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Legal Sidebar

Federal COVID-19 Vaccination Mandates and Related Litigation: An Overview

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During 2021, various federal, state, and private entities instituted Coronavirus Disease 2019 (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)—spreads in the United States. The federal COVID-19 vaccination requirements issued to date by the President or executive agencies include those 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. These employment- or workforce-based mandates—subject to accommodations required by federal law—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. (In addition to these mandates, the Secretary of Defense has mandated COVID-19 vaccination for servicemembers. For more information about the military's COVID-19 vaccination mandate, see this CRS Insight.)

The federal vaccination mandates, like those imposed by states and state entities like public universities, have generated numerous legal challenges. While both federal and state vaccination requirements are subject to constitutional provisions that protect individual rights, federal requirements imposed by the executive branch are also subject to statutory constraints. Specifically, such requirements generally must stem from the federal government's existing statutory authority and may be subject to additional context-specific statutory limits. Thus, each federal mandate raises unique legal issues specific to the particular statutory framework, in addition to legal issues raised by governmental vaccination requirements generally.

This Sidebar provides an overview of each set of federal COVID-19 vaccination requirements and the statutory authorities cited for their basis. It then highlights some of the key legal issues raised by the pending legal challenges against each mandate, and provides some potential considerations for Congress based on a preliminary order issued by the U.S. Court of Appeals for the Fifth Circuit in the early stages of one of the pending proceedings.

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Table 1. Summary of Federal Non-Military COVID-19 Vaccination Mandates

As of December 1, 2021

Federal Mandate	Statutory Authority	Covered Individuals/Entities	Vaccination Requirement	Compliance Deadline(s)	Status
Executive Order 14,043 (Federal Employee)	5 U.S.C. §§ 3301, 3302, 7301	Federal executive branch employees	Employees must be fully vaccinated 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
Executive Order 14,042 (Federal Contractor)	40 U.S.C. § 101 et seq.; 3 U.S.C. § 301	Federal contractors and 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 in three states (Kentucky, Ohio, Tennessee). In effect in other jurisdictions.
Centers for Medicare & Medicaid Services (CMS) Interim Final Rule (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 December 6, 2021, (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 January 4, 2022	Enjoined by courts

Federal Mandate	Statutory Authority	Covered Individuals/Entities	Vaccination Requirement	Compliance Deadline(s)	Status
Occupational Safety and Health Administration's (OSHA's) Emergency Temporary Standard (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 December 6, 2021. Covered employees must receive either a one-dose vaccine or a two-dose vaccine series, or begin regular testing by January 4, 2022.	Stayed by court

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

Executive Agency Employee Mandate

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

Under the Task Force's guidance, federal employees must be fully vaccinated or obtain an exception by November 22, 2021. Because employees will be considered fully vaccinated two weeks after they complete the requisite number of COVID-19 vaccine doses, federal employees must have received either a one-dose vaccine or a two-dose vaccine series by no later than November 8, 2021. The vaccination requirements apply to employees who are under maximum telework or remote-work arrangements. Employees who refuse to be 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. Under the guidance, however, the removal or termination would be preceded by a brief period of education and counseling and a suspension period up to 14 days.

Several federal employees and at least one employee union have sued to challenge the federal employee mandate. These suits raise a variety of claims, including some claims that are common to challenges to state vaccination requirements. For example, one common claim is based on an alleged violation of the plaintiffs' substantive due process rights to bodily integrity or a right to refuse unwanted medical treatment. In the context of COVID-19 vaccination mandate litigation to date, courts have generally

rejected those claims, concluding that a fundamental right is not implicated by the vaccination mandate, which reasonably furthers a legitimate government interest.

Another common claim is based on the emergency use authorization (EUA) provision of the Federal Food, Drug & Cosmetic Act. Plaintiffs asserting this claim generally allege that a vaccination mandate violates the informed consent requirement of the EUA provision, which directs the Secretary of the Department of Health and Services (HHS), when issuing an EUA for a medical product, to impose conditions necessary to protect the public health, including appropriate conditions designed to inform individuals "of the option to accept or refuse administration of the product." Courts to date have also generally rejected this claim, holding that the EUA's informed consent provision only requires *medical providers* administering the vaccines to inform would-be recipients of the vaccines' risks and their right to refuse it. 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. 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.

