



COVID-19 Guidance

COVID-19 Vaccine and Employer Mandates


Developing, distributing, and administering a safe and effective vaccine to limit transmission of COVID-19 has remained a vital priority since the onset of the global COVID-19 pandemic. In the United States, vaccines must be approved by the Food and Drug Administration (FDA) before they can be marketed and distributed, which is normally a lengthy process.¹ In exigencies, a vaccine that has not yet been formally approved by FDA can be granted emergency use authorization (EUA), allowing an otherwise unapproved product to be used and distributed during a public health or other emergency.²

On December 11, 2020, FDA issued an EUA for a COVID-19 vaccine developed by Pfizer and German partner BioNTech,³ which has demonstrated upwards of 90% efficacy in trials.⁴ On December 18, 2020, FDA issued an EUA for Moderna's COVID-19 vaccine.⁵ FDA is currently assessing Johnson & Johnson's vaccine for EUA authorization,⁶ and additional EUA applications for other vaccine candidates are anticipated. Amid increasing distribution of the vaccines, public and private employers across the U.S. have already begun considering issuing vaccine mandates to their workforces, especially among health care workers (HCWs). This memorandum addresses employer-mandated vaccination during the COVID-19 pandemic, providing key legal and factual updates for public health officials and employers.

Questions:

1. What is the difference between *mandatory* vaccination and *compulsory* vaccination?
2. Can public and private sector employers mandate employees to obtain vaccines?
3. As current COVID-19 vaccines are authorized by FDA via an EUA, rather than a full biologics license, does the EUA status of a vaccine impact whether an employer can mandate it?

Response 1: To understand the legality of vaccine mandates, it is important to distinguish between *mandatory* and *compulsory* vaccination. Mandatory public health powers impose conditions on an individual (i.e., conditioning specific benefits, rights to access, or attaching fines to vaccination) to encourage participation.⁷



One example is conditioning school attendance on obtaining certain vaccinations. In contrast, compulsory public health powers do not allow for individual choice, but rather may be accomplished by force.⁸ Compulsory public health powers are not utilized often because of the ethical concerns involved and potential infringement of individual liberties.⁹ Nonetheless, while *mandates* provide for individual choice, albeit with conditions attached, *compulsory* actions do not.

Response 2: Yes. Public and private-sector vaccine mandates have generally been accepted in the United States for decades, especially in public health emergencies.

In 1905, the U.S. Supreme Court upheld a mandatory smallpox vaccination requirement in *Jacobson v. Massachusetts*.¹⁰ The requirement, issued by the City of Cambridge, imposed a \$5 fine on those who refused vaccination.¹¹ The Court acknowledged that state and local governments are authorized to enact reasonable laws or regulations to protect public health and safety,¹² including tailored vaccine requirements for persons who would not likely be harmed directly by the vaccination itself.


Since the Court's seminal decision in *Jacobson*, states and localities have lawfully required vaccinations precedent to school or day care attendance as well as pursuant to employment in specific health care settings.¹³ Several state statutes also allow for compulsory (or forcible) vaccination during public health emergencies (although these are subject to considerable constitutional challenges).¹⁴ Many states also recognize a variety of medical, religious, or philosophical exemptions to these requirements.¹⁵

Unbound from constitutional requirements, private sector employers have considerable leeway in requiring employee immunization.¹⁶ HCW vaccine mandates are often justified legally by balancing competing interests between assuring public and workplace safety versus respecting HCWs' vaccination concerns.¹⁷ Some scholars intimate that the sheer scale of the COVID-19 pandemic could lend courts to uphold mandates against challenges.¹⁸ Additionally, the Occupational Safety and Health Administration (OSHA)¹⁹ and the Equal Employment Opportunity Commission (EEOC)²⁰ have previously approved employer-mandated influenza vaccination schemes that comply with anti-discrimination laws.

The federal Occupational Safety and Health Act requires employers to provide places of employment that are "free from recognized hazards that are causing or are likely to cause death or serious physical harm."²¹ OSHA published new workplace guidance on January 29, 2021, which does not mandate vaccination, but recommends "[m]aking a COVID-19 vaccine or vaccination series available at no cost to all eligible employees," and providing information on vaccine benefits and safety.²² Additionally, in prior guidance, OSHA emphasized that employees should be properly informed of vaccine benefits.²³

The federal Americans with Disabilities Act (ADA) allows employers to mandate vaccination so long as reasonable accommodations are provided to employees with disabilities.²⁴ Accommodations are not required in cases of undue hardship or where others may be directly threatened and there is no way to provide a reasonable accommodation that would eliminate or reduce the direct threat.²⁵ Additionally, Title VII of the Civil Rights Act requires reasonable accommodation for employees with religious objections to vaccination, except in cases of undue hardship.²⁶

In prior vaccine-related guidance, EEOC has recommended that ADA-covered employers simply "encourage employees to get the influenza vaccine" rather than requiring it.²⁷ Encouraging vaccination (and the means to access vaccines) may help avoid complex ethical debates and legal concerns over certain exemptions or required actions prior to implementing a mandate. For example, unionized employees may raise legal issues if vaccines are mandated outside the collective bargaining process.²⁸ Since vaccines are never fool-proof,



encouraging, rather than requiring, vaccination can help mitigate any potential legal challenges arising in the event of a vaccine-related injury.

