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SUMMARY

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State and Federal Authority to Mandate COVID-19 Vaccination

The Coronavirus Disease 2019 (COVID-19) vaccines licensed or authorized by the U.S. Food and Drug Administration (FDA) are a critical tool to reduce the spread and severity of COVID-19. FDA initially authorized the vaccines, between December 2020 and February 2021, under Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), a regulatory pathway that allows certain medical products to be made available in the market prior to full FDA approval under specified circumstances, including during a public health emergency. In August 2021, FDA licensed the first COVID-19 vaccine, Pfizer's Comirnaty, for the prevention of COVID-19 in individuals 16 years of age and older, after determining that the vaccine, for the licensed use, meets the standards for safety, purity, and potency (i.e., effectiveness) under the Public Health Service Act.

Given the data supporting the safety and efficacy of the licensed and authorized COVID-19 vaccines, many public health experts view promoting high COVID-19 vaccination rates—along with continued engagement in community mitigation activities that prevent transmission, such as mask wearing in certain settings—as key components of the United States' pandemic response.

One available legal tool for increasing vaccination rates is for governments to require vaccination. In 2021, various state, local, and federal governmental entities instituted COVID-19 vaccination requirements to address the pandemic, particularly as the Delta variant—a highly contagious strain of SARS-CoV-2 (the virus that causes COVID-19)—spread in the United States. Under the United States' federalist system, states and the federal government share regulatory authority over public health matters, with states traditionally exercising the bulk of the authority in this area pursuant to their general police power. That power authorizes states, within constitutional limits, to enact laws "to provide for the public health, safety, and morals" of the states' inhabitants. In contrast to this general power, the federal government's powers are confined to those enumerated in the Constitution.

This report provides an overview of state and federal authority to mandate vaccination. The first part of the report provides background on state and local authority to mandate vaccination under the states' general police power. It discusses the Supreme Court's long-standing recognition of state and local authority to mandate vaccination as an exercise of their police power, and modern courts' analyses of more recent challenges to state vaccination mandates based on the First Amendment's Free Exercise Clause. The report then analyzes the Supreme Court's evolving free exercise jurisprudence and the questions it raises regarding whether and when governments must provide for or grant religious exemptions to vaccination requirements. It then looks at how courts have addressed challenges to COVID-19 vaccination requirements imposed by states and state entities.

The second part of the report provides an overview of federal authority to mandate vaccination. It discusses several sources of existing federal statutory authority that could serve, or have been invoked, as the basis for federal COVID-19 vaccination mandates. It then provides an overview of four employment-based civilian mandates issued by the executive branch to date directed at (1) federal executive agency civilian employees; (2) federal contractors for executive departments, agencies, and offices; (3) most Medicare- and Medicaid-certified providers and suppliers; and (4) employers with 100 or more employees. The report then discusses the state of litigation challenging these mandates. This part also reviews the extent of Congress's constitutional authority under the Constitution's Spending and Commerce Clauses to mandate vaccination.

The report concludes with a brief discussion of a legal issue specific to COVID-19 vaccination mandates, particularly before FDA's licensure of Comirnaty. Namely, it reviews how courts have addressed some litigants' argument that the Emergency Use Authorization status of COVID-19 vaccines preclude entities from mandating COVID-19 vaccination.

Contents

Tables

Contacts

The Coronavirus Disease 2019 (COVID-19) vaccines licensed or authorized by the U.S. Food and Drug Administration (FDA) are a critical tool to reduce the spread and severity of COVID-19.[1] Until August 2021, all COVID-19 vaccines were authorized under Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act),[2] a regulatory pathway that allows certain medical products to be made available in the market prior to FDA approval under specified circumstances, including during public health emergencies.[3] FDA issued the Emergency Use Authorizations (EUAs) under Section 564 after determining that the COVID-19 vaccines met the applicable statutory standards and the Agency's specific safety and efficacy standards.[4] Among other information, data supporting the EUA requests show that the vaccines are effective at preventing symptomatic COVID-19 in vaccinated individuals.[5] Since receiving the EUAs, each COVID-19 vaccine manufacturer, building on the clinical trial safety and effectiveness data previously submitted to FDA in support of their EUA requests, has submitted or is in the process of submitting a biologics license application (BLA) to obtain full approval of the vaccines for specified uses.[6] In August 2021, FDA licensed the first COVID-19 vaccine, Pfizer's Comirnaty, for the prevention of COVID-19 in individuals 16 years of age and older, after determining that the vaccine, for the licensed use, meets the standards for safety, purity, and potency (i.e., effectiveness) under the Public Health Service Act (PHSA).[7]

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[1] *See, e.g.*, *Vaccines Prevented Up to 140,000 COVID-19 Deaths in U.S.*, NAT'L INST. HEALTH, NIH RESEARCH MATTERS (Aug. 24, 2021), https://www.nih.gov/news-events/nih-research-matters/vaccines-prevented-140000-covid-19-deaths-us; Eric C. Schneider et al., *How Many COVID-19 Hospitalizations and Deaths Can Be Averted if States Immediately Accelerate Their Vaccination Efforts?*, COMMONWEALTH FUND BLOG (Oct. 5, 2021), https://www.commonwealthfund.org/blog/2021/how-many-covid-19-hospitalizations-deaths-averted-states-accelerate-vaccination.

[2] FDA authorized three COVID-19 vaccines under Emergency Use Authorizations between December 2020 and February 2021. *See FDA Takes Key Action in Fight Against COVID-19 by Issuing Emergency Use Authorization for First COVID-19 Vaccine*, U.S. FOOD & DRUG ADMIN. (Dec. 11, 2020), https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19; *FDA Takes Additional Action in Fight Against COVID-19 by Issuing Emergency Use Authorization for First COVID-19 Vaccine*, U.S. FOOD & DRUG ADMIN. (Dec. 18, 2020), https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid; *FDA Issues Emergency Use Authorization for Third COVID-19 Vaccine*, U.S. FOOD & DRUG ADMIN, (Feb. 27, 2021), https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine [hereinafter, and collectively, FDA EUA Press Releases].

[3] *See* 21 U.S.C. § 360bbb-3. *See also* CRS In Focus IF10745, *Emergency Use Authorization and FDA's Related Authorities*, by Agata Bodie.

[4] FDA EUA Press Releases, *supra* note 2. *See also* CRS Report R46399, *Legal Issues in COVID-19 Vaccine Development and Deployment*, by Kevin J. Hickey, Wen W. Shen, and Erin H. Ward, at 12–14.

[5] FDA EUA Press Releases, *supra* note 2. At the time of the COVID-19 vaccines' authorization, data supporting their EUA requests showed that the vaccines were between 67%–95% effective at preventing symptomatic COVID-19. *See id.*

[6] *See FDA Approves First COVID-19 Vaccine*, U.S. FOOD & DRUG ADMIN. (Aug. 23, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine [hereinafter FDA Comirnaty Press Release]; *Moderna Completes Submission of Biologics License Application to the U.S. Food and Drug Administration for Its COVID-19 Vaccine*, MODERNA (Aug. 25, 2021), https://investors.modernatx.com/news-releases/news-release-details/moderna-completes-submission-biologics-license-application-us; Johnson & Johnson Single-Shot COVID-19 Vaccinations to Resume in the U.S. for All Adults Aged 18 and Older Following CDC and FDA Decision, JOHNSON & JOHNSON (Apr. 23, 2021), https://www.jnj.com/johnson-johnson-single-shot-covid-19-vaccinations-to-resume-in-the-u-s-for-all-adults-aged-18-and-older-following-cdc-and-fda-decision.

[7] *See* FDA Comirnaty Press Release, *supra* note 6. *See also* 42 U.S.C. § 262(a)(2)(C). For more information about FDA's approval of Comirnaty, see CRS Report R46913, *FDA Approval of the Pfizer-BioNTech COVID-19 Vaccine: Frequently Asked Questions*, by Kevin J. Hickey, Erin H. Ward, and Agata Bodie.

Given the data supporting the safety and efficacy of the licensed and authorized COVID-19 vaccines, many public health experts view promoting high COVID-19 vaccination rates—along with continued engagement in community mitigation activities that prevent transmission, such as mask wearing in certain settings—as key components of the United States' pandemic response.[8] One available legal tool for increasing vaccination rates is for governmental entities to require vaccination.[9] During 2021, various state, local, and federal governmental entities instituted COVID-19 vaccination requirements to address the pandemic, particularly as the Delta variant—a highly contagious strain of SARS-CoV-2 (the virus that causes COVID-19)—spread in the United States.[10] For instance, some states imposed COVID-19 vaccination requirements on certain state employees and/or health care workers;[11] many state entities, such as public universities, likewise imposed vaccination requirements on their staff and students.[12] Several cities issued ordinances or orders that require certain indoor business establishments to verify their patrons' proof of vaccination before permitting entry.[13] The federal government issued several employment- or workforce-based mandates that either directly require certain employees to receive COVID-19 vaccinations or direct certain employers to impose a vaccination or vaccination-and-testing

[8] *See, e.g.*, *COVID-19: Prevent Getting Sick*, CTRS FOR DISEASE CONTROL & PREVENTION (Apr. 27, 2021), https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/index.html; Stacy Wood & Kevin Schulman, *Beyond Politics—Promoting Covid-19 Vaccination in the United States*, NEW ENG. J. MED. (Feb. 18, 2021), https://www.nejm.org/doi/full/10.1056/NEJMms2033790; Mary Van Beusekom, *Experts Propose Steps to Promote, Distribute COVID Vaccine*, CIDRAP NEWS (Dec. 15, 2020), https://www.cidrap.umn.edu/news-perspective/2020/12/experts-propose-steps-promote-distribute-covid-vaccine; Gypsyamber D'Souza & David Dowdy, *Rethinking Herd Immunity and the COVID-19 Response End Game*, JOHNS HOPKINS (Sept. 13, 2021), https://publichealth.jhu.edu/2021/what-is-herd-immunity-and-how-can-we-achieve-it-with-covid-19.

[9] While it is beyond the scope of this report, there are also a range of public policy and other legal tools available (such as education, accessibility, and outreach efforts) to increase vaccine uptake short of a mandate. *See* Kevin G. Volpp et al., *Behaviorally Informed Strategies for a National COVID-19 Vaccine Promotion Program*, JAMA (Dec. 14, 2020), https://jamanetwork.com/journals/jama/fullarticle/2774381; Matt Motta et al., *Encouraging COVID-19 Vaccine Uptake Through Effective Health Communication*, FRONTIER IN POL. SCI. (Jan. 28, 2021), https://www.frontiersin.org/articles/10.3389/fpos.2021.630133/full. *See also* Dorit Rubinstein Reiss & Lois A. Weithorn, *Responding to the Childhood Vaccination Crisis: Legal Frameworks and Tools in the Context of Parental Vaccine Refusal*, 63 BUFF. L. REV. 881, 958–79 (2015) (describing a continuum of legal tools to increase vaccination rates).

[10] *Delta Variant: What We Know About the Science*, CTRS. FOR DISEASE CONTROL & PREVENTION (Aug. 26, 2021), https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html. As of December 20, 2021, a new variant of SARS-CoV-2 first detected in the United States in late November 2021—the Omicron variant—has overtaken Delta to become the dominant strain for new COVID-19 infections in the United States. *See COVID Data Tracker*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://covid.cdc.gov/covid-data-tracker/#variant-proportions (last accessed Dec. 21, 2021).

[11] *See, e.g.*, N.M. DEP'T OF HEALTH, AMENDED PUBLIC HEALTH EMERGENCY ORDER REQUIRING ALL SCHOOL WORKERS COMPLY WITH CERTAIN HEALTH REQUIREMENTS AND REQUIRING CONGREGATE CARE FACILITY WORKERS, HOSPITAL WORKERS, AND EMPLOYEES OF THE OFFICE OF THE GOVERNOR BE FULLY VACCINATED (Sept. 15, 2021), https://www.nmhealth.org/publication/view/rules/6875/; OFF. OF THE GOVERNOR, COMMONWEALTH OF MASS., IMPLEMENTING A REQUIREMENT FOR COVID-19 VACCINATION FOR THE COMMONWEALTH'S EXECUTIVE DEPARTMENT EMPLOYEES (Aug. 19, 2021), https://www.mass.gov/doc/august-19-2021-executive-department-employee-vaccination-order/download; Code Me. R. tit. 10-144, ch. 264, § 2 (2021) (emergency regulation issued by Maine's Department of Health and Human Services adding COVID-19 vaccination to the list of required vaccinations for most health care workers); 10 N.Y.C.R.R. § 2.61 (emergency regulation issued by the New York Department of Health requiring COVID-19 vaccination for certain health care workers).

[12] *See* Elissa Nadworny, *Full FDA Approval Triggers More Universities to Require the COVID-19 Vaccine*, NPR (Sept. 1, 2021), https://www.npr.org/2021/09/01/1031385629/full-fda-approval-triggers-more-universities-to-require-the-covid-19-vaccine.

[13] *See, e.g.*, 10 L.A. Municipal Code § 200.122 (2021), https://clkrep.lacity.org/onlinedocs/2021/21-0878_ord_187219_11-08-21.pdf; CITY OF N.Y., EMERGENCY EXECUTIVE ORDER NO. 228, § 4 (Aug. 25, 2021), https://www1.nyc.gov/assets/home/downloads/pdf/executive-orders/2021/eeo-228.pdf.

requirement on their employees or staff.[14] With the exception of a few state health care worker vaccination requirements that provide only for medical exemptions, the governmental vaccination mandates issued to date generally provide exceptions from the vaccination requirements based on a disability, medical condition, or sincerely held religious belief.[15]

Under the United States' federalist system, states and the federal government share regulatory authority over public health matters, with states traditionally exercising the bulk of the authority in this area pursuant to their general police power.[16] This power authorizes states, within constitutional limits, to enact laws "to provide for the public health, safety, and morals" of the states' inhabitants.[17] In contrast to this general power, the federal government's powers are confined to those enumerated in the Constitution.[18]

This report provides an overview of state and federal authority to mandate vaccination. The first part of the report provides background on state and local authority to mandate vaccination under the states' general police power. It discusses the Supreme Court's long-standing recognition of state and local authority to mandate vaccination as an exercise of their police power, and modern courts' analyses of more recent challenges to state vaccination mandates based on the First Amendment's Free Exercise Clause. It then analyzes the Supreme Court's evolving Free Exercise Clause jurisprudence and the questions it raises regarding whether and when governments must provide for or grant religious exemptions to vaccination requirements.[19] It then takes a look at how courts have addressed challenges to COVID-19-vaccination requirements imposed by state and state entities to date.[20]

The second part of the report provides an overview of federal authority to mandate vaccination. It begins by discussing several sources of existing federal statutory authority that could serve, or have been invoked, as the basis for federal COVID-19 vaccination mandates. It then provides an overview of four employment-based civilian mandates issued by the executive branch to date directed at (1) federal executive agency civilian employees; (2) federal contractors for executive departments, agencies, and offices; (3) most Medicare- and Medicaid-certified providers and suppliers; and (4) employers with 100 or more employees. The report then analyzes the litigation challenging these mandates,[21] before reviewing the extent of Congress's constitutional authority under the Spending and Commerce Clauses to potentially mandate vaccination.[22]

The report concludes with a brief discussion of a legal issue specific to COVID-19 vaccination mandates, particularly before FDA's licensure of Comirnaty. Namely, it looks at how courts have

[14] *See infra* "Executive Branch Authority to Mandate Vaccination."

