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September 25, 2020

VIA ELECTRONIC FILING

Mr. Mark J. Langer
Clerk of the Court
United States Court of Appeals for the D.C. Circuit
E. Barrett Prettyman U.S. Courthouse and
William B. Bryant Annex
333 Constitution Avenue, NW
Washington, D.C. 20001

Re: *American Hospital Association et al. v. Azar*, No. 20-5193 (argument scheduled Oct. 15, 2020)

Dear Mr. Langer:

Under Federal Rule of Appellate Procedure 28(j), Appellants attach the Executive Order on An America-First Healthcare Plan (Sept. 24, 2020), which discusses HHS's challenged price-disclosure rule. The order states that, "[i]n the absence of congressional action," the Administration has acted "to make healthcare prices more transparent." The order indicates that the price-disclosure rule followed from "Executive Order 13877," which "direct[ed] certain agencies—for the first time ever—to make sure patients have access to meaningful price and quality information prior to the delivery of care." The order refers to the price-disclosure rule as follows: "Beginning January 1, 2021, hospitals will be required to publish their real price for every service, and publicly display in a consumer-friendly, easy-to-understand format the prices of at least 300 different common services that are able to be shopped for in advance." The order also requires HHS, within 180 days,

to update the Medicare.gov Hospital Compare website to indicate, *inter alia*, "whether the hospital is in compliance with" the challenged rule.

The Executive Order pertains to Appellants' challenge for several reasons:

- The order describes the rule as mandating disclosure of hospitals' "real price[s]." Appellants argue that section 2718(e)'s reference to hospitals' "standard charges" cannot reasonably refer to the varying prices for each item or service that hospitals agree to accept in "particular circumstances" for "identifiable group[s] of individuals." AHA Br. 26-37.

- The order describes the rule as requiring two disclosures—hospitals' "real price for every service," and a "public[] display in a consumer-friendly, easy-to-understand format" of "the prices of at least 300 different common services." Appellants argue that the rule exceeds HHS's authority to mandate publication of "a list" of standard charges by requiring multiple lists. AHA Br. 37-40.

- The order characterizes Executive Order 13,877 as "directing" the rule's requirements. Appellants argue that *Chevron* does not apply to HHS's interpretation of "standard charges," which reflects a presidential directive. AHA Br. 43-44.

- The order states the rule's effective date as January 1, 2021, thus apparently rejecting Appellants' request to delay the rule's effective date given hospitals' challenges in addressing the ongoing COVID-19 pandemic. AHA Br. 23-24.

Respectfully submitted,

/s/ *Lisa S. Blatt*
Lisa S. Blatt
Counsel for Appellants

cc: Counsel of Record via ECF

EXECUTIVE ORDERS

Executive Order on An America-First Healthcare Plan

HEALTHCARE

Issued on: **September 24, 2020**

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By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Purpose. Since January 20, 2017, my Administration has been committed to the goal of bringing great healthcare to the American people and putting patients first. To that end, my Administration has taken monumental steps to improve the efficiency and quality of healthcare in the United States.

(a) My Administration has been committed to restoring choice and control to the American patient.

On December 22, 2017, I signed into law the repeal of the burdensome individual-mandate penalty, liberating millions of low-income Americans from a tax that penalized them for not purchasing health-insurance coverage they did not want or could not afford. Through Executive Order 13813 of October 12, 2017 (Promoting Healthcare Choice and Competition Across the United States), my Administration has expanded coverage options for millions of Americans in several ways. My Administration increased the availability of renewable short-term, limited-duration healthcare plans, providing options that are up to 60 percent cheaper than the least expensive alternatives under the Patient Protection and Affordable Care Act (ACA) and are projected to cover 500,000 individuals who would otherwise be uninsured. My Administration expanded health reimbursement arrangements, which have been projected by the Department of the Treasury to reach 800,000 businesses and over 11 million employees and to expand coverage to more than

800,000 individuals who would otherwise be uninsured. My Administration also issued a rule to increase the availability of association health plans for small businesses, which, upon implementation of the rule, are projected to cover up to 400,000 previously uninsured individuals for on average 30 percent less cost.

