UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
PENSACOLA DIVISION

STATE OF FLORIDA,

Plaintiff,

v. Case No. 3:21-cv-2722

DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, in his official capacity as Secretary of the Department of Health and Human Services; The UNITED STATES OF AMERICA; CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare and Medicaid; THE CENTERS FOR MEDICARE AND MEDICAID,

Defendants.
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COMPLAINT FOR TEMPORARY RESTRAINING ORDER, PRELIMINARY AND PERMANENT INJUNCTIVE RELIEF, AND DECLARATORY RELIEF

INTRODUCTION

1. Many American workers were able to stay home at the peak of the pandemic. But our healthcare workers were on the front lines, risking their lives to keep us safe. Working conditions were tough, exacerbating an already worsening staffing shortage.

2. While these same workers continue to bravely discharge their duties, President Biden is now telling over 10 million of them that they must get vaccinated or lose their jobs. In his words, any resistance to this mandate—even by those with natural immunity—is claiming the "freedom to kill [others] with [their] COVID."[1]

3. This action is unprecedented. As the federal government concedes, it has "not previously required" mandatory vaccination for the healthcare industry. *See Medicare and Medicaid Programs: Omnibus COVID-19 Health Care Staff Vaccination*, 86 Fed. Reg. 61,555 (Nov. 5, 2021) (the mandate). In fact, the federal government has "not previously required" mandatory vaccination for *any* private industry. Just months ago, the Biden Administration made clear that mandating vaccines is "not the role of the federal government."[2]

4. It is also reckless. The healthcare industry is in the throes of what "some are calling the worst U.S. health-care labor crisis in memory."[3] Indeed, pandemic-related burnout has created critical staffing shortages nationwide. Compounding the problem, many healthcare employees do not want to take the COVID-19 vaccine, particularly in small, rural areas already short on personnel. Combined, these factors

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[1] *CNN Presidential Town Hall With President Joe Biden*, CNN (Oct. 21, 2021), https://transcripts.cnn.com/show/se/date/2021-10-21/segment/01.

[2] *Press Briefing by Press Secretary Jen Psaki, July 23, 2021*, The White House (July 23, 2021), https://www.whitehouse.gov/briefing-room/press-briefings/2021/07/23/press-briefing-by-press-secretary-jen-psaki-july-23-2021/.

[3] Carey Goldberg & Jonathan Levin, *Vaccine Mandates Hit Amid Historic Health-Care Staff Shortage*, Bloomberg (Oct. 2, 2021), https://www.bloomberg.com/news/articles/2021-10-02/vaccine-mandates-hit-amid-historic-health-care-staff-shortage.

have created a powder keg, and healthcare officials fear a vaccine mandate could spark an exodus of workers from the industry. Given these severe conditions, even a minor loss of staff could have a "disastrous impact" on patient care.[4]

5. Against this backdrop, the federal government previously determined that less-intrusive safety regulations were appropriate to combat the spread of COVID-19 in healthcare facilities. *E.g.*, Medicare and Medicaid Programs; COVID-19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals With Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff, 86 Fed. Reg. 26,306 (May 13, 2021); Occupational Exposure to COVID-19; Emergency Temporary Standard, 86 Fed. Reg. 32,376 (June 21, 2021).

6. But as healthcare workers grappled with the deeply personal decision of whether to take a vaccine, President Biden's "patience . . .w[ore] thin," and he grew "ang[ry] at those who haven't gotten vaccinated."[5] Unwilling to wait any longer, on September 9, 2021, President Biden announced several administrative actions aimed at mandating vaccines, which together affect roughly 100 million Americans.[6]

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[4] *Health care group worried vaccine mandate will impact Missouri nursing homes*, Fox 2 Now (Nov. 5, 2021), https://fox2now.com/news/health-care-group-worried-vaccine-mandate-will-impact-missouri-nursing-homes/.

[5] *Remarks by President Biden on Fighting the COVID-19 Pandemic*, The White House (Sept. 9, 2021), https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/09/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-3/.

[6] *Id.*

7. As relevant here, he announced that the Department of Health & Human Services (HHS) would issue a rule requiring vaccination for all employees working in Medicare- or Medicaid-participating facilities.[7] On November 5, 2021, the Centers for Medicare and Medicaid (CMS), an HHS component, did so. *See* 86 Fed. Reg. at 61,555.

8. In its effort to fast-track the President's agenda, however, CMS exceeded its statutory authority and flouted key procedural safeguards that Congress enacted to protect the public from hasty and reactive decision-making.

9. To start, CMS lacks the power to issue an industry-wide vaccination mandate. The statutes it relies on do not provide it such sweeping authority. In fact, CMS is forbidden from exerting this level of control over the healthcare industry. *See* 42 U.S.C. § 1395.

10. Lack of authority aside, CMS also failed to fulfill its statutory duty "to consult with appropriate State agencies" in developing the mandate, *see* 42 U.S.C. § 1395z—a grievous dereliction of duty given that CMS has never before mandated vaccination and thus lacks an understanding of how its mandate will affect the States.

11. Making matters worse, CMS sidestepped the notice and comment process set out in the Administrative Procedure Act (APA). *See* 5 U.S.C. § 553. And

[7] *Biden-Harris Administration to Expand Vaccination Requirements for Health Care Settings*, CMS (Sept. 9, 2021), https://www.cms.gov/newsroom/press-releases/biden-harris-administration-expand-vaccination-requirements-health-care-settings.

though it claims "good cause" to do so, *see id.* § 553(b)(B), its primary justifications—the two-year-old COVID-19 pandemic and the Delta variant—do not satisfy the exceedingly high and exceptional "good cause" standard.

12. On top of all this, CMS acted arbitrarily and capriciously in issuing the mandate. *See* 5 U.S.C. § 706(2)(A). It fails to adequately consider the viability of less-intrusive measures like testing, the harmful effects the mandate will have on the healthcare staffing crisis and vaccine-education efforts, the effects of natural immunity and new COVID-19 treatments, the reliance interests of healthcare employers and employees, and the incongruence between its vaccine requirement and its stated goal of protecting patients and staff. It also fails to connect the statistics driving its mandate with most of the facilities covered by it or to sufficiently justify its extreme departure from the federal government's prior practices.

13. Finally, the mandate violates the Spending Clause—which requires that conditions on federal funds be unambiguous—by changing the terms of an agreement Florida has with the federal government midstream and without notice.

14. Because CMS's rushed and unlawful mandate threatens to defund the State's medical facilities, bleed them of vital staff, hamper the quality of their medical care, and harm both Florida's economy and the health of its citizens, Florida seeks immediate relief from this Court.

PARTIES

15. Plaintiff State of Florida is a sovereign State and has the authority and responsibility to protect its public fisc and the health, safety, and welfare of its citizens. It is also the operator of medical-service providers that receive Medicare or Medicaid funding. And its health agency—the Agency for Health Care Administration (AHCA)—administers Florida's Medicaid plan and assists CMS in regulating facilities that participate in Medicare.

16. Defendants are the United States, appointed officials of the United States government, and United States governmental agencies responsible for the issuance and implementation of the challenged administrative actions.

17. Florida sues Defendant the United States of America under 5 U.S.C. §§ 702–703 and 28 U.S.C. § 1346.

18. Defendant CMS issued the mandate and is a component of HHS.

19. Defendant Chiquita Brooks-LaSure is the Administrator of CMS. She is sued in her official capacity.

20. Defendant HHS oversees CMS.

21. Defendant Xavier Becerra is the Secretary of HHS. He is sued in his official capacity.

JURISDICTION AND VENUE

22. The Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1346, 1361 and 5 U.S.C. §§ 702–03.

23. The Court is authorized to award the requested declaratory and injunctive relief under 5 U.S.C. § 706, 28 U.S.C. §§ 1361, 2201–02, the Constitution, and the Court's equitable powers.

24. Venue lies in this district pursuant to 28 U.S.C. § 1391(e)(1) because the State of Florida is a resident of every judicial district in its sovereign territory, including this judicial district (and division). *See California v. Azar*, 911 F.3d 558, 570 (9th Cir. 2018).[8] And because medical facilities receive Medicare and Medicaid funding in this district and division, a substantial part of the events or omissions giving rise to Florida's claims occurred here.

FACTUAL BACKGROUND

The Medicare and Medicaid Schemes

25. Medicare and Medicaid are federal programs that pay medical expenses for certain individuals.

[8] *Accord Alabama v. U.S. Army Corps of Eng'rs*, 382 F. Supp. 2d 1301, 1329 (N.D. Ala. 2005); *see also Atlanta & F.R. Co. v. W. Ry. Co. of Ala.*, 50 F. 790, 791 (5th Cir. 1892) (explaining that "the state government . . . resides at every point within the boundaries of the state").

26. Medicare is an insurance program.[9] It provides health-insurance coverage to individuals who are at least 65-years-old and are entitled to monthly Social Security benefits, and to disabled individuals who meet certain requirements. 42 U.S.C. § 1395 *et seq.* CMS administers the program on behalf of the Secretary of HHS. *See Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 651 n.3 (2003).

27. Medicaid is an assistance program.[10] It pays medical bills for low-income individuals. 42 U.S.C. § 1396 *et seq.* It is "the primary federal program for providing medical care to indigents at public expense." *Mem'l Hosp. v. Maricopa Cnty.*, 415 U.S. 250, 262 n.19 (1974). The program is administered jointly by the States and the federal government through a "contract[ual]" relationship. *NFIB v. Sebelius*, 567 U.S. 519, 577 (2012). Federal funds are distributed to qualifying States, which administer their Medicaid programs pursuant to federal requirements.

28. To be eligible to receive payments from either Medicare or Medicaid, participating medical-care providers must enter into agreements with the federal government or the administering State in which they agree to comply with federally imposed conditions of participation, coverage, or certification. *E.g.*, 42 U.S.C.

[9] *What is the difference between Medicare and Medicaid*, HHS, https://www.hhs.gov/answers/medicare-and-medicaid/what-is-the-difference-between-medicare-medicaid/index.html.
[10] *Id.*

§§ 1395cc(b)(2), 1396a(a)(33)(B). Some requirements are created by statute. *E.g.*, 42 U.S.C. § 1395x. Others are created by CMS regulations. *E.g.*, 42 C.F.R. part 482.

29. To ensure compliance with these conditions, CMS contracts with state health agencies to "survey" participating medical-care providers. 42 U.S.C. §§ 1395aa(a), 1396a(a)(33)(B). Florida is no exception—AHCA surveys participating providers on behalf of CMS.

Current State of the Healthcare Industry

30. The COVID-19 pandemic has placed tremendous strain on the nation's healthcare industry, creating perhaps the "worst U.S. health-care labor crisis in memory."[11] As of October 1, 2021, about 16% of U.S. hospitals had "critical staffing shortages."[12] In some places, as many as 25% of beds are going unfilled because the facilities lack adequate staffing.[13] And rural areas are bearing a disproportionate share of the burden, making up 60% of staffing shortages nationwide[14] despite serving less than 20% of the population.[15]

[11] Carey Goldberg & Jonathan Levin, *Vaccine Mandates Hit Amid Historic Health-Care Staff Shortage*, Bloomberg (Oct. 2, 2021), https://www.bloomberg.com/news/articles/2021-10-02/vaccine-mandates-hit-amid-historic-health-care-staff-shortage.
[12] *Id.*
[13] *Id.*
[14] Aallyah Wright, *Rural Hospitals Can't Find the Nurses They Need to Fight COVID*, Stateline (Sept. 1, 2021), https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2021/09/01/rural-hospitals-cant-find-the-nurses-they-need-to-fight-covid.
[15] *Rural Report: Challenges Facing Rural Communities and the Roadmap to Ensure Local Access to High-quality, Affordable Care*, American Hospital Association at 2, https://www.aha.org/system/files/2019-02/rural-report-2019.pdf.

