Nos. 21A240 & 21A241

In the Supreme Court of the United States

JOSEPH R. BIDEN, JR., PRESIDENT OF THE UNITED STATES OF AMERICA, ET AL.,

Applicants,

v.

STATE OF MISSOURI, ET AL.,

Respondents.

XAVIER BECERRA, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,

Applicants,

v.

STATE OF LOUISIANA, ET AL.,

Respondents.

On Applications for Stays

MOTION OF FORMER SECRETARIES OF HEALTH AND HUMAN SERVICES, FORMER ADMINISTRATORS OF THE CENTERS FOR MEDICARE AND MEDICAID SERVICES, AND OTHER FORMER FEDERAL HEALTH OFFICIALS FOR LEAVE TO FILE BRIEF AS *AMICI CURIAE* AND BRIEF AS *AMICI CURIAE* IN SUPPORT OF APPLICANTS

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MOTION OF FORMER SECRETARIES OF HEALTH AND HUMAN SERVICES, FORMER ADMINISTRATORS OF THE CENTERS FOR MEDICARE AND MEDICAID SERVICES, AND OTHER FORMER FEDERAL HEALTH OFFICIALS FOR LEAVE TO FILE BRIEF AS *AMICI CURIAE* IN SUPPORT OF APPLICANTS

Donald M. Berwick, Sylvia M. Burwell, Margaret A. Hamburg, Tom Scully, Kathleen Sebelius, Donna Shalala, Andrew M. Slavitt, and Bruce C. Vladeck respectfully move under Rule 37.2(b) of the Rules of this Court for leave to file the attached brief as *amici curiae* in support of Applicants Joseph R. Biden, Jr., et al., and Xavier Becerra, et al.

Applicants took no position on the filing of this brief. Respondents consented to the filing of a timely *amicus* brief.

Amici are former Secretaries of Health and Human Services (HHS), former Administrators of the Centers for Medicare and Medicaid Services (CMS), and another former senior federal health official appointed by Presidents Clinton, George W. Bush, and Obama. They are:

Donald M. Berwick, Administrator, Centers for Medicare and Medicaid Services, 2010-2011

Sylvia M. Burwell, Secretary of Health and Human Services, 2014-2017

Margaret A. Hamburg, Commissioner, Food and Drug Administration, 2009-2015

Tom Scully, Administrator, Centers for Medicare and Medicaid Services, 2001-2004

Kathleen Sebelius, Secretary of Health and Human Services, 2009-2014

Donna Shalala, Secretary of Health and Human Services, 1993-2001

Andrew M. Slavitt, Acting Administrator, Centers for Medicare and Medicaid Services, 2015-2017

Bruce C. Vladeck, Administrator, Health Care Financing Administration (predecessor of Centers for Medicare and Medicaid Services), 1993-1997.

These cases involve challenges to a rule promulgated by the Department of Health and Human Services that requires certain employees of health care providers that receive federal funds under the Medicare and Medicaid programs to be vaccinated against COVID-19. See Medicare and Medicaid Programs: Omnibus COVID-19 Health Care Staff Vaccination (Rule), 86 Fed. Reg. 61555 (Nov. 5, 2021).

COVID-19 has produced the deadliest—and most widespread—health crisis in our nation's history.

This disease is particularly severe for older Americans and individuals who suffer from pre-existing conditions. Those are the very groups most likely to seek health care, and therefore interact with employees of health care providers such as hospitals and nursing homes. The Rule seeks to protect the health and safety of these individuals—who receive health care under the Medicare and Medicaid programs—by minimizing the risk that health care workers will contract COVID-19 and infect their patients.

As a result of their lengthy combined experience—totaling 32 years of government service—*amici* have significant expertise regarding the issues presented in these cases regarding the agencies' statutory author-

ity, the considerations that should be taken into account in promulgating rules pursuant to that authority, and the health issues raised by COVID-19.

Because of the unprecedented nature of the COVID-19 threat, the question before the Court—whether the Rule should be permitted to take effect—is extraordinarily important. Permitting the filing of the attached brief would give the Court the benefit of *amici*'s experience and expertise, and in addition provide information not brought to the Court's attention by Applicants.

For the foregoing reasons, *amici* respectfully request that they be allowed to file the attached brief as *amici curiae*.

Respectfully submitted.