As set forth in the Economic Report of the President (February 2020), my Administration's expansion of health savings accounts will further help millions of Americans pay for health expenditures by allowing them to save more of their own money free from Federal taxation, and will especially help Americans with chronic conditions who now have more flexibility to enroll in plans that fit their complicated care needs and can be paired with a tax-advantaged account.

At the beginning of the current COVID-19 pandemic, my Administration acted to dramatically increase the accessibility and availability of telehealth services for Medicare beneficiaries, enabling millions of individuals to use these services. Pursuant to Executive Order 13941 of August 3, 2020 (Improving Rural Health and Telehealth Access), the Secretary of Health and Human Services will make permanent many of the new policies that improve the accessibility and availability of telehealth services. In addition, pursuant to that order, the Secretary of Health and Human Services and the Secretary of Agriculture will develop and implement a strategy to improve the physical and communications healthcare infrastructure available to rural Americans.

Through our State Relief and Empowerment Waivers, my Administration has given States additional health-insurance flexibility, which has expanded health-insurance coverage options for consumers and lowered costs for patients. These waivers allow States to move away from the ACA's rigid structure and are estimated to have lowered premiums by approximately 11 percent in Wisconsin, 20 percent in Minnesota, and 43 percent in Maryland. Due to actions my Administration took, like the State Relief and Empowerment Waivers, after years of dwindling choices and escalating prices, plan options for consumers increased and for 2019, for the first time ever, benchmark premiums actually decreased on Healthcare.gov. For 2020, the average benchmark premium dropped by nearly 4 percent.

After the prior Administration spent tens of billions of dollars creating electronic health records systems unable to accurately or effectively record and communicate patient data, my Administration has paved the way for a new wave of innovation to allow patients to safely send their own medical records to care providers of their choosing. My Patients over Paperwork initiative has cut red tape for doctors and nurses so they can spend more time with their patients,

which the Centers for Medicare and Medicaid Services (CMS) within the Department of Health and Human Services (HHS) has estimated to save over 40 million hours of wasted time for providers and suppliers between 2017 and 2021.

(b) My Administration has been ceaseless in its efforts to lower costs to make healthcare more affordable for American patients.

Under my tenure, prescription drugs saw their largest annual price decrease in nearly half a century. For three consecutive years, we have approved a record number of generic drugs. The Council of Economic Advisers has estimated that these approvals saved patients $26 billion in the first 18 months of my Administration alone. As part of the Further Consolidated Appropriations Act, 2020, I signed into law the Creating and Restoring Equal Access to Equivalent Samples Act, which will pave the way for even more generic drugs and is projected to save taxpayers $3.3 billion from 2019 to 2029.

CMS has acted to offer Medicare beneficiaries prescription drug plans with the option of insulin capped at $35 in out-of-pocket expenses for a 30-day supply. We are also reducing Government payments to overcharging hospitals participating in the 340B Drug Pricing Program by instead paying rates that more accurately reflect the hospitals' acquisition costs, which CMS estimated would save Medicare beneficiaries $320 million on copayments for drugs alone.

As a result of Executive Order 13937 of July 24, 2020 (Access to Affordable Life-Saving Medications), low-income Americans who receive care from a federally qualified health center will have access to insulin and injectable epinephrine at prices lower than ever before. Under Executive Order 13938 of July 24, 2020 (Increasing Drug Importation to Lower Prices for American Patients), my Administration will be the first to complete a rulemaking to authorize the safe importation of certain lower-cost prescription drugs from Canada. Pursuant to Executive Order 13939 of July 24, 2020 (Lowering Prices for Patients by Eliminating Kickbacks to Middlemen), my Administration is taking action to eliminate wasteful payments to middlemen by passing drug discounts through to patients at the pharmacy counter without increasing premiums for beneficiaries or cost to Federal taxpayers. And my Administration is taking action to ensure that Medicare patients receive the lowest price that drug companies offer comparable foreign nations through Executive Order 13948 of September 13, 2020 (Lowering Drug Prices by Putting America First).

