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Secretary Xavier Becerra
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

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

Submitted via Postal and Electronic Mail

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

Dear Secretary Becerra and Administrator Brooks-LaSure:

We write in support of a recent petition for rulemaking filed by Montana and 21 other States. That petition asks your agency to repeal an Interim Final Rule imposing a nationwide vaccine mandate on millions of American healthcare workers. *See Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination*, 86 Fed. Reg. 61,555 (Nov. 5, 2021) ("the Rule").

The Rule requires all staff in the medical industry to be fully vaccinated against COVID-19 as a condition of employment. 86 Fed. Reg. at 61,568-69. The Centers for Medicare & Medicaid Services ("CMS") promulgated the Rule in November 2021 without notice or comment near the beginning of the "Delta wave" out of concern over that highly transmissible variant. *Id.* at 61,583. Over ten million healthcare workers fall under CMS's jurisdiction, *id.* at 61,603, and CMS reasoned that the Rule's threat of job loss would coerce many of them into vaccination, *id.* at 61,607. And the agency believed that the expected costs—such as disrupting access to care or exacerbating healthcare staffing shortages, *id.* at 61,608—were justified given the Delta variant's potential risks, *id.* at 61,568, 61,583.

The Rule—along with the Biden administration's various other vaccine mandates—has been the subject of much legal controversy. *See generally Biden v. Missouri*, 142 S. Ct. 647 (2022); *see also Nat'l Fed'n of Indep. Bus. v. OSHA*, 142 S. Ct. 661 (2022) (OSHA vaccine mandate for private employers); *Kentucky v. Biden*, 23 F.4th 585 (6th Cir. 2022) (vaccine mandate for federal

contractors); *Louisiana v. Becerra*, 577 F. Supp. 3d 483 (W.D. La. 2022) (Head Start vaccine mandate). West Virginia and many others strongly argued that CMS lacked legal authority to issue the Rule and conducted a flawed cost-benefit analysis to justify it. Yet the Rule ultimately survived an effort to stay implementation of the Rule that made its way to the Supreme Court. *Missouri*, 142 S. Ct. at 651-52.

Though we disagreed with the decision to issue the Rule, the Rule should not continue on into effect now. The Rule, after all, was an *interim* measure: It was issued through a rushed process without input from the public. 86 Fed. Reg. at 61,567. Perhaps most importantly, we know more about COVID-19 and the Rule's effects today—and that understanding has shown us that the vaccine mandate reflected in the Interim Final Rule is counterproductive. As the Rule has no merit, we urge you to repeal it and all its related guidance.

Discussion

A. The Rule has undermined healthcare quality by accelerating and prolonging a worker shortage.

At the Rule's release, it affected ten million workers—about a quarter of whom were unvaccinated. 86 Fed. Reg. at 61,603, 61,606. The Rule targeted the jobs of the very people praised as heroes for their bravery in providing care when the COVID-19 virus appeared in the United States. Patrick Adcroft, *De Blasio Promises Ticker-Tape Parade for Health Care Workers After Coronavirus Pandemic Ends*, SPECTRUM NEWS NY1 (Apr. 22, 2020, 6:11 AM), http://bit.ly/3hTbgjr. CMS acknowledged that it did not know how many unvaccinated workers would submit to the Rule's requirements, 86 Fed. Reg. at 61,607, 61,612, and it recognized that COVID-19 itself was already constraining staffing in the healthcare industry. But it nevertheless predicted that a "relatively small fraction of that turnover [] w[ould] be due to vaccination mandates." *Id*. at 61,609.

Today, we know that CMS was wrong when it predicted that the Rule would affect a "small fraction" of healthcare workers. 86 Fed. Reg. at 61,609. Instead, it has fueled a pervasive, nationwide worker shortage in the industry. The American Hospital Association has called the worker shortages in hospitals a "national emergency" "fueling soaring burnout levels that 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, 4:45 PM) (cleaned up), http://bit.ly/3UGzNqp. Patients face "dangerous care practices and outcomes" when healthcare facilities are understaffed. *See* Sai Balasubramanian, *The Healthcare Industry is Crumbling Due to Staffing Shortages*, FORBES (Aug. 26, 2022, 5:13 PM) (cleaned up), http://bit.ly/3URDKbS. And the onset of flu season, a nationwide outbreak of respiratory syncytial virus (RSV), and new COVID-19 variants are likely to worsen patient loads in the midst of this critical shortage. *See, e.g.*, Charles Young, *West Virginia Officials Concerned RSV Cases Could Further Strain Hospitals*, WVNEWS (Nov. 2, 2022), http://bit.ly/3tChuH9.