Plaintiffs have also asserted several claims more specific to the federal employee mandate. One set of claims, for instance, challenged the agencies' alleged denial of religious exemption requests as violating the Religious Freedom Restoration Act and the First Amendment's Free Exercise Clause. 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 has a pending request for exemption and has not suffered any adverse employment consequence. Another claim 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 Administrative Procedure Act (APA). This claim is currently subject to a pending motion for preliminary injunction by the plaintiffs, but the district court is likely to consider whether the mandate falls under an exception from APA rulemaking requirements as "a matter relating to agency management or personnel."

Federal Contractor Mandate

Executive Order 14,042 (Federal Contractor EO), 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. 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 exceptions required by law. Covered contractor-employees include those working on or in connection with a covered contract or working at a covered contractor workplace. Covered contractor-employees working remotely are subject to the vaccination requirements.

Consistent with the Federal Contractor EO, the guidance sets forth a phase-in period for the new clause to be added to federal contracts. 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. As of 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. 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. For more information about Federal Contractor EO's requirements, see this CRS Insight.

The Federal Contractor EO 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. 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, the purpose of which is to provide "an economical and efficient system" for, among other objectives, federal procurement. The Federal Contractor EO 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. 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."

The Federal Contractor EO, 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 and efficiency in Federal contracting." 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. The Federal Contractor EO 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. The Council issued the guidance on September 30, 2021.

More than twenty states, on behalf of their state agencies and political subdivisions that may have a covered contract subject to the Federal Contractor EO, have filed at least four separate suits in different district courts to challenge the federal contractor mandate. Plaintiffs in each case filed a motion for preliminary injunction seeking to enjoin—or suspend—the mandate while the litigation is pending. In November 2021, one district court—in the challenge filed by Kentucky, Ohio, and Tennessee—granted the plaintiffs-states' motion and enjoined the mandate while the litigation is pending. Among other determinations, the court concluded that the President likely exceeded his statutory authority under the Procurement Act in imposing the vaccination requirement because the requirement, as a public health measure, does not "ha[ve] a close enough nexus to economy and efficiency in federal procurement." The motions for preliminary injunctions remain pending in the other cases.

Vaccination Requirement for Most Medicare- and Medicaid-Certified Providers and Suppliers

On November 4, 2021, the Centers for Medicare & Medicaid Services (CMS) released an Interim Final Rule (IFR), effective November 5, 2021, that requires specified Medicare- and Medicaid-certified providers and suppliers to establish and enforce a policy that requires, subject to legally required exceptions, all eligible staff 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. This requirement applies to 15 provider and supplier types that participate in Medicare and Medicaid, including hospitals, long-term-care facilities, and rural health clinics. The requirement does not apply to other health care entities such as physician offices, organ procurement organizations, and portable X-Ray suppliers.

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). 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. 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.

According to CMS, the IFR is based on its determination that COVID-19 vaccination "is central to any multi-pronged approach for reducing health system burden, safeguarding health care workers and the people they serve, and ending the COVID-19 pandemic." 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). In particular, the agency based this determination on several considerations, including (1) that outbreaks associated with the Delta variant have shown 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.

CMS relies on several layers of statutory authorities in issuing the IFR. Across all providers and suppliers, CMS invokes SSA Section 1102, a provision that grants the HHS Secretary with 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. 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. Finally, for each provider and supplier, CMS also relies on certain provider- and supplier-specific provisions, many of which, for instance, authorize the Secretary to impose requirements he "finds necessary in the interest of the health and safety of individuals" who receive service from the relevant entities.

At least 24 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. Plaintiffs in each case filed a motion for preliminary injunction seeking to enjoin the IFR while the litigation is pending. In November 2021, one district court, in the challenge filed by the state of Florida, declined to enjoin the IFR, concluding the state had not shown "irreparable harm" to justify an injunction. 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.

