IN THE UNITED STATES DISTRICT COURT
FOR THE 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 M. 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 COMMONWEALTH OF KENTUCKY,
By and through its Attorney General,
DANIEL CAMERON;

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

THE STATE OF OHIO,
By and through its Attorney General,
DAVE YOST;

Civil Action No. 3:21-cv-03970

District Judge Terry A. Doughty

Magistrate Judge Kayla D. McClusky

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 TENNESSEE,
By and through its Attorney General,
HERBERT H. SLATERY III;

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

THE COMMONWEALTH OF VIRGINIA,
By and through its Attorney General,
JASON S. MIYARES;

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

PLAINTIFFS,

v.

XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, et al.,

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 & MEDI-

CAID SERVICES;

DEFENDANTS.

SECOND AMENDED AND SUPPLEMENTAL COMPLAINT

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

INTRODUCTION

1. The President's scheme to federalize vaccination policy has hit the skids. The OSHA vaccine mandate was struck down for lack of authorization, *Nat'l Fed'n of Indep. Bus. v. OSHA*, 595 U.S.__, 142 S. Ct. 661 (2022), and the remnants shelved. *See* Stephen Dinan, *OSHA cancels business vaccine mandate after Supreme Court loss*, Wash. Times (Jan. 25, 2022), https://www.washingtontimes.com/news/2022/jan/25/. The federal contractor vaccine mandate is enjoined. *see Georgia v. Biden*, No. 1:21-cv-163 (S.D. Ga. Dec. 7, 2021); as is the federal employee vaccine mandate. *see Feds for Med. Freedom v. Biden*, No. 3:21-CV-356, __F. Supp. 3d__, 2022 WL 188329 (S.D. Tex. Jan. 21, 2022). All that remains is the Interim Final Rule ("IFR") establishing the Centers for Medicare and Medicaid Services ("CMS") mandate ("Vaccine Mandate"), which survived certain challenges on appeal and was remanded.

2. But things have dramatically changed. First and foremost, the Secretary's rationale for the rule and for avoiding public comment no longer exists. The

Delta variant has run its full course. *See Biden v. Missouri*, 142 S. Ct. 647, 651 (2022) ("Th[e] good cause was, in short, the Secretary's belief that any 'further delay' would endanger patient health and safety given the spread of the Delta variant and the upcoming winter season."); *see also* Centers for Disease Control and Prevention ("CDC") COVID Data Tracker, *Variant Proportions* (Updated Jan. 25, 2022), https://covid.cdc.gov/covid-data-tracker/#variant-proportions (identifying the Delta variant as responsible for 98.7% of all cases as of November 6, 2021, the week the Interim Final Rule was implemented).

3. Instead, the Delta variant effectively disappeared within weeks of the passage of the IFR, replaced by the milder Omicron variant, which now accounts for 99.9% of all COVID cases in the United States. *Id.* Omicron's transmission is largely undeterred by the vaccines. *See* Mark G. Thompson , et al. *Effectiveness of a Third Dose of mRNA Vaccines Against COVID-19–Associated Emergency Department and Urgent Care Encounters and Hospitalizations Among Adults During Periods of Delta and Omicron Variant Predominance — VISION Network, 10 States, August 2021–January 2022*. CDC MMWR Morb Mortal Wkly Rep 2022; 71:139–145, (Jan. 21, 2022), http://dx.doi.org/10.15585/mmwr.mm7104e3 (showing that vaccine efficacy is drastically reduced at preventing the transmission of the Omicron variant). Even Dr. Anthony Fauci recently warned that "Omicron, with its extraordinary, unprecedented degree of . . . transmissibility, will ultimately find just about everybody" and that even those who have received the initial vaccine and subsequent booster "will still get infected." Travis Caldwell, et al., *The highly conta-*

gious Omicron variant will 'find just about everybody,' Fauci says, but vaccinated people will still fare better, CNN (Jan. 12, 2022), https://www.cnn.com/2022/01/11/health/us-coronavirus-tuesday/index.html.

4. Simply put, the situation has changed. And that reveals a fundamental, structural defect in the rule—its one-size-fits-all approach doesn't account for developing data and circumstances. In recent weeks, federal authorities have begun to walk back prior claims about the efficacy of the three domestically available vaccines against the now dominant Omicron variant. CDC, *Omicron Variant: What You Need to Know* (Dec. 20, 2021), https://www.cdc.gov/coronavirus/2019-ncov/variants/omicron-variant.html. And that comes amid increasing warnings about the risks and side effects posed by the vaccines. *E.g.*, CDC, *Selected Adverse Events Reported after COVID-19 Vaccination* (Jan. 24, 2022), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html ("CDC has also identified nine deaths that have been caused by or were directly attributed to [thrombosis with thrombocytopenia syndrome] following J&J/Janssen COVID-19 vaccination."); Matthew E. Oster et al., *Myocarditis Cases Reported After mRNA-Based COVID-19 Vaccination in the US From December 2020 to August 2021*, 327(4) J. Am. Med. Ass'n 331 (Jan. 25, 2022), https://jamanetwork.com/journals/jama/fullarticle/2788346; Jennifer Couzin-Frankel & Gretchen Vogel, *In rare cases, coronavirus vaccines may cause Long Covid-like symptoms*, 375 Science 6579 (Jan. 20 2022), https://www.science.org/content/article/rare-cases-coronavirus-vaccines-may-cause-

long-covid-symptoms. The IFR purports to address an emergency situation in emergency (and unprecedently heavy-handed) ways. But its rigid prescription—the Vaccine Mandate—utterly fails to account for the fact this emergency is continually evolving. And this structural defect renders the IFR arbitrary and capricious and otherwise unlawful under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 551–559, in multiple ways.

5. Additionally, as warned, the Vaccine Mandate is causing havoc in the healthcare labor market, contrary to the Secretary's predictions. During the time when it was preliminarily enjoined, several of the nation's largest providers who previously implemented the Vaccine Mandate suspended the requirement because it exacerbated existing labor shortages. Robbie Whelan & Melanie Evans, *Some Hospitals Drop Covid-19 Vaccine Mandates to Ease Labor Shortages*, Wall St. J. (Dec. 13, 2021), https://on.wsj.com/3ojiwW8. Meanwhile, in an effort to address the urgent staffing crisis, Governors have already sought relief from CMS due to the acute labor shortages in rural areas due to the Vaccine Mandate. *See, e.g.*, Kathleen Steele Gaivin, *Citing staffing concerns, 2 governors ask for relief from CMS vaccine mandate*, Business Daily News, (Feb. 2, 2022), https://bit.ly/34gyBF4. Facilities face a Hobson's choice of terminating or being unable to hire much-needed staff, or falling below mandatory staffing requirements. And the CDC, also under the same Secretary of Health and Human Services ("HHS"), has recognized staffing shortages by issuing new guidance that permits Covid *positive* employees to return to work, even if they are still testing positive, while the IFR *prohibits* COVID-negative un-

vaccinated individuals from working in covered facilities at all, unless they obtain an exemption. CDC, *Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2* (Jan. 21, 2022), https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html. Even then, the facility is limited in where the employee may work and with whom they may work. These restrictions also extend to suppliers, contractors, and volunteers. And healthcare facilities now have to compete for employees – especially entry-level employees – with nonhealthcare businesses which are not required to ensure that their employees are vaccinated. The ultimate burden of losing access to care falls upon the Medicaid beneficiaries.