Rural States like West Virginia are particularly suffering. *See* BIPARTISAN POLICY CENTER, THE IMPACT OF COVID-19 ON THE RURAL HEALTH CARE LANDSCAPE 62-63 (2022). Healthcare leaders in rural areas have expressed alarm about the negative impact the Rule has on staffing and care delivery. Aallyah Wright, *Biden's Vaccine Mandate Could Further Strain Rural Hospitals*, PEW (Oct. 21, 2021), http://bit.ly/3GtjUPW. This fear is real: Outside of our nation's wealthy metropolises, States still suffer from extreme staffing shortages in nursing homes. *AARP Nursing Home COVID-19 Dashboard*, AARP, http://bit.ly/3ghwYwZ (last updated Nov. 17, 2022). Eight States (all rural) have more than fifty percent of their nursing homes understaffed, while another seven saw more than forty percent of homes understaffed. *Id*. The Federal Reserve Bank of Richmond published research noting how "stretched thin" the healthcare supply chain is, especially in these rural States. *See* Tim Sablik, *The Rural Nursing Shortage*, ECON FOCUS, First Quarter 2022, at 4, http://bit.ly/3hJhMci. Staffing shortages have led to record closures of rural hospitals, depriving forgotten Americans of both care and jobs. Jacqueline LaPointe, *Low Reimbursement, Staffing Shortages Lead to Rural Hospital Closures*, REVCYCLE INTEL.: PRAC. MGMT. (Sep. 13, 2022), http://bit.ly/3AunFAS.

CMS should not continue to visit these serious harms on the States through the Rule's vaccine mandate.

B. The benefits that CMS cited in implementing the Rule do not justify its costs.

CMS acknowledged but understated the costs of its mandate, 86 Fed. Reg. at 61,608, and it justified the Rule by claiming that the benefits outweighed those downplayed costs. But any imagined benefits from the Rule have either disappeared or become far less certain. The agency's original cost-benefit analysis is thus doubly flawed.

The primary motivation behind the Rule was combatting the Delta variant of COVID-19, which was both (a) highly transmissible and (b) still relatively deadly. *Missouri*, 142 S. Ct. at 651; 86 Fed. Reg. at 61,568, 61,583. But today, the Delta variant is nonexistent in the United States: As of October 2022, the milder Omicron variant was 100% of American cases. *COVID Data Tracker: Variant Proportions*, CDC, http://bit.ly/3tIrBdu (last updated Nov. 11, 2022). We are unaware of any medical evidence that suggests that the Delta variant is likely to reemerge. Thus, the particular threat that CMS originally used to justify the Rule is gone.

We are also are no longer in a "battle against COVID-19," so the "wartime" benefit from the vaccine mandate simply is not the same. Joseph Biden, President, Remarks by President Biden on Fighting the COVID-19 Pandemic (Sep. 9, 2022), http://bit.ly/3UOKt6t. President Biden has himself declared that "the pandemic is over." Kate Sullivan et al., *Biden: 'The pandemic is over,'* CNN (Sep. 18, 2022, 9:39 PM), http://bit.ly/3EnDYAq. The national economy is reopen. *Id.* Major mask mandates no longer exist, including on interstate crowded transit. *Federal Mask Requirement for Transit*, FED. TRANSIT ADMIN., http://bit.ly/3VbmH4r (last visited Nov. 18, 2022). Many states that adopted early vaccine mandates—including for healthcare workers—have since reversed these policies as the pandemic subsides. Shawn Zeller et al., *The Last of the Covid*

Vaccine Mandates, POLITICO (Oct. 28, 2022, 2:00 PM), http://bit.ly/3tIbOeC. And other federal agencies, including those whose workers are exposed to COVID-19 daily, have rolled back their own vaccine mandates, too. Jeannie Taer, *'Finally Backing Down': Border Patrol Lifts Vaccine Mandate for Personnel*, DAILY CALLER (Nov. 11, 2022, 5:34 PM), http://bit.ly/3hOeLYh (disclosing a CBP memo). CMS, then, is a step behind.