Later in the same month, however, two district courts granted the plaintiffs-states' motions in each respective case. Together, these orders enjoined the IFR nationwide during the pendency of the litigation. Among other determinations, both courts generally 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; the agency likely lacked "good cause" to waive the notice-and-comment rulemaking procedures; and the plaintiffs-states sufficiently demonstrated they would suffer irreparable harm—including in the form of significant staffing shortages—if the IFR was not enjoined.

Vaccination and Testing Emergency Temporary Standard (ETS) for Employers with 100 or More Employees

On the same day that CMS released its IFR, the Occupational Safety and Health Administration (OSHA) released an ETS that generally requires private employers with 100 employees or more to establish and enforce a policy that *either* (1) requires all employees to receive COVID-19 vaccination, subject to legally required exceptions; *or* (2) requires employees to receive 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. For the 26 states, Puerto Rico, and the U.S. Virgin Islands that have opted to adopt their own OSHA-approved state plans, as discussed in more detail in this CRS report, the ETS also applies to state agency and local government employers. To the extent a workplace is subject to both the ETS and one of the preceding mandates, the more specific 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) or that compliance with the other mandate is deemed sufficient to meet the employers' obligations under the ETS (in the case of executive agencies).

Under the ETS, employees who are not fully vaccinated—including those who have been granted exceptions—generally must be tested at least once every seven days if they report at least once every seven days to a work site where others are present. 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. 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. Covered employers can, but are not required to, pay for any costs associated with testing, and they must provide employees with paid leave to receive and recover from the vaccination. Covered employers must establish and begin to implement the relevant vaccination policy by December 6, 2021, and ensure their employees have received a one-dose vaccine or a two-dose vaccine series by January 4, 2022. After that, all covered employers must ensure that employees who are not fully vaccinated are subject to regular COVID-19 testing. Noncompliant covered employers could face OSHA citations and civil monetary penalties. (For more information about the ETS's requirements, see this CRS Report and Sidebar.)

The vaccination and testing ETS is based on OSHA's authority under Section 6(c) of the Occupational Safety and Health Act of 1970. 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." 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. 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.

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 courts of appeals. 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. On November 12, 2021, the court affirmed the stay, largely based on its conclusion that the ETS "grossly exceeds OSHA's statutory authority."

In the court'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. 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." 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. 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.

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. 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."

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 U.S. Court of Appeals for the Sixth Circuit (Sixth Circuit) as the court in which all of the pending petitions will be consolidated for review. The Sixth Circuit may modify, revoke, or extend the Fifth Circuit's stay while adjudicating the merits of the petitions.

Considerations for Congress

The federal vaccination requirements imposed by the executive branch to date are based on the President's or the relevant executive agencies' existing statutory authorities. Thus, Congress—subject to constitutional limits—can generally clarify the scope or parameter of such authorities as they apply to vaccination requirements. The Fifth Circuit's statement that the ETS likely exceeds the federal government's authority under the Commerce Clause, however, may have broader implications. Under the Fifth Circuit rationale, Congress could lack authority under the Commerce Clause to require private employers to institute a vaccination policy for their employees.

It is unclear whether other courts would agree with the Fifth Circuit on this issue. In considering a Commerce Clause challenge to a provision of the Affordable Care Act (ACA) that requires employers to offer a minimum level of health insurance coverage to their employees and dependents, for instance, the Fourth Circuit rejected the argument that the employer mandate at issue there impermissibly compels employers to engage in unwanted economic activity. All employers, the Fourth Circuit observed, "by their very nature" are already "engaged in economic activity" and "in the market for labor." Thus, the Fourth Circuit held that the ACA's employer mandate does not compel employers "to become active in commerce," but rather "merely 'regulate[s] existing commercial activity." Under this reasoning, a requirement on employers to institute a vaccination policy for its employees could be considered another regulation of existing commercial activity, not unlike other federal workplace or employment regulations.

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 on quarantine laws used to prevent the introduction or spread of disease, for example, the Supreme Court wrote in *Minnesota Rate Cases*, 230 U.S. 352, 406 (1913), that "[s]uch laws undoubtedly operate upon interstate and foreign commerce" and "could not be effective otherwise." The significant impact of the COVID-19 pandemic on the national economy, discussed in detail in other CRS products, may give weight to the Court's observation from more than a century ago.

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