

**In the Supreme Court of the United States**

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

v.

STATE OF MISSOURI, ET AL.

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

v.

STATE OF LOUISIANA, ET AL.

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*On Applications for Stays of Injunctions Issued by the United States District Courts  
for the Western District of Louisiana and Eastern District of Missouri  
Pending Appeals to the United States Courts of Appeals  
for the Fifth and Eighth Circuits*

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**MOTION OF AMERICAN PUBLIC HEALTH ASSOCIATION,  
ASSOCIATION OF AMERICAN MEDICAL COLLEGES,  
22 DEANS OF LEADING ACADEMIC PROGRAMS, AND  
126 LEADING PUBLIC HEALTH AND HEALTH POLICY SCHOLARS FOR LEAVE TO FILE  
ATTACHED BRIEF AS *AMICI CURIAE* IN SUPPORT OF APPLICANTS**

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December 23, 2021

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## MOTION FOR LEAVE TO FILE AN *AMICUS* BRIEF

American Public Health Association, Association of American Medical Colleges, 22 deans of leading academic programs, and 126 leading public health and health policy scholars respectfully move for leave to file the attached brief as *amici curiae* in support of the applicants' applications for stays of injunctions issued by the United States District Courts for the Eastern District of Missouri and the Western District of Louisiana.

The proposed *amici* seek to file this brief to demonstrate to the Court that the overwhelming public-health and scientific consensus supports the need to mandate vaccination of eligible staff at Medicaid and Medicare facilities to protect Medicare and Medicaid patients, as well as the healthcare workers who provide them care. Through this brief, the proposed *amici* also seek to explain that well-established evidence, buttressed by more recent, cutting-edge empirical studies during the pandemic, shows that vaccination can effectively reduce SARS-CoV-2 exposure and transmission in healthcare settings. The proposed *amici* are concerned that the injunctions entered in these cases will delay measures needed to control the spread of COVID-19 and will further endanger American healthcare workers and patients.

Given the Court's expedited consideration of this matter of significant national interest, the proposed *amici* provided notice to all parties of their intent to file by email on December 22, 2021. Counsel for the respondents in No. 21A240 stated that they consent to the filing, and counsel for the respondents in No. 21A241 stated that they do not object to it. The applicants take no position on this motion.

To the extent that leave is required, the proposed *amici* respectfully move for leave to file the attached brief on 8½- by 11-inch paper rather than in booklet form, given the expedited briefing. Should the Clerk’s Office or the Court so require, the proposed *amici* commit to re-filing expeditiously in booklet format. *See* S. Ct. Rule 21.2(c).

### CONCLUSION

For the foregoing reasons, the proposed *amici* respectfully request that the Court grant leave to file the attached *amicus* brief in the format and at the time submitted.

Respectfully submitted,

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## INTEREST OF *AMICI CURIAE* AND SUMMARY OF ARGUMENT<sup>1</sup>

Even before the Delta and Omicron variants, COVID-19 had profoundly transformed American life. As we are all too aware, the brunt of this pandemic has been disproportionately shouldered by America's most vulnerable: Elderly people, the chronically ill, pregnant women, and people with disabilities all face far higher risks of infection, hospitalization, and death than the general population. Since the pandemic's earliest days, nursing homes and long-term care facilities have repeatedly emerged as our nation's worst hotspots, visiting serious illness and death on residents and staff alike.

Throughout all of this, America's healthcare workers have been toiling day-in and day-out at the front lines to keep their patients and their communities safe. Despite their heroic efforts, however, it is clear that this pandemic is not ending anytime soon. Cases and hospitalizations are once again increasing and, as long as much of the world remains unvaccinated, new variants will continually emerge. Even when vaccination cannot prevent COVID-19 entirely, the science is clear: vaccinations reduce transmissibility and severity. To protect the country's most vulnerable people and its healthcare workers, the Secretary of Health and Human Services issued a rule requiring that facilities serving Medicare and Medicaid patients ensure that their staff are fully vaccinated. *Omnibus COVID-19 Health Care Staff Vaccination*, 86 Fed. Reg. 61,555, 61,601 (Nov. 5, 2021).

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<sup>1</sup> *Amici* have moved for leave to file this brief. No party's counsel authored this brief, in whole or in part, and no party or party's counsel, nor anyone other than *amici* or their counsel, contributed money intended to fund its preparation or submission.

As the Solicitor General persuasively explains, the Secretary of Health and Human Services acted well within his statutory authority in issuing a vaccination rule for healthcare facilities that receive federal dollars. *See* App. for Stay at 20–25, *Becerra v. Louisiana*, No. 21A241; App. for Stay at 18–24, *Biden v. Missouri*, No. 21A240. This brief—on behalf of many of the nation’s leading public-health and healthcare scholars and professional organizations—explains how that rule also reflects the most recent scientific evidence and research. This evidence is clear: The nature of both the virus and healthcare facilities puts Medicare and Medicaid recipients, and the staff who care for them, especially at risk of COVID-19 transmission and infection. Because it is an airborne pathogen primarily transmitted through the inhalation of small respiratory particles, SARS-CoV-2 spreads particularly well between people who must spend hours together in close quarters indoors—which accurately describes those who receive and provide care in America’s hospitals, nursing homes, long-term care facilities, and other healthcare settings.<sup>2</sup>

The scientific evidence is also clear about the best way to combat COVID-19’s spread: vaccines. All the evidence shows that vaccination significantly reduces the likelihood that healthcare workers will transmit COVID-19 and infect patients and other workers. And vaccination *drastically* reduces the chance of hospitalization and death for those who contract COVID-19. For these reasons, a number of private healthcare employers and states have already imposed vaccine requirements on healthcare staff, which have engendered widespread vaccination uptake and have consistently proven effective.