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BRIEF OF FORMER SECRETARIES OF HEALTH AND HUMAN SERVICES, FORMER ADMINISTRATORS OF THE CENTERS FOR MEDICARE AND MEDICAID SERVICES, AND OTHE FORMER FEDERAL HEALTH OFFICIALS AS *AMICI CURIAE* IN SUPPORT OF APPLICANTS

INTEREST OF THE *AMICI CURIAE*[1]

Amici curiae are former Secretaries of Health and Human Services (HHS), former Administrators of the Centers for Medicare and Medicaid Services (CMS), and another senior former federal health official appointed by Presidents Clinton, George W. Bush, and Obama. They are:

Donald M. Berwick, Administrator, Centers for Medicare and Medicaid Services, 2010-2011

Sylvia M. Burwell, Secretary of Health and Human Services, 2014-2017

Margaret A. Hamburg, Commissioner, Food and Drug Administration, 2009-2015

Tom Scully, Administrator, Centers for Medicare and Medicaid Services, 2001-2004

Kathleen Sebelius, Secretary of Health and Human Services, 2009-2014

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[1] Pursuant to Rule 37.6, *amici* affirm that no counsel for a party authored this brief in whole or in part and that no person other than *amici* and their counsel made a monetary contribution to its preparation or submission. Counsel of record for all parties received notice of *amici*'s intention to file this brief more than 10 days prior to the due date for respondents' brief. Applicants take no position on the filing of this brief. Respondents consented to a timely-filed *amicus* brief.

Donna Shalala, Secretary of Health and Human Services, 1993-2001

Andrew M. Slavitt, Acting Administrator, Centers for Medicare and Medicaid Services, 2015-2017

Bruce C. Vladeck, Administrator, Health Care Financing Administration (predecessor of Centers for Medicare and Medicaid Services), 1993-1997.

This case involves a challenge to a rule issued by the Centers for Medicare and Medicaid Services—a component of the Department of Health and Human Services. As a result of their lengthy combined experience leading these and other federal health agencies—totaling 32 years of government service—*amici* have significant expertise in the issues presented regarding the agencies' statutory authority, the considerations that should be taken into account in promulgating rules pursuant to that authority, and the health issues raised by COVID-19. They file this brief to assist the Court in its consideration of these extremely important questions by explaining why the rule at issue in these cases is a lawful and reasonable exercise of the Department's authority.

SUMMARY OF ARGUMENT

COVID-19 has produced the deadliest—and most widespread—health crisis in our nation's history. Unfortunately, as recent reports document, that crisis is not over.

A significant percentage of Americans remain unvaccinated, and unvaccinated individuals face a greater risk of infection and a greater chance of serious illness or death—and also have been found more likely to transmit the disease to others. Cold weather in many parts of the country, combined with holiday travel and gatherings, increase the risk of virus transmission. And the new Omicron variant's very substantial increased transmissibility, together with uncertainty about the severity of infections that result, compounds the problem.

This disease is particularly severe for older Americans and individuals who suffer from pre-existing conditions. Those are the very groups most likely to seek health care, and therefore interact with employees of health care providers such as hospitals and nursing homes.

For these reasons, it is critically important to minimize the risk that health care workers will contract COVID-19.

There is a consensus of medical experts that the best way to accomplish this goal is to require health care workers to be vaccinated. That is the recommendation of the Centers for Disease Control and Prevention and it is the position adopted by 60 organizations that together represent virtually the entire health care profession in the United States.

Multiple studies have found that transmission of COVID-19 from health care workers to patients and to fellow workers is more likely when workers are not vaccinated than when they are vaccinated. In addition, vaccinated workers are less likely to become infected and, if they do, suffer shorter and less severe illnesses—reducing absences and therefore increasing the availability of health care services.

Against this background, the Secretary acted lawfully and reasonably in adopting the rule requiring vaccination of health care workers at facilities that receive Medicare and Medicaid funds. See Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination (Rule), 86 Fed. Reg. 61555 (Nov. 5, 2021).

To begin with, the governing statutes expressly authorize the Secretary to impose conditions on recipients of Medicare funds that he "finds necessary in the interest of the health and safety of" patients. *E.g.*, 42 U.S.C. § 1395x(e)(9). And the Secretary has similar statutory authority under the Medicaid law. HHS has long exercised that authority to require health care providers to take actions to reduce the risk of patient infection—and the broad, unrestricted statutory text easily encompasses a vaccination requirement.

The Secretary's decision to require vaccination to address COVID-19's unprecedented threat rests on an entirely reasonable assessment of the relevant considerations that is neither arbitrary nor capricious. He also carefully considered possible alternatives and particularly assessed the risk that a vaccination requirement could produce staff shortages. Finally, the Secretary concluded that good cause permitted the rule to take effect without prior notice and comment.

These determinations, which rest on the assessment of scientific evidence and balancing of policy considerations squarely within the Secretary's expertise, are well within the "zone of reasonableness" permitted for agency action. Because the Secretary "reasonably considered the relevant issues and reasonably explained the decision," *FCC* v. *Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021), the Court should allow the rule to take effect.

ARGUMENT

The Court Should Allow The Health Care Worker Vaccination Rule To Take Effect.

A. COVID-19 Continues To Pose Unique Threats In The Health Care Context.

COVID-19 is, by far, the deadliest disease in American history—with more than 802,000 deaths in our country, compared to 675,000 Americans killed by the 1918 flu.[2] That extraordinary death toll results from multiple factors.