31. A chief driver of the crisis is employee burnout, which has reached "epidemic proportions."[16] In one study, "[a]n overwhelming 55% of frontline-health care workers reported burnout (defined as mental and physical exhaustion from chronic workplace stress)."[17] Almost 30% have considered "leaving the medical field" altogether,[18] and over 500,000 have done so already.[19]

32. Another driver is money. Drawn by lucrative salary raises—some approaching 800%—many healthcare workers have left in-house staffs for contract staffing agencies.[20] Depleted by these losses, healthcare providers have been forced to turn to these very agencies to fill their staffing gaps, paying "well above normal" for their services.[21] This staffing arms race has hit healthcare providers across the board,[22] but it has been especially difficult for small rural hospitals that cannot afford

[16] Dharam Kaushik, *Medical burnout: Breaking bad*, AAMC (June 4, 2021), https://www.aamc.org/news-insights/medical-burnout-breaking-bad.
[17] *Id.*
[18] *Id.*
[19] Mallory Hackett, *Healthcare lost 17,500 jobs in September amid ongoing labor shortage*, Healthcare Finance (Oct. 11, 2021), https://www.healthcarefinancenews.com/news/healthcare-lost-17500-jobs-september-amid-ongoing-labor-shortage.
[20] Leticia Miranda, *Rural hospitals losing hundreds of staff to high-paid traveling nurse jobs*, NBC News (Sept. 15, 2021), https://www.nbcnews.com/business/business-news/rural-hospitals-losing-hundreds-staff-high-paid-traveling-nurse-jobs-n1279199.
[21] Bertha Coombs, *Regulations slow urgent hiring of doctors and nurses amid coronavirus outbreak, staffing firms say*, CNBC (Mar. 28, 2020), https://www.cnbc.com/2020/03/28/coronavirus-regulations-slow-hiring-of-doctors-and-nurses-staffing-firms-say.html.
[22] *Hospitals and Health Systems Face Unprecedented Financial Pressures Due to COVID-19*, American Hospital Association (May 2020), https://www.aha.org/guidesreports/2020-05-05-hospitals-and-health-systems-face-unprecedented-financial-pressures-due.

to pay inflated contract staffing rates or increase salaries to keep their employees in-house.[23]

33. Florida has not been immune to this staffing emergency. For example, 92% of long term care facilities in Florida face a staffing crunch; for 75% of them, it is "the number one concern."[24] And Florida's vacancy rate for nurses is 11%—more than a full percentage point above the national average.[25]

34. Compounding the staffing crisis, many healthcare workers, both nationally and in Florida, do not want to receive the COVID-19 vaccine. A nationwide survey found that 25% of nurses had personal concerns about taking the vaccine.[26] In Florida, data published just a few months ago found that between 40–50% of hospital employees had not been vaccinated.[27] And in rural areas—which

[23] Leticia Miranda, *Rural hospitals losing hundreds of staffto high-paid traveling nurse jobs* (Sept. 15, 2021), https://www.nbcnews.com/business/business-news/rural-hospitals-losing-hundreds-staff-high-paid-traveling-nurse-jobs-n1279199.

[24] Jake Stofan, *Health care industry asking Florida lawmakers to address chronic staffing shortages*, WFLA (Nov. 1, 2021), https://www.wfla.com/news/florida/health-care-industry-asking-florida-lawmakers-to-address-chronic-staffing-shortages/.

[25] *Id.*

[26] Christopher O'Donnell, *Tampa Bay hospitals push COVID vaccine – but won't mandate it for their workers*, Tampa Bay Times (Sept. 3, 2021), https://www.tampabay.com/news/health/2021/09/03/tampa-bay-hospitals-push-covid-shot-but-wont-mandate-it-for-their-workers/.

[27] Liz Crawford, *AHCA: 42% of Florida hospital workers weren't vaccinated, as of June 4*, WTSP (July 22, 2021), https://www.wtsp.com/article/news/health/coronavirus/vaccine/hospital-workers-not-vaccinated/67-9e842ff1-e5b0-4f1f-8f9f-ccfec865ccbf; David Bauerlein, *UF Health Jacksonville finding widespread vaccine hesitancy among its own staff*, Jacksonville.com (July 23, 2021), https://www.jacksonville.com/story/news/2021/07/23/uf-health-ceo-says-overcoming-vaccine-hesitancy-challenge-among-staff/8075987002/.

have the most "dire" staffing shortages of all[28]—the statistics are even bleaker. One study found that in 30% of rural hospitals nationwide, less than half of the staff have received a COVID-19 vaccine.[29]

35. This confluence of factors has left many healthcare administrators worried that a vaccine mandate could push the industry over the edge. They fear "many employees [will] quit rather than comply"—a "huge concern" given current staffing deficiencies.[30] The concern is not merely speculative: In some places, triple-digit numbers of workers have resigned or been fired for refusing to take a vaccine.[31] One Florida-based administrator estimates that a mandate would cause him to "lose 10 to 15 percent of [his] staff."[32] But this estimate is on the low end: A recent survey found that 37% of unvaccinated workers would leave their jobs if their employers

[28] Aallyah Wright, *Rural Hospitals Can't Find the Nurses They Need to Fight COVID*, Stateline (Sept. 1, 2021), https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2021/09/01/rural-hospitals-cant-find-the-nurses-they-need-to-fight-covid.
[29] Tamara Keith, *Why Lagging COVID Vaccine Rate At Rural Hospitals 'Needs To Be Fixed Now'*, NPR (May 4, 2021), https://www.npr.org/2021/05/04/993270974/why-lagging-covid-vaccine-rate-at-rural-hospitals-needs-to-be-fixed-now.
[30] Christopher O'Donnell, *Tampa Bay hospitals push COVID vaccine – but won't mandate it for their workers*, Tampa Bay Times (Sept. 3, 2021), https://www.tampabay.com/news/health/2021/09/03/tampa-bay-hospitals-push-covid-shot-but-wont-mandate-it-for-their-workers/.
[31] Dan Diamond, *153 people resigned or were fired from a Texas hospital system after refusing to get vaccinated*, The Washington Post (June 22, 2021), https://www.washingtonpost.com/health/2021/06/22/houston-methodist-loses-153-employees-vaccine-mandate/.
[32] Hannah Mitchell, *'Like hand-to-hand combat': Florida health system battles vaccine hesitancy 1 employee at a time*, Becker's Hospital Review (Nov. 4, 2021), https://www.beckershospitalreview.com/hospital-management-administration/like-hand-to-hand-combat-florida-health-system-battles-vaccine-hesitancy-1-employee-at-a-time.html.

mandated vaccination or weekly testing.[33] And if mandatory vaccination is the only option, 72% say they will quit.[34]

36. Employee flight does not just hamper the healthcare industry's capacity to fight COVID-19, but to address other healthcare risks as well. As the CEO of one Florida health system put it: "If today I said, 'everybody's required to take the vaccine or you're terminated,' then I have a problem being able to take care of people who show up to our ER with strokes, or chest pains, or medical admissions or surgical admissions."[35] And as CMS concedes, 86 Fed. Reg. at 61,612, given the already-severe staffing shortage in the healthcare industry, "[e]ven a small fraction of" so-called "recalcitrant unvaccinated employees" could "disrupt facility operations," *id.*, and have a "disastrous impact" on patient care.[36]

37. To be sure, *encouraging* vaccination of healthcare workers is good policy. Indeed, such measures have proven effective in Florida. To cite one example,

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[33] Liz Hamel et al., *KFF COVID-19 Vaccine Monitor: October 2021*, KFF (Oct. 28, 2021), https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-october-2021/.

[34] *Id.*

[35] Jacqueline LaPointe, *Hospitals Staffing Shortages a Concerns with Mandatory Vaccinations*, Revcycle Intelligence (July 26, 2021), https://revcycleintelligence.com/news/hospital-staffing-shortages-a-concern-with-mandatory-vaccinations.

[36] *Health care group worried vaccine mandate will impact Missouri nursing homes*, Fox 2 Now (Nov. 5, 2021), https://fox2now.com/news/health-care-group-worried-vaccine-mandate-will-impact-missouri-nursing-homes/.

a healthcare system raised staff vaccination rates by 10% through vaccination-education strategies.[37]

38. Mandates, however, are another matter altogether. In addition to the issues already discussed, they may even "chill" individuals who might otherwise take the vaccine voluntarily.[38]

The Federal Government's Response to the COVID-19 Pandemic

39. In January 2020, HHS declared the COVID-19 pandemic a public health emergency. Though public health emergency designations naturally expire after 90 days, 42 U.S.C. § 247d, HHS has renewed the designation each time it was set to expire.[39]

40. Almost a year ago, in December 2020, COVID-19 vaccines began to become available to the general public. On December 11, 2020, the Food & Drug Administration (FDA) authorized the emergency use of the two-dose Pfizer-Biotech vaccine. A week later, FDA did the same for the two-dose Moderna vaccine. On

[37] Hannah Mitchell, *'Like hand-to-hand combat': Florida health system battles vaccine hesitancy 1 employee at a time*, Becker's Hospital Review (Nov. 4, 2021), https://www.beckershospitalreview.com/hospital-management-administration/like-hand-to-hand-combat-florida-health-system-battles-vaccine-hesitancy-1-employee-at-a-time.html.
[38] Bailey LeFever, *Majority of Florida's long-term care staffers refused coronavirus vaccine*, Tampa Bay Times (Apr. 1, 2021), https://www.tampabay.com/news/health/2021/04/01/majority-of-floridas-long-term-care-staffers-refused-coronavirus-vaccine/.
[39] *COVID-19 Public Health and Medical Emergency Declarations and Waivers*, PHE (Apr. 16, 2021), https://www.phe.gov/emergency/events/COVID19/Pages/2019-Public-Health-and-Medical-Emergency-Declarations-and-Waivers.aspx.

February 27, 2021, FDA did the same for the one-dose Johnson & Johnson vaccine.[40] And almost immediately, healthcare workers became eligible to take the vaccine.[41]

41. Despite these authorizations and the longstanding public health emergency declaration, the federal government never sought to mandate vaccinations to fight COVID-19 in any sector, let alone the healthcare sector. Rather, it opted for less-intrusive measures. In May 2021, for instance, CMS issued an interim final rule (IFR) that required long term care facilities and intermediate care facilities for individuals with intellectual disabilities to educate staff and residents about the vaccine and make the vaccine available to them. 86 Fed. Reg. at 26,306 (May IFR). This, in CMS's view, was "necessary to help protect the health and safety" of residents. *Id.* Mandatory vaccination, however, was not required.

42. Similarly, in June 2021, the Occupational Health and Safety Administration (OSHA) issued a COVID-19 Healthcare Emergency Temporary Standard (ETS), which aimed to protect healthcare workers from occupational exposure to COVID-19. 86 Fed. Reg. at 32,376 (June ETS). Under the June ETS—which remains in effect—covered healthcare employers must implement measures like transmission-based precautions, personal protective equipment, and physical

[40] Carl Zimmer et al., *Coronavirus Vaccine Tracker*, The New York Times, https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html.

[41] Maggie Fox, *Some Americans should start getting the first Covid-19 vaccine today. It will take months before everyday people get the shots*, CNN (Dec. 14, 2020), https://www.cnn.com/2020/12/14/health/covid-vaccine-timeline/index.html (reporting that healthcare workers would be eligible for vaccination in December 2020).

distancing. *Id.* at 32,426–57. The June ETS also requires employers to provide paid leave for employees to receive COVID-19 vaccines. *Id.* at 32,599. But like CMS's May IFR, the June ETS did not mandate vaccination.

