hfma
healthcare financial management association

December 18, 2020

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

File Code: CMS-5528-IFC

Re: **Most Favored Nation (MFN) Model Interim Final Rule (IFC)**

Dear Administrator Verma:

The Healthcare Financial Management Association (HFMA) would like to thank the Centers for Medicare & Medicaid Services (CMS) for the opportunity to comment on the *Most Favored Nation (MFN) Model* Interim Final Rule (hereafter referred to as the Interim Final Rule (IFC)) published in the Federal Register on November 27, 2020. HFMA is a professional organization of more than 56,000 individuals involved in various aspects of healthcare financial management. HFMA is committed to helping its members improve the management of and compliance with the numerous rules and regulations that govern the industry.

Introduction

HFMA would like to commend CMS for its thorough analysis and discussion issues related to drug price inflation for Part B drugs that are separately payable. HFMA members agree that the unchecked increases in drug prices has presented a longstanding issue for Medicare beneficiaries, the Medicare program and providers who provide medically necessary services that reduce morbidity and mortality to Medicare beneficiaries. However, we believe the MFN Model implemented in the IFC does not address the root cause driving ever-increasing drug costs – manufacturer list prices. Furthermore, HFMA members believe that the rule will, as CMS discusses in the IFC, lead to the rationing of care as payment to providers for furnishing drugs covered under the model will not cover their acquisition costs. Finally, we believe that CMS has overstepped its rulemaking authority by creating a national mandatory "payment pilot" for separately payable drugs when it issued the MFN as an interim final rule instead of using the regular rule making process. **Therefore, HFMA members request that CMS withdraw the MFN Model immediately and begin a process of working with impacted stakeholders to develop and propose a payment model pilot that will actually address this root cause of unchecked inflation in drug costs – manufacturer prices. We believe any model that addresses manufacturer prices should not just address separately payable Part B drugs, but all drugs covered by Medicare Parts A, B, C and D.**

The remainder of this letter addresses key concerns of HFMA's members in detail.

We are specifically concerned about the MFN IFC's:

- Adverse Impact to Medicare Beneficiaries and Providers Who Administer High Volumes of MFN Covered Drugs
- Misappropriation of the Center for Medicare & Medicaid Innovation's (CMMI's) Writ Subvert Congress's Authority and Implement a National Payment Cut for Selected Separately Payable Part B Drugs
- Failure to Give Stakeholders an Adequate Notice and Opportunity to Comment as Required by the Administrative Procedures Act (APA)
- Scope and Timing

Below, please find specific comments on the items above.

Adverse Impact to Medicare Beneficiaries and Providers Who Administer High Volumes of MFN Covered Drugs

Based on a review of the data included in the IFC, HFMA members are deeply concerned the MFN rule will harm Medicare beneficiaries and the physicians who care for them by administering drugs included in the MFN. The access issues that CMS's own analysis suggests Medicare beneficiaries will experience related to MFN covered drugs will spill over into Medicaid and the commercial sector. Additionally, changes in market structure as a result of this model – particularly for hematology/oncology, internal medicine and medical oncology will potentially raise costs for commercially insured patients.

Medicare Beneficiaries: The rule will significantly limit Medicare beneficiary access to medically necessary, lifesaving treatments. Based on CMS's own analysis, Table 11 in the IFC finds that beneficiaries will lose access to 19% of the current volume of separately payable Part B drugs covered in the MFN model. An additional 11% of beneficiaries will have to seek those drugs from other providers, likely increasing the time to next available appointment and the distances some Medicare beneficiaries – particularly those in rural areas – will need to travel to access these lifesaving drugs. For the 30% of beneficiaries who either lose access to these drugs completely or have significantly delayed and reduced access to these drugs, this is tantamount to rationing medically necessary care to eligible Medicare beneficiaries in a misguided and counterproductive effort to save money. Furthermore, instead of ameliorating disparities in health equity and outcomes (which is a statutory focus of the CMMI – which are particularly acute in cancer care[1] – this model will further exacerbate disparities in access and outcomes.

Physician Impacts: HFMA members are deeply concerned about the financial impact the model will have on physician practices – particularly independent physician practices with large complements of hematology/oncology, internal medicine and medical oncology specialists, given they are the most frequent prescribers of drugs on the initial MFN list. The COVID-19 public health emergency has

[1] American Society of Clinical Oncology. "Nation's Cancer Doctors Say Bolder, More Aggressive Steps Needed to Achieve Cancer Care Equity," August 12, 2020.

significantly increased the financial fragility of these practices. Almost half of independent physicians in a recent McKinsey and Company survey report that they are concerned about their practice "making it through the COVID-19 challenge."[2] The financial challenges presented by COVID-19 are particularly acute for primary care[3] and oncology practices.[4] We believe that implementing this model will likely be the proverbial "straw that breaks the camel's back," causing many of these practices to either close – eliminating access – or merge with a larger entity that can better withstand the financial losses this model will create for providers who continue to administer the drugs included in the MFN model.