As part of the Further Consolidated Appropriations Act, 2020, I also signed into law the repeal of the medical device tax, the annual fee on health-insurance providers, and the "Cadillac" tax on certain employer-sponsored health insurance, which threatened to dramatically increase the cost of healthcare for working families.

My Administration is transforming the black-box hospital and insurance pricing systems to be transparent about price and quality. Regardless of health-insurance coverage, two-thirds of adults in America still worry about the threat of unexpected medical bills. This fear is the result of a system under which individuals and employers are unable to see how insurance companies, pharmacy benefit managers, insurance brokers, and providers are or will be paid. One major culprit is the practice of "surprise billing," in which a patient receives unexpected bills at highly inflated prices from providers who are not part of the patient's insurance network, even if the patient was treated at a hospital that was part of the patient's network. Patients can receive these bills despite having no opportunity to select around an out-of-network provider in advance.

On May 9, 2019, I announced four principles to guide congressional efforts to prohibit exorbitant bills resulting from patients' accidentally or unknowingly receiving services from out-of-network physicians. Unfortunately, the Congress has failed to act, and patients remain vulnerable to surprise billing.

In the absence of congressional action, my Administration has already taken strong and decisive action to make healthcare prices more transparent. On June 24, 2019, I signed Executive Order 13877 (Improving Price and Quality Transparency in American Healthcare to Put Patients First), directing certain agencies — for the first time ever — to make sure patients have access to meaningful price and quality information prior to the delivery of care. Beginning January 1, 2021, hospitals will be required to publish their real price for every service, and publicly display in a consumer-friendly, easy-to-understand format the prices of at least 300 different common services that are able to be shopped for in advance.

We have also taken some concrete steps to eliminate surprise out-of-network bills. For example, on April 10, 2020, my Administration required providers to certify, as a condition of receiving supplemental COVID-19 funding, that they would not seek to collect out-of-pocket expenses from a patient for treatment related to COVID-19 in an amount greater than what the patient would have otherwise been required to pay for care by an in-network provider. These initiatives have made important progress, although additional efforts are necessary.

Not all hospitals allow for surprise bills. But many do. Unfortunately, surprise billing has become sufficiently pervasive that the fear of receiving a surprise bill may dissuade patients from seeking appropriate care. And research suggests a correlation between hospitals that frequently allow surprise billing and increases in hospital admissions and imaging procedures, putting patients at risk of receiving unnecessary services, which can lead to physical harm and threatens the long-term financial sustainability of Medicare.

Efforts to limit surprise billing and increase the number of providers participating in the same insurance network as the hospital in which they work would correspondingly streamline the ability of patients to receive care and reduce time spent on billing disputes.

On May 15, 2020, HHS released the Health Quality Roadmap to empower patients to make fully informed decisions about their healthcare by facilitating the availability of appropriate and meaningful price and quality information. These transformative actions will arm patients with the tools to be active and effective shoppers for healthcare services, enabling them to identify high-value providers and services, and ultimately place downward pressure on prices.

My Administration has cracked down on waste, fraud, and abuse that direct valuable taxpayer resources away from those who need them most. My Administration implemented a “site neutral” payment system between hospital outpatient departments and physicians’ offices, to ensure Medicare beneficiaries are charged the same price for the same service regardless of where it takes place, which CMS estimates will save them approximately $160 million in co-payments for 2020. We also changed the rules to enable Government watchdogs to proactively identify and stop perpetrators of fraud before money goes out the door.

(c) My Administration has been dedicated to providing better care for all Americans.

This includes a steadfast commitment to always protecting individuals with pre-existing conditions and ensuring they have access to the high-quality healthcare they deserve. No American should have to risk going without health insurance based on a health history that he or she cannot change.

