AUSTIN KNUDSEN

STATE OF MONTANA

November 17, 2022

Submitted Via Federal Express & Via Email
Xavier Becerra
Secretary, U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Chiquita Brooks-LaSure
Administrator, Center for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: ***Section 553(e) Petition for Rulemaking***

Dear Secretary Becerra & Administrator Brooks-LaSure:

The undersigned Attorneys General submit the attached petition under 5 U.S.C. § 553(e) to request that the U.S. Department of Health and Human Services ("HHS") and Center for Medicare & Medicaid Services ("CMS") promptly repeal *Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination*, 86 Fed. Reg. 61555 (Nov. 5, 2021) (the "IFR") and withdraw any associated guidance.

Just over a year ago, CMS rushed to impose the IFR on millions of healthcare workers. And it relied on a purported emergency—the rapid spread of the Delta variant—to sidestep the Administrative Procedure Act's notice-and-comment requirements, even though it was unsure if the vaccines would prevent transmission. But evidence available *at that time*, and evidence that has emerged since, demonstrates that full vaccination doesn't prevent infection or transmission. Delta is long gone, replaced by the milder, more transmissible Omicron variant, which is even more resistant to vaccines. Breakthrough infections are common. And to make matters worse, studies increasingly show heightened health risks associated with the vaccines. Yet the outdated emergency IFR remains in force.

The emergency IFR intensified existing staffing shortages, especially in rural and frontier States. The result was a double-edged sword. On one side, the IFR modestly reduced patients' risk of contracting COVID. But on the other side, the IFR significantly limited many patients' access to needed medical care. The IFR imposed substantial costs on patients and healthcare workers without any corresponding benefits.

DEPARTMENT OF JUSTICE

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Even if the IFR made sense at one time, it has long since outlived its utility. CMS should cast the IFR and all related guidance in the trash bin where it belongs.

Sincerely,

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UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES

&

CENTERS FOR MEDICARE & MEDICAID SERVICES

In re: Centers for Medicare & Medicaid Services Interim Final Rule, Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, RIN 0938-AU75

Petition by the States of Montana, Louisiana, Tennessee, Arizona, Alabama, Alaska, Arkansas, Florida, Indiana, Kansas, Kentucky, Mississippi, Missouri, Nebraska, New Hampshire, Ohio, Oklahoma, South Carolina, Texas, Utah, Virginia, Wyoming

PETITION FOR RULEMAKING

1. The States of Montana, Louisiana, Tennessee, Arizona, Alabama, Alaska, Arkansas, Florida, Indiana, Kansas, Kentucky, Mississippi, Missouri, Nebraska, New Hampshire, Ohio, Oklahoma, South Carolina, Texas, Utah, Virginia, and Wyoming, respectfully petition the Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS) under the Administrative Procedure Act, *see* 5 U.S.C. § 553(e), to repeal the Interim Final Rule (IFR) [1] and withdraw any related guidance.

[1] *Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination*, 86 Fed. Reg. 61555, 61615 (Nov. 5, 2021).

SUMMARY OF PETITION

2. Pfizer never tested its vaccine to see if it prevented transmission of COVID-19.[2] And when CMS issued the IFR, it didn't know whether the vaccines would prevent COVID transmission.[3] No data at the time conclusively demonstrated that the vaccines would prevent infection and transmission.[4] Indeed, fully vaccinated individuals contracted and transmitted COVID-19. That trend has continued—even with the introduction of first-generation boosters[5] and the new, bivalent Omicron booster.[6] This data merely confirms what CMS should have known in November

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[2] Frank Chung, *Pfizer Did Not Know Whether Covid Vaccine Stopped Transmission Before Rollout, Executive Admits*, DAILY TELEGRAPH (Oct. 13, 2022) (Ex. A).

[3] *See* 86 Fed. Reg. at 61615 (Nov. 5, 2021) (acknowledging that "the effectiveness of the vaccine[s] to prevent disease transmission by those vaccinated [is] not currently known").

[4] This is no surprise given the various documented efforts by the Biden administration, the medical establishment, and tech companies like Facebook and Twitter to suppress information that did not align with the Administration's preferred COVID policies. *See* Yaffa Shir-Raz et al., *Censorship and Suppression of COVID-19 Heterodoxy: Tactics and Counter-Tactics*, at 7–12 MINERVA (Nov. 1, 2021) (Ex. B) (describing various tactics used to silence doctors and research scientists who concluded that various COVID policies were ineffective, including exclusion, denigration, online censorship, censorship by academic establishment, and more); Alex Berenson, *Pfizer Board Member Scott Gottlieb Secretly Pressed Twitter to Censor Me Days Before Twitter Suspended My Account Last Year*, SUBSTACK (Oct. 13, 2022) (Ex. C) (detailing a concerted effort by a Pfizer board member, in cahoots with federal officials, to silence a reporter claiming that the vaccines weren't effective).

[5] Michael Shear, *Covid News: Biden Tests Positive for Virus*, NEW YORK TIMES (July 21, 2022) (Ex. D) (explaining that the President "tested positive for Covid-19" and was "fully vaccinated and twice boosted").

[6] Jamie Gumbrecht & Alaa Elassar, *CDC Director Tests Positive for Covid-19*, CNN (Oct. 22, 2022) (Ex. E) (noting that CDC Director Wolensky contracted COVID even after being up to date on COVID-19 vaccinations and boosters, including the new bivalent booster).

2021—full vaccination doesn't prevent infection or transmission.[7] But that didn't stop CMS from jamming through the IFR's draconian vaccine mandate. Indeed, to purportedly stem the spread of the Delta variant—invoking supposed 'emergency' grounds to sidestep both notice-and-comment rulemaking and its obligation to consult with appropriate State agencies—CMS announced its unprecedented vaccine requirement on most staff in the medical industry.[8] But Delta is long gone, replaced by the milder, more transmissible, Omicron variant.[9] And vaccines have proven largely impotent to prevent COVID transmission.[10] A New York state judge recently

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[7] *See* Anika Singanayagam et al., *Community Transmission and Viral Load Kinetics of the SARS-CoV-2 Delta (B.1.617.2) Variant in Vaccinated and Unvaccinated Individuals in the UK: A Prospective, Longitudinal, Cohort Study*, THE LANCET (Oct. 28, 2021) (Ex. F) ("[F]ully vaccinated individuals with breakthrough infections have peak viral load similar to unvaccinated cases and can efficiently transmit infection in household setting, including to full vaccinated contacts.").

[8] *See* 86 Fed. Reg. at 61568 (finding that the growing threat of the Delta variant justified holding consultation requirements until after the issuance of the rule); *see id.* at 61583 (finding "good cause" to waive notice-and-comment procedures because of the "outbreak associated with the … Delta variant"); *see also Biden v. Missouri*, 142 S. Ct. 647, 651 (2022) (observing that the Secretary's reason for bypassing these procedural requirements was that "any 'further delay' would endanger patient health and safety given the spread of the Delta variant" (quoting 86 Fed. Reg. at 61583–86)).

[9] *See* CDC, COVID Data Tracker, *Variant Proportions* (updated Oct. 29, 2022) (Ex. G) (Omicron variant accounted for 100.0% of cases for week ending October 29, 2022) ; *see also* CDC, *Genomic Surveillance for SARS-CoV-2 Variants: Predominance of the Delta (B.1.617.2) and Omicron (B.1.1.529) Variants — United States, June 2021–January 2022*, CDC MMWR 2022; 71:206–211, (Feb. 11, 2022) (Ex. H) (explaining that by late December 2021, Omicron overtook Delta as the dominant variant, and by early January 2022 it comprised more than 95% of all cases).