[15] *See infra* "State COVID-19 Vaccination Mandates and Related Litigation" and "Executive Branch Authority to Mandate Vaccination." In addition to governmental entities, private entities—especially private employers—have also opted to institute vaccination requirements in response to the pandemic. For more information about legal constraints on vaccination requirements imposed by private employers, see CRS Legal Sidebar LSB10573, *COVID-19 Vaccination Requirements: Potential Constraints on Employer Mandates Under Federal Law*, by April J. Anderson and Victoria L. Killion.

[16] *See* Elizabeth Y. McCuskey, *Body of Preemption: Health Law Traditions and the Presumption Against Preemption*, 89 TEMPLE L. REV. 95, 113–20 (2016).

[17] Barnes v. Glen Theatre, Inc., 501 U.S. 560, 569 (1991).

[18] *See* CRS Report R45323, *Federalism-Based Limitations on Congressional Power: An Overview*, coordinated by Andrew Nolan and Kevin M. Lewis, at 1.

[19] *See infra* "Legal Background."

[20] *See infra* "State COVID-19 Vaccination Mandates and Related Litigation."

[21] *See infra* "Executive Branch Authority to Mandate Vaccination."

[22] *See infra* "Congress's Constitutional Authority to Mandate Vaccination."

addressed some litigants' argument that the EUA status of COVID-19 vaccines precludes entities from mandating COVID-19 vaccination.[23]

State and Local Authority to Mandate Vaccination

Legal Background

State and local vaccination requirements—as government actions—are subject to constitutional constraints, including those that protect individual rights.[24] For instance, the government is prohibited by the Bill of Rights from infringing the free exercise of religion or violating due process of law.[25] For more than a century, however, the Supreme Court has recognized few rights-based constraints on states' ability to mandate vaccination, holding instead that the states' general police power to promote public health and safety encompasses authority to mandate vaccination.[26]

In the early part of the 20th century, the Supreme Court twice considered constitutional challenges to state vaccination mandates.[27] Each time, the Court rejected the challenges to the mandates and recognized such laws as falling squarely within the states' police power.[28] In 1905, the Supreme Court in *Jacobson v. Massachusetts* upheld a state law that gave municipal boards of health the authority to require the vaccination of persons over the age of 21 against smallpox, determining the vaccination program had a "real [and] substantial relation to the protection of the public health and safety."[29] In doing so, the Court rejected an argument that such a program violated a liberty interest that, under more modern jurisprudence, the plaintiff might have asserted as a substantive due process right.[30]

Less than two decades later, in *Zucht v. King*, parents of a child who was excluded from school due to her unvaccinated status challenged the local ordinance requiring vaccination for schoolchildren, arguing that the ordinance violated the Fourteenth Amendment's Equal Protection and Due Process Clauses.[31] Relying on *Jacobson*, the Supreme Court rejected the constitutional challenges, concluding "it is within the police power of a State to provide for compulsory vaccination" and that the ordinance bestowed "only that broad discretion required for the protection of the public health."[32]

Based on the Supreme Court's recognition of this authority, states and localities have enacted vaccination mandates for certain populations and circumstances. All 50 states and the District of Columbia, for instance, currently have laws requiring all students enrolled in both public and

[23] *See infra* "Emergency Use Authorization and Vaccination Mandates."

[24] *See* U.S. CONST. art. XIV, cl. 1, § 1; Edmonson v. Leesville Concrete Co., 500 U.S. 614, 619 (1991) ("The Constitution's protections of individual liberty and equal protection apply in general only to action by the government.").

[25] *See* U.S. CONST. amends. I & XIV.

[26] *See* Jacobson v. Massachusetts, 197 U.S. 11, 39 (1905).

[27] *Id.*; Zucht v. King, 260 U.S. 174 (1922).

[28] *Jacobson*, 197 U.S. at 39; *Zucht*, 260 U.S. at 175–77.

[29] *Jacobson*, 197 U.S. at 31.

[30] *See* Reiss & Weithorn, *supra* note 9, at 897–98.

[31] *Zucht*, 260 U.S. at 175–77.

[32] *Id.* at 176–77.

private schools to receive specified vaccines as a condition of school entry.[33] With respect to adults, states—to the extent they have mandated vaccination—have typically limited the mandates to health care workers, who are required to be vaccinated against certain vaccine-preventable diseases as a condition of their employment.[34] These vaccination requirements are generally subject to certain exemptions, which vary from state to state.[35] While most vaccination mandates generally provide for some degree of medical exemption (i.e., when individuals have a contraindication to a vaccine that makes receipt of the vaccine harmful or unsafe),[36] many mandates also include exemptions for those whose religious beliefs counsel against immunization.[37] In the case of student vaccination mandates, several states also provide a broader philosophical exemption for those who object to immunizations because of personal, moral, or other beliefs.[38]

These state and local vaccination mandates have withstood more recent legal challenges.[39] While the Supreme Court's constitutional jurisprudence has evolved substantially since *Jacobson* and *Zucht*,[40] modern courts have continued to rely on these cases to reject due process and equal protection claims against vaccination mandates, giving considerable deference to the states' use of their police power to require immunizations to protect public health.[41]

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[33] *States with Religious and Philosophical Exemptions From School Immunization Requirements*, NAT'L CONF. OF STATE LEGISLATURES (NCSL) (Nov. 22, 2021), https://www.ncsl.org/research/health/school-immunization-exemption-state-laws.aspx.

[34] *See* Brian Dean Abramson, *Vaccine Law in the Health Care Workplace*, 12 J. HEALTH & LIFE SCI. L. 22, 24–27 (2019) (describing different approaches states have taken to impose vaccination requirements on health care workers: some states require health care workers to receive annual flu vaccines; several others require hospitals or other health care facilities to ensure their employees have been vaccinated against certain vaccine-preventable diseases, including hepatitis B, rubella, and mumps; and still others require hospital employees to provide proof of immunization against certain vaccine-preventable diseases).

[35] *See id.* at 28–31 (describing scope of medical and religious exemptions for vaccination mandates for health care workers); NCSL, *supra* note 33 (describing exemptions for student vaccination mandates).

[36] *See, e.g.*, N.Y. Pub. Health Law § 2164(8) (providing a medical exemption from school vaccination requirements if a licensed physician "certifies that such immunization may be detrimental to a child's health").

[37] Abramson, *supra* note 34, at 28–31; NCSL, *supra* note 33.

[38] NCSL, *supra* note 33.

[39] *See, e.g.*, Phillips v. City of New York, 775 F.3d 538, 542–44 (2d Cir. 2015); Workman v. Mingo Cty. Bd. of Edu. 419 F. App'x 348 (4th Cir. 2011); Whitlow v. California, 203 F. Supp. 3d 1079, 1085–89 (S.D. Cal. 2016); Boone v. Boozman, 217 F. Supp. 2d 938, 952–57 (E.D. Ark. 2002). Prior to the COVID-19 pandemic, challenges against state vaccination mandates have primarily occurred in the context of student vaccination requirements. However, in 2009, following the emergence of a new strain of type A influenza (H1N1), New York State issued a regulation that made vaccination against seasonal and H1N1 influenza a condition of employment for health care workers who have direct contact with patients or who may expose patients to disease. This directive drew several legal challenges from local health care workers who argued that the regulation violated the Fourteenth Amendment's Due Process Clause, the First Amendment's Free Exercise Clause, and the right to "freedom of contract" guaranteed by the Fifth and Fourteenth Amendments. *See* Alexander M. Stewart, *Mandatory Vaccination of Health Care Workers*, NEW ENG. J. OF MED. (Nov. 19, 2009), https://www.nejm.org/doi/full/10.1056/nejmp0910151. The litigation, however, was mooted in its early stages after the governor suspended the regulation due to a vaccine shortage. *See* Joe Nocera, *When New York Mandated Vaccinations, Nurses Sued*, BLOOMBERG BUSINESSWEEK (Mar. 23, 2020), https://www.bloomberg.com/news/articles/2020-03-23/can-states-mandate-vaccinations-for-health-care-workers.

[40] Commentators have observed, for instance, that the Supreme Court decided *Jacobson* and *Zucht* before the advent of tiered scrutiny, which may subject regulations that infringe upon certain fundamental liberty interests to heightened scrutiny. Reiss & Weithorn, *supra* note 9, at 896–97. A regulation survives the most heightened level of scrutiny only if it is narrowly tailored to serve a compelling government interest. *See* Reno v. Flores, 507 U.S. 292, 301–02 (1993).

[41] *See, e.g.*, *Phillips*, 775 F.3d at 543; *Workman*, 419 F. App'x at 352–54; *Whitlow*, 203 F. Supp. 3d at 1085–87.

Prior to the COVID-19 pandemic, courts have also generally upheld state vaccination requirements that do not provide for a religious exemption. While most states' school vaccination requirements provide for religious exemptions, several states—some in response to concerns over outbreaks of vaccine-preventable diseases and/or declining vaccination rates—have eliminated those exemptions to permit only medical exemptions.[42]

In the modern era, these mandates without religious exemptions have been subject to several legal challenges, in which plaintiffs have argued the applicable mandate violated their rights under the First Amendment's Free Exercise Clause.[43] Courts generally rejected these claims and concluded that a state is not constitutionally required to provide for a religious exemption.[44] The courts reasoned that, under *Employment Division v. Smith* and its progeny, the vaccination mandates at issue were neutral, generally applicable laws—i.e., laws that do not single out religion or selectively burden religiously motivated conduct.[45] As such, the vaccination mandates, in these courts' view, were not subject to heightened scrutiny under *Smith*.[46] Applying rational-basis review, a lenient standard under which courts generally uphold laws that reasonably further legitimate government interests, courts have held that "the right to free exercise of religion . . . [is] subordinated to society's interest in protecting against the spread of disease."[47]

In 2021, however, the Supreme Court issued two decisions that potentially weaken these precedents involving free exercise challenges to vaccination mandates. In *Tandon v. Newsom*, the Court ruled that a law is not neutral and generally applicable if it treats "*any* comparable secular activity more favorably than religious exercise."[48] "[W]hether two activities are comparable for purposes of the Free Exercise Clause," the Court explained, depends on "the asserted government

[42] *See* James Colgrove & Abigail Lowin, *A Tale of Two States: Mississippi, West Virginia, And Exemptions to Compulsory School Vaccination Laws*, HEALTH AFFS. (Feb. 2016), https://www.healthaffairs.org/doi/10.1377/hlthaff.2015.1172. From 1979 to 2016, Mississippi and West Virginia were the only two states that did not offer nonmedical exemptions. Since 2016, four additional states—California, New York, Maine, and Connecticut—have eliminated nonmedical exemptions. *See* NCSL, *supra* note 33.

[43] *See, e.g.*, *Phillips*, 775 F.3d at 543; *Workman*, 419 F. App'x at 352–54; *Whitlow*, 203 F. Supp. 3d at 1085–87; *Boone*, 217 F. Supp. 2d at 952–55.

[44] *See, e.g.*, *Phillips*, 775 F.3d at 543; *Workman*, 419 F. App'x at 352–54; *Whitlow*, 203 F. Supp. 3d at 1085–87; *Boone*, 217 F. Supp. 2d at 952–55. The alleged violation of the Free Exercise Clause was not a claim available to the plaintiffs in *Jacobson* or *Zucht* because at that time, the Supreme Court had not yet held that the First Amendment applied to the states. *See Phillips*, 775 F.3d at 543.

[45] *See, e.g.*, *Phillips*, 775 F.3d at 543; *Workman*, 419 F. App'x at 352–54; *Whitlow*, 203 F. Supp. 3d at 1085–87; *Boone*, 217 F. Supp. 2d at 952–55.

[46] *See, e.g.*, *Phillips*, 775 F.3d at 543; *Workman*, 419 F. App'x at 352–54; *Whitlow*, 203 F. Supp. 3d at 1085–87; *Boone*, 217 F. Supp. 2d at 952–55.

[47] *Boone*, 217 F. Supp. 2d at 954; *see also Phillips*, 775 F.3d at 543; *Workman*, 419 F. App'x at 352–54; *Whitlow*, 203 F. Supp. 3d at 1085–87. In cases where a vaccination mandate includes a religious exemption, plaintiffs have also filed suit to challenge their unsuccessful invocation of the exemption. In these cases, courts, applying the relevant state law, typically considered whether the plaintiffs' objections to vaccination are based on a sincerely held religious belief. *See, e.g.*, N.M. v. Hebrew Acad. Long Beach, 155 F. Supp. 3d 247, 257–58 (E.D.N.Y. 2016) (finding that plaintiff failed to establish her objections to vaccination were religious in nature); *In re* Christine M., 157 Misc. 2d 4, 21 (N.Y. 1992) (finding that plaintiff's objections to vaccination were based on plaintiff's personal and medical, rather than religious, beliefs); Lewis v. Sobol, 710 F. Supp. 506, 516 (S.D.N.Y. 1989) (finding that plaintiffs' objections to vaccination stemmed from their religious beliefs, which entailed "views of spiritual perfection" that they apply in their dietary and medical practices).