In an attempt to justify the ACA, the previous Administration claimed that, absent action by the Congress, up to 129 million (later updated to 133 million) non-elderly people with what it described as pre-existing conditions were in danger of being denied health-insurance coverage. According to the previous Administration, however, only 2.7 percent of such individuals actually gained access to

health insurance through the ACA, given existing laws and programs already in place to cover them. For example, the Health Insurance Portability and Accountability Act of 1996 has long protected individuals with pre-existing conditions, including individuals covered by group health plans and individuals who had such coverage but lost it.

The ACA produced multiple other failures. The average insurance premium in the individual market more than doubled from 2013 to 2017, and those who have not received generous Federal subsidies have struggled to maintain coverage. For those who have managed to maintain coverage, many have experienced a substantial rise in deductibles, limited choice of insurers, and limited provider networks that exclude their doctors and the facilities best suited to care for them.

Additionally, approximately 30 million Americans remain uninsured, notwithstanding the previous Administration's promises that the ACA would address this intractable problem. On top of these disappointing results, Federal taxpayers and, unfortunately, future generations of American workers, have been left with an enormous bill. The ACA's Medicaid expansion and subsidies for the individual market are projected by the Congressional Budget Office to cost more than $1.8 trillion over the next decade.

The ACA is neither the best nor the only way to ensure that Americans who suffer from pre-existing conditions have access to health-insurance coverage. I have agreed with the States challenging the ACA, who have won in the Federal district court and court of appeals, that the ACA, as amended, exceeds the power of the Congress. The ACA was flawed from its inception and should be struck down. However, access to health insurance despite underlying health conditions should be maintained, even if the Supreme Court invalidates the unconstitutional, and largely harmful, ACA.

My Administration has always been committed to ensuring that patients with pre-existing conditions can obtain affordable healthcare, to lowering healthcare costs, to improving quality of care, and to enabling individuals to choose the healthcare that meets their needs. For example, when the COVID-19 pandemic hit, my Administration implemented a program to provide any individual without health-insurance coverage access to necessary COVID-19-related testing and treatment.

My commitment to improving care across our country expands vastly beyond the rules governing health insurance. On July 10, 2019, I signed Executive Order 13879 (Advancing American Kidney

Health) to improve care for the hundreds of thousands of Americans suffering from end-stage renal disease. Pursuant to that order, my Administration launched a program to encourage home dialysis and promote transplants for patients, and expects to enroll approximately 120,000 Medicare beneficiaries with end-stage renal disease in the program. We also have removed financial barriers to living organ donation by adding additional financial support for living donors, such as by reimbursing expenses for lost wages, child care, and elder care. HHS, together with the American Society of Nephrology, issued two phases of awards through KidneyX's Redesign Dialysis Price Competition to work toward the creation of an artificial kidney.

My Administration has taken unprecedented action to improve the quality of and access to care for individuals with HIV, as part of our goal of ending the epidemic of HIV in the United States by 2030. HHS has awarded at least $226 million to expand access to HIV care, treatment, medication, and prevention services, focused on 48 counties, Washington, D.C., and San Juan, Puerto Rico, where more than 50 percent of new HIV diagnoses occurred in 2016 and 2017, as well as seven States with a substantial rural HIV rate. We secured a historic donation of a groundbreaking HIV preventive medication that is available at no cost to eligible patients.

My Administration has started a transformation in healthcare in rural America. This includes a new effort, pursuant to my directive in Executive Order 13941, to support small hospitals and health clinics in rural communities in transitioning from volume-based Medicare and Medicaid reimbursement, which has failed rural communities that struggle with a lack of patient volume, and toward value-based payment mechanisms that are tailored to meet the needs of their communities. We updated Medicare payment policies to address a problem in the program's payment calculation that has historically disadvantaged rural hospitals, and released a Rural Action Plan to incorporate recommendations from experts and leaders across the Federal Government. We have also dedicated a special focus on improving care offered through the Indian Health Service (IHS) within HHS, including by creating the Office of Quality, implementing an increase in annual funding for IHS by $243 million from 2019 to 2020, and expanding nationwide IHS's successful Alaska Community Health Aide Program.

