UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

STATE OF TEXAS; TEXAS HEALTH AND HUMAN SERVICES COMMISSION, Plaintiffs,	§	
v.	§	
XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare & Medicaid Services; MEENA SESHAMANI, in her official capacity as Deputy Administrator and Director of Center for Medicare; DANIEL TSAI, in his official capacity as Deputy Administrator and Director of Medicaid and CHIP Services; THE CENTERS FOR MEDICARE & MEDICAID SERVICES; JOSEPH R. BIDEN, in his official capacity as President of the United States; UNITED STATES OF AMERICA; Defendants.	§	Case No. _________

ORIGINAL COMPLAINT

I. INTRODUCTION

1. Plaintiffs, the State of Texas and Texas Health and Human Services Commission ("HHSC") (collectively, "Texas"), bring this action to challenge the Centers for Medicare & Medicaid Services' ("CMS") Interim Final Rule with Comment Period entitled "Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination." 86 Fed. Reg. 61,555

(Nov. 5, 2021). That rule—i.e., the "CMS Vaccine Mandate"—imposes an unprecedented federal vaccine mandate on nearly every full-time employee, part-time employee, student, intern, volunteer, and contractor working at a wide range of healthcare facilities receiving Medicare or Medicaid funding.

2. The CMS Vaccine Mandate threatens millions of healthcare workers with termination if they choose not to be vaccinated.

3. Critically, the CMS Vaccine Mandate also threatens to exacerbate an alarming shortage of healthcare workers, particularly in rural communities. The circumstances in Texas—which CMS did not fully consider because it skipped notice-and-comment rulemaking—foreshadow an impending disaster in the healthcare industry. By ignoring the facts on the ground and unreasonably dismissing concerns about workforce shortages, the CMS Vaccine Mandate jeopardizes the health of all Texans.

4. This case illustrates why the police power over compulsory vaccination has always been the province of—and still properly belongs to—the States. Vaccination requirements are matters that depend on local factors and conditions. Whatever might make sense in other States could be decidedly counterproductive and harmful in a large and diverse State such as Texas.

5. Federalism allows States to tailor such matters in the best interests of their communities. The heavy hand of CMS's nationwide mandate does not. CMS's claim of expansive authority under 42 U.S.C. §§ 1302 and 1395hh to regulate conditions of employment in the name of "health and safety" is unprecedented. This Court should thus set aside the CMS Vaccine Mandate as unlawful agency action under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701–706, and an unconstitutional act by the federal government.

II. PARTIES

6. Plaintiff Texas is a sovereign State. Texas brings this suit to vindicate its sovereign, quasi-sovereign, and proprietary interests and on behalf of its citizens *parens patriae*.

7. Plaintiff HHSC is an administrative agency organized under the laws of Texas. HHSC operates thirteen state supported living centers, nine state hospitals, and one residential youth center. HHSC is the state agency designated to administer Texas's Medicaid program. HHSC is responsible for oversight of survey and investigation activities to determine if Medicaid providers comply with program requirements.

8. Defendant Xavier Becerra, named in his official capacity, is the Secretary of the United States Department of Health and Human Services ("HHS").

9. Defendant HHS is a federal agency organized under the laws of the United States. It is responsible for administering federal healthcare policy and is the cabinet-level department of which the Centers for Medicare & Medicaid Services ("CMS") is a part.

10. Defendant Chiquita Brooks-LaSure, named in her official capacity, is the Administrator of CMS.

11. Defendant Meena Seshamani, named in her official capacity, is the Deputy Administrator and Director of Center for Medicare.

12. Defendant Daniel Tsai, named in his official capacity, is the Deputy Administrator and Director of Center for Medicaid and CHIP Services.

13. CMS is a federal agency organized under the laws of the United States. It is responsible for federally administering Medicare and Medicaid. CMS is a part of HHS.

14. Defendant Joseph R. Biden, Jr., named in his official capacity, is the President of the United States of America.

15. Defendant United States of America is the federal sovereign.

III. JURISDICTION AND VENUE

16. This Court has jurisdiction pursuant to 5 U.S.C. §§ 702–703 and 28 U.S.C. §§ 1331, 1361, and 2201.

17. This Court is authorized to award the requested declaratory and injunctive relief under 5 U.S.C. §§ 702 and 706, 28 U.S.C. §§ 1361 and 2201–2202, Federal Rules of Civil Procedure 57 and 65, and its inherent equitable powers.

18. Venue lies in this district pursuant to 28 U.S.C. § 1391(e)(1) because the United States, two federal agencies, four federal officers in their official capacities, and President Biden in his official capacity are Defendants. Plaintiffs the State of Texas and HHSC reside in this judicial district, and a substantial part of the events or omissions giving rise to Texas's claims occurred in this district.

IV. FACTUAL BACKGROUND

A. The Healthcare Worker Crisis

19. For many years, the healthcare industry in the United States has been experiencing severe workforce shortages. "In 2019, the Association of American Medical Colleges issued a report projecting supply and demand for physicians nationally from 2017 to 2032. Results from this report indicate that there will be an estimated shortage of between 46,900 and 121,900 physicians nationwide by 2032. This projected shortage includes 21,100 to 55,200 primary care physicians and 24,800 to 65,800 specialty care physicians." *Texas Physician Supply and Demand Projections, 2018-2032*, HHSC (May 2020), https://www.dshs.state.tx.us/legislative/2020-Reports/TexasPhysicianSupplyDemandProjections-2018-2032.pdf., at 5.

20. Like the rest of the nation, Texas is experiencing a healthcare worker shortage. According to a HHSC report from May 2020, Texas is suffering from a statewide shortage of

physicians that "is projected to increase from 6,218 full-time equivalents (FTEs) in 2018 to 10,330 FTEs in 2032." *Id.* at 1. "[G]eneral internal medicine is projected to have the greatest absolute shortage in 2032, as an additional 2,607 FTEs will be needed statewide to meet projected demand." *Id.* "[F]amily medicine is projected to have the greatest shortage increase in FTEs between 2018 and 2032, as the shortage of family medicine physicians statewide is projected to increase from 1,034 FTEs in 2018 to 2,495 FTEs in 2032." *Id.* at 2.

21. Texas is experiencing a critical shortage of psychiatrists "in all regions of the state except Central Texas." *Id.* "Pediatrics is identified as a critical shortage in all regions of the state except the Gulf Coast . . . and Central Texas." *Id.* "Family medicine is identified as a critical shortage in all regions of the state except the Panhandle . . . , North Texas . . . , Central Texas, and South Texas." *Id.*

22. "In summary, there is a shortage of physicians in Texas and this shortage will increase through 2032. Current projections in medical school enrollment and resident positions . . . indicate that the state's graduate medical education system will not create a supply of physicians that can meet projected demand." *Id.*

23. The nursing shortage has been a problem in Texas and across the nation even before the pandemic. Julian Gill, *'We are in a crisis': Houston nursing shortage comes to a head as 'onslaught' of patients swarm LBJ hospital*, Houston Chronicle (Aug. 4, 2021), https://www.houstonchronicle.com/news/houston-texas/health/article/Houston-nursing-shortage-comes-to-a-head-as-16361747.php. The shortage of nurses has been attributed to "[a]n aging population and dwindling nursing school faculty" as well as "nursing programs [with a] limited capacity to accept students." *Id.* The nursing shortage has been exacerbated by the pandemic, with fatigue and burnout leading to retirements and nurses leaving the profession. *See id.*

24. An HHS report from February 2021, which documents how the COVID-19 pandemic has significantly strained health care delivery found:

> Turnover was particularly high among nurses, according to the hospitals. One hospital in a high-poverty and socially vulnerable community in Texas (which was operating at 100-percent ICU occupancy the week before our survey) report that its annual average for nurse turnover increased from 2 percent prior to the pandemic to 20 percent in 2020. Hospitals also reported losing other types of staff in the past year, including respiratory therapists, certified nursing assistants, phlebotomists, laboratory technicians, and other support staff vital to hospital operations.

Hospitals Reported That the COVID-19 Pandemic Has Significantly Strained Health Care Deliver – Results of a National Pulse Survey, February 22–26, 2021, U.S. Dep't of HHS Office of Inspector General, https://oig.hhs.gov/oei/reports/OEI-09-21-00140.pdf ("HHS IG Report"), at 10.

25. Texas stepped in to help recruit out-of-state medical workers to address staffing shortages. Lauren Margolis, *State deploys nurses to help East Texas hospitals with staffing shortages*, KETK.com (Aug. 19, 2021), https://www.ketk.com/news/health/coronavirus/state-deploys-nurses-to-help-east-texas-hospitals-with-staffing-shortages/; Governor Abbott Takes Action to Expand Nursing Workforce (Mar. 31, 2020), https://gov.texas.gov/news/post/governor-abbott-takes-action-to-expand-nursing-workforce. But even with the State's assistance, Texas healthcare providers continued to experience critical staffing shortages. *See* Margolis, *supra*.

26. Many healthcare workers in Texas will choose not to comply with the CMS Vaccine Mandate. Some do not consider the vaccine to be safe. Others would prefer to rely on natural immunity acquired from prior infection and recovery from COVID-19. Some nurses have personally seen patients suffering from adverse reactions to COVID-19 vaccinations and do not wish to risk similar reactions themselves. Some healthcare workers are concerned about how the vaccines will affect them based on their medical history. For others, the risks of vaccination are simply not worth the benefits, particularly for those who have already recovered from COVID-19.

And other healthcare workers have firmly-held religious or moral objections to receiving the COVID-19 vaccine. Whatever their reasons, and whatever others may think of those reasons, the CMS Vaccine Mandate will result in healthcare workers being terminated and further staffing shortages.

27. Recent examples of vaccine mandates being imposed by Texas hospitals show this to be true. When Houston Methodist imposed a vaccine mandate, more than 150 employees resigned or were fired. Associated Press, *More than 150 fired, resign over Covid vaccine requirement at Houston hospital* (June 23, 2021), https://www.nbcnews.com/news/us-news/more-150-fired-resign-over-covid-vaccine-requirement-houston-hospital-n1272071. In response to a vaccine mandate by Ascension Seton, employees protested and indicated they would resign. Jala Washington, *Ascension Seton Hays employees protest hospital's COVID-19 vaccine mandate as deadline looms* (Nov. 11, 2021), https://www.kxan.com/news/local/hays/ascension-seton-hays-employees-to-protest-hospitals-covid-19-vaccine-mandate-as-deadline-looms/.

28. Hospital administrators have heard from their employees that they will resign if they are required to get the COVID-19 vaccine. Both private and state hospitals are at risk of staff resignations resulting from the CMS Vaccine Mandate. With widespread staff shortages, these healthcare providers can ill afford to lose even more staff. Those providers have legitimate concerns that they will not be able to provide patients the care they need if they have to terminate employees because of the CMS Vaccine Mandate. *See* Andrea Hsu, *Nurses Are In Short Supply. Employers Worry Vaccine Mandate Could Make It Worse*, GBH News (Sept. 23, 2021), https://www.wgbh.org/news/national-news/2021/09/23/nurses-are-in-short-supply-employers-worry-vaccine-mandate-could-make-it-worse.

29. A recent survey from the Kaiser Family Foundation confirmed that vaccine mandates pose substantial threats to existing workforce shortages. That survey found that seventy-two percent of "unvaccinated workers say they will quit" rather than submit to a vaccine mandate. Chris Isidore and Virginia Langmaid, *72% of unvaccinated workers vow to quit if ordered to get vaccinated*, CNN.com (Oct. 28, 2021), https://www.cnn.com/2021/10/28/business/covid-vaccine-workers-quit/index.html.

30. The loss of even a few staff members, particularly in rural and underserved communities would be catastrophic. It will result in the loss of services, and patients will be required to travel long distances to obtain care. In rural regions in Texas, there simply are not enough qualified individuals to take the place of employees that resign or are terminated as a result of the CMS Vaccine Mandate. Many hospitals cannot afford to lose staff, and they also cannot afford to lose out on Medicare and Medicaid reimbursements. The CMS Vaccine Mandate puts the viability of these providers at risk, and that, in turn, puts Texans at risk of not being able to obtain healthcare services that they need.

31. Texas anticipates that the CMS Vaccine Mandate will have devastating adverse effects on healthcare services in the State, particularly in its rural communities.

B. Texas's Role in Medicare and Medicaid

32. Medicaid is a cooperative state–federal program in which States may choose to participate.

33. Medicaid is a program that helps States finance the medical expenses of their citizens.

34. Texas has entered into agreements with the federal government to participate in Medicaid.

35. Medicare is a medical-funding program paid for and administered by the federal government.

36. Texas employs state surveyors who regularly evaluate healthcare facilities' compliance with Medicaid requirements.

37. Texas also has state-run healthcare facilities that receive Medicare and Medicaid funding. HHSC operates thirteen state supported living centers, nine state hospitals, and one residential youth center.

38. Texas's state supported living centers provide campus-based direct services and support to people with intellectual and developmental disabilities in thirteen locations—Abilene, Austin, Brenham, Corpus Christi, Denton, El Paso, Lubbock, Lufkin, Mexia, Richmond, Rio Grande, San Angelo, and San Antonio. These living centers are certified as Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IDD). There are currently 2,700 individuals in these facilities. In fiscal year 2021, these facilities received $515 million in Medicaid funding from the federal government.