[48] 141 S. Ct. 1294, 1296 (2021) (per curiam) (alteration in original). The Supreme Court's *Tandon* ruling was issued on the Court's non-merits docket. For more information about the potential differences in the precedential value of the Court's non-merits versus merits decisions, see *infra* note 110.

interest that justifies the regulation at issue."[49] Applying this standard, the Court concluded that the state regulations at issue in *Tandon*, which limited religious gatherings in response to the COVID-19 pandemic, treated some comparable secular activities—such as getting haircuts and retail shopping—more favorably without showing that these secular activities posed a lower risk of transmission of COVID-19.[50] Thus, the Court applied heightened scrutiny and granted a preliminary injunction, staying enforcement of the state regulations during pendency of the litigation.[51]

A few months after the *Tandon* ruling, the Supreme Court, in *Fulton v. City of Philadelphia*, considered whether a city's contract provision prohibiting sexual orientation discrimination by contractors violated a religious foster care agency's free exercise rights.[52] The contract provision at issue generally prohibited providers from rejecting a child or family for services based on their sexual orientation unless a specified city official, at his "sole discretion," granted an exception.[53] Even though the City had never granted an exception under the provision, the Court held that this exemption system meant that the nondiscrimination policy was not generally applicable under *Smith*.[54] This system, in the Court's view, "incorporate[d] a system of individual exemptions" that invited the government "to decide which reasons for not complying with the policy are worthy of solicitude."[55] Because a law lacks general applicability "if it prohibits religious conduct while permitting secular conduct that undermines the government's asserted interest in a similar way," the Court held that the City "may not refuse to extend that exemption system to cases of religious hardship without compelling reason."[56] The Court concluded that the City failed to offer any compelling reason for "why it has a particular interest in denying an exception to [the plaintiff foster care agency] while making them available to others."[57]

Together, *Fulton* and *Tandon* could suggest that where a governmental requirement provides a secular exemption from the requirement (but no religious exemption), and the exemption system is to some extent discretionary, the requirement may not be neutral and generally applicable for purposes of the Free Exercise Clause.[58] This interpretation would mean that a governmental requirement with only a secular exemption—assuming that the secular exemption is comparable to a hypothetical religious exemption as measured against the asserted government interest underlying the requirement—may be subject to heightened scrutiny.[59]

For state vaccination requirements—which typically provide, at a minimum, medical exemptions to those with contraindications—*Fulton* and *Tandon* thus raise a number of questions that potentially unsettle the law concerning vaccination requirements and religious freedom. These questions include whether a vaccination requirement that provides only for a medical exemption—a secular exemption—is not neutral and generally applicable; whether that analysis depends on the extent to which the medical exemption process is discretionary; and whether

[49] *Tandon*, 141 S. Ct. at 1296.

[50] *Id.* at 1297.

[51] *Id.* at 1297–98.

[52] 141 S. Ct. 1868

[53] *Id.* at 1878.

[54] *Id.*

[55] *Id.* at 1879.

[56] *Id.* at 1877–78 (internal alterations and quotations omitted) (quoting Emp. Div., Dep't of Hum. Res. of Or. v. Smith, 494 U.S. 872, 884 (1990)).

[57] *Id.*

[58] *See id.* at 1878–79; Tandon v. Newsom, 141 S. Ct. 1294, 1297–98 (2021) (per curiam).

[59] *See Fulton*, 141 S. Ct. at 1878–79; *Tandon*, 141 S. Ct. at 1297–98.

medical and religious exemptions—as measured against the relevant underlying government interest for vaccination requirements—are comparable exemptions in the context of this analysis. To the extent a vaccination requirement that provides only a medical exemption would be subject to heightened scrutiny, *Fulton* and *Tandon* also leave unanswered whether there are certain circumstances under which the requirement would survive such scrutiny.

While courts have historically upheld state vaccination requirements generally, more recent developments in the Supreme Court's free exercise jurisprudence raise questions regarding whether, when, and under what circumstances states must provide or grant religious exemptions to a vaccination requirement.

State COVID-19 Vaccination Mandates and Related Litigation

In 2021, various state and local entities instituted COVID-19 vaccination requirements to address the pandemic, particularly as the Delta variant began to cause surges in COVID-19 cases across the country. Many public universities, for instance, imposed vaccination requirements on their students and staff as a condition of in-person attendance and employment.[60] A few cities required certain indoor business establishments in their jurisdictions to verify their patrons' proof of vaccination before permitting their entry.[61] To date, only a few states have imposed statewide vaccination requirements, and these requirements are generally limited to health care workers.[62] At least one state—California—announced in 2021 plans to add COVID-19 vaccination to the list of required student vaccinations. The requirement is expected to be phased-in by grade span in 2022, applying to grades 7 through 12 starting on July 1, 2022.[63] With the exception of several state health care worker mandates (as well as California's expected student vaccination requirements) that provide only for a medical exemption,[64] most of these state and local vaccination requirements provide for both medical and religious exemptions.

Many of these state COVID-19 vaccination requirements have drawn legal challenges. To date, consistent with the discussion in the preceding section, courts have generally upheld these requirements, particularly if the requirements provide for both medical and religious exemptions.[65] Some of the common claims raised in these challenges include, for instance, an alleged violation of the plaintiffs' substantive due process rights to bodily integrity or right to refuse unwanted medical treatment, or an alleged violation of their equal protection rights. Courts

[60] *See supra* note 12 and accompanying text.

[61] *See supra* note 13 and accompanying text.

[62] *See supra* note 11 and accompanying text.

[63] *California Becomes First State in Nation to Announce COVID-19 Vaccine Requirements for Schools*, OFF. OF GOVERNOR (Oct. 1, 2021), https://www.gov.ca.gov/2021/10/01/california-becomes-first-state-in-nation-to-announce-covid-19-vaccine-requirements-for-schools/.

[64] As noted *supra* in note 42, California eliminated, in 2016, nonmedical exemptions for its student vaccination requirements generally.

[65] *See, e.g.*, Klaassen v. Trustees of Ind. Univ., 7 F.4th 592 (7th Cir. 2021) (affirming district court's denial of a motion to enjoin a state university's policy requiring COVID-19 vaccination as a condition of in-person attendance); Norris v. Stanley, No. 1:21-CV-756, 2021 WL 4738827, at *4 (W.D. Mich. Oct. 8, 2021) (denying plaintiff's motion to enjoin a state university policy requiring employees to receive COVID-19 vaccination); Kheriaty v. Regents of the Univ. of Cal., No. 8:21-cv-01367, 2021 WL 4714664 (C.D. Cal. Sept. 29, 2021) (similar); Dixon v. De Blasio, No. 21-cv-5090, 2021 WL 5740187, at *14 (E.D.N.Y. Oct. 12, 2021) (denying plaintiffs' motion to enjoin several mayoral executive orders that require certain business entities to prevent individuals who have not received a COVID-19 vaccine from remaining in certain indoor facilities); Valdez v. Grisham, No. 21-cv-783, 2021 WL 4145746, at *4–5 (D.N.M. Sept. 13, 2021) (denying plaintiffs' motion to enjoin state public health orders that require all hospital workers and state fair exhibitors to be vaccinated against COVID-19).

have generally rejected these claims, relying on *Jacobson* to conclude that a fundamental right or a suspect class is not implicated by the vaccination mandates, which reasonably further a legitimate government interest under rational-basis review.[66]

The principal area of legal uncertainty as to state vaccination requirements, as explained in the preceding section, is whether and when state vaccination requirements must provide for religious exemptions, and the circumstances under which such exemptions may be granted or denied. On this issue, the federal courts of appeals have reached arguably conflicting results.

In *Dahl v. Board of Trustees of Western Michigan University*, the district court preliminarily enjoined (i.e., temporarily suspended) a state university's policy requiring student-athletes to be vaccinated in order to participate in team activities.[67] The university's policy—which applied only to student-athletes and not the student body at large—provided that "[m]edical or religious exemptions and accommodations will be considered on an individual basis."[68] Several student-athletes who were denied religious exemptions and barred from participation sued to challenge the policy, alleging, among other claims, that the policy violated their free exercise rights.[69] In considering the university's motion to lift the preliminary injunction, the U.S. Court of Appeals for the Sixth Circuit (Sixth Circuit) concluded that the university's discretionary exemption process provided a "mechanism for individualized exemptions" under *Fulton* that rendered the policy *not* generally applicable, subjecting it to heightened scrutiny.[70] Applying heightened scrutiny, the Sixth Circuit concluded that the student-athletes were likely to succeed on their free exercise claim because while the university had a compelling interest "in fighting COVID-19," the policy was not narrowly tailored to achieve that.[71] The court reasoned that nonathlete students were not required to be vaccinated, undermining the university's stated interest in prohibiting conduct that created health risks.[72] The court also drew comparisons to other university policies that allowed exemptions, suggesting the university's vaccination policy might have been unnecessarily "severe."[73]

In *Does v. Mills*, the U.S. Court of Appeals for the First Circuit (First Circuit) considered Maine's August 2021 emergency regulation that added COVID-19 vaccination to the list of required vaccinations that employees of licensed health care facilities must receive.[74] The state legislature in 2019 eliminated all nonmedical exemptions to the state's health care worker and student vaccination requirements, citing declining vaccination rates and the need to protect those who are

[66] *See, e.g.*, *Klaasen*, 7 F.4th at 592–94; *Norris*, 2021 WL 4738827, at *2-4; *Dixon*, 2021 WL 5740187, at *4–6, *8–9; *Valdez*, 2021 WL 4145746, at *5–9. In addition to these claims, another common claim raised by plaintiffs challenging COVID-19 vaccination requirements—particularly before FDA fully approved a COVID-19 vaccine—is a claim asserting that the vaccination requirements in question violate the EUA provision of the FD&C Act. *See infra* "Emergency Use Authorization and Vaccination Mandates" for additional discussion.

[67] 2021 WL 3891620, at *3 (W.D. Mich. Aug. 31, 2021).

[68] Dahl v. Bd. of Tr. of W. Mich. Univ., 15 F.4th 728, 730 (6th Cir. 2021) (per curiam).

[69] *See id.*

[70] *Id.* at 733–34.

[71] *Id.* at 734–35.

[72] *Id.*

[73] *Id.* On November 18, 2021, the parties in *Dahl* voluntarily dismissed the appeal after entering into a consent decree, wherein the university agreed not to prevent plaintiffs from participating in team activities because of their unvaccinated status. Under the consent decree, the university may require unvaccinated plaintiffs to submit to COVID-19 testing weekly or more frequently, and may also require them to wear face coverings during team activities. *See* Dahl v. Bd. of Tr. of W. Mich. Univ., Consent Decree ¶ 2, ECF No. 46, Nov. 16, 2021 (M.D. Mich.). Accordingly, no final decision on the merits is expected in this case.

[74] 16 F.4th 20, 28 (2021).

immunocompromised and reliant on others' vaccinations for protection.[75] In issuing the August 2021 regulation, the Maine Department of Health and Human Services and Maine's Center for Disease Control determined that the rule was necessary because the highly contagious Delta variant had caused a 300% increase in COVID-19 cases between June and July 2021; health care facilities are uniquely susceptible to outbreaks of infectious diseases like COVID-19; such outbreaks hamper the state's ability to care for its residents suffering from both COVID-19 and other conditions; the size of Maine's health care workforce is limited; alternatives to vaccination (such as regular testing or reliance on personal protective equipment) would not be as effective; and no health care facility types at the time—despite the states' various efforts at promoting voluntary vaccination—had achieved vaccination rates above 90%, which the state public health agency determined was the minimum rate required to prevent community transmission of the Delta variant.[76] Several then-unvaccinated health care workers sued to challenge the regulation, alleging, among other claims, that the COVID-19 vaccination requirement violates their free exercise rights because it lacks a religious exemption.[77]

In affirming the district court's denial of a preliminary injunction, the First Circuit concluded that the plaintiffs were not likely to succeed on their free exercise claim. In the court's view, Maine's vaccination requirement was a neutral and generally applicable law that (1) did not "single[] out religious objections . . . because of their religious nature" and (2) "applie[d] equally across the board" without requiring the state government "to exercise discretion in evaluating individual requests for exemptions."[78] According to the First Circuit, the availability of a general medical exemption to employees who provide a written statement from specified licensed medical professionals that the vaccination is medically inadvisable did not render the vaccination requirement not generally applicable. Unlike the exemption system at issue in *Fulton*, the medical exemption, in the court's view, was "a single objective exemption" that did not call for discretionary evaluation, nor did it permit "secular conduct that undermines the government's asserted interests in a similar way" as would a religious exemption.[79] Instead, according to the court, exempting only those whose health would be endangered by vaccination *reinforced* the state's underlying interests in protecting the health and safety of its residents, including that of the health care workforce and those who are most vulnerable because they cannot be vaccinated for medical reasons.[80] Because the medical exemption is meaningfully different from a religious exemption—the availability of which would *undermine* the relevant state interests—the court concluded that Maine's vaccination requirement was generally applicable and subject to rational-basis review, which it "easily satisfie[d]."[81]

Even though the court did not need to reach this issue, the First Circuit further concluded that even if heightened scrutiny applied, the vaccination requirement would likely survive such scrutiny. According to the court, the state has a compelling interest in both stemming the spread of COVID-19 and in denying an exception to plaintiffs, who provide health care services, because exemptions from the requirement for non-health-related reasons threaten "the most vulnerable

[75] *Id.* at 24–25. The amended exemptions became effective in 2020. *See id.*

[76] *See id.* at 27–28.

[77] *Id.* at 28.

[78] *Id.* at 30.

[79] *Id.* at 30–31.

[80] *Id.*

[81] *Id.* at 31–32.

Mainers."[82] The vaccination requirement, according to the court, was also sufficiently narrowly tailored to achieve those interests, given that (1) Maine considered alternatives such as testing, masking, and social distancing, but found them to be inadequate in meeting the state's goals particularly in the face of the spread of the Delta variant; (2) Maine "demonstrated that it ha[d] tried many alternatives to get its healthcare workers vaccinated short of a mandate" but such efforts failed to achieve the at least 90% vaccination rate necessary to halt community transmission; and (3) the requirement was not underinclusive—in that it applies to all except those who have a medical contraindication—or overinclusive—in that it was limited to "the narrow sphere of healthcare workers . . . who regularly enter healthcare facilities."[83]

In *We the Patriots USA, Inc. v. Hochul*, the U.S. Court of Appeals for the Second Circuit (Second Circuit) considered an emergency rule adopted by the New York Department of Health, 10 N.Y.C.R.R. § 2.61, that directed specified health care facilities in the state to require certain employees to receive COVID-19 vaccines.[84] Like the Maine emergency regulation, New York's vaccination requirement provided only a medical exemption, which applied "only until such immunization is found no longer to be detrimental to [the employees'] health and must be supported by a certification from a licensed physician or nurse practitioner issued in accordance with generally accepted medical standards, including recommendations of the Advisory Committee on Immunization Practices."[85] Several health care workers sued to challenge New York's rule, asserting, among other claims, that it violated the Free Exercise Clause.[86]

The Second Circuit concluded that the plaintiffs did not demonstrate a likelihood of success on their free exercise claim at the preliminary injunction phase.[87] Like the First Circuit, the Second Circuit concluded that the plaintiffs did not meet their burden to show that New York's rule—by providing a medical but not a religious exemption—was not a neutral, generally applicable law under *Smith*, or that the rule did not satisfy rational-basis review.[88] Similar to the First Circuit, the Second Circuit found that the medical and religious exemptions were not "comparable" exemptions relative to the asserted government interests—which included protecting the health of health care employees to reduce staffing shortages that can compromise patient safety—because a medical exemption furthered those interests while a religious exemption would undermine them.[89] Also similar to the First Circuit, the Second Circuit found that § 2.61's medical exemption did not create a system of individualized exemptions under *Fulton* because the rule "provide[d] for an objectively defined category of people to whom the vaccine requirement does not apply"—i.e., those who present the appropriate certification from a specified medical professional in accordance with generally accepted medical standards.[90] Because the plaintiffs, in the court's view, did not demonstrate that § 2.61 is not neutral or generally applicable, the court applied rational-basis review. An emergency rule that requires health care employees to be vaccinated in the face of an especially contagious variant of the virus that has claimed the lives of more than

[82] *Id.* at 32.