There is strong, recent historical precedent for this. The Medicare Modernization Act (MMA) reduced payments from a profit margin above the wholesale price to an average sales price. As a result, after the MMA went into effect, an analysis of oncology practice expenses by the Community Oncology Alliance and Avalere Health showed Medicare payments covered only 57% of the cost of providing these services." [5] This unsustainable margin trend was exacerbated when commercial health plans adopted a similar payment methodology en masse. The Community Oncology Alliance's 2011 Practice Impact report found that 241 oncology clinics closed between 2006 and 2010. Their 2020 report finds that over the last 12 years, 1,748 community oncology clinics and/or practices have closed, been acquired by hospitals, undergone corporate mergers or reported that they are struggling financially.[6]

HFMA members note that some in the policy community have expressed concern about the impact of physician merger and acquisition activity on healthcare costs[7,8] and commercial premiums.[9] Additionally, private equity funds[10] have recently shown an interest in oncology practices. Given HFMA's commitment to Patient Friendly Billing, price transparency, patient financial communications, financial assistance and account resolution processes that are fair and balanced for all stakeholders, our members are concerned about the impact increased ownership of physician practices may have on consumers due to the potential for increased use of aggressive collection practices once a physician practice is acquired by a private equity firm. [11]

In using the CMMI to implement a policy that is a de facto nationwide payment cut for all Medicare providers who administer one of the drugs included in the MFN model, CMS is repeating the mistakes of the past to the detriment of both Medicare beneficiaries, Medicaid beneficiaries and individuals and families covered by commercial health plans. **Therefore, HFMA members ask that CMS retract the MFN interim final rule.**

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[2] McKinsey & Company, "What's behind physician burnout?"
[3] Abelson, R., "Doctors are calling it quits under the stress of the pandemic," *The New York Times*, November 15, 2020.
[4] Bin Han Ong, M., "COVID-19 vs. community oncology: Flatiron's data provides first damage assessment," The Cancer Letter, May 1, 2020.
[5] Ullman, K., "Oncologist practice consolidation continues," AJMC, December 7, 2012.
[6] Community Oncology Alliance, "2020 Community Oncology Alliance Practice Impact Report," April 24, 2020.
[7] Capps, C., Dranove, D., and Ody, C., "The effect of hospital acquisitions of physician practices on prices and spending," Northwestern University, February 2015.
[8] Cameron, S., Zabinski, D., and Stensland, J., "Congressional request on health care provider consolidation," MedPAC, November 7, 2019.
[9] Neprash, H.T., Chernew, M., and Hicks, A., "Association of financial integration between physicians and hospitals with commercial health care prices," JAMA Internal Medicine, December 2015.
[10] Kickrillo, V.M., "Oncology on the rise: private equity investment in cancer care," VMG Health, August 13, 2019.
[11] Thomas, W., et al., "This doctors group is owned by a private equity firm and repeatedly sued the poor until we called them," ProPublica, November 27, 2019.

Misappropriation of the CMMI's Writ Subvert Congress's Authority and Implement a National Payment Cut for Selected Separately Payable Part B Drugs

The payment methodology for separately payable Medicare Part B drugs is proscribed by Congress in section 1847A of the Social Security Act (SSA). CMS is attempting to implement a mandatory nationwide payment "model" for selected separately payable Part B drugs that compels all providers (with limited exclusions) to participate using the authority granted to it by Congress to test new payment models under section 1115A of the SSA which created the CMMI. HFMA members believe that a more accurate way to describe the "MFN payment model" is the "MFN payment system," given that it will replace the average sales price methodology Congress promulgated under section 1847A of the Social Security Act for all providers who prescribe drugs included on the MFN list nationwide, with limited exceptions.

Section 1115A(a)(1), in describing CMMI states that, "The purpose of the CM(M)I is to ***test*** (emphasis added) innovative payment and service delivery models to reduce program expenditures under the applicable titles ***while preserving or enhancing the quality of care furnished to individuals under such titles***" (emphasis added).

The **MFN is not a "test," but a payment system whose implementation under the aegis of CMMI subverts Congress's intent under section 1847A of the Social Security Act to define a payment system for separately payable Medicare Part B drugs.**

In the MFN IFC, CMS attempts to contort the language of the statue to allow it to implement a mandatory nationwide model as a test. The IFC states:

> *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.*

However, a closer reading of Section 1115A(a)(5)'s text suggests that Congress's intent was not to give CMMI unlimited authority over payment policy for all providers nationwide under the guise of a test. The full provision is included below.

