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January 25, 2021

Elizabeth Richter
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS–5528–IFC, Most Favored Nation (MFN) Model Interim Final Rule with Comment Period (Vol. 85, No. 229), November 27, 2020.

Dear Ms. Richter:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Most Favored Nation (MFN) model interim final rule with comment period.

The AHA shares CMS' concern about the skyrocketing cost of drugs. Indeed, we frequently reiterate that an unaffordable drug is not a lifesaving drug. America's hospitals rely on innovative drug therapies to save lives every day. High and rising drug prices are putting access and quality of care at risk by straining providers' ability to access the drug therapies they need to care for their patients.

That said, we have very deep concerns about the legality and substance of CMS' MFN rule. The MFN rule's legal infirmities run wide and deep, falling into three major categories: (1) failure to follow proper procedures in promulgating the rule, (2) exceeding statutory authority, and (3) constitutional violations. Its policy deficiencies also are substantial.

Specifically, instead of holding drug companies accountable for their own pricing, this rule drastically reduces reimbursement to hospitals. Instead of directly tackling the skyrocketing cost of drugs, this rule puts hospitals in the untenable position of having to divert resources from other patient care simply to buy the drug therapies they need for their patients. **And instead of enacting thoughtful policies that attempt to lower**



drug prices, this rule puts patients at risk. Indeed, CMS itself states that it expects beneficiaries' access to drugs to be impeded, requiring them to accept less-effective treatments or forgo or postpone necessary care. In addition, the agency makes the breathtaking estimate that, within three years, nearly one in five Medicare Part B enrollees may have no access to drugs subject to the MFN rule.

It is particularly disturbing that CMS has issued this operationally burdensome policy in the middle of a pandemic, with COVID-19 cases and hospitalizations at record levels and with inadequate notice before the model begins. Many of our nation's hospitals are already overwhelmed caring for surges of COVID-19 patients, and this rule completely disregards that reality.

The AHA strongly opposes the MFN rule. We urge CMS to withdraw it immediately and replace it with a serious effort at drug pricing reform.

Our concerns include that:

- The rule is unlawful. The agency failed to follow proper procedures in promulgating it; it exceeds the Health and Human Services' (HHS) Secretary's statutory authority; and it violates the constitutional requirement for presentment, as well as the non-delegation doctrine.
- The rule will not achieve its stated goal of lowering drug prices and patients' out-of-pocket costs. Instead, it will harm patients' access to critical, lifesaving drugs.
- The rule places the entire onus of reducing drug prices on hospitals, rather than on drug companies or on Medicare, thereby placing additional financial burdens on hospitals that are already under-compensated and forcing them to make difficult decisions about the services they offer.
- The MFN model's methodology lacks transparency and includes careless errors and questionable assumptions.

Our detailed comments are attached. If you have any questions concerning our comments, please feel free to contact Roslyne Schulman, AHA director of policy, at 202-626-2273 or rschulman@aha.org.

Sincerely,

/s/

Ashley B. Thompson
Senior Vice President
Public Policy Analysis and Development

LEGAL INFIRMITIES IN THE MOST FAVORED NATIONS RULE

On November 27, 2020, CMS promulgated an interim final rule with comment period¹ implementing the MFN model to pay for the highest cost drugs furnished to Medicare beneficiaries under Part B. CMS invoked section 1115A of the Social Security Act (SSA), which established the Center for Medicare and Medicaid Innovation (CMMI) to “test innovative payment and service delivery models,” as the legal basis for the MFN rule. Under the MFN rule, each of 50 drugs designated by CMS will be reimbursed at the lowest price paid by any of approximately two dozen other countries rather than at the “average sales price” contemplated under the Medicare statute. CMS estimates that this would lower Medicare spending by \$85.5 billion by reducing the amount doctors, hospitals and other providers are paid both for furnishing these drugs as well as their associated handling fees.

The MFN rule was scheduled to become effective immediately;² it applies to drugs provided under Medicare Part B for seven years beginning Jan. 1, 2021. Each year, CMS is required to designate a new list of the 50 highest cost drugs (and the number of drugs subject to the MFN rule is expected to grow because drugs already on the list from a prior year likely will not be removed).