[10] *See No Omicron immunity without booster, study finds*, THE HARVARD GAZETTE (Jan. 7, 2022) (Ex. I) (finding that "traditional dosing regimens of COVID-19 vaccines available in the U.S. don't produce antibodies capable of recognizing and neutralizing the Omicron variant"); Jinyan Liu et al., *Vaccines Elicit Highly Conserved Cellular Immunity to SARS-CoV-2 Omicron*, 603 NATURE 493, 495 (Jan. 31, 2022) (Ex. J) (explaining that the Omicron variant "dramatically evades neutralizing antibody

declared that "[b]eing vaccinated does not prevent an individual from contracting or transmitting Covid-19."[11] Nor have added protections—uncontemplated by the IFR—helped: NIAIH Director Anthony Fauci had a breakthrough infection after receiving a second booster, and CDC Director Rochelle Wollensky had one after receiving an updated bivalent booster (which was designed to target Omicron).[12] Not only that, but studies have shown increased health risks associated with the vaccines.[13] And yet, against the tide of overwhelmingly adverse data, the outdated emergency vaccine mandate remains in force.

3. CMS relied on a purported emergency—the rapid spread of the Delta variant—to sidestep notice-and-comment rulemaking and impose the IFR on millions

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responses" so it can infect those with prior vaccine-induced immunity); *see also* Daniel Halperin, *Omicron is Spreading. Resistance is Futile*, THE WALL ST. J. (Jan. 25, 2022) (Ex. K).

[11] *See* Order, *Garvey et al. v. City of N.Y. et al.*, No. 85163/2022 (N.Y. Sup. Ct. Oct. 24, 2022) (Ex. L).

[12] *See* Jamie Gumbrecht & Jen Christensen, *Fauci Tests Positive for Covid-19*, CNN (June 15, 2022) (Ex. M); Krista Mahr, *CDC Director Tests Positive for Covid-19*, POLITCO (Oct. 22, 2022) (Ex. N).

[13] *See, e.g.*, Stephanie Le Vu et al., *Age and Sex-Specific Risks of Myocarditis and Pericarditis Following COVID-19 Messenger RNA Vaccines*, Nature Commc'ns, June 25, 2022, at 5 (finding that "vaccination with both mRNA vaccines was associated with an increased risk of myocarditis and pericarditis with the first week after vaccination") (Ex. O), https://www.nature.com/articles/s41467-022-31401-5; Hui-Lee Wong et al., *Risk of Myocarditis and Pericarditis After the COVID-19 mRNA Vaccination in the USA: A Cohort Study in Claims Database*, 399 THE LANCET 2191, 2191 (June 11, 2022) (Ex. P) (finding an increased risk of myocarditis after vaccination in men aged 18–25); Jennifer Couzin-Frankel & Gretchen Vogel, *Vaccines May Cause Rare, Long Covid-Like Symptoms*, 375 SCIENCE 364 (Jan. 28, 2022) (Ex. Q) ; *see also* Joseph Fraiman et al., *Serious Adverse Events of Special Interest Following mRNA Vaccination in Randomized Trials* 40 VACCINE 5798, 5800 (Sept. 9, 2022) (Ex. R) (explaining that the excess risk of serious adverse events of special interest surpassed

of healthcare workers,[14] despite its own professed uncertainty *at that time* about whether the vaccines would prevent COVID transmission.[15] Shortly after that, the Delta variant disappeared and with it the justification for the IFR. Rather than amend or repeal the IFR, federal authorities—including federal public health authorities—have simply walked back claims about the vaccines' effectiveness in preventing transmission of the Omicron variant.[16]

4. Studies show that the compelled vaccination of millions of healthcare workers will not meaningfully limit COVID transmission.[17] And Pfizer never tested

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the risk reduction for COVID-19 hospitalization relative to the placebo group in both Pfizer and Moderna trials).

[14] *See* 86 Fed. Reg. at 61586 (relying on the "good cause" exception to notice-and-comment rulemaking because it "believe[d] it would be impracticable and contrary to the public interest … to undertake normal notice and comment procedures").

[15] *See supra* note 3.

[16] CDC Newsroom, *CDC Streamlines COVID-19 Guidance to Help the Public Better Protect Themselves and Understand Their Risk* (Aug. 11, 2022) (Ex. S) (stating that the "[p]rotection provided by the current vaccine against symptomatic infection and transmission is less than that against severe disease and diminishes over time, especially against the currently circulating variants").

[17] *See supra* notes 10–12 (Exs. I–N); *see also* Mark G. Thompson, et al. *Effectiveness of a Third Dose of mRNA Vaccines Against COVID-19–Associated Emergency Department and Urgent Care Encounters and Hospitalizations Among Adults During Periods of Delta and Omicron Variant Predominance — VISION Network, 10 States, August 2021–January 2022*. CDC MMWR 2022; 71:139–145, (Jan. 21, 2022) (Ex. T) (showing that vaccine efficacy is drastically reduced at preventing the transmission of the Omicron variant); Ori Magen et al., *Fourth Dose of BNT162b2 mRNA COVID-19 Vaccine in a Nationwide Setting*, 386 NEW ENG. J. MED. 1603, 1604 (Apr. 28, 2022) (Ex. U) (explaining that the Omicron variant "has generated the largest waves of infection in the [COVID-19] pandemic thus far, even in countries with successful mass-vaccination campaigns"); Heba N. Altarawneh, et al., *Effects of Previous Infection and Vaccination of Symptomatic Omicron Infections*, 387 NEW ENG. J. MED. 21, 21 (July 7, 2022) (Ex. V) ("The effectiveness of vaccination with two doses of

the vaccine to determine if it was effective at preventing transmission.[18] Even worse, the emergency vaccine mandate left healthcare facilities—already struggling to maintain needed staff ratios—in dire straits,[19] further worsening staffing shortages in the healthcare sector, especially in rural and frontier states.[20] Studies also show that the vaccines carry increased health risks among normally healthy populations.[21] When paired with the vaccines' lack of protection against symptomatic infection and

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BNT162b2 and no previous infection was negligible."), https://www.nejm.org/doi/full/10.1056/NEJMoa2203965.

[18] Chung, *supra* note 2 (Ex. A).

[19] Many healthcare facilities fired unvaccinated employees because of the IFR. *See* Chantal Da Silva, *Mayo Clinic Fires 700 Workers Who Failed to Comply With COVID Vaccine Mandate*, NBC NEWS (Jan. 5, 2022) (Ex. W); Kelly Gooch, *Vaccination-Related Employee Departures at 55 Hospitals, Health Systems*, BECKER HOSP. REV. (Feb. 17, 2022) (Ex. X).