The Biden Administration's Actions

43. Despite pushing the envelope in numerous ways during the COVID-19 pandemic, *e.g.*, *Ala. Ass'n of Realtors v. HHS*, 141 S. Ct. 2485, 2486 (2021); *Florida v. Becerra*, 8:21-cv-839, 2021 WL 2514138 (M.D. Fla. June 18, 2021), the Biden Administration at first drew a hard line on vaccine mandates: In its view, mandating vaccines was "not the role of the federal government."[42]

44. Not long after, though, the President's "patience" with the unvaccinated "w[ore] thin," prompting him to announce three new administrative actions aimed at compelling much, if not most, of the adult population in the United States to receive a COVID-19 vaccine.[43]

45. First, the President announced that he would issue an executive order requiring all executive branch employees and federal contractors to be vaccinated.[44]

[42] *Press Briefing by Press Secretary Jen Psaki, July 23, 2021*, The White House (July 23, 2021), https://www.whitehouse.gov/briefing-room/press-briefings/2021/07/23/press-briefing-by-press-secretary-jen-psaki-july-23-2021/.
[43] *Remarks by President Biden on Fighting the COVID-19 Pandemic*, The White House (Sept. 9, 2021), https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/09/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-3/.
[44] *Id.*

46. Second, the President announced that the Department of Labor would develop an emergency rule mandating that private employers with 100 or more employees require their employees to become fully vaccinated or submit to weekly testing.[45]

47. Finally, as relevant here, the President announced that the federal government would publish a rule mandating vaccines for employees who work at healthcare facilities that accept Medicare and Medicaid.[46] Even though he stated a month earlier that HHS would only require nursing homes to vaccinate their employees,[47] he expanded this mandate, announcing that the rule would require all participating facilities to have their employees vaccinated.[48]

The Mandate

48. CMS published that regulation—the mandate—on November 5, 2021. 86 Fed. Reg. at 61,555.

[45] *Id.*
[46] *Id.*
[47] *FACT SHEET: President Biden to Announce New Actions to Protect Americans from COVID-19 and Help State and Local Leaders Fight the Virus*, The White House (Aug. 18, 2021), https://www.whitehouse.gov/briefing-room/statements-releases/2021/08/18/fact-sheet-president-biden-to-announce-new-actions-to-protect-americans-from-covid-19-and-help-state-and-local-leaders-fight-the-virus/.
[48] *Biden-Harris Administration to Expand Vaccination Requirements for Health Care Settings*, CMS (Sept. 9, 2021), https://www.cms.gov/newsroom/press-releases/biden-harris-administration-expand-vaccination-requirements-health-care-settings.

49. The mandate directs participating facilities[49] to ensure that covered employees[50] submit to COVID-19 vaccination, unless the employees are eligible for a religious or medical exemption. *Id.* at 61,572.

50. The mandate deploys "a common set of provisions for each" participating facility; there are "no substantive regulatory differences across settings." *Id.* at 61,570.

51. It operates in two phases. Phase 1 requires that covered employees receive either the first dose of a two-dose vaccine or the sole dose of a single-dose vaccine by December 6, 2021. *Id.* at 61,573. Phase 2 requires that covered employees receive the second dose of a two-dose vaccine by January 4, 2022. *Id.*

52. To comply with the mandate, a participating facility must implement a "process for tracking and securely documenting the COVID-19 vaccination status

[49] Participating facilities subject to the mandate include: 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, generally referred to as nursing homes; intermediate care facilities for individuals with intellectual disabilities; home health agencies; comprehensive outpatient rehabilitation facilities; critical access hospitals; clinics, rehabilitation agencies, and 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. 86 Fed. Reg. at 61,569–70.

[50] Covered employees subject to the mandate include: facility employees; licensed practitioners; students, trainees, and volunteers; and individuals who provide care, treatment, or other services for the facility and/or its patients, under contract or other arrangement. 86 Fed. Reg. 61,570. The requirements also extend to staff who provide care outside of a formal clinical setting and to "any individual that performs their duties at any site of care, or has the potential to have contact with anyone at the site of care." *Id.* at 61,570–71. Employees working 100% remotely are exempt. *Id.* at 61,571.

of all staff," including booster-shot status. 42 C.F.R. § 416.51(c)(3)(iv)–(v). It must also "track[] and securely document[]" all exemptions. *Id.* § 416.51(c)(3)(vi)–(vii). And it must implement "[c]ontingency plans" for all persons who are "not fully vaccinated." *Id.* § 416.51(c)(3)(x).

53. As for enforcement, CMS intends to issue "interpretive guidelines" that outline "enforcement remedies" CMS can pursue against participating facilities that do not comply. 86 Fed. Reg. at 61,574. These will include "civil money penalties, denial of payments for new admissions, or termination of the Medicare/Medicaid provider agreement." *Id.* A senior White House official has made clear that CMS "will not hesitate to use [its] full enforcement authority" to carry out the mandate.[51]

54. CMS, however, does not intend to enforce the mandate alone—it expects the States to help. Consistent with their contracts with CMS, *see* 42 U.S.C. § 1395aa(a), States must verify that healthcare facilities operating in their borders comply with the mandate. CMS plans to "advise and train State surveyors on how to assess compliance with the new requirements" and how to review "the entity's records of staff vaccinations." 86 Fed. Reg. at 61,574. It will also "instruct surveyors

[51] *Background Press Call on OSHA and CMS Rules for Vaccination in the Workplace*, The White House (Nov. 3, 2021), https://www.whitehouse.gov/briefing-room/press-briefings/2021/11/04/background-press-call-on-osha-and-cms-rules-for-vaccination-in-the-workplace/.

to conduct interviews staff [sic] to verify their vaccination status," and will tell surveyors how they "should cite" facilities "when noncompliance is identified." *Id.*

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

56. The mandate has "near-universal applicability" to healthcare staff, covering an estimated 10.3 million employees. *Id.* at 61,603. By CMS's own estimate, about 2.4 million of these employees are unvaccinated. *Id.* at 61,607. And, as CMS concedes, the mandate's chief aim is to coerce these unvaccinated employees to submit to vaccination upon pain of unemployment. *See id.* ("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 61,608 ("[I]t is possible there may be disruptions in cases where substantial numbers of health care staff refuse vaccination and are not granted exemptions and are terminated, with consequences for employers, employees, and patients.").

CMS's Failure to Consult or Engage in Notice and Comment

57. CMS concedes that this is new ground for the agency. By its own admission, it has "not previously required" mandatory vaccinations as a condition for participation in Medicare or Medicaid. *Id.* at 61,567. In fact, the federal

government has never required any private industry to submit to mandatory vaccination.

58. Despite this marked departure from prior practice, though, CMS did not "consult" with "appropriate State agencies" before issuing its Mandate, as it is required to do under 42 U.S.C. § 1395z. *Id.* at 61,567. In CMS's view, the consultation statute does not require that it consult *before* publishing a rule. *Id.* And even if it did, says CMS, there is no agency with which it would be "appropriate" to consult before publishing the rule "[g]iven the urgent need" for a mandate here. *Id.*

59. Similarly, CMS did not engage with interested stakeholders through the notice and comment process. *Id.* at 61,583 (citing 5 U.S.C § 553(b); 42 U.S.C § 1395hh(b)(1)). Instead, it found for "good cause" that it would "be impracticable and contrary to the public interest . . . to undertake normal notice and comment procedures." *Id.* at 61,586. It supported its good-cause determination based primarily on the COVID-19 pandemic, the Delta variant, and the upcoming flu season. *See id.* at 61,583–84.

CMS's Justifications for the Mandate

60. In justifying its mandate, CMS offers internally inconsistent reasoning and fails to adequately consider data that undermined its decision.

61. To start, CMS claims to consider "concerns about health care workers choosing to leave their jobs rather than be vaccinated," yet it ultimately finds that

the mandate was justified given that there is "insufficient evidence to quantify and compare adverse impacts on patient and resident care associated with temporary staffing losses due to mandates and absences due to quarantine for known COVID-19 exposures and illness." *Id.* at 61,569.

62. This lack of data, however, is not cause to issue an industry-wide mandate; it is cause to exercise *restraint* in issuing such a mandate.

63. As CMS concedes, there "might be a certain number of health care workers who choose" to leave the medical field because of the mandate. *Id.* at 61,569. And because it is "unknown . . . how rapidly those quitting rather than being vaccinated could be replaced," *id.* at 61,612, CMS admits that current "endemic staff shortages . . . may be made worse if any substantial number of unvaccinated employees leave health care employment altogether," *id.* at 61,607. Indeed, given the already "critical staffing shortage," *id.* at 61,559, CMS acknowledges that worker resignations need not even be substantial to do damage: If "[e]ven a small fraction of" those CMS pejoratively labels "recalcitrant unvaccinated employees" quit, it "could disrupt facility operations." *Id.* at 61,612. In some cases, this impact will be "disastrous,"[52] especially in rural areas, which, as CMS admits, are "having greater problems with employee vaccination." *Id.* at 61,613.

[52] *Health care group worried vaccine mandate will impact Missouri nursing homes*, Fox 2 Now (Nov. 5, 2021), https://fox2now.com/news/health-care-group-worried-vaccine-mandate-will-impact-missouri-nursing-homes/.

64. Along with this, CMS recognizes that the "providers and suppliers regulated under this rule are diverse in nature, management structure, and size." *Id.* at 61,602. Even so, CMS relies mostly on facts and figures involving long term care facilities—providers who serve mostly elderly and often immunocompromised patients—to justify applying the mandate to other Medicare- and Medicaid-certified providers. *See, e.g.*, *id.* at 61,585 (discussing "case rates among [long term care] facility residents," and claiming, without citation that those facilities' "experience may generally be extrapolated to other settings"). CMS does so despite conceding that "[a]ge remains a strong risk factor for severe COVID-19 outcomes," *id.* at 61,566, and that "risk of death from infection from an unvaccinated 75- to 84-year-old person is 320 times more likely than the risk for an 18- to 29-years old person," *id.* at 61,610 n.247.

65. CMS also claims to have "considered requiring daily or weekly testing of unvaccinated individuals" instead of mandatory vaccination. *Id.* at 61,614. But it rejects this alternative in about a sentence, concluding that vaccination is a "more effective infection control measure." *Id.* OSHA, by contrast, issued a vaccine mandate on the same day that includes a weekly testing alternative. *See* COVID-19 Vaccination and Testing; Emergency Temporary Standard, 86 Fed. Reg. 61,402, 61,450 (Nov. 5, 2021). Indeed, despite concluding that testing is "not as effective as vaccination," OSHA permitted testing because it is "still effective" and because

OSHA had concerns about imposing a "strict vaccination mandate with no alternative" on such short notice given the potential "economic and health impacts" of such a decision.[53] *Id.* at 61,433, 61,436.

66. CMS further "considered whether it would be appropriate to limit COVID-19 vaccination requirements to staff who have not previously been infected by SARS-CoV-2." 86 Fed. Reg. at 61,614. Yet it decides against that option because it does not think that "natural immunity" is "equivalent to receiving the COVID-19 vaccine." *Id.* at 61,559. Elsewhere, however, CMS recognizes the value of natural immunity when it states that each day 100,000 people are "recover[ing] from infection," that they "are *no longer sources of future infections*," and that their natural immunity "reduce[s] the risk to both health care staff and patients substantially." *Id.* at 61,604 (emphasis added). And indeed, a highly reported study from Israel found that "natural immunity confers longer lasting and stronger protection" against the Delta variant than vaccination.[54]

67. CMS claims that the mandate is needed to protect patients from COVID-19 infection, yet it does not require that patients be vaccinated and

[53] OSHA also could not establish a "grave danger" to most healthcare workers because it found that its June ETS adequately protects against COVID-19 risk. 86 Fed. Reg. at 61,421. CMS does not acknowledge this finding.

[54] *See* Sivan Gazit et al., *Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections*, medRxiv (Aug. 24, 2021), https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1.

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

Irreparable Harm to Florida

68. The mandate places Florida in an untenable position. On the one hand, if Florida refuses to comply with the mandate, its state-run facilities that participate in Medicare and Medicaid will be subject to fines and lose millions of dollars in funding. On the other hand, if Florida complies with the mandate, its facilities will lose critical staff, exacerbating an already-severe staffing crisis. To weather the staffing dip, its facilities will either need to pay exorbitant premiums to contract staffing agencies or provide a diminished quality of patient care. They will also bear the cost of ensuring that their employees have complied with the mandate, which they cannot recover in a suit against the federal government. *See Chiles v. Thornburgh*, 865 F.2d 1197, 1209 (11th Cir. 1989); *Odebrecht Const., Inc. v. Sec'y, Fla. Dep't of Transp.*, 715 F.3d 1268, 1289 (11th Cir. 2013). And adding insult to injury, compliance will make Florida complicit in an unlawful policy that it fundamentally opposes, undermining its sovereignty.

69. Florida's AHCA also faces an equally untenable choice. It is obligated by contract and the mandate to survey participating facilities to verify compliance with the mandate. If it refuses to comply, it stands to lose millions in federal funding. And if it submits, it will be forced to expend additional resources while carrying out

CMS's compliance checks, which it again cannot recover in a suit against the federal government. *See Chiles*, 865 F.2d at 1209.

70. Further, the mandate will require private healthcare facilities in Florida to bear the administrative cost of ensuring compliance with the mandate, which they too cannot recover. *Id.* They will also lose employees who refuse to submit to vaccination, further straining the resources of those facilities, injuring the public health, and taxing Florida's economy.