The MFN rule was immediately challenged in at least four federal courts by plaintiffs including the Pharmaceutical Research and Manufacturing Association (PhRMA), the Biotechnology Innovation Organization (BIO) and Association of Community Cancer Centers.³ The plaintiffs sought emergency relief to prevent the MFN rule from going into effect or from being applied to a specific drug. The AHA provided support in the form of a declaration in one of the lawsuits.

On December 23, 2020, the federal district court in Maryland granted the request for a temporary restraining order (TRO) based on procedural violations in promulgating the MFN rule, and on Jan. 6, 2021, that court extended the TRO and requested additional briefing on alleged violations of Section 1115A. Shortly thereafter, the Federal District Court for the Northern District of California issued a nationwide injunction against the MFN rule, largely adopting the reasoning in the Maryland decision. A third case was filed in Federal District Court for the Southern District of New York by Regeneron Pharmaceuticals seeking a preliminary injunction to prevent the MFN rule from being

¹ 85 Fed. Reg. 76,180 (Nov. 27, 2020), available at <https://www.govinfo.gov/content/pkg/FR-2020-11-27/pdf/2020-26037.pdf>.

² CMS found “good cause to waive the notice and comment requirements under section[] 553(b)(B) of the [Administrative Procedure Act] and section 1871(b)(2)(C) [of the Social Security Act] because of the particularly acute need for affordable Medicare Part B drugs now, in the midst of the COVID-19 pandemic.” 85 Fed. Reg. at 76,249.

³ The cases are: *Association of Community Cancer Centers v. Azar*, No. 1:20-cv-03531 (D. Md.); *Biotechnology Innovation Org. v. Azar*, No. 3:20-cv-08603 (N.D. Cal.); *Regeneron Pharm., Inc. v. Azar*, No. 7:20-cv-10488 (S.D.N.Y.); and *Community Oncology Alliance, Inc. v. Azar*, No. 1:20-cv-03604 (D.D.C.).

applied to its drug, EYLEA. The court granted that request based on procedural violations in adopting the MFN rule. On January 19, 2021, the parties in the BIO case sought and were granted a stay of the litigation pending CMS's decision on whether to rescind the rule or adopt it in final.

Because the MFN Rule has been enjoined on only a temporary basis and the BIO case has been stayed until April 23, the courts are likely to have to consider whether the rule should be permanently set aside unless it is withdrawn first by the administration.

Legal Issues. We urge the Administration to withdraw the MFN rule immediately and identify better ways to address the problem of high drug prices that do not place the burden of doing so on providers, do not hurt beneficiaries, and do not pose the legal and policy infirmities described below. The MFN rule's legal infirmities fall into three major categories: (1) failure to follow proper procedures in promulgating the rule, (2) exceeding statutory authority and (3) constitutional violations.

Procedural Defects. The MFN rule is procedurally defective because CMS failed to comply with the requirements of the Administrative Procedure Act (APA) in promulgating the rule. Under the APA, an agency must publish a "[g]eneral notice of proposed rulemaking ... in the Federal Register" and then "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments."⁴ In addition, an agency is required to publish a substantive rule at least 30 days before its effective date, unless it finds good cause to do otherwise and explains that rationale in the rule.⁵

CMS did not provide notice and an opportunity for comment before adopting the MFN rule. Rather, the agency said it had good cause to waive notice and comment. Similarly, CMS did not publish the MFN rule 30 days in advance of its effective date, adopting the same reasoning it used in explaining why good cause existed to forgo notice and comment.

Three courts have concluded that the plaintiffs are likely to succeed on the merits of their claim that CMS lacked good cause to waive notice and comment in promulgating the MFN rule. Indeed, the courts emphasized that it is "virtually certain ... that the government violated the APA's notice and comment requirements."⁶

As the California federal court explained:

⁴ 5 U.S.C. § 553(b), (c).

⁵ 5 U.S.C. § 553(d)(3).

⁶ Order Granting Motion for Preliminary Injunction, *Cal. Life Sciences Ass'n v. CMS*, No. 20-CV-08603 *2 (N.D. Cal. Dec. 28, 2020); Opinion and Order Granting Motion for Preliminary Injunction, *Regeneron Pharm., Inc. v. U.S. Dep't of Health and Human Servs.*, No. 7:20-CV-10488 *27 (S.D.N.Y. Dec. 30, 2020). Plaintiffs challenging the MFN Rule focused largely on the absence of notice and comment and not the failure to delay the rule's effective date.