[20] The American Hospital Association has called the staffing shortages in hospitals a "national emergency," and these shortages have "fuel[ed] soaring burnout levels that experts say raise the risk of medical errors and, consequently, potential harm to Americans." Stephen R. Johnson, *Staff Shortages Choking U.S. Health Care System*, U.S. NEWS (July 28, 2022) (Ex. Y); Sai Balasubramanian, *The Healthcare Industry is Crumbling Due to Staffing Shortages*, FORBES (Aug. 26, 2022) (Ex. Z) (stating that "severe shortages in nursing staff" has "le[]d to dangerous patient care practices and outcomes."). Many healthcare facilities fired staff for noncompliance with the IFR, and the impact of those departures hit smaller communities disproportionately. *See* Bipartisan Policy Center, *The Impact of COVID-19 on the Rural Health Care Landscape* at 62–63 (May 2022) (Ex. AA); *see also Mont. Med. Ass'n v. Knudsen*, No. 9:21-cv-00108-DWM, ECF No. 51-2 (D. Mont. Mar. 2, 2022) (Ex. BB) (expressing "grave concerns about the survivability of rural healthcare as a result of this mandate"). Some of the states that joined this petition filed dozens of declarations outlining the devastation the IFR would have on healthcare staffing, particularly in rural America. *See Missouri v. Biden*, No. 4:21-cv-1329-MTS, ECF Nos. 9-1 to 9-30 (E.D. Mo. Nov. 12, 2021) (Ex. CC).

[21] *See supra* note 13 (Exs. O–R).

transmission, these studies show that compelled vaccination was flawed from the start.

5. The IFR was designed to work in tandem with several other vaccine mandates—including the OSHA mandate, the federal contractor mandate, and the Head Start mandate—to coerce most working Americans into choosing vaccination over unemployment. But those mandates have all been either set aside or enjoined.[22] So many of the unvaccinated workers targeted by the IFR, especially those who have thus far refused the vaccines, are far more likely to pursue employment elsewhere, leaving many covered facilities short-staffed and reducing patients' access to care.

6. Not content with the mandate alone, CMS also co-opted the states' surveyor staffs to ensure compliance with the IFR. It issued multiple directives treating the state surveyors like federal employees (the State Surveyor Directives), ordering them to go out and enforce the IFR, and providing them with detailed yet changing

[22] *See Nat'l Fed'n of Indep. Bus. v. OSHA*, 142 S. Ct. 661 (2022) (OSHA); *Kentucky v. Biden*, 23 F.4th 585 (6th Cir. 2022) (federal contractor); *Georgia v. President of the U.S.*, 46 F.4th 1283 (11th Cir. 2022) (same); *Louisiana v. Becerra*, 577 F. Supp. 3d 483 (W.D. La. 2022) (Head Start).

instructions on how to do so.[23] CMS recently consolidated these directives into one guidance document (the State Surveyor Guidance).[24]

7. Now that "the pandemic is over,"[25] and given the likely violations of the numerous statutory and constitutional rights outlined below, the Secretary and CMS should take immediate action to repeal the IFR and withdraw the State Surveyor Guidance.

STATEMENT OF INTEREST

8. The Petitioner States, as sovereigns, retain all power not delegated to the federal government in the Constitution. *See* U.S. Const. amend. X. So they possess an abiding interest in ensuring that the federal government's actions—like the

[23] *See, e.g.*, CMS, QSO-22-12-ALL, *State Obligations to Survey to the Entirety of Medicare and Medicaid Health and Safety Requirements Under the 1864 Agreement* (Feb. 9, 2022) (Ex. DD); CMS, QSO-22-09-ALL (Revised 4/05/22), *Revised Guidance for the Interim Final Rule – Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination* (Jan. 14, 2022; revised Apr. 5, 2022) (Ex. EE) (applying to all Petitioner States other than Tennessee and Virginia); CMS, QSO-22-07-ALL (Revised 4/05/22), *Revised Guidance for the Interim Final Rule – Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination* (Jan. 14, 2022; revised Apr. 5, 2022) (Ex. FF) (applying to Tennessee and Virginia); CMS, QSO-22-17-ALL, *Surveys for compliance with Omnibus COVID-19 Health Care Staff Vaccination Requirements* (June 14, 2022) (Ex. GG) (collectively, the State Surveyor Directives).

[24] *See* CMS, QSO-23-02-ALL, *Revised Guidance for Staff Vaccination Requirements* (Oct. 26, 2022) (Ex. HH).

[25] *See* Dan Diamond, *Biden's Claim that 'Pandemic Is Over' Complicates Effort to Secure Funding*, WASH. POST (Sept. 19, 2022) (Ex. II).

IFR and the State Surveyor Guidance here—do not intrude upon the exercise of their police powers to compel (or prohibit the compulsion of) vaccination.

9. Because the IFR is an agency action that violates the law and the Constitution, evaded legally required procedures, and is arbitrary and capricious, it must be set aside. *See* 5 U.S.C. § 706(2)(A), (C), (D); *see also e.g.*, U.S. Const. art. I, § 1; *Gundy v. United States*, 139 S. Ct. 2116 (2019); *West Virginia v. EPA*, 142 S. Ct. 2587 (2022); *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519 (2012); *Printz v. United States*, 521 U.S. 898 (1997). The Petitioner States thus have an interest in safeguarding their sovereignty from the agency's unlawful actions.

BACKGROUND

I. The Medicare and Medicaid Framework.

10. Since 1965, the federal government and the Petitioner States have worked together to provide medical assistance to certain vulnerable populations under Titles XVIII and XIX of the Social Security Act (the Act), commonly known as Medicare and Medicaid. *See* 42 U.S.C. §§ 1395–96w-6; *see also Alexander v. Choate*, 469 U.S. 287, 289 n.1 (1985). As a cooperative State–federal program, Medicaid helps states to finance the medical expenses of their poor and disabled citizens.

11. The Act tasks the Secretary with a wide range of administrative responsibilities related to maintaining the programs under his purview, including Medicare and Medicaid. *See* 42 U.S.C. § 301 *et seq*.

12. The Act also delegates to the Secretary limited authority to issue rules and regulations necessary for the efficient administration of the functions assigned

to him under the Act, so long as such rules and regulations are not inconsistent with the Act. *See* 42 U.S.C. § 1302(a). To that end, Congress authorized the Secretary to promulgate, as a condition of a certain facilities' participation in these programs, requirements he "finds necessary in the interest of the health and safety of individuals *who are furnished services in the institution*." 42 U.S.C. § 1395x(e)(9) (hospitals) (emphasis added); *see, e.g.*, §§ 1395x(cc)(2)(J) (outpatient rehabilitation facilities), 1395i-3(d)(4)(B) (skilled nursing facilities), 1395k(a)(2)(F)(i) (ambulatory surgical centers); *see also* §§ 1396r(d)(4)(B), 1396d(*l*)(1), 1396d(*o*) (similar provisions in Medicaid Act).

13. CMS has primary responsibility for overseeing the Medicare program and the federal role in the Medicaid program.

14. The Secretary may withhold federal Medicaid funds from states for noncompliance with the IFR. *See Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 328 (2015).

II. The Interim Final Rule.

15. As President-Elect, Biden promised that he would not compel vaccinations. Jacob Jarvis, *Fact Check: Did Joe Biden Reject Idea of Mandatory Vaccines in December 2020*, Newsweek (Sept. 10, 2021) (Ex. JJ). But in September 2021, the Biden administration abandoned persuasion for brute force, announcing a series of mandates designed to compel most of the adult population of the United States to get a COVID vaccine. The White House, *Remarks by President Biden on Fighting the COVID-19 Pandemic* (Sept. 9, 2021) (Ex. KK). He did that even though the White House knew in the summer of 2021, months before this mandate was decreed, that

the vaccines "did a far worse job of blocking infection than originally expected." Ashley Parker, et al., *Inside the Successes, Missteps, and Failures of Biden's Early Presidency*, WASH. POST (Oct. 22, 2022) (Ex. LL), https://www.washingtonpost.com/politics/2022/10/22/joe-biden-presidency/.

