UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
MONROE DIVISION

THE STATE OF LOUISIANA,
By and through its Attorney General, JEFF LANDRY;

THE STATE OF MONTANA,
By and through its Attorney General, AUSTIN KNUDSEN;

THE STATE OF ARIZONA, By and through its Attorney General, MARK BRNOVICH;

THE STATE OF ALABAMA, By and through its Attorney General, STEVE MARSHALL;

THE STATE OF GEORGIA, By and through its Attorney General, CHRISTOPHER CARR;

THE STATE OF IDAHO, By and through its Attorney General, LAWRENCE G. WASDEN;

THE STATE OF INDIANA, By and through its Attorney General, THEODORE M. ROKITA;

THE STATE OF MISSISSIPPI, By and through its Attorney General, LYNN FITCH;

THE STATE OF OKLAHOMA, By and through its Attorney General, JOHN M. O'CONNOR;

THE STATE OF SOUTH CAROLINA, By and through its Attorney General, ALAN WILSON;

THE STATE OF UTAH, By and through its Attorney General, SEAN D. REYES;

THE STATE OF WEST VIRGINIA, By and through its Attorney General, PATRICK MORRISEY;

CIVIL ACTION NO. ________________

PLAINTIFFS,

v.

XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services;

THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES;

CHIQUITA BROOKS-LASURE, in her official capacity of Administrator of the Centers for Medicare & Medicaid Services;

CENTERS FOR MEDICARE & MEDICAID SERVICES;

DEFENDANTS.

COMPLAINT

The States of Louisiana, Montana, Arizona, Alabama, Georgia, Idaho, Indiana, Mississippi, Oklahoma, South Carolina, Utah, and West Virginia bring this civil action against the above-listed Defendants for declaratory and injunctive relief and allege as follows:

INTRODUCTION

1. The Biden Administration is playing statutory shell games with the courts, straining to justify an unjustifiable and unprecedented attempt to federalize public health policy and diminish the sovereign States' constitutional powers. The Administration has announced three COVID-19 vaccine mandates to—as the President himself has confirmed—increase societal vaccination rates. There's just one problem: no statute authorizes the federal Executive to mandate vaccines to increase societal immunity. The Administration's solution? Use statutory schemes never before interpreted to allow federal vaccine mandates to shoehorn the President's goals into the fabric of American society. In one instance, the Administration grabbed an obscure workplace safety statute to impose a vaccine mandate on 100 million Americans. That mandate suffers from so many patent constitutional and statutory

problems that the Fifth Circuit stayed it a day after it issued and reaffirmed its stay within a week. *BST Holdings, L.L.C. v. OSHA*, No. 21-60845 (Nov. 12, 2021). Second, the Administration tried to use the federal procurement system to impose a vaccine mandate on another fifth of the American workforce. That mandate, too, is already subject to multiple challenges. The third mandate is the one at issue here: the Administration has coopted the Medicare and Medicaid system to impose a vaccine on 17 million healthcare workers.

2. But the Social Security Act focuses on *patient* welfare and *patient* access to care. By forcing a significant number of healthcare workers to take the shot(s) or exit the Medicare and Medicaid workforce, CMS's Vaccine Mandate harms access to (and thus quality of) patient care. This "one-size-fits-all sledgehammer" expressly undermines the Social Security Act's singular focus on providing access to care. *BST Holdings,* No. 21-60845, slip op. at 6 (5th Cir. Nov. 12, 2021). By forcing employees to choose "between their job(s) and their jab(s)," *id.* at 19, the Mandate completely ignores the unprecedented labor shortage prevailing in the healthcare sector and patient wellbeing in favor of the President's ambition to increase societal vaccination rates.

3. Aside from being fundamentally at odds with the Social Security Act, the Vaccine Mandate suffers from a host of fatal flaws. It exceeds CMS's statutory authority; violates the Social Security Act's prohibition on regulations that control the selection and tenure of healthcare workers; is arbitrary and capricious; and violates the Spending Clause, the Anti-Commandeering doctrine, and the Tenth Amendment. Furthermore, CMS flouted the basic procedural requirements that Congress imposed on it, including the Administrative Procedure Act's notice-and-comment requirement, the Congressional Review Act's publication-and-review requirements, and the Social Security Act's consultation and regulatory-impact-analysis requirements. The Vaccine Mandate causes grave danger to the vulnerable persons whom Medicare and Medicaid were designed to protect—the poor, children, sick, and the elderly—by forcing the termination of millions of essential "healthcare heroes."

PARTIES

4. Plaintiff State of Louisiana is a sovereign State of the United States of America. Plaintiff Jeff Landry is the Attorney General of the State of Louisiana. He is authorized by Louisiana law to sue on the State's behalf. His offices are located at 1885 North Third Street, Baton Rouge, Louisiana 70802, and the Northeast Louisiana State Office Building, 24 Accent Drive, Suite 117, Monroe, Louisiana, 71202.

5. Plaintiff State of Montana is a sovereign State of the United States of America. Plaintiff Austin Knudsen is the Attorney General of the State of Montana. He is authorized by Montana law to sue on the State's behalf. His offices are located at 215 North Sanders Street, Helena, Montana 59601.

6. Plaintiff State of Arizona is a sovereign State of the United States of America. Plaintiff Mark Brnovich is the Attorney General of the State of Arizona. He is authorized by Arizona law to sue on the State's behalf. His offices are located at 2005 North Central Avenue, Phoenix, Arizona 85004.

7. Plaintiff State of Alabama is a sovereign State of the United States of America. Plaintiff Steve Marshall is the Attorney General of the State of Alabama. He is authorized by Alabama law to sue on the State's behalf. His offices are located at 501 Washington Avenue Montgomery, AL 36104.

8. Plaintiff State of Georgia is a sovereign State of the United States of America. Plaintiff Christopher Carr is the Attorney General of the State of Georgia. He is authorized by Georgia law to sue on the State's behalf. His offices are located at 40 Capitol Square, SW, Atlanta, GA 30334.

9. Plaintiff State of Idaho is a sovereign State of the United States of America. Plaintiff Lawrence G. Wasden is the Attorney General of the State of Idaho. He is authorized by Idaho law to sue on the State's behalf. His offices are located at 700 W. Jefferson Street, Boise, Idaho 83720.

10. Plaintiff State of Indiana is a sovereign State of the United States of America. Plaintiff Theodore M. Rokita is the Attorney General of the State of Indiana. He is authorized by Indiana law to sue on the State's behalf. His offices are located at 302 West Washington Street, 5th Floor, Indianapolis, IN 46204.

11. Plaintiff State of Mississippi is a sovereign State of the United States of America. Plaintiff Lynn Fitch is the Attorney General of the State of Mississippi. She is authorized by Mississippi law to sue on the State's behalf. Her offices are located at 550 High Street, Jackson, Mississippi 39201.

12. Plaintiff State of Oklahoma is a sovereign State of the United States of America. Plaintiff John M. O'Connor is the Attorney General of the State of Oklahoma. He is authorized by Oklahoma law to sue on the State's behalf. His offices are located at 313 NE 21st Street, Oklahoma City, OK 73105.

13. Plaintiff State of South Carolina is a sovereign State of the United States of America. Plaintiff Alan Wilson is the Attorney General of the State of South Carolina. He is authorized by South Carolina law to sue on the State's behalf. His offices can be reached at P.O. Box 11549, Columbia, South Carolina 29211.

14. Plaintiff State of Utah is a sovereign State of the United States of America. Plaintiff Sean D. Reyes is the Attorney General of the State of Utah. He is authorized by Utah law to sue on the State's behalf. His offices are located at 350 North State Street, Suite 230, Salt Lake City, Utah 84114.

15. Plaintiff West Virginia is a sovereign State of the United States of America. Plaintiff Morrisey is the Attorney General of the State of West Virginia. He is authorized by West Virginia law to sue on the State's behalf. His offices are located at the State Capitol Complex, Bldg. 1, Room E-26 Charleston, WV 25305.

16. Defendants are officials of the United States government and United States governmental agencies responsible for promulgating or implementing the Vaccine Mandate.

17. Defendant Xavier Becerra is the Secretary of Health and Human Services. He oversees, among other things, CMS and the Medicare program. He is sued in his official capacity.

18. Defendant United States Department of Health and Human Services is an executive department of the United States Government headquartered in Washington, D.C., and responsible for CMS and the Medicare program.

19. Defendant Chiquita Brooks-LaSure is the CMS Administrator. She administers the Medicare program on behalf of the Secretary. She is sued in her official capacity.

20. Defendant Center for Medicare & Medicaid Services is an administrative agency within HHS that is headquartered in Baltimore County, MD, and administers the Medicare program and the federal role in the Medicaid program administered by State Medicaid agencies.

JURISDICTION AND VENUE

21. This Court has subject-matter jurisdiction over this case because it arises under the Constitution and laws of the United States. *See* 28 U.S.C. §§1331, 1346, 1361; 5 U.S.C. §§701-06. An actual controversy exists between the parties within the meaning of 28 U.S.C. §§2201(a), and this Court may grant declaratory relief, injunctive relief, and other relief under 28 U.S.C. §§2201-02, 5 U.S.C. §§705-06, and its inherent equitable powers.