71. Finally, the Florida Legislature is currently contemplating legislation that would prohibit vaccine mandates.[55] This legislation is likely to pass within the next few days. Once it does, Florida will face an additional sovereign injury.

CLAIMS

COUNT 1

Agency action that is not in accordance with law and is in excess of authority, in violation of the APA

72. Florida repeats and incorporates by reference ¶¶ 1–71.

73. Under the APA, a court must "hold unlawful and set aside agency action" that is "not in accordance with law," "in excess of statutory . . . authority, or

[55] *Governor DeSantis Joined By President Simpson and Speaker Sprowls to Announce Legislative Agenda for Special Session of the Florida Legislature*, Florida Governor's Office (Nov. 8, 2021), https://www.flgov.com/2021/11/08/governor-desantis-joined-by-president-simpson-and-speaker-sprowls-to-announce-legislative-agenda-for-special-session-of-the-florida-legislature/.

limitations, or short of statutory right," or "without observance of procedure required by law." *See* 5 U.S.C. § 706(2)(A), (C)–(D).

74. The mandate is contrary to law for at least two reasons.

75. *First*, the mandate violates 42 U.S.C. § 1395z because it was issued without required consultation with the States.

76. Under § 1395z, CMS "shall consult with appropriate State agencies and recognized national listing or accrediting bodies" in "carrying out [its] functions" relating to "determination of conditions of participation" for many healthcare providers subject to the mandate. 42 U.S.C. § 1395z.[56] CMS did not do so.

77. *Second*, the mandate exceeds CMS's statutory authority.

78. Indeed, Congress speaks clearly when it "authoriz[es] an agency to exercise powers of vast economic and political significance." *Ala. Ass'n of Realtors*, 141 S. Ct. at 2489. And courts apply a presumption that Congress "preserves the constitutional balance between the National Government and the States." *Bond v. United States*, 572 U.S. 844, 862 (2014). But nothing in the several provisions that govern Medicaid and Medicare clearly authorizes a vaccine mandate.

[56] Specifically, the consultation requirement applies to conditions of participation for hospitals under § 1395x(e)(9), psychiatric hospitals under § 1395x(f)(4), skilled nursing facilities under §§ 1395x(j) and 1395i-3, home health agencies under § 1395x(o)(6), comprehensive outpatient rehabilitation facilities under § 1395x(cc)(2), hospices under § 1395x(dd)(2), critical access hospitals under §§ 1395x(mm)(1) and 1395i-4(e), and ambulatory surgical centers under § 1395k(a)(2)(F)(i).

79. To the contrary, § 1395 makes clear that no federal officer may "exercise any supervision or control" over (a) "the practice of medicine or the manner in which medical services are provided," (b) "the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services," or (c) "the administration or operation of any such institution, agency, or person." 42 U.S.C. § 1395. The mandate does just that.

80. For these reasons, the mandate is contrary to law.

COUNT 2

Failure to conduct notice and comment in violation of the APA

81. Florida repeats and incorporates by reference ¶¶ 1–71.

82. The APA requires notice of, and comment on, agency rules that "affect individual rights and obligations." *Chrysler Corp. v. Brown,* 441 U.S. 281, 303 (1979); *see* 5 U.S.C. §§ 553, 706(2)(D). The Medicare and Medicaid schemes track these requirements. *See* 42 U.S.C § 1395hh(b)(1).

83. CMS concedes that it did not engage in notice and comment. 86 Fed. Reg. at 61,583. Instead, it invokes the "good cause" exception, which permits an agency to waive notice and comment when it finds for "good cause" that the process is "impracticable, unnecessary, or contrary to the public interest." *Id.* at 61,583 (citing 5 U.S.C § 553(b)(B)). This standard is notoriously difficult to satisfy. *See Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 93 (D.C. Cir. 2012).

84. CMS relies on the COVID-19 pandemic for good cause, along with related circumstances like the Delta variant. *Id.* at 61,583–84. Of course, no one contests the seriousness of the COVID-19 pandemic. But after almost two years, COVID-19 is a persistent feature of life and cannot itself constitute good cause. *See Becerra*, 2021 WL 2514138, at *45; *Regeneron Pharms., Inc. v. HHS*, 510 F. Supp. 3d 29, 48 (S.D.N.Y. 2020). To hold otherwise would effectively repeal notice and comment requirements for the duration of the pandemic.

85. In fact, CMS's own delay is what caused its so-called emergency. Vaccines have been available to healthcare workers for nearly a year. 86 Fed. Reg. at 61,584.[57] But until now, CMS made no efforts to mandate vaccination. "Good cause cannot arise as a result of the agency's own delay." *Nat. Res. Def. Council v. Nat'l Highway Traffic Safety Admin.*, 894 F.3d 95, 114 (2d Cir. 2018). And CMS waited nearly three additional months between announcing the mandate and publishing it.

86. CMS's other good-cause justifications fare no better. Most prevalent, it cites the possibility for a "more severe" flu season as support for good cause given the risks of "coinfection" and increased "stress" on the healthcare system. *See* 86

[57] Maggie Fox, *Some Americans should start getting the first Covid-19 vaccine today. It will take months before everyday people get the shots*, CNN (Dec. 14, 2020), https://www.cnn.com/2020/12/14/health/covid-vaccine-timeline/index.html (reporting that healthcare workers would be eligible for vaccination in December 2020).

Fed. Reg. at 61,584. Yet in the next breath, CMS admits that "the intensity of the upcoming 2021–2022 influenza season cannot be predicted" and that "influenza activity during the 2020–2021 season was low throughout the U.S." *Id.*

87. Moreover, notice and comment is needed to bolster the "fairness, wisdom, and political legitimacy" of a rule of this magnitude. *Becerra*, 2021 WL 2514138, at *45 (quoting Hickman & Pierce, Administrative Law Treatise § 5.10 (6th ed. 2020)).

88. For these reasons, notice and comment was required.

COUNT 3

Arbitrary and capricious agency action in violation of the APA

89. Florida repeats and incorporates by reference ¶¶ 1–71.

90. Under the APA, a court must "hold unlawful and set aside agency action" that is "arbitrary [or] capricious." 5 U.S.C. § 706(2)(A). The mandate is arbitrary and capricious for several reasons.

91. First, the mandate does not adequately consider the alternative of testing requirements. *See DHS v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1913 (2020). CMS claims to have "considered requiring daily or weekly testing of unvaccinated individuals" instead of mandatory vaccination. 86 Fed. Reg. at 61,614. But it dismisses this alternative in a cursory sentence, proclaiming that vaccination is a "more effective infection control measure." *Id.*

92. Second, CMS fails to "articulate a satisfactory explanation" for why its mandate is "rational" given that unvaccinated workers may flee the industry. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

93. Third, CMS fails to adequately consider the impact its mandate will have on vaccination-education efforts. In Florida, those efforts have had great success, sometimes raising vaccination rates by ten percent.[58] Yet CMS fails to consider to what extent its mandate will "chill" individuals who might otherwise take the vaccine voluntarily.

94. Fourth, CMS does not rationally connect its statistics to most of the healthcare facilities covered by its mandate. Indeed, CMS recognizes that the "providers and suppliers regulated under this rule are diverse in nature, management structure, and size." *Id.* at 61,602. Still, CMS relies mostly on facts and figures involving long term care facilities—providers that serve mostly elderly or immunocompromised patients—to justify applying the mandate to other providers. *See, e.g.*, *id.* at 61,585.

95. Fifth, CMS does not consider the rate at which "game-changing" COVID-19 treatments minimize the more-serious health risks of COVID-19. Nor

[58] Hannah Mitchell, *'Like hand-to-hand combat': Florida health system battles vaccine hesitancy 1 employee at a time*, Becker's Hospital Review (Nov. 4, 2021), https://www.beckershospitalreview.com/hospital-management-administration/like-hand-to-hand-combat-florida-health-system-battles-vaccine-hesitancy-1-employee-at-a-time.html.

does CMS consider the viability of state-by-state approaches to mandatory vaccination, despite acknowledging that, in some States, COVID-19 cases "are trending downward." *Id.* at 61,583–84.

96. Sixth, CMS concludes that prior COVID-19 infection should not qualify a covered employee for an exemption from the mandate because it is not equivalent to receiving a COVID-19 vaccine. *Id.* at 61,559, 61,614. Elsewhere, however, CMS recognizes the value of natural immunity. *See id.* at 61,604 (finding natural immunity "reduce[s] the risk to both health care staff and patients substantially"); *id.* (noting that those who recover are "in very rare cases still infectious").

97. Seventh, CMS inconsistently claims the mandate will protect patients while recognizing, in its cost-benefit analysis, that "the effectiveness of the vaccine to prevent disease transmission by those vaccinated [is] not currently known." *E.g.*, 86 Fed. Reg. at 61,569, 61,615.

98. Eighth, CMS fails to consider the interests of millions of healthcare workers who pursued their careers without knowing they would be subject to mandated vaccination. *Regents*, 140 S. Ct. at 1913. And it ignores the reliance interests of healthcare employers, including the States, who ordered their affairs under the assumption that Medicaid and Medicare dollars would be available without this onerous condition.

99. Ninth, the mandate is the product of political pressure, not measured judgment. *Aera Energy LLC v. Salazar*, 642 F.3d 212, 220 (D.C. Cir. 2011). The true impetus is clear: facing a scandal over his actions in Afghanistan, dismal approval numbers on his COVID response, and an inability to advance his legislative agenda, President Biden succumbed to pressure to control the healthcare decisions of millions. He did so even though his Administration had assured the public that vaccine mandates are "not the role of the federal government."[59]

100. Finally, CMS fails to adequately explain its extreme departure from its prior practice of not mandating vaccines. *See E. Bay Sanctuary Covenant v. Trump*, 349 F. Supp. 3d 838, 858 (N.D. Cal. 2018); *accord Regents*, 140 S. Ct. at 1913.

101. For these reasons, the mandate is arbitrary and capricious.

COUNT 4

Violation of the Spending Clause

102. Florida repeats and incorporates by references ¶¶ 1–71.

103. The mandate is also an unconstitutional condition on Florida's receipt of federal funds.

"[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."

[59] *Press Briefing by Press Secretary Jen Psaki, July 23, 2021*, The White House (July 23, 2021), https://www.whitehouse.gov/briefing-room/press-briefings/2021/07/23/press-briefing-by-press-secretary-jen-psaki-july-23-2021/.

Pennhurst State Sch. & Hosp. v. Halderman, 451 U.S. 1, 17 (1981). Here, Florida agreed to a lucrative contract, paying millions in federal funds, to enforce Medicare and Medicaid requirements on healthcare providers. When it agreed to do so, however, it was given no notice that it would have to enforce vaccination requirements. Florida now faces the untenable choice of refusing to enforce the mandate, and losing millions, or acquiescing. But the Spending Clause does not allow the government to put Florida to this choice—any conditions must have been disclosed to Florida from the beginning. *Pennhurst*, 451 U.S. at 17; *cf. NFIB*, 567 U.S. at 584.

104. For this reason, the mandate violates the Spending Clause.

COUNT 5

Declaratory judgment that the Biden Administration's policy is unlawful

105. Florida repeats and incorporates by reference ¶¶ 1–71.

106. For the same reasons described in Counts 1–4, Florida is entitled to a declaratory judgment that Defendants are violating the law.

PRAYER FOR RELIEF

For these reasons, Florida asks the Court to:

a) Hold unlawful and set aside the mandate.

b) Issue a temporary restraining order and preliminary and permanent injunctive relief enjoining Defendants from enforcing the mandate.

c) Issue declaratory relief declaring Defendants' actions unlawful.

d) Award Florida costs and reasonable attorney's fees.

e) Award such other relief as the Court deems equitable and just.

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
PENSACOLA DIVISION

STATE OF FLORIDA,

Plaintiff,

v. Case No. 3:21-cv-2722

DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants.
_____/

FLORIDA'S MOTION FOR A TEMPORARY RESTRAINING ORDER OR PRELIMINARY INJUNCTION

Even before the COVID-19 pandemic, the healthcare industry faced a worker shortage. The pandemic has made it far worse. Over half-a-million employees have left the industry since the pandemic began, with hundreds more departing each day. Rural America has been hit hardest. Despite this crisis, the Biden Administration has given frontline healthcare workers an unrelenting ultimatum: submit to mandatory COVID vaccination or lose your job.