16. President Biden's mandates—issued through unilateral executive action—targeted different populations. These included the federal contractor vaccine mandate, *see* Exec. Order No 14042, 86 Fed. Reg. 50985 (Sept. 9, 2021), the OSHA vaccine mandate on private businesses, *see COVID-19 Vaccination and Testing; Emergency Temporary Standard*, 86 Fed. Reg. 61402-01 (Nov. 5, 2021), the Head Start Mandate, *see* 86 Fed. Reg. 68052 (Nov. 30, 2021), and the IFR at issue here.

17. In early November 2021, CMS published the IFR, which required vaccination of staff of certain Medicare and Medicaid providers and suppliers. *See Medicare and Medicaid Programs; Omnibus COVID-19 Heath Care Staff Vaccinations*, 86 Fed. Reg. 61555 (Nov. 5, 2021).

18. The IFR governs 21 types of Medicare and Medicaid certified providers and suppliers that are subject to Medicare or Medicaid conditions of participation, conditions for coverage, or requirements for participation. *See id.* at 61556. A non-exhaustive list of those facilities includes hospitals, ambulatory surgical centers, hospices, psychiatric residential treatment facilities, long-term care facilities (including skilled nursing facilities), intermediate care facilities for individuals with intellectual disabilities, home health agencies, comprehensive outpatient rehabilitation facilities,

critical access hospitals, providers of outpatient physical therapy and speech-language pathology services, rural health clinics, and more. *See id.*

19. The regulations require that every entity "develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID–19." *See, e.g.*, 42 C.F.R. § 416.51(c). The IFR considers staff "fully vaccinated if it has been 2 or more weeks since they completed a primary vaccination series for COVID-19." 86 Fed. Reg. at 61563. That requires receiving a single-dose vaccine or all doses of a multi-dose vaccine. *Id.* It does not mandate any COVID-19 booster series.

20. The policy must apply to every person who provides care, treatment or other services for the facility or its patients—including employees, contractors, trainees, students, and volunteers—regardless of whether they have any patient-care responsibilities or even any contact with patients. *E.g.*, 42 C.F.R. § 416.51(c)(1).

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

22. The entity may provide an exemption for those granted temporary delays based on the CDC's recommendations or for those who are eligible for exemptions under certain federal statutes. *E.g.*, 42 C.F.R. § 416.51(c)(3)(i)–(ii). But the entity must "track[] and securely document[] information provided by those staff who have requested, and for whom the [entity] has granted, an exemption" or a temporary delay. *Id.* § 416.51(c)(3)(vi)–(vii). And it must ensure that all documentation

"support[ing] staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner." *Id.* § 416.51(c)(3)(viii).

23. The entity must implement a "process for tracking and securely documenting the COVID–19 vaccination status of all staff," including booster-shot status. *See, e.g.*, *id.* § 416.51(c)(3)(iv)–(v). And it must implement "[c]ontingency plans for staff who are not fully vaccinated." *Id.* § 416.51(c)(3)(x).

24. The only way for an entity to avoid those regulations is to forfeit its federal Medicare and Medicaid funding. If an entity fails to comply with the regulations, it may face penalties up to and including "termination of the Medicare/Medicaid provider agreement." 86 Fed. Reg. at 61574. The termination of those provider agreements would spell disaster for healthcare providers and for access to care for numerous Americans.

25. Medicaid providers receive this funding for services through provider contracts with individual states, so states bear the burden of issuing sanctions or terminating provider contracts. CMS E-Bulletin, *Medicaid Provider Agreements Snapshot* (Aug. 2016) (Ex. MM). And the Petitioner States have all entered into agreements with the federal government to participate in Medicaid. *See* CMS, *1864 Agreement* (Ex. NN).

26. This is the first *and only* mandatory vaccination program in the history of the Medicare or Medicaid programs. 86 Fed. Reg. at 61567 ("We have not previously required any vaccinations[.]"); *id.* at 61568 ("[W]e have not previously imposed

such requirements[.]"). Nothing in any State's agreement with HHS has ever contemplated being required to implement and enforce a vaccination requirement.

III. Changed Circumstances Undermine the Interim Final Rule.

27. The Petitioner States don't believe that the circumstances justified the IFR's mandate at the time of its publication. But even if they did, the circumstances have now unmistakably changed, and the agency's reliance, as justification for both the vaccination requirement and "good cause" to avoid notice-and-comment rulemaking, on the now-dissipated Delta variant has been stale since the emergence of the Omicron variant—shortly after the IFR's publication. Many of the Petitioner States explained as much in a comment letter to CMS in January 2022. Even after receiving that notice, CMS failed to consult with Petitioner States over the vaccine requirements or the State Surveyor Directives.

28. When CMS issued the IFR in November 2021, Delta was the prominent variant, accounting for nearly all of the COVID cases in the United States. *See* Ex. H. But by late-December, Omicron replaced Delta as the prominent strain. *Id.* And now, Omicron accounts for all cases. Ex. G.

29. Yet the threat posed by the Delta—not Omicron—variant formed the gravamen of the IFR. *See Biden v. Missouri*, 142 S. Ct. 647, 651 (2022) (finding good cause based on "the Secretary's belief that any 'further delay' would endanger patient health and safety given the spread of the Delta variant").

30. Nearly all studies show that, while the Omicron variant is more transmissible than its predecessors, it causes less severe disease and fewer deaths and

hospitalizations. CDC, *Trends in Disease Severity and Health Care Utilization During the Early Omicron Variant Period Compared with Previous Sars-CoV-2 High Transmission Periods—United States, December 2020—January 2022* (Jan. 25, 2022) (Ex. OO). The CDC Director acknowledged as much. *CDC's Walensky cites study showing Omicron has 91% lower risk of death than Delta*, YAHOO!NEWS (Jan. 12, 2022) (Ex. PP). Current research shows that standard COVID-19 vaccinations provide little protection against transmission of the Omicron variant. *See supra* notes 7–10, 15.

IV. Implications for Americans Seeking Necessary Healthcare.

31. The IFR regulates over 10 million healthcare workers and suppliers in the United States. 86 Fed. Reg. at 61603. Of those, CMS estimated that 2.4 million were unvaccinated when it issued the IFR. *Id.* at 61606.

32. CMS's objective is to coerce the unvaccinated workforce into submission or cause them to lose their livelihoods, *id.* at 61607 ("The most important inducement will be the fear of job loss, coupled with the examples set by fellow vaccine-hesitant workers who are accepting vaccination more or less simultaneously."), even if that disrupts patients' access to care or exacerbates healthcare staffing shortages, *id.* at 61608 ("[I]t is possible there may be disruptions in cases where substantial numbers of healthcare staff refuse vaccination and are not granted exemptions and are terminated, with consequences for employers, employees, and patients.").

33. Many of the 2.4 million unvaccinated healthcare workers who have not submitted thus far will not submit to federally coerced vaccination. If CMS succeeds in coercing states to enforce the IFR against their own citizens, these healthcare

workers will lose their jobs (or not return if they already have), states will lose front-line healthcare workers, providers, suppliers, and services, and America's most vulnerable populations will lose access to necessary medical care.