My Administration has additionally demonstrated an incredible dedication to protecting and improving care for those most in need, including senior citizens, those with substance use disorders, and those to whom our Nation owes the greatest debt: our veterans.

I have protected the viability of the Medicare program. For example, on February 9, 2018, I signed into law the repeal of the Independent Payment Advisory Board, which would have been a group of unelected bureaucrats created by the ACA, designed to be insulated from the will of America's elected leaders for the purpose of cutting the spending of this important program. On October 3, 2019, I signed Executive Order 13890 (Protecting and Improving Medicare for Our Nation's Seniors), to modernize the Medicare program and continue its viability. According to CMS estimates, seniors have saved $2.65 billion in lower Medicare premiums under my Administration while benefiting from more choices. For example, the average monthly Medicare Advantage premium has declined an estimated 28 percent since 2017, and Medicare Advantage has included about 1,200 more plan options since 2018. New Medicare Advantage supplemental benefits have helped seniors stay safe in their homes, improved respite care for caregivers, and provided transportation, more in-home support services and assistance, and non-opioid pain management alternatives like therapeutic massages. Medicare Part D premiums are at their lowest level in their history, with the average basic premium declining 13.5 percent since 2016.

My Administration has directed unprecedented attention on the substance use disorder epidemic, with a focus on reducing overdose deaths from prescription opioids and the deadly synthetic opioid fentanyl. On October 24, 2018, I signed the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, enabling the expenditure of billions of dollars of funding for important programs to support prevention and recovery. My Administration has provided approximately $22.5 billion from 2017 to 2020 to address the opioid crisis and improve access to prevention, treatment, and recovery services. We saw a 34 percent decrease in total opioids dispensed monthly by pharmacies between 2017 and 2019, an approximate increase of 64 percent in the number of Americans who receive medication-assisted treatment for opioid use disorder since 2016, and a 484 percent increase in naloxone prescriptions since 2017. Data show that drug overdose deaths fell nationwide for the first time in decades between 2017 and 2018, with many of the hardest-hit States leading the way.

Improving care for our Nation's veterans has been a priority since the beginning of my Administration. On June 6, 2018, I signed the VA Maintaining Internal Systems and Strengthening Integrated Outside Networks (MISSION) Act of 2018, which authorized billions of dollars to improve options for veterans to receive care outside of Department of Veterans Affairs (VA) healthcare providers. Since taking effect, the VA estimates that more than 2.4 million veterans have benefited from more than 6.5 million referrals to the 725,000 private healthcare providers with which the VA is now working. On June 23, 2017, I signed the Department of Veterans Affairs Accountability and

Whistleblower Protection Act of 2017 to hold our civil servants accountable for maintaining the best quality of care possible for our Nation's veterans by giving the Secretary of Veterans Affairs more power to discipline employees and shorten an appeals process that can last years. On March 5, 2019, I signed Executive Order 13861 (National Roadmap to Empower Veterans and End Suicide) to ensure that the Federal Government leads a collective effort to prevent suicide among our veterans.

I have used scientific research to focus on areas most pressing for the health of Americans. On September 19, 2019, I signed Executive Order 13887 (Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health), recognizing the threat that pandemic influenza continues to represent and putting forward a plan to prepare for future influenza pandemics. To modernize influenza vaccines and promote national security and public health, HHS issued a 6-year, $226 million contract to retain and increase capacity to produce recombinant influenza vaccine domestically, and the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health within HHS, initiated the Collaborative Influenza Vaccine Innovation Centers program.