[I]t seems obvious—based on both common sense and the way the interim final rule is written—that the reasons the government offers for dispensing with the notice and comment requirements are contrived. The real reason is that the current presidential administration is in its waning days and would not have time to enact the policy if it adhered to these requirements. While there’s nothing unlawful per se about rushing to enact policy in the final days of a presidential administration (indeed, it’s a time-honored tradition), executive branch officials may not circumvent clear legal requirements in the eleventh hour to achieve goals they couldn’t accomplish in the normal course.⁷

CMS’ finding of “good cause” to waive notice and comment was based on risks flowing from high drug prices and the effects of the COVID-19 pandemic.⁸ CMS stated that “[h]igh drug prices in the U.S. have serious economic and health consequences for beneficiaries in need of treatment” and “cause beneficiaries “to divert scarce resources to pharmaceutical treatments or skip doses.”⁹ And the agency explained that more than two thirds of the increase in Medicare Part B drug spending was due to an increase in price.

CMS also tried to link high drug prices and the COVID-19 pandemic, saying that “[h]igh drug prices could cause improper medication adherence or skipped treatment,” which would result in “poor clinical outcomes for chronic disease management.” The agency stated that “the 6 million Medicare fee-for-service beneficiaries without supplemental coverage and over 12 million beneficiaries dually eligible for Medicare and Medicaid” require “urgent relief from high drug prices in order to prevent stinting on care and alleviate general financial instability worsened by the COVID-19 pandemic.”¹⁰

As three courts have already found, CMS’ explanation for “good cause” rings hollow. High drug prices do not constitute good cause to eschew notice and comment for many reasons including: CMS was aware of high drug costs for years and failed to act; the agency has contemplated taking action to link Part B drug payments to international prices since 2018; and an agency’s self-imposed delay cannot support a finding of good cause.¹¹

Moreover, health and economic risks to Medicare Part B beneficiaries during the pandemic similarly do not constitute good cause for forgoing notice and comment because, among other things:

⁷ *Cal. Life Sciences Ass’n v. CMS* at *2–*3.

⁸ 85 Fed. Reg. at 76,248–49.

⁹ *Id.* at 249.

¹⁰ *Id.*

¹¹ “Good cause cannot arise as a result of the agency’s own delay, because otherwise, an agency unwilling to provide notice or an opportunity to comment could simply wait . . . raise up the ‘good cause’ banner and promulgate rules without following APA procedures.” *Nat. Res. Def. Council v. Nat’l Highway Traffic Safety Admin.*, 894 F.3d 95, 114-15 (2d Cir. 2018).

- CMS does not suggest that the MFN rule will improve COVID-19 outcomes. The agency says that “high drug prices could lead to improper medication adherence or skipped treatment,” that this “can result in poor clinical outcomes for chronic disease management,” and that “[t]he risk of severe illness from COVID-19 increases with age and the presence of chronic illness.”¹² But CMS does not cite any studies or say that better chronic disease management improves outcomes for Medicare beneficiaries who get COVID-19. Indeed, as the Maryland court noted: “for the proposition, central to CMS’s justification for dispensing with notice and comment, that ‘the COVID-19 pandemic has rapidly exacerbated’ the problem of high drug prices, CMS does not cite to any source at all.”¹³
- While courts consider “a situation of acute health or safety risk,” in evaluating good cause,¹⁴ and the pandemic presents a major health risk, the MFN rule is untethered from improving outcomes for beneficiaries with the COVID-19 virus.
- The MFN rule was not promulgated in response to the conditions of the pandemic as the above discussion of the timing and delays associated with the release of the rule show. In announcing it, neither the President nor CMS suggested that the rule would address the pandemic.
- The MFN rule specifically excludes drugs authorized to treat patients with suspected or confirmed COVID-19.
- There is no evidence to support CMS’ notion that the MFN rule will alleviate the hardships to beneficiaries caused by COVID-19. CMS admits that “does not have a reliable precedent” for the effect of the rule, whose effects are “unusually ... uncertain[.]”¹⁵
- Information CMS presented indicates that the MFN rule will actually add to the beneficiary hardship because many will not obtain their drugs through the Medicare benefit.
- CMS suggests, but did not show, that the MFN rule would prevent potential further economic harms from the pandemic.
- The rule is not a response to a temporary emergency. It will be in effect for seven years.