22. Defendants' publication of the Rule in the Federal Register on November 5, 2021 constitutes a final agency action that is judicially reviewable under the APA. 5 U.S.C. §§704, 706.

23. Venue is proper in this Court under 28 U.S.C. §1391(e)(1) because (1) Defendants are United States agencies or officers sued in their official capacities, (2) the State of Louisiana is a resident of this judicial district, (3) no real property is involved, and (4) a substantial part of the events or omissions giving rise to the Complaint occur within this judicial district. *See Atlanta & F.R. Co. v. W.*

Ry. Co. of Ala., 50 F. 790, 791 (5th Cir. 1982); *Ass'n of Cmty. Cancer Centers v. Azar*, 509 F. Supp. 3d 482 (D. Md. 2020).

BACKGROUND

I. The Medicare and Medicaid Framework Established by Congress.

24. Since 1965, the federal government and the States have worked together to provide medical assistance to certain vulnerable populations under Titles XVIII and XIX of the Social Security Act, commonly known as Medicare and Medicaid. *See* 42 U.S.C. §§1395 et seq.; 1396 et seq.; *see also Alexander v. Choate*, 469 U.S. 287, 289 n.1 (1985) (noting that Congress designed Medicaid to "subsidize[ ]" States in "funding ... medical services for the needy").

25. Medicaid is a cooperative state-federal program, implemented by the States, that helps States finance the medical expenses of their poor and disabled citizens.

26. The Social Security Act charges the Secretary of Health and Human Services with a wide range of administrative responsibilities relating to maintaining the programs under his purview, including Medicare and Medicaid. *See* 42 U.S.C. §301 et seq.

27. It also delegates to the Secretary certain limited rulemaking authority, including—as most relevant here—the authority to "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." 42 U.S.C. §1302(a).

28. The Centers for Medicare & Medicaid Services, a federal agency within the Department of Health and Human Services, has primary responsibility for overseeing the Medicare and Medicaid programs.

II. The Biden Administration's Vaccine Policy.

29. As President-Elect, Mr. Biden promised he "d[i]dn't think [vaccines] should be mandatory" and "wouldn't demand it be mandatory." Jacob Jarvis, *Fact Check: Did Joe Biden Reject Idea of*

Mandatory Vaccines in December 2020, Newsweek (Sept. 10, 2021), https://bit.ly/3ndyTn5. Toeing that line, as recently as this summer the Biden Administration disclaimed authority to require Americans to get a COVID-19 vaccine. *See, e.g.*, Press Briefing by Press Secretary Jen Psaki, July 23, 2021, https://bit.ly/3pWnJVr (mandating vaccines "not the role of the federal government"). But as time passed, the President admitted that his "patience" began "wearing thin" with those "who haven't gotten vaccinated." White House, Remarks by President Biden on Fighting the COVID-19 Pandemic (Sept. 9, 2021), https://bit.ly/3Ey4Zj6.

30. So in early September 2021, the Administration abandoned persuasion for brute force. It announced an unprecedented series of *federal* mandates aimed at compelling most of the adult population of the United States to get a COVID-19 vaccine. The White House, Remarks by President Biden on Fighting the COVID-19 Pandemic (Sept. 9, 2021), https://bit.ly/3oI0pKr. His program sought to "increase vaccinations among the unvaccinated with new vaccination requirements." *Id.*; *see also* The White House, Path Out of the Pandemic: President Biden's Covid-19 Action Plan, https://bit.ly/3adkMXx; The White House, Vaccination Requirements Are Helping Vaccinate More People, Protect Americans from COVID-19, and Strengthen the Economy (Oct. 7, 2021), https://bit.ly/3lorbp0.

31. In part, those vaccine requirements include the actions challenged here. President Biden announced he would impose—though unilateral executive action—a vaccine mandate on "a total of 17 million healthcare workers." Biden Sept. 9, 2021 Remarks, *supra*. As he explained, he'd already announced his intent to "requir[e] vaccinations that [sic] all nursing home workers who treat patients on Medicare and Medicaid," contending he "ha[s] that federal authority." *Id.* Now, invoking "that same" purported "authority," he "expand[ed] that" edict "to cover those who work in hospitals, home healthcare facilities, or other medical facilities." *Id.*

32. President Biden also expressed disrespect for state governments: "Let me be blunt. My plan also takes on elected officials and states that are undermining . . . these lifesaving actions." *Id.* Speaking 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.*

III. The Vaccine Mandate.

33. On November 5, 2021, CMS published an interim final rule requiring vaccination of staff of certain Medicare and Medicaid providers and suppliers. Medicare and Medicaid Programs; Omnibus COVID-19 Heath Care Staff Vaccinations, 86 Fed. Reg. 61555 (Nov. 5, 2021).

34. The rule governs 21 types of Medicare- and Medicaid-certified providers and suppliers that are subject to Medicare or Medicaid conditions of participation, conditions for coverage, or requirements for participation. *See id.* at 61556.

35. Specifically, the rule governs the following types of facilities: Ambulatory Surgical Centers; Hospices; Psychiatric residential treatment facilities; Programs of All-Inclusive Care for the Elderly; Hospitals; Long-Term Care Facilities, including Skilled Nursing Facilities and Nursing Facilities; Intermediate Care Facilities for Individuals with Intellectual Disabilities; Home Health Agencies; Comprehensive Outpatient Rehabilitation Facilities; Critical Access Hospitals; Clinics; rehabilitation agencies; public health agencies as providers of outpatient physical therapy and speech-language pathology services; Community Mental Health Centers; Home Infusion Therapy suppliers; Rural Health Clinics; Federally Qualified Health Centers; and End-Stage Renal Disease Facilities. *See id.*

36. The rule applies the same substantive standards to each of the 21 types of governed entities. *See id.* at 61570, 61616-61627. As CMS put it, "we are issuing a common set of provisions for each applicable provider and supplier." *Id.* at 61570. There are "no substantive regulatory differences across settings." *Id.*

37. The regulations themselves require that every entity "develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID–19." *See, e.g.*, 42 C.F.R. §416.51(c).

38. The policy must apply to every person "who provide[s] any care, treatment, or other services for the [entity] and/or its patients"—including employees, contractors, trainees, students, and volunteers—regardless of whether they have any patient-care responsibilities or even any contact with patients. *Id.* §416.51(c)(1).

39. To be exempt, a healthcare worker must "exclusively provide" telehealth or support services "outside of the [entity's] setting" and "not have any direct contact with patients and other staff." *Id.* §416.51(c)(2).

40. The entity must ensure that, by December 6, 2021, all such healthcare workers submit to at least one vaccine dose before they can provide "any care, treatment, or other services for the [entity] and/or its patients." *Id.* §416.51(c)(3)(i); 86 Fed. Reg. at 61555.

41. The entity must then ensure that, by January 4, 2022, all such healthcare workers "are fully vaccinated." 42 C.F.R. §416.51(c)(3)(ii); 86 Fed. Reg. at 61555.

42. The entity may provide an exemption for those granted temporary delays based on the CDC's recommendations or for those who are eligible for exemptions under certain federal statutes. 42 C.F.R. §416.51(c)(3). But the entity must "track[] and securely document[] information provided by those staff who have requested, and for whom the [entity] has granted, an exemption" or a temporary delay. *Id.* §416.51(c)(3)(vi)-(vii). And it must ensure that all documentation "support[ing] staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner" with specific information about which vaccines are clinically contraindicated and a statement of reasons for each. *Id.* §416.51(c)(3)(viii).

43. The entity must implement a "process for tracking and securely documenting the COVID–19 vaccination status of all staff," including booster-shot status. *Id.* §416.51(c)(3)(iv)-(v).

44. Finally, the entity must implement "[c]ontingency plans" for all persons who are "not fully vaccinated." *Id.* §416.51(c)(3)(x).

45. The only way for an entity to avoid those regulations is to forfeit its federal funding. Medicaid providers receive this funding for services via a provider contract with States. Likewise, an entity that fails to comply fully with the regulations may face penalties up to and including "termination of the Medicare/Medicaid provider agreement." 86 Fed. Reg. at 61574. The termination of those provider agreements is a death knell for healthcare providers and for access to care for millions of people.

46. This is the first—and only—mandatory vaccination program in the history of the Medicare or Medicaid programs. *See id.* at 61567 ("We have not previously required any vaccinations"); *id.* at 61568 ("We acknowledge that we have not previously imposed such requirements").

IV. CMS's Claimed Statutory Authority.

47. CMS purports to derive the authority for this unprecedented edict primarily from two statutes that grant it rulemaking authority. *See id.* at 61567. In truth, the authority those statutes provide stops well short of what would be required to authorize this sweeping mandate.

48. The first relied-upon statute delegates to the Secretary of HHS the authority to "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." 42 U.S.C. §1302(a).

49. The second delegates to the Secretary the authority to "prescribe such regulations as may be necessary to carry out the administration of the insurance programs under" the Medicare program. 42 U.S.C. §1395hh(a)(1).

50. Nothing in either statute establishes that the Secretary may mandate vaccines. Nor do the statutes to which they refer—governing the "efficient administration of the [Secretary's] functions" under the Act and "the administration of the insurance programs" under the Medicare program—supply a basis for mandating vaccines.