39. Texas's state hospitals currently serve 1,560 patients, although there are over 600 beds offline due to the inability to hire and retain adequate staffing. These facilities are largely funded by the State, but they receive Medicaid and Medicare payments for services provided to their patients. In fiscal year 2021, Texas received approximately $956,000 from Medicaid and $24.6 million from Medicare billing for services provided at Texas state hospitals.

40. The Austin State Hospital provides adult psychiatric services, child and adolescent psychiatric services, forensic competency restoration services, and specialty psychiatric services for people who are older or have an intellectual or developmental disability.

41. The Big Spring State Hospital provides hospitalization for people eighteen years of age and older with psychiatric illness.

42. The El Paso Psychiatric Center provides adult psychiatric services and child and adolescent psychiatric services.

43. The Kerrville State Hospital is for people hospitalized on a forensic commitment. The hospital's goal is to treat their mental illness so they may safely return to the community.

44. The North Texas State Hospital consists of three campuses in Wichita Falls and Vernon. The hospital provides inpatient, psychiatric services to adults, children, and adolescents. The hospital also provides psychiatric services to people with intellectual and developmental disabilities.

45. The Rio Grande State Center in Harlingen offers outpatient medical healthcare and in-patent mental health services. The services include inpatient adult psychiatric services and outpatient services, which include primary care, women's health, diagnostic services, psychiatric consults, and a prescription assistance program.

46. The Rusk State Hospital is an in-patient hospital, which provides psychiatric treatment and care. The services include adult psychiatric services, maximum security forensic psychiatric services for adult men, forensic competency restoration services, and residential psychiatric services.

47. The San Antonio State Hospital is an in-patient psychiatric hospital with complete psychiatric and rehabilitative services. The services include adult psychiatric services and forensic competency restoration services.

48. The Terrell State Hospital provides adult psychiatric services, child and adolescent psychiatric services, and forensic competency restoration services.

49. The Waco Center for Youth provides psychiatric residential treatment to adolescents with severe emotional or behavioral disorders and who have experienced serious disfunction.

C. Federal Vaccine Mandates

50. For the first six months of President Biden's administration, no federal agencies sought to impose vaccine mandates on the American people. As recently as July 23, 2021, the White House announced that mandating vaccines is "not the role of the federal government." Press Briefing by Press Secretary Jen Psaki (July 23, 2021), The White House, https://www.whitehouse.gov/briefing-room/press-briefings/2021/07/23/press-briefing-by-press-secretary-jen-psaki-july-23-2021/.

51. Then on September 9, 2021, President Biden gave a speech announcing his six-point plan to "turn the tide on COVID-19." Joseph Biden, Remarks at the White House (Sept. 9, 2021), https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/09/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-3/.

52. President Biden announced that the first plank of his plan is to "require more Americans to be vaccinated." *Id.* He said that the purpose of this plan is to "reduce the number of unvaccinated Americans." *Id.*

53. President Biden laid primary responsibility for the ongoing pandemic with unvaccinated Americans, saying that he is "frustrated with the nearly 80 million Americans who are still not vaccinated." *Id.* He stated that "[t]his is a pandemic of the unvaccinated" and that the "nearly 80 million Americans [who are] not vaccinated . . . can cause a lot of damage—and they are." *Id.* He blamed the unvaccinated for healthcare shortages: "The unvaccinated overcrowd our hospitals, are overrunning the emergency rooms and intensive care units, leaving no room for someone with a heart attack . . . or cancer." *Id.* He stated: "[O]ur patience is wearing thin. And

your refusal has cost all of us." *Id.* And he said: "For the vast majority of you who have gotten vaccinated, I understand your anger at those who haven't gotten vaccinated." *Id.*

54. President Biden repeatedly said that "the vaccines provide very strong protection from severe illness from COVID-19." *Id.*

55. President Biden announced several federal vaccine mandates—(1) a mandate from the Occupational Safety and Health Administration ("OSHA") for companies with more than 100 employees,[1] (2) a mandate for federal employees, (3) a mandate for employees of federal contractors and subcontractors, and (4) what would become the CMS Vaccine Mandate. *Id.*

56. President Biden also expressed a dismissive view of States like Texas that have used their constitutionally guaranteed police powers to adopt contrary public-health policies. *Id.* He stated: "Let me be blunt. My plan also takes on elected officials and states that are undermining . . . these lifesaving actions." *Id.* Speaking scornfully of "governor[s]" who oppose the new federal mandates, he promised that "if these governors won't help us beat the pandemic, I'll use my power as President to get them out of the way." *Id.*

D. The CMS Vaccine Mandate

57. On November 5, 2021, nearly two months after President Biden announced his federal vaccine mandates, CMS published the CMS Vaccine Mandate. 86 Fed. Reg. 61,555.

58. The CMS Vaccine Mandate covers fifteen categories of Medicare- and Medicaid-certified providers and suppliers. By expanding its reach in this way, the mandate broadly sweeps in a diverse set of healthcare providers. These include, among others, rural health clinics, hospitals,

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[1] The United Court of Appeals for the Fifth Circuit recently reaffirmed its stay of OSHA's implementation of its vaccine mandate. *BST Holdings, L.L.C. v. OSHA*, slip op. at 3 (5th Cir. Nov. 12, 2021). The Fifth Circuit held that the OSHA mandate was "fatally flawed," citing the lack of a true "emergency" when the mandate issued and concluding that "its promulgation grossly exceeds OSHA statutory authority," among other things. *Id.* at 6–7.

long-term-care facilities, and home health agencies. *Id.* at 61,569–70. Demonstrating the far reach of the mandate, CMS reported that "Medicare-participating hospitals . . . include nearly all hospitals in the U.S." *Id.* at 61,577.

59. Texas has many healthcare providers that fall within the fifteen categories of Medicare- and Medicaid-certified providers and suppliers covered by the CMS Vaccine Mandate. The CMS Vaccine Mandate will affect the nearly 4.9 million Texans receiving services from Texas Medicaid providers. *See* Healthcare Statistics, Medicaid and CHIP Monthly Enrollment by Risk Group (Sept. 2014 – Aug. 2021), https://www.hhs.texas.gov/sites/default/files/documents/about-hhs/records-statistics/research-statistics/medicaid-chip/2021/monthly-enrollment-by-risk-group-aug-2021.xlsx.

60. CMS recognized that the "providers and suppliers regulated under this rule are diverse in nature, management structure, and size." *Id.* at 61,602. Despite this, CMS relied predominantly on facts and figures involving long-term-care facilities—providers who serve mostly elderly and often immunocompromised patients—to make its case for applying the vaccine mandate to fourteen other categories of Medicare- and Medicaid-certified providers. *See, e.g.*, *id.* at 61,585 (discussing "case rates among [long-term-care] facility residents" and claiming, without citation, that those facilities' "experience may generally be extrapolated to other settings"); *id.* at 61,604 ("[W]e often use [long-term-care] facilities for examples because they pose some of the greatest risks for COVID–19 morbidity and mortality"). CMS did this while acknowledging that "[a]ge remains a strong risk factor for severe COVID–19 outcomes," *id.* at 61,566, and that "risk of death from infection from an unvaccinated 75- to 84-year-old person is 320 times more likely than the risk for an 18- to 29-years old person," *id.* at 61,610 n.247.

61. CMS acknowledged that psychiatric residential treatment facilities serve individuals under twenty-one years of age, *see id.* at 61,576, and that "rural and other community-care oriented health centers serve the full age spectrum and a lower fraction of severely health-impaired," *id.* at 61,612. Even though the individuals served by these facilities are generally at a low risk from COVID-19, the CMS Vaccine Mandate imposed the same stringent vaccine mandate on psychiatric residential treatment facilities and rural health centers as it did on long-term-care facilities.

62. CMS applied its vaccine mandate to practically every full-time employee, part-time worker, trainee, student, volunteer, or contractor working at the covered facilities. The mandate requires vaccination for all "facility staff"—a term that includes employees, trainees, students, volunteers, or contractors—"who provide any care, treatment, or *other services* for the facility," "*regardless of* . . . *patient contact*." *Id.* at 61,570 (emphasis added). This includes "administrative staff" and "housekeeping and food services," to name a few. *Id.* CMS also imposed its mandate on "any individual that . . . has the *potential* to have contact with anyone at the site of care." *Id.* at 61,571 (emphasis added). This includes "staff that primarily provide services remotely via telework" but "occasionally encounter fellow staff . . . who will themselves enter a health care facility." *Id.* at 61,570.

63. Maximizing the scope of the mandate, CMS allowed exemptions only to the extent necessary to "comply with applicable Federal anti-discrimination laws and civil rights protections" such as medical exemptions required by the Americans with Disabilities Act ("ADA") and religious exemptions required by Title VII of the Civil Rights Act of 1964. *Id.* at 61,568.

64. The CMS Vaccine Mandate became immediately effective on November 5, 2021. *Id.* at 61,555.

65. Covered providers must implement the CMS Vaccine Mandate in two thirty-day phases. *Id.* at 61,571. Phase 1 requires that staff receive the first dose of the vaccine or have requested or been granted a medical or religious exemption by December 6, 2021. *Id.* And Phase 2 requires that non-exempt staff be fully vaccinated by January 4, 2022. *Id.*

66. CMS recognized the breadth of and expedited schedule imposed by its vaccine mandate, acknowledging its "near-universal applicability" to healthcare staff, and observing that under the rule "virtually all health care staff in the U.S. will be vaccinated for COVD–19 within a matter of months." *Id.* at 61,573. CMS estimated that approximately 10.3 million employees will fall under the mandate. *Id.* at 61,603.

67. CMS chose to mandate vaccination because it determined that the "most important inducement [for vaccination] will be the fear of job loss." *Id.* at 61,607.

68. In addition to the staff-vaccination requirements, the CMS Vaccine Mandate imposes numerous regulatory burdens on Medicare and Medicaid providers and suppliers, all of which must be implemented within thirty days.

69. They must "develop and implement policies and procedures under which all staff are vaccinated for COVID-19." *Id.* at 61,570. They must also "track and securely document the vaccination status of each staff member." *Id.* at 61,572.

70. They must "establish and implement a process by which staff may request an exemption from COVID-19 vaccination requirements based on an applicable Federal law," and "[v]accine exemption requests and outcomes must also be documented." *Id.*

71. They must also implement "a process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC." *Id.* at 61,571.

72. And they must implement "a process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all staff who are not fully vaccinated for COVID-19." *Id.*

73. CMS "expect[s]" its vaccine mandate "to remain relevant for some time beyond the end" of the formal public health emergency and anticipates retaining the mandate "as a permanent requirement for facilities." *Id.* at 61,574.

E. The Impact of the CMS Vaccine Mandate on the Healthcare Worker Crisis

74. CMS admitted that "currently there are endemic staff shortages for almost all categories of employees at almost all kinds of health care providers and supplier[s]." *Id.* at 61,607. "1 in 5 hospitals," CMS noted, "report that they are currently experiencing a critical staffing shortage." *Id.* at 61,559. In addition, "approximately 23 percent of [long-term-care] facilities report[] a shortage in nursing aides; 21 percent report[] a shortage of nurses; and 10 to 12 percent report[] shortages in other clinical and non-clinical staff categories." *Id.* It is thus not surprising, CMS relayed, that "[o]ver half (58 percent) of nursing homes participating in a recent survey . . . indicated that they are limiting new admissions due to staffing shortages." *Id.*

75. In creating the CMS Vaccine Mandate, CMS was "aware of concerns about health care workers choosing to leave their jobs rather than be vaccinated" and knew that "there might be a certain number of health care workers who choose to do so." *Id.* at 61,569. In fact, CMS reported that "a large long term care association" recently issued a policy statement observing that "some in the sector fear that a vaccine mandate could lead to worker resignations." *Id.* at 61,565–66. But CMS dismissed these concerns because "there is insufficient evidence to quantify" them. *Id.* at 61,569. Instead, CMS optimistically "believe[d] that the COVID-19 vaccine requirements . . . will result in *nearly all* health care workers being vaccinated." *Id.* (emphasis added); *see also*

id. at 61,609 (finding that only a "relatively small fraction" of turnover "will be due to vaccination").

76. CMS repeatedly admitted that the current "endemic staff shortages . . . may be made worse if any substantial number of unvaccinated employees leave health care employment altogether." *Id.* at 61,607; *see also id.* at 61,608 ("[T]here may be disruptions in cases where substantial numbers of health care staff refuse vaccination and are not granted exemptions and are terminated, with consequences for employers, employees, and patients"); *id.* at 61,609 ("[I]t is true that compliance with this rule may create some short-term disruption of current staffing levels for some providers or suppliers in some places.").

77. CMS also recognized that these staffing concerns apply even if providers do not lose a substantial number of employees. In fact, "[e]ven a small fraction" of what CMS called "recalcitrant unvaccinated employees" who decline to take a vaccine "could disrupt facility operations." *Id.* at 61,612.