6. Despite these changed circumstances, CMS is even now pushing the Vaccine Mandate further, revealing—as the States have consistently argued—that the burden to implement this labyrinth of irrational rules falls upon the States, through their limited staffs of surveyors. On January 25, 2022, CMS issued new guidance applying the Vaccine Mandate to State Survey Agency and Accrediting Organization Surveyors ("January 25 Guidance Mandate"). CMS, QSO-22-10-ALL, *Vaccination Expectations for Surveyors Performing Federal Oversight* (Jan 25, 2022), https://www.cms.gov/files/document/qso-22-10-all.pdf. The Guidance imposes a brand-new vaccine mandate—this time on state employees who survey and report whether Medicare and Medicaid facilities are complying with applicable regulations, including the IFR. This extension of the Vaccine Mandate constitutes an independent, substantive rule, and yet CMS failed utterly to comply with the proce-

dures required by the APA. *See* 86 Fed. Reg. at 61,574 ("As we do with all new or revised requirements, CMS will issue interpretive guidelines, which include survey procedures, following publication of this IFC. We will advise and train State surveyors on how to assess compliance ….").

7. Finally, the Vaccine Mandate violates the Tenth Amendment, the Spending Clause, the Anti-Commandeering Doctrine, and the Nondelegation Doctrine.

PARTIES

8. 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.

9. 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.

10. 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.

11. 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.

12. Plaintiff State of Georgia is a sovereign State of the United States of America. Plaintiff Christopher M. 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.

13. 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.

14. 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.

15. Plaintiff Commonwealth of Kentucky is a sovereign State of the United States of America. Plaintiff Daniel Cameron is the Attorney General of the Commonwealth of Kentucky. He is authorized by Kentucky law to sue on the Commonwealth's behalf. His offices are located at 700 Capital Avenue, Suite 118, Frankfort, Kentucky 40601.

16. 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.

17. Plaintiff State of Ohio is a sovereign State of the United States of America. Plaintiff Dave Yost is the Attorney General of the State of Ohio. He is authorized by Ohio law to sue on the State's behalf. His offices are located at 30 E. Broad St., 17th Floor, Columbus, Ohio 43215.

18. 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.

19. 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.

20. Plaintiff State of Tennessee is a sovereign State of the United States of America. Plaintiff Herbert H. Slatery III is the Attorney General and Reporter of the State of Tennessee. He is authorized by Tennessee law to sue on the State's behalf. His offices can be reached at P.O. Box 20207, Nashville, Tennessee 37202.

21. 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.

22. Plaintiff Commonwealth of Virginia is a sovereign State of the United States of America. Plaintiff Jason S. Miyares is the Attorney General of the Commonwealth of Virginia. His powers and duties include representing the Commonwealth and its agencies in federal court on matters of public concern. His offices are located at 202 North Ninth Street, Richmond, Virginia 23219.

23. Plaintiff West Virginia is a sovereign State of the United States of America. Plaintiff Patrick 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.

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

25. 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.

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

27. 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.

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

JURISDICTION AND VENUE

29. 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.

30. 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.

31. Defendants' publication of the January 25, 2022 Guidance Mandate constitutes a final agency action that is judicially reviewable under the APA. 5 U.S.C. §§704, 706.

32. 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 Ctrs v. Azar*, 509 F. Supp. 3d 482 (D. Md. 2020).

BACKGROUND

I. The Medicare and Medicaid Framework Established by Congress.

33. 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").

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

35. The Social Security Act charges the Secretary of HHS 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.

36. 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 effi-

cient administration of the functions with which [he] is charged under this chapter." 42 U.S.C. §1302(a).

37. The Centers for Medicare & Medicaid Services, a federal agency within the Department of Health and Human Services, has primary responsibility for overseeing the Medicare program and the federal role in the Medicaid program.

38. The Secretary of Health and Human Services has the authority to withhold Medicare funds from healthcare providers and federal Medicaid funds from states for noncompliance with the Rule or the IFR. *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 328 (2015) ("The sole remedy Congress provided for a State's failure to comply with Medicaid's requirements—for the State's "'breach'" of the Spending Clause contract—is the withholding of Medicaid funds by the Secretary of Health and Human Services. 42 U.S.C. § 1396c.").

II. The Biden Administration's Vaccine Policy.

39. As President-Elect, Mr. Biden promised he "d[id]n'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. 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.

40. 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.

41. President Biden's program included the issuance of multiple vaccine mandates targeting different populations. These include the federal contractor vaccine mandate, Exec. Order No 14042, 86 Fed. Reg. 50985 (Sept. 9, 2021), federal employee vaccine mandate, Exec. Order No 14043, 86 Fed. Reg. 50989 (Sept. 9, 2021), OSHA vaccine mandate on private businesses, COVID-19 Vaccination and Testing; Emergency Temporary Standard, 86 Fed. Reg. 61402-01 (Nov. 5, 2021), the Head Start Mandate, 86 Fed. Reg. 68052 (Nov. 30, 2021), and the CMS Vaccine Mandate challenged here—the only one of Biden's vaccine mandates yet to be enjoined.

42. In September 2021, 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 "expanded that" edict "to cover those who work in hospitals, home healthcare facilities, or other medical facilities." *Id.*

43. President Biden failed to respect the sovereignty of 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 CMS Vaccine Mandate.

44. 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).

45. 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.

46. 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; Clin-

ics; 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.*

47. The rule applies the same substantive standards to each of the 21 types of covered 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.*

48. 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).

49. 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).

50. 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).

51. Originally, the rule directed providers to ensure that employees submit to at least one vaccine dose by December 6, 2021, before providing "any care, treatment, or other services for the [entity] and/or its patients," and ensure that employees be "fully vaccinated" by January 4, 2022. *Id.* §416.51(c)(3)(i)-(ii), 86 Fed.

Reg. at 61555. In states that had not brought litigation against CMS, including Tennessee and Virginia, CMS pushed the initial deadline back to January 27, 2022, and the second deadline for full vaccination back to February 28, 2022. *See* CMS, *Guidance for the Interim Final Rule – Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination* (Dec. 28, 2021), https://www.cms.gov/files/document/qso-22-07-all.pdf. After the Supreme Court granted a stay of this Court's injunction and allowed the IFR to take effect, CMS determined that affected workers must receive the first dose by February 14, 2022, and achieve full vaccination by March 15, 2022. *See* CMS, *Guidance for the Interim Final Rule – Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination* (Jan. 14, 2022), https://www.cms.gov/files/document/qso-22-09-all-injunction-lifted.pdf.

52. 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).

53. 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).

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

55. The only way for an entity to avoid those regulations is to forfeit its federal Medicare and Medicaid funding. 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 spells disaster for healthcare providers and for access to care for millions of people.

56. Medicaid providers receive this funding for services through a provider contract with individual States. States thus bear the burden of issuing sanctions and/or terminating provider contracts. *See* CMS, *Quality, Safety & Oversight – General Information* (Feb. 3, 2022), https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo.

57. 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").

58. Nothing in any State's agreements with HHS has ever contemplated being subjected to or being required to implement a vaccination requirement.

IV. The Targeted Healthcare Workers.

59. 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.

