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Administrator Chiquita Brooks-LaSure
Centers for Medicare and Medicaid Services
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Submitted Electronically via Regulations.gov

Re: Comments by the Commonwealth of Kentucky, and the States of Arizona, Louisiana, Montana, Alabama, Alaska, Arkansas, Florida, Georgia, Idaho, Indiana, Kansas, Mississippi, Missouri, Nebraska, New Hampshire, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Tennessee, Texas, Utah, West Virginia, and Wyoming on Medicare and Medicaid Programs Interim Final Rule; Omnibus COVID-19 Health Care Staff Vaccinations, 86 Fed. Reg. 61555 (Nov. 5, 2021) (Document ID CMS-2021-0168-0001).

Dear Administrator Brooks-LaSure:

The undersigned States submit the following comments on the *Medicare and Medicaid Programs Interim Final Rule; Omnibus COVID-19 Health Care Staff Vaccinations* issued in 86 Fed. Reg. 61555 (Nov. 5, 2021) ("Vaccine Mandate"). According to CMS, this Vaccine Mandate would affect 76,000 healthcare providers and over 17 million Americans.[1] The Vaccine Mandate applies to a wide swath of healthcare facilities, including Critical Access Hospitals in rural communities, Hospices, Rural Health Clinics/Federally Qualified Health Centers, and Intermediate Care Facilities for Individuals with Intellectual Disabilities.

[1] *Biden-Harris Administration Issues Emergency Regulation Requiring COVID-19 Vaccination for Health Care Workers*, CMS News Release, Nov. 4, 2021, *available* at https://perma.cc/GT6T-HC5D.

States have already filed actions in multiple United States District Courts challenging the validity of this Vaccine Mandate.[2] But in addition to violating federal law and the United States Constitution, the Vaccine Mandate would cause real-world consequences such as tightening the supply in a labor market already gripped by unmatched demand, decreasing patients' overall access to health care services, especially in rural communities, and demoralizing the essential frontline workers who have sacrificed so much for Americans throughout this pandemic.

The Vaccine Mandate also runs counter to the initial justification for the nation's concerted public health emergency response, *i.e.*, that the failure to take drastic measures would lead to a scenario in which the demand for health care services would far exceed the supply. Thus, what began as a public health effort to "flatten the curve" has now become an act of federal executive overreach, requiring our pandemic's frontline healthcare workers to choose between their liberty or their livelihoods. For the following reasons, CMS must withdraw the Vaccine Mandate.

I. CMS does not have the statutory authority to promulgate the Vaccine Mandate.

The Supreme Court "expect[s] Congress to speak clearly if it wishes to assign to an agency decisions of vast 'economic and political significance.'" *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014). In other words, an executive branch agency cannot "bring about an enormous and transformative expansion in [its] regulatory authority without clear congressional authorization." *Id.*; *see also Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159 (2000) (rejecting an agency's claim to have "jurisdiction to regulate an industry constituting a significant portion of the American economy" absent clear congressional authorization); *Whitman v. Am. Trucking Associations*, 531 U.S. 457, 468 (2001) (Congress "does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions").

Although CMS claims to be acting pursuant to the Social Security Act ("the Act"), none of the Act's provisions bestow CMS with such unfettered power. CMS relies principally upon Section 1102 and Section 1871, but those are mere general authorizations to "prescribe such regulations as may be necessary to carry out the administration of the insurance programs," 42 U.S.C. § 1395hh(a)(1), and to "make and publish such rules and regulations, not inconsistent with this chapter, as may be necessary to the efficient administration" of the Medicare program, 42 U.S.C. § 1302(a). Nothing in those grants of general rulemaking authority clearly authorizes

[2] *See State of Louisiana, et al, v. Xavier Becerra*, Case No. 3:21-cv-03970 (W.D. LA.); *State of Missouri, et al, v. Joseph Biden, et al*, Case No. 4:21-cv-01329 (E.D. MO.); *State of Texas, et al, v. Xavier Becerra, et al*, Case No. 2:21-cv-00229 (N.D. TX.)

an action with the vast economic and political significance of a national vaccine mandate.