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<sup>2</sup> “SARS-CoV-2” refers to the virus and “COVID-19” refers to the disease it causes. For the reader’s convenience, however, this brief (like much of the scientific literature) will often refer to “COVID-19” to mean both the virus and the disease.

*Amici curiae* file this brief to explain that the vaccination rule reflects this overwhelming scientific and public-health consensus. *Amici* are a diverse group of scholars and professional organizations of public health and healthcare practitioners who share a deep commitment to the health of American healthcare workers and patients. They include more than one hundred of the country’s leading educators, scholars, and public health and healthcare professionals, as well as 22 deans and associate deans of leading academic programs across the United States. The individual *amici* are joined by the American Public Health Association and Association of American Medical Colleges, organizations dedicated to advancing public health and healthcare through education, research, and advocacy.<sup>3</sup>

## ARGUMENT

### **I. COVID-19 poses a uniquely grave risk to Medicare and Medicaid recipients and healthcare workers.**

In issuing its vaccination rule, the Centers for Medicare and Medicaid Services emphasized that “[a]lmost all CMS-regulated providers and suppliers disproportionately serve people who are older, disabled, chronically ill, or who have complex health care needs.” 86 Fed. Reg. at 61,601. These groups are not only at heightened risk of contracting COVID-19—they are also more likely to experience devastating health outcomes once infected.

To see why, consider first the locations where Medicare and Medicaid recipients access medical services. Overwhelming evidence shows that the facilities that provide care to these patient populations—hospitals, inpatient rehabilitation facilities, skilled nursing facilities (also known as nursing homes or long-term care facilities), psychiatric residential

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<sup>3</sup> The identity of each *amicus curiae* is set forth in the appendix to this brief.

treatment facilities, home-health agencies, and hospices—are especially susceptible to COVID-19 outbreaks.<sup>4</sup> Patients and residents in these facilities often require close contact with staff, and these patients may have difficulty understanding information or practicing preventative measures themselves. 86 Fed. Reg. at 61,575. And, out of necessity, patients spend time in close contact with one other in shared living or treatment spaces. *Id.*

The science shows that SARS CoV-2—an airborne, respiratory virus—can run rampant under precisely these conditions.<sup>5</sup> It is well-known that nursing homes have been frequent sites of COVID-19 outbreaks, with about 94 percent experiencing two or more outbreaks of the disease among residents or staff.<sup>6</sup> But there is a heightened risk of transmission in healthcare facilities more broadly. During the first six months of the

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<sup>4</sup> See, e.g., Sally Hall Dykgraaf et al., *Protecting Nursing Homes and Long-Term Care Facilities From COVID-19: A Rapid Review of International Evidence*, 22 J. Am. Med. Dirs. Ass'n 1969, 1969–88 (Oct. 2021), <http://doi.org/10.1016/j.jamda.2021.07.027>; M. Keith Chen et al., *Nursing home staff networks and COVID-19*, 118 PNAS 1, 1–7 (Nov. 2020), <http://doi.org/10.1073/pnas.2015455118>; Ethan Geringer-Sameth, *Covid Toll at State Psychiatric Facilities Has Remained Disproportionately High*, Gotham Gazette (Feb. 26, 2021), <https://perma.cc/V5Z7-ABU6> (reporting that “one-fifth of patients in state-run inpatient psychiatric centers have contracted COVID-19 since the outbreak began”); Jeannette Kates et al., *The impact of COVID-19 on the hospice and palliative care workforce*, 38 Pub. Health Nursing 459, 459–463 (Oct. 2020), <http://doi.org/10.1111/phn.12827>; Susan R. Sama et al., *Impacts of the COVID-19 Pandemic on Home Health and Home Care Agency Managers, Clients, and Aides: A Cross-Sectional Survey, March to June, 2020*, 22 Home Health Care Management & Practice 125, 125–29 (2021), <http://doi.org/10.1177/1084822320980415>.

<sup>5</sup> See, e.g., Chen et al., *supra* n.4; 86 Fed. Reg. at 61,557–58 (citing studies).

<sup>6</sup> U.S. Gov’t Accountability Off., GAO-21-367, *COVID-19 in Nursing Homes* (2021), <https://perma.cc/LC7G-8H47>; see also 86 Fed. Reg. at 61,585 nn.207–09 (citing data).

pandemic, for example, up to one in six COVID-19 infections among hospitalized patients in England was caused by transmissions in healthcare settings.<sup>7</sup>

The risks of COVID-19 transmission and infection are compounded by the unique vulnerability of Medicare and Medicaid beneficiaries. Medicare recipients—primarily individuals who are over age 65—belong to the age group that has been at the greatest risk of hospitalization and death due to COVID-19. *See* 86 Fed. Reg. at 61,601. This cohort represents nearly 80 percent of all COVID-19 deaths.<sup>8</sup> And while infections, hospitalizations, and deaths initially declined after the widespread vaccination efforts in the first half of 2021, in recent months they have increased exponentially. *See* 86 Fed. Reg. at 61,559 (“Between late June 2021 and September 2021, daily cases of COVID-19 increased over 1200 percent; new hospital admissions, over 600 percent; and daily deaths, by nearly 800 percent.”). The Centers for Disease Control and Prevention’s data also shows that the new “waves” of COVID-19 pose a particularly grave threat to older individuals: about 70 percent of “breakthrough” infections that required hospitalization were among adults over age 65. More sobering still, this group accounted for 87 percent of all breakthrough deaths.<sup>9</sup>

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<sup>7</sup> Alex Bhattacharya et al., *Healthcare-associated COVID-19 in England: A national data linkage study*, 83 J. of Infection 565, 565-72 (2021), <http://doi.org/10.1016/j.jinf.2021.08.039>; *see also* 86 Fed. Reg. at 61,557.