34. CMS admitted that it did not know how many unvaccinated workers would submit. *Id.* at 61607, 61612. But it acknowledged that there are "endemic staff shortages for all categories of employees at almost all kinds of healthcare providers and suppliers." *Id.* at 61607. And it recognized that "these may be made worse" when unvaccinated workers leave as a result of the rule. *Id.* But it brushed these concerns aside and concluded that a "relatively small fraction of that [healthcare worker] turnover will be due to vaccination mandates." *Id.* at 61609.

35. Contrary to CMS's predictions, the staffing pinch was felt almost immediately after the IFR took effect. Bart Valdez, *The Crisis in Healthcare Staffing*, Medical Economics (Feb. 4, 2022) (Ex. QQ) (The emergence of the Omicron variant "compounded a staffing shortage of healthcare workers at a time when" they were needed the most.). Those staffing shortages have persisted, at great cost to many patients seeking needed medical care across the country. *See* Johnson, *supra* note 20 (Ex. Y).

36. A few statistics illustrate the extent of the problem. Already 34.4% of nursing homes in Montana face staff shortages. *See AARP Nursing Home COVID-19 Dashboard*, AARP Publ. Pol'y Inst. (updated Oct. 13, 2022) (Ex. RR), https://www.aarp.org/ppi/issues/caregiving/info-2020/nursing-home-covid-dashboard.html. That number exceeds 40% in Idaho, and ranges from 15.3% to 38.5% in

the remaining Petitioner States. And it's worse in many other states—more than 50% of nursing homes in Kansas, New Hampshire, and Washington face staff shortages and more than 60% of facilities in Alaska, Maine, Minnesota, and Wyoming face shortages. *Id.* Even when the IFR was implemented, a study by the AARP showed that nearly one-third of the nation's 15,000 nursing homes reported a shortage of nurses or aides. *See* Emily Paulin, *Worker Shortages in Nursing Homes Hit Pandemic Peak as Covid Deaths Continue*, (Nov. 10, 2021) (Ex. SS) (explaining that "[e]ven a small percentage of staff members leaving their jobs due to this mandate would have a disastrous impact on vulnerable seniors who need around-the-clock care").

37. Many healthcare workers in those states are still not fully vaccinated, despite having faced considerable pressure to get vaccinated. For example, in Montana, Idaho, Oklahoma, and Ohio, over 20% of healthcare workers are not fully vaccinated as of October 2022. *AARP Nursing Home COVID-19 Dashboard*, AARP Publ. Pol'y Inst. (updated Oct. 13, 2022) (Ex. TT), https://www.aarp.org/ppi/issues/caregiving/info-2020/nursing-home-covid-dashboard.html.

V. Harms to Petitioner States.

38. The Petitioner States and the healthcare facilities they operate rely heavily on federal funds provided through the Medicaid and Medicare programs. Many of those state-run facilities are small rural hospitals where staffing shortages are persistent problems. Because the Petitioner States and their state-run facilities accept federal funds, they are required to impose the IFR on their own state employees, including at facilities with ongoing staffing shortages.

39. Additionally, the Petitioner States employ state surveyors who regularly evaluate State-run and private healthcare facilities' compliance with Medicare and Medicaid requirements. When the state surveyors conduct inspections, they assess compliance with both federal and state regulations at the same time. CMS, *Quality, Safety & Oversight – General Information*, (Dec. 1, 2021) (Ex. UU). If those surveyors fail to confirm healthcare facilities' compliance with Medicare and Medicaid requirements, those state-run and private facilities are not entitled to obtain Medicare or Medicaid reimbursements. CMS, *Quality, Safety & Oversight – Enforcement*, (Dec. 1, 2021) (Ex. VV).

40. By commandeering state-run healthcare facilities and state surveyors to enforce the IFR, the Petitioner States will face increased enforcement costs because CMS guidance added the requirement to determine facilities' compliance with the IFR to surveyors' duties, as well as the additional obligation to respond to complaints filed against facilities that appear to be out of compliance. The IFR and the State Surveyor Directives forced states to increase the surveys they conducted and complicated their surveying schedules, requiring states to conduct statewide training to facilitate this new task.

41. The IFR also injures the Petitioner States because it purports to preempt their state and local laws on vaccines and the rights of their citizens. But even in states that don't have laws the IFR would purport to displace, the IFR nevertheless regulates in areas that traditionally and exclusively belong to the states. Whether to compel vaccination is a quintessential public health measure that

states—not the federal government—must consider. The IFR, therefore, violates the Petitioner States' sovereign right to enact and enforce their laws and to exercise their police power on matters such as compulsory vaccination.

42. The IFR's mandate is no take-it-or-leave-it feature of a Spending Clause program. It harms the Petitioner States because it is a fundamental change to the deal under which they agreed to participate in the Medicare and Medicaid programs. No statutory provision, nor any of the rules or contractual provisions in the provider agreements, put the Petitioner States on notice that such a dramatic seizure of power was a part of that deal.

43. The Petitioner States also have interests in protecting the rights of their citizens. The Petitioner States thus challenge unlawful actions that affect their citizens writ large. As a result of the IFR, significant numbers of their citizens who are healthcare employees have been forced to submit to bodily invasion, navigate exemption processes, or lose their jobs and their livelihoods. All their citizens will suffer as a result of the predictable and conceded exacerbation of labor shortages in hospitals and other healthcare facilities.

VI. The Rushed Enactment of the Interim Final Rule.

44. CMS bypassed the APA's and the Social Security Act's required notice and comment period, *see* 5 U.S.C. § 553; 42 U.S.C. § 1395hh(b)(1), because it "believe[d] it would be impracticable and contrary to the public interest … to undertake

normal notice and comment procedures." 86 Fed. Reg.at 61586. CMS thus found "good cause to waive" those procedures. *Id.*

45. In support of "good cause," CMS stated that "[t]he data showing the vital importance of vaccination" indicated that it could not "delay taking this action." *Id.* at 61583. But it did not reconcile that finding with its recognition that "the effectiveness of the vaccine[s] to prevent disease transmission by those vaccinated [is] not currently known." *Id.* at 61615. And a Pfizer executive recently admitted that the company had not tested the vaccine's effectiveness in preventing disease transmission before rollout. *See* Chung, *supra* note 2.

46. Even so, CMS anchored its actions in the threat posed by the Delta variant, which accounted for the vast majority of COVID cases *at that time*. But Delta disappeared shortly after the IFR was implemented.

47. CMS also recognized that the IFR was subject to 42 U.S.C. § 1395z, which requires that "the Secretary shall consult with appropriate State agencies and recognized national listing or accrediting bodies, and may consult with appropriate local agencies" when "carrying out his functions, relating to determination of conditions of participation by providers of services, under subsections (e)(9), (f)(4), (j)(15), (o)(6), (cc)(2)(I), and[] (dd)(2), and (mm)(1) of section 1395x of this title, or by ambulatory surgical centers under section 1395k(a)(2)(F)(i) of this title."

48. But it did not comply with § 1395z's consultation requirement, because it "intend[ed] to engage in consultations with appropriate State agencies ... following the issuance of th[e] rule." 86 Fed. Reg. at 61567. To date, nearly a year after

promulgating the IFR, CMS still hasn't consulted with the states about the IFR or the binding guidance documents it has issued since January 14, 2022. And the post-promulgation "Comment date" ended January 4, 2022. 86 Fed. Reg. at 61555.