First, the virus is highly contagious—and the newer SARS-CoV-2 variants are increasingly contagious. For example, a person infected with the original variant would on average infect two additional people, but someone infected with the Delta variant will infect

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[2] Centers for Disease Control and Prevention, *COVID Data Tracker* (visited Dec. 19, 2021), https://covid.cdc.gov/covid-data-tracker/#datatracker-home; Amy McKeever, *COVID-19 surpasses 1918 flu as deadliest pandemic in U.S. history*, National Geographic (Sept. 21, 2021), https://www.nationalgeographic.com/history/article/covid-19-is-now-the-deadliest-pandemic-in-us-history.

an average of five additional people.[3] Early reports indicate that that the new Omicron variant is dramatically more transmissible than Delta.[4]

Second, the adverse health effects resulting from a SARS-CoV-2 infection, and the length of the illness, are much more severe than for other viruses, such as the flu.[5]

Third, older Americans and individuals with compromised immune systems are especially vulnerable to the disease. Thus, "[s]eventy-five percent of people

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[3] Centers for Disease Control and Prevention, *Delta Variant: What We Know About The Science* (Aug. 26, 2021), https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html.

[4] Kanoko Matsuyama, *Omicron Four Times More Transmissible Than Delta in New Study*, Bloomberg (Dec. 8, 2021), https://www.bloomberg.com/news/articles/2021-12-09/omicron-four-times-more-transmissible-than-delta-in-japan-study#:~:text=The%20omicron%20variant%20of%20Covid,about%20the%20new%20strain's%20contagiousness ("The omicron variant of Covid-19 is 4.2 times more transmissible in its early stage than delta, according to a study by a Japanese scientist who advises the country's health ministry.").

[5] COVID-19 "is resulting in much higher morbidity and mortality than seasonal flu." Rule, 86 Fed. Reg. at 61569 (citing Lionel Piroth, et al., *Comparison of the characteristics, morbidity, and mortality of COVID–19 and seasonal influenza: a nationwide, population-based retrospective cohort study*, The Lancet (Dec. 17, 2020), https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(20)30527-0/fulltext; Yan Xie, et al., *Comparative evaluation of clinical manifestations and risk of death in patients admitted to hospital with covid–19 and seasonal influenza: cohort study*, BMJ (Dec. 15, 2020), https://www.bmj.com/content/bmj/371/bmj.m4677.full.pdf; Michael Klompas, *et al.*, *The Case for Mandating COVID–19 Vaccines for Health Care Workers*, Annuals of Internal Medicine (July 13, 2021), https://www.acpjournals.org/doi/10.7326/M21-2366).

who have died of the virus in the United States — or about 600,000 of the nearly 800,000 who have perished so far—have been 65 or older. One in 100 older Americans has died from the virus. For people younger than 65, that ratio is closer to 1 in 1,400."[6] And people with nineteen different pre-existing medical conditions "are more likely to get severely ill from COVID-19"—which could require hospitalization, intensive care, or a ventilator, and could lead to death.[7]

Fourth, a significant percentage of Americans remain unvaccinated, and unvaccinated individuals face a greater risk of infection, and a greater chance

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[6] Julie Bosman, Amy Harmon and Albert Sun, *As U.S. Nears 800,000 Virus Deaths, 1 of Every 100 Older Americans Has Perished*, N.Y. Times (Dec. 13, 2021), https://www.nytimes.com/2021/12/13/us/covid-deaths-elderly-americans.html?. See also Rule, 86 Fed. Reg. at 61566 (citing statistics demonstrating that "[a]ge remains a strong risk factor for severe COVID-19 outcomes").

[7] Centers for Disease Control and Prevention, *People With Certain Medical Conditions* (Dec. 14, 2021), https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html. These medical conditions are: cancer, chronic kidney disease, chronic liver disease, chronic lung diseases, dementia or other neurological conditions, diabetes (type 1 or type 2), Down syndrome, heart conditions, HIV infections, weakened immune system, mental health conditions, overweight and obesity, pregnancy, sickle cell disease or thalassemia, smoking (current or former), organ or blood stem cell transplant, stroke or cerebrovascular disease, substance use disorder (such as alcohol, opioid, or cocaine use disorder), and tuberculosis.

of serious illness.[8] Unvaccinated individuals who become infected also have been found to be more likely to transmit the disease to others.[9]

The coming months will be a challenging time for our country. Cold weather in many parts of the nation means that people are likely to spend more time in-

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[8] The CDC has determined that "[a]vailable evidence suggests the currently approved or authorized COVID-19 vaccines are highly effective against hospitalization and death for a variety of strains"—and cites numerous studies. Centers for Disease Control and Prevention, *Science Brief: COVID-19 Vaccines and Vaccination* (Sept. 15, 2021), https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html. Vaccinated individuals can suffer "breakthrough" infections, but "the risk of infection remains much higher for vaccinated than unvaccinated people"; "[f]ully vaccinated people with a vaccine breakthrough infection are less likely to develop serious illness than those who are unvaccinated"; and "[e]ven when fully vaccinated people develop symptoms, they tend to be less severe symptoms than in unvaccinated people. This means they are much less likely to be hospitalized or die than people who are not vaccinated." Centers for Disease Control and Prevention, *The Possibility of COVID-19 after Vaccination: Breakthrough Infections* (Nov. 9, 2021), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/effectiveness/why-measure-effectiveness/breakthrough-cases.html.