60. 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 healthcare staff refuse vaccination and are not granted exemptions and are terminated, with consequences for employers, employees, and patients").

61. Though medical and religious exemptions may be granted in certain circumstances, the goal of the program is to vaccinate "nearly all healthcare workers." *Id.* at 61569. This can be done only by changing millions of minds through coercion or losing millions of healthcare workers. These workers now have the freedom to work for providers not covered by the Vaccine Mandate or for employers who are no longer covered by the OSHA Mandate, which was enjoined and subsequently withdrawn.

V. The Implications for Vulnerable Americans Seeking Care.

62. 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 permanently enjoined, these healthcare workers will lose their jobs; States will lose frontline workers, providers, suppliers, and services; and ultimately America's most vulnerable populations will lose access to necessary medical care.

63. CMS acknowledges that there are currently "endemic staff shortages for all categories of employees at almost all kinds of healthcare 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.*

64. A few statistics illustrate the extent of the problem. Already 41% of nursing homes in Montana face staff shortages. *See AARP Nursing Home COVID-19 Dashboard*, AARP Publ. Pol'y Inst. (Jan. 28, 2022), 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*, (Nov. 10, 2021), 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 outcomes for residents, including more COVID-19 cases, deaths, and a higher likelihood of outbreaks. *Id.*

65. 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.*

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

67. 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 based on wishful thinking—not 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.

VI. Devastation to the Plaintiff States.

68. The Plaintiff States have all entered into agreements with the federal government to participate in Medicaid. CMS, *1864 Agreement* (last accessed Feb 2, 2022), https://qsep.cms.gov/BHFS/M1/M1S2_80.aspx.

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

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

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

72. Many of those facilities are small rural hospitals where staffing shortages are persistent problems.

73. In state fiscal year 2021, Louisiana's 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. *See* Louisiana Medicaid Forecast Reports, https://ldh.la.gov/news/5885; State Budgets, Louisiana Division of Administration, https://www.doa.la.gov/doa/opb/budget-documents/state-budgets/. 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, contracted through a competitive bidding process governed by State law. The Department of Health has approximately 216 surveying staff responsible for surveying, certification, and compliance surveying for both Medicaid and ensuring compliance with state law facility licensing requirements (which may include non-Medicaid providers, such as abortion facilities). Approximately 75% of that staff is vaccinated. Louisiana also provides safety net healthcare services through hospital districts created by statute and through a variety of cooperative endeavor contracts. *See, e.g.,* https://www.lsuhospitals.org/about_us.aspx. Louisiana also operates a number of Veteran's Homes that receive Medicare and Medicaid funding. *See*, https://www.vetaffairs.la.gov/benefit/la-veterans-homes/.

74. 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%. 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. Montana's Department of Public Health and Human Services employs approximately 26 staff responsible for duties relating to surveying, certification, and compliance surveying for both Medicare and Medicaid.

75. For state fiscal year 2020-2021, Kentucky received over $12 billion in federal funds for Medicaid services. Kentucky's federal Medicaid revenues accounted for over 25% of its total state budget. As of November 1, 2021, more than 1.5 million people—or approximately one-third of Kentuckians—are covered by Medicaid. Kentucky operates healthcare facilities that receive both Medicare and Medicaid funding and that are subject to the Vaccine Mandate, including the Thompson-Hood Veterans Center, Carl M. Brashear Radcliff Veterans Center, Paul E Patton Eastern Kentucky Veterans Center, and Joseph "Eddie" Ballard Western Kentucky Veterans Center.

76. Ohio operates state-run healthcare facilities that receive both Medicare and Medicaid funding and are subject to the Vaccine Mandate.

77. 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.

78. Plaintiff State Virginia retains 63 staff positions performing duties related to surveying and certification for 1,334 certified facilities. Virginia operates eight state-run healthcare facilities that receive both Medicare and Medicaid funding. These include Catawba Hospital, Hiram W. Davis Medical Center, Northern Virginia Mental Health Institute, Southeastern Virginia Training Center, Southern

Virginia Mental Health Institute, Southwestern Virginia Mental Health Institute, Western State Hospital, and the University of Virginia Medical Center.

79. For state fiscal year 2021, Tennessee's $41.8 billion budget included $13.1 billion in funding related to the State Medicaid program, with $4.1 billion of those funds coming from the State's general fund. As of December 2021, Tennessee added 218,499 more people to its Medicaid rolls since March 2020 when the COVID-19 outbreak began. As of December 2021, approximately 1,639,931 of Tennessee's 6.97 million residents were enrolled in Medicaid, amounting to about 23.5% of the State's population. Tennessee retains roughly 90 staff positions performing duties related to surveying and certification for over 1,780 facilities. And Tennessee operates at least 150 state-run healthcare facilities that receive Medicare and Medicaid funding and that are subject to the Vaccine Mandate.

80. For state fiscal year 2022, Virginia's $133 billion budget included $18.6 billion in funding related to the State Medicaid and CHIP programs, with $6.03 billion of those funds coming from the State's general fund. As of December 1, 2021, Virginia added 425,634 more people to its Medicaid and CHIP rolls since March 1, 2020, when the COVID-19 outbreak began. As of December 1, 2021, 1,941,629 of Virginia's estimated 8.66 million residents were enrolled in Medicaid or CHIP, amounting to about 22.4% of the State's population.

81. 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. 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.

82. The Plaintiff States employ state surveyors who regularly evaluate state-run and private 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.

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

84. 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.

85. The Vaccine Mandate commandeers 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.

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

because CMS guidance requires multiple additional surveys of facilities subject to the Vaccine Mandate, as well as the additional obligation to respond to complaints filed against facilities who appear to be out of compliance.

87. Surveying is already a costly and complicated endeavor, and it is made even more so by the Vaccine Mandate and accompanying guidance. Though the compliance dates differ for States subject to the original injunction and those not subject to the original injunction, the process is the same.

88. First, within thirty days, States must send surveyors out to ensure facilities have policies and procedures in place, that 100% of employees have received at least the first dose of the vaccine or have been granted an exemption; verify that facilities have plans to come into compliance if not already in compliance; and assess fines and penalties to be issued to noncompliant facilities. *See* CMS, *Guidance for the Interim Final Rule – Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination* (Jan. 14, 2022), https://www.cms.gov/files/document/qso-22-09-all-injunction-lifted.pdf.

89. Second, after sixty days, States must survey for additional compliance including ensuring that policies are in place and implemented, that all staff have received the second dose of the vaccine, again review policies and plans to reach compliance and follow up on past plans, and again evaluate compliance and issue fees and fines to noncompliant facilities. *Id.*

90. Finally, after ninety days, States must again survey the facilities for compliance with the previous requirements as part of the initial certification, recer-

tification, or reaccreditation of the facility's eligibility to receive Medicaid or Medicaid funds for services provided. *Id.* Of course, in typical bureaucratic fashion, the specific guidelines for compliance also vary by provider type, for which there are even more precise requirements. *Id.* at Attachments A-N.

91. Not only does the Vaccine Mandate and accompanying guidance force States to increase the number of surveys they must conduct, it also complicates their existing surveying schedules and requires States to conduct statewide training to facilitate this new task.

