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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

BIOTECHNOLOGY INNOVATION; CALIFORNIA LIFE SCIENCES ASSOCIATION; and BIOCOM CALIFORNIA

Plaintiffs,

v.

ALEX M. AZAR, II, in his official capacity as SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; SEEMA VERMA, in her official capacity as ADMINISTRATOR OF THE CENTERS FOR MEDICARE AND MEDICAID SERVICES; and THE CENTERS FOR MEDICARE AND MEDICAID SERVICES,

Defendants.

Case No. 3:20-cv-08603-VC

Hon. Vince Chhabria

[PROPOSED] AMICUS CURIAE BRIEF OF THE ALLIANCE FOR AGING RESEARCH IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

The Alliance for Aging Research (the "Alliance") hereby submits this amicus curiae brief in support of Plaintiffs' request that the Court enter a preliminary injunction. The interim final rule before the Court, which was promulgated in rushed fashion and without public notice and comment, makes sweeping and dramatic changes to the nation's healthcare system. The rule is ultra vires because while the Centers for Medicare and Medicaid Services ("CMS") purports to be exercising its authority to test innovative models for improving patient care, the rule is not a test under any plausible definition and, by CMS's own admission, will not improve patient care. If the rule is not enjoined, it will cause irreparable harm to patients, including the older-adult patients the Alliance works to protect and serve.

STATEMENT OF INTEREST

The Alliance is the leading organization dedicated to accelerating the pace of scientific discoveries and their application to improve the universal human experience of aging and health. To support this aim, the Alliance ensures that older-adult patient voices are represented and prioritized in health policy decision-making and clinical care. For more than thirty years, the Alliance has provided research resources to the federal government, patient and provider advocacy communities, and the health care industry and is well-respected for its objective, data, and fact-driven work. Given the significant impact of the rulemaking at issue on older adults, the Alliance and those for whom it speaks have a deep interest in the outcome of this matter.

ARGUMENT

The Alliance supports the arguments advanced by Plaintiffs in their Motion for Preliminary Injunction and will not repeat them here. The Alliance writes to highlight several points that support Plaintiffs' request. An injunction is urgently needed to avoid causing severe harm to patients across the nation.

I. The MFN "Model" Is an Ultra Vires Rulemaking.

CMS promulgated the Interim Final Rule, Most Favored Nation (MFN) Model, 85 Fed. Reg. 76,180 (Nov. 27, 2020) ("MFN Rule"), purportedly pursuant to its Center for Medicare and Medicaid Innovation ("CMMI") authority found at 42 U.S.C. § 1315a. (Without that authority, the

MFN Rule would directly violate the statutory requirement that Part B drugs must be paid at their "average sales price" plus 6%, 42 U.S.C. § 1395w-3a(b)(1)(B), as well as other statutory requirements.) But CMS's authority under CMMI is not unbridled. The MFN Rule goes far beyond CMS's lawful authority, attempting to disguise a sweeping and illegal change in law as a CMMI "model."

The purpose of the CMMI is to "test innovative payment and service delivery models to reduce program expenditures under the applicable subchapters while preserving or enhancing the quality of care furnished to individuals under such subchapters." 42 U.S.C. § 1315a(a)(1). The statute grants CMS authority to test and evaluate alternative payment models and other innovations, **before** complying with necessary rulemaking and other procedures to implement them more broadly. The law requires that any model must be tested within a "defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures." 42 U.S.C. § 1315a(b)(2)(A). Contrary to this basic requirement, the MFN Rule will apply to 100% of Medicare Part B beneficiaries and to 75% of all the drugs used in the Part B program. This is not a test.