Response 3: *Most likely yes.* Because COVID-19 vaccines are available without full biologics license applications (BLAs), concerns may arise whether FDA's mere authorization may circumvent vaccine mandates. The Food, Drug, and Cosmetic Act (FDCA) states that individuals receiving EUA interventions must be informed "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" ²⁹ Consistent with the Act, guidance documents for recently-authorized vaccines explain that recipients may opt to accept or refuse them, ³⁰ consistent with the legal premise that the vaccine cannot be compelled or forcibly administered among autonomous persons.

Whether individuals may refuse an EUA vaccine, however, is legally distinct from whether an EUA vaccine may be mandated as a condition of continued employment. ³¹ Nothing in FDA's letters of authorization for the Pfizer-BioNTech vaccine ³² or the Moderna vaccine ³³ expressly limits or prohibits employer mandates. In sum, there is currently no express limitation preventing employers from mandating a vaccine distributed pursuant to EUA, rather than one issued through a full BLA, provided (1) anti-discrimination protections are assured and (2) any applicable state laws or exemptions are honored. However, per legal recognition of a personal option to take or refuse the vaccine, many employers may choose to highly encourage, rather than mandate, the vaccine.

On December 16, 2020, EEOC updated its COVID-19 guidance to provide specific information related to the COVID-19 vaccine, largely supporting this analysis. ³⁴ It clarified that if an employer mandates vaccination and an employee cannot get vaccinated because of a disability or a sincerely held religious practice or belief, and no reasonable accommodation is possible, then the employer may lawfully exclude the employee from the workplace. That said, EEOC further noted that this exclusion does not automatically permit termination, as some employees may be able to telework, and additional federal, state, and local equal employment opportunity protections must be followed. Additionally, employers mandating and administering the COVID-19 vaccine should be aware that pre-screening questions may implicate ADA provisions on disability-related inquiries; any such inquiries must be "job-related and consistent with business necessity." Pre-screening questions may also implicate Title II of the Genetic Information Nondiscrimination Act (GINA), which prevents employers from acquiring or disclosing genetic information (subject to certain exceptions) and using genetic information to make decisions related to terms, conditions, and privileges of employment.

In addition to FDA's EUA and EEOC guidance, CDC's Advisory Committee on Immunization Practices (ACIP) makes its own determinations as to which vaccines it may recommend. ACIP completes its own safety review of vaccines to provide official federal vaccine recommendations that stakeholders, including state public health agencies, follow closely. ³⁵ On December 12, 2020, ACIP recommended the Pfizer-BioNTech vaccine for public use in persons above 16 years of age. ³⁶ ACIP similarly recommended the Moderna vaccine in persons above 18 years of age during a December 19, 2020 meeting. ³⁷ If FDA and ACIP disagree on utility and safety of this or other COVID-19 vaccines forthcoming, employees may have a stronger legal basis to counter a mandate related to a specific vaccine.

Mandates are already being recommended and implemented across the nation, though some employers are strongly encouraging, rather than requiring, the vaccine. In a July 1, 2020 report, the New York State Bar Association called for a statewide COVID-19 vaccine mandate as soon as a safe and viable vaccine is available and public health officials recommend it. ³⁸ Virginia State Health Commissioner Dr. Norman Oliver

also indicated a plan to mandate a safe vaccine in an August 21, 2020 interview, though Governor Ralph Northam's administration has not implemented such plans.³⁹ A November 19, 2020 Banner Health news release (applicable to its Colorado hospitals) indicated that a mandate would not be required, at least initially.⁴⁰ Conversely, the CEO of United Airlines has indicated a desire for a vaccine mandate once it is available for all workers,⁴¹ some nursing homes and long-term care facilities across the country are implementing mandates for staff,⁴² and a New York City restaurant recently terminated an employee who refused to get vaccinated.⁴³

In sum, key determinants whether a COVID-19 vaccine is mandated include (1) proof of the vaccine's efficacy and safety; (2) specific authorization via FDA; (3) review and recommendations from ACIP; (4) additional elaborations from EEOC or OSHA; (5) state- or local-based emergency orders to issue mandates; and (6) emerging guidance from public and private sector employees as to the perceived or actual need of widespread vaccination among employees to assure their safety and the safety of others.