92. Not only are state-run healthcare facilities required to enforce the Vaccine Mandate, the state surveyors who monitor and effectuate enforcement are—as of January 25—also required to be vaccinated themselves. These mandates directly infringe 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 IC 16-39-11-5, 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 Com v. New York*, 139 S. Ct. 2551, 2566 (2019).

96. States also will incur overtime costs and increased costs related to termination and/or reassignment of employees due to the Vaccine Mandate. States will likewise incur costs through their need to recruit new employees in an already tight labor market. These new personnel, either full-time or contact workers, will be more expensive to hire.

97. The Plaintiff States also 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' citizens writ large. 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.

VII. The Careless Enactment of the Vaccine Mandate.

98. 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 takes effect. 86 Fed. Reg. at 61583.

99. 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.*

100. 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.

101. 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.

102. Instead, CMS anchored its actions in the threat posed by the Delta variant, which accounted for the vast majority of COVID cases *at that time*. The depth of the Secretary's reliance on the Delta variant as justification for the rule and the emergency implementation process warrants quotation at length (with emphasis added):

Emerging evidence also suggests that vaccinated people who become infected with the SARS-CoV-2 **Delta variant** have potential to be less infectious than infected unvaccinated people, thus decreasing transmission risk. 86 Fed. Reg. at 61558.

Data suggest the current surge in COVID-19 cases associated with emergence of the **Delta variant** has exacerbated health care staffing shortages. 86 Fed. Reg. at 61559.

COVID-19 case rates among staff have also grown in tandem with broader national incidence trends since the emergence of the **Delta variant**. *Id.*

Vaccination is thus a powerful tool for protecting health and safety of patients, and, with the emergence and spread of the highly transmissible **Delta variant**, it has been an increasingly critical one to address the extraordinary strain the COVID-19 pandemic continues to place on the U.S. health system. *Id.*

While COVID-19 cases, hospitalizations, and deaths declined over the first 6 months of 2021, the emergence of the **Delta variant** reversed these trends. *Id.*

In a recent study of reported COVID–19 cases, hospitalizations, and deaths in 13 U.S. jurisdictions that routinely link case surveillance and immunization registry data, CDC found that unvaccinated individuals accounted for over 85 percent of all hospitalizations in the period between June and July 2021, when **Delta** became the predominant circulating variant. *Id.*

Moreover, **available evidence suggests that these vaccines offer protection against known variants, including the Delta variant**…*Id.* at 61565.

This threat [to the health and to the lives of staff of health care facilities and of consumers] has grown to be particularly severe since the emergence of the **Delta variant**. *Id.* at 61567.

The 2021 outbreaks associated with the SARS-Cov-2 **Delta variant** have shown that current levels of COVID-19 vaccination coverage up until now have been inadequate to protect health care consumers and staff. *Id.* at 61583.

Over the first 6 months of 2021, COVID-19 cases, hospitalizations and deaths declined. The emergence of the **Delta variant** reversed these trends. Between late June 2021 and September 2021, daily cases of COVID-19 increased over 1200 percent… *Id.*

We recognize that newly reported COVID-19 cases, hospitalizations, and deaths have begun to trend downward at a national level; nonetheless, they remain substantially elevated relative to numbers seen in May and June 2021, when the **Delta variant** became the predominant strain circulating the U.S. *Id.*

[A] combination of factors now have persuaded us that a vaccine mandate for health care workers is an essential component of the nation's COVID-19 response…These include, but are not limited to, the following: Failure to achieve sufficiently high levels of vaccination based on voluntary efforts and patchwork requirements; ongoing risk of new COVID-19 variants; potential harmful impact of unvaccinated healthcare workers on patents; continuing strain on the healthcare system, **particularly from Delta-variant-driven surging case counts** beginning in summer 2021… *Id.*

COVID-19 case rates among staff have also grown in tandem with broader national incidence trends since the **Delta variant's** emergence. *Id.* at 61585.

Vaccines continue to be effective in preventing COVID-19 associated with the now-dominant Delta variant. *Id.*

Emerging evidence also suggest that vaccinated people who become infected with **Delta** have potential to be less infectious than infected unvaccinated people, thus decreasing transmission risk. *Id.*

Some in the scientific community believe that "booster" vaccinations after 6 or 7 months would be desirable to maintain a high level of protection against the predominant Delta version of the virus. **Delta may be overtaken by other virus mutations, which creates another uncertainty.** *Id.* at 61609.

All these data and estimation limitations apply to even the short-term impacts of this rule, and **major uncertainties remain as to the future course of the pandemic, including but not limited to** vaccine effectiveness in preventing "breakthrough" disease transmission from those vaccinated, the long-term effectiveness of vaccination,

> the emergence of treatment options, and **the potential for some new disease variant even more dangerous than Delta**. *Id.* at 61612.
>
> **Given the emergency situation with respect to the Delta variant** detailed more fully above, the time did not permit usual consultation procedures the States, and such consultation would therefore be impracticable. We are, however, inviting State and local comments on the substance as well as legal issues presented by this rule… *Id.* at 61613.

103. Moreover, CMS 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."

104. But CMS did not comply with §1395z's consultation requirement, because it "intend[s] to engage in consultations with appropriate State agencies ... following the issuance of th[e] rule," 86 Fed. Reg. at 61567. And to date, CMS has not consulted with the States regarding the IFR nor the subsequent binding guidance documents it has issued since January 14, 2022.

105. The post-promulgation "Comment date" ended January 4, 2022. 86 Fed. Reg. 61555.

106. Even if CMS did not have an obligation to consult with appropriate State agencies in advance of the initial promulgation of the interim rule, it has

failed to consult with States during the implementation of the Vaccine Mandate. CMS likewise did not consult with States regarding the new "guidance" on surveyors and state employees, nor has it consulted with States following the continued promulgation of guidance.

107. In fact, on January 4, 2022, many of the Plaintiff States sent a comment letter to CMS explaining that the agency's reliance on the Delta variant to justify its actions is "already stale" in light of the Omicron variant. Even after receiving such notice, CMS still failed to consult with States over its new vaccine requirements.

VIII. Irreparable Harm to Individual Recipients and Providers.

108. 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.

109. 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 Pro. Emps., *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. That crisis has not abated; to the contrary, it continues to grow worse every day that the Vaccine Mandate hangs over providers' heads.

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

111. CMS surely knows that the termination of millions of healthcare 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 logrolling 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.

112. Now, after vaguely referencing States in the IFR, it has issued "guidance" revealing how it will be implemented: by imposing new conditions on States under the threat of lost funding.

113. Beyond that, the Vaccine Mandate deprives patients and providers of their procedural right to notice and comment under the APA, as the post-promulgation deadline for comment closed prior to emergence of data regarding the *current* COVID crisis and without reliable evidence of the actual impact of the Vaccine Mandate on the healthcare labor market and the corresponding impact on patient access to care.

114. 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." *N. Mariana Islands v. United States*, 686 F. Supp. 2d 7, 17-18 (D.D.C. 2009).

115. A State "suffers a form of irreparable injury" any time it is prevented from "effectuating" laws "enacted by representatives of its people." *New Motor Vehicle Bd. of Cal. v. Orrin W. Fox Co.*, 434 U.S. 1345, 1351 (1977); *see also Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers)).