Limiting proposed models to a defined population and having an appropriate control group are fundamental to the testing process. These widely accepted principles of scientific exploration are understood by everyone from Congress to high school students. In fact, CMMI leadership has previously stated, "[p]roviding policymakers and model participants with accurate information on model performance requires methodologically rigorous evaluation. One central issue in study design is developing a valid counterfactual comparison to each of the models—that is, how a model performs relative to what would have happened in its absence."[1] It is not surprising that this

[1] Benjamin L. Howell et al., *Guiding Principles for Center for Medicare & Medicaid Innovation Model Evaluations* JAMA Network (2015), https://jamanetwork.com/journals/jama/article-abstract/2278025; *see* Mary Earick Godby, *Control Group*, BRITANNICA.COM, https://www.britannica.com/science/control-group (last visited Dec. 13, 2020); s*ee also* Sunitha Malay & Kevin C. Chung, *The Choice of Controls for Providing Validity and Evidence in Clinical Research;* 130 PLASTIC RECONSTR. SURG. 959 (2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3461178/ (identifying confirmation bias and misclassification bias as among two possible flaws in conducting studies without appropriate controls).

principle is reflected in mandatory statutory language. The reason is fundamental—if the "model" does not prove to maintain or improve patient quality while saving money or remaining budget neutral in comparison to a control group, it should not be expanded to a larger population.

Significantly, many of the CMMI models that CMS has tested have not proven to save costs and improve care. CMS Administrator Seema Verma earlier this year noted that " . . . [t]o date, only five models have shown statistically significant savings, and of these five, only three have been expanded on a national scale."[2] Given its history, CMS should know better than to launch a mandatory nationwide model that it concedes will harm patient care. 85 Fed. Reg. at 76,180. The scope of the MFN Rule clearly runs afoul of both the text and intent of the law, which are to understand the impact of proposed changes before advancing them more broadly.

By skipping the two-step process outline in the provision of "test[ing]" and then "expand[ing]," CMS has deprived both itself and Congress of the ability to review results of the model and to make decisions regarding broader expansion. Instead of starting with a limited test, CMS has employed a national mandatory demo for 75% of the drugs used in Part B that impacts 100% of enrolled providers and beneficiaries, clearly falling outside the authority of the CMMI statute. This is the definition of ultra vires action ripe for the Court's review and reversal. *See Sierra Club v. Trump*, 963 F.3d 874, 891 (9th Cir. 2020), *cert. granted sub nom. Trump v. Sierra Club*, No. 20-138, 2020 WL 6121565 (U.S. Oct. 19, 2020); *see also City of Arlington v. FCC*, 569 U.S. 290, 297 (2013) (finding that agencies' "power to act and how they are to act is authoritatively prescribed by Congress, so that when they act improperly, no less than when they act beyond their jurisdiction, what they do is ultra vires").

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[2] Alex Spanko, *Verma: Alternative Payment Model Performance 'Deeply Concerning,' More Mandatory Programs Ahead*, SKILLED NURSING NEWS, (Oct. 15, 2020), https://skillednursingnews.com/2020/10/verma-alternative-payment-model-performance-deeply-concerning-more-mandatory-programs-ahead/. CMS attempts to explain away the lack of a control group by claiming it will use an "interrupted time series" analysis and look at the impacts on Medicare Advantage and Medicaid programs, 85 Fed. Reg. at 76,234, but it is unconvincing; for example, Medicare Advantage program rates are based upon the very same fee for service rates that will have been changed by the national mandatory model, resulting in infected data being used to measure the model.

CMMI has the ability to test payment and delivery systems among specific populations. It does not, however, have the authority to implement nationwide policies that will impact the entirety of the Medicare program without a prior test and evaluation. The intent of the CMMI authorization statute is clear—models must be tested for a limited population and may not be expanded on a national basis unless: (a) patient quality improves and the model is either budget-neutral or creates savings, or (b) patient quality remains stable but the model creates savings.