[9] Vaccinated people are much less likely to become infected. And, as the CDC has explained, vaccinated individuals who become infected "have the potential to spread the virus to others, although at much lower rates than unvaccinated people." *Science Brief: COVID-19 Vaccines and Vaccination*, *supra* n. 8. See also Mayo Clinic, *Fully vaccinated? Get the Facts* (Dec. 16, 2021), https://www.mayoclinic.org/coronavirus-covid-19/fully-vaccinated ("[p]eople with vaccine breakthrough infections may spread COVID-19 to others. However, it appears that vaccinated people spread COVID-19 for a shorter period than do unvaccinated people").

doors, which increases the risk of virus transmission.[10] Large gatherings and travel—both welcome features of the holiday season—also significantly increase transmission risk.[11] And these problems are compounded by recent demonstrations of the Omicron variant's very substantial increased transmissibility and uncertainty about the severity of infections that result.

The number of new infections in recent weeks has already increased dramatically—a ten-fold increase compared to six months ago.[12] Even the short-term increase is significant: more than 55% since November

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[10] "Respiratory virus infections typically circulate more frequently during the winter months, with peaks in pneumonia and influenza deaths typically during winter months" and "the U.S. experienced a large COVID–19 wave in the winter of 2020." Rule, 86 Fed. Reg. at 61584; see also Centers for Disease Control and Prevention, *Influenza (Flu) – Background and Epidemiology* (Aug. 26, 2021), https://www.cdc.gov/flu/professionals/acip/background-epidemiology.htm ("[p]eak activity most commonly occurs during the winter").

[11] Bridget Balch, Amer. Ass'n of Medical Colleges, *Another pandemic holiday: Can we gather safely this year?* (Dec. 14, 2021), https://www.aamc.org/news-insights/another-pandemic-holiday-can-we-gather-safely-year (discussing risks posed by travel and gatherings).

[12] The seven-day average of the number of infections was 11,812 on June 17, 2021, and 128,142 on December 17, 2021. Centers for Disease Control and Prevention, *Daily Trends in Number of COVID-19 Cases in The US Reported to CDC* (last accessed Dec. 21, 2021), https://covid.cdc.gov/covid-data-tracker/#trends_dailycases.

2.[13] Hospitalizations due to COVID have also increased dramatically.[14]

These realities have significant consequences for the nation's health care system.

Health care workers are very likely to come into contact with older Americans and those with preexisting conditions. Nursing home residents all fall into at least one of those categories, and often both. And individuals seeking treatment at hospitals and other health care centers are disproportionately older and sicker, and also more likely to suffer from pre-existing conditions.[15]

Multiple studies have found that transmission of COVID-19 from health care workers to patients is more likely when workers are not vaccinated than when they are vaccinated.[16]

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[13] *Ibid*. (70,779 on November 2 and 128,142 on December 17).

[14] The seven-day average of the number of hospitalized patients was 43,260 on November 17, 2021, and 61,008 on December 17, 2021—an increase of 20% in just one month. Centers for Disease Control and Prevention, *Prevalent Hospitalizations of Patients with Confirmed COVID-19, United States* (last accessed Dec. 21, 2021), https://covid.cdc.gov/covid-data-tracker/#hospitalizations; see also Mitch Smith, *Doctors and Nurses Are 'Living in a Constant Crisis' as Covid Fills Hospitals*, N.Y. Times (Dec. 17, 2021) ("[t]he highly contagious Omicron variant arrives in the United States at a moment when there is little capacity left in hospitals, especially in the Midwest and Northeast, where case rates are the highest").

[15] Rule, 86 Fed. Reg. at 61568 (explaining why "individuals seeking health care services are more likely to fall into the high-risk category").

[16] One study found "that case rates among [nursing home] facility residents are higher in facilities with lower vaccination coverage

Also, health care workers spend considerable time in close proximity to one another—both when performing their duties and when in rest areas. Staff-to-staff transmission has been identified as a significant cause of COVID-19 infection.[17] In addition to the threat to health care workers who become infected,