116. A constitutional violation, "for even minimal periods of time, unquestionably constitutes irreparable injury." *BST Holdings, L.L.C., v. OSHA,* 17 F.4th 604, 618 (5th Cir., 2021) (quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976)). Here, as explained below, the Vaccine Mandate violates the Spending Clause, Anti-Commandeering Doctrine, Tenth Amendment, and Nondelegation Doctrine of the United States Constitution.

PROCEEDINGS IN THIS COURT AND ON APPEAL

117. On November 30, 2021, this Court issued a Memorandum Ruling and Judgment (R. Docs. 28, 29) granting Plaintiff States' Motion for Preliminary Injunction, entering a nationwide injunction (excepting ten states covered by the preliminary injunction issued by the Eastern District of Missouri ("*Missouri* Injunc-

tion")[1] "ENJOIN[ING] and RESTRAIN[ING Defendants] from implementing the CMS Mandate." *Louisiana v. Becerra*, 2021 WL 5609846 (W.D. La. Nov. 30, 2021).

118. On December 15, 2021, the Fifth Circuit denied a request for stay of the preliminary injunction but narrowed the scope of the injunction to the original fourteen Plaintiff States. *See Louisiana v. Becerra*, __F.4th__, 2021 WL 4913302 (5th Cir. Dec. 15, 2021).

119. On January 13, 2022, the Supreme Court stayed the injunction pending disposition of Defendants' appeal on remand. *See Biden v. Missouri*, 142 S. Ct. 647, 651 (2022).

120. The Supreme Court generally found "good cause" for the "Secretary to issue[] the rule as an interim final rule, rather than through the typical notice-and-comment procedures" based on the circumstances posed by the "spread of the Delta variant and the upcoming winter season" as urged by the Secretary. *Id.*

121. One day after the Supreme Court entered its stay, CMS resumed enforcement of the Vaccine Mandate in Plaintiff States,[2] requiring healthcare workers to receive the first dose of the COVID-19 vaccine by February 14, 2022, and to be fully vaccinated by March 15, 2022. *See* CMS, *Guidance for the Interim Final Rule – Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccina-*

[1] *Missouri v. Biden*, __F. Supp. 3d__, 2021 WL 5564501 (E.D. Mo. Nov. 29, 2021) (enjoining implementation and enforcement of the Vaccine Mandate for the states of Alaska, Arkansas, Iowa, Kansas, Missouri, New Hampshire, Nebraska, Wyoming, North Dakota, and South Dakota).

[2] Tennessee and Virginia were not Plaintiffs at that time. As explained above, CMS has imposed earlier deadlines for these States.

tion (Jan. 14, 2022), https://www.cms.gov/files/document/qso-22-09-all-injunction-lifted.pdf.

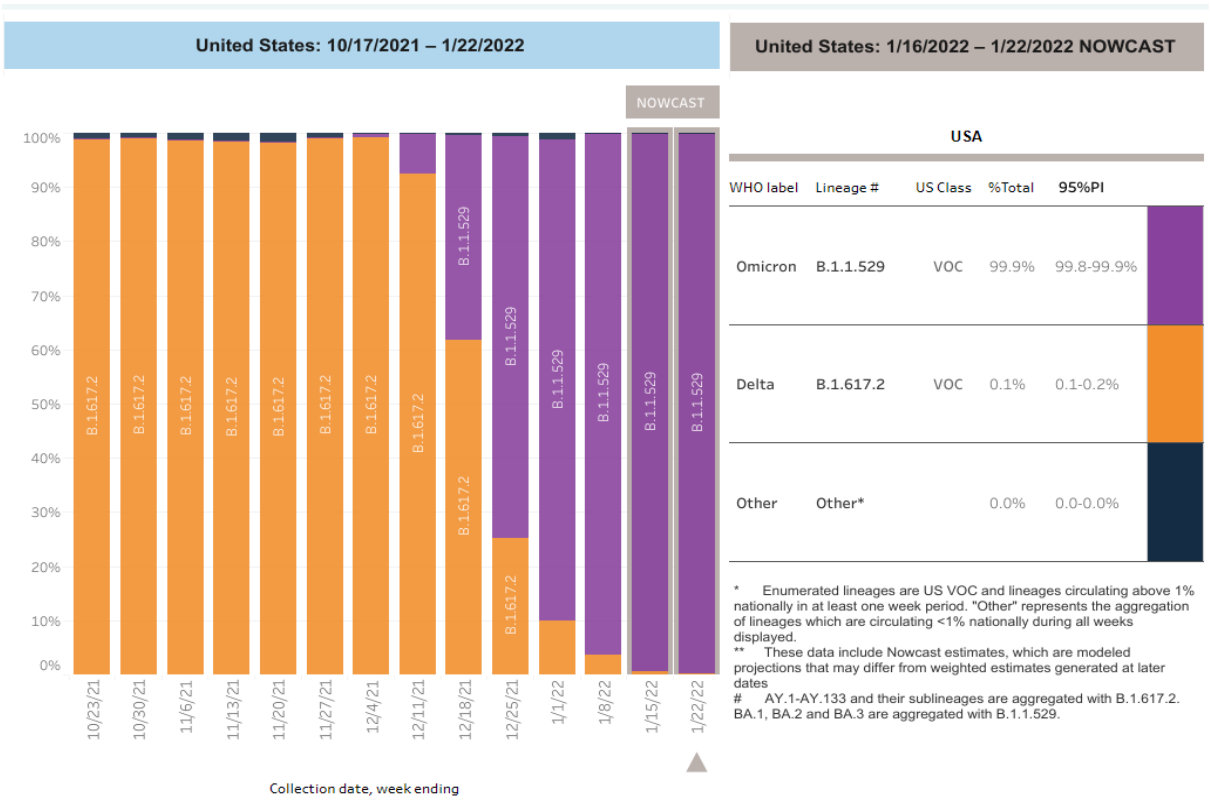
CHANGED CIRCUMSTANCES

The Delta Variant is Effectively Gone

122. CMS's Interim Final Rule mandating vaccines was issued on November 5, 2021. At that time, the Delta variant was the prominent strain of the virus, accounting for 98.7% of all reported cases in the United States. *See* CDC COVID Data Tracker, *Variant Proportions* (Updated Jan. 25, 2022), https://covid.cdc.gov/covid-data-tracker/#variant-proportions (for the week ending November 6, 2021).

123. The threat posed by the Delta variant is the gravamen of the Interim Final Rule, as recognized by the Supreme Court. *Biden,* 142 S. Ct. at 651 ("Th[e] good cause was, in short, the Secretary's belief that any 'further delay' would endanger patient health and safety given the spread of the Delta variant and the upcoming winter season.").

124. According to the CDC, by mid-December the Omicron variant replaced the Delta variant as the prominent strain. It now accounts for 99.9% of all cases in the United States:



Id. (last visited Jan. 27, 2022).

125. The Omicron variant was first detected in the United States in early December 2021, *id.*, after adoption of the Interim Final Rule.

126. Moreover, nearly all studies show that while the Omicron variant is more transmissible than previous variants, it causes less severe disease and fewer deaths and hospitalizations. *See* CDC, *Trends in Disease Severity and Health Care Utilization During the Early Omicron Variant Period Compared with Previous Sars-CoV-2 High Transmission Periods—United States, December 2020—January 2022* (Jan. 25, 2022), https://www.cdc.gov/mmw. Even the CDC Director has acknowledged that the Omicron variant is far less severe than Delta. *CDC's Walensky cites study showing Omicron has 91% lower risk of death than Delta*, yahoo!news (Jan. 12, 2022), https://news.yahoo.com/cdc-walensky.