<sup>8</sup> *See* CDC, *Demographic Trends of COVID-19 cases and deaths in the US reported to CDC* (last visited December 22, 2021), <https://perma.cc/9KLS-3K65>.

<sup>9</sup> Fiona P. Havers et al., *COVID-19-associated hospitalizations among vaccinated and unvaccinated adults ≥18 years – COVID-NET, 13 states, January 1 – July 24, 2021*, medRxiv (preprint, posted July 24, 2021), <http://doi.org/10.1101/2021.08.27.21262356>; *see also* Dierdre McPhillips, *Risk of severe breakthrough Covid-19 higher for seniors and people with underlying conditions*, CNN (Sept. 8, 2021), <https://perma.cc/3TKZ-X8UD>.



Substantial evidence likewise confirms that the low-income individuals eligible for Medicaid—which includes pregnant women, people with disabilities, and children—are also particularly vulnerable to both COVID-19 infection and serious COVID-19 complications. *See* 86 Fed. Reg. at 61,557. Medicaid covers nearly half of all births nationally, and an even greater share of births in rural areas and among minority women.<sup>10</sup> One multinational cohort study of pregnant women in 18 countries found that COVID-19 in pregnancy was associated with consistent and substantial increases in severe maternal morbidity and mortality, as well as neonatal complications.<sup>11</sup> The risk of death from COVID-19 is also higher for people with disabilities, both for those who live in household settings as well as congregate residential settings.<sup>12</sup>

The COVID-19 pandemic has also exacerbated existing health inequities suffered by people of color. Black Americans make up roughly 20 percent of Medicaid recipients, and Latino Americans make up roughly 30 percent.<sup>13</sup> The evidence shows that Black and Latino

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<sup>10</sup> Medicaid & CHIP Payment & Access Comm’n, *Medicaid’s Role in Financing Maternity Care* at 1 (Jan. 2020), <https://perma.cc/BQ9D-H5GR>.

<sup>11</sup> Jose Villar et al., *Maternal and Neonatal Morbidity and Mortality Among Pregnant Women With and Without COVID-19 Infection: The INTERCOVID Multinational Cohort Study*, 175 *JAMA Pediatrics* 817, 817–826 (Apr. 2021), <http://doi.org/10.1001/jamapediatrics.2021.1050>.

<sup>12</sup> *See, e.g.*, Tom Shakespeare et al., *Triple jeopardy: disabled people and the COVID-19 pandemic*, 397 *Lancet* 1331 (Apr. 10, 2021), [http://doi.org/10.1016/S0140-6736\(21\)00625-5](http://doi.org/10.1016/S0140-6736(21)00625-5); Scott D. Landes et al., *COVID-19 outcomes among people with intellectual and developmental disability living in residential group homes in New York State*, 13 *Disability & Health J.* (2020), <http://doi.org/10.1016/j.dhjo.2020.100969>.

<sup>13</sup> *See* Kaiser Fam. Found., *State Health Facts, Distribution of the Nonelderly with Medicaid by Race/Ethnicity* (2019), <https://perma.cc/MLP9-J77E>.

Americans are admitted to hospitals with more severe COVID-19 disease as compared with non-Hispanic White people, increasing the likelihood that these patients will require intubation, be admitted to the ICU, or die.<sup>14</sup> And a February 2021 analysis found that both groups “have experienced a disproportionate burden of COVID-19 morbidity and mortality, reflecting persistent structural inequalities that increase risk of exposure to COVID-19 and mortality risk for those infected.”<sup>15</sup>

Furthermore, emerging research confirms that viral spread from unvaccinated staff poses a significant danger to individuals with chronic conditions and complex health needs—which describes a significant portion of Medicare and Medicaid beneficiaries—even after they themselves are vaccinated. The data shows, for example, that the fully vaccinated adults who have been hospitalized with COVID-19 breakthrough cases tend to have chronic conditions like hypertension, diabetes, heart failure and lung disease. *See Kaiser Fam. Found., “Breakthrough” COVID-19 Hospitalizations Among Fully Vaccinated Patients Occur Most Often among Older Adults and Involve People with Chronic Health Conditions* (Dec. 15, 2021), <https://perma.cc/2UM8-N3V7>.

The CMS rule acknowledges that prevention and control practices like physical distancing and the use of personal protective equipment can be effective when implemented

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<sup>14</sup> CDC, *Risk of Severe Illness or Death from COVID-19* (Dec. 10, 2020), <https://perma.cc/D5L6-E7X2>.