78. CMS additionally recognized facts indicating that potential disaster awaits rural communities, including minority healthcare workers in those communities. CMS acknowledged that "vaccination rates are disproportionately low among nurses and health care aides" in rural locations and other "communities that experience social risk factors." *Id.* at 61,566. And it admitted that "early indications are that rural hospitals are having greater problems with employee vaccination . . . than urban hospitals." *Id.* at 61,613. In addition, CMS observed that "nurses and aides in these [rural and other underprivileged] settings are more likely to be members of racial and ethnic minority communities." *Id.* at 61,566. This means minority workers in rural communities are among the most likely groups to lose their jobs under the CMS Vaccine Mandate.

79. CMS nonetheless dismissed these workforce concerns because it thought that the unvaccinated employees would get jobs in other healthcare positions, such as "physician and dental offices," that are not covered by the CMS Vaccine Mandate. *Id.* at 61,607. Yet this speculation does nothing to abate the debilitating losses threatened to the healthcare facilities falling under the CMS Vaccine Mandate. It does not suggest that the healthcare worker shortage will disappear, but only that worker shortages will be further concentrated among the healthcare facilities covered by the CMS Vaccine Mandate.

80. CMS also conjectured that staffing deficiencies at facilities covered by the CMS Vaccine Mandate "might be offset by persons returning to the labor market who were unwilling to work at locations where some other employees are unvaccinated and hence provide some risk[] to those who have completed the primary vaccination series for COVID–19." *Id.* at 61,607. This was pure speculation. CMS cited no evidence that such vaccinated workers exist. In any event, a worker who harbored such fears would still have to regularly work with unvaccinated patients, and it is irrational to assume that they would be willing to work with unvaccinated patients but not unvaccinated coworkers.

81. CMS additionally dismissed workforce shortage concerns by assuming "a dynamic labor market" where "net employment opportunities . . . do not change." *Id.* at 61,608 (finding "no reason to believe" that "net employment opportunities" will "change"). But an industry with admittedly "endemic staff shortages," *id.* at 61,607, is not a dynamic labor market. Net employment opportunities in the existing healthcare industry can and do change. Indeed, if the CMS Vaccine Mandate drives out enough employees from particular facilities, those facilities might be forced to close certain divisions, cancel certain services, or shutter altogether—any of which would decrease net employment opportunities.

82. If CMS is wrong in its optimism that "nearly all health care workers" will submit to the mandate, the results will be disastrous. *Id.* at 61,569. CMS itself concluded that approximately 2.4 million healthcare workers will get vaccinated under the CMS Vaccine Mandate in the first year. *Id.* at 61,603. If even ten percent of those workers decline vaccination, the healthcare industry will lose over 200,000 employees, dealing a devastating blow to an already struggling industry. *Id.* at 21,606.

83. Further confirming that the CMS Vaccine Mandate threatens grave staffing concerns, CMS observed that many healthcare workers decline other vaccines. It noted that "studies on annual seasonal influenza vaccine uptake consistently show that half of health care workers may resist seasonal influenza vaccination nationwide." *Id.* at 61,568.

84. Despite the very real concerns about the CMS Vaccine Mandate pushing many healthcare workers out of their jobs, CMS remarkably concluded that existing staffing shortages are actually a reason to impose the mandate. In CMS's words, "the urgent need to address COVID-related staffing shortages that are disrupting patient access to care[] provides strong justification as to the need to issue this" mandate. *Id.* at 61,567. Because "unvaccinated staff" are "at greater risk for infection" and "absenteeism," CMS elaborated, allowing providers to continue hiring them might "create staffing shortages." *Id.* at 61,559. But this speculation ignores the obvious fact that maintaining a larger pool of potential workers, even if some might have a bout with COVID-19, is better than categorically excluding a class of individuals.

F. The CMS Vaccine Mandate's Contradictions, Concessions, and Omissions

85. CMS "considered requiring daily or weekly testing of unvaccinated individuals" instead of mandatory vaccination. *Id.* at 61,614. But it chose the vaccine mandate for one reason: because it believes that "vaccination is a more effective infection control measure." *Id.* In so doing, CMS failed to discuss how other countervailing considerations—such as workforce shortages and

personal liberty considerations—factored into the rejection of the periodic testing option. Nor did CMS acknowledge the disparity between its rejection of testing and OSHA's recently issued Emergency Temporary Standard ("ETS"), *see* COVID–19 Vaccination and Testing; Emergency Temporary Standard, 86 Fed. Reg. 61,402 (Nov. 5, 2021), which allows regular testing as an adequate alternative.

86. CMS "considered whether it would be appropriate to limit COVID-19 vaccination requirements to staff who have not previously been infected by SARS-CoV-2." 86 Fed. Reg. at 61,614. Yet it decided against that option because it did not think that "infection-induced immunity, also called 'natural immunity'" is "equivalent to receiving the COVID-19 vaccine." *Id.* at 61,559. But elsewhere, CMS recognized the value of natural immunity when it stated that each day 100,000 people are "recover[ing] from infection," that they "are *no longer sources of future infections*," and that their natural immunity "reduce[s] the risk to both health care staff and patients substantially." *Id.* at 61,604 (emphasis added).

87. CMS ignored key evidence indicating that natural immunity effectively guards against the Delta variant. In a study of a large population of patients in Israel, vaccinated people who had not been previously infected had thirteen times higher odds of experiencing a breakthrough infection with the Delta variant than patients who had recovered from COVID but were never vaccinated. Sevan Gazit et al., *Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: Reinfections versus breakthrough infections*, medRxiv Preprint (2021), https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1.

88. CMS repeatedly said, much like President Biden had in his September 9 speech, that the currently authorized COVID-19 vaccines are "highly effective at protecting vaccinated people against symptomatic and severe COVID-19." 86 Fed. Reg. at 61,560.

89. CMS also recognized that "the effectiveness of the vaccine to prevent disease transmission by those vaccinated [is] not currently known." *Id.* at 61,615.

90. CMS's various directives sent conflicting messages on "booster" or additional doses. On the one hand, CMS said that its mandate does not require "booster doses" or additional doses of the vaccine. *Id.* at 61,563. But on the other hand, CMS included a "booster" shot in its cost calculations, *id.* at 61,608, and acknowledged that "[s]ome in the scientific community believe that 'booster' vaccinations after 6 or 8 months would be desirable to maintain a high level of protection against the predominant Delta version of the virus," *id.* at 61,609. CMS appeared to be forecasting that if it has the power to mandate vaccines, it will eventually extend the mandate to include booster shots.

91. CMS recognized that vaccines, like all other medical interventions, are not without risks. "Serious adverse reactions also have been reported following COVID–19 vaccines," even though "they are rare." *Id.* at 61,565. The adverse reactions include "anaphylaxis," "thrombosis," and "myocarditis and/or pericarditis," to name a few. *Id.*

92. CMS never considered other important aspects of imposing its mandate. Among those are the interests of healthcare workers who—for any number of varying personal reasons—do not want to take one of the currently authorized vaccines.

93. Past CMS regulations, even ones as recent as May 2021 implemented to address COVID-19, have never required mandatory vaccines. In fact, regulations as recent as May 2021, specifically permitted staff and patients to opt out of receiving the COVID-19 vaccine even though CMS repeatedly cited its importance in reducing transmission of COVID-19. *See e.g.,* 42 C.F.R. § 483.80 ("The resident, resident representative, or staff member has the opportunity to accept or refuse a COVID–19 vaccine, and change their decision."); 42 C.F.R. § 483.460 ("The client,

client's representative, or staff member has the opportunity to accept or refuse COVID–19 vaccine, and change their decision."). In that rule, CMS cited the same concerns as it does here (1) protecting health and safety of residents, staff, and general public, 86 Fed. Reg. 26,316 (May 13, 2021), (2) increased risk to residents due to age and location, *id.* at 26,308, and (3) saving lives, *id.* at 26,311.

94. In the CMS Vaccine Mandate, an individual's choice to get vaccinated is taken away, but no education regarding the vaccine's benefits, risks, or side effects is required. CMS has seemingly decided that when healthcare staff have no choice in the matter, there is no reason to inform them of the potential consequences of the decision CMS has made for them. In promulgating the CMS Vaccine Mandate, CMS has traded the carrot for the stick.

95. Upon information and belief, some religious healthcare institutions will be subject to the CMS Vaccine Mandate. The mandate will thus require those religious institutions to terminate ministerial employees in violation of the First Amendment. *Our Lady of Guadalupe Sch. v. Morrissey-Berru*, 140 S. Ct. 2049, 2061 (2020). But CMS never considered this problem when imposing its mandate.

G. An Unprecedented Intrusion on State Police Power

96. CMS repeatedly recognized that the CMS Vaccine Mandate is unprecedented because CMS has never before mandated any vaccination. *See, e.g.*, 86 Fed. Reg. at 61,567 ("We have not previously required any vaccinations"); *id.* at 61,568 ("[W]e have not, until now, required any health care staff vaccinations"); *id.* ("We acknowledge that we have not previously imposed such requirements").

97. Past CMS regulations, even ones as recent as May 2021 implemented to address COVID-19, have never required mandatory vaccines. This further confirms that CMS knew it did not have authority to issue a vaccine mandate, and only the President's changing attitude toward

vaccine mandates has led to the CMS Vaccine Mandate. But the President's attitude, like the authority CMS cites, does not authorize CMS to mandate a medical treatment for staff, interns, or volunteers or to regulate the transmission of communicable diseases.

98. CMS has made clear that the CMS Vaccine Mandate is an attempt to nationalize the COVID-19 vaccination response. For example, it explained that "the inconsistent web of State, local, and employer COVID–19 vaccination requirements have established a pressing need for a consistent Federal policy mandating staff vaccination in health care settings that receive Medicare and Medicaid funds." *Id.* at 61,584.

99. CMS made clear that it intends for the CMS Vaccine Mandate to preempt any arguably inconsistent state and local laws. *See, e.g.*, *id.* at 61,568 ("We intend . . . that this nationwide regulation preempts inconsistent State and local laws"); *id.* at 61,572 ("[T]his IFC preempts the applicability of any State or local law providing for exemptions to the extent such law provides broader exemptions than provided for by Federal law and are inconsistent with this IFC"); *id.* at 61,613 ("This rule would pre-empt some State laws that prohibit employers from requiring their employees to be vaccinated for COVID–19.").

100. The CMS Vaccine Mandate requires certain state-run healthcare facilities that receive Medicare or Medicaid funding to force their state employees to get vaccinated. *Id.* at 61,613 ("[T]o the extent that State-run facilities that receive Medicare and Medicaid funding are prohibited by State or local law from imposing vaccine mandates on their employees, there is direct conflict between the provisions of this rule (requiring such mandates) and the State or local law (forbidding them).").

101. The CMS Vaccine Mandate forces certain state-run healthcare facilities that receive Medicare or Medicaid funding to comply with overbearing, invasive, and unnecessary record-

keeping obligations. Even for the rare healthcare staff who fall outside the CMS Vaccine Mandate, the facility still must "identify and monitor these individuals" by "documenting and tracking [their] vaccination status." *Id.* at 61,571. To what end or purpose, CMS does not say. And though the CMS Vaccine Mandate purports to require only initial vaccination and not booster shots, covered facilities must track and document the "vaccination status of any staff who have obtained any booster doses." *Id.* Again, CMS does not disclose the purpose of this seemingly arbitrary demand. In addition, "[v]accine exemption requests and outcomes must also be documented" and preserved. *Id.* at 61,572. This is so even though CMS has no interest in knowing whether healthcare facilities comply with the ADA or Title VII.

102. CMS announced that it will coopt state employees to enforce the CMS Vaccine Mandate. As it explained, CMS "will advise and train State surveyors on how to assess compliance with the new requirements." *Id.* at 61,574. Those state employees will need to "review[] the entity's records of staff vaccinations" and "interview[] staff to verify their vaccination status." *Id.* The surveyors will also "cite providers and suppliers when noncompliance is identified." *Id.*

103. Non-compliant healthcare providers are "subject to enforcement remedies imposed by CMS depending on the level of noncompliance and the remedies available under Federal law (for example, civil money penalties, denial of payment for new admissions, or termination of the Medicare/Medicaid provider agreement)." *Id.* at 61,574.

104. It appears that a covered healthcare provider that flatly refuses to comply—or otherwise cooperate—with the CMS Vaccine Mandate will face termination of its Medicare/Medicaid provider agreement. *Id.* at 61,574 (noting that the available "remedies" include "termination of the Medicare/Medicaid provider agreement"); Background Press Call on OSHA and CMS Rules for Vaccination in the Workplace (Nov. 4, 2021), The White House,

https://www.whitehouse.gov/briefing-room/press-briefings/2021/11/04/background-press-call-on-osha-and-cms-rules-for-vaccination-in-the-workplace/ ("If a facility were not making steps to come into compliance, we have a range of remedies. . . . We could . . . certainly, as a last resort, terminate them from the Medicare and Medicaid programs.").

105. CMS recognized that governing statutes require HHS Secretary Becerra to "consult with appropriate State agencies" when determining the "conditions of participation by providers of services," 42 U.S.C. § 1395z, and that no such consultation occurred before the CMS Vaccine Mandate issued, 86 Fed. Reg. at 61,567. Yet CMS claimed that it did not violate that statute because it "intend[s] to engage in consultations with appropriate State agencies . . . following the issuance of this rule," and it does not "understand the statute to impose a temporal requirement to do so in advance of the issuance of this rule." *Id.* at 61,567.