Finally, new evidence has undermined the assumption that the COVID-19 vaccine slows or stops transmission. 86 Fed. Reg. at 61,558. Although CMS conceded the "effectiveness of the vaccine[s] to prevent [] transmission" was "unknown" when it issued the Rule, *id.* at 61,615, it presumed the vaccines had some substantial transmission-hampering effect, *id.* at 61,558. At least some evidence now indicates that vaccines do not stop transmission of COVID-19. *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*, 22 LANCET INFECTIOUS DISEASES 183 (2022), http://bit.ly/3GpJRQb; Alex Gutentag, *Vaccines Never Prevented the Transmission of COVID*, TABLET (Oct. 18, 2022), http://bit.ly/3EhAeR3.

In short, time and experience have confirmed that the benefits CMS claimed when it issued the Rule cannot, in fact, support it.

C. The Rule is inconsistent with America's liberty tradition and medical ethics.

Implicit in our American heritage is "the right to earn a living." Timothy Sandefur, *The Right to Earn A Living*, 6 CHAP. L. REV. 207, 210 (2003). President Jefferson defined "the sum of good government" as one which "shall leave them otherwise free to regulate their own pursuits of industry and improvement, and shall not take from the mouth of labor the bread it has earned." Thomas Jefferson, President, First Inaugural Address (Mar. 4, 1801), http://bit.ly/3TOOgPC. Of course, this principle is not limitless; the Supreme Court long recognized Congress can regulate commerce, working conditions, and wages. *See*, *e.g.*, *Wickard v. Filburn*, 317 U.S. 111, 124 (1942); *W. Coast Hotel Co. v. Parrish*, 300 U.S. 379 (1937). But without the benefits first asserted by CMS, 86 Fed. Reg. at 61,557-58, the Rule seems to intrude on "important liberal values of self-assertiveness and social mobility" without good reason. Sandefur, *supra*, at 262.

Similarly, many healthcare workers have sincere religious or philosophical objections to this vaccine, which the Rule may not adequately respect. 86 Fed. Reg. at 61,572; *Unvaccinated Medical Workers Turn To Religious Exemptions*, MOD. HEALTHCARE (Feb. 14, 2022, 3:19 PM), http://bit.ly/3V6fiTV. The right to practice one's religion—through belief or actions—without interference from the government is fundamental to the First Amendment and American liberty writ large. *Cantwell v. Connecticut,* 310 U.S. 296, 303 (1940). But for those who have religious qualms with the vaccine, the Rule now forces them, at best, to fight their medical bureaucracy for an exemption. At worst, it compels them to choose between livelihood and God.

Finally, the Rule chafes with American medical ethics. *See generally* Robert Olick et al., *Ethical Issues in Mandating COVID-19 Vaccination for Health Care Personnel*, 96 MAYO CLINIC PROC. 2958, 2958 (2021). Informed consent is "predicated on the assumption that man is master of his destiny" and "is deeply rooted in our Western legal system." Paula Walter, *The Doctrine of Informed Consent: A Tale of Two Cultures and Two Legal Traditions*, 14 ISSUES L. & MED. 357, 358 (1999). Like the right to earn a living, informed consent is not limitless: the State can ban suicide, *Washington v. Glucksberg*, 521 U.S. 702 (1997); or drug use, *see* Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (1970); and even require vaccinations, Mary Holland, *Compulsory Vaccination, the Constitution, and the Hepatitis B Mandate for Infants and Young Children*, 12 YALE J. HEALTH POL'Y, L. & ETHICS 39, 41-42 (2012). But even in the seminal case affirming State power to mandate new vaccines for a novel virus, *Jacobson v. Massachusetts*, 197 U.S. 11, 12 (1905), the mandate had a simple exemption for the medically unfit and a *de minimis* buy-out provision for any others who did not wish to comply. The Rule has neither, and it therefore presents a more direct affront to bodily autonomy.

Because the Rule conflicts with these important American legal and medical traditions, CMS should withdraw it.

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The costs from the mandate are crippling our healthcare system and not providing any real benefits to the American people. For these reasons, and because the Rule offends the American traditions of economic liberty, religious freedom, and informed consent, I urge you to withdraw it.

Sincerely,

Patrick Morrisey
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