January 26, 2021

Liz Richter
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Ave. SW
Washington, DC 20201

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

Dear Acting Administrator Richter:

Thank you for the opportunity to submit comments on the most favored nation (MFN) model interim final rule. America’s Essential Hospitals appreciates the Centers for Medicare & Medicaid Services’ (CMS’) efforts to counter the problem of skyrocketing drug prices. Rising drug prices are unsustainable for patients, hospitals, and taxpayers and underscore the urgent need for programs that expand patients’ access to lifesaving drugs and treatment. Essential hospitals are committed to expanding access to affordable, high-quality care for their patients. However, we are deeply concerned about the procedural and substantive deficiencies of the MFN model, which will be detrimental to essential hospitals and their vulnerable patients. The reimbursement consequences of the rule on providers and the resultant effects on patient access to affordable drugs will be especially pronounced as hospitals respond to the continued threat of the COVID-19 pandemic in the midst of record-breaking numbers of hospitalizations and cases. **Due to the substantive and procedural issues with the MFN model, we urge CMS to withdraw the interim final rule.**

America’s Essential Hospitals is the leading champion for hospitals and health systems dedicated to high-quality care for all, including the vulnerable. Our more than 300 member hospitals fill a vital role in their communities. They provide a disproportionate share of the nation’s uncompensated care (UC), and three-quarters of their patients are uninsured or covered by Medicare or Medicaid. The average essential hospital provides $80 million in UC annually, about 10 times more than other hospitals. Essential hospitals provide state-of-the-art, patient-centered care while operating on margins one-third that of other hospitals—2.5 percent on average compared with 7.6 percent for all hospitals nationwide.1 These narrow operating

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margins result in minimal reserves and low cash on hand—circumstances exacerbated by financial pressures related to COVID-19.

We are concerned CMS has not provided the opportunity for public comment and has rushed the implementation of the MFN rule, providing a mere 30 days from the date of the rule’s publication before it took effect. This mandatory seven-year payment model, under the authority of the Center for Medicare and Medicaid Innovation, constitutes a sweeping overhaul of the current drug reimbursement system for Medicare providers. The final rule drastically reduces payment rates to providers for 50 of the highest volume drugs, from 106 percent of average sales price (ASP) to an estimated 45 percent of ASP.

We also are concerned the rule could further burden hospitals in the 340B Drug Pricing Program. In enacting the 340B program, Congress intended to allow covered entities to “stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” Put simply, Congress wrote the law specifically to allow qualifying hospitals to retain 340B savings so they could serve their vulnerable communities. Savings from the 340B program are indispensable to hospitals operating on narrow margins, and the program serves as one of the only remaining buffers between patients and high-cost drugs. As CMS itself acknowledges in the rule, the MFN model could further burden 340B hospitals and restrict patient access to lifesaving drugs. CMS should not have proceeded with implementation of a rule with such far-reaching consequences without first issuing a proposed rule for public comment.

1. CMS unlawfully bypassed the Administrative Procedure Act’s notice-and-comment requirements.

In bypassing a notice of proposed rulemaking, CMS violated the Administrative Procedure Act (APA) and deprived stakeholders of a meaningful opportunity to analyze the impact of the MFN model. Under the APA, federal agencies are obligated to provide an opportunity for notice and comment before issuing a final rule. The notice and comment process includes the issuance of a proposed rule, followed by a comment period, and culminating in the agency’s review and response to the public comments that were submitted. An agency can only bypass these steps when it can demonstrate that issuing a proposed rule is “impracticable, unnecessary, or contrary to the public interest.” CMS omitted a critical step in the rulemaking process and did not show good cause for issuing an interim final rule instead of a proposed rule. Instead of furthering the public interest, CMS’ action hindered the public’s ability to analyze these policies and provide input in shaping the final rule.

CMS’ glaring procedural error is underscored by two recent federal district court decisions halting implementation of the rule. In making the case for a temporary restraining order and a preliminary injunction, plaintiffs must show a reasonable likelihood that they would prevail on the merits of their claim. Two courts have ruled that the plaintiffs in cases challenging the MFN rule have met this bar—in fact, one court found that the plaintiffs are “virtually certain” to succeed on their claim that CMS

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3 Administrative Procedure Act. 5 USC 553.
violated the APA’s notice-and-comment requirements.\(^4\) While the cases still are being litigated, these early decisions in the judicial process are clear indications that CMS has not met the burden of demonstrating why it was necessary to bypass the notice-and-comment process.