[83] *Id.* at 32–33.

[84] 17 F.4th 266, 274 (2d Cir. 2021) (per curiam).

[85] *Id.* at 275.

[86] *Id.* at 273.

[87] *Id.*

[88] *Id.*

[89] *Id.* at 285.

[90] *Id.* at 289.

750,000 in the United States and some 55,000 in New York, the court reasoned, "easily m[et] that standard."[91]

In sum, *Dahl* on one hand, and *Does* and *We the Patriots* on the other hand, highlight some of the unsettled questions raised by *Fulton* and *Tandon* as they apply to vaccination requirements and the circumstances under which states may be constitutionally required to provide for or grant religious exemptions. Whereas *Dahl* suggests that the availability of a medical exemption may render a vaccination requirement not generally applicable and thus subject to heightened scrutiny, for instance, *Does* and *We the Patriots* indicate that, at least in the health care employment context, a vaccination requirement providing for only a medical exemption is a generally applicable requirement subject to rational-basis review.

The Supreme Court has so far rejected applications to stay the Maine and New York emergency rules at issue in *Does* and *We the Patriots*, allowing for their implementation.[92] The plaintiffs in *Does* filed a petition for certiorari, and the Court, if it grants the petition, may provide further clarification on these open questions.

Federal Authority to Mandate Vaccination

Like state vaccination requirements, federal vaccination requirements are government actions subject to constitutional constraints.[93] In addition to constitutional constraints based on individual rights—which apply in broadly similar ways to both state and federal vaccination mandates—federal vaccination requirements must fall within the powers granted to the federal government in the Constitution.[94] Federal requirements imposed by the executive branch are also subject to statutory constraints. Such requirements generally must rely on the federal government's existing statutory authorities.[95] Depending on the circumstances, the requirements may also be subject to statutory requirements under the Administrative Procedure Act (APA), the Religious Freedom Restoration Act of 1993 (RFRA),[96] or other context-specific statutory limits.[97]

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[91] *Id.* at 290.

[92] *See* Dr. A v. Hochul, 142 S. Ct. 552 (2021); Does v. Mills, 142 S. Ct. 17 (2021). Justices Neil Gorsuch, Clarence Thomas, and Samuel Alito dissented from the application denial in both cases. Among other determinations, the dissent concluded that the vaccination requirements at issue were not generally applicable, including because the medical exemption process was "individualized" and because both medical and religious exemptions are comparable exemptions as measured against the states' asserted interest in infectious disease control and protecting the states' health care infrastructure. *See Does*, 142 S. Ct. at 19–20; *Dr. A*, 142 S. Ct. at 556–57.

[93] *See, e.g.*, Pub. Util. Comm'n of D.C. v. Pollak, 343 U.S. 451, 461 (1952).

[94] *See* Nolan & Lewis, *supra* note 18, at 1.

[95] *See, e.g.*, City of Arlington v. Fed. Commc'ns Comm'n, 569 U.S. 290, (2013) (stating that agencies' "power to act and how they are to act is authoritatively prescribed by Congress" and thus a question concerning agencies' statutory authority "is always whether the agency has gone beyond what Congress has permitted it to do").

[96] The APA generally establishes the procedures that federal agencies use for rulemaking and adjudication, and the procedures for how courts may review those agency actions. RFRA generally imposes a heightened standard of review for federal government actions that substantially burden a person's religious exercise and creates a private right of action to those so burdened to assert that violation as a claim or defense and obtain appropriate relief against the government. For more information about the APA, see CRS In Focus IF10003, *An Overview of Federal Regulations and the Rulemaking Process*, by Maeve P. Carey; and CRS Legal Sidebar LSB10558, *Judicial Review Under the Administrative Procedure Act (APA)*, by Jonathan M. Gaffney. For more information about RFRA, see CRS In Focus IF11490, *The Religious Freedom Restoration Act: A Primer*, by Whitney K. Novak.

[97] In the military context, for instance, additional waiver requirements under 10 U.S.C. § 1107a may apply to the administration of medical products subject to EUAs to servicemembers.

This part begins by discussing the executive branch's authority to mandate vaccination, including the asserted statutory authority for the non-military federal COVID-19 vaccination mandates issued to date, and the state of the litigation challenging these mandates. This part then reviews the extent of Congress's constitutional authority under the Constitution's Spending and Commerce Clauses to mandate vaccination.

Executive Branch Authority to Mandate Vaccination

Prior to the COVID-19 pandemic, federal vaccination requirements were primarily limited to the immigration,[98] military,[99] and certain federal health care employment contexts.[100] Certain existing statutory authorities, however, could potentially encompass the authority to mandate vaccination in specified contexts.

Earlier in the COVID-19 pandemic, and even before the pandemic, some commentators believed that one likely source of authority for federal public health orders—including those related to vaccination requirements—may be Section 361(a) of the PHSA.[101] This provision, codified at 42 U.S.C. § 264(a), grants the Secretary of HHS the authority—delegated in part to the Centers for Disease Control and Prevention (CDC)[102]—to make and enforce regulations necessary "to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession."[103] Following this text, Section 361(a) states that "[f]or purposes of carrying and enforcing such regulations," the Agency "may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in [its] judgment may be necessary."[104] Based on this statutory text, some have argued that a broad construction of CDC's Section 361(a) authority may permit CDC to issue

[98] Under 8 U.S.C. § 1182(a)(1)(A), for instance, immigrants seeking permanent residence in the United States must present documentation showing they have been vaccinated against certain specified vaccine-preventable diseases.

[99] The Department of Defense's Immunization Program, for instance, requires all health care personnel working in the Department's medical treatment facilities, as well as all active duty and selected reserve personnel, to receive annual seasonal influenza vaccines or to obtain a medical or administrative exemption. DEP'T OF DEFENSE INSTRUCTION 6205.02 § 1.2b (July 23, 2019), https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/620502p.pdf?ver=2019-07-23-085404-617. For more information about the military's vaccination requirements, see CRS In Focus IF11816, *Defense Health Primer: Military Vaccinations*, by Bryce H. P. Mendez.

[100] The Indian Health Service, for instance, has required proof of immunization for measles and rubella as a condition of employment for all health care personnel since 1991. The agency added seasonal influenza vaccine as a mandatory vaccination for all health care personnel in 2015. *See* SGM 21-04, Memorandum from Elizabeth A. Fowler, Acting Director of Indian Health Serv. to all agency employees, *available at* https://www.ihs.gov/sites/ihm/themes/responsive2017/display_objects/documents/sgm/2021/covid-19-immunizations-requirement.pdf.

[101] *See, e.g.*, Lindsay F. Wiley, *CDC's Boundary-Pushing Eviction Freeze*, AM. CONST. SOC'Y (Sept. 3, 2020), https://www.acslaw.org/expertforum/cdcs-boundary-pushing-eviction-freeze/ (prior to the availability of COVID-19 vaccines, noting that "[t]he most likely source of authority for federal executive action to mandate and support social distancing and face covering is Section 361(a) of the Public Health Service Act"); Christopher T. Robertson, *Vaccines and Airline Travel: A Federal Role to Protect the Public Health*, 42 AM. J.L. & MED. 543, 566 (2016) (suggesting CDC has authority under Section 361 "to require vaccinations as a condition of airline travel").

[102] *See Legal Authorities for Isolation and Quarantine*, CTRS. FOR DISEASE CONTROL & PREVENTION (Feb. 24, 2020), https://www.cdc.gov/quarantine/aboutlawsregulationsquarantineisolation.html.

[103] 42 U.S.C. § 264(a).

[104] *Id.* § 264(a).

regulations requiring vaccination in circumstances that would prevent the foreign or interstate transmission of COVID-19.[105]

Before the COVID-19 vaccines became available under EUAs during the Trump Administration, the CDC invoked PHSA Section 361 to issue a nationwide eviction moratorium in September 2020. CDC based the moratorium on its findings that evictions threatened to increase the spread of COVID-19 as they would force people to live in new shared housing or congregate settings.[106] Numerous legal challenges to the eviction moratorium followed. By June 2021, the U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit) and the Sixth Circuit—in the context of reviewing procedural motions to stay or lift the stay of the district courts' preliminary injunction orders[107]—had reached different conclusions as to the CDC's statutory authority to issue the order. The D.C. Circuit, adopting a broad construction of Section 361, concluded that "the CDC's eviction moratorium f[ell] within the plain text of 42 U.S.C. § 264(a)."[108] The Sixth Circuit, in contrast, characterized the enumerated measures under Section 361(a) as "property interest restrictions" and concluded that the eviction moratorium was "radically unlike" such restrictions and thus "f[ell] outside the scope of the statute."[109]

The eviction moratorium litigation introduced much legal uncertainty over the scope of CDC's authority under PHSA Section 361(a), including the agency's authority to issue regulations relating to public health measures, such as vaccination, that arguably bear more directly on infectious disease control than eviction moratoria. Uncertainty as to the reach of Section 361(a) deepened after August 2021, when the Supreme Court—in the context of granting a procedural motion to lift a stay of the eviction moratorium in *Alabama Ass'n of Realtors v. Department of Health and Human Services*—concluded that the plaintiffs challenging the eviction moratorium were likely to succeed on their statutory claim.[110] Characterizing the enumerated measures under Section 361(a) as measures "directly relate[d] to preventing the interstate spread of disease by identifying, isolating, and destroying the disease itself," the Court concluded that the eviction moratorium "relate[d] to interstate infection far more indirectly" and the sheer scope of CDC's claimed authority counseled against the government's interpretation. The government has since voluntarily dismissed its appeal, and a final decision on the merits is not expected in the case. In short, while the eviction moratorium litigation indicates that the CDC's authority under Section 361(a) does not extend to issuing eviction moratoriums, it leaves unresolved the precise scope of the agency authority under the provision to take other measures to prevent the spread of communicable diseases.

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[105] *See* Robertson, *supra* note 101, at 566.

[106] 85 Fed. Reg. 55,292, 55,296 (Sept. 4, 2020).

[107] As discussed *infra* in note 110 in more detail, these orders were issued on the courts' non-merits dockets without full briefing or oral argument from the parties; thus, their precedential value beyond the cases in which they were issued is uncertain.

[108] Ala. Ass'n of Realtors v. U.S. Dep't of Health & Human Servs., No. 21-5093, 2021 WL 2221646, at *1 (D.C. Cir. June 2, 2021).

[109] Tiger Lily, LLC v. U.S. Dep't of Hous. & Urb. Dev., 992 F.3d 518, 521, 524 (6th Cir. 2021).

[110] 141 S. Ct. 2485, 2488–89 (2021) (per curiam). This order was issued on the Supreme Court's non-merits or motions docket—sometimes informally called the Court's "shadow docket"—without full briefing and oral argument. Unlike the Court's majority merits decisions, which are generally issued after considering both briefs and oral arguments from the parties as well as input from non-parties known as *amici curiae*, the precedential value of a non-merits orders beyond the case in which it was issued is more uncertain, and lower courts have not traditionally treated such orders as binding. For more discussion about the Supreme Court's non-merits orders, see CRS Legal Sidebar LSB10637, *The "Shadow Docket": The Supreme Court's Non-Merits Orders*, by Joanna R. Lampe.

To address the spread of the Delta variant in 2021, the President and several executive agencies—including the Centers for Medicare and Medicaid Services (CMS) and the Occupational Safety and Health Administration (OSHA)—ultimately invoked several other statutory authorities to issue several employment- or workforce-based COVID-19 vaccination mandates for civilians. These vaccination requirements include those that apply to (1) federal executive agency civilian employees (federal employee mandate);[111] (2) federal contractors for executive departments, agencies, and offices (federal contractor mandate);[112] (3) most Medicare- and Medicaid-certified providers and suppliers (CMS's Medicare/Medicaid provider mandate);[113] and (4) employers with 100 or more employees (OSHA's large-employer vaccination and testing mandate).[114] Subject to accommodations required by federal law for medical disabilities and religious beliefs, these employment-based mandates either directly require certain employees to receive COVID-19 vaccinations or direct certain employers to impose a vaccination or vaccination-and-testing requirement on their employees or staff.[115] (See **Table 1** for a summary of these mandates.)

Federal Employee Mandate

Executive Order 14,043, issued on September 9, 2021, instructs each executive agency to implement a program to require COVID-19 vaccination for all federal employees, subject to exceptions required by law, including those based on a disability, medical condition, or a sincerely held religious belief.[116] The federal employee mandate directs the Safer Federal Workforce Task Force (Task Force) to issue guidance on this requirement's implementation.[117] The mandate is based on the President's statutory authority under 5 U.S.C. §§ 3301, 3302, and 7301.[118] These provisions grant the President general authority to prescribe rules and/or regulations for executive branch employees.[119]

Under the Task Force's guidance, federal employees must have been fully vaccinated (i.e., two weeks after completing either a one-dose vaccine or a two-dose vaccine series) or have obtained an exception by November 22, 2021.[120] The vaccination requirement applies to employees who are under maximum telework or remote-work arrangements.[121] Employees who refuse to be

[111] Exec. Order No. 14,043 of Sept. 9, 2021, 86 Fed. Reg. 50,989 (Sept. 14, 2021).

[112] Exec. Order No. 14,042 of Sept. 9, 2021, 86 Fed. Reg. 50,985 (Sept. 14, 2021).

[113] 86 Fed. Reg. 61,555 (Nov. 5, 2021).

[114] 86 Fed. Reg. 61,402 (Nov. 5, 2021). In addition to these mandates, the Secretary of Defense mandated COVID-19 vaccination for servicemembers. For more information about the military's COVID-19 vaccination mandate, see CRS Insight IN11764, *The Military's COVID-19 Vaccination Mandate*, by Bryce H. P. Mendez.

[115] For more information about reasonable accommodations employers may need to provide—including providing exceptions from the vaccination requirement to employees who do not get vaccinated because of a disability or a sincerely held religious belief—see Anderson & Killion, *supra* note 15.