51. CMS also invokes a number of additional statutes as purported authority for applying the Vaccine Mandate to certain types of entities. 86 Fed. Reg. at 61567. For the sake of comprehensiveness—and with apologies to the reader—Plaintiff States catalogue those claimed authorities here.

52. First, for Psychiatric Residential Treatment Facilities, CMS invokes 42 U.S.C. §1396d(h)(1)(B)(i), which defines the term "inpatient psychiatric hospital services for individuals under age 21" to "include[] only . . . inpatient services which . . . involve active treatment which meets 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" inpatient psychiatric "treatment" of individuals under age 21. But a mandatory vaccine requirement for the *staff* at those facilities is not a "standard" for "active treatment" of the facilities' patients.

53. Second, CMS invokes 42 U.S.C. §1396d(d)(1) as authority for including Intermediate Care Facilities for Individuals with Intellectual Disabilities in the vaccine mandate. That statute 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 implies that the Secretary may create standards for the kinds of "health or rehabilitative services" the facility provides. But a mandatory vaccine requirement for the *staff* at those facilities is not a "health or rehabilitative service[]" for intellectually disabled individuals.

54. Third, CMS claims power under 42 U.S.C. §1395i–4(e) to subject Critical Access Hospitals to the vaccine mandate. That statute 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 Medicare 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 it does not establish that the Secretary may impose mandatory vaccines on the staff at such hospitals.

55. Fourth, End-Stage Renal Disease facilities. According to CMS, 42 U.S.C. §1395rr(b)(1)(A) subjects them to the Vaccine Mandate. That statute 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." The Secretary may create "requirements" for "institutional dialysis services," "transplantation services," and the like. But a mandatory vaccine requirement for the *staff* at those facilities is not a requirement "for" institutional dialysis services or supplies, transplantation services, or other services listed in the statute.

56. Fifth, as for Ambulatory Surgical Centers, CMS relies principally on 42 U.S.C. §1395k(a)(2)(F)(i), which provides that Medicare 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," it does not establish that the Secretary's regulatory power is so broad that he may mandate vaccines for employees of the ASCs.

57. Sixth, CMS invokes two statutes to justify subjecting Programs of All-Inclusive Care for the Elderly facilities in the vaccine mandate. The first—42 U.S.C. §1395eee(f) (Medicare)—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) (Medicaid)—is materially indistinguishable in its relevant language. Though these statutes authorize the Secretary to adopt some health- and safety-related regulations, they do not establish that the Secretary's regulatory power is so broad that he may mandate vaccines for employees.

58. As for Rural Health Clinics, CMS relies principally on 42 U.S.C. §1395x(aa)(2)(K), which 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 *staff* vaccination. This statute thus does not give the Secretary the power to mandate vaccines.

59. For Home Infusion Therapy Suppliers, CMS turns to 42 U.S.C. §1395x(iii)(3)(D)(i)(IV), which 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." The expressly listed qualifying factors include the types of services provided and staff qualifications. They do not include vaccination. This statute thus does not give the Secretary the power to mandate vaccines.

60. According to CMS, 42 U.S.C. §1395x(p)(4)(A)(v) makes facilities that provide outpatient physical therapy and speech-language pathology services subject to the vaccine mandate. 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." The expressly listed qualifying factors include the types of services provided, staff qualifications, and administrative matters. They do not include vaccination. This statute thus does not give the Secretary the power to mandate vaccines.

61. Community Mental Health Centers, in turn, are purportedly subject to the vaccine mandate under 42 U.S.C. §1395x(ff)(3)(B). That statute 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." The expressly listed qualifying factors include the types of services provided, staff qualifications, and administrative matters. They do not include vaccination. This statute thus does not give the Secretary the power to mandate vaccines.

62. Eleventh, CMS claims authority under 42 U.S.C. §1395x(e)(9) to include hospitals in the vaccine mandate. 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." The expressly listed qualifying factors include the types of services provided, staff qualifications, and administrative matters. They do not include vaccination. This statute thus does not give the Secretary the power to mandate vaccines.

63. CMS includes hospices in the vaccine mandate based on 42 U.S.C. §1395x(dd)(2)(G). That statute 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." The expressly listed qualifying factors

include the types of services provided, staff qualifications, and administrative matters. They do not include vaccination. This statute thus does not give the Secretary the power to mandate vaccines.

64. As for Comprehensive Outpatient Rehabilitation Facilities, CMS invokes 42 U.S.C. §1395x(cc)(2)(J), which 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." The expressly listed qualifying factors include the types of services provided, staff qualifications, and administrative matters. They do not include vaccination. This statute thus does not give the Secretary the power to mandate vaccines.

65. CMS next invokes two additional statutes as authority for including long-term-care facilities in the vaccine mandate. The first—42 U.S.C. §1395i–3(d)(4)(B) (Medicare)—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) (Medicaid)—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." The expressly listed qualifying factors include the types of services provided, staff qualifications, licensing requirements, sanitation issues, and administrative matters. They do not include vaccination. These statutes thus do not give the Secretary the power to mandate vaccines.

66. Finally, Home Health Agencies. Here CMS invokes a few additional statutes. 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." The second—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 give the Secretary the power to mandate vaccines for employees of home health agencies.

V. The Targeted Healthcare Workers.

67. According to CMS, the Vaccine Mandate regulates over 10 million healthcare workers and suppliers in the United States. *Id.* at 61603. Of those, CMS estimates roughly 2.4 million are currently unvaccinated. *Id.* at 61607. Those healthcare workers are the Vaccine Mandate's targets.

68. CMS's objective is to coerce the unvaccinated workforce into submission or cause them to lose their livelihoods. *See id.* at 61607 ("The most important inducement will be the fear of job loss, coupled with the examples set by fellow vaccine-hesitant workers who are accepting vaccination more or less simultaneously"); *id.* at 61608 ("it is possible there 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").

69. Though medical and religious exemptions may be granted in narrow circumstances, the goal of the program is to vaccinate "nearly all health care workers." *Id.* at 61569. This can be done

only by changing millions of minds or losing millions of healthcare workers. After all, healthcare workers can begin working for providers not subject to it, or for entities potentially subject to the now-stayed OSHA Emergency Technical Standard, which at least provides a masking-and-testing alternative. Those alternatives all but ensure that healthcare workers unwilling to receive a vaccine will leave the covered systems subject to it, decimating those covered facilities' ability to provide critical healthcare services and possibly forcing their exit from the Medicaid and Medicare programs or forcing their closure altogether.

VI. The Implications for Vulnerable Americans Seeking Care.

70. Because workers in the healthcare industry have already faced prolonged pressure to undergo vaccination and many others have not submitted to employer-imposed mandates, it stands to reason that many of the 2.4 million unvaccinated healthcare workers will not submit to federally coerced vaccination. If the Vaccine Mandate is not enjoined, these healthcare workers will lose their jobs; States will lose providers, suppliers, and services; and ultimately America's most vulnerable populations will lose access to necessary medical care.

71. CMS acknowledges that there are currently "endemic staff shortages for all categories of employees at almost all kinds of health care providers and suppliers." *Id.* at 61607. And of course, it acknowledges that "these may be made worse" when unvaccinated workers leave as a result of the rule. *Id.*

72. A few statistics illustrate the extent of the problem. Already 39% of nursing homes in Montana face staff shortages. *See AARP Nursing Home COVID-19 Dashboard*, AARP Public Policy Institute (Nov. 10, 2021), https://www.aarp.org/ppi/issues/caregiving/info-2020/nursing-home-covid-dashboard.html. That number exceeds 45% in Georgia, Idaho, and Utah, and ranges from 11% to 43% in the remaining Plaintiff States. Indeed, a recent study by the AARP shows that nearly one-third of the nation's 15,000 nursing homes recently reported a shortage of nurses or aides. *See* Emily

Paulin, *Worker Shortages in Nursing Homes Hit Pandemic Peak as Covid Deaths Continue*, https://bit.ly/3Dr8wji. According to the AARP, the numbers represent the worst staffing shortages since the government began collecting data from nursing homes in May 2020. Low staffing levels in nursing homes, particularly among registered nurses, are associated with worse outcome for residents, including more COVID-19 cases, deaths, and a higher likelihood of an outbreak. *Id.*

73. Meanwhile, somewhere between 22% and 42% of healthcare workers in those states are not fully vaccinated, despite having faced considerable pressure to get vaccinated. *Id.*

74. CMS admits that it does not know how many unvaccinated workers will submit. *Id.* at 61607, 61612.

75. It brushes aside the specter of chronic healthcare shortages with bureaucratic jargon:

> While it 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, there is no reason to think that this will be a net minus even in the short term, given the magnitude of normal turnover and the relatively small fraction of that turnover that will be due to vaccination mandates.

Id. at 61609. But CMS's self-assurance is not based on evidence or reality. It cites no evidence that—in the current climate of long-running, wide-ranging, and persistent healthcare staffing shortages—new recruitment will magically replenish staffing shortages caused by those who will leave their jobs rather than submit to federally coerced vaccination. CMS's "small fraction" appears supported by little more than wishful thinking. The Agency's glass-half-full (and fact-free) optimism offers only cold comfort to those healthcare heroes who have worked tirelessly from the outset of the pandemic and who now face joblessness as the cost for pushing back against federal overreach—and to the patients who will no longer receive healthcare because of it.