> *(5) TESTING WITHIN CERTAIN GEOGRAPHIC AREAS.—For purposes of testing payment and service delivery models under this section, the Secretary may elect to limit testing of a model to certain geographic areas.*

Instead of abdicating its authority over Medicare and Medicaid payments to CMMI, HFMA members believe that Congress's intent, given the introductory text and the repeated use of "certain," was to make it clear that CMMI had the authority to target specific geographic areas and was not required to use randomized trials of providers.

HFMA members believe this interpretation is supported by the description of the process to expand models in a Phase II. Section 1115A(c) states:

> *(c) EXPANSION OF MODELS (PHASE II).—Taking into account the evaluation under subsection (b)(4), the Secretary may, through rulemaking, expand* ***(including implementation on a nationwide basis)*** (emphasis added) *the duration and the scope of a model that is being tested under subsection (b)*

or a demonstration project under section 1866C, to the extent determined appropriate by the Secretary, if—

(1) the Secretary determines that such expansion is expected to—

(A) reduce spending under 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 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. In determining which models or demonstration projects to expand under the preceding sentence, the Secretary shall focus on models and demonstration projects that improve the quality of patient care and reduce spending.

If Congress had granted CMMI the ability to implement nationwide models compelling all impacted provides to participate in Phase 1, why would the statue include the parenthetical, "(including implementation on a nationwide basis)"? **HFMA members, based on their interpretation of sections 1115A(a)(5) and 1115A(c), do not believe Congress abdicated to CMMI its authority to implement a nationwide payment system that compels mandatory participation, even if that payment system is implemented on a time-limited basis.**

Finally, even if the MFN did qualify as a "test," HFMA members believe it still violates CMMI's Congressionally mandated purpose and would fail the third criteria to expand a model on a nationwide basis. Per section 1115(a)(1), models "tested" by CMMI must reduce expenditures while preserving or enhancing the quality of care for Medicare and Medicaid beneficiaries. Section 1115A(c)(3) states that models may only be expanded if, "the Secretary determines that such expansion would not deny or limit the coverage or provision of benefits under the applicable title for applicable individuals."
CMS's own analysis, as discussed above, finds the MFN will result in savings because of beneficiaries' reduced access to lifesaving medications. **Even if the MFN met the definition of a test, the MFN will result in rationing of care to Medicare beneficiaries and would not qualify to be expanded on a mandatory, national basis. Therefore, HFMA members believe the model must be withdrawn immediately as it violates both Medicare beneficiaries' rights to medically necessary, lifesaving treatments and the clear beneficiary protections Congress established when it created the CMMI.**

Failure to Give Stakeholders an Adequate Notice and Opportunity to Comment as Required by the Administrative Procedures Act (APA)

The APA is designed provide impacted stakeholders an opportunity to comment on regulations, thus acting as a check on the executive branch**. In promulgating the MFN as an IFC, HFMA members believe CMS violated the APA by failing to give impacted stakeholders an opportunity to comment on the model.** CMS clearly anticipated this criticism of its process and attempts to proactively refute this both explicitly and implicitly in the IFC.

Explicitly, CMS attempts to justify the need for an IFC to address rapidly escalating drug prices. In the rule, it cites a litany of well understood data points illustrating that Part B drug costs are rapidly rising and as a consequence are not only increasing spending for the program, but out-of-pocket costs for beneficiaries. HFMA members do not disagree that drug price inflation is a problem for the estimated 19%[12] who lack some form of supplemental coverage, the Program, and providers who administer Part B

[12] Sources of Supplemental Coverage Among Medicare Beneficiaries in 2016 | KFF

drugs. However, this is a longstanding problem that is more than two decades in the making. This is not an emergent issue like the COVID-19 public health emergency that – due to the potential for increased morbidity and mortality if the agency fails to provide certain regulatory flexibilities immediately – justifies setting aside the APA.

And HFMA members believe that CMS's own actions (or lack thereof) over the prior four years prove that this is not an emergent issue. First, in March of 2016, CMS – under the Obama administration – issued a proposed rule for a Part B Payment Model under the authority of the CMMI which was subsequently withdrawn. Second, on October 25, 2018, CMMI – under the current administration – released an advanced notice of proposed rulemaking (ANPRM) for its International Pricing Model (IPI), attempting to address this very issue again. In June 2019, CMS submitted an IPI proposed rule to the Office of Management and Budget (OMB) for review. However, the proposed rule languished at OMB and was never released. If this were truly the crisis CMS portrays it to be to justify ignoring its responsibilities under the APA, HFMA members believe CMS should have moved with greater haste to either finalize the Part B Drug Payment model proposed rule in 2016 using feedback from stakeholders or release a proposed IPI rule in the wake of the ANPRM. Or, if CMS truly believes, as it protests in the IFC, that this is an emergency that rises to the level of necessitating overriding the APA, it should have issued an IFC sooner –with more than 60 days left in the current administration's term.