[116] 86 Fed. Reg. 50,989, 50,990 (Sept. 14, 2021).

[117] *Id.*

[118] *Id.* at 50,989.

[119] *See* 5 U.S.C. §§ 3301 (authorizing the President to "prescribe such regulations for the admission of individuals into the civil service in the executive branch as will best promote the efficiency of that service" and to "ascertain the fitness of applicants as to . . . health"), 3302 (authorizing the President to "prescribe rules governing the competitive service"), 7301 (authorizing the President to "prescribe regulations for the conduct of employees in the executive branch").

[120] *See FAQs – Vaccinations: Vaccination Requirement for Federal Employees*, SAFER FEDERAL WORKFORCE TASK FORCE, https://www.saferfederalworkforce.gov/faq/vaccinations/ (last accessed Dec. 7, 2021).

[121] *See id.* ("Employees who are on maximum telework or working remotely are not excused from this requirement, including because employees working offsite may interact with the public as part of their duties and agencies may need to recall employees who are on maximum telework or working remotely").

vaccinated or provide proof of vaccination, and have neither an exception nor an exception request under consideration, are subject to disciplinary measures, up to and including removal or termination.[122] Under the guidance, any removal or termination would be preceded by a brief period of education and counseling and a suspension period of generally up to 14 days.[123]

Several federal employees and at least one employee union have sued to challenge the federal employee mandate.[124] These suits raise a variety of claims, including some claims common to challenges to state vaccination requirements.[125] As discussed above, courts have generally rejected these claims.[126]

Plaintiffs have also asserted several claims specific to the federal employee mandate, based on certain generally applicable statutory requirements under the RFRA and APA. One set of claims, for instance, challenged the agencies' alleged denial of religious exemption requests as violating RFRA and the First Amendment's Free Exercise Clause.[127] In a November 2021 decision, however, the district court considering these claims rejected them as unripe—or too early—for review, given that each plaintiff had a pending request for exemption and had not suffered any adverse employment consequence.[128] Another claim, raised by an employee union, challenges the manner by which the mandate was implemented. According to the plaintiffs, the vaccination requirement was implemented without undergoing the notice-and-comment rulemaking procedures required by the APA.[129] The district court in December 2021 dismissed the case for lack of standing, concluding, among other determinations, that the plaintiff failed to allege that any of its members had suffered an injury-in-fact because it was "speculative as to whether [they] would be disciplined for failure to become vaccinated because, for example, they may choose to become vaccinated or receive an exemption."[130]

Federal Contractor Mandate

Executive Order 14,042, also issued on September 9, 2021, directs federal executive departments and agencies to include in certain contracts a clause requiring compliance with the Task Force's workplace safety guidance.[131] The Task Force guidance, issued on September 24, 2021, requires federal contractors and subcontractors with a covered contract to conform to several workplace safety protocols, including COVID-19 vaccination of covered contractor-employees, subject to

[122] *See FAQs – Vaccinations: Enforcement of Vaccination Requirement for Employees*, SAFER FEDERAL WORKFORCE TASK FORCE, https://www.saferfederalworkforce.gov/faq/vaccinations/ (last accessed Dec. 7, 2021).

[123] *See id.*

[124] *See, e.g.*, Brnovich v. Biden, No. 2:21-cv-01568, Second Amended Complaint, ECF No. 70 (D. Ariz. filed Nov. 19, 2021) [hereinafter Brnovich Second Amended Complaint]; Church v. Biden, No. 1:21-cv02815, Complaint, ECF No. 1 (D.D.C. filed Oct. 24, 2021); Am. Fed. of Gov't Emp. v. Biden, No. 1:21-cv-23828, Complaint, ECF No. 1 (D. Fla. filed Oct. 30, 2021).

[125] *See, e.g.*, Brnovich Second Amended Complaint, *supra* note 124, ¶¶ 47, 55–57.

[126] *See supra* note 66 and accompanying text.

[127] *See* Order Denying Emergency Application for Temporary Restraining Order and Mot. for Preliminary Injunction, ECF No. 17, Church v. Biden, No. 1:21-cv02815 (D.D.C. Nov. 8, 2021).

[128] *See id.* at 1.

[129] *See* Mot. for Preliminary Injunction at 9–10, ECF No. 19, Am. Fed. of Gov't Emp. v. Biden, No. 1:21-cv-23828 (S.D. Fla. filed Nov. 12, 2021).

[130] *See* Order Dismissing Case for Lack of Subject Matter Jurisdiction, ECF No. 33, Am. Fed. of Gov't Emp. v. Biden, No. 1:21-cv-23828 (S.D. Fla. Dec. 22, 2021).

[131] Exec. Order No. 14,042 of Sept. 9, 2021, 86 Fed. Reg. 50,985, 50,985 (Sept. 14, 2021).

exceptions required by law.[132] Covered contractor-employees include those working on or in connection with a covered contract or working at a covered contractor workplace.[133] Covered contractor-employees working remotely are subject to the vaccination requirements.[134]

Consistent with the executive order, the federal contractor mandate sets forth a phase-in period for the new clause to be added to federal contracts.[135] Generally, new contracts awarded on or after November 14, 2021, must include the new clause, while contracts awarded prior to October 15, 2021, would incorporate the new clause only at the point at which the government renews the contract or exercises an option.[136] By January 18, 2022, covered contractors must ensure that their covered employees are fully vaccinated by the first day of performance of a new contract or when there is a renewal, extension, or exercised option on an existing contract.[137] The Task Force guidance instructs that "significant actions, such as termination of the contract," should be taken if a contractor does not take steps to comply with the requirements.[138]

The Federal Contractor executive order is based on the President's authorities under 3 U.S.C. § 301 and the Federal Property and Administrative Services Act (Procurement Act), including 40 U.S.C. § 121.[139] The Procurement Act empowers the President to "prescribe policies and directives that the President considers necessary to carry out" the Act if they are consistent with the Act,[140] the purpose of which is to provide "an economical and efficient system" for, among other objectives, federal procurement.[141] The Federal Contractor executive order states that it was issued to promote this purpose "by ensuring that the parties that contract with the Federal Government provide adequate COVID-19 safeguards to their workers" performing on or in connection with a covered contract.[142] The President determined that the safeguards would "decrease worker absence, reduce labor costs, and improve the efficiency of contractors and subcontractors at sites where they are performing work for the Federal Government."[143]

The executive order, pursuant to 3 U.S.C. § 301, tasked the Director of the Office of Management and Budget (OMB) with determining whether the Task Force's guidance "will promote economy

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[132] SAFER FEDERAL WORKFORCE TASK FORCE, COVID-19 WORKPLACE SAFETY: GUIDANCE FOR FEDERAL CONTRACTORS AND SUBCONTRACTORS (updated Nov. 10, 2021), https://www.saferfederalworkforce.gov/downloads/Guidance%20for%20Federal%20Contractors_Safer%20Federal%20Workforce%20Task%20Force_20211110.pdf [hereinafter TASK FORCE FEDERAL CONTRACTOR GUIDANCE].

[133] *Id.* at 3.

[134] *See FAQs – Federal Contractors: Workplaces*, SAFER FEDERAL WORKFORCE TASK FORCE, https://www.saferfederalworkforce.gov/faq/contractors/ (last accessed Dec. 7, 2021).

[135] *See FAQs – Federal Contractors: Scope and Applicability of Task Force Guidance for Federal Contractors*, SAFER FEDERAL WORKFORCE TASK FORCE, https://www.saferfederalworkforce.gov/faq/contractors/ (last accessed Dec. 7, 2021).

[136] *See id.*

[137] TASK FORCE FEDERAL CONTRACTOR GUIDANCE, *supra* note 132, at 5.

[138] *See FAQs – Federal Contractors: Compliance*, SAFER FEDERAL WORKFORCE TASK FORCE, https://www.saferfederalworkforce.gov/faq/contractors/ (last accessed Dec. 7, 2021). For more information about the Federal Contractor EO's requirements, see CRS Insight IN11803, *Executive Order 14042 Requirements for COVID-19 Vaccination of Federal Contractors*, coordinated by Heidi M. Peters.

[139] *See* 86 Fed. Reg. 50,985, 50,985 (Sept. 14, 2021).

[140] 40 U.S.C. § 121(a).

[141] *Id.* § 101.

[142] 86 Fed. Reg. 50,985, 50,985 (Sept. 14, 2021).

[143] *Id.*

and efficiency in Federal contracting."[144] In accordance with this delegation, the OMB Director made an affirmative determination in a *Federal Register* notice published on the same date of the Task Force guidance's release.[145] The executive order also directs the Federal Acquisition Regulatory Council to make corresponding amendments to the Federal Acquisition Regulation, and to issue guidance to federal agencies on how to comply with the federal contractor mandate in the interim.[146] The Council issued the guidance on September 30, 2021.[147]

More than 20 states, on behalf of their state agencies and political subdivisions that may have a covered contract subject to the federal contractor mandate, have filed at least four separate suits in different district courts to challenge the mandate.[148] Plaintiffs in each case filed a motion for preliminary injunction seeking to enjoin the mandate while the litigation is pending. In November 2021, one district court—in *Kentucky v. Biden*, a challenge filed by Kentucky, Ohio, and Tennessee—granted the states' motion and enjoined the mandate in those three states while the litigation is pending.[149] In December 2021, another district court—in *Georgia v. Biden*, a challenge filed by Georgia and six other states—granted the states' motion and issued a nationwide injunction.[150] Among other determinations, both district courts concluded that the President likely exceeded his statutory authority under the Procurement Act in imposing the vaccination requirement.[151]

The government has appealed the district courts' orders in both cases. On January 5, 2022, the Sixth Circuit denied the government's application to stay the injunction in *Kentucky*.[152] Among other determinations, the Sixth Circuit agreed with the district court that the federal contractor mandate likely exceeded the President's statutory authority.[153] In the Sixth Circuit's view, the relevant Procurement Act provisions authorize the President "to implement an 'economical and efficient' method of contracting . . . to obtain nonpersonal services," and this authority does not permit the President to "impose whatever medical procedure deemed 'necessary' on the relevant services personnel" *after* those services have been acquired.[154] The government's appeal in *Georgia* is pending before the U.S. Court of Appeals for the Eleventh Circuit (Eleventh Circuit).[155]

[144] *Id.* at 50,985–50,986.

[145] *See* 86 Fed. Reg. 53,691 (Sept. 24, 2021).

[146] 86 Fed. Reg. 50,985, 50,986 (Sept. 14, 2021).

[147] Memorandum from the Fed. Acquisition Regul. Council to Chief Acquisition Officers, Senior Procurement Executives, Defense Acquisition Regulations Council, Civilian Agency Acquisition Council (Sept. 30, 2021), https://www.whitehouse.gov/wp-content/uploads/2021/09/FAR-Council-Guidance-on-Agency-Issuance-of-Deviations-to-Implement-EO-14042.pdf.

[148] *See*, *e.g.*, Florida v. Nelson, No. 8:21-cv-2524 (M.D. Fla. filed Oct. 28, 2021); Kentucky v. Biden, No. 3:21-cv-00055, 2021 WL 5587446 (E.D. Ky. Nov. 30, 2021); Georgia v. Biden, No. 1:21-cv-00163 2021 WL 5779939 (S.D. Ga. Dec. 7, 2021).

[149] *Kentucky*, 2021 WL5587446, at *13–14.

[150] *Georgia*, 2021 WL 5779939, at *12.

[151] *Kentucky*, 2021 WL5587446, at *6–7; *Georgia*, 2021 WL 5779939, at *10.

[152] Kentucky v. Biden, No. 21-6147, 2022 WL 43178, at *1 (6th Cir. Jan. 5, 2022).

[153] *Id.* at *11–16.

[154] *Id.* at *12.

[155] *See* Georgia v. Biden, No. 21-14269 (11th Cir. filed Dec. 10, 2021).

CMS's Medicare/Medicaid Provider Mandate

On November 4, 2021, CMS released an Interim Final Rule (IFR), effective November 5, 2021, that requires specified Medicare- and Medicaid-certified providers and suppliers to establish a policy that requires all eligible staff (subject to legally required exceptions) to receive the first dose of a two-dose COVID-19 vaccine or a one-dose COVID-19 vaccine by December 6, 2021, and to complete their vaccination series by January 4, 2022.[156] This mandate applies to 15 provider and supplier types that participate in Medicare and Medicaid, including hospitals, long-term-care facilities, and rural health clinics.[157] The mandate does not apply to other health care entities such as physician offices, organ procurement organizations, and portable X-Ray suppliers.[158]

For providers and suppliers subject to the IFR, their vaccination policy must apply to all staff who directly provide any care, treatment, or other services for the facility and/or its patients, including (1) employees (including administrative staff as well as facility leadership); (2) licensed practitioners; (3) students, trainees, and volunteers; and (4) individuals who provide care, treatment, or other services for the facility and/or its patients under contract or other arrangements (including housekeeping and food services).[159] Individuals who provide services 100% remotely from sites of patient care and away from staff who work at sites of care—such as fully remote telehealth or payroll services—are not subject to the vaccination requirements.[160] CMS states that noncompliant providers and suppliers will be subject to enforcement remedies based on the level of noncompliance and available remedies, which may include civil monetary penalties, denial of payment for new admissions, and termination of the Medicare/Medicaid provider agreement.[161]

According to CMS, the Medicare/Medicaid provider mandate is based on its determination that a vaccination mandate for health care workers is an essential component of the nation's COVID-19 pandemic response, particularly in light of several factors, including (1) the failure to achieve sufficiently high levels of vaccination based on voluntary efforts and patchwork requirements; (2) potential harm to patients from unvaccinated health care workers; (3) continuing strain on the health care system; and (4) known efficacy and safety of available vaccines.[162] The agency found "good cause" to waive the notice-and-comment rulemaking procedures under the APA and Section 1871(b) of the Social Security Act (SSA).[163] The agency based that determination on several considerations, including (1) that Delta-variant outbreaks showed that current levels of COVID-19 vaccination coverage have been inadequate to protect health care consumers and staff; (2) the pandemic's strain on the health care system; (3) that respiratory infections typically circulate more frequently during the winter months; and (4) the onset of the 2021-2022 influenza season.[164]

[156] 86 Fed. Reg. 61,555, 61,563, 61,573 (Nov. 5, 2021).

[157] *Id.* at 61,556.

[158] *Id.*

[159] *Id.* at 61,570–61,571.

[160] *Id.* at 61,571.

[161] *Id.* at 61,574.

[162] *Id.* at 61,586.

[163] *Id.*

[164] *Id.* at 61,583–61,584, 61,586.

