



## COVID-19 Guidance

# COVID-19 Vaccine and Employer Mandates

Since the onset of the global COVID-19 pandemic, vital priorities have included developing, distributing, and administering safe and effective vaccines to limit transmission of COVID-19. In the United States, outside of emergencies, vaccines must be approved by the Food and Drug Administration (FDA) before they can be marketed and distributed, which is normally a lengthy process. In exigencies, FDA can issue an emergency use authorization (EUA) for vaccines (and other medical countermeasures), allowing otherwise unapproved products to be used and distributed subject to specific limitations.

On December 11, 2020, FDA issued an EUA for a COVID-19 vaccine developed by Pfizer and German partner BioNTech which demonstrated upwards of 90% efficacy in trials. On December 18, 2020, FDA issued an EUA for Moderna's COVID-19 vaccine. On February 27, 2020, FDA issued an EUA for a third vaccine, manufactured by Janssen, a division of Johnson & Johnson.

With widespread distribution of these vaccines, public and private employers, universities, and other entities across the U.S. have already begun issuing vaccine mandates to their workforces, especially with respect to health care workers (HCWs). 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.<sup>1</sup> While Banner Health previously indicated it may not pursue employee mandates,<sup>2</sup> it announced such mandates in Phoenix in July.<sup>3</sup> Multiple other health systems<sup>4</sup> and some nursing homes and long-term care facilities nationally are implementing their own employee mandates.<sup>5</sup> New York City is moving forward with a requirement for City workers to be either vaccinated or tested every week, starting in mid-September.<sup>6</sup> On July 26, 2021, the Department of Veterans Affairs announced it would require "115,000 of its frontline health care workers to be vaccinated against the coronavirus" within 2 months.<sup>7</sup>

This memorandum addresses a series of questions regarding COVID-19 vaccine mandates, providing key legal and factual updates for public health officials and employers.



## **Questions and Responses:**

### **1. What is the difference between *mandatory* vaccination and *compulsory* vaccination?**

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, attending school, or attaching fines to vaccination) to encourage participation.<sup>8</sup> In contrast, compulsory vaccinations do not allow for individual choice, but rather may be accomplished by force.<sup>9</sup> Compulsory public health powers are not utilized often because of significant ethical concerns involved and potential infringement of individual liberties or other rights.<sup>10</sup>

### **2. Can public and private sector employers mandate employees or others to get vaccinated?**

Yes. Public and private-sector vaccine mandates are generally accepted in the United States, especially in public health emergencies.


In 1905, the U.S. Supreme Court upheld a mandatory smallpox vaccination requirement in *Jacobson v. Massachusetts*.<sup>11</sup> The requirement, issued by the City of Cambridge, imposed a \$5 fine on those who refused vaccination.<sup>12</sup> The Court acknowledged that state and local governments are authorized to enact reasonable laws or regulations to protect public health and safety,<sup>13</sup> 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 employment in specific health care settings.<sup>14</sup> Many states also recognize a variety of medical, religious, or philosophical exemptions to these requirements.<sup>15</sup> It is important to check state-specific laws on this issue as recent legislative actions may alter the legality of exemptions in some states.<sup>16</sup>

Unbound from constitutional requirements, private sector employers have considerable leeway in requiring employee immunization.<sup>17</sup> HCW vaccine mandates are often justified legally by balancing competing interests between assuring public and workplace safety versus respecting HCWs' vaccination concerns.<sup>18</sup> Additionally, the Occupational Safety and Health Administration (OSHA)<sup>19</sup> and the Equal Employment Opportunity Commission (EEOC)<sup>20</sup> have 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."<sup>21</sup> OSHA published new workplace guidance on January 29, 2021. The guidance 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.<sup>22</sup> Updated OSHA guidance issued in June 2021 incentivizes COVID-19 vaccination in healthcare workplaces by requiring applicable employers to provide paid leave time for both vaccination and side effects occurring thereafter.<sup>23</sup> OSHA previously emphasized that employees should be properly informed of vaccine benefits.<sup>24</sup>

The federal Americans with Disabilities Act (ADA) allows employers to mandate vaccination so long as reasonable accommodations are provided to persons with disabilities.<sup>25</sup> 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.<sup>26</sup> Additionally, Title VII of the Civil Rights Act requires reasonable accommodation for employees with religious objections to vaccination, except in cases of undue hardship.<sup>27</sup>



In prior vaccine-related guidance, EEOC has recommended that ADA-covered employers simply “encourage employees to get the influenza vaccine” rather than requiring it.<sup>28</sup> 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.<sup>29</sup> Encouraging vaccination can also help mitigate any potential legal challenges arising in the event of a vaccine-related injury.

### **3. Does the EUA status of current COVID-19 vaccines (as contrasted with full FDA approval) impact whether they can be mandated?**

*Not extensively.* Some argue that mandates cannot be lawfully issued because COVID-19 vaccines are merely authorized, and not fully approved, via FDA. This is not legally accurate. 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 . . . .”<sup>30</sup> Consistent with the Act, guidance documents for recently-authorized vaccines explain that recipients may opt to accept or refuse them<sup>31</sup> on 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.<sup>32</sup> FDA’s authorizations of the Pfizer-BioNTech vaccine<sup>33</sup> or Moderna vaccine<sup>34</sup> do not expressly limit or prohibit mandates. Provided federal anti-discrimination protections are assured and applicable state laws or exemptions are honored, COVID-19 vaccine mandates may be lawful (even if employers or others currently seek to encourage, rather than require, inoculations).