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among staff"—residents in "facilities in which vaccination coverage of staff is 75 percent or lower experience higher rates of preventable COVID–19." Rule, 86 Fed. Reg. at 61558 (citing Centers for Disease Control and Prevention, *Vaccination to Prevent COVID-19 Outbreaks with Current and Emergent Variants — United States, 2021* (July 27, 2021), https://emergency.cdc.gov/han/2021/han00447.asp). Another study, at Yale New Haven Hospital, found that health care units with more than one COVID-19 case "had lower staff vaccination rates." *Ibid*. (citing Scott C. Roberts, et al., *Correlation of healthcare worker vaccination with inpatient healthcare-associated coronavirus disease 2019 (COVID–19)*, Infection Control & Hospital Epidemiology (Sept. 21, 2021), https://doi.org/10.1017/ice.2021.414). The Secretary discussed a number of additional studies. 86 Fed. Reg. at 61558 & nn. 39-41 & 43. And more recent studies reach the same conclusion. For example, an analysis of nursing home data found a greater rate of patient infections in facilities with low staff vaccination rates, compared to infections in counties with higher vaccination rates. Estimates based on the model "suggest that if all the nursing homes in our sample had been in the highest quartile of staff vaccination coverage (82.7% on average), 4775 cases among residents (29% of the total during the study window), 7501 cases among staff (29% of the total), and 703 Covid-19–related deaths among residents (48% of the total) could possibly have been prevented." Brian E. McGarry, et al., *Correspondence – Nursing Home Staff Vaccination and Covid-19 Outcomes*, The New England Journal of Medicine (Dec. 8, 2021), https://www.nejm.org/doi/full/10.1056/NEJMc2115674.

[17] Clare L. Gordon, et al., *Staff to staff transmission as a driver of healthcare worker infections with COVID-19*, 26 Infection, Disease & Health 276, 277 (Nov. 2021) (79% of health care worker infections acquired at hospital found to result from staff-to-staff transmission).

transmission among health care workers increases the risk to patients, and also requires all exposed individuals to quarantine—reducing available staff at a time when health care providers are already stretched to, and often beyond, their capacity to serve patients due to the increase in COVID-19 cases.

For these reasons, it is critically important to minimize to the greatest extent possible the risk that health care workers will contract COVID-19.

B. There Is a Broad Expert Consensus In Favor Of Mandatory Vaccination For Health Care Workers.

The strong consensus view of expert medical organizations is that best way to protect patients, health care workers, and the nation's health care system is for health care workers to be vaccinated against COVID-19.

Seven organizations representing epidemiologists and others expert in infectious diseases stated in July 2021 that "vaccination should be a condition of employment for all healthcare personnel in facilities in the United States" except for those with medical contraindications and "and other exemptions as specified by federal or state law."[18] They identified three "benefits of a fully vaccinated workforce"—"(1) reducing

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[18] *Multisociety statement on coronavirus disease 2019 (COVID-19) vaccination as a condition of employment for healthcare personnel* (July 13, 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8376851/. This statement was issued by the Society for Healthcare Epidemiology of America, the Society for Post-Acute and Long-Term Care Medicine, the Association for Professionals in Epidemiology and Infection Control, the HIV Medicine Association, the Infectious Diseases Society of America, the Pediatric

the risk of transmission within healthcare facilities among [healthcare personnel] and patients, from the community to healthcare facilities, and from healthcare facilities to the community; (2) maintaining a healthy workforce and supporting [healthcare personnel] wellness; and (3) maintaining the trustworthiness of [healthcare personnel] and healthcare institutions."[19]

The organizations observed that "[h]istorically, the most effective strategies for managing viral illnesses (eg, measles, rubella, and influenza) have been by vaccination."[20] But they concluded that "[p]rior experience and current information suggest that a sufficient vaccination rate is unlikely to be achieved without making COVID-19 vaccination a condition of employment."[21] They explained that "[t]he experience to date with voluntary influenza vaccination, as opposed to influenza vaccination as a condition of employment, suggests that without requiring COVID-19 vaccination, target coverage," which requires greater-than-90% coverage, "will rarely be achieved"—because "[c]ompliance among those who were required by their employer to receive the vaccination was 94.4%, compared to 69.6% among those without vaccination as a condition of employment."[22]

An additional 53 organizations—that together represent essentially the entire health care profession

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Infectious Diseases Society, and the Society of Infectious Diseases Pharmacists.

[19] *Id*. at 4.

[20] *Id*. at 2.

[21] *Id*. at 1.

[22] *Id*. at 5.

in the United States—have reached the same conclusion. They "advocate that all health care and long-term care employers require their workers to receive the COVID-19 vaccine. This is the logical fulfillment of the ethical commitment of all health care workers to put patients as well as residents of long-term care facilities first and take all steps necessary to ensure their health and well-being."[23]

C. The Vaccination Rule Is A Valid Exercise Of The Department's Regulatory Authority.

The rule falls within HHS's statutory authority to establish conditions for health care providers that receive Medicare and Medicaid funds; the Secretary's determination is eminently reasonable; and the Secretary properly made the rule effective immediately.

1. The Department's statutory authority plainly encompasses infection-control requirements, including a vaccination requirement.

Medicare and Medicaid are huge federal programs. The government's expenditures in calendar

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[23] *Joint Statement in Support of COVID-19 Vaccine Mandates for All Workers in Health and Long-Term Care* (Sept. 2021), https://www.acponline.org/acp_policy/statements/joint_statement_covid_vaccine_mandate_2021.pdf.