<sup>15</sup> Theresa Andrasfay & Noreen Goldman, *Reductions in 2020 US life expectancy due to COVID-19 and the disproportionate impact on the Black and Latino populations*, 118 PNAS, at 1 (2021) <http://doi.org/10.1073/pnas.2014746118>; *see also* 86 Fed. Reg. at 61,557.

correctly and consistently. 86 Fed. Reg. at 61,557. But, as CMS concluded, the evidence shows that lapses inevitably happen, and patient deaths can result. The vaccination rule cited multiple studies that demonstrate that transmission occurs between healthcare workers and patients even when universal masking and other protocols are in place. 86 Fed. Reg. at 61,557.<sup>16</sup> In many cases, healthcare staff are the linchpin—they are a “frequent source of risk through either introducing or transmitting infection” and are themselves “exposed to risk through attending [patients’] physical care needs,” just as “their absence when unwell or quarantined ha[s] substantial impact on operations and [patient] well-being.”<sup>17</sup> To take one example, a “cluster” of at least 55 infections at Baystate Medical Center in Massachusetts was traced to “staff who convened in a breakroom and removed their masks.”<sup>18</sup>

This increased risk of viral transmission in healthcare settings has had a devastating effect on patients. One need look no further than the nation’s nursing homes to understand

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<sup>16</sup> See, e.g., Chen, *supra* n.4; Jonne J. Sikkens et al., *Serologic Surveillance and Phylogenetic Analysis of SARS-CoV-2 Infection Among Hospital Health Care Workers*, 4 JAMA Network Open (July 28, 2021), <http://doi.org/10.1001/jamanetworkopen.2021.18554>; Anne E. Watt et al., *State-wide Genomic Epidemiology Investigations of COVID-19 Infections in Healthcare Workers – Insights for Future Pandemic Preparedness*, medRxiv (preprint, posted Sept. 13, 2021), <http://doi.org/10.1101/2021.09.08.21263057>.

<sup>17</sup> See Dykgraaf et al., *Protecting Nursing Homes and Long-Term Care Facilities From COVID-19* at 1984, *supra* n.4.

<sup>18</sup> Aaron Richterman et al., *Hospital-Acquired SARS-CoV-2 Infection Lessons for Public Health*, 324 JAMA 2155, 2156 (Nov. 2020), <http://doi.org/10.1001/jama.2020.21399>; see also Yin Mo et al., *Transmission of community- and hospital-acquired SARS-CoV-2 in hospital settings in the UK: A cohort study*, PLOS Medicine (Oct. 2021), <http://doi.org/10.1371/journal.pmed.1003816>.

the stunning toll: While residents of these facilities make up less than 1 percent of the U.S. population, they “accounted for more than 35 percent of all COVID-19 deaths in the first 12 months of the pandemic.” 86 Fed. Reg. at 61,566; *see also id.* at 61,601. Other long-term care and residential facilities have also been hit hard. In Minnesota, for instance, four-fifth of total COVID-19 deaths were among older people in long-term care facilities. Of these, over half were in nursing facilities, but 22 percent were in assisted living facilities and 19 percent were in community settings.<sup>19</sup> Likewise, data collected from state mental health facilities in 23 states and the District of Columbia indicate double the number of COVID-19 cases in these facilities than in the entire federal prison system.<sup>20</sup>

The impact of these outbreaks is not limited to patients. Healthcare workers, too, are at special risk of COVID-19 infection. The same features of Medicare- and Medicaid-facility settings that create vulnerabilities for patients also put critical frontline workers at risk. CDC data indicates that healthcare staff have reported over half a million COVID-19 cases since the start of the pandemic. *See* 86 Fed. Reg. at 61,559. One cohort study in the United States and the United Kingdom assessed between March and April 2020 determined that frontline healthcare workers “had a twelve-fold increase in risk of a positive [COVID-

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<sup>19</sup> Greg Arling & Priscilla Arling, *The COVID-19 Long-Term Care Situation in the state of Minnesota (USA)*, Int’l Long Term Care Pol’y Network, at 2 (July 2020), <https://perma.cc/S9VP-DG3H>.

<sup>20</sup> Kit Ramgopal, *Coronavirus in a psychiatric hospital: ‘It’s the worst of all worlds,’* NBC News (Apr. 17, 2020), <https://perma.cc/N93R-Z3VP>.

19] test.”<sup>21</sup> And these results comport with historical data: During the Ebola crisis, for instance, healthcare workers were around twenty to thirty times more likely to contract the disease than the general public. *Id.* at e481.

That the COVID-19 pandemic has been devastating for healthcare workers is also well-documented. The WHO estimates that between 80,000 and 180,000 health and care workers died from COVID-19 in the period between January 2020 to May 2021.<sup>22</sup> Even for healthcare staff who do not become seriously ill, the effects of a prolonged, global pandemic are still serious. A survey of more than 20,000 U.S. healthcare workers found that almost half experienced feelings of burnout, which was associated with fear of exposure or transmission, anxiety and depression, and work overload.<sup>23</sup> With every “wave” of new variants, healthcare facilities are forced to ration or cease routine services, repurpose clinical areas, redeploy staff to unfamiliar clinical environments, and ration personal protective equipment and medical resources due to unprecedented demand.<sup>24</sup> Frontline

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<sup>21</sup> Long H. Nguyen et al., *Risk of COVID-19 among frontline healthcare workers and the general community: a prospective cohort study*, 5 *Lancet Pub. Health* e475, e478–79 (Sept. 2020), [http://doi.org/10.1016/S2468-2667\(20\)30164-X](http://doi.org/10.1016/S2468-2667(20)30164-X).

<sup>22</sup> See WHO, *The impact of COVID-19 on health and care workers: a closer look at deaths*, Health Workforce Department – Working Paper 1, Geneva: World Health Organization, at 6–7 (Sept. 2021), <https://perma.cc/ZV42-KZYK>.