The MFN Rule Exceeds CMS’ Statutory Authority. As noted, CMS relies on Section 1115A of the SSA as authority for the MFN rule. That section charges CMS with “test[ing] innovative payment and service delivery models” through a two-phase process. In phase I, CMS selects the model “to be tested ... where ... 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.” The selected model is then tested “to determine the effect ... on program expenditures ... and the

¹² 85 Fed. Reg. at 76,249.

¹³ See *Ass’n of Cmty. Cancer Ctrs. v. Azar*, No. 20-CV-3531, 2020 WL 7640818, at *7 (D. Md. Dec. 23, 2020).

¹⁴ *Nat. Res. Def. Council*, 894 F.3d at 115.

¹⁵ 85 Fed. Reg. at 76,237.

quality of care,” and CMS subsequently “conduct[s] an evaluation of each model tested.” Following that evaluation, CMS may expand the model in phase II as long as certain requirements are met and the agency engages in rulemaking.

The MFN rule violates Section 1115A in a number of ways. First, CMS failed to identify any “defined population” with “deficits in care,” as the statute requires. Instead, the MFN rule applies to all Medicare beneficiaries who receive the drugs included on the list and the focus of the rule is on lowering Medicare outlays.¹⁶

The MFN rule also violates the two-phase process contemplated under Section 1115A: first, models are to be selected and evaluated (and certain statutory requirements may be waived, if necessary) and then, tested models may be expanded (without waiver of statutory requirements). Expansion may include “implementation on a nationwide basis,” but only through rulemaking and if data from Phase I show that expansion would meet specific requirements. The MFN rule essentially bypasses Phase I and immediately establishes a nationwide model. And the absence of an independent comparison group precludes CMS from being able to conduct the evaluation required under Section 1115A.

The nationwide, mandatory structure of the MFN rule also conflicts with Section 1115A’s design whereby CMS must include “recommendations ... for legislative action to facilitate the development and expansion of successful payment models” in annual reports to Congress. CMS’ interpretation of Section 1115A would allow a wholesale re-write of Medicare payment systems that were carefully crafted by Congress. As a result, the MFN rule exceeds CMS’ authority and is *ultra vires*.

Constitutional Violations. The MFN rule violates the constitutional requirement for presentment as well as the non-delegation doctrine. The presentment clause bars “unilateral...action that...repeals or amends parts of duly enacted statutes.”¹⁷ The MFN rule has the legal and practical effect of repealing statutes governing Part B through invocation of Section 1115A’s waiver authority to test models under Phase I. This repeal of Part B provisions established by Congress, and replacement of them with the MFN rule, is a violation of the presentment clause. In addition, if a court were to conclude that the MFN rule is authorized by Section 1115A, then that statute itself would violate the non-delegation doctrine because it would give CMS essentially unfettered authority to repeal large portions of the Medicare statute in violation of the separation of powers.

Other Concerns. The MFN rule marks a sea change in the way in which Section 1115A models have been adopted and implemented. It is the first nationwide, mandatory model. It is not a narrow test, but instead makes wholesale changes in the way that Part B pays for drugs. In doing so, the MFN rule is likely to have major impacts beyond lowering Part B drug spending.

¹⁶ 85 Fed. Reg. at 76,181.

¹⁷ *Clinton v. City of N.Y.*, 524 U.S. 417, 439 (1998).

Indeed, CMS itself has admitted that some providers may suffer extreme financial hardship from the MFN rule because they will be reimbursed significantly less than what they pay for critical medicines such as cancer drugs. Some providers will close and their patients will have to deal with the fallout. The agency itself also has made the admission that it expects the MFN rule to impede beneficiaries' access to drugs, requiring them to accept less-effective treatments or forgo or postpone necessary care. In addition, CMS estimates that, within three years, nearly one in five Medicare Part B enrollees may have no access to drugs subject to the MFN rule, and that the reduction in utilization of these drugs will account for half of the rule's projected savings to Medicare.

Pharmaceutical companies believe that CMS' interpretation of Section 1115A would infringe on Congress' authority to regulate foreign commerce and improperly gives the agency power over the patent system by exempting generic drugs from the MFN rule. They further believe it will slash incentives for research and development, resulting in fewer innovative medicines.

Comments on the MFN rule and further briefing in the pending cases are likely to reveal additional harms that may result from the rule's implementation.