The statement was joined by the American Medical Association, American College of Surgeons, American College of Physicians, National Medical Association, and many other physician specialty societies. Other signing organizations include the American Nursing Association and a number of other organizations representing nurses; and organizations representing pharmacists and other medical professionals.

year 2020 totaled nearly $1.2 trillion.[24] Medicare provides health care for 62.8 million Americans 65 or older and certain younger disabled individuals; Medicaid covers 76.5 million low-income Americans, including many who are disabled or elderly.[25]

Given the very large number of Americans whose health is dependent on these programs (over 40% of the country), it is not surprising that Congress has conferred upon the Department of Health and Human Services broad authority to impose conditions on the recipients of this enormous amount of federal funds—to ensure that the government's money is properly utilized and that the beneficiaries of these important programs are properly protected. That authority plainly includes the power to impose requirements to protect patients against infection, such as the vaccination rule at issue in this case.

Providers of health care services are eligible for payment under the Medicare and Medicaid statutes only if they meet the conditions for participation in those programs. 42 U.S.C. § 1395cc(b)(2); 42 U.S.C. § 1396a. The statutes expressly authorize the Secretary to impose conditions to protect the health and safety of patients receiving services paid for by those programs.

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[24] CMS, *National Health Expenditure Data*, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet.

[25] CMS, *Fast Facts* (Nov. 2021), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Fast-Facts (Medicare data for calendar year 2020; Medicaid data for fiscal year 2020).

Thus, the Medicare law authorizes payments for "hospital services," 42 U.S.C. § 1395d(a), and imposes a number of requirements in defining the "hospital" that is eligible to receive such payments, see *id.* § 1395x(e). One such requirement is that the hospital must "meet such * * * requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution." *Id.* § 1395x(e)(9).

Similar authority applies to the other categories of health care providers that receive payments under Medicare. See, *e.g.*, 42 U.S.C. § 1395i-3(d)(4)(B) ("[a] skilled nursing facility must meet such other requirements relating to the health, safety, and well-being of residents * * * as the Secretary may find necessary"); *id.* § 1395k(a)(2)(F)(i) (ambulatory surgical center must "meet[] health, safety, and other standards specified by the Secretary in regulations"); *id.* § 1395x(p)(4)(A)(v) (outpatient physical therapy services); *id.* § 1395x(aa)(2)(K) (rural health clinics); *id.* § 1395x(cc)(2)(J) (comprehensive outpatient rehabilitation facilities); *id.* § 1395x(dd)(2)(G) (hospice facilities).

And the government has similar statutory authority under the Medicaid law. 42 U.S.C. § 1396r(d)(4)(B) (requiring nursing homes to "meet such other requirements relating to the health and safety of residents or relating to the physical facilities thereof as the Secretary may find necessary"); see also, *e.g.*, 42 U.S.C. §§ 1396d(h), 1396d(*l*)(1), 1396d(o) (incorporating Medicare standards for various categories of health care providers).

The agency has used this authority to require health care providers to take a variety of actions to address and reduce the risk of patient infection. See,

e.g., 42 C.F.R. § 483.80 (requiring long term care facilities to maintain an "infection prevention and control program" to "help prevent the development and transmission of communicable diseases and infections" and specifying particular standards to prevent transmission of viruses); 42 C.F.R. § 482.42 (specifying requirements for "active hospital-wide programs for the surveillance, prevention, and control of [healthcare-associated infections] and other infectious diseases"); 42 C.F.R. § 485.640 (same for critical access hospitals); 42 C.F.R. § 484.70(b) (same for home health agencies); 42 C.F.R. § 416.51 (same for ambulatory surgical services); 42 C.F.R. § 418.60 (same for hospice care); 42 C.F.R. § 494.30 (same for end-stage renal disease facilities); 42 C.F.R. § 485.725 (same for outpatient physical therapy and speech-language pathology services).

The Department has not previously imposed a vaccination requirement, but the broad statutory text—authorizing requirements the Secretary "finds necessary in the interest of the health and safety" of patients—plainly encompasses such a requirement. Certainly there is no basis for reading that unqualified language to exclude a vaccination requirement. See also *Jacobson* v. *Massachusetts*, 197 U.S. 11, 28 (1905) (holding that vaccination requirement falls within a State's police power "to protect the public health and secure the public safety").

Indeed, "vaccination requirements, like other public-health measures, have been common in this nation." *Klaassen* v. *Trustees of Ind. Univ.*, 7 F.4th 592, 593 (7th Cir. 2021). Congress's expansive grant of "health and safety" authority to protect patients receiving care under the Medicare and Medicaid programs cannot reasonably be read to prevent the

agency from adopting a measure that States have found necessary to protect the health and safety of their citizens.

