IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

ASSOCIATION OF COMMUNITY CANCER CENTERS, on behalf of itself and its members; GLOBAL COLON CANCER ASSOCIATION, on behalf of itself and its members; NATIONAL INFUSION CENTER ASSOCIATION, on behalf of itself and its members; and PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, on behalf of itself and its members, *Plaintiffs*, v. ALEX M. AZAR II, in his official capacity as Secretary of the U.S. Department of Health and Human Services; the U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; SEEMA VERMA, in her official capacity of Administrator of the Centers for Medicare and Medicaid Services; CENTERS FOR MEDICARE AND MEDICAID SERVICES; BRAD SMITH, in his official capacity as the Director of the Center for Medicare and Medicaid Innovation; CENTER FOR MEDICARE AND MEDICAID INNOVATION *Defendants*.	Civil Action No. 1:20-cv-03531

DECLARATION OF JOANNA HIATT KIM IN SUPPORT OF PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER

I, Joanna Hiatt Kim, hereby declare and state the following:

1. My name is Joanna Hiatt Kim. I am over 21 years of age and competent to testify to the facts set forth herein. I am an adult citizen of the United States. I reside in McLean, Virginia.

2. The facts set forth in this declaration are based on my personal knowledge and upon information available to me through the files and records of the American Hospital Association (AHA). If called upon as a witness, I could and would testify to these facts.

3. I am the Vice President, Payment Policy and Analysis of AHA. I have served in this capacity since January 2016. From January 2013 through January 2016, my title was Vice President, Payment Policy. In both roles, I have been responsible for leading AHA's work on Medicare payment policy initiatives, including those relating to outpatient payments. In my capacity as Vice President, Payment Policy and Analysis, I have personal knowledge of the impact the rule at issue in this lawsuit will have on AHA's members.

4. AHA is a national, not-for-profit organization headquartered in Washington, D.C. AHA represents and serves nearly 5,000 hospitals, health care systems, and networks, and over 43,000 individual members. Its mission is to advance the health of individuals and communities by leading, representing, and serving the hospitals, systems, and other related organizations that are accountable to the community and committed to health improvement. AHA provides extensive education for healthcare leaders and is a source of valuable information and data on health care issues and trends. It also ensures that members' perspectives and needs are heard and addressed in national health-policy development, legislative and regulatory debates, and judicial matters. One of the critical ways in which AHA serves its mission is to protect its members'

interests in connection with policy changes initiated by the Centers for Medicare & Medicaid Services (CMS) through advocacy and litigation.

5. The Association of Community Cancer Centers and its co-plaintiffs have filed this lawsuit challenging as unlawful the Most Favored Nation Rule, Most Favored Nation (MFN) Model, 85 Fed. Reg. 76,180, 76,237 (Nov. 27, 2020). I am submitting this declaration in support of the plaintiffs' challenge to ensure that the Court is aware of the adverse impacts AHA's members will face under the Rule.

6. Reimbursement under Medicare Part B is an important revenue source for hospitals. Although hospitals are perhaps best known for their inpatient services reimbursed under Medicare Part A, they also provide extensive outpatient and other clinical services reimbursed under Medicare Part B. The MFN Rule creates a new, nation-wide payment model implemented by CMS's Center for Medicare & Medicaid Innovation that will significantly reduce reimbursement to hospitals and providers under Medicare Part B.

7. Right now, Medicare pays for drugs under Part B in a variety of ways, depending on the drug and the provider. However, payment is regularly based on a pharmaceutical manufacturer's reported average sales price plus 6%. But under the MFN Rule, CMS will no longer base its reimbursement rate on the manufacturer's average sale price for certain high-cost, separately payable Medicare Part B drugs. Instead, starting January 1, 2021, CMS will peg Medicare Part B payments for those drugs to the lowest price available in one of almost two dozen other countries. And instead of the 6% add-on payment under the current formula, the Rule allows a flat add-on payment that is the same for every drug to which the rule applies.

8. The MFN Rule will cause AHA's members to see a significant reduction in reimbursement under Medicare Part B. By CMS's own estimates, MFN prices average 65%

below average sales prices. So, starting January 1, hospitals will, on average, be purchasing drugs at average sales prices, and yet will be reimbursed at a significantly lower amount. And, the flat add-on payment, rather than a percentage add-on payment, may be particularly damaging to hospitals (as opposed to other Part B providers), because hospitals tend to provide more costly drugs, for which the flat add-on will equal less than 6% of the average sales price of the drug.

9. Reduced reimbursement under Medicare Part B places additional financial burdens on hospitals that are already undercompensated by Medicare. 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. AHA members now face even greater under-compensation. Indeed, CMS estimates—across all categories—the final rule will result in approximately $85.5 billion less in payments from Medicare. Hospitals will shoulder a significant portion of that reduction in compensation.

10. The substantial reduction 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.

11. CMS suggests that hospitals and providers can avoid these harms by purchasing covered drugs at lower prices, shrinking the difference between the price providers pay and the rule's substantially lower reimbursement amounts. Of course, AHA members have already purchased covered drugs at the current market rate, and come January 1, 2021, those drugs will be reimbursed only at a significant discount.

12. More fundamentally, it is simply impossible for AHA's members to renegotiate their current drug-purchasing contracts before the rule takes effect in three weeks. These contracts are complex, and they take substantial time and resources to negotiate. Re-negotiating those contracts is made only more challenging by the current strain on hospitals' administrative resources during the COVID-19 pandemic. CMS's proposal essentially requires that hospital administrators at hundreds of health systems—who are already busy ensuring that they have adequate resources to treat patients, protect workers and care providers, and prepare for the roll out of an imminent vaccine—to also try to fix the Nation's drug-pricing policies on a contract-by-contract basis. That cannot be done in 22 days.

13. The harm to hospitals is compounded by their inability to comment on the MFN Rule before it was promulgated. Congress required notice and comment for rules that change substantive legal standards governing Medicare services for good reason. When it comes to Medicare, even small changes can have outsized effects. And the MFN is no small change. Had AHA been able to comment on the MFN Rule before it was issued, it would have informed CMS of these many harms that the rule imposes on its members. Indeed, AHA commented on the separate advance notice of proposed rulemaking CMS published in October 2018 which offered a so-called International Pricing Index proposal as a potential solution to its concerns about the high prices paid for drugs under Medicare Part B relative to their costs in other countries. CMS

took no public steps to adopt that plan. And even though the MFN Rule was a stark departure from that deficient 2018 proposal, CMS did not offer AHA and other affected stakeholders a new opportunity to comment on it. Notice and comment allows stakeholders and the public to engage with agencies and allows agencies to craft effective and appropriate public policies that forestall or lessen harms to stakeholders like AHA's members. AHA was therefore harmed by its inability to comment on the MFN Rule.

I declare under penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct.

DocuSigned by:
Joanna Hiatt Kim
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Joanna Hiatt Kim
Vice President, Payment Policy and Analysis
American Hospital Association

Dated: December 10, 2020.