These criteria underscore Congress's decision to prioritize testing patient care improvement **and** program savings through CMMI models. 42 U.S.C. § 1315b(d)(4). But the MFN Rule does not include sufficient criteria to monitor patient outcomes and thereby fails to meet the standard of qualification as a CMMI model. 42 U.S.C. § 1315a(b)(3)(B). The MFN Rule does not include direct measurement of patient outcomes; rather, it provides only a subjective "experience of care" patient survey, as well as a vague commitment to "conduct a variety of analyses to monitor access to the included drugs and assess early effects of the model."[3] The CMMI has the authority to test payment models, while preserving or enhancing the quality of care furnished, but the MFN Rule fails to include measurements to appropriately evaluate care quality. Real-time assessment and measurement of outcomes are critical given the immediate risk of irreparable harm to patients due to restrictions in access to covered drugs. 85 Fed. Reg. at 76,237.

CMS acknowledges the shortcomings of its "study" design: "Given the uncertainty of these impacts, we are unable to quantify these potential effects of the MFN Model." *Id.* at 76,225, 76,244. Given the high risk of irreparable harm in terms of patient impact and CMS's inability to assess the impacts of the model, a mandatory and national MFN model is irresponsible and fundamentally counter to basic study design. Uncertainty about these impacts[4] betrays the reality

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[3] CMS, Fact Sheet: Most Favored Nation Model for Medicare Part B Drugs and Biologicals Interim Final Rule With Comment Period, CMS.gov (Nov. 20, 2020), https://www.cms.gov/newsroom/fact-sheets/fact-sheet-most-favored-nation-model-medicare-part-b-drugs-and-biologicals-interim-final-rule.

[4] Ironically, in some instances Medicare costs will not go down, but will increase. For example, Medicare reimbursement for one of the "Top 50" drugs, Orthovisc (HCPCS code J7324, ranked 45th on the list) Medicare payments will actually increase from an estimated $135 (the "average

that the "model" is not a test at all—it is a bald, sweeping, and illegal change posing as a mere model. Particularly given the harm to patients who will have to forego lifesaving medication, 85 Fed. Reg. at 76,237, this ultra vires rule should be stopped by the Court.

In sum, the MFN Rule's "blunderbuss operation falls beyond any reasonable exercise of the Secretary's statutorily assigned power." *Merck & Co. v. HHS*, 962 F.3d 531, 536 (D.C. Cir. 2020) (rejecting rulemaking mandating disclosure of "wholesale acquisition cost" prices). The MFN Rule should therefore be set aside as contrary to the APA and an ultra vires violation of the Medicare statute.

II. The MFN Rule's Irreparable Harm Supports Immediate Injunctive Relief.

There can be no reasonable debate about the irreparable harm that the MFN Rule will cause starting January 1. The MFN Rule itself acknowledges that "beneficiaries may . . . receiv[e] an alternative therapy that may have lower efficacy or greater risks, or postpon[e] or forg[o] treatment." 85 Fed. Reg. at 76,244. Defendants admit that nearly 10% of Medicare beneficiaries may have no access to their Part B drugs through Medicare next year, *id.* at 76,237, and one in five beneficiaries may have no access to drugs covered by MFN within three years of implementation. *Id*. at 76,237–38. CMS further concedes that patients, such as those that are the focus of the Alliance's work, will face limitations in the form of their doctor's ability to offer medications covered by the MFN, stating "providers and suppliers will need to decide if the difference between the amount that Medicare will pay and the price that they must pay to purchase the drugs would allow them to continue offering the drugs." *Id.* at 76,236.

The MFN Rule painfully continues: patients will "experience access to care impacts by . . . having to travel to seek care from an excluded provider, receiving an alternative therapy that may have lower efficacy or greater risks, or postponing or forgoing treatment." *Id.* at 76,244. Sadly, CMS relies on the loss of access to treatment to generate half of the savings in the model. *Id.* at

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sales price" plus 6%) to an estimated $244 to $252 (the Japanese price plus the $184 add on under the MFN Rule). *See* HHS, CMS-5528-IFC, Interim Final Rule with Comment Period, Most Favored Nation (MFN) Model, 89–95, tbl. 6 (Nov. 20, 2020), https://innovation.cms.gov/media/document/mfn-ifc-rule.