Implicitly acknowledging that failing, CMS also cites additional statutes to try to justify applying the Vaccine Mandate to specific types of facilities. 86 Fed. Reg. at 61567. Not one of those statutes, however, expressly authorizes CMS to impose a vaccine mandate. Instead, they grant generic authority to govern unexceptional day-to-day aspects of certain healthcare facilities: for example, to specify "standards" for "active treatment" of "inpatient psychiatric hospital services for individuals under age 21," 42 U.S.C. § 1396d(h)(1)(B)(i); or "standards" for "provid[ing] health or rehabilitative services for [intellectually disabled] individuals" at Intermediate Care Facilities, *id*. § 1396d(d)(1); or "health, safety, and other standards" at Ambulatory Surgical Centers, *id*. § 1395k(a)(2)(F)(i); or standards for "the health and safety of individuals enrolled" in Programs of All-Inclusive Care for the Elderly, *id*. §§ 1395eee(f), 1396u–4(f), or Rural Health Clinics, *id*. § 1395x(aa)(2)(K), or Hospitals, id. § 1395x(e)(9), or Hospices, *id*. § 1395x(dd)(2)(G). Even passing scrutiny of each of those cited secondary authorities readily confirms that those provisions of the Act are "a wafer-thin reed on which to rest such sweeping power." *Alabama Ass'n of Realtors v. HHS*, 141 S. Ct. 2485, 2489 (2021).

Simply put, if any branch of the federal government could enact a policy so sweeping that it would force Americans to choose between their liberty and their livelihoods, it is Congress. And Congress has not expressly authorized the CMS to make this choice in its stead.

II. The Vaccine Mandate violates the Social Security Act in at least three discrete ways.

The Vaccine Mandate violates several discrete sections of the Social Security Act. Each violation standing alone is fatal to the rule's validity. In the aggregate, they represent a willful disregard of the governing law.

First, under 42 U.S.C. § 1395z, "the Secretary shall consult with appropriate State agencies and recognized national listing or accrediting bodies, and may consult with appropriate local agencies," when "carrying out his functions, relating to determination of conditions of participation by providers of services, under subsections (e)(9), (f)(4), (j)(15), (o)(6), (cc)(2)(I), and[] (dd)(2), and (mm)(1) of section 1395x of this title, or by ambulatory surgical centers under section 1395k(a)(2)(F)(i) of this title." CMS acknowledges that this consultation requirement applies to the Vaccine Mandate—and concedes that it did not comply with it. 86 Fed. Reg. at 61567. CMS's "inten[t] to engage in consultations with appropriate State agencies . . . following the issuance of th[e] rule," 86 Fed. Reg. at 61567, is no adequate substitute; the statute plainly requires consultation with States *before* a rule is issued whenever

the Secretary is "carrying out his functions[] relating to determination of conditions of participation by providers of services." 42 U.S.C. § 1395z.

Second, 42 U.S.C. § 1395 provides that nothing in Title 18 of the Social Security Act "shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person." The Vaccine Mandate violates 42 U.S.C. § 1395 by purporting to authorize federal officials at CMS to exercise "supervision" and "control" over the "selection" and "tenure" of employees (including state employees) and other persons "providing health services." It does so by prohibiting covered healthcare facilities from hiring unvaccinated employees and forcing those facilities to terminate—and thus end the tenure of—unvaccinated employees. The Vaccine Mandate also violates § 1395 because it authorizes federal officials at CMS to exercise "supervision" and "control" over the "administration" and "operation" of institutions, agencies, and persons that provide health services (including state facilities and employees) by dictating the hiring and firing policies of those institutions for unvaccinated workers.