CMS attempts to justify its waiver of proposed rulemaking by citing rising drug prices and the COVID-19 pandemic’s economic and health effects, including the rise in unemployment. These arguments, while compelling justification for the need to tackle runaway drug prices, fall flat considering CMS had more than two years in which to issue a proposed rule. The agency floated a concept similar to the MFN model in its October 2018 advance notice of proposed rulemaking (ANPRM) on the international pricing index model. In that ANPRM, CMS noted it would issue a proposed rule in the spring of 2019. CMS drafted a proposed rule and submitted it to the Office of Management and Budget for review in June 2019, giving the agency nearly a year and a half in which to publish a proposed rule. Instead, CMS delayed the proposed rule and, in the last weeks of the administration, issued an interim final rule in its place, putting in place a policy with a projected impact of nearly $100 billion without any opportunity for public input. **We urge CMS to withdraw this flawed rule and work with stakeholders to devise concrete solutions to tackle rising drug prices.**

2. **The MFN model would undermine essential hospitals and their vulnerable patients.**

CMS’ MFN model will disrupt existing drug distribution and reimbursement practices, with inevitable implications for patients’ access to lifesaving drugs. In fact, CMS clearly acknowledges the potential adverse consequences of the model on 340B hospitals. CMS currently reimburses providers for separately payable Part B drugs, which are primarily administered in hospital outpatient departments and physician offices, at ASP plus 6 percent. Since 2018, 340B hospitals have been reimbursed at 77.5 percent of ASP—another unlawful policy that America’s Essential Hospitals has called on the agency to reverse since it was first proposed. Providers purchase Part B drugs from drug wholesalers or manufacturers, administer or dispense them to the patient, and then bill Medicare for the drug. The types of drugs reimbursed under Part B include lifesaving injectable drugs, intravenous cancer drugs, immunosuppressive drugs, and hemophilia blood clotting factors.

Through the MFN model, CMS will tie the prices of 50 drugs to the lowest international price from a group of 22 Organisation for Economic Co-operation and Development (OECD) countries. The lower prices will be phased in over four years, with the fully phased-in MFN prices in effect in years four through seven of the model. Prices in these OECD countries are substantially lower than in the United States due to entirely different market forces, drug negotiation practices in these countries, more aggressive government intervention in setting drug prices, and drug manufacturer pricing decisions. By tying U.S. reimbursement to international levels without putting pressure on drug manufacturers to reduce prices in the United States, CMS places providers at real risk of becoming financially insolvent.

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In CMS’ illustrative list of the lowest OECD price for the top 50 Part B drugs, many drugs are priced at nearly 10 percent of ASP. Once the lower prices are fully phased in, CMS will set the Medicare reimbursement rate based on these international prices, without regard for what the manufacturer charges providers to purchase the drug. The ASP-based reimbursement system Medicare currently uses is intended to make providers whole by approximating the price a provider pays to purchase a drug (by using ASP) and reimbursing a provider at ASP plus an add-on payment to cover additional administrative costs. Under the MFN model, absent aggressive price reductions from drug manufacturers (which are highly unlikely), providers will purchase drugs at prices similar to what they pay today but will be reimbursed at a rate far below ASP. As a result, these providers will incurring substantial losses on these drugs.

These losses will be even more pronounced for 340B hospitals and would deprive them of their ability to receive discounts and realize savings as intended under the 340B statute. The program, codified in section 340B of the Public Health Service Act, was created by Congress to allow covered entities to “stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” Under the 340B program, covered entities can purchase certain outpatient drugs at discounted prices, enabling savings that are critical to the operations of hospitals that fill a safety-net role. The 340B program is structured by statute to provide hospitals discounts for covered outpatient drugs, regardless of the receiving patient’s insurance status. Congress expected various public and private payers would reimburse hospitals at higher rates than the discounts they received from drug manufacturers, which is how hospitals were expected to stretch resources to expand access to medications and other vital services.

By grossly underpaying providers for Part B drugs without exerting pressure on manufacturers to lower their prices, CMS would deprive 340B hospitals of savings on Part B drugs. Thus, the model negates the benefit of the 340B program to hospitals and, ultimately, to patients that benefit from hospitals’ use of related savings. CMS clearly acknowledges these unfavorable outcomes in the rule, noting that 340B hospitals may have “fewer resources available for their 340B program activities” and “will face the same or increased burden from model participation.”