For a myriad of reasons, many healthcare workers in Florida will refuse the vaccine and be forced into unemployment, triggering a cascade of harmful effects across the State. Healthcare staffing rates will plummet, especially in rural areas. Florida will struggle to care for its disabled; its veterans will find it harder to obtain admission to nursing homes; prisoners will face delays in obtaining emergency

medical services; the mentally incompetent will spend more time in jail as treatment facilities work through the backlog; and the sick and vulnerable will receive inferior care.

These ills would have been readily apparent had the federal government followed the procedural protections designed to prevent this type of hasty decision-making. Had the Administration, for example, consulted with the States as required by law, Florida would have informed the government of the terrible effects the mandate would have. Similarly, had the government conducted notice and comment—rather than deploying an implausible "good cause" finding—the public would have explained the many drawbacks of the mandate.

Instead, the Biden Administration published an interim final rule on November 5 that requires covered employees to receive their first dose by December 6. To prevent the many harms that will accompany that deadline, Florida requests a preliminary injunction before December 6 and a temporary restraining order if the Court cannot afford preliminary relief by then.

BACKGROUND

Medicare and Medicaid

Medicare and Medicaid are federal programs that pay medical expenses for certain individuals. Medicare is an insurance program that covers medical bills for elderly and disabled individuals; Medicaid is an assistance program that pays

medical bills for low-income individuals.[1] The Centers for Medicare & Medicaid Services (CMS) primarily administers Medicare and partners with States to administer Medicaid. *See Douglas v. Indep. Living Ctr. of S. Cal., Inc.*, 565 U.S. 606, 610 (2012) (discussing CMS's role in Medicaid); *Cape Cod Hosp. v. Sebelius*, 630 F.3d 203, 205 (D.C. Cir. 2011) (discussing CMS's role in Medicare).

To be eligible to receive payments from either Medicare or Medicaid, participating providers must agree to comply with federally imposed conditions of participation, coverage, or certification. *E.g.*, 42 U.S.C. §§ 1395cc(b)(2), 1396a(a)(33)(B). Some requirements are created by statute. *E.g.*, *id.* § 1395x. Others are created by CMS regulations. *E.g.*, 42 C.F.R. part 482.

To ensure compliance with these conditions, CMS contracts with state health agencies to "survey" participating providers. 42 U.S.C. §§ 1395aa(a), 1396a(a)(33)(B). Florida is no exception—its Agency for Health Care Administration (AHCA) surveys participating providers on behalf of CMS. Ex. 1 ¶¶ 5–7.

[1] *What is the difference between Medicare and Medicaid*, HHS, https://www.hhs.gov/answers/medicare-and-medicaid/what-is-the-difference-between-medicare-medicaid/index.html.

Current State of the Healthcare Industry

Reeling from the COVID-19 pandemic, the healthcare industry is facing the "worst U.S. health-care labor crisis in memory."[2] Frontline workers—who unwaveringly faced the worst days of the pandemic—are experiencing unprecedented levels of exhaustion and fatigue, with almost 30% considering leaving the medical field[3] and over 500,000 having done so already.[4] Further exacerbating this crisis, many have left healthcare facilities for private staffing companies that can promise higher wages,[5] causing many facilities to turn to these private companies to fill the gaps—often paying an exorbitant premium.[6]

All this has put the healthcare industry on life support. For example, last month about 16% of U.S. hospitals reported "critical staffing shortages."[7] In some

[2] Carey Goldberg & Jonathan Levin, *Vaccine Mandates Hit Amid Historic Health-Care Staff Shortage*, Bloomberg (Oct. 2, 2021), https://www.bloomberg.com/news/articles/2021-10-02/vaccine-mandates-hit-amid-historic-health-care-staff-shortage.

[3] Dharam Kaushik, *Medical burnout: Breaking bad*, AAMC (June 4, 2021), https://www.aamc.org/news-insights/medical-burnout-breaking-bad.

[4] Mallory Hackett, *Healthcare lost 17,500 jobs in September amid ongoing labor shortage*, Healthcare Finance (Oct. 11, 2021), https://www.healthcarefinancenews.com/news/healthcare-lost-17500-jobs-september-amid-ongoing-labor-shortage.

[5] Leticia Miranda, *Rural hospitals losing hundreds of staff to high-paid traveling nurse jobs*, NBC News (Sept. 15, 2021), https://www.nbcnews.com/business/business-news/rural-hospitals-losing-hundreds-staff-high-paid-traveling-nurse-jobs-n1279199.

[6] Bertha Coombs, *Regulations slow urgent hiring of doctors and nurses amid coronavirus outbreak, staffing firms say*, CNBC (Mar. 28, 2020), https://www.cnbc.com/2020/03/28/coronavirus-regulations-slow-hiring-of-doctors-and-nurses-staffing-firms-say.html.

[7] Carey Goldberg & Jonathan Levin, *Vaccine Mandates Hit Amid Historic Health-Care Staff Shortage*, Bloomberg (Oct. 2, 2021), https://www.bloomberg.com/news/articles/2021-10-02/vaccine-mandates-hit-amid-historic-health-care-staff-shortage.

places, as many as 25% of beds are going unfilled because the facilities lack adequate staffing.[8] And rural areas are bearing a disproportionate share of the burden, making up 60% of staffing shortages nationwide[9] despite serving less than 20% of the population.[10]

Florida has not been immune to this crisis. For instance, 92% of long term care facilities in Florida face a staffing crunch; for 75% of them, it is "the number one concern."[11] And Florida's vacancy rate for nurses is 11%—more than a full percentage point above the national average.[12]

A vaccine mandate threatens to make these dire conditions worse. As of a few months ago, 40–50% of hospital employees in Florida had not been vaccinated.[13] And in rural areas, the statistics are even bleaker, with some reports showing that

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[8] *Id.*

[9] Aallyah Wright, *Rural Hospitals Can't Find the Nurses They Need to Fight COVID*, Stateline (Sept. 1, 2021), https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2021/09/01/rural-hospitals-cant-find-the-nurses-they-need-to-fight-covid.

[10] *Rural Report: Challenges Facing Rural Communities and the Roadmap to Ensure Local Access to High-quality, Affordable Care*, American Hospital Association at 2, https://www.aha.org/system/files/2019-02/rural-report-2019.pdf.

[11] Jake Stofan, *Health care industry asking Florida lawmakers to address chronic staffing shortages*, WFLA (Nov. 1, 2021), https://www.wfla.com/news/florida/health-care-industry-asking-florida-lawmakers-to-address-chronic-staffing-shortages/.

[12] *Id.*

[13] Liz Crawford, *AHCA: 42% of Florida hospital workers weren't vaccinated, as of June 4*, WTSP (July 22, 2021), https://www.wtsp.com/article/news/health/coronavirus/vaccine/hospital-workers-not-vaccinated/67-9e842ff1-e5b0-4f1f-8f9f-ccfec865ccbf; David Bauerlein, *UF Health Jacksonville finding widespread vaccine hesitancy among its own staff*, Jacksonville.com (July 23, 2021), https://www.jacksonville.com/story/news/2021/07/23/uf-health-ceo-says-overcoming-vaccine-hesitancy-challenge-among-staff/8075987002/.

30% of rural hospitals nationwide have less than half of their employees vaccinated.[14]

Healthcare administrators are already preparing for the fallout of a vaccine mandate. One Florida-based administrator estimates that a mandate would cause him to "lose 10 to 15 percent of [his] staff."[15] Indeed, a recent study confirms his fears, reporting that 37% of unvaccinated workers would leave their jobs if their employers mandated vaccination or weekly testing and 72% would leave if the only option were vaccination.[16]

The Biden Administration's Actions

On September 9, 2021, President Biden announced three sweeping and unprecedented initiatives aimed at compelling roughly two-thirds of American workers to receive a COVID-19 vaccine.[17] Florida has already challenged two of the initiatives—the Occupational Safety and Health Administration (OSHA) mandate and the federal contractor mandate—and challenges the third here.

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[14] Tamara Keith, *Why Lagging COVID Vaccine Rate At Rural Hospitals 'Needs To Be Fixed Now'*, NPR (May 4, 2021), https://www.npr.org/2021/05/04/993270974/why-lagging-covid-vaccine-rate-at-rural-hospitals-needs-to-be-fixed-now.

[15] Hannah Mitchell, *'Like hand-to-hand combat': Florida health system battles vaccine hesitancy 1 employee at a time*, Becker's Hospital Review (Nov. 4, 2021), https://www.beckershospitalreview.com/hospital-management-administration/like-hand-to-hand-combat-florida-health-system-battles-vaccine-hesitancy-1-employee-at-a-time.html.

[16] Liz Hamel et al., *KFF COVID-19 Vaccine Monitor: October 2021*, KFF (Oct. 28, 2021), https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-october-2021/.

[17] *Remarks by President Biden on Fighting the COVID-19 Pandemic*, The White House (Sept. 9, 2021), https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/09/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-3/.

On November 5, 2021, as directed by the President, CMS published an interim final rule titled "Omnibus COVID-19 Health Care Staff Vaccination." 86 Fed. Reg. 61,555 (Nov. 5, 2021). The mandate directs participating facilities to ensure that covered employees submit to COVID-19 vaccination unless the employees are eligible for a religious or medical exemption. *Id.* at 61,570–73. Whether employees opt for a single-dose or double-dose vaccine, they must receive their first shot by December 6. *Id.* at 61,573. Participating facilities must track vaccination status of their employees. *Id.* at 61,572.

In the mandate, CMS claims to have considered "concerns about health care workers choosing to leave their jobs rather than be vaccinated," yet ultimately finds there is "insufficient evidence to quantify and compare" that effect with "absences due to quarantine for known COVID-19 exposures and illness." *Id.* at 61,569. CMS concedes there "might be a certain number of health care workers who choose" to leave the medical field because of the mandate. *Id.* And CMS admits that current "endemic staff shortages . . . may be made worse if any substantial number of unvaccinated employees leave health care employment altogether." *Id.* at 61,607.

CMS also recognizes that participating facilities range dramatically in "nature, management structure, and size." *Id.* at 61,602. Even so, CMS relies mostly on facts and figures involving long term care facilities—providers who primarily serve elderly or immunocompromised patients—to justify applying the mandate to

other providers. *See, e.g.*, *id.* at 61,585 (discussing "case rates among [long term care] facility residents," and claiming, without citation, that those facilities' "experience may generally be extrapolated to other settings").

CMS claims to have "considered requiring daily or weekly testing of unvaccinated individuals" instead of mandatory vaccination but, in a single sentence, concludes that vaccination is a "more effective infection control measure." *Id.* at 61,614. The OSHA mandate, in contrast, includes a weekly testing alternative. *See* COVID-19 Vaccination and Testing; Emergency Temporary Standard, 86 Fed. Reg. 61,402, 61,450 (Nov. 5, 2021). Indeed, despite concluding that testing is "not as effective as vaccination," OSHA permitted testing because it is "still effective" and because OSHA had concerns about imposing a "strict vaccination mandate with no alternative" on such short notice given the potential "economic and health impacts" of such a decision.[18] *Id.* at 61,433, 61,436.

CMS similarly claims to have considered limiting vaccination requirements to those who have not been infected with COVID-19, but cursorily concludes that prior infection is not equivalent to vaccination. 86 Fed. Reg. at 61,614. Even so, CMS recognizes that those who recover are "in very rare cases still infectious." *Id.*

[18] OSHA also could not establish a "grave danger" to most healthcare workers because it found that a rule it passed in June—which requires precautionary measures but does not mandate vaccines—is adequate to protect against COVID-19 risk. 86 Fed. Reg. at 61,421. CMS did not acknowledge this finding.

at 61,604. And indeed, a highly reported study from Israel found that "natural immunity confers longer lasting and stronger protection" against the Delta variant than vaccination.[19]

All these considerations brushed aside, CMS barrels through to its ultimate conclusion that a vaccine mandate is the only measure adequate to combat the pandemic. *Id.* at 61,560 ("[W]e are compelled to require staff vaccinations for COVID-19."). While the mandate relies on the existence of a declared public health emergency to justify much of its reasoning, CMS admits that this is not its true basis, previewing that the mandate will be "a permanent requirement for facilities." *Id.* at 61,574.