Third, 42 U.S.C. § 1302(b)(1) requires that "[w]henever the Secretary [of HHS] publishes a general notice of proposed rulemaking for any rule or regulation proposed under subchapter XVIII, subchapter XIX, or part B of [title IX of the Social Security Act] that may have a significant impact on the operations of a substantial number of small rural hospitals, the Secretary shall prepare and make available for public comment an initial regulatory impact analysis." 42 U.S.C. § 1302(b)(1) applies because the Vaccine Mandate will have a significant impact on the operations of a substantial number of small rural hospitals. The CMS Vaccine Mandate threatens to exacerbate already devastating shortages in healthcare staffing by forcing small rural hospitals to terminate their unvaccinated workers. That, in turn, will compel those hospitals to close certain divisions, cancel certain services, or shutter altogether. Those dire consequences stretch across rural America, and their collective force required CMS to prepare a regulatory impact analysis. It refused to do so.

III. The Vaccine Mandate is arbitrary and capricious for several reasons.

A. The Social Security Act is focused on *patient* wellbeing rather than the health of providers. And the Vaccine Mandate ignores patient wellbeing by reducing the number of health care providers.

Each prong of the President's vaccination policy is aimed at the same overarching goal: increasing individual vaccination rates.[3] But the evidence, even that which CMS relied upon, shows that mandating vaccines will harm patient health and wellbeing. For example, the Vaccine Mandate will cause nursing home staff shortages that will significantly harm patient health and well-being. There is already a critical shortage of healthcare workers. In Montana alone, there is a 39% nurse and aide shortage in nursing homes.[4] And studies show that Vaccine Mandates will exacerbate those shortages.[5] In fact, New York's imposition of a vaccine mandate on health care workers in that State led to such labor shortages that the Governor was forced to call in the National Guard to alleviate the shortage.[6] Thus, the conclusion that a vaccine mandate will cause labor shortages does "not rest on mere speculation about the decisions of third parties" but instead on "the predictable effect of Government action on the decisions of third parties," meaning CMS a fortiori knows the Vaccine Mandate's deleterious effects on the parties it wants to regulate. *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2566 (2019).

The havoc this Vaccine Mandate will cause in rural America is even more predictable. Hospitals in rural America have historically suffered from poorer economic conditions than urban area hospitals. This is why Congress originally created the Medicare Rural Hospital Flexibility Program ("Flex Program") under the Balanced Budget Act of 1997, which established certain criteria for "Critical Access Hospitals." Although the Flex Program has been amended several times over the years, the general purpose for enacting special rules for rural hospitals was Congress's recognition that "one-size-fits-all" policies cannot be sustained in rural health care systems. Rural hospitals are less likely to benefit from economies of scale, given that they treat fewer patients, many of whom are Medicaid and Medicare beneficiaries. In 2019, the American Hospital Association cited rural hospital dependency on Medicaid and Medicare beneficiaries as one of many "persistent problems."[7] Rural hospitals also already suffer from "workforce shortage[s]." That is why, in 2019, the American Hospital Association advocated for policy solutions that would provide "[r]egulatory relief from antiquated requirements that do not improve

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[3] *See* Remarks by President Biden on Fighting the COVID-19 Pandemic" (Sept. 9, 2021), *available* at https://perma.cc/YZ57-EDUX (CMS Vaccine Mandate part of President's plan to "increase vaccinations among the unvaccinated with new vaccination requirements").

[4] AARP, "AARP Nursing Home COVID-19 Dashboard" (updated Nov. 10, 2021), https://bit.ly/3HhAWyy.

[5] *See* Liz Hamel, et al., KFF COVID-19 Vaccine Monitor: Oct, 2021, Kaiser Family Foundation (Oct. 28, 2021), https://perma.cc/D5FF-LAY9; Chris Isidore & Virginia Langmaid, 72% of unvaccinated workers vow to quit if ordered to get vaccinated, CNN.com (Oct. 28, 2021), https://perma.cc/87A3-7EPB.