H. Failure to Comply with Notice and Comment Requirements

106. CMS recognized that the Administrative Procedure Act, 5 U.S.C. § 553, and the Social Security Act, 42 U.S.C. 1395hh(b)(1), ordinarily require notice and a comment period before a rule like the CMS Vaccine Mandate takes effect. *Id.* at 61,583. But CMS "believe[d] it would be impracticable and contrary to the public interest . . . to undertake normal notice and comment procedures." *Id.* at 61,586. It thus found "good cause to waive" those procedures. *Id.*

107. Trying to justify its good cause finding, CMS stated that "[t]he data showing the vital importance of vaccination" indicates that it "cannot delay taking this action." *Id.* at 61,583. But CMS did not reconcile that finding with its acknowledgement that "the effectiveness of the vaccine[s] to prevent disease transmission by those vaccinated [is] not currently known." *Id.* at 61,615.

108. CMS recognized that although summer brought a Delta-variant-driven COVID-19 surge, "newly reported COVID–19 cases, hospitalizations, and deaths have begun to trend

downward at a national level." *Id.* at 61,583. Yet CMS still sought to immediately impose the CMS Vaccine Mandate because it claimed, without citing any support, that "there are emerging indications of potential increases in . . . northern states where the weather has begun to turn colder." *Id.* at 61,584.

109. CMS also asserted that it must immediately implement the CMS Vaccine Mandate because "the 2021–2022 influenza season" will soon begin. *Id.* CMS offered this justification while simultaneously admitting that "the intensity of the upcoming 2021–2022 influenza season cannot be predicted" and that "influenza activity during the 2020–2021 season was low throughout the U.S." *Id.* There is no rational correlation between the incidence of influenza and the incidence of COVID-19. As COVID-19 cases surged through the fall of 2020 and into the spring of 2021, influenza cases were "historically low." Adrianna Rodriguez, *Flu cases were at an all-time low during the 2020-2021 season. What experts say to expect in next season's vaccine*, USA Today (May 10, 2021), https://www.usatoday.com/story/news/health/2021/05/10/flu-cases-historically-low-during-covid-what-expect-fall/7088318002/.

110. In claiming that it must immediately implement the CMS Vaccine Mandate, CMS ignored that it waited almost two months after President Biden's directive before it promulgated the CMS Vaccine Mandate to the public.

I. Purported Statutory Authority for the Vaccine Mandate

111. CMS's alleged statutory authority for the CMS Vaccine Mandate rests on two sets of laws. *Id.* at 61,567, 61,616–27. First, it relies on two statutes that grant general rulemaking power to HHS. *Id.* Second, it relies on more specific statutes that purportedly give it authority to apply the CMS Vaccine Mandate to specific covered classes of healthcare facilities. *Id.*

112. The two statutes that grant general rulemaking power to HHS are in the Social Security Act. The first—42 U.S.C. § 1302(a)—provides that "the Secretary of Health and Human

Services . . . shall make and publish such rules and regulations, not inconsistent with this chapter, as may be necessary to the efficient administration of the functions with which [he] is charged under this Act." 86 Fed. Reg. at 61,560. The second—42 U.S.C. § 1395hh(a)(1)—states that the "Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under" Title XVIII of the Social Security Act (Medicaid). *Id.* These statutes do not establish authority for CMS to mandate vaccines. "[T]he basic power that Congress gave to the Secretary was to establish rules and regulations for 'running' or 'managing' the federal public health insurance programs through CMS." *Merck & Co. v. United States Dep't of Health & Hum. Servs.*, 385 F. Supp. 3d 81, 90 (D.D.C. 2019) (interpreting §§ 1302 and 1395hh), *aff'd*, 962 F.3d 531 (D.C. Cir. 2020).

113. CMS cites one specific statute to support its inclusion of Psychiatric Residential Treatment Facilities ("PRTFs") in the CMS Vaccine Mandate —42 U.S.C. § 1396d(h)(1). 86 Fed. Reg. at 61,567. Section 1396d is a list of "Definitions" for "Grants to States for Medical Assistance Programs." Subsection (h)(1) merely defines the term "inpatient psychiatric hospital services for individuals under age 21." The definition specifies what constitutes a PRTF and, as part of that definition, includes specific requirements followed by—or "such standards as may be prescribed in regulations by the Secretary." This statute implies that the Secretary may create regulations setting "standards" for the "active treatment" of individuals under age twenty-one needing inpatient psychiatric services; but a definition, to the extent there is any implied rulemaking authority, must be interpreted within the context of the statute's other provisions. This statute does not establish that the Secretary may impose mandatory vaccines on the staff at PRTFs.

114. CMS cites one specific statute to support its inclusion of Intermediate Care Facilities for Individuals with Intellectual Disabilities ("ICFs-IID") in the CMS Vaccine

Mandate—42 U.S.C. § 1396d(d)(1). This is also a definition. Subsection (d)(1) defines those facilities to mean an institution whose "primary purpose . . . is to provide health or rehabilitative services for [intellectually disabled] individuals" if "the institution meets such standards as may be prescribed by the Secretary." This statute implies that the Secretary may create standards concerning the kinds of "health or rehabilitative services" the facility provides; but a definition, to the extent there is any implied rulemaking authority, must be interpreted within the context of the statute's other provisions. This statute does not authorize the Secretary to impose mandatory vaccines on the staff at ICFs-IID.

115. CMS cites one specific statute to support its inclusion of Critical Access Hospitals ("CAHs") in the CMS Vaccine Mandate —42 U.S.C. § 1395i–4(e). Subsection (e) says that "[t]he Secretary shall certify a facility as a critical access hospital if the facility—(1) is located in a State that has established a [M]edicare rural hospital flexibility program . . . ; (2) is designated as a critical access hospital by the State in which it is located; and (3) meets such other criteria as the Secretary may require." This statute implies that the Secretary may create "other criteria" similar to the two expressly listed requirements. But this statute does not authorize the Secretary to impose mandatory vaccines on the staff at CAHs.

116. CMS cites one specific statute to support its inclusion of End-Stage Renal Disease ("ESRD") facilities in the CMS Vaccine Mandate —42 U.S.C. § 1395rr(b)(1)(A). Subsection (b)(1)(A) authorizes payments for end-stage renal disease services to "providers of services and renal dialysis facilities which meet such requirements as the Secretary shall by regulation prescribe for institutional dialysis services and supplies . . . , transplantation services, self-care home dialysis support services which are furnished by the provider or facility, and routine professional services performed by a physician during a maintenance dialysis episode . . . ." This statute acknowledges

that the Secretary may create "requirements" for "institutional dialysis services," "transplantation services," and the like. But this statute does not authorize the Secretary to impose mandatory vaccines on the staff at ESRD facilities.

117. CMS cites a few specific statutes to support its inclusion of Ambulatory Surgical Centers ("ASCs") in the CMS Vaccine Mandate. The main statute that CMS cites—42 U.S.C. § 1395k(a)(2)(F)(i)—provides that Medicaid benefits shall include payments for "services furnished in connection with surgical procedures specified by the Secretary . . . performed in an ambulatory surgical center (which meets health, safety, and other standards specified by the Secretary in regulations)." Though this statute implies that the Secretary may create regulations setting "health, safety, and other standards" for ASCs, it does not grant the Secretary broad regulatory power to mandate vaccines.

118. CMS cites two specific statutes to support its inclusion of Programs of All-Inclusive Care for the Elderly ("PACE") facilities in the CMS Vaccine Mandate. The first—42 U.S.C. § 1395eee(f)—provides that "[t]he Secretary shall issue interim final or final regulations to carry out this section," and that "[n]othing in this subsection shall be construed as preventing the Secretary from including in regulations provisions to ensure the health and safety of individuals enrolled in a PACE program." The second—42 U.S.C. § 1396u–4(f)—is materially indistinguishable in its relevant language. Though these statutes authorize the Secretary to adopt some health- and safety-related regulations, they do not grant the Secretary unfettered regulatory power to mandate vaccines—something CMS has never done before.

119. CMS cites a few specific statutes to support its inclusion of Rural Health Clinics ("RHCs") in the CMS Vaccine Mandate. The primary statute that CMS cites—42 U.S.C. § 1395x(aa)(2)(K)—defines the term "rural health clinic" to "mean[] a facility which," among

certain qualifying factors, "meets such other requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are furnished services by the clinic." The expressly listed qualifying factors include the types of services provided, staff qualifications, medication requirements, and administrative matters. They do not include vaccination. This statute does not authorize the Secretary to mandate vaccines. CMS also cites 42 U.S.C. § 1396d(l)(2)(B). This is a definition in § 1396d defining "rural health clinic." A definition, to the extent there is any implied rulemaking authority, must be interpreted within the context of the statute's other provisions. Subsection (l)(2)(B) makes no reference to vaccines. This statute also does not authorize the Secretary to mandate vaccines.

120. CMS cites one specific statute to support its inclusion of Home Infusion Therapy ("HIT") Suppliers in the CMS Vaccine Mandate—42 U.S.C. § 1395x(iii)(3)(D)(i)(IV). That statute defines the term "qualified home infusion therapy supplier" to "mean[] a pharmacy, physician, or other provider of services or supplier" that, among certain qualifying factors, "meets such other requirements as the Secretary determines appropriate, taking into account the standards of care for home infusion therapy established by Medicare Advantage plans under part C and in the private sector." A definition, to the extent there is any implied rulemaking authority, must be interpreted within the context of the statute's other provisions. The statute's expressly listed qualifying factors include the types of services provided and staff professional qualifications. They do not include vaccination. This statute does not authorize the Secretary to mandate vaccines.

121. CMS cites one specific statute to support its inclusion of facilities that provide outpatient physical therapy and speech-language pathology services in the CMS Vaccine Mandate —42 U.S.C. § 1395x(p)(4)(A)(v). That statute defines "outpatient physical therapy services" to exclude services "furnished by a clinic or rehabilitation agency" that does not, among certain

qualifying factors, "meet[] such other conditions relating to the health and safety of individuals who are furnished services by such clinic or agency on an outpatient basis, as the Secretary may find necessary." But a definition, to the extent there is any implied rulemaking authority, must be interpreted within the context of the statute's other provisions. The statute's expressly listed qualifying factors include the types of services provided, staff professional qualifications, and administrative matters. They do not include vaccination. This statute does not authorize the Secretary to mandate vaccines.

122. CMS cites a few specific statutes to support its inclusion of Community Mental Health Centers ("CMHCs") in the CMS Vaccine Mandate—42 U.S.C. §§ 1395x(ff)(3), 1395k(a)(2)(J), and 1395cc(e)(2). The primary statute that CMS cites—42 U.S.C. § 1395x(ff)(3)(B)—defines a "community mental health center" to "mean[] an entity that," among certain qualifying factors, "meets such additional conditions as the Secretary shall specify to ensure . . . the health and safety of individuals being furnished such services." But a definition, to the extent there is any implied rulemaking authority, must be interpreted within the context of the statute's other provisions. The expressly listed qualifying factors include the types of services provided, staff professional qualifications, and administrative matters. They do not include vaccination. This statute does not authorize the Secretary to mandate vaccines.

123. CMS cites one specific statute to support its inclusion of hospitals in the CMS Vaccine Mandate —42 U.S.C. § 1395x(e)(9). That statute defines the term "hospital" to "mean[] an institution which," among certain qualifying factors, "meets such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution." A definition, to the extent there is any implied rulemaking authority, must be interpreted within the context of the statute's other provisions. The expressly listed

qualifying factors include the types of services provided, staff professional qualifications, and administrative matters. They do not include vaccination. This statute does not authorize the Secretary to mandate vaccines.

124. CMS cites one specific statute to support its inclusion of hospices in the CMS Vaccine Mandate. That statute—42 U.S.C. § 1395x(dd)(2)(G)—says that "[t]he term 'hospice program' means a public agency or private organization (or a subdivision thereof) which," among certain qualifying factors, "meets such other requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are provided care and services by such agency or organization." A definition, to the extent there is any implied rulemaking authority, must be interpreted within the context of the statute's other provisions. The expressly listed qualifying factors include the types of services provided, staff professional qualifications, and administrative matters. They do not include vaccination. This statute does not authorize the Secretary to mandate vaccines.

125. CMS cites one specific statute to support its inclusion of Comprehensive Outpatient Rehabilitation Facilities (CORFs) in the CMS Vaccine Mandate. That statute—42 U.S.C. § 1395x(cc)(2)(J)—provides that "[t]he term 'comprehensive outpatient rehabilitation facility' means a facility which," among certain qualifying factors, "meets such other conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such facility, including conditions concerning qualifications of personnel in these facilities." A definition, to the extent there is any implied rulemaking authority, must be interpreted within the context of the statute's other provisions. The expressly listed qualifying factors include the types of services provided, staff professional

qualifications, and administrative matters. They do not include vaccination. This statute does not authorize the Secretary to mandate vaccines.