Despite the unprecedented nature of mandatory vaccinations—indeed, CMS acknowledges that it has "not previously required" vaccinations as a condition for participation—CMS issued the mandate as an interim final rule without notice and comment. *Id.* at 61,567. In support of "good cause" to dispense with notice and comment, CMS's points to the "strain on the health care system" caused by the pandemic, *id.* at 61,584, the "emergence of the Delta variant," *id.* at 61,583, and the upcoming flu season, *id.* at 61,584. CMS admits, however, that vaccines first became

[19] *See* Sivan Gazit et al., *Comparing SARS-CoV-2 Natural Immunity to Vaccine-Induced Immunity: Reinfections Versus Breakthrough Infections*, medRxiv (2021 preprint), https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1.

available in December 2020—almost a year ago—and that "health care workers were among the first groups provided access to vaccinations." *Id.* at 61,584.

CMS also declined to comply with its statutory obligation to consult with appropriate state agencies. *See* 42 U.S.C. § 1395z. But unlike for notice and comment, there is no "good cause" exception to that requirement. Despite attempting to regulate countless state agencies, CMS concludes that there is no "entity with which it would be appropriate to engage in these consultations in advance of issuing" the mandate. 86 Fed. Reg. at 61,568.

Eventually, CMS intends to issue "interpretive guidelines" that outline "enforcement remedies" for facilities that do not comply with the mandate. *Id.* at 61,574. Remedies will include "civil money penalties, denial of payments for new admissions, or termination of their Medicare/Medicaid provider agreement." *Id.* A senior White House official has made clear that CMS "will not hesitate to use [its] full enforcement authority" to carry out the mandate.[20]

CMS, however, does not intend to enforce the mandate alone—it expects the States to help. Consistent with their contracts with CMS, *see* 42 U.S.C. § 1395aa(a);

[20] *Background Press Call on OSHA and CMS Rules for Vaccination in the Workplace*, The White House (Nov. 3, 2021), https://www.whitehouse.gov/briefing-room/press-briefings/2021/11/04/background-press-call-on-osha-and-cms-rules-for-vaccination-in-the-workplace/.

Ex. 1 ¶¶ 5–6, 11, States must verify that healthcare facilities operating in their borders comply with the mandate. 86 Fed. Reg. at 61,574.

Irreparable Harm to Florida

If Florida does not comply with the mandate, it faces civil penalties and loss of funding for state-run facilities. For example, Medicare-Medicaid accounts for roughly a quarter of the funding for State Veterans Nursing Homes run by Florida's Department of Veterans' Affairs. Ex. 5 ¶ 10. Moreover, individuals insured by Medicare and Medicaid would lose access to these facilities. If the Department of Health were to lose funding for its qualified health centers, for instance, patients in lower-income and rural areas would need to travel up to 60 miles for prenatal services. Ex. 3 ¶¶ 12, 14.

The harm to Florida extends beyond its own healthcare facilities. The Florida Department of Corrections relies on private hospitals to provide emergency medical services to inmates. Ex. 4 ¶¶ 7–9, 19–20. At these hospitals, corrections officers must be present to protect the safety of medical personnel and other patients. *Id.* ¶¶ 10–11. But the mandate requires vaccination of these officers before they can enter the hospital. *Id.* ¶¶ 4, 13. The Department of Corrections expects the mandate to cause delays in obtaining emergency medical services for inmates, which could be catastrophic to prisoner health and subject the Department to liability for Eighth Amendment violations. *Id.* ¶¶ 16–18.

If Florida instead chooses to comply with the mandate, it similarly faces irreparable harm. Healthcare facilities across the state are suffering from staffing shortages. Ex. 4 ¶ 12; Ex. 2 ¶ 10; Ex. 5 ¶ 9; Ex. 6 ¶¶ 16, 29. This is especially true in Florida's rural areas, which have an inherently limited workforce. Ex. 2 ¶ 10; Ex. 6 ¶¶ 6, 16, 29; *supra* at 5–6. And since many Florida employees would leave if faced with mandatory vaccination, compliance would decrease already limited staff numbers. Ex. 6 ¶ 18 (staff survey suggests a ten percent loss of staff if mandate takes effect).

Resulting staff shortages pose two problems for Florida. First, facilities would be forced to turn to private contractors to fill staffing gaps at a much higher cost. Ex. 5 ¶¶ 9, 11; Ex. 6 ¶¶ 15, 21. Second, if facilities were unable to curb the staffing shortage, they would be unable to provide the same level of care. Florida's Department of Veterans' Affairs, for instance, may need to reduce occupancy at its facilities, forcing veterans onto a waiting list for critical services. Ex. 5 ¶ 12. The Department of Children and Families, meanwhile, would be unable to provide effective treatment programs or safe environments for the mentally incompetent, meaning they would remain imprisoned until a vacancy arises. Ex. 2 ¶ 11–14. At the same time, the Department of Health would need to "cancel[] or significantly delay[]" many healthcare services in rural areas. Ex. 3 ¶ 19. And the Agency for Persons with Disabilities would need to decrease emphasis on direct care and shift

employees to different roles, risking even greater employee burnout and providing less tailored methods of treatment. Ex. 6 ¶¶ 21, 25.

In some cases, a decrease in staff would even put the facilities in jeopardy of failing to comply with state and federal legal requirements, like patient-staff ratios. *See id.* ¶¶ 11–13 (citing 42 C.F.R. § 483.430(c)–(d)), 20. Failure to provide adequate care could also place facilities at risk of emergency action for Immediate Jeopardy—a CMS enforcement mechanism that could result in fines or complete exclusion from the Medicaid-Medicare programs. *See id.* ¶¶ 9–10 (citing 42 C.F.R. part 442).

Adding insult to injury, the mandate also requires AHCA to ensure compliance at public and private facilities statewide. Ex. 1 ¶ 5. AHCA thus faces an untenable choice between losing federal funds or allocating resources to enforce the unlawful mandate. *Id.* ¶¶ 9–11.

Because Defendants imposed a deadline of December 6 for individuals to receive a vaccination and for facilities to have policies in place to track employee vaccination status, Florida's irreparable harm is imminent.

ARGUMENT

A plaintiff seeking a temporary restraining order or preliminary injunction must establish (1) "that he is likely to succeed on the merits," (2) "that he is likely to suffer irreparable harm in the absence of preliminary relief," (3) "that the balance of equities tips in his favor," and (4) "that an injunction is in the public interest."

Winter v. Nat. Res. Def. Council, Inc., 555 U.S. 7, 20 (2008); *accord Schiavo ex rel. Schindler v. Schiavo*, 403 F.3d 1223, 1225–26 (11th Cir. 2005) (explaining that the same standard applies to temporary restraining orders).[21]

I. FLORIDA IS LIKELY TO SUCCEED ON THE MERITS OF ITS CLAIMS.

a. The challenged actions are contrary to law and in excess of statutory authority.

Under the Administrative Procedure Act (APA), courts must "hold unlawful and set aside agency action" that is "not in accordance with law," "in excess of statutory . . . authority, or limitations, or short of statutory right," or "without observance of procedure required by law." *See* 5 U.S.C. § 706(2)(A), (C)–(D). Because the mandate violates multiple statutes, CMS has "gone beyond what Congress has permitted it to do." *City of Arlington v. FCC*, 569 U.S. 290, 298 (2013).

i. CMS failed to consult with appropriate state agencies before issuing the mandate.

Under § 1395z, CMS "shall consult with appropriate State agencies and recognized national listing or accrediting bodies" in "carrying out [its] functions" relating to "determination of conditions of participation" for many healthcare providers subject to the mandate. 42 U.S.C. § 1395z.[22] CMS also "may consult with

[21] Upon filing, Florida will notify the U.S. Department of Justice and the U.S. Attorney for the Northern District of Florida via email.

[22] Specifically, the consultation requirement applies to conditions of participation for hospitals under 42 U.S.C. § 1395x(e)(9), psychiatric hospitals under § 1395x(f)(4), skilled nursing facilities under §§ 1395x(j) and 1395i-3, home health agencies under § 1395x(o)(6), comprehensive outpatient rehabilitation facilities under § 1395x(cc)(2), hospices under § 1395x(dd)(2), critical

appropriate local agencies." *Id.* CMS did not do so. Instead, CMS does not "understand the statute to impose a temporal requirement to do so in advance of the issuance of" the mandate. 86 Fed. Reg. at 61,567.

The problem for CMS, however, is that the text of § 1395z requires the consultation to occur *before* new conditions are promulgated. The statute describes the required consultation as "relating to *determination* of conditions of participation by providers of services." 42 U.S.C. § 1395z (emphasis added). A "determination" is "[t]he act of deciding something officially." *Determination*, Black's Law Dictionary (11th. ed. 2019). The provision's title confirms this meaning by referring to "[c]onsultation with State agencies . . . *to develop* conditions of participation." 42 U.S.C. § 1395z (emphasis added). Consultation after the conditions have been set, as CMS did here, thus violates § 1395z.

CMS also attempts to justify its dereliction by asserting that there is no state agency that is "appropriate" for CMS to consult with. 86 Fed. Reg. at 61,567. Yet CMS misunderstands the meaning of "appropriate" in the statutory phrase requiring it to "consult with appropriate State agencies." 42 U.S.C. § 1395z. The word "appropriate" merely expresses that certain state agencies—those connected with Medicare and Medicaid—are the agencies that CMS must consult with. It does not

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access hospitals under §§ 1395x(mm)(1) and 1395i-4(e), and ambulatory surgical centers under § 1395k(a)(2)(F)(i).

invite CMS to decide for itself whether consultation is "appropriate" given the circumstances. If consultation with state agencies were optional, or at CMS's discretion, Congress would not have used the mandatory "shall" to describe consultation with state agencies and the discretionary "may" to describe consultation with local agencies. *See Jennings v. Rodriguez*, 138 S. Ct. 830, 844 (2018) ("Unlike the word 'may,' which implies discretion, the word 'shall' usually connotes a requirement."); *NFIB v. Sebelius*, 567 U.S. 519, 544 (2012) ("Where Congress uses certain language in one part of a statute and different language in another, it is generally presumed that Congress acts intentionally.").

Because the government failed to consult with States, including Florida, the mandate violates § 1395z.

ii. The mandate exceeds CMS's statutory authority.

Congress speaks clearly when it "authoriz[es] an agency to exercise powers of vast economic and political significance." *Ala. Ass'n of Realtors v. HHS*, 141 S. Ct. 2485, 2489 (2021). And courts apply a presumption that Congress "preserves the constitutional balance between the National Government and the States." *Bond v. United States*, 572 U.S. 844, 862 (2014). Moreover, Spending Clause legislation, like the Medicare and Medicaid programs, is "binding on States only insofar as it is 'unambiguous.'" *Wos v. E.M.A. ex rel. Johnson*, 568 U.S. 627, 654 (Roberts, C.J., dissenting) (quoting *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17

(1981)). CMS's position, however, wrongly assumes that Congress would authorize a vaccine mandate for an entire industry—treading on the police powers of the States—in a "cryptic . . . fashion." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160–61 (2000).

CMS first cites its general rulemaking powers. *See* 86 Fed. Reg. at 61,567 (citing 42 U.S.C. §§ 1302(a), 1395hh(a)(1)). But these provisions merely authorize the Secretary of HHS to "make and publish such rules and regulations . . . as may be necessary to the efficient administration of the functions with which [he] is charged under" the Social Security Act, 42 U.S.C. § 1302(a), and to "prescribe such regulations as may be necessary to carry out the administration of the" Medicare program, *id.* § 1395hh(a)(1). These provisions raise two problems for CMS.

First, "necessary" is a "word of limitation" and is synonymous with "required," "indispensable," and "essential." *Vorcheimer v. Phila. Owners Assoc.*, 903 F.3d 100, 105 (3d Cir. 2018); *accord In re Microsoft Corp. Antitrust Litig.*, 355 F.3d 322, 327 (4th Cir. 2004). And nothing about the mandate is "essential" for the "efficient administration" of Medicaid or "to carry out the administration" of Medicare. *Id.* §§ 1302(a), 1395hh(a)(1). In short, CMS appears to assume that the word "necessary" is far more capacious than its plain meaning.