<sup>23</sup> Kriti Prasad et al., *Prevalence and correlates of stress and burnout among U.S. healthcare workers during the COVID-19 pandemic: A national cross-sectional survey study*, 35 *EClinicalMedicine* (May 2021), <http://doi.org/10.1016/j.eclinm.2021.100879>.

<sup>24</sup> Carlo Giacomo Leo et al., *Burnout Among Healthcare Workers in the COVID 19 Era: A Review of the Existing Literature*, 9 *Frontiers in Pub. Health* (Oct. 2021), <http://doi.org/10.3389/fpubh.2021.750529>.

healthcare workers involved in the management of COVID-19 are particularly exposed to overwhelming pressure and, unsurprisingly, report physical and mental exhaustion. *Id.* And the pandemic’s effects on healthcare workers ripple far beyond individual health outcomes to the overall ability of our national healthcare system to deal with the crisis. As the CMS rule explains, staff absenteeism due to COVID–19-related exposures or illness exacerbates healthcare staffing shortages, disrupts patient care, and burdens staff that are already stretched impossibly thin. *See* 86 Fed. Reg. at 61,559.

## **II. Vaccines are by far the most effective tools for reducing COVID-19 infection and transmission among patients and workers in the healthcare setting.**

There is no better way to prevent the transmission, morbidity, and mortality of COVID-19 than vaccination. So far, vaccines have prevented approximately 1.1 million additional COVID-19 deaths and 10.3 million COVID-19-related hospitalizations.<sup>25</sup> As CMS explained, numerous large-scale studies have confirmed the power of vaccines to safely protect individuals from transmission and infection of COVID-19. 86 Fed. Reg. at 61,558.<sup>26</sup> Unvaccinated adults of prime working age (18 to 49 years) are 15.2 times more likely to be

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<sup>25</sup> Eric C. Schneider et al., *The U.S. COVID-19 Vaccination Program at One Year: How Many Deaths and Hospitalizations Were Averted?*, Commonwealth Fund (Dec. 14, 2021), <https://perma.cc/U5B7-8ZRX>.

<sup>26</sup> *See also, e.g.*, Seyed M. Moghadas et al., *The impact of vaccination on COVID-19 outbreaks in the United States*, Nat’l Inst. of Health at 2 (*preprint*, revised Jan. 2, 2021), <http://doi.org/10.1101/2020.11.27.20240051> (finding that widespread COVID-19 vaccination has made a “substantial impact on mitigating COVID-19 outbreaks”); Lok Wong Samson et al., *Associations Between County-level Vaccination Rates and COVID-19 Outcomes Among Medicare Beneficiaries*, Rep. No. HP-2021-23, Office of the Assistant Secretary for Planning and Evaluation, U.S. Dep’t of Health and Hum. Servs., at 1 (Oct. 2021), <https://perma.cc/PN3Y-8J32> (estimating reduction of approximately 265,000 COVID-19 infections and 39,000 deaths among Medicare beneficiaries).

hospitalized and 17.2 times more likely to die of COVID-19 than fully vaccinated people in the same age range.<sup>27</sup> And so-called “natural immunity” is no substitute: Vaccines are five times more effective in preventing serious illness and hospitalization than a previous COVID-19 infection.<sup>28</sup> This appears even more true in light of early reports indicating that the antibodies generated by previous infection are less effective than vaccination at neutralizing Omicron.<sup>29</sup>

Although vaccines are generally effective at preventing infection, hospitalization, and death, they are particularly so in healthcare facilities. Extensive evidence has shown vaccination “prevent[s] morbidity and mortality associated with COVID-19” and is “effective[] against asymptomatic SARS-CoV-2 infection.” 86 Fed. Reg. at 61,558.<sup>30</sup> This is true for two straightforward reasons. *First*, vaccinated healthcare workers are in the

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<sup>27</sup> Heather M. Scobie et al., CDC, *Monitoring Incidence of COVID-19 Cases, Hospitalizations, and Deaths, by Vaccination Status—13 U.S. Jurisdictions, April 4–July 17, 2021*, 70 *Morbidity & Mortality Weekly Rpt.* 1284 (Sept. 10, 2021), <https://perma.cc/QD6J-P24N>.

<sup>28</sup> Catherine H. Bozio et al., CDC, *Laboratory-Confirmed COVID-19 Among Adults Hospitalized with COVID-19–Like Illness with Infection-Induced or mRNA Vaccine-Induced SARS-CoV-2 Immunity—Nine States, January–September 2021*, 70 *Morbidity & Mortality Weekly Rpt.* 1539 (Oct. 29, 2021), <https://perma.cc/RS9F-FPXJ>.

<sup>29</sup> See, e.g., Lihong Liu et al., *Striking Antibody Evasion Manifested by the Omicron Variant of SARS-CoV-2*, bioRxiv (preprint, posted Dec. 17, 2021), <http://doi.org/10.1101/2021.12.14.472719>.