[6] Evan Simko-Bednarski and Amy Simonson, *Three Northeast states deploy National Guard amid medical capacity crisis due to pandemic*, CNN.com (Dec. 9, 2021), https://perma.cc/V9W9-7FYM.

[7] Challenges Facing Rural Communities and the Roadmap to Ensure Local Access to High-quality, Affordable Care, AHA, *available at* https://perma.cc/MU3Z-97CH.

patient care" and "[w]orkforce programs targeting rural areas that continue to be hard hit by provider shortages."[8] But the Vaccine Mandate does just the opposite–it imposes a regulatory burden that does "not improve patient care" and it would force rural hospitals to terminate health care providers, thus exacerbating the "provider shortages" that rural areas faces.

Consider just a few real-world examples. As one Hospital Director put it, "I fear that our rural hospital will soon face closing the doors permanently" because of the Vaccine Mandate. Ex. 1 ¶ 5; see also Ex. 2 ¶ 7 ("While the percentage of over-all employees that the hospital will lose because of the mandate may not be significant, because we have very small departments and employee specialties are not interchangeable, losing even 10 or 20 employees, which is a likely outcome of the mandate, may have devastating results to our ability to provide the level of care we have provided in the past."). The owner of a skilled nursing facility in Pollock, Louisiana, that employs 56 staff members verifies "that approximately 43% of [its] employees are not vaccinated with the coronavirus vaccine"; that "most, if not all," of those employees will "either be unwilling or unable to take the vaccine against coronavirus as mandated by CMS"; and that if it "lose[s] 57% of our workforce, [it] will be unable to provide safe and efficient care to our residents," raising the specter that "our rural nursing facility will soon face closing the doors permanently." Ex. 3 ¶¶ 4–5.[9]

Similarly, the CEO of two rural hospitals in Utah reports that the Vaccine Mandate "may be devastating" and the loss of unvaccinated employees "may force the cessation of some hospital services and possibly the closure of some departments, all of which will reduce the amount and quality of healthcare services offered to our patients." Ex. 4 ¶ 5; Ex. 5 ¶ 7 (noting likely loss of 20 or 30 employees leading to "devastating results" to patient care); Ex. 6 ¶ 6 (noting Utah healthcare worker shortage at crisis level); Ex. 7 ¶ 5–9.

State officials confirm the damage to patient wellbeing caused by the Vaccine Mandate. The Director of the Utah State Hospital and Utah Developmental Center similarly confirmed that "Utah already has a serious direct care shortage in both its State Hospital and State Developmental center that is jeopardizing client and staff safety and care." Ex. 8 ¶ 11. "[T]he number of vacant staff positions" at those facilities "has roughly doubled from September 2020 to September 2021," jumping "from 74 to 141" at the State Hospital and "from 50 to 109" at the State Development Center. *Id.* ¶ 12. "These entities cannot afford to lose any additional staff," *id.* ¶ 13, but "[i]mplementation of a vaccine mandate without a weekly testing option will likely

[8] *Id.*
[9] *See also Rural COVID patients in ICUs at higher risk of dying than urban counterparts, according to WVU researcher*, WVU Today (Nov. 11, 2021), https://perma.cc/QW58-CFCK.

cause resignations of staff members," and "even a few resignations will exacerbate an understaffing problem that already exists," *id*. ¶ 15. The CFO of the Alabama Department of Public Health (ADPH) estimates that "roughly 40% of our covered unvaccinated employees will resign" if the Vaccine Mandate is implemented, which "jeopardizes the ability of ADPH . . . to perform its home-health services to a particularly vulnerable population." Ex. 9 ¶¶ 12–13; *see also* Ex. 10 ¶¶ 9–11; Ex. 11 ¶¶ 12–18.

In short, patient wellbeing is not served by preventing the hiring and retention of qualified healthcare workers.