SUPPORTERS



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¹ 42 U.S.C.A. § 262(a)(2)(C)

² 21 U.S.C.A. § 360bbb-3(a), (b)(1)(C).


³ [Katie Thomas et al., *F.D.A. Clears Pfizer Vaccine, and Millions of Doses Will Be Shipped Right Away*, N.Y. TIMES \(Dec. 11, 2020\), <https://www.nytimes.com/2020/12/11/health/pfizer-vaccine-authorized.html>.](https://www.nytimes.com/2020/12/11/health/pfizer-vaccine-authorized.html)

⁴ Katie Thomas, *New Pfizer Results: Coronavirus Vaccine Is Safe and 95% Effective*, N.Y. TIMES (Nov. 18, 2020), <https://www.nytimes.com/2020/11/18/health/pfizer-covid-vaccine.html?action=click&module=RelatedLinks&pgtype=Article>.

⁵ Denise Grady et al., *F.D.A. Authorizes Moderna Vaccine, Adding Millions of Doses to U.S. Supply*, N.Y. TIMES (Dec. 18, 2020), <https://www.nytimes.com/2020/12/18/health/covid-vaccine-fda-moderna.html>.

⁶ Carl Zimmer, *New Analyses Show Johnson & Johnson's One-Dose Vaccine Works Well*, N.Y. TIMES (Feb. 24, 2021), <https://www.nytimes.com/2021/02/24/science/johnson-johnson-covid-vaccine.html>.

⁷ James G. Hodge, Jr., *Preventing & Treating Communicable Conditions* 107, in PUBLIC HEALTH LAW IN A NUTSHELL (3rd ed. 2018).



⁸ *Id.* at 108.

⁹ *Id.*

¹⁰ *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

¹¹ *Id.* at 12.

¹² *Id.* at 25.

¹³ KATHLEEN S. SWENDIMAN, CONG. RESEARCH SERV., RS21414, MANDATORY VACCINATIONS: PRECEDENT AND CURRENT LAWS 2, 4 (2011).

¹⁴ *Id.* at 6.

¹⁵ *Id.* at 3, 4.

¹⁶ *Id.* at 5; see also Rene F. Najera & Dorit R. Reiss, *First Do No Harm: Protecting Patients Through Immunizing Health Care Workers*, 26 HEALTH MATRIX: J. L. MED. 363, 380 (2016).

¹⁷ Christine Nero Coughlin et al., *When Doctors Become “Patients”: Advocating a Patient-Centered Approach for Health Care Workers in the Context of Mandatory Influenza Vaccinations and Informed Consent*, 45 WAKE FOREST L. REV. 1551, 1556 (2010).

¹⁸ Brian Dean Abramson, *Preparing Health Care Providers for a COVID-19 Vaccine*, 13 J. HEALTH & LIFE SCI. L. 2, 3 (2020).

¹⁹ Letter from OSHA Acting Assistant Secretary Jordan Barab to Congresswoman Marcy Kaptur (Nov. 9, 2009), <https://www.osha.gov/laws-regs/standardinterpretations/2009-11-09>.

²⁰ EEOC, PANDEMIC PREPAREDNESS IN THE WORKPLACE AND THE AMERICANS WITH DISABILITIES ACT (Mar. 21, 2020), <https://www.eeoc.gov/laws/guidance/pandemic-preparedness-workplace-and-americans-disabilities-act>.

²¹ 29 U.S.C.A. § 654(a)(1).

²² OSHA, *Protecting Workers: Guidance on Mitigating and Preventing the Spread of COVID-19 in the Workplace* (Jan. 29, 2021), <https://www.osha.gov/coronavirus/safework>.

²³ *Supra* note 19.

²⁴ 42 U.S.C.A. §§ 12112, 12113.

²⁵ *Id.*; see also EEOC, *What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws*, https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws?utm_content=&utm_medium=email&utm_name=&utm_source=govdelivery&utm_term= (last updated Dec. 16, 2020).

²⁶ 42 U.S.C.A. §§ 2000e(j), 2000e-2(a)(1).

²⁷ *Supra* note 20.

²⁸ *Va. Mason Hosp. v. Wash. State Nurses Ass’n*, 511 F.3d 908 (9th Cir. 2007).

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

³⁰ Pfizer-BioNTech, *Fact Sheet for Healthcare Providers Administering Vaccine* (Vaccination Providers) 7, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/media/144413/download> (last visited Dec. 14, 2020); Pfizer-BioNTech, *Fact Sheet for Recipients and Caregivers* 4, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/media/144414/download> (last visited Dec. 14, 2020); Moderna, *Fact Sheet for Healthcare Providers Administering Vaccine* (Vaccination Providers) 4, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/media/144637/download> (last visited Feb. 26, 2021); Moderna, *Fact Sheet for Recipients and Caregivers* 4, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/media/144638/download> (last visited Feb. 26, 2021).

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