<sup>30</sup> See, e.g., Yoel Angel et al., *Association Between Vaccination With BNT162b2 and Incidence of Symptomatic and Asymptomatic SARS-CoV-2 Infections Among Health Care Workers*, 325 *JAMA* 2457 (June 2021), <http://doi.org/10.1001/jama.2021.7152>; Mark W. Tenford, et al., *Effectiveness of SARS-CoV-2 mRNA Vaccines for Preventing Covid-19 Hospitalizations in the United States*, medRxiv (preprint, posted July 8, 2021), <http://doi.org/10.1101/2021.07.08.21259776>.

aggregate significantly less likely to bring the virus into medical facilities. *Id* at 61,558–59.<sup>31</sup> *Second*, even those vaccinated workers who get infected are far less likely to spread the virus. *See, e.g.*, Marc C. Shamier et al., *Virological characteristics of SARS-CoV-2 vaccine breakthrough infections in health care workers*, medRxiv (preprint, posted Aug. 21, 2021), <http://doi.org/10.1101/2021.08.20.21262158> (concluding that infectious virus shedding is reduced in cases of breakthrough infections among vaccinated healthcare workers). Both of these rationales are critically important for protecting Medicare and Medicaid patients—from elderly people and pregnant women to low-income children—who, as discussed, remain vulnerable to serious COVID-19 vaccinations even after they themselves are vaccinated. *See supra*, 5 n.9, 7.

While it is true that COVID-19 vaccines, like other vaccines, do not *completely* prevent transmission of COVID-19 to others, growing evidence shows that they significantly decrease it.<sup>32</sup> A recent study of vaccine uptake in nursing homes, for example,

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<sup>31</sup> *See, e.g.*, Tamara Pilishvili et al., *Effectiveness of mRNA Covid-19 Vaccine among U.S. Health Care Personnel*, 385 N. Eng. J. Med. e90(1) (Sept. 22, 2021), <http://doi.org/10.1056/NEJMoa2106599>; Annalee Yassi et al., *Infection control, occupational and public health measures including mRNA-based vaccination against SARS-CoV-2 infections to protect healthcare workers from variants of concern: a 14-month observational study using surveillance data*, 16 PLOS ONE (2021), <http://doi.org/10.1371/journal.pone.0254920>.

<sup>32</sup> *See, e.g.*, Ashley Fowlkes et al., CDC, *Effectiveness of COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance*, 70 Morbidity & Mortality Weekly Rpt. 1167 (Aug. 27, 2021), <https://perma.cc/Q3EW-4GYM> (finding that “full vaccination with COVID-19 vaccines was 80% effective in preventing” COVID-19 infection in frontline workers, “further affirming the highly protective benefit of full vaccination up to and through the most recent summer U.S. COVID-19 pandemic waves”); Anika Singanayagam et al., *Community transmission and viral load kinetics of SARS-CoV-2 Delta (B.1.617.2) variant*



found that in counties with the highest community prevalence of COVID-19, nursing homes with the lowest staff vaccination coverage had 132% more COVID-19 cases among residents and 195% more COVID-related resident deaths than facilities in the same counties that had the highest vaccination coverage.<sup>33</sup> And this finding held even when nursing home residents themselves were vaccinated. *See id.* Other research during the COVID-19 pandemic has confirmed the efficacy of vaccination against transmission between healthcare staff.<sup>34</sup>

The evidence also shows that vaccinating healthcare workers has broader positive effects on the healthcare system. For example, it improves facility efficiency and effectiveness—vaccinated staff, on average, miss fewer days of work and experience milder symptoms if they are infected.<sup>35</sup> A study of five tertiary-care hospitals in Greece found that COVID-19 vaccination prevented nearly seven out of ten episodes of absenteeism among

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*in vaccinated and unvaccinated individuals*, *Lancet Infectious Diseases* (2021), [http://doi.org/10.1016/S1473-3099\(21\)00648-4](http://doi.org/10.1016/S1473-3099(21)00648-4) (vaccinated individuals spread Delta to the unvaccinated at twice the rate as to the vaccinated); Po Ying Chia et al., *Virological and serological kinetics of SARS-CoV-2 Delta variant vaccine-breakthrough infections: a multi-center cohort study*, *medRxiv* (preprint, posted July 31, 2021), <http://doi.org/10.1101/2021.07.28.21261295> (shorter infectious period and decreased viral load for vaccinated individuals); Ross J. Harris et al., *Effect of Vaccination on Household Transmission of SARS-CoV-2 in England*, *New Eng. J. of Med.* (Aug. 19, 2021), <http://doi.org/10.1056/NEJMc2107717>.

<sup>33</sup> Brian E. McGarry et al., *Nursing Home Staff Vaccination and Covid-19 Outcomes*, *New Engl. J. Medicine* (Dec. 8, 2021), <http://doi.org/10.1056/NEJMc2115674>.

<sup>34</sup> *See, e.g.*, Pilishvili et al., *supra* n.31; Yassi et al., *supra* n.31.

<sup>35</sup> *See* 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*, *medRxiv* (preprint, posted Nov. 21, 2021), <http://doi.org/10.1101/2021.11.17.21266479>.

healthcare personnel, and it significantly reduced the length of absences.<sup>36</sup> And the knock-on effects of more adequately staffed facilities are significant: better patient outcomes, lower patient mortality, and less staff burnout.<sup>37</sup>

Given the compelling data, it is not surprising that numerous states, private health systems, and individual healthcare employers across the country have recognized the need to require vaccination. At least 25 states and 39 cities have required vaccines for some portion of healthcare workers.<sup>38</sup> Numerous private facilities responded with vaccine requirements covering their entire workforce, which have proved highly effective at achieving adherence. For example, when Houston Methodist Hospital required its 25,000 workers to get the vaccine, 99.5% of its staff complied. Sanford Health, a dominant provider

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<sup>36</sup> Helena C. Maltezos et al., *COVID-19 vaccination significantly reduces morbidity and absenteeism among healthcare personnel: A prospective multicenter study*, 39 *Vaccine* 7021, 7021–27 (Nov. 26, 2021), <http://doi.org/10.1016/j.vaccine.2021.10.054>.