THE MFN RULE WILL NOT ACHIEVE THE GOALS OF LOWERING DRUG PRICES OR PATIENT OUT-OF-POCKET COSTS

This rule will not achieve CMS' policy aims of lowering drug prices and patient out-of-pocket costs. Instead, it abdicates Medicare's responsibility for achieving these goals, putting it entirely on the shoulders of hospitals and other providers, and harming beneficiaries in the process. CMS suggests that hospitals and other providers can avoid the cuts imposed by the MFN rule by purchasing covered drugs at lower prices, shrinking the difference between the price providers pay and the rule's substantially lower reimbursement amounts. However, this is not realistic. Hospitals will not be able to negotiate, and manufacturers will not allow them to negotiate, a 65% discount in drug prices. As such, it will be difficult to impossible for hospitals to obtain these drugs at or below the MFN rate. This is especially true at the outset of the policy because hospitals already have purchased these drugs at the current market rate and when the MFN commences in January, they will be reimbursed at a significant discount.

More fundamentally, it is simply impossible for hospitals to renegotiate their drug-purchasing contracts before the MFN rule takes effect, even with the delay imposed by the courts. These contracts are complex, and they take substantial time and resources to negotiate. Re-negotiating those contracts is even more challenging due to the current strain on hospitals' administrative resources during the COVID-19 pandemic. CMS' MFN rule essentially requires that hospital administrators at hundreds of hospitals and health systems – who are already overwhelmed ensuring that they have adequate resources to treat patients, protect their workforce, and roll out the COVID-19 vaccine –

also try to fix the nation's drug-pricing policies on a contract-by-contract basis. This is not something that can or should be done, especially quickly.

CMS also intends the MFN rule to reduce out-of-pocket costs to Medicare beneficiaries by reducing reimbursements for Part B drugs. However, this, again, is misguided. Specifically, even if large cuts to drug prices are achieved, the effects on Medicare beneficiary out-of-pocket costs will be severely limited because the vast majority of beneficiaries, estimated at 91%,¹⁸ have supplemental coverage that alleviates their out-of-pocket costs. This coverage includes Medigap plans, supplemental employer plans, dual Medicaid eligibility and Medicare Advantage plans.

Indeed, rather than lowering drug prices and beneficiary out-of-pocket costs, this rule will cause significant harm to patients by reducing their access to critical and lifesaving drugs. **That is, the rule will force beneficiaries to accept less-effective treatments or skip needed care all together – CMS itself has actually stated that it expects this to occur.** In Table 11 in the rule, the agency's Office of the Actuary assumes savings of 9% in the first year of the model due to beneficiaries losing access to drugs under Medicare. This percentage rises to 14% in the second year and 19% in each of the remaining model years. **Thus, as noted previously, in the last five years of the model, nearly one in five Medicare beneficiaries are expected to lose access to the drugs subject to the MFN rule.**

THE MFN RULE WILL FURTHER HARM ALREADY UNDER-COMPENSATED HOSPITALS

Reimbursement under Medicare Part B is an important revenue source for hospitals, helping fund their provision of extensive outpatient and other clinical services required by Medicare beneficiaries. Yet, it is already substantially below the cost of care. The MFN payment model will make this underpayment worse by substantially reducing reimbursement to hospitals under Medicare Part B even further.

In 2018, Medicare and Medicaid undercompensated hospitals by more than \$56.9 billion combined, and hospitals received payment of only 87 cents for every dollar spent caring for Medicare patients.¹⁹ Hospital outpatient Medicare margins were -13.9% in FY 2018. In addition, negative aggregate margins may obscure the breadth and depth of financial losses associated with Medicare payment for individual hospitals. In 2018, among nearly 5,200 hospitals surveyed by AHA, approximately two-thirds – more than 3,400 hospitals – lost money caring for Medicare patients. Such widespread low margins already make it very difficult for providers to meet emergency demands, such

¹⁸ Freed, Meredith, Anthony Damico and Tricia Neuman, "Medicare Beneficiaries Without Supplemental Coverage Are at Risk for Out-of-Pocket Costs Relating to COVID-19 Treatment," Kaiser Family Foundation, April 14, 2020.

¹⁹ AHA Fact Sheet: Underpayment by Medicare and Medicaid. <https://www.aha.org/fact-sheets/2020-01-07-fact-sheet-underpayment-medicare-and-medicaid>.

as the current public health emergency, or maintain access to care for Medicare patients and their communities over the long term.