Furthermore, the IFC attempts to address comments from the ANPRM in an effort to give the implicit impression that it did take into account stakeholder comments in developing the IFC. HFMA members do not believe this brings CMS into compliance with the APA. While the IPI ANPRM and the MFN IFC both address provider payments for separately payable Part B Drugs, the similarities in the two rules stop there. These rules are as different as day and night in the manner in which they impact providers. Key differences include:

1. The IPI ANPRM, while mandatory, was limited to selected geographic area and therefore truly a pilot. The MFN, as discussed above, is a mandatory national payment model that for seven years will subvert Congress's authority to set the reimbursement mechanism for separately payable Part B drugs as delineated in section 1847A of the Social Security Act.
2. The IPI relied on a vendor sourcing model. These vendors would aggregate purchasing power, thus providing a realistic opportunity to use scaled purchasing power to gain price concessions from manufacturers of single source drugs. The MFN, on 60 days' notice, requires tens of thousands of individual providers and hospitals, none of whom have scaled purchasing power, to extract significant pricing concessions from manufacturers whose products have few (if any) viable substitutes.
3. CMS changed the target international reference price from the ANPRM to the IFR, thus moving the goal posts providers with limited negotiating power would need to reach to provide impacted drugs without losing money. The ANPRM envisioned using prices from a set of 16 countries and bringing down Part B prices closer to a target price derived from those countries, hoping to obtain a 30% savings in spending for the targeted drugs. The IFR's target price is the *lowest* price—adjusted for per-capita gross domestic product (GDP)—of any OECD country with a GDP per capita at least 60% of that of the United States.
4. In the IPI, CMS stated that the model would not place restrictions on patient access to separately payable Part B drugs. Now, CMS's own analysis shows that the model will generate savings by rationing care as 19% of Part B drug utilization may be eliminated because Medicare beneficiaries can no longer access the impacted drugs from their providers.

HFMA members believe that a reasonable layperson would understand that these are material differences and that stakeholders – particularly the Medicare beneficiaries whose access to lifesaving medications will be curtailed – should be provided an opportunity to comment on the MFN before CMS moves forward with the rule. Therefore, HFMA members believe CMS should rescind the model.

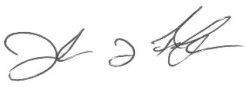
Timing

If CMS elects to continue implementing this illegal policy that will ration medically necessary care to Medicare beneficiaries, **HFMA members believe CMS needs to delay implementation of the model by at least 18 months.** The current 60-day implementation timeframe is insufficient to allow providers to renegotiate their contracts with manufacturers or distributors so that they can acquire these drugs at a cost (if possible) that is in line with CMS's new reimbursement rates. Additionally, HFMA members are concerned that manufacturers will not be willing to provide discounts off of current prices unless they are certain that the model will survive anticipated court challenges and the change in administration. Therefore, we are deeply concerned that if CMS implements this rule on Jan 1, 2021, as put forth in the IFC, those providers who continue to administer the impacted drugs will do so at a significant loss.

HFMA looks forward to any opportunity to provide assistance or comments to support CMS's efforts to control Part B drug price inflation. As an organization, we take pride in our long history of providing balanced, objective financial technical expertise to Congress, CMS and advisory groups.

We are at your service to help CMS gain a balanced perspective on this complex issue. If you have additional questions, you may reach me or Richard Gundling, Senior Vice President of HFMA's Washington, DC, office, at (202) 296-2920. The Association and I look forward to working with you.

Sincerely,



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About HFMA

HFMA is the nation's leading membership organization for more than 56,000 healthcare financial management professionals. Our members are widely diverse, employed by hospitals, integrated delivery systems, managed care organizations, ambulatory and long-term care facilities, physician practices, accounting and consulting firms and insurance companies. Members' positions include chief executive officer, chief financial officer, controller, patient accounts manager, accountant and consultant. HFMA is a nonpartisan professional practice organization. As part of its education, information and professional development services, HFMA develops and promotes ethical, high-quality healthcare finance practices. HFMA works with a broad cross-section of stakeholders to improve the healthcare industry by identifying and bridging gaps in knowledge, best practices and standards.