<sup>37</sup> See Linda H. Aiken et al., *Effects of Nurse Staffing and Nurse Education on Patient Deaths in Hospitals With Different Nurse Work Environments*, 42 *J Nursing Admin.* (Oct. Supplement) S10, S10–S16 (2012) <http://doi.org/10.1097/01.NNA.0000420390.87789.67>. This finding is also supported by evidence from other frontline workplace contexts. For example, a recent study found that the incidence of COVID-19 in unvaccinated firefighters was five times higher than in vaccinated firefighters—and *twenty times* higher for unvaccinated law enforcement officers. Alberto J. Caban-Martinez et al., *High Burden of COVID-19 among Unvaccinated Law Enforcement Officers and Firefighters*, medRxiv at 6 (preprint, posted Nov. 26, 2021), <http://doi.org/10.1101/2021.11.24.21266396>. Given that first responders on average were sick with COVID-19 for over two weeks and missed close to 40 hours of work due to their illness, the study’s authors found that “state and local governments with large numbers of unvaccinated first responders may face major disruptions in their workforce due to COVID-19 illness” absent vaccination requirements. *Id.* at 4.

<sup>38</sup> See *Where 12 Million U.S. Employees Are Affected by Government Vaccine Mandates*, N.Y. Times (Dec. 18, 2021), <https://perma.cc/8HDP-DJR7>.

of healthcare in the Upper Midwest and one of the largest rural healthcare systems in the country, reported that 97% of its 48,000 workforce has complied with its vaccine requirement. And after Louisiana-based Ochsner Health instituted its vaccine requirement, 99% of its 30,000 employees complied.<sup>39</sup> In short, as CMS explained in its rule, evidence from numerous health systems and individual healthcare employees shows the “effectiveness of strong vaccination policies.” 86 Fed. Reg. at 61,566; *see also, e.g.*, Shawn Hubler, ‘Mandates Are Working’: Employer Ultimatums Lift Vaccination Rates, *So Far*, N.Y. Times (Sept. 30, 2021), <https://perma.cc/JE86-3T69> (observing that when employers require workers to get vaccinated, vaccination rates increase to over 90 percent).

Substantial evidence likewise supports CMS’s finding that quit rates among healthcare workers in response to vaccine mandates remain low. In Houston Methodist, for instance, only 153 workers out of 25,000 were fired or resigned after the vaccine mandate was instituted. In rural Alabama, a state with one of the lowest vaccine uptake rates, Hanceville Nursing & Rehab Center lost only six of its 260 employees when it imposed a vaccine mandate. And even where facilities lose a small number of workers, these workers have been replaced as part of the normal churn of turnover in healthcare facilities. Med Center Health in Bowling Green, Kentucky, for example, lost only 180 staff members after it required its staff of 3,600 to be vaccinated, and it promptly hired 178 new vaccinated staff

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<sup>39</sup> *See* Ezekiel J. Emanuel & David J. Skorton, *Mandating COVID-19 Vaccination for Health Care Workers*, *Annals of Internal Med.* (Sept. 2021), <http://doi.org/10.7326/M21-3150>; James MacPherson, *Sanford: 97% of workforce complying with vaccine mandate*, AP News (Oct. 29, 2021), <bit.ly/30Z3nRu>; Andrew Capp, *Amid court challenges, just 1% of impacted Ochsner staff rebuffs vax mandate*, *Lafayette Daily Advertiser* (Dec. 2, 2021), <https://perma.cc/ZR9R-ULT6>.

to replace them.<sup>40</sup> Both evidence and experience show, in other words, that a vaccine requirement is likely to cause little, if any, staffing shortages—and that any such shortages would be far outweighed by the benefits of the requirement. *See* App. for Stay at 31–34, No. 21A240; App. for Stay at 33–34, No. 21A241.

Finally, it should not be overlooked that vaccination reduces the opportunities for the virus to continue to mutate by reducing transmission and length of infection—meaning that vaccination could prevent future, more deadly, variants of COVID-19.<sup>41</sup> This is particularly important in the case of medically fragile and immunosuppressed populations the CMS rule is designed to protect. Some scientists hypothesize that Omicron’s numerous mutations arose because the virus mutated significantly inside a single immune-suppressed person.<sup>42</sup> The global concerns about the rapidly spreading Omicron variant serve as a timely reminder that vaccination is a critical tool that not only protects individual patient health and safety, but can prevent widescale social and economic disruption.

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<sup>40</sup> Paul Stinson, *Houston Methodist Fires Employees Who Snubbed Vaccine Mandate*, Bloomberg Law (June 23, 2021), <https://perma.cc/L4EV-FQRF>; Bernard Condon & Matt Sedensky, *Nursing home to workers: Get vaccine or lose your job*, ABC News (Aug. 4, 2021), <https://perma.cc/9Ezt-6HWQ>; Med Center Health, *Statement* (Sept. 3, 2021), <https://perma.cc/Y8EV-BSRH>.

<sup>41</sup> *See* Ting-Yu Yeh & Gregory P. Contreras, *Full vaccination against COVID-19 suppresses SARS-CoV-2 delta variant and spike gene mutation frequencies and generates purifying selection pressure*, medRxiv at 2 (preprint, posted Aug. 10, 2021), <http://doi.org/10.1101/2021.08.08.21261768> (study of 16 countries finding that “the vaccination coverage rate is inversely correlated to the mutation frequency of the . . . SARS-CoV-2 delta variants”).