126. CMS cites two specific statutes to support its inclusion of long-term-care ("LTC") facilities in the CMS Vaccine Mandate. The first—42 U.S.C. § 1395i–3(d)(4)(B)—states that "[a] skilled nursing facility must meet such other requirements relating to the health, safety, and well-being of residents or relating to the physical facilities thereof as the Secretary may find necessary." The second—42 U.S.C. § 1396r(d)(4)(B)—likewise provides that "[a] nursing facility must 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." Sections 1395i–3 and 1396r cannot be construed in a vacuum. They expressly list qualifying factors, including the types of services provided, staff professional qualifications, licensing requirements, sanitation issues, and administrative matters. They do not include vaccination. These statutes do not authorize the Secretary to mandate vaccines.

127. CMS cites a few specific statutes to support its inclusion of Home Health Agencies ("HHAs") in the CMS Vaccine Mandate. The statutes address definitions for HHAs. The first—42 U.S.C. § 1395x(o)(6)—defines a "home health agency" to "mean[] a public agency or private organization, or a subdivision of such an agency or organization, which," among certain qualifying factors that do not include vaccination requirements, "meets the conditions of participation specified in [42 U.S.C. § 1395bbb(a)] and such other conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such agency or organization." But a definition, to the extent there is any implied rulemaking authority, must be interpreted within the context of the statute's other provisions. The second—42 U.S.C. § 1395x(m)—defines "home health services," but the definition makes no reference to

standards or other requirements established by the Secretary. The third—42 U.S.C. § 1395bbb—outlines various "conditions of participation that a home health agency is required to meet," none of which include vaccination requirements. *See* 42 U.S.C. § 1395bbb(a). That statute also says that "[i]t is the duty and responsibility of the Secretary to assure that the conditions of participation and requirements specified in or pursuant to [42 U.S.C. § 1395x(o)] and subsection (a) of this section and the enforcement of such conditions and requirements are adequate to protect the health and safety of individuals under the care of a home health agency." 42 U.S.C. § 1395bbb(b). While these statutes give the Secretary authority to protect the health and safety of people served by HHAs, they do not authorize the Secretary to mandate vaccines.

128. None of these cited authorities authorize the Secretary or CMS to mandate that providers and suppliers require healthcare staff, students, interns, and volunteers to be vaccinated against COVID-19. Nor do they authorize CMS to require providers and suppliers to keep records of staff, students', interns', and volunteers' vaccination status.

J. Texas's Harm Resulting from the CMS Vaccine Mandate

129. The CMS Vaccine Mandate directly injures Texas.

130. Texas is party to a Medicaid agreement with HHS. But the CMS Vaccine Mandate seeks to transform that agreement in drastic ways far beyond any terms that Texas has accepted.

131. Texas operates healthcare facilities that are CMS-certified. They are thus required to impose the CMS Vaccine Mandate on their own state employees and comply with its burdensome requirements.

132. Texas's surveyors are state employees who enforce Medicaid compliance pursuant to HHSC's role as the state survey agency and its agreement with CMS. The CMS Vaccine Mandate seeks to commandeer those state employees to become enforcers of CMS's unlawful

attempt to federalize national vaccine policy and override Texas's police power on matters of health and safety.

133. By requiring state-run healthcare facilities and state surveyors to enforce the CMS Vaccine Mandate, Texas will face increased implementation and enforcement costs.

134. By requiring state-run healthcare facilities and state surveyors to enforce the CMS Vaccine Mandate, that mandate directly infringes Texas's sovereign authority.

135. Texas is injured because the CMS Vaccine Mandate purports to preempt its state and local laws on matters of vaccines and the rights of its citizens. This violates Texas's "sovereign interest in the power to create and enforce a legal code." *Texas v. United States*, 809 F.3d 134, 153 (5th Cir. 2015) (quotation omitted). It also violates Texas's sovereign right to exercise its police power on matters such as compulsory vaccination.

136. The Governor of Texas has issued an executive order prohibiting mandatory vaccination requirements by entities in Texas. Texas EO GA-40 (Oct. 11, 2021). However, the CMS Vaccine Mandate purports to "preempt[] inconsistent State and local laws as applied to Medicare- and Medicaid-certified providers and suppliers." 86 Fed. Reg. at 61,568; *see also id.* at 61,572, 61,613.

137. Texas will suffer other pocketbook injuries. The CMS Vaccine Mandate requires covered healthcare facilities to maintain documentation of their staff's vaccination status. 86 Fed. Reg. at 61,572. This includes state-run facilities.

138. Texas has a quasi-sovereign and *parens patriae* interest in protecting the rights of its citizens and vindicating them in court. Texas thus may sue to challenge unlawful actions that "affect the [States'] public at large." *In re Debs*, 158 U.S. 561, 584 (1895).

139. A natural and predictable consequence of the CMS Vaccine Mandate is that numerous state and private healthcare workers may be fired, retire, or quit their jobs. Texas healthcare providers face the Catch-22 of closure due to staffing shortages or closure due to the loss of Medicare and Medicaid reimbursements. *See* Leah Barkoukis, *Biden's Vaccine Mandate May Force Texas Hospital to Close*, Townhall (Sept. 16, 2021), https://townhall.com/tipsheet/leahbarkoukis/2021/09/16/texas-hospital-vaccine-mandate-n2595937. The effect of rural communities in Texas would be devastating. *See id.*

140. Medicare and Medicaid providers in Texas, particularly rural providers, are already burdened by a labor market short of nurses, particularly in highly-skilled areas. The COVID-19 pandemic has resulted in "higher than normal turnover among medical staff, resulting in concerning staffing shortages." HHS IG Report, at 10. "One hospital in a high-poverty and socially vulnerable community in Texas . . . reported [to HHS] that its annual average for nurse turnover increased from 2 percent prior to the pandemic to 20 percent in 2020." *Id.*

141. These providers have worked hard to increase staff vaccination rates through incentives and have avoided major outbreaks of COVID-19. But the CMS Vaccine Mandate now threatens to cause further hardship to these providers, particularly in rural communities. Mandating that providers terminate employees who refuse vaccination will lead to a reduction in healthcare services. Staff have already indicated that they will choose to resign instead of getting vaccinated. If these providers lose even a few nurses, services will be halted, and rural patients will have to travel long distances to obtain the medical care they require. Rural communities simply do not have enough qualified nurses to take the place of those that choose to resign.

142. The impact of the CMS Vaccine Mandate on state-run healthcare facilities is likely to have downstream impacts to local health systems, jails, and courts as well.

143. This injures Texas's quasi-sovereign and *parens patriae* interest in the health and economic well-being of its citizens. This injury is especially acute because of the already critical healthcare workforce shortage that Texas is experiencing. An exodus of healthcare workers further injures Texas by increasing the burden on Texas's unemployment insurance funds.

144. State universities and their students are also impacted by the CMS Vaccine Mandate. Those universities operated healthcare facilities that receive Medicaid and Medicare funding. Thus, they will be subject to the CMS Vaccine Mandate as well. The education of students enrolled in medical programs at these universities who object to mandatory vaccination, may risk losing out on rotations, clinical experience, and credits required for graduation.

145. Texas is injured because the CMS Vaccine Mandate discriminates between citizens of Texas who are vaccinated and those who are not by denying the latter employment opportunities available to the former. Texas has a quasi-sovereign and *parens patriae* interests in protecting their citizens from discriminatory policies. *See Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez*, 458 U.S. 592, 609 (1982) ("This Court has had too much experience with the political, social, and moral damage of discrimination not to recognize that a State has a substantial interest in assuring its residents that it will act to protect them from these evils.").

146. Declaratory relief announcing that the CMS Vaccine Mandate is unlawful, an injunction enjoining its enforcement, and an order setting aside the CMS Vaccine Mandate will remedy these harms to Texas's interests.

V. CLAIMS FOR RELIEF

147. Texas incorporates the allegations in each paragraph in this Complaint in each following count. To the extent that there is any perceived inconsistency, Texas expressly pleads each count in the alternative.

COUNT I
Violation of Statutory Limits on Agency Power

148. HHS, which includes CMS, is a federal agency subject to the requirements of the APA.

149. CMS's adoption and promulgation of the CMS Vaccine Mandate is a major agency action that could not lawfully be conducted without compliance with the APA.

150. Under the APA, courts must "hold unlawful and set aside agency action" that is "not in accordance with law" or "in excess of statutory . . . authority[] or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C).

A. Congress did not authorize CMS to mandate vaccinations.

151. CMS cites 42 U.S.C §§ 1302 and 1395hh as its primary authority for issuing the CMS Vaccine Mandate. 86 Fed. Reg. at 61,560, 61,616–26.

152. 42 U.S.C. § 1302(a) provides: "the Secretary of Health and Human Services . . . shall make and publish such rules and regulations, not inconsistent with this chapter, as may be necessary *to the efficient administration* of the functions with which [he] is charged under this chapter."

153. 42 U.S.C. § 1395hh provides: "The Secretary shall prescribe regulations as may be necessary to carry out *the administration* of the insurance programs under this subchapter."

154. Both relate to "administration." Neither authorizes CMS to regulate the transmission of communicable diseases or mandate medical treatment for the staff of healthcare facilities. They do not mention vaccinations at all.

155. An agency may implement a rule only when Congress authorized it to do so. "[A]n agency literally has no power to act . . . unless and until Congress confers power upon it." *La. Pub.*

Serv. Comm'n v. FCC, 476 U.S. 355, 374 (1986). Agency actions that do not fall within the scope of a statutory delegation of authority are *ultra vires* and must be invalidated.

156. The CMS Vaccine Mandate is contrary to law and in excess of statutory authority because CMS's statutory rulemaking authority does not include the authority to regulate the transmission of communicable diseases or mandate medical treatment for the staff of healthcare facilities.

B. CMS does not have limitless authority to regulate health and safety.

157. CMS asserts that it has authority to mandate COVID-19 vaccination of staff, interns, and volunteers because of its purported "broad statutory authority to establish health and safety regulations." 86 Fed. Reg. at 61,560. CMS's assertion of unfettered authority to regulate "health and safety" is unfounded.

158. "The Secretary's administrative authority is undoubtedly broad. But it is not boundless." *Merck & Co. v. United States Dep't of Health & Hum. Servs.*, 962 F.3d 531, 537–38 (D.C. Cir. 2020) (citations omitted).

159. CMS's assertion of authority to issue a vaccine mandate under vague statutory language generally referencing health and safety creates a "serious danger," if allowed to stand, that CMS and other agencies will "choose to broadly exert power in a variety of contexts." *Am. Health Care Ass'n v. Burwell*, 217 F. Supp. 3d 921, 934–35 (N.D. Miss. 2016).

160. Permitting CMS to exercise such boundless authority would render the separation-of-powers principles set forth in the United States Constitution meaningless.

161. Just this year, the Supreme Court rejected the assertion by a federal agency of such broad authority based on vague statutory language. The authority granted an agency by statute is not based on vague language in isolation, but is informed by the context in which that language

appears. *See Alabama Ass'n of Realtors v. Dep't of Health and Hum. Servs.*, 141 S. Ct. 2485, 2488 (2021).

162. Though various provisions in the Social Security Act authorize CMS to take certain actions concerning the health and safety of participants in programs over which CMS has oversight, that authority is circumscribed by 42 U.S.C §§ 1302 and 1395hh. *Merck & Co.*, 962 F.3d at 537–38. "To fall within the Secretary's regulatory authority, rules must be 'necessary to the efficient administration of the functions with which the Secretary is charged,' 42 U.S.C. § 1302(a), or 'necessary to carry out the administration of the insurance programs under' the Medicare subchapter of the Social Security Act." *Id.* at 537. The CMS Vaccine Mandate is not.

163. If the CDC—which (unlike CMS) has authority to "make and enforce such regulations . . . necessary to prevent the introduction, transmission, or spread of communicable diseases," *Alabama Ass'n of Realtors*, 141 S. Ct. at 2487 (quoting 42 U.S.C. § 264(a))—cannot issue an eviction moratorium to control the spread of communicable diseases, *id.* at 2489, then CMS, lacking similar authority, cannot regulate the transmission of communicable diseases by mandating vaccinations.

164. CMS's read of 42 U.S.C. §§ 1302 and 1395hh, and vague statutory references to health and safety, "would give [CMS] a breathtaking amount of authority." *Id.* at 2489. "It is hard to see what measures this interpretation would place outside [CMS's] reach, and the Government has identified no limit in [this authority] beyond the requirement that [CMS] deem a measure 'necessary.'" *Id.* at 2489.

165. CMS's assertion of such expansive authority under 42 U.S.C §§ 1302 and 1395hh, and vague statutory references to health and safety, is unprecedented, "not in accordance with the

law," "in excess of [its] statutory . . . authority," "in excess of statutory . . . limitations," and "short of [its] statutory right." 5 U.S.C. § 706(2)(A), (C).

C. CMS lacks authority to regulate communicable diseases or mandate medical treatment for the staff of healthcare facilities.

166. CMS relies on Title XI of the Social Security Act—titled General Provisions, Peer Review, and Administrative Simplification—for its purported authority to issue the Vaccine Mandate.