76,239. No clearer statement of harm should be needed. *See All. for Wild Rockies v. Cottrell*, 632 F.3d 1127, 1134 (9th Cir. 2011) (explaining that the Ninth Circuit will enjoin conduct where clear irreparable injury would otherwise result and at least "serious questions" going to the merits are raised).

CMS's broad justification for these drastic changes is that less spending on medications will benefit patients. But this assumption places the value of savings over access and patient outcomes. The MFN Rule assessment was unable to consider differences in efficacy that may result in worse outcomes and greater long-term costs due to taking a less effective medication, taking a medication with a higher risk of side effects, or ending therapy in the many cases where no other treatment exists. In fact, this is one of the critical arguments that the Alliance would have addressed in rulemaking had it occurred prior to implementation.

The MFN Rule also threatens the financial solvency of health practices, and particularly those that provide treatment to patient populations who are often older, sicker, and poorer compared to national averages.[5] Under the MFN Rule, rural hospitals will experience drug payment reductions and overall payment reductions similar to urban entities. The MFN Rule notes that these reductions will "have a significant impact on small rural hospitals." 85 Fed. Reg. at 76,246. These cuts are particularly worrisome as rural hospitals are already in crisis. This crisis is in large part due to payer mixes dominated by Medicare and Medicaid and decreases in reimbursement rates. Since 2005, more than 163 rural hospitals have closed in the United States; 19 closed in 2019,[6] and more than 650 are vulnerable to closure.[7] Critically, the MFN Rule does not demonstrate how it will achieve the stated purpose and rationale supporting the need for emergency implementation in advance of receiving public comment. The MFN Rule, at its core,

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[5] *Rural Aging*, RURAL HEALTH INFO. HUB (2018), https://www.ruralhealthinfo.org/topics/aging.

[6] *176 Rural Hospital Closures: January 2005 – Present (134 Since 2010)*, CECIL G. SHEPS CTR. FOR HEALTH SERVS. RESEARCH, https://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/ (last visited Dec. 13, 2020).

[7] Press Release, iVantage Health Analytics, *Rural Hospital Closures Predicted to Escalate* (Feb. 26, 2016),.https://www.ivantagehealth.com/news-release-february-2-2016/.

distorts the aim of reducing costs for patients by excessively cutting patient access to medication and to care providers.

HHS's assumption that healthcare providers will find alternative treatments is also wrong. For example, pembrolizumab and nivolumab are two immunotherapy drugs on the MFN's "Top 50" list for which there are no alternatives. These drugs are given by infusion and are used to treat a number of different types of advanced cancers, including: melanoma; lung cancer; and cancers of the kidney, bladder, or urinary tract; among others. For some types of cancer, these drugs may only be given only if the patient's tumor has a specific genetic marker determined through an FDA-approved test. Aflibercept and ranibizumab, other prescription medicines on the MFN list, are used to maintain and improve vision in patients with diabetic retinopathy or diabetic edema as well as wet, age-related macular degeneration. These medications are administered by injection into the eye, and there are no other FDA approved substitutes for patients to access. Thus, the MFN Rule will create conditions akin to drug shortages (such as when product is not available to patients in need due to supply chain interruptions).

Research indicates that increased patient mortality, increased rates of adverse drug reactions, and increased hospitalization are frequently observed in shortage situations.[8] While the MFN Rule purports to take care to avoid interrupting availability or causing shortages of drugs related to Coronavirus 2019 ("COVID-19"), it fails to do so for other conditions such as cancer that are also lethal and highly time-sensitive in terms of their treatment and outcomes. This distinction creates an arbitrary and adverse impact to patients with drugs covered under the MFN Rule.