CMS relied on several layers of statutory authorities in issuing the IFR.[165] Across all providers and suppliers, CMS invokes SSA Section 1102, a provision that grants the Secretary of HHS general authority to issue rules "as may be necessary to the efficient administration of the functions" with which the Secretary is charged under the SSA.[166] For Medicare providers and suppliers, CMS additionally relies on SSA Section 1871, which authorizes the Secretary to prescribe regulations "as may be necessary to carry out the administration" of the Medicare programs.[167] Finally, for each provider and supplier, CMS also relies on certain provider- and supplier-specific provisions, many of which authorize the Secretary to impose requirements he finds necessary to protect the health and safety of individuals who receive services from the relevant entities.[168]

At least 25 states, on behalf of certain state-run health care facilities that may be subject to the vaccination requirements, filed four separate suits to challenge the IFR shortly after its issuance.[169] Plaintiffs in each case filed a motion for preliminary injunction seeking to enjoin the IFR while the litigation proceeds. In November 2021, one district court, in *Florida v. Department of Health & Human Services*, declined to enjoin the IFR, concluding the state had not shown "irreparable harm" to justify an injunction.[170] In the court's view, the state had not provided sufficient factual evidence to demonstrate that the vaccination requirements' alleged likely adverse impact, such as potential staffing shortages, would result if the requirements were not halted.[171]

Later in the same month, however, two district courts—in *Missouri v. Biden* and *Louisiana v. Becerra*—granted the plaintiffs' motions in each respective case.[172] The *Missouri* court enjoined the IFR in 10 plaintiff states, while the *Louisiana* court enjoined the rule in the remaining states.[173] Among other determinations, both courts concluded that CMS likely exceeded its statutory authority in issuing the IFR because the applicable provisions do not specifically authorize the agency to mandate vaccination;[174] the agency likely lacked "good cause" to waive notice-and-comment rulemaking procedures;[175] and the plaintiffs sufficiently demonstrated they would suffer irreparable harm—including in the form of significant staffing shortages—if the IFR was not enjoined.[176] The U.S. Court of Appeals for the Fifth Circuit (Fifth Circuit), in considering the government's motion to stay the preliminary injunction in *Louisiana*, narrowed the scope of

[165] *Id.* at 61,567.

[166] 42 U.S.C. § 1302(a).

[167] *Id.* § 1395hh(a).

[168] *See, e.g.*, 42 U.S.C. §§ 1395x(e)(9) (authorizing the Secretary to impose requirements on hospitals that he "finds necessary in the interest of the health and safety of individuals" who receive service from the hospitals), 1395x(dd) (similar for hospices), 1395x(aa) (rural health clinics), 1395i-3(d)(4)(B) (long-term care facilities).

[169] *See* Florida v. Dep't of Health & Human Servs., No. 3:21-cv-2722, 2021 WL 5416122 (N.D. Fla. Nov. 20, 2021); Missouri v. Biden, No. 4:21-cv-1329, 2021 WL 5564501 (E.D. Mo. Nov. 29, 2021); Louisiana v. Becerra, No. 3:32-cv-3970, 2021 WL 5609846 (W.D. La. Nov. 30, 2021); Texas v. Becerra, No. 2:21-cv-229, 2021 WL 5964687 (N.D. Tex. filed Nov. 15, 2021).

[170] *Florida*, 2021 WL 5416122, at *1.

[171] *Id.* at *3–4.

[172] *Missouri*, 2021 WL 5564501, at *15; *Louisiana*, 2021 WL 5609846, at *17.

[173] *Missouri*, 2021 WL 5564501, at *15; *Louisiana*, 2021 WL 5609846, at *17.

[174] *See Missouri*, 2021 WL 5564501, at *3; *Louisiana*, 2021 WL 5609846, at *10-11.

[175] *See Missouri*, 2021 WL 5564501, at *5–6; *Louisiana*, 2021 WL 5609846, at *8–9.

[176] *See Missouri*, 2021 WL 5564501, at *12–13; *Louisiana*, 2021 WL 5609846, at *16.

the injunction to the 14 plaintiff states.[177] Since the Fifth Circuit's order, the U.S. District Court for the Northern District of Texas, in *Texas v. Becerra*, issued a preliminary injunction order enjoining the IFR's enforcement in that state.[178] As of December 31, 2021, CMS is enjoined from enforcing the IFR in the 25 states that are plaintiffs in *Missouri*, *Louisiana*, or *Texas*.

As noted by the Fifth Circuit in *Louisiana*, one key legal question on the merits concerning the Medicare/Medicaid provider mandate litigation is whether the rule exceeds the agency's statutory authority because the relevant provisions do not explicitly authorize the agency to mandate vaccination. Characterizing this issue as a "close call," the Fifth Circuit—in upholding the preliminary injunction in the 14 plaintiff states—concluded that the government had not sufficiently demonstrated that the rule fell within the agency's statutory authority.[179]

On this issue, a divided panel of the Eleventh Circuit, in considering Florida's motion for an injunction pending its appeal of the district court's order in *Florida*, concluded that the relevant Medicare and Medicaid provisions "plainly encompass[]" the IFR's vaccination requirement.[180] In the Eleventh Circuit's view, the relevant Medicare and Medicaid statutes expressly "authorized the Secretary to set standards to protect the health and safety of patients" served by Medicare and Medicaid facilities.[181] The IFR's vaccination requirements, according to the Eleventh Circuit, fell squarely within this grant of authority, given that COVID-19 is a deadly, highly transmissible disease, health care workers have long been required to obtain inoculations for infectious diseases, and required vaccination is "a common-sense measure designed to prevent healthcare workers . . . from making [patients] sicker."[182] Thus, in the Eleventh Circuit's view, "when it comes to vaccination mandates, there was no reason for Congress to be more specific than authorizing the Secretary to make regulations for the 'health and safety' of Medicare and Medicaid recipients."[183] To suggest otherwise, the court continued, "would mean that Congress had to have anticipated both the unprecedented COVID-19 pandemic and the unprecedented politicization of the disease to regulate vaccination against it."[184] The dissent's analysis, on the other hand, largely echoes that of the district courts in *Missouri* and *Louisiana*.[185]

On December 30, 2021, CMS announced that the IFR will be implemented and enforced, on a modified timeline, in the jurisdictions *not* subject to the preliminary injunctions in *Missouri*, *Louisiana*, and *Texas*.[186] The deadline to receive the first dose of a vaccine is extended to January 27, 2022, and the deadline to complete the vaccination series is extended to February 28, 2022.[187]

The government filed an application with the Supreme Court seeking to stay the preliminary injunctions in both *Louisiana* and *Missouri*. On January 13, 2022, the Supreme Court granted the

[177] Louisiana v. Becerra, 2021 WL 5913302, at *2–3 (5th Cir. Dec. 15, 2021).

[178] Texas v. Becerra, 2021 WL 5964687, at *16.

[179] *See Louisiana*, 2021 WL 5913302, at *1.

[180] Florida v. Dep't of Health & Human Servs., 2021 WL 5768796, at *12.

[181] *Id.*

[182] *Id.*

[183] *Id.*

[184] *Id.*

[185] *Id.* at 24.

[186] *See Current Emergencies*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page (last accessed Dec. 30, 2021).

[187] *Id.*

application.[188] Among other determinations, the Court concluded that the IFR "fits neatly" within the Secretary's statutory authority to impose necessary conditions to protect the "health and safety" of patients served by the relevant providers and suppliers, particularly given that the Secretary routinely imposes conditions of participation that relate to the qualification and duties of health care workers and the fact that vaccination requirements for health care workers are "a common feature of the provision of healthcare in America."[189]

Following the Court's decision, CMS issued an updated guidance on the IFR for the 24 states previously subject to the preliminary injunctions in *Missouri* and *Louisiana*.[190] In these states, the deadline to receive the first dose of a vaccine is February 14, 2022, and the deadline to complete the vaccination series is March 15, 2022.[191]

OSHA's Large-Employer Vaccination and Testing Mandate

On November 4, 2021, OSHA released an emergency temporary standard (ETS) that generally requires private employers with 100 or more employees to establish and enforce a policy that either (1) requires all employees to receive a COVID-19 vaccination, subject to legally required exceptions; or (2) requires employees to receive either a COVID-19 vaccination or provide proof of regular COVID-19 testing and wear a face covering when indoors or occupying a vehicle with another person.[192] For the 26 states, Puerto Rico, and the U.S. Virgin Islands that have opted to adopt their own OSHA-approved state plans, the ETS also applies to state agency and local government employers.[193] To the extent a workplace is subject to both the ETS and one of the preceding mandates, the non-OSHA-ETS mandate generally applies. For those workplaces, OSHA specifically states either that the ETS does not apply (in the case of federal contractors or health care providers and suppliers)[194] or that compliance with the other mandate is deemed sufficient to meet the employers' obligations under the ETS (in the case of executive agencies).[195]

Under the large-employer vaccination and testing mandate, employees who are not fully vaccinated—including those who have been granted exceptions—generally must be tested at least

[188] Biden v. Missouri, No. 21A240, 2022 WL 120950, *1 (Jan. 13, 2022) (per curiam).

[189] *Id.* at *3. The Court acknowledged that not all statutory provisions invoked by CMS contain the "health and safety" statutory language. *See id.* at *2 n.*. Noting, however, that facilities not subject to the statutory language represent less than 3% of the workers covered by the rule, and that the pertinent statutory language "may be read as incorporating the 'health and safety' authorities applicable to the other 97%," the Court saw no reason to let the 3% "wag the . . . dog." *Id.*

[190] CTRS. FOR MEDICARE & MEDICAID SERVS., CTRS. FOR CLINICAL STANDARDS AND QUALITY/QUALITY, SAFETY & OVERSIGHT GRP., GUIDANCE FOR THE INTERIM FINAL RULE – MEDICARE AND MEDICAID PROGRAMS; OMNIBUS COVID-19 HEALTH CARE STAFF VACCINATION (Jan. 14, 2022), https://www.cms.gov/files/document/qso-22-09-all-injunction-lifted.pdf.

[191] *Id.* at 3.

[192] 86 Fed. Reg. 61,402, 61,552 (Nov. 5, 2021) (adding 29 C.F.R. § 1910.501(d)).

[193] Section 18 of the Occupational Safety and Health Act of 1970 (29 U.S.C. § 667) authorizes states, subject to OSHA's approval, to develop and enforce their own state plans of occupational safety and health standards that are "at least as effective" as OSHA's federal standards and enforcement. Whereas OSHA's jurisdiction does not extend to state agency and local government as employers, *see* 29 U.S.C. § 652(5), OSHA-approved state plans must provide coverage for state agencies and local government entities as employers, *see* 29 U.S.C. § 667. For more information about OSHA's jurisdiction and coverage of OSHA-approved state plans, see CRS In Focus IF11619, *OSHA Jurisdiction Over Public Schools and Other State and Local Government Entities: COVID-19 Issues*, by Scott D. Szymendera.

[194] *See* 86 Fed. Reg. 61,402, 61,447 (Nov. 5, 2021).

[195] *See id.* at 61,402.

once every seven days if they report at least once every seven days to a work site where others are present.[196] Employees who do not report to such a workplace during a period of seven or more days must be tested within seven days prior to returning to the workplace.[197] Employees exempt from the ETS's requirements include (1) employees who work remotely or at a site where other people are not present; and (2) employees who work exclusively outside.[198] Covered employers can, but are not required to, pay for any costs associated with testing,[199] but they must provide employees with paid leave to receive and recover from the vaccination.[200] Covered employers must establish and begin to implement the relevant vaccination policy by December 6, 2021, and ensure their employees have completed a one-dose vaccine or a two-dose vaccine series by January 4, 2022.[201] After that, all covered employers must ensure that employees who are not fully vaccinated are subject to regular COVID-19 testing.[202] Noncompliant covered employers could face OSHA citations and civil monetary penalties.[203]

The large-employer vaccination and testing mandate is based on OSHA's authority under Section 6(c) of the Occupational Safety and Health Act of 1970 (29 U.S.C. § 655(c)).[204] The provision authorizes the agency to issue an ETS that takes effect immediately upon publication in the *Federal Register*, without undergoing the APA's rulemaking proceedings, if it determines "(A) that employees are exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new hazards, and (B) that such emergency standard is necessary to protect employees from such danger."[205] OSHA issued the ETS upon its determination that unvaccinated workers face a grave danger from exposure to SARS-CoV-2 in the workplace, given that COVID-19 has killed more than 725,000 people in the United States in fewer than two years; that unvaccinated individuals remain at much higher risk of severe health outcomes; and that evidence demonstrates the virus's transmissibility in the workplace and the prevalence of infections in employee populations.[206] OSHA further determined that the ETS is necessary to protect unvaccinated workers from the risk of contracting COVID-19 given the potential severe health consequences from occupational exposure to COVID-19 and the fact that vaccination provides the most effective and efficient control available, with the use of other mitigation measures further protecting workers who remain unvaccinated.[207]

On the same day the ETS was issued, numerous petitioners—including covered employers, states, and religious groups—moved to stay and permanently enjoin the mandate in several federal

[196] *See id.* at 61,553 (adding 29 C.F.R. § 1910.501(g)).

[197] *See id.* at 61,553 (adding 29 C.F.R. § 1910.501(g)(ii)).

[198] *See id.* at 61,419.

[199] *See id.* at 61,553 (Note 1 to paragraph (g)(1)).

[200] *See id.* at 61,553 (adding § 1910.501(f)).

[201] *See id.* at 61,554 (adding § 1910.501(m)(2)).

[202] *See id.*

[203] *See id.* at 61,443; *see also OSHA Penalties*, OCCUPATIONAL SAFETY & HEALTH ADMIN., https://www.osha.gov/penalties (last accessed Dec. 13, 2021). For more information about the ETS's requirements, see CRS Report R46288, *Occupational Safety and Health Administration (OSHA): COVID-19 Emergency Temporary Standards (ETS) on Health Care Employment and Vaccinations and Testing for Large Employers*, by Scott D. Szymendera; and CRS Legal Sidebar LSB10658, *Fifth Circuit Stays OSHA Vaccination and Testing Standard*, by Jon O. Shimabukuro.

[204] 86 Fed. Reg. 61,402, 61,402 (Nov. 5, 2021).

[205] 29 U.S.C. § 655(c)(1).

[206] *See* 86 Fed. Reg. 61,402, 61,402–61,403 (Nov. 5, 2021).