Finally, 42 U.S.C. § 1395, which bars federal "supervision or control over the practice of medicine or the manner in which medical services are provided," does not bar the imposition of a vaccination requirement—any more than it bars the infection control measures required under long-established CMS regulations. The vaccination regulation says nothing about how medical services are provided to patients or how doctors and nurses practice medicine. Accord, *Florida* v. *Department of Health and Human Services*, No. 21-14098, 2021 WL 5768796, at *12 (11th Cir. Dec. 6, 2021).[26]

2. The Secretary's determination that a vaccination requirement is necessary to protect patients' health and safety is not arbitrary or capricious.

The parties challenging the rule also argue that it is arbitrary and capricious. But this Court has made

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[26] The Missouri district court stated (21A240 App. 9a) that clear congressional authorization is required because the rule interferes with traditional state authority. The statutory text here is clear; but that requirement does not apply because the rule simply sets the terms for the use of federal funds. "Congress may attach conditions on the receipt of federal funds, and has repeatedly employed the power 'to further broad policy objectives by conditioning receipt of federal moneys upon compliance by the recipient with federal statutory and administrative directives.'" *South Dakota* v. *Dole*, 483 U.S. 203, 206 (1987) (citation omitted) (upholding condition on State's use of federal funds). There can be no dispute that the condition here relates to a federal policy objective—protection of patient health and safety—that is tied directly to the purpose of the federal programs.

clear that judicial review under this standard is "deferential"—"a court may not substitute its own policy judgment for that of the agency. A court simply ensures that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision." *Prometheus Radio Project*, 141 S. Ct. at 1155. The Secretary's determinations satisfy that standard.

To begin with, the Secretary reasonably determined that COVID-19's unique threat justifies a vaccination requirement. He based that decision on:

- The virus's high transmissibility and the often-severe consequences of infection—particularly for the older Americans covered by Medicare and the disabled Americans covered by both Medicare and Medicaid—and the risk posed by new variants, *Rule*, 86 Fed. Reg. at 61556-57, 61566, 61568, 61609;
- Significant levels of infection among health care workers and patients, *id.* at 61559, 61585;
- The expert consensus supporting vaccination, *id.* at 61565;[27]

[27] See pages 12-14, *supra*. The Secretary also pointed out that AARP, an organization representing 38 million older Americans, advocated mandatory vaccination for nursing home workers. 86 Fed. Reg. at 61565 & n.124. AARP explained that "more than 186,000 residents and staff of nursing homes and other long-term care facilities have died from COVID-19 – representing around 30% of deaths, even though less than 1% of the population lives in these facilities"; that "[o]nly one-quarter of nursing homes had at least 75% of staff vaccinated, which is the benchmark goal the

- Studies showing staff-to-patient transmission is higher when health care workers are not vaccinated, *id.* at 61557, 61559, 61566, 61583;[28]
- The effectiveness of the vaccine in preventing infection, *id.* at 61558, 61583, 61585-86;
- Low vaccination rates among health care workers, and significant variation of vaccination rates across geographic regions and types of facilities, *id.* at 61559, 61566, 61584-85; and
- The beneficial effect of vaccination in alleviating staff shortages, *id.* at 61558-59, 61608.[29]

The Secretary also assessed possible alternative approaches. For example, he explained that studies had found that already-existing protective measures

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industry has set"; and that "the vaccination rates vary dramatically by state and location. Staff vaccination rates ranged from a low of 44% in Louisiana to 87% in Hawaii." AARP, *New AARP Analysis Shows Nursing Homes Vaccination Rates Still Well Short of Benchmark as COVID Cases Trend Upwards* (Aug. 12, 2021), https://press.aarp.-org/2021-8-12-New-AARP-Analysis-Shows-Nursing-Homes-Vaccination-Rates-Still-Well-Short-of-Benchmark-as-COVID-Cases-Trend-Upwards.

[28] See also note 16, *supra*. The Secretary also observed that vaccination is more effective that other measures in preventing staff-to-patient flu infections. Rule, 86 Fed. Reg. at 61557-58.

[29] Additional studies confirm that vaccinated health care workers are less likely to be infected, and miss fewer days of work if they are. See, *e.g.*, Earl Strum, et al., *Healthcare workers benefit from second dose of COVID-19 mRNA vaccine: Effects of partial and full vaccination on sick leave duration and symptoms* (preprint, posted Nov. 21, 2021), https://doi.org/10.1101/2021.-11.17.21266479.

were not effective in preventing staff-to-patient transmission. 86 Fed. Reg. at 61557, 61559, 61566, 61583. He "considered requiring daily or weekly testing of unvaccinated individuals," but—after "review[ing] scientific evidence on testing"—found vaccination a "more effective infection control measure." *Id*. at 61614. And he rejected the option of exempting previously-infected health care workers because of "uncertainties about * * * the strength and length of this immunity compared to people who are vaccinated," and also cited the CDC recommendation that previously-infected individuals get vaccinated. *Ibid*.; see also *id*. at 61559.