Essential hospitals provide lifesaving drugs and services through programs made possible by their 340B savings. Specifically, savings from the 340B program have enabled essential hospitals to reduce emergency department use, increase access to coordinated care, reduce readmissions, and increase availability of lifesaving prescription drugs to low-income patients. CMS shares the goals of these initiatives, which benefit the health care system more broadly. By withdrawing the model and preserving access to 340B discounts, CMS will ensure essential hospitals can continue to use their limited resources to develop programs that achieve their shared goals.

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3. **The MFN model could cause changes in manufacturer drug prices, affecting 340B ceiling prices and possibly changing 340B discounts.**

The MFN model will affect manufacturer drug prices and, in turn, could drive up the prices providers pay for 340B drugs. CMS’ stated purpose of the model is to reduce Medicare spending on Part B drugs and presumably put downward pressure on drug prices. As manufacturer drug prices change, 340B discounts could change and even become smaller. Under the 340B program, manufacturers cannot charge providers more than a ceiling price. The Health Resources and Services Administration calculates the ceiling price for a given drug as the difference between the average manufacturer price (AMP) for that drug and the unit rebate amount (URA). The URA for a given drug is determined by a statutory formula that uses a drug’s AMP and best price, which is the lowest price offered by the manufacturer to a provider, wholesaler, or other entity. If manufacturers decrease their prices for Part B drugs and these prices are included in the calculation of AMP, this will bring down AMP. It also could change the best price for these drugs if the price offered by a manufacturer on a model drug ends up being the lowest price offered by the manufacturer in the market. Because the URA is either a percentage of AMP or the difference between AMP and best price, a lower AMP would result in a lower URA, which would increase the 340B ceiling price. In this way, 340B hospitals could end up paying more for these drugs, both reducing their savings and affecting vulnerable patients’ access to the drugs.

4. **The MFN model does not address the root causes of rising drug prices.**

Like CMS, America’s Essential Hospitals is concerned about rising drug prices. Essential hospitals, which are on the front lines of treating low-income patients, have firsthand experience with the pressures associated with annual drug price increases. The rising cost of prescription drugs can have serious consequences for patient access and for the health care system at large, especially if patients are unable to afford the very drugs meant to keep them out of the hospital. Report after report confirm this unsustainable trajectory, caused by manufacturers’ unfettered discretion to set prices as they see fit. Year-after-year, drug manufacturers increase drug prices with impunity. A recent study of pharmacy claims found drug list prices doubled in a seven-year span, with associated out-of-pocket costs increased by up to 85 percent. This trend is bound to continue, with prescription drug spending projected to outpace overall health care spending growth through 2026, mainly due to rapid growth in drug prices. Rising drug prices put pressure on patients’ pocketbooks and strain taxpayers and government programs, including Medicare and Medicaid. Essential hospitals directly bear the consequences of such price increases, which put increasing strain on hospital budgets and operating margins.

While the evidence is clear that drug list prices have risen from year to year, CMS provided no evidence of how lowering reimbursement to hospitals would counter this trend. Instead of reducing provider reimbursement, CMS must craft policies that incentivize manufacturers to reduce their prices. The data CMS provides in its impact

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analysis support the proposition that the rule will undermine providers and their patients. In the final rule, CMS acknowledges there is a high degree of uncertainty about the behavioral responses of stakeholders, including manufacturers, in response to the rule. However, CMS concedes providers could lose money on drugs, which would restrict beneficiary access to those drugs, causing beneficiaries to find other providers that offer those drugs or forgo access altogether. Even more troubling is the fact CMS notes manufacturers could increase their international drug prices to protect their profits on drugs worldwide. Given the lack of evidence on how the model would reduce drug prices and the evidence that it will be detrimental to beneficiaries and providers, it is astounding CMS would finalize policies backed by so little research and fraught with so much uncertainty. **We urge CMS to consider the consequences of the MFN model on providers treating the nation’s vulnerable patients, as well as the beneficiaries they serve, and withdraw the rule.**

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America’s Essential Hospitals appreciates the opportunity to submit these comments. If you have questions, please contact Senior Director of Policy Erin O’Malley at 202-585-0127 or eomalley@essentialhospitals.org.

Sincerely,

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President and CEO