VII. Devastation to the Plaintiff States.

76. The Plaintiff States have all entered into agreements with the federal government to participate in Medicaid.

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

78. The Plaintiff States and the facilities within them rely heavily on funds provided through the Medicaid and Medicare programs.

79. The Plaintiff States also operate state-run healthcare facilities that receive Medicare and Medicaid funding. They are thus required to impose the mandate on their own state employees.

80. Many of those facilities are small rural hospitals.

81. In state fiscal year 2021, Louisiana's $43 billion budget was composed of $16 billion in funding related to the State Medicaid program, with $1.8 billion coming from the State's general fund. Louisiana added 300,000 more people to its Medicaid rolls since March 2020 when the COVID-19 outbreak began. As of May 2021, about 1.9 million of 4.5 million residents in Louisiana were enrolled in Medicaid, amounting to about 40% of the States' population. Thousands of facilities participate, including every hospital provider in the State. Louisiana, in part, implements its Medicaid program through Managed Care Contractors.

82. In state fiscal year 2021, Montana received $1.78 billion in Medicaid federal revenues. Of its total state budget, federal Medicaid revenues alone account for 25%.

83. Likewise, in state fiscal year 2022, West Virginia received $3.9 billion in Medicaid funding. Federal Medicaid dollars are expected to account for almost 18% of West Virginia's total projected revenue for fiscal year 2022. Roughly a third of West Virginians are on Medicaid.

84. Plaintiff State South Carolina retains 51.5 staff positions performing duties related to surveying and certification for 6,385 Medicare facilities. South Carolina's state survey agency for Medicaid, the Department of Health and Environmental Control, follows the procedures set forth in the CMS State Operations Manual for certifying and surveying facilities and investigating complaints.

85. Montana operates six state-run healthcare facilities that receive both Medicare and Medicaid funding and are subject to the Vaccine Mandate. These include the Montana State Hospital, the Montana Mental Health Nursing Care Center, the Montana Chemical Dependency Center, the Montana Veteran's Home, the Eastern Montana Veteran's Home, and the Southwestern Montana Veteran's Home.

86. Similarly, West Virginia operates seven state-run healthcare facilities that receive Medicare and Medicaid funding, including Hopemont Hospital, Jackie Withrow Hospital, John Manchin Sr. Health Care Center, Lakin Hospital, Mildred Mitchell-Bateman Hospital, Welch Community Hospital, and William R. Sharpe Jr. Hospital. Many of these facilities serve rural communities that otherwise lack access to necessary medical care.

87. The Plaintiff States employ state surveyors who regularly evaluate healthcare facilities' compliance with Medicare and Medicaid requirements. When the state surveyors conduct inspections, they assess compliance with both federal and state regulations at the same time.

88. Unless state surveyors confirm a healthcare facilities' compliance with Medicare and Medicaid requirements, those facilities are not entitled to obtain Medicare or Medicaid reimbursements.

89. When state surveyors find that a healthcare facility is not in compliance with federal Medicare or Medicaid regulations, they send the facility a violation report—known as a 2567 Form—informing it of the deficiencies.

90. The Vaccine Mandate seeks to commandeer the state-employee surveyors and certification staff to become enforcers of CMS's unlawful attempt to federalize national vaccine policy and override the States' police power on matters of health and safety.

91. By requiring state-run healthcare facilities and state surveyors to enforce the Vaccine Mandate, the Plaintiff States will face increased enforcement costs.

92. By requiring state-run healthcare facilities and state surveyors to enforce the Vaccine Mandate, that mandate directly infringes the Plaintiff States' sovereign authority.

93. The Plaintiff States are injured because the Vaccine Mandate purports to preempt their state and local laws on matters of vaccines and the rights of their citizens. This violates the Plaintiff States' sovereign right to enact and enforce their laws. It also violates the Plaintiff States' sovereign right to exercise their police power on matters such as compulsory vaccination.

94. For example, the Vaccine Mandate purports to preempt Montana's H.B. 702, which prohibits discrimination based on vaccination status; Indiana's H.B. 1405, which prohibits government entities from requiring anyone—including employees—to show proof of vaccination; Utah's H.B. 308, which prohibits state agencies from conditioning employment on vaccination; and West Virginia's H.B. 335, which provides for broader medical and religious exemptions to vaccination requirements. It similarly purports to preempt Alabama law, which prohibits any state government entity from soliciting its employees' vaccination status, *see* Ala. Act. 2021-493 §1(a), and Louisiana law, which permits students at all levels to opt-out of vaccine requirements, *see* La. R.S. 17:180(E), without being barred from admission (or exclusion after admission).

95. The Plaintiff States will suffer other pocketbook injuries. The Vaccine Mandate requires covered healthcare facilities to maintain documentation of their staff's vaccination status. 86 Fed. Reg. at 61572. That documentation can consist of records from the "State immunization information system." *Id.* A predictable consequence of the Vaccine Mandate is thus to increase the number of people seeking documentation from the Plaintiff States regarding vaccination status. *See Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2566 (2019).

96. The Plaintiff States have quasi-sovereign and *parens patriae* interests in protecting the rights of their citizens and vindicating them in court. The Plaintiff States thus may sue to challenge unlawful actions that "affect the [States'] public at large." *In re Debs*, 158 U.S. 561, 584 (1895). As a

result of the Vaccine Mandate, significant numbers of their citizens who are healthcare employees will be forced to submit to bodily invasion or lose their jobs and their livelihoods. All of their citizens will suffer as a result of the predictable and conceded exacerbation of labor shortages in hospitals and other healthcare facilities.

VIII. The Careless Enactment of the Vaccine Mandate.

97. 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 this one takes effect. 86 Fed. Reg. at 61583.

98. But CMS "believe[d] it would be impracticable and contrary to the public interest . . . to undertake normal notice and comment procedures." *Id.* at 61586. For those reasons, it thus found "good cause to waive" those procedures. *Id.*

99. 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 61583.

100. 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 61615.

101. 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 61583. Yet CMS still sought to immediately impose the 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 61584.

102. CMS also asserted that it must immediately implement the vaccine mandate because "the 2021–2022 influenza season" will soon begin. *Id.* at 61584. 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.* (Notably, the CMS did not mandate *flu* vaccines.)

103. In claiming that it must immediately implement the Vaccine Mandate, CMS ignored that it waited almost two months after President Biden's directive before it promulgated the IFC to the public—and waited much longer than that for the vaccine mandate for nursing homes.

104. CMS also recognized that the Vaccine Mandate is a "major rule" for purposes of the Congressional Review Act, and that the CRA Act requires all rules to be submitted to Congress to allow it an opportunity to pass a resolution disapproving the rule. A "major rule" must also receive a report from the Government Accountability Office and its effective date must be delayed. 5 U.S.C. §801.

105. Yet CMS did not even purport to comply with those procedural requirements. Nor did it demonstrate how the IFC satisfies the exacting standards required for an exception from them.

106. CMS also recognized that the Vaccine Mandate was subject to 42 U.S.C. §1395z, which requires that "the Secretary shall consult with appropriate State agencies and recognized national listing or accrediting bodies, and may consult with appropriate local agencies" 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 this title, or by ambulatory surgical centers under section 1395k(a)(2)(F)(i) of this title."

107. CMS conceded that it did not comply with §1395z's consultation requirement. Fed. Reg. at 61567.

108. CMS instead "intend[s] to engage in consultations with appropriate State agencies ... following the issuance of th[e] rule," 86 Fed. Reg. at 61567—action that on its face does not satisfy 42 U.S.C. §1395z.

109. CMS also failed to comply with 42 U.S.C. §1302(b)(1), which requires that "[w]henever the Secretary [of HHS] 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, the Secretary shall prepare and make available for public comment an initial regulatory impact analysis."

110. The Vaccine Mandate threatens to exacerbate already devastating shortages in healthcare staffing by forcing small rural hospitals to terminate their unvaccinated workers. healthcare workers at rural hospitals can quit working at rural hospitals subject to the Vaccine Mandate and begin working at places not subject to it, or at jobs potentially subject to the now-stayed OSHA Emergency Technical Standard, which at least provides a masking-and-testing alternative to mandatory vaccination. If unvaccinated workers quit or are fired, that will compel those hospitals to close certain divisions, cancel certain services, or shutter altogether. Those dire consequences stretch across rural America, and their collective force required CMS to prepare a regulatory impact analysis.

IX. Irreparable Harm to Individual Recipients and Providers.

111. If the Vaccine Mandate goes into effect, it will irreparably harm patients and providers by impeding access to care for the elderly and for persons who cannot afford it—a complete reversal of the core objectives of Medicare and Medicaid.

112. The direct relationship between the healthcare labor crisis and access to care is well known by CMS and all Medicaid providers. *See, e.g.*, Dep't for Professional Employees, *Safe Staffing: Critical for Patients and Nurses* (Apr. 2019), https://bit.ly/3Ddhdxw; Am. Hosp. Ass'n, *Fact Sheet: Strengthening the Health Care Workforce* (May 2021), https://bit.ly/3osJ4Ui; Charlene Harrington, et al., *Appropriate Nurse Staffing Levels for U.S. Nursing Homes*, Sage Journals (June 29, 2020), https://bit.ly/3C8tMsv.