167. Title XI has four parts: Part A—General Provisions, Part B—Peer Review of the Utilization and Quality of Healthcare Services, Part C—Administrative Simplification, and Part D—Comparative Clinical Effectiveness Research.

168. The purpose of Title XI is to improve the Medicare program under Title XVIII of the Social Security Act, the Medicaid program under Title XIX of the Act, and the efficiency and effectiveness of the health care system by encouraging the development of a health information systems through the establishment of standards and requirements to enable the electronic exchange of certain health information.

169. Title XI of the Social Security act authorizes CMS to regulate specified matters relating to the general administration of the Medicare and Medicaid programs, such as requiring certain quality standards, establishing reporting requirements, and identifying enforcement procedures and authority. None of these functions charge CMS with regulating the transmission of communicable diseases or mandating medical treatment for the staff of healthcare facilities.

170. CMS also cites purported authority for the CMS Vaccine Mandate in Title XIX of the Social Security Act, which is titled Grants to States for Medical Assistance Programs. 86 Fed. Reg. at 61,567, 61,615–27.

171. The purpose of Title XIX is to "establish[] a Medical Assistance (Medicaid) program, under which participating States financially assist qualified individuals in five general categories of medical treatment, state plans being required to establish 'reasonable standards . . . for determining . . . the extent of medical assistance under the plan which are consistent with' Title XIX's objectives." *Beal v. Doe*, 432 U.S. 438, 438 (1977).

172. Title XIX authorizes CMS to regulate certain requirements related to Medicaid standards, such as eligibility requirements, state requirements for certain programs, and optional programs that a State may implement. None of these functions charge CMS with regulating the transmission of communicable diseases or mandating medical treatment for the staff of healthcare facilities.

173. Nowhere in Titles XI or XIX of the Social Security Act is CMS authorized to regulate the transmission of communicable diseases or mandate medical treatment for the staff of healthcare facilities.

174. CMS also relies on 42 U.S.C. § 1395hh for its purported authority to issue the CMS Vaccine Mandate. 86 Fed. Reg. at 61,560, 61,567, 61,615–27. Under 42 U.S.C. § 1395hh, the Secretary "shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under [Title XVIII of the Social Security Act]."

175. Title XVIII of the Social Security Act—titled Health Insurance for the Aged and Disabled—is the federal government's health insurance program for the elderly and for persons with certain disabilities. This title governs the administration and standards of Medicare as well as miscellaneous areas of Medicaid.

176. Title XVIII authorizes CMS to regulate Medicare and Medicaid insurance program administration. For example, it authorizes CMS to regulate coverage, benefits, and payments. A

vaccine mandate is distinct from requiring certain processes or services. It is a mandate that healthcare facility staff submit to a specific medical treatment.

177. Nowhere in Title XVIII of the Social Security Act is CMS authorized to regulate the transmission of communicable diseases or mandate medical treatment for the staff of healthcare facilities.

178. CMS does not identify any statute authorizing it to regulate the transmission of communicable diseases or mandate medical treatment for the staff of healthcare facilities. Instead, CMS merely refers to 42 U.S.C. §§ 1302 and 1395hh and its purported "broad authority" to implement "health and safety" regulations. Those statutes do not grant CMS the authority it seeks to exercise via the CMS Vaccine Mandate.

D. The CMS Vaccine Mandate is unrelated, let alone necessary, to administration of Medicare and Medicaid.

179. Under 42 U.S.C. §§ 1302 and 1395hh, CMS must establish that its regulations are (1) necessary to the efficient administration of the Secretary's functions and (2) necessary to carry out the administration of the insurance programs under Title XVIII, respectively.

180. The CMS Vaccine Mandate establishes the opposite—it will result in significant inefficiencies, and it has no relation to the administration of CMS's functions or the insurance programs under Title XVIII.

181. "Administration" is the operative term and focus of 42 U.S.C. §§ 1302 and 1395hh. "When the Social Security Act was enacted in 1935, this meant 'the practical management and direction of' its various programs (including eventually Medicare and Medicaid), as well as their 'management' and 'conduct.'" *Merck & Co.*, 962 F.3d at 537.

182. A rule issued under the authority granted by 42 U.S.C. §§ 1302 or 1395hh must have an "operational focus . . . on those two programs, and the rule's effect must be more than tangential." *Id.* at 538.

183. "[F]or a regulation to be 'necessary' to the programs' 'administration,'" CMS must "demonstrate an actual and discernible nexus between the rule and the conduct or management of Medicare and Medicaid programs." *Id.*

184. "For example, the Secretary would be hard pressed to defend as necessary to program administration a rule forbidding vending machines or smoking breaks at businesses that employ Medicare or Medicaid recipients just because those measures could promote healthier living and thereby reduce program costs. In other words, the further a regulation strays from truly facilitating the 'administration' of the Secretary's duties, the less likely it is to fall within the statutory grant of authority." *Id.*

185. CMS did not, and cannot, demonstrate that the CMS Vaccine Mandate is necessary to program administration, let alone efficient program administration.

186. Moreover, the CMS Vaccine Mandate does not concern "administration" of health insurance programs. Instead, it is a requirement for medical treatment.

187. CMS did not, and cannot, "demonstrate an actual and discernible nexus between the rule and the conduct or management of Medicare and Medicaid programs." *Id.*

188. "To qualify as administering the Medicare or Medicaid statutes, a program of such intrusive regulation must do more than identify a hoped-for trickle-down effect on the regulated programs." *Id.* at 537.

E. Congress did not clearly authorize the scope of authority being claimed by CMS.

189. "[T]he sweeping 'nature and scope of the authority being claimed by' [CMS] underscores the unreasonableness of [its] claim that it is just engaged in general 'administration.'" *Merck & Co.*, 962 F.3d at 540.

190. Moreover, "the sheer scope of [CMS's] claimed authority . . . would counsel against" CMS's broad view of its own authority. *Ala. Ass'n of Realtors*, 141 S. Ct. at 2489. The Supreme Court "expect[s] Congress to speak clearly when authorizing an agency to exercise powers of vast economic and political significance." *Id.* (quotation marks omitted) (quoting *Utility Air Regulatory Grp. v. EPA*, 573 U.S. 302, 324 (2014)). "That is exactly the kind of power that [CMS] claims here." *Id.*

191. CMS asserts that under the CMS Vaccine Mandate "virtually all health care staff in the U.S. will be vaccinated for COVD–19 within a matter of months." 86 Fed. Reg. at 61,573.

192. CMS estimates that 76,054 providers and suppliers, and approximately 10.3 million employees, will fall under the mandate. *Id.* at 61,603.

193. CMS estimates that the costs associated with the CMS Vaccine Mandate will be almost $1.4 billion dollars. *Id.* at 61,612.

194. If CMS can mandate medical treatment for tens of millions of workers, it "would give [CMS] a breathtaking amount of authority," and "[i]t is hard to see what measures this interpretation would place outside [CMS's] reach." *Ala. Ass'n of Realtors*, 141 S. Ct. at 2489.

195. CMS's authority does not extend to exercising powers of vast economic and political significance without limit as it attempts with the CMS Vaccine Mandate.

196. "Congress . . . does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001).

F. The CMS Vaccine Mandate conflicts with limitations in 42 U.S.C. § 1395.

197. 42 U.S.C. § 1395 provides that nothing in Title XVIII of the Social Security Act "shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person."

198. The CMS Vaccine Mandate violates 42 U.S.C. § 1395 because it authorizes federal officials at CMS to exercise "supervision" and "control" over the "selection" and "tenure" of employees (including state employees) and other persons "providing health services." It does so by prohibiting covered healthcare facilities from hiring unvaccinated employees and forcing those facilities to terminate—and thus end the tenure of—unvaccinated employees.

199. The CMS Vaccine Mandate also violates 42 U.S.C. § 1395 because it authorizes federal officials at CMS to exercise "supervision" and "control" over the "administration" and "operation" of institutions, agencies, and persons that provide health services (including state facilities and employees). It does so by dictating the hiring and firing policies of these institutions concerning unvaccinated workers.

200. For all these reasons, CMS's promulgation of the CMS Vaccine Mandate is contrary to law and in excess of statutory authority, and it should be held unlawful and set aside.

COUNT II
Failure to Provide Notice and Comment in Violation of the APA

201. HHS, which includes CMS, is a federal agency subject to the requirements of the APA.

202. CMS's adoption and promulgation of the CMS Vaccine Mandate was a major agency action that could not lawfully be conducted without compliance with the APA.

203. Prior to publishing the CMS Vaccine Mandate, CMS did not publish notice of proposed rulemaking in the Federal Register or give all interested members of the public an opportunity to comment.

204. Generally, the APA requires agencies to provide notice of proposed rulemaking through publication in the Federal Register. 5 USC § 553(b). The notice must include, among other things, a statement of the time, place, and nature of public proceedings, and either the terms or substance of the proposed rule or a description of the subjects and issues involved. *Id*.

205. After publishing notice, agencies must give interested persons an opportunity to participate in the rulemaking process through public comment. *Id*. § 553(c). The Social Security Act requires CMS to provide notice of a proposed regulation for at least sixty days for public comment. 42 U.S.C. § 1395hh(b)(1).

206. "The more expansive the regulatory reach of these rules, of course, the greater the necessity for public comment." *Am. Fed'n of Gov't Emp., AFL-CIO v. Block*, 655 F.2d 1153, 1156 (D.C. Cir. 1981).

207. The APA provides an exception to the general rulemaking requirements "when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 USC § 553(b)(B); *see also* 42 U.S.C. § 1395hh(b)(2)(C).

208. The good-cause exception should be read narrowly and should not be used to circumvent the notice and comment requirements whenever an agency finds it inconvenient to comply. *U.S. Steel Corp. v. EPA*, 595 F.2d 207, 214 (5th Cir. 1979). "Generally, the 'good cause'

exception to notice and comment rulemaking is to be 'narrowly construed and only reluctantly countenanced.'" *Jifry v. FAA*, 370 F.3d 1174, 1179 (D.C. Cir. 2004) (citation omitted) (quoting *Tennessee Gas Pipeline Co. v. FERC*, 969 F.2d 1141, 1144 (D.C. Cir. 1992)).

209. An agency's self-imposed delay cannot support a finding of good cause. "Good cause cannot arise as a result of the agency's own delay, because otherwise, an agency unwilling to provide notice or an opportunity to comment could simply wait . . . raise up the 'good cause' banner and promulgate rules without following APA procedures." *Nat. Res. Def. Council v. NHTSA*, 894 F.3d 95, 114–15 (2d Cir. 2018).

210. CMS asserts that it has good cause to waive notice-and-comment requirements for the CMS Vaccine Mandate because:

> [A] combination of factors, including but not limited to failure to achieve sufficiently high levels of vaccination based on voluntary efforts and patchwork requirements, potential harm to patients from unvaccinated healthcare workers, and continuing strain on the health care system and known efficacy and safety of available vaccines, have persuaded us that a vaccine mandate for health care workers is an essential component of the nation's COVID-19 response. Further, it would endanger the health and safety of patient, and be contrary to the public interest for us to delay imposing it.

86 Fed. Reg. at 61,586; *see id.* at 61,583–86. CMS also identified the cold weather and imminent influenza season. *Id*. at 61,584.

211. CMS acknowledges that newly reported COVID-19 cases, hospitalizations, and deaths have begun to trend downward. *Id*. at 61,584.

212. CMS fails to support its claim that the upcoming cold months and influenza season justify waiving notice-and-comment rulemaking. The data upon which it relied is outdated, as it is based on the influenza season in 2020—before a COVID-19 vaccine was available, before most of the country was vaccinated, and before many of the remaining unvaccinated possessed natural immunity.

213. When CMS issued the CMS Vaccine Mandate, CDC data indicated that the rates of new COVID-19 cases, hospital admissions, daily deaths were at some of the lowest levels since the pandemic began and that they were trending downward.

214. COVID-19 vaccines have been available since December 2020, but CMS delayed until November 5, 2021, to issue the CMS Vaccine Mandate. CMS's lack of urgency undermines its claim of good cause to skip notice-and-comment rulemaking now, almost a year later.

215. CMS cited insufficient and outdated research to justify waiving notice-and-comment rulemaking. CMS cited no data showing that there is an increased risk of COVID-19 infection when long-term-care facility staff are vaccinated at rates exceeding 75%, which they were when CMS issued the CMS Vaccine Mandate.

216. When CMS waived notice-and-comment rulemaking and issued the CMS Vaccine Mandate, it was aware that CDC data showed that the rate of COVID-19 infection of healthcare workers was low, nearly the lowest at any point since the pandemic started.

217. Moreover, CMS cannot claim that it is impracticable or contrary to the public interest to comply with notice-and-comment requirements when President Biden announced his intention to mandate vaccinations on September 9, 2021, but CMS waited until November 5, 2021, to promulgate the CMS Vaccine Mandate. This delay shows that CMS had ample time to provide notice and seek comments.

218. When CMS issued the CMS Vaccine Mandate on November 5, 2021, COVID-19 cases had dramatically declined and were continuing to trend downward, while voluntary vaccination rates were rising, with the vast majority of Americans aged twelve and older already partially vaccinated.