127. Moreover, emerging research shows that standard COVID-19 vaccinations provide little protection against transmission of the Omicron variant. *See No Omicron immunity without booster, study finds*, THE HARVARD GAZETTE (Jan. 7, 2022), https://news.harvard.edu/gazette/story/2022/01/no-omicron-immunity-without-booster-study-finds/ ("Researchers found that traditional dosing regimens of COVID-19 vaccines available in the U.S. don't produce antibodies capable of recognizing and neutralizing the Omicron variant."); *see also* Daniel Halperin, *Omicron is Spreading. Resistance is Futile*, The Wall St. J. (Jan. 25, 2022), https://www.wsj.com/articles/omicron.

128. Simply put, the Delta variant is gone, and with it the rationale for the Interim Final Rule.

The New Vaccine Mandate on State Survey Agency Employees

129. Despite the fundamental change in underlying circumstances, CMS issued further guidance on January 25, 2022, imposing the Vaccine Mandate on state surveyors performing federal oversight of facilities that accept Medicaid and Medicare funds. CMS, QSO-22-10-ALL, *Vaccination Expectations for Surveyors Performing Federal Oversight* (Jan. 25, 2022), https://www.cms.gov/files/document/qso-22-10-all.pdf.[3] The January 25 Guidance Mandate directs that "[s]urveyors who are not fully vaccinated (unless vaccination is medically contraindicated or the individual is legally entitled to a reasonable ac-

[3] The January 25 Guidance Mandate applies to surveyors from State Survey Agencies or Accrediting Organizations who "enter[] provider and supplies locations …." *Id.* at 2.

commodation under federal civil rights laws because they have a disability or sincerely held religious beliefs, practices, or observances that conflict with the vaccination requirement) should not participate as part of the onsite survey team performing federal oversight of certified providers and suppliers ...." *Id.* at 2. CMS further noted that "[c]urrent performance and timeliness standards for State Survey Agencies and AOs remain, and consideration will not be provided for failures to meet these expectations due to a lack of vaccinated surveyors to complete the mandated workload." Apparently emboldened by the Supreme Court's preliminary decision, the federal government has extended its lone, remaining mandate to employees of the State.

130. State Survey Agencies perform their federal oversight functions pursuant to agreements with the Secretary. *See* 42 U.S.C. § 1395aa(a). Among other things, these varied functions include:

I. Identifying potential participants in the Medicare/Medicaid programs;

II. Explaining to facilities the requirements they must meet in order to qualify for and maintain participation in the Medicare/Medicaid programs;

III. Periodically assessing whether facilities are qualified to participate in the Medicare/Medicaid programs;

IV. Surveying periodically to determine how well various entities comply applicable conditions of participation;

V. Investigating complaints alleging violations of applicable requirements and standards.

131. Many of these surveying functions necessarily require State Survey Agency employees to enter facilities which participate in the Medicaid/Medicare programs. Plaintiffs States have dedicated employees tasked with performing these survey functions; many are not vaccinated against COVID-19 and do not wish to undergo the vaccination procedure. And while the January 25 Guidance Mandate—per CMS—charges State Survey Agencies with "ultimate[] responsibil[ity] for compliance," Jan. 25 Guidance at 3, several States' laws flatly prohibit these agencies from actively enforcing this mandate.

132. While previous guidance directed surveyors to use appropriate personal protective equipment when entering facilities, or to not enter if they were symptomatic, the January 25 Guidance's Mandate is *sui generis*. Never before has CMS purported to demand that—under the operative agreements—state employees performing surveying functions for all participating facilities obtain vaccinations as a criteria for meeting the States' obligations under the agreements. The January 25 Guidance Mandate significantly alters the federal-state balance by, among other things, cutting deeply into the States' traditional prerogatives to manage its own personnel.

133. And though CMS invokes the States' "activities in conducting federal program responsibilities" under the agreements as a basis for its January 25 Guidance Mandate, Jan. 25 Guidance at 3, it follows directly from the antecedent IFR,

itself. *See* 86 Fed. Reg. at 61,574 ("As we do with all new or revised requirements, CMS will issue interpretive guidelines, which include survey procedures, following publication of this IFC. We will advise and train State surveyors on how to assess compliance ….). The January 25 Guidance Mandate—newly arrived—is part and parcel with the Vaccine Mandate; however, none of the new guidance was subject to notice and comment as it was not even revealed until over a month after the IFR.

CLAIMS FOR RELIEF

COUNT I

Notice and Comment Under 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 vis-à-vis (1)(B)(i) (providing for a 30-day delay in effective date). The Vac-

cine Mandate was a major change in the program that will clearly impact healthcare access for millions in predictable ways. By forcing healthcare workers to choose between their jobs or an experimental vaccine they do not want, CMS is affirmatively pinching an already strained workforce—and particularly so in rural areas within the States.

139. Congress also understood that the Medicare-Medicaid programs were quintessential exercises of cooperative federalism. While States rely on the federal government for funding, the federal government relies extensively on the States to administer the programs. That's why in 42 U.S.C. 1395z, Congress directs, [i]n carrying out his functions, relating to determination of conditions of participation by providers of services … the Secretary shall consult with appropriate State agencies ….." The IFR obviously constitutes a major change in the conditions providers must meet to participate in the programs. *See* 86 Fed. Reg. at 61,567 ("We have not previously required any vaccinations ….."). CMS did not consult with State agencies before publication of the IFR, and the Supreme Court indicated that was permissible. Biden, 142 S. Ct. at 654 ("the Secretary … was not required to 'consult with the appropriate State agencies,' 42 U.S.C. §1395z, in advance of issuing the interim rule …. consultation during the deferred notice-and-comment period is permissible."). Yet during the deferred notice-and-comment period—and to date—CMS has not consulted with the States regarding the Rule. States are not bit players in CMS policymaking, and "shall," 42 U.S.C. §1395z, is not a suggestion. Defendants have

violated and continue to violate this mandatory consultation requirement in 42 U.S.C. §1395z.

140. The CMS Vaccine 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 enactment of the Vaccine Mandate aimed to deliver on the President's mass vaccine demands, not to stem the pandemic by enacting measures based on emerging data and best practices.

141. CMS relied on 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) vis-à-vis (e)(1)(B)(ii).

142. The Supreme Court found good cause for issuance of the Interim Final Rule based on the Secretary's concerns about the Delta variant. 142 S. Ct. at 651 ("Th[e] good cause was, in short, the Secretary's belief that any 'further delay' would endanger patient health and safety given the spread of the Delta variant and the upcoming winter season.")

143. It is now established beyond any serious question that the Secretary's speculation was wrong. The Delta variant effectively disappeared from the scene

within weeks of the issuance of the rule. Now, the Omicron variant accounts for roughly 99.9% of the country's cases. CDC, *Covid Data Tracker Weekly Review* (Jan. 28, 2022), https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/past-reports/01282022.html. And studies demonstrate that—even as private protections—standard doses of the three generally available vaccines prevent Omicron infections at diminishing rates. *No Omicron immunity without booster, study finds*, The Harvard Gazette (Jan 7, 2022), https://news.harvard.edu/gazette/story/2022/01/no-omicron-immunity-without-booster-study-finds/.