Second, the two general grants of rulemaking authority cannot grant CMS this authority on their own. Instead, CMS must identify the specific statutes governing

Medicare and Medicaid that it believes it is "administ[ering]" or "carry[ing] out. *Id.* Attempting to do so, CMS runs through a variety of provisions, each of which is specific to particular categories of facilities. 86 Fed. Reg. at 61,567. None of these provisions authorizes the mandate.

As a preliminary matter, the significant variances provision-to-provision call into question the wisdom—as well as the legality—of issuing a singular mandate applicable to so many different facilities. In any event, none of these provisions authorize the mandate. And to prevail, CMS would need to identify adequate statutory authority for *each* type of facility, which it certainly cannot do.

CMS points to several provisions that merely define certain types of services. *See* 86 Fed. Reg. at 61,567 (citing 42 U.S.C. §§ 1396d(h)(1)(B)(i), 1396d(d)(1), 1395x(iii)(3)(D)(i)(IV), 1395x(aa)(2)(K), 1395x(p)(4)(A)(v), 1395x(ff)(3)(B)(iv), 1395x(e)(9), 1395x(dd)(2)(G), 1395x(cc)(2)(J), 1395x(o)(6)). For example, one defines a "qualified home infusion therapy supplier" to include an entity that "meets such other requirements as the Secretary determines appropriate." *Id.* § 1395x(iii)(3)(D)(i)(IV). But even assuming Congress buried a grant of authority in a definitional provision—rather than merely acknowledging that the Secretary may impose requirements by some separate authority—this provision says nothing about vaccine mandates and is far too nebulous to satisfy the clear statement rule

applicable here. *See Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001) (explaining that Congress does not "hide elephants in mouseholes").

CMS also points to provisions governing the criteria for certification of a facility, preconditions for facilities to receive payment, and types of services provided. *See* 42 U.S.C. §§ 1395i-4(e), 1395i-3(d)(4)(B), 1395bbb, 1395rr(b)(1)(A), 1395k(a)(2)(F)(i), 1395eee(f), 1396u-4(f). To illustrate, one provision states that "[a] skilled nursing facility must meet such other requirements relating to the health, safety, and well-being of residents or relating to the physical facilities thereof as the Secretary may find necessary." *Id.* § 1395i-3(d)(4)(B). Again, this language does not clearly authorize an industry-wide vaccine mandate.

If anything, the statute forecloses CMS's position. Section 1395 makes clear that no federal officer may "exercise any supervision or control" over (a) "the practice of medicine or the manner in which medical services are provided," (b) "the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services," or (c) "the administration or operation of any such institution, agency, or person." 42 U.S.C. § 1395. The mandate does just that. It seeks to compel participating facilities to require employees to receive a vaccine, track and gather data about employee vaccination status, and terminate employees who refuse to comply. 86 Fed. Reg. at 61,571–72.

Given the clear statement rule that applies to CMS's sweeping mandate, and the clarification provided by § 1395, the mandate exceeds CMS's authority.

b. Defendants failed to conduct notice and comment.

The APA requires notice of, and comment on, agency rules that "affect individual rights and obligations." *Chrysler Corp. v. Brown*, 441 U.S. 281, 303 (1979); *see* 5 U.S.C. §§ 553, 706(2)(D). The Medicare and Medicaid schemes track these requirements. *See* 42 U.S.C § 1395hh(b)(1).

CMS concedes that it did not engage in notice and comment. 86 Fed. Reg. at 61,583. Instead, it invokes the "good cause" exception, which permits an agency to waive notice and comment when it finds for "good cause" that the process is "impracticable, unnecessary, or contrary to the public interest." *Id.* (citing 5 U.S.C § 553(b)(B)). This standard is notoriously difficult to satisfy. *See Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 93 (D.C. Cir. 2012).

CMS relies on the COVID-19 pandemic for good cause, along with related circumstances like the Delta variant. 86 Fed. Reg. at 61,583–84. Of course, no one contests the seriousness of the COVID-19 pandemic. But after almost two years, COVID-19 is a persistent feature of life and cannot itself constitute good cause. *See Florida v. Becerra*, 8:21-cv-839, 2021 WL 2514138, at *45 (M.D. Fla. June 18, 2021); *Regeneron Pharms., Inc. v. HHS*, 510 F. Supp. 3d 29, 48 (S.D.N.Y. 2020).

To hold otherwise would effectively repeal notice and comment requirements for the duration of the pandemic.

Tellingly, CMS invoked many of the same concerns to justify a finding of good cause in an interim final rule published six months ago, namely the existence of a public health emergency, the need to protect vulnerable patient populations, and strain on the healthcare industry. *See* Medicare and Medicaid Programs; COVID-19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff, 86 Fed. Reg. 26,306, 26,320–21 (May 13, 2021). If the same conditions were present nearly six months ago, it strains credulity to assert them now. *See Chamber of Commerce v. SEC*, 443 F.3d 890, 908 (D.C. Cir. 2006) ("The [good cause] exception excuses notice and comment in *emergency* situations." (emphasis added)).

In fact, CMS's own delay is what caused its so-called emergency. Vaccines have been available to healthcare workers for nearly a year. 86 Fed. Reg. at 61,584.[23] But until now, CMS made no efforts to mandate vaccination. "Good cause cannot

[23] Maggie Fox, *Some Americans should start getting the first Covid-19 vaccine today. It will take months before everyday people get the shots*, CNN (Dec. 14, 2020), https://www.cnn.com/2020/12/14/health/covid-vaccine-timeline/index.html (reporting that healthcare workers would be eligible for vaccination in December 2020).

arise as a result of the agency's own delay," *Nat. Res. Def. Council v. Nat'l Highway Traffic Safety Admin.*, 894 F.3d 95, 114 (2d Cir. 2018).

Further undercutting CMS's good cause is its nearly three-month delay between announcing the mandate and publishing it. *See Regeneron*, 510 F. Supp. 3d at 48 (CMS's two-month delay "suggest[ed] a lack of urgency" that belied a finding of good cause). President Biden first announced a CMS vaccine mandate on August 18, gave specifics about the one here on September 9, and finally published the mandate on November 5. CMS therefore took longer to issue the mandate than participating facilities have to meet its terms. This delay "suggests a lack of urgency" incompatible with a genuine finding of good cause. *Id.*

On top of this, CMS does not appear to believe its own good-cause rationale. To underscore that the pandemic justifies good cause, CMS relies heavily on the declared public health emergency. *E.g.*, 86 Fed. Reg. at 61,583. Yet CMS disclaims the public health emergency as justification for the mandate and makes clear that the mandate will continue to apply even after the public health emergency terminates. *See id.* at 61,574. Put differently, that the mandate is a lasting one, rather than a limited measure during a public health emergency, contradicts CMS's good-cause explanation.

CMS's other good-cause justifications fare no better. Most prevalent, it cites the possibility for a "more severe" flu season as support for good cause given the

risks of "coinfection" and increased "stress" on the healthcare system. *See id.* at 61,584. Yet in the next breath, CMS admits that "the intensity of the upcoming 2021–2022 influenza season cannot be predicted" and that "influenza activity during the 2020–2021 season was low throughout the U.S." *Id.*

Moreover, notice and comment is needed to bolster the "fairness, wisdom, and political legitimacy" of a rule of this magnitude. *Becerra*, 2021 WL 2514138, at *45 (quoting Hickman & Pierce, *Administrative Law Treatise* § 5.10 (6th ed. 2020)). The "more expansive the regulatory reach of" a rule, "the greater the necessity for public comment" to allow those affected to be heard. *Am. Fed'n of Gov't Emp. v. Block*, 655 F.2d 1153, 1156 (D.C. Cir. 1981). And there is no overlooking the magnitude of this rule. CMS has "not previously required" mandatory vaccination for the healthcare industry. 86 Fed. Reg. at 61,567. In fact, no federal agency has *ever* mandated vaccination for a private industry. The mandate represents a sea change in prior practices, meaning that CMS lacks historical perspective about the effect its mandate will have. *See Harris v. McRae*, 448 U.S. 297, 308–09 (1980).

And indeed, the notice and comment process is even more vital in the context of Medicare and Medicaid. These programs "touch[] the lives of nearly all Americans," and are two of the "largest federal program[s]" in the country. *See Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808 (2019). Even "minor changes" to the way the programs are 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 for changes to the "substantive legal standard" affecting the payment for services. 42 U.S.C. § 1395hh(a)(2), (b)(1); *see also id.* § 1395hh(e)(1)(B)(i) (providing for a 30-day delay in effective date for retroactive applications). That provision applies here, and so good cause should be especially difficult to establish.

The Biden Administration claims this is a "once-in-a-generation pandemic."[24] But it is equally true that this is a once-in-a-generation mandate. Notice and comment was required.

c. The mandate is arbitrary and capricious.

Under the APA, a court must "hold unlawful and set aside agency action" that is "arbitrary [or] capricious." 5 U.S.C. § 706(2)(A). The mandate is arbitrary and capricious for several reasons.

First, the mandate does not adequately consider the alternative of testing requirements. *See DHS v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1913 (2020). CMS claims to have "considered requiring daily or weekly testing of unvaccinated individuals" instead of mandatory vaccination. 86 Fed. Reg. at 61,614. But it

[24] *Press Briefing by Press Secretary Jen Psaki*, July 27, 2021, The White House (July 27, 2021), https://www.whitehouse.gov/briefing-room/press-briefings/2021/07/27/press-briefing-by-press-secretary-jen-psaki-july-27-2021/.

dismisses this alternative in a cursory sentence, proclaiming that vaccination is a "more effective infection control measure." *Id.* This mere lip service to a less-restrictive alternative—one that OSHA found "effective" given the short timeframe and the unknown "economic and health impacts" of a strict vaccine mandate, 86 Fed. Reg. at 61,433, 61,436—is insufficient. So is CMS's failure to grapple with OSHA's finding that it could not establish any "grave danger" to most healthcare workers so long as they complied with the COVID-19 precautions outlined in OSHA's June ETS. *Id.* at 61,421.

Second, CMS fails to "articulate a satisfactory explanation" for why its mandate was "rational" given that unvaccinated workers may flee the industry. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Despite recognizing that there "might be a certain number of health care workers who choose" to resign because of the mandate, 86 Fed. Reg. at 61,569, CMS rejects these concerns in a single sentence, concluding that it had "insufficient evidence to quantify and compare adverse impacts on patient and resident care associated with temporary staffing losses" and "absences due to quarantine for known COVID-19 exposures and illness," *id.* A lack of data, however, is not reason to issue an industry-shaking vaccine mandate; it is reason to *refrain* from issuing such a mandate.

In any event, CMS ignores much to reach its cursory conclusion. A week before it issued its rule, a survey found that 72% of unvaccinated workers would quit

rather than vaccinate.[25] CMS itself cites at least one instance where triple-digit numbers of workers resigned or were fired for refusing to take a vaccine. *Id.* at 61,569 n.155 (citing a report that 153 employees of Houston Methodist Hospital quit following its vaccination mandate).[26] As CMS recognizes, "if any substantial number of unvaccinated employees leave health care employment altogether," the already "endemic staff shortages . . . may be made worse." *Id.* at 61,607. And this will have a particularly acute impact on healthcare in rural areas, which, as CMS admits, are "having greater problems with employee vaccination." *Id.* at 61,613. Glazing over these problems, however, does not make them disappear and does not satisfy the reason-giving requirements of the APA. *See Regents*, 140 S. Ct. at 1913.

Third, CMS fails to adequately consider the impact its mandate will have on vaccination-education efforts. In Florida, those efforts have had great success, sometimes raising vaccination rates by ten percent.[27] Yet CMS does not consider to what extent its mandate would "chill" individuals who might otherwise take the

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[25] Liz Hamel et al., *KFF COVID-19 Vaccine Monitor: October 2021*, KFF (Oct. 28, 2021), https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-october-2021/.

[26] Dan Diamond, *153 people resigned or were fired from a Texas hospital system after refusing to get vaccinated*, The Washington Post (June 22, 2021), https://www.washingtonpost.com/health/2021/06/22/houston-methodist-loses-153-employees-vaccine-mandate/.