The MFN Model will make this under compensation even worse. Currently, Medicare pays for drugs under Part B in a variety of ways, depending on the drug and the provider. However, in general, payment for most non-340B drugs is based on a drug manufacturer's reported average sales price (ASP) plus 6%. However, under the MFN rule, CMS will no longer base its reimbursement rate on the manufacturer's ASP for certain high-cost, separately payable Medicare Part B drugs. Instead, starting in January 2021, CMS will peg Medicare Part B payments for those drugs to the lowest price available in one of almost two dozen other countries. In addition, instead of the 6% add-on payment under the current formula, the MFN rule calculates a flat add-on payment that is the same for every drug to which the rule applies.

By CMS' own estimates, MFN prices average 65% below ASP. Therefore, starting in January, hospitals will, on average, still be purchasing drugs at ASP and yet will be reimbursed at a significantly lower amount. And the model's flat add-on payment will disproportionately harm hospitals, as opposed to the other Part B providers participating in the MFN model, because hospitals tend to care for sicker Medicare beneficiaries and provide more costly drugs for which the flat add-on will equal less than 6% of the ASP of the drug.

Indeed, CMS estimates that – across all categories – the final rule will cut payments by \$64.4 billion (Table 12 in the rule). Hospitals will shoulder a disproportionate portion of that reduction in reimbursement. They account for 34% of allowed charges for separately payable Medicare Part B drugs (Table 1 in the rule), yet, according to an AHA analysis, will shoulder 45% of the overall MFN cut over seven years. This 45% equates to a total reduction of \$29 billion.²⁰

CMS states that 340B hospitals will be reimbursed for a given MFN drug at the lesser of either the MFN payment rate or the 340B payment rate, which is currently 22.5% below the drug's ASP. The rule also provides for the flat add-on payment which is currently not part of 340B reimbursement policy under OPSS. CMS estimates that 340B hospitals will see modest increases in revenue due to the addition of the flat add-on payment but it "would potentially be offset by higher facility costs for acquiring drugs," suggesting that little to no impact would occur for 340B hospitals. However, an AHA analysis found that despite modest increases in revenue in Year 1 of the model due to the add-on payment, 340B hospitals would see a net reduction in payment of approximately \$15.4 billion over the seven-year demonstration. This is because as the MFN prices fall below the current 340B payment rate of ASP minus 22.5% over the course of the seven-year demonstration, 340B hospitals will be reimbursed at the MFN payment rate instead of the current policy, which will result in payment reductions. In fact, CMS admits that this

²⁰ This is AHA's best estimate based on the limited data made available by CMS and the unclear methodology provided by CMS in calculating the impact of the MFN Rule.

will likely occur by stating “To the extent these entities receive payment under the model that is lower than their current Medicare payment, there may be fewer resources available for their 340B program activities.” For some 340B hospitals, these losses could be so damaging that it may jeopardize their continued participation in the program, thereby harming critical services and programs their patients rely on.

In addition to these losses, the MFN rule will likely have an impact on the Average Manufacturer Price (AMP) and “best price” provision within the Medicaid Drug Rebate Program, both of which are critical in determining the 340B ceiling price for a given drug. A higher 340B ceiling price combined with lower reimbursement under the MFN model surely will result in significant reductions in program savings for hospitals which will once again jeopardize access to important programs and services for the millions of Americans who seek care at 340B hospitals.

These substantial reductions in reimbursement under the MFN rule will force hospitals to make difficult decisions about whether to reduce or even eliminate some services, as resources may need to be re-directed to ensure that patients can continue to receive drugs subject to the MFN rule. In addition, the revenue lost by hospitals will affect their ability to expand clinical services and invest in necessary infrastructure. These decisions will be particularly difficult as hospitals face a growing number of COVID-19 cases, which can burden hospital-bed and staff capacity and force the cancellation of elective procedures, further straining hospitals’ financial and infrastructure resources.