III. The Balance of the Equities and the Public Interest Also Favor an Injunction.

The MFN rule introduces significant challenges to both precedent and patient interest. CMS's failure to provide a public comment period prior to implementation prevented the Alliance and other stakeholders from providing substantive feedback. The equities and public interest

[8] Jonathan Minh Phuong et al., *The Impacts of Medication Shortages on Patient Outcomes: A Scoping Review*, PLoS ONE (2019), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0215837.

strongly favor an injunction before the January 1, 2021 implementation date as well as rejection of the MFN Rule on the merits.

The equities and public interest are directly implicated by the MFN Rule's use of international reference pricing policies which rely upon discriminatory cost-effectiveness standards often used by the very OECD countries that the MFN prices will come from.[9] Many of the countries referenced in the MFN Rule, including the United Kingdom and Canada, make drug reimbursement and coverage decisions based on cost-effectiveness assessments measured in quality-adjusted life-years, or QALYs, which discriminate against the sick, the disabled, and elderly. The QALY assigns a financial value to a human life on a scale between 0 (dead) and 1 (perfect health) discounting ratings for people with chronic conditions and/or a disability, and older adults. Treatments that extend the life or improve the quality of life for individuals with disabilities are calculated as less cost-effective, and treatments for older adults are given a lower priority in assessments because of expected reduced life-expectancy. Stated differently, QALYs place a lower value on people's lives due to having less "life years" or "perfect health" ahead of them.

On November 6, 2019, the National Council on Disability, an independent federal agency, published a report on QALYs that explicitly called on the Trump administration to rescind its earlier International Pricing Index (IPI) proposal, the predecessor policy to the MFN, because it would rely on prices set internationally using discriminatory metrics of value.[10] Yet, the Administration ignored its own Council's Report and continued to promulgate regulations that include reference prices from OECD countries that utilize QALY in their cost-setting and coverage processes.[11]

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[9] Press Release, Alliance for Aging Research, *Alliance for Aging Research Statement on White House "Most Favored Nation" Drug Pricing Rule* (Nov. 20, 2020), https://www.agingresearch.org/press-release/alliance-for-aging-research-statement-on-white-house-most-favored-nation-drug-pricing-rule/.

[10] Nat'l Council on Disability, *Quality-Adjusted Life Years and the Devaluation of Life with Disability* 53 (2019), https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf.

[11] *Id.* ("The IPI would base the prices of certain drugs covered under Medicare Part B on reference prices from 16 other countries. Many of these countries—for instance, the United Kingdom,

This is not only an equitable consideration; it is also an outright violation of law. Congress in 2010 explicitly prohibited the Secretary from using QALYs in reimbursement. More specifically, section 1182(e) of the Social Security Act (42 U.S.C. § 1320e-1(e)) provides:

> The Patient-Centered Outcomes Research Institute established under section 1320e(b)(1) of this title shall not develop or employ a dollars-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual's disability) as a threshold to establish what type of health care is cost effective or recommended. The Secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs under subchapter XVIII.

CMMI is attempting to do an end run around the statute by using OECD QALY-based prices rather than setting QALY-based prices itself. The MFN Rule has not waived Section 1182, *see* 85 Fed. Reg. at 76,221 (waiving only specified sections of Title XVIII, and not waiving any sections of Title XI), meaning it has full force and effect and is directly violated by the MFN Rule. By adopting OECD MFN prices that are set through the very QALYs the Secretary is prohibited from utilizing, the Secretary has not only violated the Medicare statute but has tilted the equities and consideration of public policy strongly in favor of an injunction.

This Court should not countenance reference prices from the OECD that the statute expressly prohibits CMS from using in the United States. Nor should CMS discriminate against older adults and people with disabilities—the very populations covered by the Medicare program. The equities and the public interest support entry of an injunction.

Ireland, and Canada—use QALYs to make benefits and coverage decisions and limit their healthcare costs." (footnotes omitted))

CONCLUSION

For the foregoing reasons, the Alliance urges this Court to enter an injunction prohibiting the MFN Rule from taking effect on January 1, 2021.

Dated: December 15, 2020

Respectfully submitted,

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