[27] Hannah Mitchell, *'Like hand-to-hand combat': Florida health system battles vaccine hesitancy 1 employee at a time*, Becker's Hospital Review (Nov. 4, 2021), https://www.beckershospitalreview.com/hospital-management-administration/like-hand-to-hand-combat-florida-health-system-battles-vaccine-hesitancy-1-employee-at-a-time.html.

vaccine voluntarily, a key factor OSHA considered in establishing its employer vaccine mandate. *See* 86 Fed. Reg. at 61,436 (reasoning that the testing aspect of the vaccine mandate "would elicit more effective employee participation").

Fourth, CMS fails to rationally connect its statistics to most of the healthcare facilities covered by its mandate. Indeed, CMS recognizes that the "providers and suppliers regulated under this rule are diverse in nature, management structure, and size." 86 Fed. Reg. at 61,602. Still, CMS relies mostly on facts and figures involving long term care facilities—providers that serve mostly elderly or immunocompromised patients—to justify applying the mandate to other providers. *See, e.g.*, *id*. at 61,585 (discussing "case rates among [long term care] facility residents," and claiming, without citation, that those facilities' "experience may generally be extrapolated to other settings"). At the same time, CMS concedes that "[a]ge remains a strong risk factor for severe COVID-19 outcomes." *Id.* at 61,566. In short, the statistics that it claims justify its action do not represent most facilities caught within the mandate.

Fifth, CMS does not consider the rate at which "game-changing" COVID-19 treatments minimize the more-serious health risks of COVID-19. Nor does CMS consider the viability of state-by-state approaches to mandatory vaccination, despite acknowledging that, in many states, COVID-19 cases "are trending downward." *Id.*

at 61,583–84. This is particularly true in Florida, which had the lowest number of COVID-19 cases in the nation at the start of November 2021.[28]

Sixth, CMS concludes that prior COVID-19 infection could not qualify a covered employee for an exemption from the mandate because it was not equivalent to receiving a COVID-19 vaccine. *Id.* at 61,559–60, 61,614. Elsewhere, however, CMS recognizes the value of natural immunity. *See id.* at 61,604 (finding natural immunity "reduce[s] the risk to both health care staff and patients substantially"); *id.* (noting that those who recover are "in very rare cases still infectious"). CMS is in good company in acknowledging natural immunity. Many experts have reached the same conclusion, *e.g.*, *United States v. Arencibia*, No. 18-294, 2021 WL 2530209, at *4 (D. Minn. June 21, 2021),[29] including the authors of a highly reported study from Israel, which concluded that "natural immunity confers longer lasting

[28] David Schutz, *Florida Has Lowest COVID Cases Per Capita in US, Data Shows*, South Florida Sun Sentinel (Oct. 28, 2021), https://www.sun-sentinel.com/coronavirus/fl-ne-florida-covid-19-lowest-case-rate-in-nation-20211028-gvcy2hxdnngufnv3vpwm23yuae-story.html.

[29] *Accord* Yair Goldberg et al., *Protection of Previous SARS-CoV-2 Infection Is Similar to That of BNT162b2 Vaccine Protection: A Three-Month Nationwide Experience from Israel*, medRxiv (2021 preprint), https://www.medrxiv.org/content/10.1101/2021.04.20.21255670v1 (concluding that the "overall estimated level of protection from prior . . . infection" was comparable to that from vaccination); Nabin K. Shrestha et al., *Necessity of COVID-19 Vaccination in Previously Infected Individuals*, medRxiv, (2021 preprint), https://www.medrxiv.org/content/10.1101/2021.06.01.21258176v2 (concluding that those with natural immunity are "unlikely to benefit from COVID-19 vaccination"); Galit Perez et al., *A 1 to 1000 SARS-Cov-2 Reinfection Proportion in Members of a Large Healthcare Provider in Israel: A Preliminary Report*, medRxiv, (2021 preprint), https://www.medrxiv.org/content/10.1101/2021.03.06.21253051v1 (finding that approximately 1/1000 of participants in a study of persons who previously tested positive for COVID-19 were reinfected).

and stronger protection against infection . . . caused by the Delta variant."[30] CMS's unexplained inconsistency in agency position renders the mandate "arbitrary and capricious." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016).

Seventh, CMS inconsistently claims the mandate will protect patients while recognizing, in its cost-benefit analysis, that "the effectiveness of the vaccine to prevent disease transmission by those vaccinated [is] not currently known." *E.g.*, 86 Fed. Reg. at 61,569, 61,615. If the benefits of the mandate are so uncertain, CMS should not assume that they outweigh the substantial costs Florida has identified.

Eighth, CMS fails to consider the interests of millions of healthcare workers who pursued their careers without knowing they would be subject to mandated vaccination. *Regents*, 140 S. Ct. at 1913. And it ignores the reliance interests of healthcare employers, including the States, who ordered their affairs under the assumption that Medicaid and Medicare dollars would be available without this onerous condition. *Cf. NFIB*, 567 U.S. at 584 ("A State could hardly anticipate that Congress's reservation of the right to 'alter' or 'amend' the Medicaid program included the power to transform it so dramatically.").

Ninth, the mandate is the product of political pressure, not measured judgment. *Aera Energy LLC v. Salazar*, 642 F.3d 212, 220 (D.C. Cir. 2011). The

[30] *See* Sivan Gazit et al., *Comparing SARS-CoV-2 Natural Immunity to Vaccine-Induced Immunity: Reinfections Versus Breakthrough Infections*, medRxiv (2021 preprint), https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1.

true impetus is clear: facing a scandal over his actions in Afghanistan, dismal approval numbers on his COVID response, and an inability to advance his legislative agenda, President Biden succumbed to pressure to control the healthcare decisions of millions. He did so even though his Administration had assured the public that vaccine mandates are "not the role of the federal government."[31] And even a month before announcing the mandate, the Administration said that CMS would be promulgating a much narrower mandate directed only at nursing homes.[32] These "sudden[] revers[als]" of course "create[] the plausible inference that political pressure may have caused the agency to take action it was not otherwise planning to take," *Connecticut v. Dep't of Interior*, 363 F. Supp. 3d 45, 64–65 (D.D.C. 2019), which justifies setting the action aside, *Aera Energy*, 642 F.3d at 220; *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2576 (2019) ("Accepting contrived reasons would defeat the purpose of [judicial review.]").

Finally, CMS fails to adequately explain its extreme departure from its prior practice of not mandating vaccines. *See E. Bay Sanctuary Covenant v. Trump*, 349 F. Supp. 3d 838, 858 (N.D. Cal. 2018); *accord Regents*, 140 S. Ct. at 1913. The

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[31] *Press Briefing by Press Secretary Jen Psaki, July 23, 2021*, The White House (July 23, 2021), https://www.whitehouse.gov/briefing-room/press-briefings/2021/07/23/press-briefing-by-press-secretary-jen-psaki-july-23-2021/.

[32] *FACT SHEET: President Biden to Announce New Actions to Protect Americans from COVID-19 and Help State and Local Leaders Fight the Virus*, The White House (Aug. 18, 2021), https://www.whitehouse.gov/briefing-room/statements-releases/2021/08/18/fact-sheet-president-biden-to-announce-new-actions-to-protect-americans-from-covid-19-and-help-state-and-local-leaders-fight-the-virus/.

closest CMS comes is to suggest that mandatory vaccination is not extraordinary given that "many health care workers already comply with employer or State government vaccination requirements." 86 Fed. Reg. at 61,567. But that does not explain such a monumental shift by the *federal government*. It shows only that the Biden Administration has lost track of the difference between a limited federal government of enumerated powers and the rights reserved to private individuals and the States—a distinction fundamental to our Constitution.

For these reasons, the mandate is arbitrary and capricious.

d. The challenged actions violate the Spending Clause.

"[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*, 451 U.S. at 17. Here, Florida agreed to a lucrative contract, paying millions in federal funds, to enforce Medicare and Medicaid requirements on healthcare providers. Ex. 1 ¶¶ 5, 9. When it agreed to do so, however, it was given no notice that it would have to enforce vaccination requirements. Florida now faces the untenable choice of refusing to enforce the mandate, and losing millions, or acquiescing. But the Spending Clause does not allow the government to put Florida to this choice—any conditions must have been disclosed to Florida from the beginning. *Pennhurst*, 451 U.S. at 17; *cf. NFIB*, 567 U.S. at 584.

For this reason, the mandate violates the Spending Clause.

II. FLORIDA HAS STANDING AND IS IRREPARABLY HARMED BY THE CHALLENGED ACTIONS.

States are entitled to "special solicitude" in establishing standing. *Massachusetts v. EPA*, 549 U.S. 497, 520 (2007); *see also Alfred L. Snapp & Son, Inc. v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 607 (1982) (recognizing the States' "quasi-sovereign interest in the health and well-being—both physical and economic—of its residents"). Moreover, a "state has standing to sue in its sovereign capacity when it has suffered an economic injury" or must "expend[] any of its resources." *Chiles v. Thornburgh*, 865 F.2d 1197, 1208 (11th Cir. 1989). Florida has standing to challenge an allegedly illegal agency action that "*may* adversely impact" its "economy" and "thereby injur[e]" Florida. *Alabama v. U.S. Army Corps of Eng'rs*, 424 F.3d 1117, 1130 (11th Cir. 2005) (emphasis added).

Economic harm caused by federal agency action also establishes irreparable harm. These harms "cannot be undone through monetary remedies," *Ferrero v. Associated Materials Inc.*, 923 F.2d 1441, 1449 (11th Cir. 1991), because the United States has sovereign immunity, *Odebrecht Const., Inc. v. Sec'y, Fla. Dep't of Transp.*, 715 F.3d 1268, 1289 (11th Cir. 2013).[33] And sovereign injury—such as preemption of state law or interference with state policy—is also irreparable harm

[33] The procedural harm from the failure to provide notice and comment may also be irreparable. *See Becerra*, 2021 WL 2514138, at *47.

because it likewise cannot be addressed through monetary remedies.[34] *See Kansas v. United States*, 249 F.3d 1213, 1227–28 (10th Cir. 2001).

As explained above, *supra* at 11–13, Florida faces each of these harms absent this Court's intervention.

III. THE BALANCE OF THE EQUITIES AND PUBLIC INTEREST FAVOR PRELIMINARY INJUNCTIVE RELIEF.

The equities and public-interest factors merge for federal-government action. *Nken v. Holder*, 556 U.S. 418, 435 (2009). Both favor an injunction here. "Forcing federal agencies to comply with the law is undoubtedly in the public interest." *Cent. United Life, Inc. v. Burwell*, 128 F. Supp. 3d 321, 330 (D.D.C. 2015). Moreover, "[t]here is clearly a robust public interest in safeguarding prompt access to health care." *Whitman-Walker Clinic, Inc. v. DHS*, 485 F. Supp. 3d 1, 61 (D.D.C. 2020) (citing *New York v. DHS*, 969 F.3d 42, 87–88 (2d Cir. 2020), and *California v. Azar*, 911 F.3d 558, 582 (9th Cir. 2018)). "The effect on the health of the local economy is [also] a proper consideration in the public interest analysis." *All. for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1138 (9th Cir. 2011). And it is "against

[34] The Florida legislature is currently contemplating legislation that would prohibit vaccine mandates. *See Governor DeSantis Joined By President Simpson and Speaker Sprowls to Announce Legislative Agenda for Special Session of the Florida Legislature*, Florida Governor's Office (Nov. 8, 2021), https://www.flgov.com/2021/11/08/governor-desantis-joined-by-president-simpson-and-speaker-sprowls-to-announce-legislative-agenda-for-special-session-of-the-florida-legislature/. This legislation is likely to pass within the next few days. Once it does, Florida will face an additional sovereign injury.

the public interest to force a person out of a job." *Vencor, Inc. v. Webb*, 829 F. Supp. 244, 251 (N.D. Ill. 1993).

CONCLUSION

For the foregoing reasons, the Court should preliminarily enjoin Defendants from enforcing, implementing, or giving any effect to the mandate. If the court cannot reach a decision by December 6, 2021, it should enter a temporary restraining order by that date.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This motion complies with the requirements of Local Rule 7.1(F) because it contains 7,648 words.

CERTIFICATE OF SERVICE

I hereby certify that on this 17th day of November, 2021, a true and correct copy of the foregoing was filed with the Court's CM/ECF system and furnished by US Mail to:

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