These determinations fall well within the "zone of reasonableness" established by the arbitrary-and-capricious standard. That is particularly true because they rest on the assessment of scientific evidence and policy considerations squarely within the Secretary's expertise.

Finally, the Missouri district court erred in concluding (21A240 App. 25a-31a) that the Secretary did not adequately consider the risk that a vaccination requirement could produce staff shortages.

The Secretary specifically addressed that concern, stating that "there might a certain number of health care workers who choose to" leave their jobs rather than be vaccinated. Rule, 86 Fed. Reg. at 61569. But he explained that "many COVID-19 vaccination mandates have already been successfully initiated in a variety of health care settings, systems and states." *Ibid*. And he cited examples of health care systems that had

adopted vaccination requirements with 99.5%, 99%, and 95% compliance. *Id*. at 61569 & nn. 156-59.[30]

The Secretary further stated that "COVID-related staff shortages are occurring absent the rule due to numerous factors, such as infection, quarantine and staff illness," that would be reduced dramatically as a result of the rule. He determined that, accordingly, "there is no reason to think" that resignations due to the vaccination requirement "will be a net minus even in the short term" even though there may be "some short-term disruption of current levels for some providers or suppliers in some places." 86 Fed. Reg. at 61608-09. That is especially true, the Secretary added, because of the large "magnitude of normal turnover" of health care employees—which he estimated at more than 25% annually. *Ibid*.

The Secretary also explained that "[t]he current patchwork of regulations undermines the efficacy of COVID–19 vaccine mandates [adopted by individual hospital or nursing home systems or States] by encouraging unvaccinated workers to seek employment at providers that do not have such patient protections,

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[30] Information released after issuance of the rule provides additional support for the Secretary's conclusion: numerous health care providers from throughout the country have reported extremely high rates of compliance with vaccination requirements. See Dave Muoio, Fierce Healthcare, *How many employees have hospitals lost to vaccine mandates? Here are the numbers so far* (Nov. 23, 2021), https://www.fiercehealthcare.com/hospitals/how-many-employees-have-hospitals-lost-to-vaccine-mandates-numbers-so-far (compiling data, with links to the companies' reports, with the overwhelming majority of providers reporting greater than 95% compliance and most with compliance in excess of 98%). Of course, this report does not compile information on the countervailing benefits realized from staff vaccination—in terms of reduced sick and quarantine leave.

exacerbating staffing shortages, and creating disparities in care across populations." Rule, 86 Fed. Reg. at 61584. The rule prevents such a "race to the bottom" by putting all Medicare and Medicaid health care providers on an equal footing.

The Secretary concluded that "the COVID-19 vaccine requirements [imposed by the rule] will result in nearly all health care workers being vaccinated, thereby benefitting all individuals in health care settings." *Id*. at 61569.

That determination, too, falls squarely within the Secretary's authority—especially given the predictive nature of the judgment. The Secretary "reasonably considered the relevant issue[] and reasonably explained the decision." *Prometheus Radio Project*, 141 S. Ct. at 1155.

3. The Secretary's decision to make the rule immediately effective is supported by good cause.

The Administrative Procedure Act (APA) permits an agency to issue immediately-effective rules if the agency finds "good cause" that "notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b); see also 42 U.S.C. § 1395hh(b)(2)(C) (incorporating the APA standard).

That standard is satisfied here, because the rule addresses an imminent threat to patients' life and health. See *Sorenson Communications Inc.* v. *FCC*, 755 F.3d 702, 706 (D.C. Cir. 2014) ("[W]e have approved an agency's decision to bypass notice and comment where delay would imminently threaten life."); Rule, 86 Fed. Reg. at 61612 (estimating significant "patient and resident benefits" in terms of hundreds

or thousands of "lives saved" each month); *Florida*, 2021 WL 5768796, at *14 (upholding good cause determination).

The Missouri district court stated that the agency's "good cause claim is undermined by its *own* delay in promulgating the mandate." 21A240 App. 13a. But the Secretary correctly explained, in detail, why it would not have been proper to act earlier.

COVID vaccines were authorized for health care workers in December 2020, and the agency chose initially "to encourage rather than mandate vaccination, believing that" education campaigns and other actions would produce a high level of vaccination. Rule, 86 Fed. Reg. at 61583. But the Secretary found that vaccination levels are "insufficient to protect the health and safety of individuals receiving health care services" under Medicare and Medicaid, * * * particularly given the advent of the Delta variant and the potential for new variants" (*ibid.*)—a potential recently realized with Omicron. See also *id.* at 61584 (listing multiple factors supporting conclusion that delay "would contribute to negative health outcomes for patients, including loss of life"—including insufficient level of vaccination, risk of new variants, strain on the health care system from Delta variant, full licensure of vaccines by FDA, and additional evidence regarding the efficacy and safety of vaccines).

Given the Secretary's expertise on these matters, that assessment is more than sufficient to establish good cause.

CONCLUSION

The applications for stays should be granted.

Respectfully submitted.

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