113. In fact, CMS has developed criteria tying reimbursements to staffing. *See e.g.*, Centers for Medicare & Medicaid Services, *Design for* Care Compare *Nursing Home Five-Star Quality Rating System: Technical Users' Guide* at 1 (Oct. 2021), https://go.cms.gov/30nko7w.

114. CMS surely knows that the termination of millions of health care workers will have an immediate catastrophic impact on access to care for eligible Medicaid or Medicare recipients, more so in minority and already-underserved communities. Its failure to address this critical issue while log-rolling an interim rule is patently unlawful. CMS also openly acknowledges that the Vaccine Mandate targets "aides" who it believes account for more of the under-vaccinated, *see* 86 Fed. Reg. at 61560, but who are predominately women and minorities.

115. Beyond that, the Vaccine Mandate deprives patients and providers of their procedural right to notice and comment under the APA. The "depriv[ation] of the opportunity to offer comments" on a rule "may constitute irreparable injury while a rule promulgated in violation of [the APA] is in effect, provided that plaintiffs suffer some additional concrete harm as well." *E. Bay Sanctuary Covenant v. Trump*, 349 F. Supp. 3d 838, 865 (N.D. Cal. 2018), *aff'd as amended on denial of reh'g en banc*, 993 F.3d 640 (9th Cir. 2021). An affected party thus suffers irreparable harm where a rule improperly promulgated without notice and comment "will dramatically alter" a "complex and far-reaching regulatory regime" and the affected party has articulated "meaningful concerns." *Northern Mariana Islands v. United States*, 686 F. Supp. 2d 7, 17-18 (D.D.C. 2009).

CLAIMS FOR RELIEF

COUNT I

The Vaccine Mandate Is in Excess of CMS's Statutory Authority

116. Plaintiff States repeat and incorporate by reference each of the Complaint's allegations stated above.

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

118. The Vaccine Mandate is in excess of CMS's statutory authority because the Social Security Act does not clearly authorize CMS to impose a vaccine mandate.

119. CMS has never relied upon its Social Security Act authority to mandate healthcare worker vaccination. *See, e.g.*, 86 Fed. Reg. at 61567 ("We have not previously required any vaccinations"); *id.* at 61568 ("[W]e have not, until now, required any health care staff vaccinations"); *id.* ("We acknowledge that we have not previously imposed such requirements"). Although "there is a first time for everything ... sometimes 'the most telling indication of [a] severe constitutional problem ... is the lack of historical precedent.'" *NFIB*, 567 U.S. at 549.

120. The Vaccine Mandate raises major issues of vast political, social, and economic importance.

121. The Vaccine Mandate imposes hundreds of millions of dollars in cost on industry and has other major economic effects.

122. The Vaccine Mandate imposes obligations on States that exceed the limits of the federal government's authority under the Spending Clause and Commerce Clause.

123. CMS's interpretation of the Social Security Act to authorize it to impose the Vaccine Mandate raises grave constitutional questions under the Nondelegation Doctrine about the breadth of the Social Security Act's delegation of authority. If Defendants are right that the Social Security Act grants authority to mandate vaccination, both "the degree of agency discretion" and "the scope of the power congressionally conferred" must be limitless. *Id.* at 475. Yet Congress lacks authority to delegate "unfettered power" over the American economy to an executive agency. *Tiger Lily, LLC v. HHS*, 5 F.4th 666, 672 (6th Cir. 2021); *see also State v. Becerra*, 2021 WL 2514138, at *20, *37. Accordingly,

Congress's "delegation ... of authority to decide major policy questions"—such as whether all healthcare workers must be vaccinated—would violate the nondelegation doctrine. *Paul v. United States*, 140 S. Ct. 342 (2019) (statement of Justice Kavanaugh respecting the denial of certiorari); *see also Tiger Lily*, 5 F.4th at 672 ("[T]o put 'extra icing on a cake already frosted,' the government's interpretation of § 264(a) could raise a nondelegation problem."); *State v. Becerra*, 2021 WL 2514138, at *37.

124. Accordingly, CMS's Vaccine Mandate triggers three separate clear statement rules. First, "[a]bsent a clear statement of intention from Congress, there is a presumption against a statutory construction that would significantly affect the federal-state balance." *Boelens v. Redman Homes, Inc.*, 748 F.2d 1058, 1067 (5th Cir. 1984); *see United States v. Bass*, 404 U.S. 336, 349 (1971). Second, the Executive cannot unilaterally "push the limit of congressional authority." *Solid Waste Agency of N. Cook Cnty. v. U.S. Army Corps of Engr's*, 531 U.S. 159, 172-73 (2001). And third, Congress must clearly delegate power to the Executive to address issues of "deep economic and political significance." *King v. Burwell*, 576 U.S. 473, 486 (2015).

125. CMS cites no statutes clearly authorizing a vaccine mandate—nor any previous interpretation of those statutes during the past 55 years of the Medicare and Medicaid programs that would support this exercise of authority.

126. The Act's conferrals of general rulemaking authority do not contain a clear statement authorizing the Vaccine Mandate. The main authorities CMS relies upon, Section 1102 and Section 1871, are general authorizations to "make and publish such rules and regulations, not inconsistent with this chapter, as may be necessary to the efficient administration" of the Medicare program, 42 U.S.C. §1302(a), and to "prescribe such regulations as may be necessary to carry out the administration of the insurance programs," *id.* §1395hh(a)(1). These grants of general rulemaking authority are not sufficient to authorize an action as major as the Vaccine Mandate.

127. If the Act's general rulemaking provisions were interpreted to authorize the Vaccine Mandate, their constitutionality would be doubtful under the Nondelegation Doctrine, the Tenth Amendment, and the Spending Clause. Accordingly, the Act's general grants should be construed to avoid those grave constitutional issues.

128. For the reasons discussed in paragraphs 47-66, the specific statutes that CMS cites also do not provide the clear authority needed to impose the Vaccine Mandate.

129. Because the Vaccine Mandate is a federal action involving issues of major economic, social, and political significance, and is not authorized by a clear statement in the Social Security Act, it is beyond CMS's statutory authority. *See Ala. Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 141 S. Ct. 2485, 2489 (2021).

COUNT II

The Vaccine Mandate Violates 42 U.S.C. §1395

130. Plaintiff States repeat and incorporate by reference each of the Complaint's allegations stated above.

131. 42 U.S.C. §1395 provides that nothing in Title 18 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." That limit is hardly surprising "given the structure and limits of federalism, which allow the States great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006) (cleaned up); *see also id.* (noting that federal law "presume[s] and rel[ies] upon a functioning medical profession regulated under the States' police powers").

132. The Vaccine Mandate violates 42 U.S.C. §1395 by authorizing 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.

133. The Vaccine Mandate also violates §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 those institutions for unvaccinated workers.

COUNT III

The Vaccine Mandate Was Issued Without Notice and Comment in Violation of the APA & Social Security Act

134. Plaintiff States repeat and incorporate by reference each of the Complaint's allegations stated above.

135. The APA provides that courts must "hold unlawful and set aside agency action" that is "without observance of procedure required by law." 5 U.S.C. §706(2)(D).

136. The APA requires agencies to publish notice of all "proposed rule making" in the Federal Register, *id.* §553(b), and to "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments," *id.* §553(c). Likewise, the Social Security Act requires the HHS Secretary, before issuing the relevant types of regulations "in final form," to "provide for notice of the 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).

137. Such requirements "are not mere formalities" but rather "are basic to our system of administrative law." *NRDC v. Nat'l Highway Traffic Safety Admin.*, 894 F.3d 95, 115 (2d Cir. 2018).

"Section 553 was enacted to give the public an opportunity to participate in the rule-making process. It also enables the agency promulgating the rule to educate itself before establishing rules and procedures which have a substantial impact on those who are regulated." *U.S. Dep't of Labor v. Kast Metals Corp.*, 744 F.2d 1145, 1153 n.17 (5th Cir. 1984); *see also NRDC*, 894 F.3d at 115 (notice and comment serves "the public interest by providing a forum for the robust debate of competing and frequently complicated policy considerations having far-reaching implications and, in so doing, foster reasoned decisionmaking"); *Spring Corp. v. FCC*, 315 F.3d 369, 373 (D.C. Cir. 2003) (notice and comment "ensures fairness to affected parties[] and provides a well-developed record that enhances the quality of judicial review").

138. Congress has specifically emphasized the importance of a robust period of notice and comment for considering changes to the Medicare system. The Supreme Court has explained that "Medicare touches the lives of nearly all Americans … as the largest federal program after Social Security." *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808 (2019). Even "minor changes" to the way the program is administered "can impact millions of people and billions of dollars in ways that are not always easy for regulators to anticipate." *Id.* at 1816. "Recognizing this reality," *id.* at 1808, Congress doubled the standard 30-day comment period under the APA for any establishment of or change to a "substantive legal standard" affecting the payment for services under Medicare. 42 U.S.C. §1395hh(a)(2), (b)(1); *see also id.* §1395hh(e)(1)(B)(i) (providing for a 30-day delay in effective date).