Investments my Administration has made in scientific research will help tackle some of our most pressing medical challenges and pay dividends for generations to come. This includes working to increase funding for Alzheimer's disease research by billions of dollars since 2017 and a plan to invest more than $500 million over the next decade to improve pediatric cancer research. On December 18, 2018, I signed the Sickle Cell Disease and Other Heritable Blood Disorders Research, Surveillance, Prevention, and Treatment Act of 2018 to provide support for research into sickle cell disease, which disproportionately impacts African Americans and Hispanics, and to authorize programs relating to sickle cell disease surveillance, prevention, and treatment.

On May 30, 2018, I signed the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, which gives terminally ill patients the right to access certain treatments without being blocked by onerous Federal regulations.

In response to the COVID-19 pandemic, my Administration launched Operation Warp Speed, a groundbreaking effort of the Federal Government to engage with the private sector to quickly develop and deliver safe and effective vaccines, therapeutics, and diagnostics for COVID-19. On August 6, 2020, I signed Executive Order 13944 (Combating Public Health Emergencies and Strengthening National Security by Ensuring Essential Medicines, Medical Countermeasures, and

Critical Inputs Are Made in the United States), to protect Americans through reduced dependence on foreign manufacturers for essential medicines and other items and to strengthen the Nation's Public Health Industrial Base.

Taken together, these extraordinary reforms constitute an ongoing effort to improve American healthcare by putting patients first and delivering continuous innovation. And this effort will continue to succeed because of my Administration's commitment to delivering great healthcare with more choices, better care, and lower costs for all Americans.

Sec. 2. Policy. It has been and will continue to be the policy of the United States to give Americans seeking healthcare more choice, lower costs, and better care and to ensure that Americans with pre-existing conditions can obtain the insurance of their choice at affordable rates.

Sec. 3. Giving Americans More Choice in Healthcare. The Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services shall maintain and build upon existing actions to expand access to and options for affordable healthcare.

Sec. 4. Lowering Healthcare Costs for Americans. (a) The Secretary of Health and Human Services, in coordination with the Commissioner of Food and Drugs, shall maintain and build upon existing actions to expand access to affordable medicines, including accelerating the approvals of new generic and biosimilar drugs and facilitating the safe importation of affordable prescription drugs from abroad.

(b) The Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services shall maintain and build upon existing actions to ensure consumers have access to meaningful price and quality information prior to the delivery of care.

(i) Recognizing that both chambers of the Congress have made substantial progress towards a solution to end surprise billing, the Secretary of Health and Human Services shall work with the Congress to reach a legislative solution by December 31, 2020.

(ii) In the event a legislative solution is not reached by December 31, 2020, the Secretary of Health and Human Services shall take administrative action to prevent a patient from receiving a bill for out-of-pocket expenses that the patient could not have reasonably foreseen.

(iii) Within 180 days of the date of this order, the Secretary of Health and Human Services shall update the Medicare.gov Hospital Compare website to inform beneficiaries of hospital billing quality, including:

(A) whether the hospital is in compliance with the Hospital Price Transparency Final Rule, as amended (84 *Fed*. *Reg*. 65524), effective January 1, 2021;

(B) whether, upon discharge, the hospital provides patients with a receipt that includes a list of itemized services received during a hospital stay; and

(C) how often the hospital pursues legal action against patients, including to garnish wages, to place a lien on a patient's home, or to withdraw money from a patient's income tax refund.

(c) The Secretary of Health and Human Services, in coordination with the Administrator of CMS, shall maintain and build upon existing actions to reduce waste, fraud, and abuse in the healthcare system.

Sec. 5. Providing Better Care to Americans. (a) The Secretary of Health and Human Services and the Secretary of Veterans Affairs shall maintain and build upon existing actions to improve quality in the delivery of care for veterans.

(b) The Secretary of Health and Human Services shall continue to promote medical innovations to find novel and improved treatments for COVID-19, Alzheimer's disease, sickle cell disease, pediatric cancer, and other conditions threatening the well-being of Americans.

Sec. 6. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.