[207] *See id.* at 61,403. Under 29 U.S.C. § 655(f), any person adversely affected by an ETS may file a petition to challenge the validity of the standard in the federal court of appeals in which the person resides.

courts of appeals.[208] In response to a petition and motion to stay filed by several covered employers and four states, the Fifth Circuit stayed the enforcement of the ETS the day after it was issued.[209]

On November 12, 2021, the Fifth Circuit affirmed the stay, largely based on its conclusion that the ETS "grossly exceeds OSHA's statutory authority."[210] In the Fifth Circuit's view, an airborne virus like SARS-CoV-2 likely falls outside the scope of a "new hazard" within the meaning of Section 6(c) under a canon of statutory construction known as *noscitur a sociis*, which counsels that the more precise meaning of a word should be determined by the neighboring words with which it is associated.[211] Because "new hazard" is neighbored by "substances or agents" and "toxic or physically harmful"—phrases that, in the court's view, connote toxicity and poisonousness—the term likely does not encompass an airborne virus that is both widely present in society and "non-life-threatening to a vast majority of employees."[212] Moreover, the court concluded that COVID-19 does not pose the required "grave danger" for purposes of Section 6(c), given that the agency cannot demonstrate that all covered workplaces are in fact exposed to COVID-19, the effects of COVID-19 could be mild, and the status of the virus's spread has changed over time.[213] The ETS, in the court's view, was also not "necessary" to protect unvaccinated workers given its "staggering[] overb[readth]," such that it was both overinclusive—applying to employers and employees in virtually all industries and workplaces in America without an attempt to account for differences in COVID-19 exposure—and underinclusive—disregarding workplaces with 99 or fewer employees.[214]

Pursuant to 28 U.S.C. § 2112, which specifies the procedures for review when an agency order is challenged in more than one federal appellate court, the Judicial Panel on Multistate Litigation, on November 16, 2021, randomly selected the Sixth Circuit as the court in which all of the pending petitions will be consolidated for review. Under § 2112(a)(4), the Sixth Circuit may modify, revoke, or extend the Fifth Circuit's stay.[215]

On December 17, 2021, a divided panel of the Sixth Circuit, in *In re: MCP No. 165, Occupational Safety and Health Administration, Interim Final Rule: COVID-19 Vaccination and Testing*, granted the government's motion to dissolve the stay issued by the Fifth Circuit.[216] In the Sixth Circuit's view, based on the OSH Act's language, structure, and direct instances of congressional approval following the law's enactment, OSHA has a "clear and exercised authority to regulate viruses" and wide discretion under this authority "to form and implement the best possible solution to ensure the health and safety of all workers" under the OSH Act.[217]

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[208] *See* BST Holdings, LLC v. Occupational Safety & Health Admin., 17 F. 4th 604, 610 (5th Cir. 2021).

[209] *See id.*

[210] *Id.* at 612.

[211] *Id.* at 613.

[212] *Id.*

[213] *Id.* at 613–14.

[214] *Id.* at 611, 615. In addition to its statutory analysis, the court commented that the ETS likely exceeds the federal government's authority under the Constitution's Commerce Clause. *Id.* Characterizing the relevant regulated activity as compulsory vaccination, the Fifth Circuit expressed the view that the ETS impermissibly "regulates noneconomic inactivity that falls squarely within the States' police power." *Id.* As discussed *infra* in note 228, the Sixth Circuit disagreed with this conclusion.

[215] 28 U.S.C. § 2112(a)(4).

[216] 2021 WL 5989357, at *1 (6th Cir. Dec. 17, 2021).

[217] *Id.* at *5–6.

According to the Sixth Circuit, the text of Section 6(c) expressly encompasses the authority to regulate viruses because a virus is an "agent" (i.e., a biologically active principle) that is physically harmful (i.e., causes bodily harm) within the meaning of the provision.[218] This authority to regulate viruses and infectious diseases, the court continued, is reinforced by other provisions of the OSH Act that reference "illnesses arising out of work situations" and "health hazards," as well as a provision that contemplates "medical examination, immunization, or treatment" as possible measures the agency may employ.[219] This interpretation, in the court's view, is further consistent with several instances of Congress's approval of OSHA's authority to regulate bloodborne pathogens and viruses such as HIV, hepatitis B, and hepatitis C.[220] According to the Sixth Circuit, this clear authority to regulate viruses necessarily encompasses "the authority to regulate infectious diseases that are not unique to the workplace."[221] Because "no virus—HIV, [hepatitis B], COVID-19—is unique to the workplace and affects only workers," the court reasoned, OSHA's authority to regulate hazards extends to those that "co-exist in the workplace and in society but are at heightened risk in the workplace."[222] In the court's view, OSHA's issuance of the ETS "[was] not a novel expansion of OSHA's power; it [was] an existing application of authority to a novel and dangerous worldwide pandemic."[223]

After concluding that OSHA did not exceed its statutory authority, the Sixth Circuit further concluded that the agency's determination that the ETS was warranted was supported by substantial evidence, including the agency's determination that employees were exposed to "grave danger" from COVID-19 and that the ETS was "necessary to protect employees from such danger."[224] Under Section 6(f) of the OSH Act, the Secretary's determinations are "conclusive if supported by substantial evidence in the record considered as a whole."[225]

As to the existence of "grave danger," the Sixth Circuit found, for instance, that OSHA has demonstrated "the pervasive danger that COVID-19 poses to workers—unvaccinated workers in particular—in their workplaces," explaining why traditional indoor workplaces place workers at heightened risk of contracting COVID-19; evidence of the severity of the harm from COVID-19; the likelihood that the ETS would save over 6,500 worker lives and prevent more than 250,000 hospitalizations over the next six months; and that voluntary guidance on vaccination proved inadequate, particularly in the face of the Delta variant.[226] As to the necessity of the ETS, the court found, for instance, that OSHA sufficiently demonstrated that the evolving course of the pandemic—and in particular, the emergence of the Delta variant—necessitated an ETS at this time and that extensive evidence cited by the agency showed that vaccination reduces the presence and severity of COVID-19 cases in the workplace.[227] The choice to limit the ETS to employers with 100 or more employees, in the court's view, did not undermine the standard's necessity because the agency demonstrated the relationship between this chosen threshold and the underlying regulatory problem, given that "larger employers are better able to implement the

[218] *Id.* at *4.

[219] *Id.* (citing, for instance, 29 U.S.C. §§ 651(a), 651(b)(1), 669(a)(5)).

[220] *Id.* at *5.

[221] *Id.* at *6.

[222] *Id.*

[223] *Id.* at *7.

[224] *Id.* at *8, 10–16.

[225] 29 U.S.C. § 655(f).

[226] *In re MCP No. 165*, 2021 WL 5989357, at *10–13.

[227] *Id.* at *14.

policies, are at heightened risk, and regulating them will be a significant step in protecting the entire workforce from COVID-19 transmission."[228]

In the dissent's view, OSHA lacked statutory authority to issue the ETS because the agency did not appropriately establish the standard's "necessity" or the existence of a "grave danger" in the workplace. According to the dissent, an ETS is "necessary" within the meaning of Section 6(c) only if it is an "indispensable" means of addressing COVID-19 in the workplace.[229] Because OSHA "failed to explore whether other feasible alternatives would have allowed [it] to tackle the problem," the dissent reasoned that the agency cannot show the ETS was "necessary" for purposes of Section 6(c).[230] Additionally, the dissent found that OSHA had not provided substantial evidence that all covered employees faced a "grave danger" from COVID-19 because not all employees have a high risk both of contracting COVID-19 and suffering severe consequences from it.[231] Finally, in the dissent's view, OSHA's authority under the OSH Act is limited to "the workplace walls," and thus, such authority does not extend to the regulation of a virus that is not uniquely a workplace condition, particularly when the agency "cannot state with precision the total number of workers in our nation who have contracted COVID-19 at work."[232] The authority to protect "employees" from a "grave danger" under Section 6(c), in the dissent's view, is limited to regulating "workplace hazards with workplace solutions."[233] Thus, the dissent reasoned, this authority does not encompass the authority to mandate safety measures beyond the workplace boundary, "even if taking such precautions would save many 'employee' lives."[234]

Following the Sixth Circuit's dissolution of the stay, several petitioners filed an application with the Supreme Court seeking to stay the ETS. On January 13, 2022, the Supreme Court granted the application and stayed the enforcement of the ETS.[235] The Court concluded that a stay was warranted because the applicants were likely to succeed on the merits of their claim that the ETS exceeded OSHA's statutory authority, which authorizes the agency "to set *workplace* safety standards, not broad public health measures."[236] Because the ETS does not distinguish between workplaces that pose a heightened risk of COVID-19 exposure because of the particular features of an employee's job or the nature of the workplace, and workplaces that pose a generalized risk of exposure from COVID-19 that is not different in kind from the risk presented by other nonwork settings in which people gather, it is, in the Court's view, an impermissible general public health measure rather than a permissible occupational safety or health standard.[237] The Court suggested, for instance, that targeted regulations that address workplaces that face a

[228] *Id.* at *15. The Sixth Circuit also found that OSHA sufficiently determined that the ETS is economically feasible, including considering the Standard's costs in relation to the financial health of the affected industries and its impact on consumer prices. *Id.* at *15–16. The Sixth Circuit also disagreed with the Fifth Circuit's view that the ETS likely exceeded the federal government's Commerce Clause authority because it regulates noneconomic inactivity. *Id.* at *16. In the Sixth Circuit's view, the ETS regulates employers that are "indisputabl[y] . . . engag[ing] in commercial activity that Congress has the power to regulate." To hold otherwise, according to the Sixth Circuit, "would upend nearly a century of precedent upholding laws that regulate employers to effectuate a myriad of employee workplace policies." *Id.*

[229] *See id.* at 22.

[230] *Id.* at *23–24.

[231] *Id.* at *25.

[232] *Id.* at *26 (quoting 86 Fed. Reg. at 61,424).

[233] *Id.* at *27.

[234] *Id.*

[235] Nat'l Fed. of Ind. Bus. v. Dep't of Labor, No. 21A244, 2022 WL 120952, at *1 (Jan. 13, 2022) (per curiam).

[236] *Id.* at *3.

[237] *Id.*

heightened risk of contracting COVID-19 beyond the everyday risk that all face "are plainly permissible."[238] As examples, the Court stated that "OSHA could regulate researchers who work with the COVID-19 virus" or "regulate risks associated with working in particularly crowded or cramped environments."[239]

The Court's decision stays enforcement of the ETS while the consolidated cases proceed before the Sixth Circuit. In the meantime, the comment period for the ETS, which also acts a notice of proposed rulemaking for a permanent standard, remains open through January 19, 2022.[240] As part of this notice-and-comment rulemaking process, OSHA may consider the comments as well as the Court's decision and issue a more narrowly tailored permanent rule. OSHA may also opt to withdraw the ETS in its entirety.

Table 1. Summary of Federal Nonmilitary COVID-19 Vaccination Mandates

As of January 18, 2022

Federal Mandate	Statutory Authority	Covered Individuals/ Entities	Vaccination Requirement	Compliance Deadline(s)	Status
Federal Employee Mandate (Executive Order 14,043)	5 U.S.C. §§ 3301, 3302, 7301	Federal executive branch employees	Employees must be fully vaccinated,[a] unless granted a legally required exception based on a disability/ medical condition or a sincerely held religious belief. Remote-working employees are subject to requirement.	Receive a one-dose vaccine or two-dose vaccine series by November 8, 2021. Be fully vaccinated by November 22, 2021.	In effect

[238] *Id.* at *4.

[239] *Id.*

[240] *See Covid-19 Vaccination and Testing ETS*, OCCUPATIONAL SAFETY & HEALTH ADMIN. (Jan. 13, 2022), https://www.osha.gov/coronavirus/ets2.

Federal Mandate	Statutory Authority	Covered Individuals/ Entities	Vaccination Requirement	Compliance Deadline(s)	Status
Federal Contractor (Executive Order 14,042)	40 U.S.C. § 101 *et seq.*; 3 U.S.C. § 301	Federal contractors/ subcontractors that have a covered contract with executive departments and agencies	Covered contractors must ensure covered contractor-employees are fully vaccinated, except in circumstances where an employee is legally entitled to an exemption based on a disability/medical condition or a sincerely held religious belief. Remote-working covered contractor-employees are subject to requirement.	As of January 18, 2022, covered contractor-employees must be fully vaccinated on the first day of performance on a new contract or the renewal, extension, or exercised option of an existing contract.	Enjoined by courts: Kentucky v. Biden, No. 21-6147), 2022 WL 43178 (6th Cir. Jan. 5, 2022) (declining to stay the district court's preliminary injunction in KY, OH, and TN); Georgia v. Biden, No. 1:21-cv-00163 2021 WL 5779939 (S.D. Ga. Dec. 7, 2021) (enjoined the vaccination requirement nationwide).
CMS's Medicare/ Medicaid Provider Mandate (CMS IFR)	42 U.S.C. §§ 1302, 1395hh, and other provider- or supplier-specific provisions	Specified provider and supplier types that participate in Medicare and Medicaid	Covered providers and suppliers must ensure covered staff who directly provide care or other services for their facilities and/or patients are fully vaccinated, except in circumstances where a staff member is legally entitled to an exemption based on a disability/medical condition or a sincerely held religious belief. Staff who work 100% remotely from sites of patient care or away from onsite staff are *not* subject to the requirement.	By January 27, 2022, (1) covered providers and suppliers must establish and begin to implement the vaccination policies and (2) covered staff must receive first dose of a two-dose vaccine or a one-dose vaccine. Covered staff must complete two-dose vaccine series by February 28, 2022.	In effect in all jurisdictions except TX. (Preliminary injunctions in 24 states stayed by the U.S. Supreme Court in Biden v. Missouri, No. 21A240, 2022 WL 120950 (Jan. 13, 2022))[b]

Federal Mandate	Statutory Authority	Covered Individuals/ Entities	Vaccination Requirement	Compliance Deadline(s)	Status
OSHA's Large-Employer Vaccination and Testing Mandate (OSHA ETS)	29 U.S.C. § 655(c)	In all jurisdictions, private employers with 100 or more employees. In 26 states, Puerto Rico, and the U.S. Virgin Islands with OSHA-approved state plans, state and local government employers with 100 or more employees.	A covered employer must establish and enforce a policy that either (1) ensures employees are fully vaccinated, except in circumstances where an employee is legally entitled to an exemption based on a disability/medical condition or sincerely held religious belief; or (2) requires employees to be fully vaccinated *or* provide proof of regular COVID-19 testing and wear a face covering when indoors. Employees who work remotely, at a site where other people are not present, or exclusively outside are *not* subject to the requirements.	Covered employers must establish and begin to implement the vaccination policies by January 10, 2022. Covered employees must receive either a one-dose vaccine or a two-dose vaccine series, or begin regular testing by February 9, 2022.	Stayed by the U.S. Supreme Court. (*See* Nat'l Fed. of Indep. Bus. v. Dep't of Labor, No. 21A244, ---S. Ct.---, 2022 WL 120952 (Jan. 13, 2022))

Source: CRS analysis of the relevant Executive Orders, CMS IFR, and OSHA ETS, as well as related litigation.

a. For purposes of the relevant Executive Orders, CMS IFR, and OSHA ETS, individuals are considered "fully vaccinated" for COVID-19 two weeks after they have received either a one-dose vaccine or a two-dose vaccine series.

b. As of January 18, 2022, the IFR remains enjoined in Texas, where a district court issued a separate preliminary injunction that was not before the Supreme Court. The government's motion to stay the preliminary injunction, based on the Supreme Court's order in *Biden v. Missouri*, is pending before the district court.