B. CMS failed to consider less restrictive alternatives, including an exemption for those who have natural immunity.

CMS rejected daily or weekly testing. 86 Fed. Reg. at 61614 ("We have reviewed scientific evidence on testing and found that vaccination is a more effective infection control measure."). That conclusion is facially deficient: it fails to identify the "evidence" supporting this decision or to explain how such evidence relates to the goal of protecting workers or patients in a healthcare setting. It also contradicts existing evidence in the States. Since July 2021, employees at the Utah State Hospital and Utah State Developmental Center have been required to be vaccinated or take a weekly COVD-19 test; 14% of employees at the Hospital (119 employees) and 30% of employees at the Developmental Center (164 employees) take the test each week, Ex. 8 ¶¶ 7–9, and that alternative approach has created no apparent harm to patients or staff. That's just one data point confirming there is no evidence that vaccination is the only acceptable way to protect workers and patients in a healthcare setting. CMS's careful wording reveals as much; its goal here is "effective infection control," 86 Fed. Reg. at 61614, not protection in any particular environment.

The rejection of natural immunity as a basis for exemption is equally dismissive and unsupported. *See id*. For example, a highly reported study from Israel involving review of 74,000 cases of infection concluded that a person with natural immunity is 27 times less likely to be re-infected than a vaccinated person. *See* Ex. 12 ¶¶ 29–35; Ex. 13 ¶¶ 47–53. Other studies support this conclusion. *Id*. (collecting sources). And a recent study from South Africa, where the Omicron variant was first detected, has linked both natural immunity from previous infections and vaccination to "the uncoupling of the high case rates seen with the Omicron variant and the rates of severe disease."[10]

[10] Shabir A. Madhi, Ph.D., ET. AL., *South African Population Immunity and Severe Covid-19 with Omicron Variant*. MEDRXIV. Preprint. Dec. 21, 2021, *available* at https://perma.cc/BG2P-LE46.

Consider other justifications CMS provides without explaining how a less restrictive alternative could suffice. CMS states that it "has received anecdotal reports suggesting individuals in care are refusing care from unvaccinated staff, limiting the extent to which providers and suppliers can effectively meet the health care needs of their patients and residents." 86 Fed. Reg. at 61558. Yet CMS fails to explain how these anecdotal patients will receive care when the unvaccinated worker is permanently unable to provide care and has not been replaced due to labor shortages. Clearly, a less restrictive alternative for these "anecdotal" reports, for which CMS fails to provide a number, would be for such patients to wait until a vaccinated employee could arrive to provide services. The unvaccinated employee could then care for a patient who did not have this concern, while the vaccinated employee could tend to the anecdotal patient. Under the Vaccine Mandate, the health care provider has only one employee to care for two patients, as opposed to two employees available based on the preferences of the two patients. CMS fails to explain how the reduction in such services increases patient wellbeing.

C. The Vaccine Mandate fails to account for "breakthrough" cases, and as the Omicron variant spreads, it is unclear how the vaccines will stop the spread of new infections.

The primary justification given by CMS is that *patients* will fear the *risk of infection* from health care workers, and therefore decline to obtain crucial services. 86 Fed. Reg. at 61558. But new data shows that the Omicron variant is particularly infectious despite inducing milder symptomatic disease. In fact, even the CDC "expects that anyone with Omicron infection can spread the virus to others, *even if they are vaccinated* or don't have symptoms."[11] Moreover, the CDC states that "breakthrough infections in people who are fully vaccinated are likely to occur."[12] Thus, if the CDC is publishing guidance that those fully vaccinated are still "likely" to be infected with the Omicron variant, and that such individuals "can spread the virus to others," it is not clear how the Vaccine Mandate will alleviate patient fear of being infected in a health care setting. CMS's justification is already stale.