144. Moreover, while vaccination's effects on transmissibility have always been the subject of serious debate, studies now demonstrate that the primary course of vaccination as mandated by the IFR will not appreciably prevent transmission of the Omicron variant. *See*, CDC, *Omicron Variant: What You Need to Know* (Dec. 20, 2021), https://www.cdc.gov/coronavirus/2019-ncov/variants/omicron-variant.html ("breakthrough infections in people who are fully vaccinated are likely to occur").

145. The January 25 Guidance Mandate bears all the hallmarks of a substantive rule that requires notice and comment. It doesn't explain what CMS believes the IFR means or requires; it extends the Vaccine Mandate to an entirely new category of individuals. It both creates new legal requirements and affects individual rights, rendering it subject to the APA's notice and comment requirements. *See Davidson v. Glickman*, 169 F.3d 996, 999 (5th Cir. 1999).

146. No good cause supports CMS's decision to forego notice and comment and immediately impose the January 25 Guidance Mandate.

147. "[I]t 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.").

148. 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.

149. 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).

150. As noted above, the residual "good cause" asserted by CMS and blessed by the Supreme Court related to the IFR can no longer serve as good cause to forego notice and comment prior to publication of the January 25 Guidance Mandate. The very premises of Delta variant-related concerns have dissipated, and the efficacy of standard vaccine dosages vis-à-vis the Omicron variant is doubtful at best.

151. No rationale set forth in the four corners of the January 25 Guidance Mandate constitutes good cause, either. CMS indicates that "Current data (https://data.cms.gov/covid-19/covid-19-nursing-home-data) shows a strong correlation between the number of COVID-19 cases in nursing homes and lower staff vaccination rates. This demonstrates the importance of vaccination as a primary means for reducing the incidence and spread of COVID-19 in healthcare facilities." January 25 Guidance Mandate at 1–2. First, this data applies only to nursing homes and says nothing about the many other types of facilities with which state surveyors must work. Second, whatever light these nursing home statistics may shed on the situation for surveyors—and CMS provides no explanation—the "correlation" CMS identifies between staff vaccination and resident COVID-19 cases is just that—a correlation. It does not demonstrate causation. Nor could it. The data itself demonstrates this. Compare, for example, Montana and Rhode Island. Rhode Island ranks highest among the States for staff vaccination rates at 99.44%. Montana ranks near the bottom at 69.61%. Yet in Rhode Island nursing homes, confirmed COVID-19 cases per 1,000 residents sits at 826.96. In Montana, meanwhile, the data shows only 692.45 confirmed COVID-19 cases per 1,000 residents.

This data only provides a glimpse into nursing homes, and any purported correlation between staff vaccination rates and resident infections is dubious, at best.

152. Next, the January 25 Guidance Mandate directs surveyors to get vaccinated irrespective of past COVID-19 infection, "because research has not yet shown how long individuals are protected from getting COVID-19 again after being infected." January 25 Guidance Mandate at 2. The Guidance supports this with the following proposition: "Also, vaccination helps protect individuals even if they have already had COVID-19. One study suggested that unvaccinated people who already had COVID-19 may be more than two times as likely as fully vaccinated people to get COVID-19 again." *Id.* Of course, that study investigated incidences of reinfection in May-June 2021, before even Delta became the dominant variant in the U.S. Once again, this Guidance fails to account for contemporaneous COVID-19 infection data. *See, e.g.*, MMWR, *COVID-19 Cases and Hospitalizations by COVID-19 Vaccination Status and Previous COVID-19 Diagnosis—California and New York, May–November 2021*, https://www.cdc.gov/mmwr/volumes/71/wr/mm7104e1.htm?s_cid=mm7104e1_w#contribAff (Jan. 19, 2022) (showing that individuals who survived a previous COVID-19 infection had lower rates of COVID-19 compared to do those who were vaccinated alone during the time when Delta was the dominant variant). And importantly, even the outdated study CMS cited related only to personal COVID-19 infection—not transmissibility.

153. In sum, if these scant justifications can even be understood as "proffered rationales" sufficient to establish good cause and dispense with notice-and-comment procedures, they can't stand up under the requisitely close judicial review. *See Ross*, 848 F.3d at 1132; *Council of the S. Mountains*, 653 F.2d at 580.

154. The January 25 Guidance Mandate is a substantive rule that should have been published—if at all—only after notice and comment procedures. The good cause exception doesn't apply. In fact, the January 25 Guidance Mandate didn't request comments even after-the-fact. Accordingly, its publication violated the APA and the Social Security Act.

COUNT II

Arbitrary and Capricious Enforcement

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. E*ncino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2127 (2016).

160. The IFR utterly fails to account for changes in data and circumstances, a self-evident mainstay of the pandemic so far. In only the recent weeks, new data has shown that neither the Vaccine Mandate nor its underlying rationale remain factually sound. The ground has shifted, for the medical understanding of the virus, its variants, and the available vaccines' risks and rewards undermine the reasoning and the methodology employed by the IFR. If it was true before, the data now unequivocally shows that forcibly vaccinating healthcare workers—if they submitted—will not protect their patients from COVID. But the IFR, by design, can't account for that new reality. Instead, it demands draconian implementation of a Vaccine

Mandate that will do little—if anything—to prevent transmission of the now dominant COVID variant to patients and fellow staff.. That inflexibility reveals a structural defect in the IFR; a failure to consider that things could change. And that oversight is inexcusable given the rapid evolution of this disease and our constantly changing understanding of it over the past two years.

161. The Vaccine Mandate also utterly fails to account for changes in the legal and regulatory landscape of mandated vaccines. The rule was initially designed to work in tandem with mandates on other types of employers, including Head Start Programs, federal contractors, federal employees, and employers with over 100 employees. This would limit the alternative choices of employment for healthcare workers subject to the CMS Vaccine Mandate, further forcing them to choose vaccination over unemployment. Now that these other mandates are enjoined, withdrawn, or otherwise unenforceable, healthcare workers have choices. They are more likely and more freely able to leave their employers if covered by the Vaccine Mandate and seek employment elsewhere—without fear of facing unemployment. And that, of course, will further worsen the staffing shortages in the healthcare sector. The illegality or non-enforcement of the other mandates was not considered by CMS, who was instead deeply reliant on this collective patchwork of mandates. This change in circumstances further undermines the legitimacy of the Vaccine Mandate.

162. The unprecedented magnitude of the Vaccine Mandate, and the failure to consider that its strictures might eventually prove an ill fit to the problem it seeks to address, renders it arbitrary and capricious.

163. For the reasons expressed above, the January 25 Guidance Mandate is also arbitrary and capricious. Both the paucity and irrelevance of the cited justifications demonstrate a fatal lack of "reasoned decisionmaking." *Michigan*, 576 U.S. at 750-52. CMS clearly failed to "examine all relevant factors and record evidence." *Am. Wild Horse Pres. Campaign*, 873 F.3d at 923. Rather, it cherry-picked two studies, neither of which support the anti-transmission goals of the January 25 Guidance Mandate. Indeed, the January 25 Guidance Mandate relies entirely on "conclusory statements"—which is patently arbitrary and capricious. *Encino Motorcars*, 136 S. Ct. at 2127.