VII. Related Legal Proceedings.

49. On November 29, 2021, the U.S. District Court for the Eastern District of Missouri entered a preliminary injunction barring CMS from enforcing the IFR in the states that filed that suit. *See Missouri v. Biden*, 571 F. Supp. 3d 1079 (E.D. Mo. 2021). On November 30, 2021, the U.S. District Court for the Western District of Louisiana granted Petitioner States' Motion for Preliminary Injunction, entering a nationwide injunction—excepting ten states covered by the preliminary injunction issued by the Eastern District of Missouri ("*Missouri* Injunction"). *See Louisiana v. Becerra*, 571 F. Supp. 3d 516, 544 (W.D. La. 2021).

50. On December 15, 2021, the Fifth Circuit denied a request for stay of the preliminary injunction but narrowed the scope of the injunction to the original fourteen Petitioner States. *See Louisiana v. Becerra*, 20 F.4th 260 (5th Cir. 2021). Around that same time, the Eighth Circuit similarly denied a request to stay the *Missouri* Injunction.

51. On January 13, 2022, the Supreme Court stayed both injunctions pending disposition of Defendants' appeal on remand. *See Biden v. Missouri*, 142 S. Ct. 647, 651 (2022). The Supreme Court generally found "good cause" for the "Secretary to issue[] the rule as an interim final rule, rather than through the typical notice-

and-comment procedures" based on the circumstances posed by the "spread of the Delta variant and the upcoming winter season" as urged by the Secretary. *Id.*

52. Immediately after the Supreme Court entered its stay, CMS resumed enforcement of the IFR, requiring healthcare workers to receive the first dose of the COVID-19 vaccine by February 14, 2022, and to be fully vaccinated by March 15, 2022. *See* CMS, *Revised Guidance for the Interim Final Rule* (Jan. 14, 2022; revised Apr. 5, 2022) (Ex. EE).

53. On June 13, 2022, the Fifth Circuit vacated the now-stale preliminary injunction and remanded to the district court "for further consideration in the light of the Supreme Court opinion." *Louisiana v. Becerra*, --- F.4th ---, 2022 WL 2116002 (5th Cir. June 13, 2022). On October 3, 2022, the Supreme Court declined to grant certiorari in the *Missouri* case, so that case is now back before that district court. The IFR and the State Surveyor Guidance face uncertain fates in those district courts.

RATIONALE FOR REQUESTED ACTION

I. The Interim Final Rule is Arbitrary and Capricious.

54. Agency action that is "arbitrary [or] capricious" or "otherwise not in accordance with law" must be "set aside." *See* 5 U.S.C. § 706(2)(A).

55. "[A]gency action is lawful only if it rests on a consideration of the relevant factors" and "important aspect[s] of the problem." *Michigan v. EPA*, 576 U.S. 743, 750, 752 (2015) (requiring "reasoned decisionmaking") (quotation marks omitted). This means agencies must "examine all relevant factors and record evidence." *Am. Wild Horse Pres. Campaign v. Perdue*, 873 F.3d 914, 923 (D.C. Cir. 2017). And

agencies act arbitrarily and capriciously when they "entirely fail[] to consider an important aspect of the problem." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

A. The Interim Final Rule is Structurally Defective: It is a Rigid Emergency Rule That Fails to Account for Changed Facts.

56. The IFR entirely fails to account for changes in data and circumstances even though the IFR recognized that changes were likely. *See Michigan*, 576 U.S. at 750–52 (requiring "reasoned decisionmaking"). If anything has been constant during the pandemic, it's that things change, often rapidly. But not the IFR. The one-size-fits-none rule relied entirely on the impact of the Delta variant. But the Delta variant is long gone. And studies now show that neither the IFR nor its underlying rationale were factually sound. Even if the IFR was defensible at the time (it wasn't), the evidence now unequivocally shows that forcibly vaccinating healthcare workers—if they submitted—does not protect their patients from contracting COVID. And the IFR doesn't account for that. That inflexibility reveals a structural defect in the IFR: it fails to consider that things could change—an inexcusable oversight given the rapid evolution of this disease and our constantly changing understanding of it.

B. The Interim Final Rule Fails to Account for Changes in the Legal and Regulatory Landscape.

57. The IFR failed, and still fails, to account for changes in the legal and regulatory landscape. *See id.* The rule was designed to work in tandem with mandates on other types of employers, including Head Start Programs, federal contractors, and employers with over 100 employees. This limited the alternative employment options for healthcare workers subject to the IFR, forcing them to choose

vaccination over unemployment. Now that these other mandates are enjoined or otherwise unenforceable, unvaccinated healthcare workers have more options to seek employment with non-covered employers. That, of course, further worsens healthcare staffing shortages. This change in circumstances further undermines the legitimacy of the IFR.

C. The Evidence Never Supported the Interim Final Rule as a Measure to Protect Patients from Contracting COVID.

58. The evidence has never supported imposing an industrywide vaccination requirement as a measure to protect patient health. *See id.* Even at the time the IFR was issued, the Secretary was uncertain if the vaccines would prevent disease transmission. *See* 86 Fed. Reg. at 61615 (acknowledging that "the effectiveness of the vaccine[s] to prevent disease transmission by those vaccinated [is] not currently known"). And for good reason: a Pfizer executive admitted that the vaccines were not tested to determine if they were effective at preventing transmission. *See* Chung, *supra* note 2. Recent studies, and studies close in time to the issuance of the IFR, show that compelled vaccination will not meaningfully limit COVID transmission. *See supra* notes 7–10, 15 (collecting authorities). A New York state judge recently put a finer point on it: "Being vaccinated does not prevent an individual from contracting or transmitting Covid-19." *See supra* note 11.

59. The IFR's inflexible rigidity, its failure to consider changing circumstances, and the absence of evidence (when it was issued and now) supporting its efficacy as a measure to protect patient health renders the IFR arbitrary and capricious.

D. The State Surveyor Directives Suffer From the Same Flaws.

60. For the same reasons, the State Surveyor Directives are arbitrary and capricious. Both the paucity and irrelevance of the cited justifications demonstrate a fatal lack of "reasoned decisionmaking." *Michigan*, 576 U.S. at 750–52. CMS clearly failed to "examine all relevant factors and record evidence." *Am. Wild Horse Pres. Campaign*, 873 F.3d at 923. Indeed, the June 14 guidance, declared that the "highly transmissible Omicron subvariants," not the Delta variant that CMS cited to justify the IFR, was responsible for existing COVID-19 cases and acknowledged that "hospitalizations and deaths currently remain relatively low nationwide." CMS, *Surveys for compliance with Omnibus COVID-19 Health Care Staff Vaccination Requirements* (June 14, 2022) (Ex. GG), https://www.cms.gov/files/document/qso-22-17-all.pdf.

61. Any reason for the IFR or the State Surveyor Directives disappeared with the Delta variant. Indeed, CMS stated that it saw "a significant increase in COVID-19 cases in parts of the country" but did not even specify what parts of the country or tailor its dictates to those parts of the country. *Id.* The State Surveyor Directives simply relied on "conclusory statements"—which is patently arbitrary and capricious. *Encino Motorcars*, 136 S. Ct. at 2127. And in any event, the State Surveyor Guidance—which recently replaced the State Surveyor Directives—declared that hospitalizations and deaths "remain relatively low nationwide." CMS, *Revised Guidance for Staff Vaccination Requirements* (Oct. 26, 2022) (Ex. HH), https://www.cms.gov/files/document/qs0-23-02-all.pdf.

II. The Interim Final Rule Exceeds CMS's Statutory Authority.

62. CMS purports to derive the authority for its unprecedented IFR primarily from two statutes that grant the Secretary rulemaking authority. *See* 86 Fed. Reg. at 61567.

