic on cancer patients and providers, in an article in Science magazine and since then.[2] He has highlighted modeling that suggests there will be excess deaths from cancer due to interruptions in screening and treatment during the pandemic. In addition to the suffering cancer patients will face because of the pandemic, there is a substantial cost associated with the mitigation efforts necessary to restore treatment substantially to pre-pandemic practice.

The pandemic has revealed and exacerbated disparities that have long existed in our health care system. Coronavirus has had a serious effect on medically underserved Americans, whose rate of infection is high and who have poor outcomes from COVID-19. In addition, these Americans may experience in a disproportionate manner the other health care disruptions related to the pandemic. We have a great challenge to manage the effects of the pandemic on cancer care, including the harsh impact on minority and medically underserved communities.

The pandemic is far from over, with the number of cases, hospitalizations, and deaths climbing. Our challenge in helping people with cancer through the pandemic is far from over.

[2] Norman E. Sharpless, COVID-19 and Cancer. Science; 368-1290, June 19, 2020.

Now is not the time to implement a new system of payment for Medicare Part B drugs. The MFN proposal is at odds with the Medicare statute, was not properly proposed with opportunity for public comment, and will adversely affect access to cancer care at a time when the system is already challenged.

We respectfully urge CMS to withdraw the MFN interim final rule without delay.

Sincerely,

Cancer Leadership Council

Association for Clinical Oncology
Cancer*Care*
Fight Colorectal Cancer
Hematology/Oncology Pharmacy Association
International Myeloma Foundation
LUNGevity Foundation
Lymphoma Research Foundation
National Coalition for Cancer Survivorship
Ovarian Cancer Research Alliance
Prevent Cancer Foundation
Susan G. Komen

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