COUNT III

The Vaccine Mandate Violates the Spending Clause

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

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

166. "[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).

167. 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.

168. And for the reasons discussed above, the Vaccine Mandate goes far beyond the federal interest in patient health and wellbeing. The Vaccine Mandate is one element of President Biden's otherwise unsuccessful attempt to force COVID-19 vaccination on Americans in every sector of the economy. By treating Medicaid and Medicare as an "element of a comprehensive national plan" to "pressure[e] the States to accept policy changes" related to COVID-19 vaccination, Defendants have attempted to "accomplish[] a shift in kind, not merely degree," in the purpose of those federal programs. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 580, 583 (2012). Because it is not unambiguously clear that forced vaccination is necessary to protect the federal interests specific to Medicaid and Medicare, the CMS Vaccine Mandate violates the Spending Clause.

169. 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 IV

The Vaccine Mandate Violates the Anti-Commandeering Doctrine

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

171. 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).

172. The Vaccine Mandate violates this doctrine by requiring Plaintiff States' state-run hospitals and other facilities that are covered by the Mandate to either fire their unvaccinated employees or forgo all Medicaid (and/or, where applicable, Medicare) funding. This draconian choice is no choice at all for the state-run facilities serving on the front lines.

173. The Vaccine Mandate also commandeers the States because it forces State surveyors to enforce the Mandate by verifying healthcare facility compliance. This commandeering is made worse by the January 25 Guidance Mandate because it now seeks to impose a vaccine mandate on state employees who perform surveying, certification, and enforcement functions on behalf of CMS.

174. The surveyors are state employees who are tasked by the Plaintiff States to enforce compliance with federal regulatory requirements. States typically set policies and procedures for utilizing their limited resources to survey facilities in compliance with federal requirements related to a host of health and safety concerns, but the prioritization has now been set by CMS instead.

175. The January 25 Guidance Mandate not only dictates with granular detail the safety precautions it demands States require of their surveyors, but also requires surveyors to obtain a vaccine, document state employee compliance, and develop policies to enforce state employee compliance. State Survey Agency Surveyors must also set policies to govern enforcement of the Vaccine Mandate upon their own state employees. They are "ultimately responsible" for compliance with the Vaccine Mandate.

176. This "dragoons" States into enforcing federal policy by threatening Plaintiff States' Medicaid (and, where applicable, Medicare) funds. States are left with no real choice but to allow their employees to be commandeered and used to enforce federal policy.

COUNT V

The Vaccine Mandate Violates the Tenth Amendment

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

178. "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.

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

180. The Vaccine Mandate seeks to exercise power beyond what was delegated to the federal government. The power to impose vaccine mandates, to the extent any such power exists, is a power reserved to the states. 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. Massachusetts*, 197 U.S. 11, 24 (1905); *see also Hillsborough Cnty. v. Auto. Med. Labs.*, 471 U.S. 707, 719 (1985) ("[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.").

181. Reading CMS's authority as including the power to mandate vaccines throughout an entire industry violates the Tenth Amendment by trampling on the traditional authority of the States to regulate public health within their borders, including the topic of compulsory vaccination. *Cf. Alabama Ass'n of Realtors*, 141 S. Ct. 2485, 2489 (2021). ("[Supreme Court] precedents require Congress to enact exceedingly clear language if it wishes to significantly alter the balance between federal and state power and the power of the Government over private property."). The January 25 Guidance Mandate for state surveyors amplifies the Tenth Amendment violation by further disrupting the traditional balance between the States and the federal government.

182. Reading CMS's authority as including the power to completely override States' authority to manage state personnel violates the Tenth Amendment. But the January 25 Guidance Mandate requires that state employees obtain a vaccine, a policy decision that would ordinarily fall squarely within a State's police power. Even though States regularly enter into agreements with the federal government to use state personnel to carry out certain policies or implement programs, this arrangement must include a limit. It is simply not possible to presume CMS has this sort of limitless power without violating the core structure of the Constitution.

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

COUNT VI

The Vaccine Mandate is Based Upon an Unconstitutional Delegation of Authority

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

185. "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." U.S. Const. amend. X. The U.S. Constitution provides that "[a]ll legislative powers herein granted shall be vested in a Congress of the United States," *not* in the Federal Executive. U.S. Const. art. I, § 1.

186. Under the U.S. Supreme Court's precedent, "a statutory delegation is constitutional as long as Congress lays down by legislative act an intelligible principle to which the person or body authorized to exercise the delegated authority is directed to conform." *Gundy v. United States*, 139 S. Ct. 2116, 2123 (2019). Congress must offer "specific restrictions" that "meaningfully constrain[]" the agency's exercise of authority. *Mistretta v. United States*, 488 U.S. 361, 372 (1989). Moreover, Congress must "speak clearly when authorizing an agency to exercise powers of vast economic and political significance." *Alabama Assn. of Realtors v. Department of HHS*, 594 U.S. __, __ (2021) (slip. op. at 6).

187. As previously explained, the Vaccine Mandate and January 25 Guidance Mandate intrude on the States' historic and traditional authority to regulate health and safety in healthcare settings. This federal policy preference implicates vast political considerations, perhaps the most contentious political issue of the day, and will significantly harm the ability of States to continue to provide healthcare to

their populations by forcing millions of healthcare workers to obtain a vaccine or lose their jobs.

188. Here, even if CMS has the statutory authority it claims it has in promulgating the Vaccine Mandate and January 25 Guidance Mandate, such a delegation of authority would be unlawful. There is no intelligible principle to guide CMS nor any limit or direction for how it is to exercise such power.

189. 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" are limitless. *Whitman v. Am. Trucking Assoc.*, 531 U.S. 457, 475 (2001). Yet Congress lacks authority to delegate "unfettered power" over the American economy to an executive agency. *Tiger Lily, LLC v. HUD*, 5 F.4th 666, 672 (6th Cir. 2021). 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.").

190. If Congress truly granted CMS the authority to issue the Vaccine Mandate and the January 25 Guidance Mandate under the Social Security Act, then the Act and CMS's reliance on it to issue the Vaccine Mandate and the January 25 Guidance Mandate violate the Nondelegation Doctrine.

PRAYER FOR RELIEF

NOW, THEREFORE, Plaintiffs request an order and judgment:

1. Declaring that the Interim Final Rule and the January 25 Guidance Mandate fail to comply with the notice and comment requirement of the APA and Social Security Act;
2. Declaring that the Interim Final Rule and the January 25 Guidance Mandate are arbitrary and capricious;
3. Declaring that the Interim Final Rule and the January 25 Guidance Mandate violate the Constitution;
4. Preliminarily and permanently enjoining, without bond, Defendants from imposing and enforcing the Vaccine Mandates;
5. Tolling the Mandates' compliance deadlines pending judicial review;
6. Granting all other relief to which Plaintiff States are entitled, including but not limited to attorneys' fees and costs.

Dated: February 4, 2022

Respectfully Submitted,

By: */s/ Elizabeth Murrill*

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* *Pro Hac Vice Forthcoming*

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that I presented the above and foregoing for filing and uploading to the CM/ECF system which will send electronic notification of such filing to all counsel of record.

Alexandria, Louisiana, this 4th day of February, 2022.

/s/ Elizabeth Murrill
OF COUNSEL