Congress's Constitutional Authority to Mandate Vaccination

Although states have traditionally exercised the bulk of authority over public health matters, including vaccination, Congress shares certain concurrent authority in this area emanating from its enumerated powers in the Constitution.[241] This authority derives from, among other sources, the Constitution's Spending and Commerce Clauses, which may be used by Congress to clarify

[241] McCuskey, *supra* note 16, at 113–20. For instance, while the Supreme Court has long recognized the states' central role in regulating public health, the Court has also recognized, for equally as long albeit in dicta, Congress's power over infectious disease control under its Commerce Clause authority. Commenting in 1913 on quarantine laws used to prevent the introduction or spread of disease, for example, the Supreme Court stated that "[s]uch laws undoubtedly operate upon interstate and foreign commerce" and "could not be effective otherwise." Minnesota Rate Cases, 230 U.S. 352, 406 (1913).

existing statutory authorities as they relate to vaccination requirements, or create additional sources of authority for or limitations on such requirements.[242]

The Spending Clause empowers Congress to tax and spend money for the general welfare.[243] Under this authority, which is subject to several limitations, Congress may offer federal funds to nonfederal entities and prescribe the terms and conditions under which the funds are accepted and used by recipients.[244] Over the past century, Congress has frequently invoked this authority in the public health context, including for purposes of controlling specified diseases, establishing neighborhood or community health centers, and creating federal health insurance programs, including Medicare and Medicaid.[245]

Applying its spending authority in the context of a vaccination mandate, Congress could, for instance, encourage states to enact a vaccination mandate meeting certain federal requirements by imposing it as a condition of receiving certain federal funds.[246] This use of Spending Clause authority, assuming it falls within the broad parameters of being for the "general welfare," would be permissible so long as (1) Congress provides clear notice of the vaccination mandate that states (or other funding recipients) must enact or implement; (2) the mandate is related to the purpose of the federal funds; (3) this conditional grant of funds is not otherwise barred by the Constitution; and (4) the amount of federal funds offered is not "so coercive as to pass the point at which pressure turns into compulsion."[247]

In addition, the Commerce Clause grants Congress the power "[t]o regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes."[248] This authority empowers Congress to regulate "three broad categories of activities": (1) "channels of interstate commerce," like roads and canals; (2) instrumentalities of, or persons or things in, interstate commerce; and (3) activities that substantially affect interstate commerce.[249] Congress relied on the Commerce Clause to enact some of the earliest federal health laws aimed at protecting the public from contagion and products posing health concerns.[250] As the federal government increased its role in public health, Congress relied on the Commerce Clause to pass more comprehensive national health regulations, beginning with the Food and Drug Act of 1906.[251]

While Congress's authority under the Commerce Clause is expansive, a majority of the Supreme Court in *National Federation of Independent Business (NFIB) v. Sebelius* agreed that there is a

[242] *See id.* at 116–19.

[243] U.S. CONST. art. I, § 8, cl. 1.

[244] *See* Nolan & Lewis, *supra* note 18, at 29–31 (discussing South Dakota v. Dole, 483 U.S. 203, 207–08 (1987)).

[245] *See* James G. Hodge, Jr., *The Role of New Federalism and Public Health Law*, 12 J.L. & HEALTH 309, 335–37 (1998); McCuskey, *supra* note 16, at 118–19.

[246] *See Dole*, 483 U.S. at 211–12 (holding that 23 U.S.C. § 158, which conditioned the provision of certain federal highway funds upon a state's enactment of a minimum drinking age of 21, was a valid exercise of Congress's spending clause authority).

[247] *See id.* at 207–08, 211 (internal quotations omitted).

[248] U.S. CONST. art. I, § 8, cl. 3.

[249] United States v. Lopez, 514 U.S. 549, 558–59 (1995).

[250] McCuskey, *supra* note 16, at 116–19 (noting that the Commerce Clause enabled several early federal health laws, including a law that authorized the quarantine of diseased livestock and people, and a law that regulated certain drugs and food products posing health concerns).

[251] *See id.*; *see also* Medtronic, Inc. v. Lohr, 518 U.S. 470, 475 (1996); Hodge, *supra* note 245, at 335–36 (noting that "[f]ederal regulation now reaches broad aspects of public health such as air and water quality, food and drug safety, tobacco advertising, pesticide production and sales, consumer product safety, occupational health and safety, and medical care").

discrete limit to this authority—it cannot *compel* individuals to engage in commercial activity.[252] According to Chief Justice John Roberts, in a portion of the opinion not joined by other Justices but largely echoed in the view of the four dissenting Justices, the Commerce Clause did not empower Congress "to regulate individuals precisely because they are doing nothing."[253] While it is uncertain whether this conclusion constitutes binding precedent,[254] it suggests that a direct federal mandate on individuals to receive a vaccine may be susceptible to challenge because such mandates could be construed as compelling individuals who are "doing nothing" to engage in the commercial activity of receiving a specified health care service.[255] On the other hand, a federal mandate that requires vaccination as a condition to engage in existing economic activities, such as employment or interstate travel, may raise fewer constitutional concerns.[256]

Even if a vaccine mandate falls within Congress's enumerated powers, other constitutional provisions may constrain the government's action.[257] In the context of public health regulations, the key constraints are those grounded in federalism and the protection of individual rights.[258] For example, the Supreme Court has interpreted the Tenth Amendment to prevent the federal government from commandeering or requiring states or localities to adopt or enforce federal policies.[259] In the context of vaccination, this principle prevents Congress from directly requiring states or localities to pass mandatory vaccination laws or implement federal vaccination laws.[260] It does not, however, impede Congress from using its Spending Clause authority to incentivize states to do so, as long as the amount offered is not so significant as to effectively coerce, or functionally commandeer, states into enacting the mandate.[261]

As to protection of individual rights, courts have recognized few rights-based constraints on the ability to impose mandatory vaccination requirements.[262] As explained above, courts have largely rejected due process and equal protection challenges to compulsory vaccination under *Jacobson* and *Zucht*. As with state vaccination requirements, the principal area of legal uncertainty as to rights-based constraints on federal requirements is whether and under what circumstances states must provide religious exemptions to a vaccination requirement.[263]

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[252] *See* Nolan & Lewis, *supra* note 18, at 10.

[253] *See id.* at 10–11 (quoting NFIB v. Sebelius, 567 U.S. 519, 551 (2012) (opinion of Roberts, C.J.)).

[254] S*ee id.* at 11.

[255] *See NFIB*, 567 U.S. at 551.

[256] *See In re* MCP No. 165, Occupational Safety & Health Admin., Interim Final Rule: COVID-19 Vaccination and Testing, 2021 WL 5989357, at *16 (6th Cir. 2021) (commenting that OSHA's large-employer vaccination and testing mandate regulates employers that are "indisputabl[y] . . . engag[ing] in commercial activity that Congress has the power to regulate," and stating that holding otherwise "would upend nearly a century of precedent upholding laws that regulate employers to effectuate a myriad of employee workplace policies"); *see also* Liberty Univ., Inc. v. Lew, 773 F.3d 72, 93 (4th Cir. 2013) (rejecting a Commerce Clause challenge to an Affordable Care Act requirement that certain employers offer a minimum level of health insurance coverage to their employees and dependents on the grounds that the requirement merely regulates an existing commercial activity). *But see* BST Holdings, LLC v. Occupational Safety & Health Admin., 17 F. 4th 604, 615 (5th Cir. 2021) (commenting that OSHA's large-employer vaccination and testing mandate impermissibly "regulates noneconomic inactivity that falls squarely within the States' police power").

[257] *See* Nolan & Lewis, *supra* note 18, at 24–25.

[258] *See id.* at 19, 24–25.

[259] *Id.* at 25.

[260] *See id.*

[261] *See id.*

[262] *See supra* notes 39–47 and accompanying text.

[263] *See supra* "State COVID-19 Vaccination Mandates and Related Litigation."

Emergency Use Authorization and Vaccination Mandates

Prior to the COVID-19 pandemic, all vaccines subject to governmental mandates were licensed under a biological license application (BLA), the standard regulatory framework under which vaccines are typically introduced into interstate commerce.[264] By contrast, as of December 2021, only one COVID-19 vaccine—Pfizer's Comirnaty—is licensed by FDA under a BLA.[265] Several other COVID-19 vaccines are authorized for emergency use under the FD&C Act's EUA provision, which allows the Secretary of HHS to permit patient access to an unlicensed vaccine for emergency use under specified conditions, including during a public health emergency.[266]

Before FDA licensed Pfizer's COVID-19 vaccine, some commentators raised a legal issue unique to COVID-19 vaccination mandates. Specifically, they argued that Section 564(e)(1) of the EUA provision precludes entities—including governmental entities—from mandating the COVID-19 vaccines.[267] Section 564(e)(1) directs the Secretary of HHS, when issuing an EUA for a medical product, to impose such necessary conditions to protect the public health, including appropriate conditions designed to inform individuals "of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks."[268] Because each individual must be provided with "the option to accept or refuse," some commentators asserted that this provision "suggests that mandates are categorically prohibited."[269]

[264] *See, e.g.*, CRS Report R46593, *Vaccine Safety in the United States: Overview and Considerations for COVID-19 Vaccines*, by Kavya Sekar and Agata Bodie, at 15, 34–35.

[265] For more information about FDA's approval of Comirnaty, the Pfizer-BioNTech COVID-19 vaccine, see Hickey, Ward & Bodie, *supra* note 7.

[266] *See id.*; *see also* Hickey et al., *supra* note 2, at 12–14.

[267] *See* Efthimios Parasidis & Aaron S. Kesselheim, *Assessing the Legality of Mandates for Vaccines Authorized Via an Emergency Use Authorization*, HEALTH AFFAIRS (Feb. 16, 2021), https://www.healthaffairs.org/do/10.1377/hblog20210212.410237/full/.

[268] 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III).

[269] Parasidis & Kesselheim, *supra* note 267.

After some state and private entities began mandating COVID-19 vaccinations in 2021, some litigants advanced this argument in court, asserting that COVID-19 vaccination requirements violated Section 564(e) of the FD&C Act. Courts have generally rejected this claim, holding that Section 564(e) imposes only an informed consent requirement on medical providers administering the vaccines to inform would-be recipients of the vaccines' risks and their right to refuse it.[270] As a result, courts generally have concluded that the provision does not prohibit entities from requiring individuals, duly informed by their medical providers, to be vaccinated.[271] Now that FDA has fully licensed Comirnaty, a COVID-19 vaccine, legal challenges to COVID-19 vaccination requirements based on the EUA statute are largely moot.[272]

Considerations for Congress

A vaccination mandate is one available legal tool that governments could use to increase COVID-19 vaccine uptake. Whether the federal government has existing statutory authority to mandate COVID-19 vaccination in certain contexts is an issue in several pending lawsuits.[273] Depending on whether Congress determines that the executive branch's use of these authorities, including provisions of the Procurement Act, the SSA, and the OSH Act, appropriately reflects congressional intent, Congress—subject to constitutional limits—can generally clarify the scope of these statutory provisions as they apply to vaccination requirements.

To the extent Congress determines that a federal vaccination mandate may be necessary to address the evolving pandemic, Congress could also impose a mandate through other legislative actions. Any such legislation, however, must be grounded in Congress's enumerated constitutional authority and structured consistently with constitutional due process and religious freedom guarantees.

[270] *See, e.g.*, Valdez v. Grisham, No. 21-cv-783, 2021 WL 4145746, at *4–5 (D.N.M. Sept. 13, 2021); Norris v. Stanley, No. 1:21-cv-756, 2021 WL 4738827, at *3 n.2 (W.D. Mich. Oct. 8, 2021) (rejecting plaintiffs' argument that a university's vaccination requirement is preempted by Section 564(e) because the policy "does not preclude Plaintiff from receiving informed consent, nor does it prevent her from accepting or refusing administration of the vaccine"); Johnson v. Brown, 3:21-cv-1494, 2021 WL 4846060, at *18 (D. Ore. Oct. 18, 2021) (holding that Section 564(e)'s "conditions of informed consent only relate to . . . the medical providers who administer the vaccine, not those who issue vaccine mandates").

[271] *See Valdez*, 2021 WL 4145746, at *4–5; *Norris*, 2021 WL 4738827, at *3 n.2; *Johnson*, 2021 WL 4846060, at *18; *see also* Bridges v. Houston Methodist Hosp., No. H-21-1774, 2021 WL 2399994, at *2 (S.D. Tex. Jun 12, 2021) (holding that Section 546(e) "confers certain powers and responsibilities to the Secretary of Health and Human Services in an emergency," such that "[i]t neither expands nor restricts the responsibilities of private employers"); *see also* U.S. DEP'T OF JUSTICE, OFF. OF LEGAL COUNS., WHETHER SECTION 564 OF THE FOOD, DRUG, AND COSMETIC ACT PROHIBITS ENTITIES FROM REQUIRING THE USE OF A VACCINE SUBJECT TO AN EMERGENCY USE AUTHORIZATION, 45 Op. O.L.C. __, 2021 WL 3418599 (July 6, 2021) (concluding that "section 564 specifies only that certain information be provided to potential vaccine recipients and does not prohibit entities from imposing vaccination requirements"). In addition, courts have emphasized that at least one COVID-19 vaccine has received full FDA approval and is therefore no longer being distributed under an EUA, rendering this claim moot as to that vaccine. *See, e.g.*, *Valdez*, 2021 WL 4145746, at *4.

[272] *See, e.g.*, Norris v. Stanley, No. 1:21-CV-756, 2021 WL 3891615, at p. *2 (W.D. Mich. Aug. 31, 2021) ("[S]hould Plaintiff be offered the FDA-approved Pfizer Comirnaty vaccine, her argument under the EUA statute would be moot . . . ."). The legal issue may remain open with respect to vaccine mandates imposed on individuals 12 to 15 years old, however, as no vaccine is licensed under a BLA for use in this age group, as of the time of this writing.

[273] *See supra* "Executive Branch Authority to Mandate Vaccination."

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