IV. The Vaccine Mandate violates the Spending Clause, the Tenth Amendment, and the Anti-Commandeering doctrine.

"[I]f Congress intends to impose a condition on the grant of federal moneys, it must do so unambiguously" so that "States [can] exercise their choice knowingly." *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981). Nothing in federal law gave States clear notice that a vaccine mandate would be a condition of accepting federal Medicare or Medicaid funds. And for the reasons discussed above, the Vaccine

[11] *Omicron Variant: What you Need to Know*, CDC, https://perma.cc/5XUT-H9CP.
[12] *Id.*

Mandate goes far beyond the federal interest in patient health and wellbeing. Additionally, because noncompliance with the Vaccine Mandate threatens a substantial portion of States' budgets, it violates the Spending Clause by leaving the States with no choice but to acquiesce. *See NFIB v. Sebelius,* 567 U.S. 519, 582 (2012) ("The threatened loss of over 10 percent of a State's overall budget, in contrast, is economic dragooning that leaves the States with no real option but to acquiesce in the Medicaid expansion.").

The federal government's powers are limited and enumerated. Thus, the "powers not delegated to the United States by the Constitution, nor prohibited by it to the states, are reserved to the states respectively, or to the people." U.S. Const. amend. X. "The authority of the state to enact this statute [mandating a smallpox vaccine] is to be referred to what is commonly called the police power,—*a power which the state did not surrender* when becoming a member of the Union under the Constitution. *Jacobson v. Massachusetts*, 25 S.Ct. 358, 360 (1905) (emphasis added). Congress, on the other hand, possesses no such general police power. *See, e.g., United States v. Lopez*, 115 S.Ct. 1624, 1624 (1995) (holding that the Commerce Clause did not authorize Congress to enact the Gun-Free School Zones Act of 1990 because the Commerce Clause cannot be converted "to a general police power of the sort retained by the States"). "Quarantine laws, for example, may be considered as affecting commerce; yet they are, in their nature, *health laws*." *Gibbons v. Ogden*, 22 U.S. 1, 9 (1824) (emphasis original). As such, "making quarantine regulations[ ] has hitherto been exclusively exercised by the several States." *Id*. at 44. Thus, it is doubtful whether Congress could disguise a Vaccine Mandate as regulating commercial activity, because vaccine requirements—like quarantine laws—are health laws. And only the States have the power to enact such measures. Clearly, CMS has no general police power to enact this Vaccine Mandate.

The Vaccine Mandate also violates the Tenth Amendment's Anti-Commandeering Doctrine. The Tenth Amendment and the Constitution's structure 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 v. United States*, 521 U.S. 898, 928 (1997). The Vaccine Mandate violates this doctrine by requiring State-run hospitals with state employees to either fire their unvaccinated employees or lose Medicare and Medicaid funding. The Vaccine Mandate also commandeers the States because it forces State surveyors to enforce the Vaccine Mandate by verifying healthcare provider compliance. *E.g.*, Ex. 9 ¶ 18; Ex. 14. This "dragoons" States into enforcing federal policy by threatening state Medicare and Medicaid funds in violation of the Anti-Commandeering Doctrine.

* * *

We appreciate the opportunity to provide input on the CMS Interim Final Rule. But to be clear, the undersigned believe that the President, and CMS acting at his direction, have overstepped their authority by coercing health care employees to undergo vaccination through an unprecedented use of a statute intended to ensure patient access to health care services. The Interim Final Rule should be vacated, and we hope that the Biden Administration reconsiders its position and abandons its efforts to force vaccination on the American public.

Respectfully submitted,

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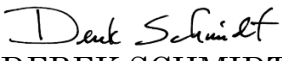

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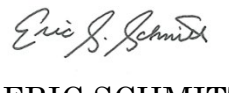

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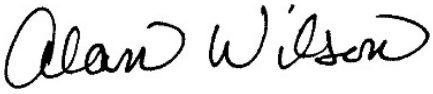

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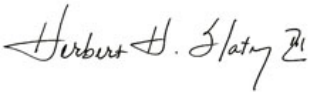

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