63. The first statute delegates to the Secretary the authority to "make and publish such rules and regulations, not inconsistent with this chapter, as may be necessary to the efficient administration of the functions with which [he] is charged under this chapter." 42 U.S.C. § 1302(a). The second delegates to the Secretary the authority to "prescribe such regulations as may be necessary to carry out the administration of the insurance programs under" the Medicare program. 42 U.S.C. § 1395hh(a)(1). But those statutes, alone or in combination, fall far short of granting the Secretary authority to mandate vaccines.

64. CMS also leans on a hodgepodge of facility-specific statutes as purported authority to issue health and safety regulations, including the IFR. 86 Fed. Reg. at 61567. Five of these statutes provide no authority *at all* to regulate generally for patients' health and safety. *See* 42 U.S.C. §§ 1396d(d)(1), (h)(1)(B)(i), 1395rr(b)(1)(A), 1395x(iii)(3)(D)(i)(IV), 1395i–4(e); *see also Biden*, 142 S. Ct. at 656 (Thomas, J., dissenting, joined by Alito, Gorsuch, Barrett, JJ.) (explaining that these five "facility-specific statutes do not authorize CMS to impose 'health and safety' regulations at all"). And those statutes only authorize the Secretary to create standards for the provision of services at those facilities, not industrywide compulsory vaccination.

65. CMS finally relies on several other statutes that define the requirements to be a covered facility, including such other requirements that "the Secretary finds necessary in the interest of the health and safety of the individuals" provided services in those facilities—patients. 42 U.S.C. § 1395x(e)(9); *see, e.g.*, *id.* § 1395x(p)(4)(A)(v), (aa)(2)(K), (cc)(2)(J), (dd)(2)(G), (ff)(3)(B), 1395i–3(d)(4)(B), 1396r(d)(4)(B). But these statutes do not confer the broad authority claimed here. CMS cites other authorities that grant the Secretary some authority to promulgate limited health and safety regulations, but none so broad to permit an unprecedented, industrywide vaccine mandate. *See* 42 U.S.C. §§ 1395x(o)(6), 1395k(a)(2)(F)(i), 1395bbb, 1395eee(f), 1396u–4(f).

66. CMS cites no statutes clearly authorizing a vaccine mandate—nor any previous interpretation of those statutes during the past 57 years of the Medicare and Medicaid programs that would support this exercise of authority. And under the APA, agency actions that are "not in accordance with law" or is "in excess of statutory … authority[] or limitations, or short of statutory right" must be set aside. 5 U.S.C. § 706(2)(A), (C).

67. Even if the Act's general grants of authority or the hodgepodge of facility-specific statutes could be construed to authorize the IFR, the IFR would run afoul of the major questions doctrine.

68. That doctrine is grounded in Article I's vesting clause, *see* U.S. Const. art. I, § 1 ("All legislative Powers herein granted shall be vested in a Congress of the United States," *not* in the Federal Executive), which implies that "important

subjects … must be entirely regulated by the legislature itself," even if the Executive may "act under such general provisions to fill up the details" *see Wayman v. Southard*, 23 U.S. (10 Wheat.) 1, 43 (1825). And it recognizes that courts "presume that Congress intends to make major policy decisions itself, not leave those decisions to agencies." *West Virginia*, 142 S. Ct. at 2609 (citation and internal quotation marks omitted). After all, "[e]xtraordinary grants of regulatory authority are rarely accomplished through 'modest words,' 'vague terms,' or 'subtle device[s].'" *Id.* (citation omitted).

69. Under the major questions doctrine, an agency claiming authority to resolve a question of substantial economic, social, or political importance "must point to 'clear congressional authorization' for the power it claims." *Id.* (quoting *Utility Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014)); *see also id.* ("[S]omething more than a plausible textual basis for the agency action is necessary"); *Ala. Ass'n. of Realtors v. HHS*, 141 S. Ct. 2485, 2489 (2022) (Congress must "speak clearly when authorizing an agency to exercise powers of vast economic and political significance.") (quotation marks omitted).

70. The IFR also triggers two other clear statement rules. First, "[a]bsent a clear statement of intention from Congress, there is a presumption against a statutory construction that would significantly affect the federal-state balance." *Boelens v. Redman Homes, Inc.*, 748 F.2d 1058, 1067 (5th Cir. 1984); *see United States v. Bass*, 404 U.S. 336, 349 (1971). Second, the Executive cannot unilaterally "push the limit

of congressional authority." *Solid Waste Agency of N. Cook Cnty. v. U.S. Army Corps of Engr's*, 531 U.S. 159, 172–73 (2001).

71. Without question, the IFR regulates an issue of substantial political, social, and economic importance—the compulsory vaccination of millions of healthcare workers—and it intrudes on the states' traditional authority to regulate matters of public health and safety, and the medical professions within their borders. Not only that, but it far surpasses any regulatory exertions in the agency's past practice. *See Biden*, 142 S. Ct. at 653 ("Of course the vaccine mandate goes further than what the Secretary has done in the past to implement infection control."); *see also id.* at 656 (Thomas, J., dissenting) (observing that the agency claimed "to find virtually unlimited vaccination power, over millions of healthcare workers" in a handful of "ancillary provisions").

72. The Secretary has never, in the 57-year history of the Medicare and Medicaid programs, construed those statutes to authorize an industrywide vaccination requirement, so courts must be skeptical of CMS's claim that certain scattered provisions of the Social Security Act provide the requisite "clear congressional authorization" to impose the IFR. *See West Virginia*, 142 S. Ct. at 2609–10 ("[T]he want of assertion of power by those who presumably would be alert to exercise it, is … significant in determining whether such power was actually conferred.").

73. Indeed, the very fact that CMS does not point to clear statutory authorization and instead collects a hodgepodge of different statutes to support its claimed authority is perhaps the best evidence of the major questions violation. *See id.* at 2609

(concluding that agencies may not "assert[] highly consequential power"—such as the power to impose an industrywide vaccination requirement—unless it can point to "*clear congressional authorization*" (emphasis added) (citation and internal quotation marks omitted)); *cf. Griswold v. Connecticut*, 381 U.S. 479, 484–85 (1965) (finding a right to privacy somewhere in the "penumbras" and "emanations" of the Bill of Rights, including the First Amendment, the Third Amendment, Fourth Amendment, the Self-Incrimination Clause of the Fifth Amendment, and the Ninth Amendment).

III. The Interim Final Rule is Unconstitutional Several Times Over.

A. The Interim Final Rule violates the Tenth Amendment.

74. Through the IFR, the State Surveyor Directives, and now the State Surveyor Guidance, the Secretary and CMS—and by extension the Executive—encroaches on power reserved to the states. *See* U.S. Const. amend. X. (specifying that "[t]he powers not delegated by the Constitution to the United States, nor prohibited by it to the States, are reserved to the States respectively, or to the people").

75. Public health, including compulsory vaccinations, has long been recognized as part of the police power reserved to the states, not the federal government. *See, e.g.*, *Jacobson v. Massachusetts*, 197 U.S. 11, 24 (1905); *Hillsborough Cnty. v. Auto. Med. Labs.*, 471 U.S. 707, 719 (1985) ("[T]he regulation of health and safety matters is primarily, and historically, a matter of local concern."); *S. Bay United Pentecostal Church v. Newsom*, 140 S. Ct. 1613 (2020) (Roberts, C.J., concurring in the denial of application for injunctive relief) (our Constitution principally entrusts "[t]he safety and the health of the people" to the politically accountable officials of the states "to guard and protect").