219. CMS did not, and could not, demonstrate "good cause" to justify its failure to comply with its notice-and-comment obligations under the APA.

For all these reasons, CMS's promulgation of the CMS Vaccine Mandate violated APA procedural requirements, and the CMS Vaccine Mandate should be held unlawful and set aside.

COUNT III
Failure to Provide Notice and Comment in Violation of the Social Security Act

220. HHS, which includes CMS, is a subject to the procedural rulemaking requirements in the Social Security Act.

221. Under the Social Security Act, CMS "shall provide for notice of [a] proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon." 42 U.S.C. § 1395hh(b)(1).

222. Prior to issuing the CMS Vaccine Mandate, CMS did not publish notice of proposed rulemaking in the Federal Register or give all interested members of the public an opportunity to comment.

223. The Social Security Act's notice and comment requirements, like the APA's similar requirements, do not apply if "good cause" establishes that they "are impracticable, unnecessary, or contrary to the public interest" under the circumstances. 42 U.S.C. § 1395hh(b)(2)(C).

224. CMS did not, and could not, demonstrate "good cause" to justify its failure to comply with its notice-and-comment obligations under the Social Security Act.

225. For all these reasons, CMS's promulgation of the CMS Vaccine Mandate violated the Social Security Act's procedural requirements, and the CMS Vaccine Mandate should be held unlawful and set aside.

COUNT IV
Violation of 42 U.S.C. § 1395z – Failure to Consult

226. HHS, which includes CMS, is a federal agency subject to the requirements of the APA.

227. CMS's adoption and promulgation of the CMS Vaccine Mandate is a major agency action that could not lawfully be conducted without compliance with the APA.

228. Under the APA, a court must "hold unlawful and set aside agency action" that is found to be "not in accordance with law" or "without observance of procedure required by law." 5 U.S.C. § 706(2)(A), (D).

229. 42 U.S.C. § 1395z imposes a consultation requirement on the Secretary of HHS to "consult with appropriate State agencies and recognized national listing or accrediting bodies" when "carrying out his functions, relating to determination of conditions of participation by providers of services, under subsections (e)(9), (f)(4), (j)(15), (o)(6), (cc)(2)(I), and (dd)(2), and (mm)(1) of section 1395x of [Title 42], or by ambulatory surgical centers under section 1395k(a)(2)(F)(i) of [Title 42]." 42 U.S.C. § 1395z.

230. Consultation is required by 42 U.S.C. § 1395z because "conditions prescribed under any of such subsections may be varied for different areas or different classes of institutions or agencies." *Id.*

231. 42 U.S.C. § 1395z applies to the CMS Vaccine Mandate because it purports to establish conditions of participation for hospitals under 42 U.S.C. § 1395x(e)(9), long-term-care facilities (also known as skilled nursing facilities) under 42 U.S.C. § 1395x(j) and 42 U.S.C. § 1395i–3, Home Health Agencies ("HHAs") under 42 U.S.C. § 1395x(o)(6), Comprehensive Outpatient Rehabilitation Facilities ("CORFs") under 42 U.S.C. § 1395x(cc)(2), hospices under 42 U.S.C. § 1395x(dd)(2), Critical Access Hospitals ("CAHs") under 42 U.S.C. § 1395x(mm)(1)

and 42 U.S.C. § 1395i–4(e), and Ambulatory Surgical Centers ("ASCs") under 42 U.S.C. § 1395k(a)(2)(F)(i).

232. CMS did not consult State agencies and recognized national listing or accrediting bodies prior to issuing the CMS Vaccine Mandate. 86 Fed. Reg. at 61,567.

233. CMS's "inten[t] to engage in consultations with appropriate State agencies . . . following the issuance of th[e] rule," *id.*, does not satisfy 42 U.S.C. § 1395z.

234. 42 U.S.C. § 1395z requires that consultation take place before a rule is issued. The statutory text requires consultation when the Secretary is "carrying out his functions[] relating to determination of conditions of participation by providers of services." The Secretary, via CMS, has already determined that the CMS Vaccine Mandate should be a condition of participation by providers. Thus, the time for the required consultation has passed, and the Secretary, acting through CMS, has violated 42 U.S.C. § 1395z.

235. For all these reasons, CMS's promulgation of the CMS Vaccine Mandate violated 42 U.S.C. § 1395z, and it should be held unlawful and set aside. 5 U.S.C. § 706(2)(A), (D).

COUNT V
Violation of 42 U.S.C. § 1302 – Regulatory Impact Analysis

236. HHS, which includes CMS, is a federal agency subject to the requirements of the APA.

237. CMS's adoption and promulgation of the CMS Vaccine Mandate is a major agency action that could not lawfully be conducted without compliance with the APA.

238. Under the APA, a court must "hold unlawful and set aside agency action" that is found to be "not in accordance with law" or "without observance of procedure required by law." 5 U.S.C. § 706(2)(A), (D).

239. 42 U.S.C. § 1302(b)(1) requires that the Secretary of HHS "prepare and make available for public comment an initial regulatory impact analysis" whenever he "publishes a general notice of proposed rulemaking for any rule or regulation proposed under subchapter XVIII, subchapter XIX, or part B of [title IX of the Social Security Act] that may have a significant impact on the operations of a substantial number of small rural hospitals."

240. 42 U.S.C. § 1302(b)(1) applies to the CMS Vaccine Mandate because CMS cites statutory authority under Titles XVIII and XIX of the Social Security Act and because the CMS Vaccine Mandate will have a significant impact on the operations of a substantial number of small rural hospitals.

241. The CMS Vaccine Mandate threatens to exacerbate already devastating shortages in healthcare staffing by forcing small rural hospitals to terminate their unvaccinated workers. That, in turn, will compel those hospitals to close certain divisions, cancel certain services, or shutter altogether. These dire consequences stretch across rural America, and require CMS to prepare a regulatory impact analysis.

242. CMS's promulgation of the CMS Vaccine Mandate violated 42 U.S.C. § 1302(b)(1), and it should be held unlawful and set aside. 5 U.S.C. § 706(2)(A), (D).

COUNT VI
Arbitrary and Capricious Agency Action

243. HHS, which includes CMS, is a federal agency subject to the requirements of the APA.

244. CMS's adoption and promulgation of the CMS Vaccine Mandate is a major agency action that could not lawfully be conducted without compliance with the APA.

245. Under the APA, a court must "hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

246. "Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

247. In reviewing an agency's action, courts may consider only the reasoning "articulated by the agency itself" at the time of the agency action and cannot consider post hoc rationalizations. *Id.* at 50 (citing *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962)); *see also Dep't of Homeland Sec. v. Regents of the Univ. of California*, 140 S. Ct. 1891, 1908 (2020).

248. CMS did not engage in reasoned decision-making, but acted arbitrarily and capriciously, in issuing the CMS Vaccine Mandate.

249. CMS acted arbitrarily and capriciously by not fully considering the economic impacts on the healthcare industry, labor-force disruptions in the healthcare industry, and loss of jobs in the healthcare industry.

250. CMS acted arbitrarily and capriciously by ignoring or arbitrarily rejecting the adverse effects resulting from resignations of unvaccinated healthcare workers, which is a particularly important problem for an economy already experiencing a critical labor shortage in the healthcare industry, particularly in rural communities.

251. CMS acted arbitrarily and capriciously by ignoring or arbitrarily rejecting the interests of healthcare workers who—for any number of varying personal reasons—do not want to take one of the currently authorized COVID-19 vaccines.

252. CMS acted arbitrarily and capriciously by refusing to provide a testing option for employees who decline to take one of the available COVID-19 vaccines. This decision arbitrarily and capriciously conflicts with OSHA's recently issued ETS, which allows periodic testing as an alternative to compulsory vaccines.

253. CMS acted arbitrarily and capriciously by refusing to provide an exemption to persons with natural immunity to COVID-19 because natural immunity is at least as effective as vaccination in preventing re-infection, transmission, and severe health outcomes.

254. CMS acted arbitrarily and capriciously by not fully considering the costs to States and their agencies.

255. CMS acted arbitrarily and capriciously by ignoring or arbitrarily rejecting the adverse effects of the CMS Vaccine Mandate on States like Texas, which operate state-run hospitals that participate in Medicare and Medicaid, and which incur costs associated with enforcing the vaccine mandate, including enforcement through state surveyors.

256. CMS acted arbitrarily and capriciously by not fully considering the current health risks of COVID-19, the current limitations of COVID-19 vaccines, the benefits of natural immunity to COVID-19, and basic distinctions among workers, such as those with natural immunity to COVID-19 and those who work with limited in-person contacts.

257. CMS ignored or arbitrarily rejected the fact that the CMS Vaccine Mandate will have a disparate impact on minority and economically-disadvantaged communities that have

relatively low rates of vaccination by inflicting disproportionately greater unemployment, job losses, loss of healthcare services, and economic injury on those disadvantaged communities.

258. CMS ignored that the CMS Vaccine Mandate will cover religious healthcare institutions and thus require them to terminate ministerial employees in violation of the First Amendment. *Our Lady of Guadalupe Sch. v. Morrissey-Berru*, 140 S. Ct. 2049, 2060 (2020).

259. CMS ignored that its actions were contrary to law, as they were not authorized by the Social Security Act, and were also unconstitutional.

260. CMS acted arbitrarily and capriciously by basing its decision to issue the CMS Vaccine Mandate on a pretextual justification when the true purpose of the CMS Vaccine Mandate was a political decision and an attempt to federalize public-health issues involving vaccination that belong within the States' police power.

261. CMS acted arbitrarily and capriciously because its finding that the CMS Vaccine Mandate is necessary was undermined by its delay in adopting it. Vaccines have been authorized for almost a year, yet CMS did not impose this mandate until two months after it was instructed to do so by the President as part of his "six-point plan" to federalize public-health policy.

262. CMS acted arbitrarily and capriciously by ignoring or unreasonably rejecting the important reliance interests of many institutions and individuals in Texas. These reliance interests are longstanding and deep-seated since the federal government has never before tried to impose a vaccine requirement on healthcare workers. These specific reliance interests include (1) Texas's reliance interests in its healthcare providers continuing to operate under the existing rules without facing this new mandate that threatens to cause significant harm to Texas's citizens, particularly those in rural communities; (2) healthcare providers' similar reliance interests in staffing their facilities under the existing rules without facing this new mandate that threatens their workforce,

the services they provide, and their very existence; and (3) healthcare workers' reliance interests, especially the interests of minority workers and workers in rural communities, in selecting a job and building a career under the existing rules.

263. The broad scope of healthcare providers covered by the CMS Vaccine Mandate is arbitrary and capricious. The mandate reaches many categories of healthcare facilities, such as psychiatric residential treatment facilities for individual under twenty-one years of age, *see* 86 Fed. Reg. at 61576, that are not related to CMS's asserted interest in protecting elderly and infirm patients from the transmission of COVID-19. Indeed, CMS recognizes that "risk of death from infection from an unvaccinated 75- to 84-year-old person is 320 times more likely than the risk for an 18- to 29-years old person." *Id.* at 61,610 n.247.

264. The broad scope of workers, volunteers, and contractors covered by the CMS Vaccine Mandate is arbitrary and capricious. The mandate applies to "any individual that . . . has the potential to have contact with anyone at the site of care." *Id.* at 61,571. This includes "staff that primarily provide services remotely via telework" but "occasionally encounter fellow staff . . . who will themselves enter a health care facility." *Id.* at 61,570. The vast reach of this mandate is far removed from the purported purpose of protecting patient safety.

265. The CMS Vaccine Mandate is arbitrary and capricious because CMS failed to consider that new COVID-19 cases among healthcare workers were virtually non-existent. When CMS issued the CMS Vaccine Mandate, new cases among healthcare workers were nearly at their lowest level since the start of the pandemic according to CDC, likely due to voluntary vaccinations and natural immunity following the surge of Delta variant cases.

266. The CMS Vaccine Mandate is arbitrary and capricious because CMS failed to consider the vaccination rates of LTC residents and staff, an error which was magnified by CMS's

decision to extrapolate information regarding LTCs industry wide. The CMS Vaccine Mandate is also arbitrary and capricious because CMS failed to consider the vaccination rate among Medicaid and Medicare populations and the vaccination rate among the general public.

267. Nearly all LTC residents are at least partially vaccinated against COVID-19. The CDC reported that 88.3% of LTC residents were vaccinated, with 86.6% fully vaccinated, as of October 31, 2021.

268. CMS was aware of the CDC data showing nearly 90% of LTC residents were vaccinated. 86 Fed. Reg. at 61,604 n.229. CMS assumed a 90% LTC resident vaccination rate, and an 80% vaccination rate among all other patients and clients, in its impact statements when it issued the CMS Vaccine Mandate, but it failed to consider these vaccination rates when considering whether a vaccine mandate was necessary. *Id*. at 61,604, 61,607.

269. Most Medicare beneficiaries are 65 or older. In 2019, 83% of Medicare beneficiaries were 65 or older, while 17% were under 65 but qualified for Medicare because of a permanent disability.