<sup>42</sup> *See* Sarah Wild, *How the Omicron Variant Got So Many Scary Mutations So Quickly*, Scientific American (Dec. 3, 2021), <https://perma.cc/59MN-AXTU>.

**III. Ample evidence supports the Secretary’s determination that staff vaccination will provide critical protection for patients and healthcare workers.**

When Congress established the Medicare and Medicaid programs, it granted the Secretary of Health and Human Services express statutory authority to require that every Medicare- and Medicaid-participating facility 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.” 42 U.S.C. § 1395x(e)(9); *see also, e.g., id.* §§ 1395i-3(d)(4)(B), 1396r(d)(4)(B). As explained above, the public-health evidence makes abundantly clear that the vaccination rule is necessary to protect patient health and safety. The virus that causes COVID-19 is highly transmissible and dangerous, and it is readily spread among healthcare workers and from healthcare workers to patients. 86 Fed. Reg. at 61,556-57. And unvaccinated healthcare workers in particular are highly susceptible to transmitting the virus to their colleagues and patients. *Id.* at 61,558 & n.42. Unvaccinated staff, therefore, pose a serious threat to Medicare and Medicaid patients—many of whom are more likely to face a high risk of developing severe disease and experiencing severe outcomes from COVID-19 infection. *Id.* at 61,566, 61,609.

Given the evidence, the Secretary reasonably decided that the CMS vaccine rule was necessary to address the grave danger that COVID-19 poses to Medicare and Medicaid recipients, as well to as the efficient administration of the Medicare and Medicaid programs. And this decision falls well within the Secretary’s grant of authority. For decades, CMS has “established, maintained, and regularly updated extensive health and safety requirements . . . for Medicare- and Medicaid-certified providers and suppliers” that “focus a great deal on infection prevention and control standards.” 86 Fed. Reg. at 61,568. And healthcare

workers have long been required to receive vaccinations for infectious diseases like measles, rubella, mumps, among others. *See id.* at 61,567–68. As the Eleventh Circuit explained, “vaccination is a common-sense measure designed to prevent healthcare workers, whose job it is to improve patients’ health, from making them sicker.” *State of Fla. v. Dep’t of Health & Hum. Servs.*, 19 F.4th 1271, 2021 WL 5768796, at \*12 (11th Cir 2021). CMS determined that, in the case of COVID-19, merely offering vaccination to healthcare staff would be insufficient. *See* 86 Fed. Reg. 61,586. To protect against the spread of this rapidly transmitted virus, it was necessary to require vaccination. *See id.* at 61,559, 61,613–14.

That determination warrants deference. As Chief Justice Roberts has recognized, the “precise question” of what restrictions should be imposed during “the pandemic is a dynamic and fact-intensive matter subject to reasonable disagreement.” *S. Bay United Pentecostal Church v. Newsom*, 140 S. Ct. 1613, 1613 (2020) (Roberts, C.J., concurring in denial of certiorari). Congress has entrusted CMS with the responsibility to protect the health and safety of Medicare and Medicaid patients, particularly when these high-risk populations face a novel and dangerous threat like COVID-19. Based on an extensive administrative record replete with public-health and scientific evidence showing that vaccination is the most effective tool to prevent COVID-19 transmission and infection in medical facilities, the agency issued its vaccination rule.

Given this careful and deliberative process, CMS’s rule “should not be subject to second-guessing by an ‘unelected federal judiciary,’ which lacks the background, competence, and expertise to assess public health.” *Id.* at 1614. This Court has held that CMS “is comparatively expert in the statute’s subject matter,” and it has emphasized that

where the delegation provision of a statute is broad and general, “the agency’s expertise is relevant in determining its application,” *Douglas v. Indep. Living Ctr. of S. Cal., Inc.*, 565 U.S. 606, 614 (2012); *see also Thorpe v. Hous. Auth. of Durham*, 393 U.S. 268, 277 n.28 (1969). Even more so when, as here, the agency adopted its rule to deal with “changing facts on the ground.” *S. Bay United*, 140 S. Ct. at 1614 (Roberts, C.J., concurring).

And the facts on the ground continue to change. In just the last few weeks, countries around the world have again closed their borders and instituted lockdowns in response to the threat of a new, more transmissible COVID-19 variant. Cases are once again rising, and increased hospitalizations and deaths are likely to follow. The public-health evidence has uniformly concluded that vaccines are the primary way to protect against the rise and spread of such variants, and the threat they pose to our country’s most vulnerable populations. Because CMS’s vaccination rule appropriately reflects this overwhelming scientific consensus, this Court should uphold it.

### CONCLUSION

The *amici curiae* respectfully request that this Court grant the stay applications.

Respectfully submitted,

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## APPENDIX

### INSTITUTIONAL *AMICI CURIAE*

**American Public Health Association.** APHA champions the health of all people and all communities; strengthens the profession of public health; shares the latest research and information; promotes best practices; and advocates for public health issues and policies grounded in scientific research. APHA represents more than 22,000 individual members and is the only organization that combines a nearly 150-year perspective, a broad-based member community, and the ability to influence federal policy to improve the public's health.

**Association of American Medical Colleges.** AAMC is a nonprofit association dedicated to transforming health through medical education, health care, medical research, and community collaborations. Its members are all 155 accredited U.S. and 17 accredited Canadian medical schools; more than 400 teaching hospitals and health systems; and more than 70 academic societies.

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\* *Amici* listed here have joined this brief in their individual capacity only, and do not represent the interests of any institution with which they may be affiliated.

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