139. The CMS Vaccination Mandate was issued as an interim final rule—without either notice or comment—with an effective date of November 5, 2021, the day of the Rule's publication in the Federal Register. 86 Fed. Reg. 61555 (Nov. 5, 2021). This bypass of the APA's keystone requirement was unnecessary and unlawful. At bottom, CMS rushed to enact the mandate not to stem the pandemic, but to deliver on the President's promotions before the crisis expired.

140. CMS does not dispute that the IFC is a final agency action and substantive legislative rule that ordinarily would be required to go through notice and comment. Instead, CMS's sole reason for not pursuing notice and comment is a brief reference to the APA's "good cause" exception, which allows agencies to dispense with notice-and-comment procedures only "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 U.S.C. §553(b)(B); *see id.* §553(d)(3); 42 U.S.C. §§1395hh(b)(2)(C) and (e)(1)(B)(ii). CMS claims that it faces such an emergency in this case "as a result of the COVID-19 public health emergency." 86 Fed. Reg. at 61555. CMS concludes that "[i]n light of [its] responsibility to protect the health and safety of individuals providing and receiving care and services from Medicare-and Medicaid-certified providers and suppliers," CMS is "compelled to require staff vaccinations for COVID-19 in these settings" without required notice and comment. *Id.* at 61560.

141. Contrary to CMS's claims, however, "it is well established that the 'good cause' exception to notice-and-comment should be read narrowly in order to avoid providing agencies with an 'escape clause' from the requirements Congress prescribed." *United States v. Johnson*, 632 F.3d 912, 928 (5th Cir. 2011); *see also Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 93 (D.C. Cir. 2012) (good-cause exception is not an "escape clause[]" to be "arbitrarily utilized at the agency's whim"). "[T]he good cause exception should not be used to circumvent the notice and comment requirements whenever an agency finds it inconvenient to follow them." *Johnson*, 632 F.3d at 929; *see also Ass'n of Cmty. Cancer Centers v. Azar*, 509 F. Supp. 3d 482, 498 (D. Md. 2020) ("[A]n agency may not dispense with notice and comment procedures merely because it wishes to implement what it sees as a beneficial regulation immediately. Agencies presumably always believe their regulations will benefit the public. If an urgent desire to promulgate beneficial regulations could always satisfy the requirements of the good cause exception, the exception would swallow the rule and render notice and comment a dead letter.").

142. Instead, the exception "is to be narrowly construed and only reluctantly countenanced." *United States v. Ross*, 848 F.3d 1129, 1132 (D.C. Cir. 2017) (quotation marks and citation omitted). "[C]ircumstances justifying reliance on this exception are 'indeed rare' and will be accepted only after the court has 'examine[d] closely proffered rationales justifying the elimination of public procedures.'" *Council of the S. Mountains, Inc. v. Donovan*, 653 F.2d 473, 580 (D.C. Cir. 1981) (citation omitted). Courts therefore generally restrict agencies' use of the "good cause" exception "to emergency situations," *Mack Trucks*, 682 F.3d at 93 (citation omitted), such as where a "delay would imminently threaten life or physical property" or risk "fiscal calamity," *Sorenson Commc'ns Inc. v. FCC*, 755 F.3d 702, 706-07 (D.C. Cir. 2014). And courts "must rely only on the 'basis articulated by the agency itself'" for invoking the exception "at the time of the rulemaking." *Johnson*, 632 F.3d at 929.

143. CMS's good-cause explanation comes nowhere close to meeting those exacting standards.

144. CMS gave two reasons for immediately implementing the vaccine mandate. First, it thought immediate implementation necessary "[d]ue to the urgent nature of the vaccination requirements established in this IFC." 86 Fed. Reg. at 61573. Second, "to provide protection to residents, patients, clients, and PACE program participants (as applicable)," CMS "believe[d] it is necessary to begin staff vaccinations as quickly as reasonably possible." *Id.* In suggesting those reasons, however, CMS ignored that it waited almost two months after President Biden's directive before it promulgated the IFC to the public. Beyond that, CMS's finding that the vaccine mandate is necessary was undermined by its delay in adopting it. Vaccines have had a Food & Drug Administration Emergency Use Authorization for almost a year, yet CMS did not impose this mandate until two months after the President instructed it to do so as part of his "six-point plan" to federalize public-health policy—and three months after CMS announced the plan to require nursing home employees to be vaccinated.

145. Here, there is no "emergency" sufficient to justify CMS dispensing with proper rule-making. *Florida v. Becerra*, 8:21-cv-839-SDM-AAS, 2021 WL 2514138, at *45 (M.D. Fla. June 18, 2021) (concluding that the COVID-19 pandemic was insufficient for "good cause"); *Regeneron Pharms. v. HHS*, 510 F. Supp. 3d 29, 48 (S.D.N.Y. 2020) (similar).

146. By all measures, the justifications and data cited by CMS are stale, misleading, and one-sided. As recently stated by the Los Angeles County Sheriff faced with a local mandatory vaccine order threatening his staff, "[t]his mandate is like putting up storm windows after the storm has passed." Joshua R. Miller, *Los Angeles County sheriff blasts vaccine mandate causing 'mass exodus,'* N.Y. Post (Oct. 29, 2021), https://bit.ly/3n5I9tm.

147. What's more, the pandemic is a feeble excuse for avoiding transparency and public input considering the year-long public debate over mandatory vaccines. *See Chamber of Commerce of the U.S. v. Dep't of Homeland Sec.,* No. 20-CV-07331, 2020 WL 7043877, at *8 (N.D. Cal. Dec. 1, 2020) (*Chamber of Commerce* Order) (rejecting the pandemic as justification for proceeding by interim rule and stating that "even if the problems [the Administration] purport[s] to solve with the Rule[] may have been exacerbated by the COVID-19 pandemic, [the Administration] do[es] not suggest they are new problems"); *see also Ass'n of Cmty. Cancer Centers v. Azar*, 509 F. Supp. 3d at 496 ("CMS here relies more on speculation than on evidence to establish that the COVID-19 pandemic has created an emergency in Medicare Part B drug pricing sufficient to justify dispensing with valuable notice and comment procedures"); *Regeneron Pharms., Inc. v. U.S. Dep't of Health & Human Servs.*, 510 F. Supp. 3d 29, 47 (S.D.N.Y. 2020) (rejecting claim that a "new surge in COVID-19 cases … may lead to additional hardship and require immediate action" justifying good cause for interim rule on drug pricing).

148. Finally, considering the magnitude of the impact on the healthcare system, the healthcare labor market, and areas of State authority, it was incumbent on CMS to consult with the States on both the wisdom and implementation of such a far-reaching endeavor. Its failure to do so

was not harmless error. *See Johnson*, 632 F.3d at 931 ("An overreaching harmless error doctrine would allow the agency to inappropriately 'avoid the necessity of publishing a notice of a proposed rule and perhaps, most important, [the agency] would not be obliged to set forth a statement of the basis and purpose of the rule, which needs to take account of the major comments—and often is a major focus of judicial review.'").

149. Under these circumstances, the failure of CMS to comply with the APA's notice and comment provisions is fatal to the CMS interim final rule. *Id.* at 928-29 ("Without good cause, we must enforce Congress's choice in favor of the traditional, deliberative rulemaking process.").

COUNT IV

The Vaccine Mandate Violates the Congressional Review Act

150. Plaintiff States repeat and incorporate by reference each of the Complaint's allegations stated above.

151. The Congressional Review Act requires all rules to be submitted to Congress to allow it an opportunity to pass a resolution disapproving the rule. A "major rule" must also receive a report from the Government Accountability Office and its effective date must be delayed. 5 U.S.C. §801.

152. CMS concedes that the Vaccine Mandate is a "major rule" for purposes of the CRA. 86 Fed. Reg. at 61602. Yet it relies on the CRA's "limited exception[]" for rules which "an agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rule issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. §808.

153. For the reasons discussed regarding the APA good-cause exception, CMS's dismissal of its CRA obligations comes nowhere close to meeting the exacting standards allowing a major rule to avoid the CRA's exacting procedures. *Sorenson Commc'ns Inc. v. FCC*, 755 F.3d 702, 706 (D.C. Cir.

2014) ("Deference to an agency's invocation of good cause—particularly when its reasoning is potentially capacious, as is the case here—would conflict with this court's deliberate and careful treatment of the exception in the past."); *see also* OMB, *Guidance on Compliance with the Congressional Review Act*, M-19-14 (Apr. 11, 2019) (noting APA good-cause standard applies in CRA context).

154. Accordingly, the IFC violates the Congressional Review Act.

COUNT V

The Vaccine Mandate Is Arbitrary and Capricious

155. Plaintiff States repeat and incorporate by reference all the Complaint's allegations stated above.

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

157. "[A]gency action is lawful only if it rests on a consideration of the relevant factors" and "important aspects of the problem." *Michigan v. EPA*, 576 U.S. 743, 750-52 (2015) (requiring "reasoned decisionmaking"). This means agencies must "examine all relevant factors and record evidence." *Am. Wild Horse Pres. Campaign v. Perdue*, 873 F.3d 914, 923 (D.C. Cir. 2017).