270. Nearly everyone over 65 is at least partially vaccinated against COVID-19. The CDC reported that, "[a]s of November 4, 2021, 97.8% of people ages 65 years or older have received at least one dose of vaccine and 85.6% are fully vaccinated." *Profile of Medicare Beneficiaries by Race and Ethnicity: A Chartpack*, Kaiser Family Foundation, https://tinyurl.com/yk522jzf.

271. More than two-thirds of people over age twelve are at least partially vaccinated against COVID-19. The CDC reported that, as of November 4, 2021, 80.3% of people ages eighteen and older had received at least one dose of vaccine, with 69.9% fully vaccinated, while

78.4% of people ages twelve and older had received at least one dose of vaccine, with 68.1% fully vaccinated.

272. The vaccination rate among residents and patients, or the absence of an available vaccine, was a critical factor in all of the cited research relied upon by CMS for its mandate determination. Yet, CMS failed to consider this information when deciding that a mandate was necessary. And failing to consider this information was arbitrary and capricious.

273. The CMS Vaccine Mandate is arbitrary and capricious because CMS failed to consider important information and set forth a reasonable timeframe for implementation and compliance. The CMS Vaccine Mandate allows only until December 6, 2021, for the millions of impacted individuals to receive a first vaccine dose, and until January 4, 2022, to obtain a second vaccine shot (if taking the Pfizer or Moderna version of the vaccine). 86 Fed. Reg. at 61,574. CMS failed to consider the time that healthcare workers must wait between doses of the vaccine. CMS failed to consider the impact of the holidays occurring between the date the CMS Vaccine Mandate issued and the dates on which compliance is required on the ability to comply with the tight deadlines. CMS also failed to consider the impact that requiring so many individuals to comply with the CMS Vaccine Mandate in such a short period of time would have on their ability to comply with the mandate.

274. CMS concluded that the CMS Vaccine Mandate was necessary because it found that "health care staff vaccination rates remain too low in too many health care facilities and regions." 86 Fed. Reg. at 61,559. CMS relied on a number of studies and CDC data to reach this conclusion. *Id*. at 61,558–59.

275. CMS found:

> The best data come from long term care [(LTC)] facilities, as early implementation of national reporting requirements have resulted in a comprehensive, longitudinal,

> high quality data set. Data from CDC's National Healthcare Safety Network (NHSN) have shown that case rates among LTC facility residents are higher in facilities with lower vaccination coverage among staff; specifically, *residents of LTC facilities in which vaccination coverage of staff is 75 percent or lower experience higher rates of preventable COVID-19*.

Id. at 61,558 (emphasis added).

276. CMS based the 75% staff vaccination number on a CDC handout containing preliminary data that actually found that the difference between infection rates at LTC facilities where 60-74% of staff were vaccinated, and those where 75-100% were vaccinated, was "not significant." *Id.* at 61,558 n.38 (citing *CDCHAN-00447: Vaccination to Prevent COVID-19 Outbreaks with Current and Emergent Variants – United States, 2020 (July 27, 2021)*, available at https://emergency.cdc.gov/han/2021/han00447.asp).

277. CMS concluded that "while similarly comprehensive data [is] not available for all Medicare- and Medicaid-certified provider and supplier types, we believe the LTC facilities experience may generally be extrapolated to other settings." *Id.* at 61,585.

278. The 75% staff vaccination rate was the only quantifiable metric provided by the research relied upon by CMS to determine the staff vaccination rate necessary to prevent COVID-19 infections at LTC facilities.

279. CMS concluded that the CMS Vaccine Mandate was necessary because the CDC weekly vaccine report showed staff vaccinations rates at LTC facilities were only 67% in September 2021. *Id.* at 61,559.

280. However, as of October 31, 2021, the CDC weekly vaccine data relied on by CMS showed the complete and partial staff vaccination rates at LTC facilities was 78.2%, including 76% fully vaccinated.[2]

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[2] https://www.cdc.gov/nhsn/covid19/ltc-vaccination-dashboard.html.

281. Contrary to CMS's contention that the voluntary vaccination rate among LTC facility staff had stalled, the fully vaccinated staff rate increased by 37.18% over five months, from 55.4% on May 23, 2021, to 76% on October 31, 2021.

282. The October 31, 2021, CDC weekly vaccination data showing a 76% fully vaccinated staff rate at LTC facilities was available to CMS prior to issuing the CMS Vaccine Mandate on November 5, 2021.

283. CMS cited the same online publicly-available CDC vaccination data in its impact statements.

284. CMS assumed that when the CMS Vaccine Mandate became effective that approximately 75% of LTC staff, 90% of LTC residents, and 80% of all other patients and clients would already be vaccinated. *Id*. at 61,604, 61,607.

285. Yet, when evaluating the need for the CMS Vaccine Mandate, CMS relied on months-old data from August and September—at the height of the Delta-variant surge. *Id.* at 61,559, 61,576.

286. The CMS Vaccine Mandate is arbitrary and capricious because CMS failed entirely to consider an important aspect of the problem—namely, staff vaccination rates at LTC facilities exceeding 75% at the time it issued the mandate.

287. CMS's reliance on outdated research is a persistent problem throughout the CMS Vaccine Mandate. For example, CMS contends that patients are forgoing necessary medical care due to the fear of being treated by unvaccinated staff. *Id.* at 61,558–59. Yet, CMS's evidence to support this conclusion comprises studies that were conducted, or relied on data, from 2020—before there was a COVID-19 vaccine. *See id.* at 61,558 nn. 44–48.

288. CMS decided that the CMS Vaccine Mandate was necessary because staff vaccination rates at LTC facilities did not exceed 75% in September 2021, two months before the CMS Vaccine Mandate issued, and it then extrapolated this finding industry wide.

289. The CMS Vaccine Mandate is also arbitrary and capricious because the offered explanation for CMS's decision to impose a mandate runs counter to the CDC data before CMS on LTC staff vaccination rates as of October 31, 2021.

290. For all these reasons, CMS's promulgation of the CMS Vaccine Mandate was arbitrary and capricious, and the CMS Vaccine Mandate should be held unlawful and set aside. 5 U.S.C. § 706(2)(A).

COUNT VII
Unconstitutional Exercise of Spending Power

291. The CMS Vaccine Mandate is an unconstitutional condition on Texas's receipt of federal funds.

292. "[I]f Congress intends to impose a condition on the grant of federal moneys, it must do so unambiguously," so "States [can] exercise their choice knowingly." *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981). Moreover, the federal government may not surprise States by imposing new conditions post-acceptance. *Miss. Comm'n on Env't Quality v. EPA*, 790 F.3d 138, 179 (D.C. Cir. 2015) (per curium).

293. No federal law provides Texas with notice that CMS would require vaccination of all staff at healthcare facilities receiving Medicare or Medicaid funding, including state-run facilities, as a condition of receiving that funding, nor that CMS would require state surveyors to enforce such a requirement as a condition of receiving that funding.

294. "[C]onditions on federal spending" must "be related 'to the federal interest in particular national projects or programs." *United States v. Lipscomb*, 299 F.3d 303, 322 (5th Cir. 2002) (quoting *South Dakota v. Dole*, 483 U.S. 203, 207 (1987)).

295. The scope of the CMS Vaccine Mandate reaches far beyond any federal interest in patient safety. For example, the CMS Vaccine Mandate is so broad that it purports to apply to a contracted "crew working on a construction project whose members use shared facilities (restrooms, cafeteria, break rooms) during their breaks." 86 Fed. Reg. at 61,571. The CMS Vaccine Mandate also covers healthcare providers, such as psychiatric residential treatment facilities for individuals under twenty-one years of age, that exclusively serve patients at very low risk from COVID-19. *Id.* at 61,576. The vast reach of the CMS Vaccine Mandate is far removed from its supposed purpose of protecting patients.

296. The federal government cannot use the spending power to "commandeer[] a State's . . . administrative apparatus for federal purposes," *NFIB v. Sebelius*, 567 U.S. 519, 577 (2012), or "conscript state [agencies] into the national bureaucratic army," *id.* at 585.

297. The CMS Vaccine Mandate conscripts state agencies by forcing state-run hospitals to either fire their unvaccinated employees or risk their Medicare and Medicaid funding.

298. The CMS Vaccine Mandate conscripts state agencies by forcing state surveyors to enforce the mandate by verifying the compliance of healthcare providers. If Texas refuses to enforce the CMS Vaccine Mandate, providers and suppliers in Texas may not be able to receive Medicare and Medicaid reimbursements.

299. Forcing Texas to comply with the CMS Vaccine Mandate, and to enforce compliance with the CMS Vaccine Mandate, under threat of the loss of Medicare and Medicaid

funding is unconstitutionally coercive; it is a gun to the head that compels Texas to participate against its will.

300. For all these reasons, the CMS Vaccine Mandate was adopted by CMS pursuant to an unconstitutional exercise of authority, and the CMS Vaccine must be held unlawful and set aside.

COUNT VIII
Violation of Anti-Commandeering Doctrine

301. "[T]he Federal Government may not compel the States to implement, by legislation or executive action, federal regulatory programs." *Printz v. United States*, 521 U.S. 898, 925 (1997).

302. The CMS Vaccine Mandate compels Texas to administer a federal regulatory program by forcing state-run hospitals to either fire their unvaccinated employees or risk their Medicare and Medicaid funding.

303. The CMS Vaccine Mandate compels Texas to administer a federal regulatory program by forcing state surveyors to enforce the mandate by verifying the compliance of healthcare providers. If Texas refuses to enforce the CMS Vaccine Mandate, providers and suppliers in Texas that are subject to the rule may not be able to receive Medicare and Medicaid reimbursements.

304. Forcing Texas to comply with the CMS Vaccine Mandate, and to enforce compliance with the CMS Vaccine Mandate, under threat of the loss of all Medicare and Medicaid funding is unconstitutionally coercive; it is a gun to the head that compels Texas to participate against its will.

305. For all these reasons, the CMS Vaccine Mandate was adopted pursuant to an unconstitutional exercise of authority and must be held unlawful and set aside.

COUNT IX
Violation of the Tenth Amendment

306. The structure of the U.S. Constitution and the text of the Tenth Amendment protect federalism.

307. The powers not delegated by the Constitution to the federal government are reserved to the States.

308. Through the CMS Vaccine Mandate, the federal government seeks to exercise power far beyond what was delegated to the federal government under the United States Constitution.

309. The power to impose vaccine mandates, to the extent that any such power exists, is a power reserved to the States.

310. "[T]he police power of a state" includes, above all, the authority to adopt regulations seeking to "protect the public health," including the topic of mandatory vaccination. *Jacobson v. Massachusetts*, 197 U.S. 11, 24–25 (1905). These matters "do not ordinarily concern the national government." *Id.* at 38.

311. By interfering with the traditional balance of power between the States and the federal government, CMS violated the Tenth Amendment and structural principles of federalism.

312. For all these reasons, the CMS Vaccine Mandate was adopted pursuant to an unconstitutional exercise of authority and must be held unlawful and set aside.

COUNT X
Violation of the U.S. Constitution, Art. I, § 1
Unconstitutional Delegation of Legislative Power

313. Pursuant to Article I, § 1 of the U.S. Constitution, "[a]ll legislative powers herein granted shall be vested in a Congress of the United States." Under Article I, § 1, only Congress may engage in lawmaking.

314. "Congress is not permitted to abdicate or to transfer to others the essential legislative functions with which it is thus vested." *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 529–30 (1935).

315. The nondelegation doctrine bars Congress from transferring its legislative power to another branch of government.

316. While Congress may delegate power to executive agencies, the statutory delegation must include an intelligible principle to which the delegee "is directed to conform." *J.W. Hampton, Jr., & Co v. U.S.*, 276 U.S. 394, 409 (1928).

317. The nondelegation doctrine is based on the principle of preserving the separation of powers.

318. CMS's interpretation of its statutory authority as "broad authority to establish health and safety regulations, which includes authority to establish vaccination requirements," 86 Fed. Reg. at 61,567, is not supported by a statutory directive within the Social Security Act or any other federal law.

319. Accordingly, the CMS Vaccine Mandate must be held unlawful and set aside.

VI. PRAYER FOR RELIEF

Wherefore, Plaintiffs pray the Court:

a. Declare that the CMS Vaccine Mandate is arbitrary and capricious and unlawful under the APA;

b. Declare that the CMS Vaccine Mandate is contrary to law and in excess of statutory authority under the APA;

c. Declare that the CMS Vaccine Mandate violates APA procedural requirements;

d. Declare that the CMS Vaccine Mandate violates Social Security Act procedural requirements;

e. Declare that the CMS Vaccine Mandate violates 42 U.S.C. § 1395z because CMS failed to consult with the appropriate state agencies;

f. Declare that the CMS Vaccine Mandate violates 42 U.S.C. § 1302(b)(1) because CMS did not prepare a regulatory impact analysis;

g. Declare that the CMS Vaccine Mandate violates the Spending Clause, the anti-commandeering doctrine, and the Tenth Amendment;

h. Set aside the CMS Vaccine Mandate;

i. Enjoin Defendants, and any other agency or employee of the United States, or any individual working in concert with them, from enforcing the CMS Vaccine Mandate;

j. Award Plaintiffs their costs and reasonable attorneys' fees; and

k. Award such other and further relief as this Court deems equitable and just.

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