76. Reading CMS's statutory delegation of authority as including the power to mandate vaccines throughout an entire industry would violate the Tenth Amendment by trampling on the traditional authority of the states to regulate public health within their borders and on their prerogative to regulate the medical profession. *Cf. Ala. Ass'n of Realtors*, 141 S. Ct. at 2489 ("[Supreme Court] precedents require Congress to enact exceedingly clear language if it wishes to significantly alter the balance between federal and state power and the power of the Government over private property.").

B. The Interim Final Rule Violates the Nondelegation Doctrine and the Major Questions Doctrine.

77. Reading CMS's statutory delegation of authority this broadly would also run headlong into two other constitutional limitations: the nondelegation doctrine and the major questions doctrine. Both doctrines are grounded in Article I's vesting clause. *See* U.S. Const. art. I, § 1 (providing that "[a]ll legislative Powers herein granted shall be vested in a Congress of the United States," *not* in the Federal Executive).

78. Under the nondelegation doctrine, a statutory delegation is constitutional only if "Congress lays down by legislative act an intelligible principle to which the person or body authorized to exercise the delegated authority is directed to conform." *Gundy*, 139 S. Ct. at 2123. And Congress must offer "specific restrictions" that "meaningfully constrain[]" the agency's exercise of authority. *Mistretta v. United States*, 488 U.S. 361, 372 (1989).

79. And as discussed above, under the major questions doctrine, an agency claiming authority to resolve a question of substantial economic, social, or political importance "must point to 'clear congressional authorization' for the power it claims." *West Virginia*, 142 S. Ct. at 2609 (quoting *Utility Air*, 573 U.S. at 324); *see also id.* ("[S]omething more than a plausible textual basis for the agency action is necessary").

80. If the Social Security Act grants authority to mandate industrywide staff vaccination, both "the degree of agency discretion" and "the scope of the power congressionally conferred" are limitless. *Whitman*, 531 U.S. at 475. It would thus lack an intelligible principle that could meaningfully constrain the agency's discretion. *See Gundy*, 139 S. Ct. at 2123; *Mistretta*, 488 U.S. at 372. Yet Congress also lacks authority to delegate "unfettered power" over the American economy to an executive agency. *Tiger Lily*, 5 F.4th at 672. So its "delegation ... of authority to decide major policy questions"—such as whether all healthcare workers must be vaccinated—would violate the nondelegation doctrine, *see Paul*, 140 S. Ct. 342; *see also Tiger Lily*, 5 F.4th at 672 ("[T]o put 'extra icing on a cake already frosted,' the government's interpretation of § 264(a) could raise a nondelegation problem."), and the major questions doctrine too, *see West Virginia*, 142 S. Ct. at 2609–10.

81. By encroaching upon the states' traditional police power, particularly without clear congressional authorization or an intelligible principle to guide its discretion, the agency has exceeded its their authority in violation of the Tenth Amendment, the nondelegation doctrine, and the major questions doctrine.

C. The Interim Final Rule Violates the Spending Clause and the Anti-Commandeering Doctrine.

82. But those are not the IFR's and the State Surveyor Guidance's only constitutional deficiencies. They also impose an unconstitutional condition on Petitioner States' receipt of federal funds and impermissibly commandeer the Petitioner States' officers and employees into administering a federal program.

1. The Rule Imposes a New Condition on Receipt of Medicaid/Medicare Funds Without Notice and is Impermissibly Coercive.

83. "[I]f Congress intends to impose a condition on the grant of federal moneys, it must do so unambiguously," so "States [can] exercise their choice knowingly," *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981).

84. Nothing in federal law or past regulatory practice (or very recent Executive Branch public comments)[26] gave states clear notice that a vaccine mandate would be a condition of accepting federal Medicaid (or, where applicable, Medicare) funds. Indeed, just three years ago the entire U.S. Senate unanimously agreed that ultimately "each State determines the vaccination requirements for the people of that State." S. Res. 165, 116th Cong. (2019) (Ex. XX) (introduced by Senator Duckworth of Illinois and Senators Blackburn and Alexander of Tennessee). The Senate's understanding of the law in 2019 is irreconcilable with CMS's contention that the

[26] As President-Elect, Mr. Biden promised he "d[id]n't think [vaccines] should be mandatory" and "wouldn't demand it be mandatory." Jacob Jarvis, *Fact Check: Did Joe Biden Reject Idea of Mandatory Vaccines in December 2020*, Newsweek (Sept. 10, 2021) (Ex. JJ). In late July 2021, President Biden's Press Secretary admitted that it was "not the role of the federal government" to issue vaccine mandates. White House, *Press Briefing by Press Secretary Jen Psaki* (July 23, 2021) (Ex. WW).

federal government had given the states clear notice that CMS could issue a vaccine mandate for every state or private facility receiving Medicaid (or, where applicable, Medicare) funds.

85. And for the reasons discussed above, the IFR and accompanying State Surveyor Guidance go far beyond the federal interest in patient health and wellbeing. The IFR is one element of President Biden's otherwise unsuccessful attempt to force COVID-19 vaccination on Americans in every sector of the economy. By treating Medicaid and Medicare as an "element of a comprehensive national plan" to "pressur[e] the States to accept policy changes" related to COVID-19 vaccination, Defendants have attempted to "accomplish[] a shift in kind, not merely degree," in the purpose of those federal programs. *NFIB*, 567 U.S. at 580, 583. Because it is not unambiguously clear that forced vaccination is necessary to protect the federal interests specific to Medicaid and Medicare, the IFR violates the Spending Clause.

86. Additionally, because noncompliance with the IFR and State Surveyor Guidance threatens a substantial portion of Petitioner States' budgets, it violates the Spending Clause by leaving the states with no choice but to acquiesce. *See id.* at 581–82 (explaining that courts consider whether the "financial inducement" was so coercive that it passed the point at which "pressure turns to compulsion," and concluding that the "threatened loss of over 10 percent of a State's overall budget" was "more than relatively mild encouragement—it [wa]s a gun to the head" (citations and internal quotation marks omitted)).

2. The Rule Improperly Conscripts State Surveyors to Ensure Compliance with Federal Regulatory Program.

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

88. The IFR violates this doctrine by requiring Petitioner States' State-run hospitals and other facilities that are covered by the mandate to either fire their unvaccinated employees or forgo all Medicaid (and/or, where applicable, Medicare) funding. This draconian choice is no choice at all for the State-run facilities.

89. The IFR and accompanying State Surveyor Guidance also commandeer the states because they force state surveyors to enforce the vaccine mandate by verifying healthcare facility compliance. The stream of State Surveyor Directives demonstrates how CMS has grown accustomed, since the promulgation of the IFR, to treat state surveyors like federal employees.

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

91. The State Surveyor Guidance not only dictates with granular detail the time, method, and results of the surveys, but CMS—not the states and their state

survey agencies—is the one making all the important decisions about how state surveyors carry out their jobs.

92. This "dragoons" Petitioner States into enforcing federal policy by threatening Petitioner States' Medicaid (and, where applicable, Medicare) funds.

REQUESTED ACTION

93. Petitioner States respectfully petition the agency to immediately repeal the IFR and withdraw the State Surveyor Guidance and any other related guidance.

Dated November 17, 2022

Respectfully Submitted,

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