Moreover, the payment reduction is particularly difficult for rural hospitals and others serving vulnerable communities that already operate at low or negative margins. The AHA’s analysis found that the MFN rule will reduce payment to rural hospitals by nearly \$4.5 billion, at a time when rural hospitals are under immense financial pressure due to the pandemic and 134 rural hospitals have closed since 2010, 17 of them in 2020.²¹

THE METHODOLOGY OF THE MFN MODEL LACKS TRANSPARENCY AND INCLUDES CARELESS ERRORS AND QUESTIONABLE ASSUMPTIONS

The AHA has concerns about the lack of transparency in CMS’ calculations and the apparent haste with which it developed its methodology. These concerns reinforce the inappropriateness of issuing this model without public comment.

Lack of Transparency. CMS does not provide the information needed for stakeholders to replicate the MFN drug payment amounts and validate that CMS has followed its purported methodology correctly. For instance, CMS neither discloses the MFN prices used to calculate the model’s drug payment amounts nor reveals the specific non-U.S. Organization for Economic Co-operation and Development member countries used to calculate each of the first quarter MFN drug payment amounts. The agency also does

²¹ North Carolina Rural Health Research Program at <https://www.shepscenter.unc.edu/programs-projects/rural-health/>.

not provide the details on its data sources, how it is validating the data, if it is making adjustments to the data, and how it is controlling for different factors, such as packaging in different countries and the timing of reporting. **Given the significant financial impact that the MFN model will have on hospitals and beneficiaries, this lack of transparency is troublesome and inappropriate.**

Errors and Questionable Assumptions. The AHA has found errors and questionable assumptions in the MFN rule that raise concerns about the care with which the rule was developed. For instance, although CMS notes that the MFN model only applies to sole-source, separately payable drugs, it lists a packaged drug among its 50 selected drugs. Specifically, CMS includes HCPCS code J2785, Regadenoson injection, in the model, although it has a status indicator N, which indicates that it is a packaged drug.

CMS also makes a number of assumptions about how pricing and behavior will change over the course of the seven-year model period. Yet, it provides neither sufficient detail about how it arrived at these assumptions nor about how their validity can be tested over time. For example, in Table 11, “Assumptions Reflected in OACT Estimate”, CMS assumes that drug utilization patterns of 340B hospitals will not change at all throughout the seven-year demo. However, this is a very questionable assumption. Specifically, there is no reason to think that 340B hospitals would be able to purchase the drugs at or below the MFN drug payment rate, whereas non-340B hospitals would not (as CMS has acknowledged). The underlying rationale between the different assumptions for these two groups of hospitals is not clear.

OTHER OPTIONS FOR ADDRESSING INCREASING DRUG PRICES

As noted, the AHA has deep concerns about the substance and legality of the MFN model. Instead of holding drug companies accountable for drug prices, it slashes reimbursement to hospitals for drugs. **We urge the Administration to withdraw this rule immediately and replace it with a serious effort at drug pricing reform.**

We have worked with our members to document the challenges hospitals and health systems face with drug prices and to develop policy solutions that protect access to critical therapies while encouraging and supporting much-needed innovation. Our full set of recommendations are outlined on the AHA’s [webpage](#).

Of note, the AHA is particularly encouraged by the work of the Food and Drug Administration (FDA) in speeding more generic drugs and biosimilar products to the market, and we believe that more can be done to support these efforts. We also encourage HHS to more closely evaluate other anti-competitive behaviors on the part of drug companies, like pay-for-delay, the ever-greening of patents and price collusion; addressing these will likely have a far greater impact on drug pricing than any reimbursement levers. We recognize that the FDA may need additional legislative authority to fully prevent and address these issues, and the AHA is eager to work on specific solutions with Congress and the Administration.

Several other policy proposals the AHA supports are listed below:

- Disallowing co-pay assistance cards. Some drug manufacturers offer co-pay assistance cards to encourage patients to request certain higher-cost drugs. While these cards may lower patients' out-of-pocket costs for certain high-priced drugs, they have a number of negative consequences that drive up overall costs for patients and the health care system. These cards often inappropriately steer patients to higher cost drugs rather than less costly alternatives. They also disrupt insurance plan design by enabling consumers to use the value of the card to more quickly reach out-of-pocket maximums. As a result, patients appear to be shielded from the cost of the drugs. However, insurers facing substantial increases in prescription drug costs must raise consumer premiums to cover the cost of the drug. This proposal would prohibit drug manufacturers from using co-pay cards as a patient inducement.
- Increasing disclosure requirements related to drug pricing, research and development at the time of application for drug approval.
- Aligning payment with the most commonly used dosage.