158. For starters, an agency cannot "entirely fail[ ] to consider an important aspect of the problem." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); *see also Am. Wild Horse*, 873 F.3d at 931 ("the Service's Finding of No Significant Impact not only failed to take a 'hard look' at the consequences of the boundary change, it averted its eyes altogether"); *Gresham v. Azar*, 363 F. Supp. 3d 165, 177 (D.D.C. 2019) ("The bottom line: the Secretary did no more than acknowledge—in a conclusory manner, no less—that commenters forecast a loss in Medicaid coverage").

159. Further, agencies must actually analyze the relevant factors. "'Stating that a factor was considered ... is not a substitute for considering it.'" *State v. Biden*, 10 F.4th 538, 556 (5th Cir. 2021) The agency must instead provide more than "conclusory statements" to prove it considered the relevant statutory factors. *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2127 (2016).

160. The IFC is arbitrary and capricious for several independently sufficient reasons.

161. First, it ignores the Social Security Act's focus on patient wellbeing rather than the health of providers. Each prong of the President's vaccination policy is aimed at the same overarching goal: increasing individual vaccination rates in society. *See* Remarks by President Biden on Fighting the COVID-19 Pandemic" (Sept. 9, 2021), https://bit.ly/3oI0pKr (CMS Vaccine Mandate part of President's plan to "increase vaccinations among the unvaccinated with new vaccination requirements"); The White House, Path Out of the Pandemic: President Biden's Covid-19 Action Plan, https://bit.ly/3adkMXx

162. And the evidence, even that relied upon by CMS, shows that mandating vaccines will *harm* patient health and wellbeing. For example, the Mandate will cause or exacerbate nursing home staff shortages that will significantly harm patient health and well-being. There is already a critical shortage of healthcare workers. In Montana alone, there is already a 39% nurse and aide shortage in nursing homes. AARP, "AARP Nursing Home COVID-19 Dashboard" (updated Nov. 10, 2021), https://bit.ly/3HhAWyy. Likewise, hospitals in West Virginia—particularly rural ones—are facing a serious strain when it comes to nursing and support staff in intensive care units and other critical care facilities. Aaron Williams, *WV's COVID Crisis: Hospital Staffing Shortages and the Toll It's Taking Inside the ICU and Beyond*, 12WBOY (Oct. 5, 2021), https://bit.ly/3nctZ9J. Studies also show that Vaccine Mandates will exacerbate those shortages. *See* Liz Hamel, et al., *KFF COVID-19 Vaccine Monitor: October 2021*, Kaiser Family Foundation (Oct. 28, 2021), https://bit.ly/3wEiJWN; Chris Isidore & Virginia Langmaid, *72% of unvaccinated workers vow to quit if ordered to get vaccinated*, CNN.com (Oct. 28, 2021),

https://cnn.it/3HdgDlw.[1] And CMS acted arbitrarily and capriciously by failing to consider an exemption from the requirement to terminate employees who refused to be vaccinated for healthcare facilities in HPSAs, where those facilities cannot replace terminated employees.

163. Second, the Secretary failed to consider or arbitrarily rejected obvious alternatives to a Vaccine Mandate. The Secretary rejected daily or weekly testing—an option that even OSHA approved in its ETS. 86 Fed. Reg. 61614 (Nov. 5, 2021) ("We have reviewed scientific evidence on testing and found that vaccination is a more effective infection control measure.") That conclusion is facially deficient: it fails to identify the "evidence" supporting this decision, or to explain how such evidence relates to the goal of protecting workers or patients in a healthcare setting. In fact, there is no relationship, as CMS's careful wording reveals. The goal here is "effective infection control," not protection in any particular environment.

164. The rejection of natural immunity as a basis for exemption is equally dismissive and unsupported. 86 Fed. Reg. at 61614 ("There remain many uncertainties about as to the strength and length of this [natural] immunity compared to people who are vaccinated… [It] would have potentially reduced benefits… It would have also[] complicated administration and likely require standards that do not now exist for reliably measuring the declining levels of antibodies over time in relation to the risk of reinfection. Because of current CDC guidance and understanding of relevant scientific findings, we found that it was not warranted to exempt previously infected individuals.").

[1] Because CMS did not conduct notice and comment, outside sources and studies are appropriately used in review of the IFC. *Cf. Asbestos Info. Ass'n/N. Am. v. Occupational Safety & Health Admin.*, 727 F.2d 415, 426 (5th Cir. 1984) ("We say no more than that evidence based on risk-assessment analysis is precisely the type of data that may be more uncritically accepted after public scrutiny, through notice-and-comment rulemaking, especially when the conclusions it suggests are controversial or subject to different interpretations."); *see also id.* at 420 n.12 ("Because of the extraordinary posture of the court reviewing an ETS, made more extraordinary by the statutory requirement that we review it under a substantial evidence standard, 29 U.S.C. § 655(f), we also considered the unfavorable reviews as well as the favorable ones to aid us in our understanding of this technologically complex case. To do otherwise 'would convert the reviewing process into an artificial game.'").

165. In short, the Secretary fails to identify the evidence supporting his decision, proffers a vague "administrative" excuse, and punts to the CDC *despite* an intense public debate and a trove of scientific data on the strength and durability of natural immunity from COVID-19, alone and compared to vaccine-induced immunity.

166. For example, a highly reported study from Israel involving review of 74,000 cases of infection concluded that a person with natural immunity is 27 times less likely to be reinfected than a vaccinated person. *See* Sivan Gazit, Roei Shlezinger, et al., *Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections*, MEDRXIV (Aug. 30, 2021), https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1. Additional studies support this conclusion.[2]

167. Emerging studies show that natural immunity affords benefits comparable to or better than vaccination. *See e.g.,* Melissa Healy, *Study shows dramatic decline in effectiveness of all three COVID-19 vaccines over time,* L.A. Times (Nov. 4, 2021), https://lat.ms/30hQIbj ("As the Delta variant became the dominant strain of coronavirus across the United States, all three COVID-19 vaccines available to Americans lost some of their protective power, with vaccine efficacy among a large group of veterans dropping between 35% and 85%, according to a new study"). Experts have suggested that natural immunity is both superior to and more durable than the vaccines. *See, e.g.*, Sivan Gazit et al., *Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections*, Medrxiv (Aug. 25, 2021), https://bit.ly/3DnKzIZ ("This study demonstrated that natural immunity confers longer lasting and stronger protection against infection, symptomatic disease and hospitalization

[2] *See* Dr. Michel C. Nussenzweig, Senior Physician, *Natural infection versus vaccination: Differences in COVID antibody responses emerge*, THE ROCKEFELLER UNIVERSITY (Aug. 24, 2021), https://bit.ly/3ojdfNz; Don W. Hackett, Robert Carlson, M.D., *Natural Immunity After Covid-19 Found Durable and Robust*, PRECISION VACCINATIONS (updated Aug. 2, 2021), https://bit.ly/30goyOE; Sharon Reynolds, *Lasting immunity found after recovery from COVID-19*, NATIONAL INSTITUTE OF HEALTH (Jan. 26, 2021), https://bit.ly/3kPYFwb.

caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2 two-dose vaccine-induced immunity. And it is unclear if vaccination of an individual who has natural immunity will provide any perceptible benefit in fighting future infection."); Yair Goldberg, et al., *Protection of previous SARS-CoV-2 infection is similar to that of BNT162b2 vaccine protection: A three-month nationwide experience from Israel*, Medrxiv (Apr. 24, 2021), https://bit.ly/3n8uXTe; *see also, e.g.*, Martin Kuldorff and Jay Bhattacharya, *The ill-advised push to vaccinate the young*, The Hill (June 17, 2021), https://bit.ly/2Z2ZpX6; R. R. Goel et al., *mRNA vaccines include durable immunity to SARS-CoV-2 and variants of concern*, Science (Oct. 14, 2021), https://bit.ly/3DXLS1K ("[B]oosting of pre-existing immunity from prior infection with mRNA vaccination mainly resulted in a transient benefit to antibody titers with little-to-no long-term increase in cellular immune memory.").

168. Third, CMS failed to estimate benefits to patients from requiring vaccines for those several steps removed from patient care and interaction. This failing is particularly glaring in light of the Social Security Act's focus on the health and wellbeing of *patients* rather than of healthcare workers.

169. Fourth, the IFC is arbitrary and capricious because its rationales are flagrantly pretextual. As recounted above, the President has stated several times that the CMS Vaccine Mandate is part of a broader program aimed at increasing vaccination rates throughout American society, writ large. The IFC, however, eschews this rationale and tries (unsuccessfully and after-the-fact) to pigeonhole the Mandate into the Social Security Act's statutory factors. Such obvious regulatory reframing of the Mandate here leads to the inescapable conclusion that the IFC's stated rationale is pretextual. And the presence of such blatant pretext is enough to render the CMS Vaccine Mandate arbitrary and capricious. *Dep't of Com. v. New York*, 139 S. Ct. 2551, 2575-76 (2019). What's more, the Administration's shifting rationales across all vaccine mandates demonstrate pretext. For example, the OSHA ETS declares that vaccines are necessary to protect worker safety. But that rationale that would not be sufficient under the Social Security Act. So CMS fabricated a new rationale to cram the mandate

into the Social Security Act. Accepting CMS's description of the Vaccine Mandate requires this Court to "'exhibit a naiveté from which ordinary citizens are free.'" *Id.*

170. Fifth, the CMS rule completely ignores State reliance interests. Plaintiff States have overwhelming reliance interests in their Medicaid systems. Specifically, the IFC ignores: (1) the Plaintiff States' reliance interests in their healthcare providers continuing to operate under existing rules without facing this new mandate that threatens to cause significant harm to the States' 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 in rural communities, in selecting a job and building a career under the existing rules. The IFC is arbitrary and capricious because it utterly ignores these reliance interests. *See Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1913-14 (2020).

171. Sixth, the scope of the Vaccine Mandate is arbitrary and capricious. The mandate reaches many categories of healthcare facilities, such as psychiatric residential treatment facilities for individual under 21 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 61610 n.247. Beyond that, the mandate applies to "any individual that . . . has the potential to have contact with anyone at the site of care." *Id.* at 61571 (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 61570. And the mandate also covers a contracted "crew working on a construction project whose members use shared facilities (restrooms, cafeteria, break rooms) during their breaks." *Id.* at 61571. The mandate's vast reach is far removed from the purported purpose of protecting patient safety.

172. Finally, CMS fails to weigh important civil liberty implications from forced vaccination—the right to refuse medical treatment rooted in the doctrine of informed consent under state law[3] and the impact (as opposed to merely the benefits) of the mandate on protected demographics in the health care labor market—or the principles of federalism threatened by imposing such far-reaching requirement on States without consultation or consent.

173. For each of these independently sufficient reasons, the OMB Rule is arbitrary and capricious.

COUNT VI

The Vaccine Mandate Violates 42 U.S.C. §1395z

174. Plaintiff States repeat and incorporate by reference each of the Complaint's allegations stated above.

175. Under 42 U.S.C. §1395z, "the Secretary shall consult with appropriate State agencies and recognized national listing or accrediting bodies, and may consult with appropriate local agencies" 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 this title, or by ambulatory surgical centers under section 1395k(a)(2)(F)(i) of this title."

176. As CMS acknowledges, this consultation requirement applies to the Vaccine Mandate because that mandate 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),

[3] Louisiana, in particular, has a robust right "to refuse medical treatment" rooted in the State constitution. *See* La. Const. art. 1, §5; *Hondroulis v. Schuhmacher*, 553 So. 2d 398, 414 (La. 1989) ("we conclude that the Louisiana Constitution's right to privacy also provides for a right to decide whether to obtain or reject medical treatment").

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).

177. CMS concedes that it did not comply with §1395z's requirement that it "consult with appropriate State agencies." 86 Fed. Reg. at 61567.

178. CMS's "inten[t] to engage in consultations with appropriate State agencies ... following the issuance of th[e] rule," 86 Fed. Reg. at 61567, does not satisfy 42 U.S.C. §1395z. The statute requires that the consultation with States when the Secretary is "carrying out his functions[] relating to determination of conditions of participation by providers of services," 42 U.S.C. §1395z, or *before* a rule is issue. Yet the Secretary, via CMS, has already determined—without consulting with States—that the vaccine mandate should be a condition of participation for providers. Since he did not complete the statutory consultation requirement before adopting the IFC, the Secretary, acting through CMS, violated 42 U.S.C. §1395z.

179. The Vaccine Mandate thus violates 42 U.S.C. §1395z and must be vacated and enjoined.

COUNT VII

The Vaccine Mandate Violates 42 U.S.C. §1302

180. Plaintiff States repeat and incorporate by reference each of the Complaint's allegations stated above.

181. 42 U.S.C. §1302(b)(1) requires that "[w]henever the Secretary [of HHS] 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, the Secretary shall prepare and make available for public comment an initial regulatory impact analysis."

182. 42 U.S.C. §1302(b)(1) applies to the CMS Vaccine Mandate because CMS's cited statutory authority for its vaccine mandate falls under Titles 18 and 19 of the Social Security Act and because the mandate will have a significant impact on the operations of a substantial number of small rural hospitals.

183. 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. Those dire consequences stretch across rural America, and their collective force required CMS to prepare a regulatory impact analysis.

184. Accordingly, the IFC violates 42 U.S.C. §1302(b)(1) because CMS did not prepare a regulatory impact analysis.

COUNT VIII

The Vaccine Mandate Violates the Spending Clause

185. Plaintiff States repeat and incorporate by reference each of the Complaint's allegations stated above.

186. The CMS Vaccine Mandate is an unconstitutional condition on Plaintiff States' receipt of federal funds.

187. "[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).

188. Nothing in federal law gave States clear notice that a vaccine mandate would be a condition of accepting federal Medicaid (or, where applicable, Medicare) funds.

189. And for the reasons discussed above, the Vaccine Mandate goes far beyond the federal interest in patient health and wellbeing. Thus, the CMS Vaccine Mandate violates the Spending Clause because it is not necessary to preventing the spread of COVID-19. *See Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 579 (2012).

190. Additionally, because noncompliance with the Vaccine Mandate threatens a substantial portion of Plaintiff States' budgets, it violates the Spending Clause by leaving the States with no choice but to acquiesce. *See id.* at 581-82 ("[T]he States have developed intricate statutory and administrative regimes over the course of many decades to implement their objectives under existing Medicaid. It is easy to see how the *Dole* Court could conclude that the threatened loss of less than half of one percent of South Dakota's budget left that State with a 'prerogative' to reject Congress's desired policy, 'not merely in theory but in fact.' The threatened loss of over 10 percent of a State's overall budget, in contrast, is economic dragooning that leaves the States with no real option but to acquiesce in the Medicaid expansion.").

COUNT IX

The Vaccine Mandate Violates the Anti-Commandeering Doctrine

191. Plaintiff States repeat and incorporate by reference each of the Complaint's allegations stated above.

192. The Tenth Amendment and structure of the Constitution deprive Congress of "the "the power to issue direct orders to the governments of the States," *Murphy v. NCAA*, 138 S. Ct. 1461, 1476 (2018), and forbid the federal government to commandeer State officers "into administering federal law," *Printz v. United States*, 521 U.S. 898, 928 (1997).

193. The Vaccine Mandate violates this doctrine by requiring Plaintiff States' state-run hospitals that are covered by the Mandate to either fire their unvaccinated employees or forgo all Medicaid (or, where applicable, Medicare) funding.

194. The Vaccine Mandate also commandeers the States because it forces State surveyors to enforce the Mandate by verifying healthcare provider compliance. This "dragoons" States into enforcing federal policy by threatening Plaintiff States' Medicaid (and, where applicable, Medicare) funds.

COUNT X

The Vaccine Mandate Violates the Tenth Amendment

195. "The powers not delegated by the Constitution to the United States, nor prohibited by it to the States, are reserved to the States respectively, or to the people." U.S. Const. amend. X.

196. No clause of the Constitution authorizes the federal government to impose the Vaccine Mandate. Public health—and vaccinations in particular—have long been recognized as an aspect of police power reserved to the *States*, not the Federal Government. *See, e.g.*, *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11, 24 (1905); *see also Hillsborough Cty.*, 471 U.S. at 719 ("[T]he regulation of health and safety matters is primarily, and historically, a matter of local concern."); *S. Bay United Pentecostal Church v. Newsom*, 140 S. Ct. 1613 (2020) (Roberts, C.J., concurring in the denial of application for injunctive relief) (our Constitution principally entrusts "[t]he safety and the health of the people" to the politically accountable officials of the States "to guard and protect"); *State v. Becerra*, 2021 WL 2514138, at *15 (M.D. Fla. June 18, 2021) ("The history shows ... that the public health power ... was traditionally understood — and still is understood — as a function of state police power.").

197. By encroaching upon the States' traditional police power, particularly without clear authorization from Congress, Defendants have exceeded their authority and violated the Tenth Amendment.

PRAYER FOR RELIEF

NOW, THEREFORE, Plaintiffs request an order and judgment:

1. Declaring, under 28 U.S.C. §2201, that the IFC is arbitrary and capricious and unlawful under the APA;

2. Declaring, under 28 U.S.C. §2201, that the IFC is contrary to law and in excess of statutory authority under the APA;

3. Declaring, under 28 U.S.C. §2201, that the Vaccine Mandate violates the APA and Social Security Act because it was promulgated without notice and comment;

4. Declaring, under 28 U.S.C. §2201, that the Vaccine Mandate violates 42 U.S.C. §§1302(b)(1), 1395, and 1395z;

5. Declaring that the Vaccine Mandate violates the Constitution;

6. Holding the Vaccine Mandate unlawful and vacating it;

7. Preliminarily and permanently enjoining, without bond, Defendants from imposing the Vaccine Mandate;

8. Tolling the Mandate's compliance deadlines pending judicial review;

9. Granting all other relief to which Plaintiff States are entitled, including but not limited to attorneys' fees and costs.

Dated: November 15, 2021

Respectfully submitted,

By: */s/ Elizabeth B. Murrill*

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