Two federal courts have recently adjudicated COVID-19 vaccine mandates.<sup>35</sup> On June 14, 2021, a federal district court in Texas upheld Houston Methodist Hospital’s employee COVID-19 vaccine mandate consistent with FDCA’s permissive language.<sup>36</sup> A month later, a federal district court in Indiana on July 20, 2021, upheld Indiana University’s COVID-19 vaccine mandate, rejecting students’ constitutional arguments based in substantive due process and free exercise.<sup>37</sup> Both cases have been appealed to their respective Circuits.

In addition, administrative agencies have provided specific COVID-19 vaccine-related guidance. On December 16, 2020, and May 28, 2021, EEOC updated its COVID-19 guidance to provide specific information related to the COVID-19 vaccine, largely supporting the analysis that mandates are permissible.<sup>38</sup> It clarified that “federal EEO laws do not prevent an employer from requiring all employees physically entering the workplace to be vaccinated for COVID-19,” subject to certain EEO considerations outlined in the ADA and Title VII of the Civil Rights Act. EEOC further noted that additional federal, state, and local equal employment opportunity protections must be followed. This includes employers allowing reasonable accommodations, such as wearing a face mask, maintaining socially distanced workspaces, and allowing for teleworking. EEOC also provided guidance on the permissibility of encouraging employees to get vaccinated via employer incentives.

Employers mandating 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.

On July 6, 2021, the U.S. Department of Justice’s (DOJ) Office of Legal Counsel (OCL) issued an opinion addressing the legality of COVID-19 vaccine mandates given the EUA status of the currently-authorized vaccines.<sup>39</sup> OCL reasoned that the relevant section<sup>39</sup> of the FDCA “does not prohibit public or private entities from imposing vaccination requirements, even when the only vaccines available are those authorized under EUAs.”<sup>40</sup>

Specifically, FDCA's language only requires that certain information be made available to vaccine recipients, and does not prohibit mandates.<sup>41</sup>

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.<sup>42</sup> On December 12, 2020, ACIP recommended the Pfizer-BioNTech vaccine for public use in persons above 16 years of age,<sup>43</sup> and subsequently for use in those between the ages of 12-15.<sup>44</sup> ACIP similarly recommended the Moderna vaccine in persons above 18 years of age during a December 19, 2020 meeting,<sup>45</sup> and the Johnson & Johnson vaccine for those over 18 years of age on February 28, 2021.<sup>46</sup> 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, though court decisions and DOJ guidance also present important considerations.

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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, OSHA, OCL, and others; (5) state or local laws authorizing or inhibiting mandates; and (6) emerging findings as to the perceived or actual need of vaccination among employees or other to assure public health and safety.

## SUPPORTERS



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<sup>1</sup> NEW YORK STATE BAR ASS'N, HEALTH LAW SECTION, *COVID-19 Report* 64-65 (July 1, 2020), [https://nysba.org/app/uploads/2020/07/7-1-20\\_REV-2-Final-NYSBA-HEALTH-LAW-SECTION-TASK-FORCE-REPORT-w-Vacc-update.pdf](https://nysba.org/app/uploads/2020/07/7-1-20_REV-2-Final-NYSBA-HEALTH-LAW-SECTION-TASK-FORCE-REPORT-w-Vacc-update.pdf).

<sup>2</sup> *Banner Health Offers COVID-19 Update for its Colorado Hospitals*, FORT MORGAN TIMES (Nov. 19, 2020), <https://www.fortmorgantimes.com/2020/11/19/banner-health-offers-covid-19-update-for-companys-colorado-hospitals/>.

<sup>3</sup> *Banner Health Requiring All Staff to Be Fully Vaccinated Against COVID-19 by November 1*, ABC15 ARIZONA (Jul. 20, 2021), <https://www.abc15.com/news/vaccine-in-arizona/banner-health-requiring-covid-19-vaccinations-for-employees-by-november-1>.

<sup>4</sup> Dan Diamond, *153 People Resigned or Were Fired from a Texas Hospital System After Refusing to Get Vaccinated*, WASH. POST (Jun. 22, 2021), <https://www.washingtonpost.com/health/2021/06/22/houston-methodist-loses-153-employees-vaccine-mandate/>.

<sup>5</sup> Tony Galli, *Rock County Nursing Home Likely First to Require Staff to Be Vaccinated; Workers Express Concern*, WKOW.COM (Jan. 15, 2021), <https://wkow.com/2021/01/15/rock-county-nursing-home-likely-first-to-require-staff-to-be-vaccinated-workers-express->

[concern/](https://www.washingtonpost.com/local/nursing-homes-vaccine-decline/2021/01/27/22a602f6-5fe2-11eb-afbe-9a11a127d146_story.html); Rachel Chason et al., *Most Nursing Home Workers Don't Want the Vaccine. Here's What Facilities Are Doing About It*, WASH. POST (Jan. 27, 2021), [https://www.washingtonpost.com/local/nursing-homes-vaccine-decline/2021/01/27/22a602f6-5fe2-11eb-afbe-9a11a127d146\\_story.html](https://www.washingtonpost.com/local/nursing-homes-vaccine-decline/2021/01/27/22a602f6-5fe2-11eb-afbe-9a11a127d146_story.html) (“Some local providers . . . are taking a stricter approach: requiring their employees to take the vaccine.”).

<sup>6</sup> *New York will Require City Workers to Be Vaccinated or Tested Weekly by Mid-September*, N.Y. TIMES (Jul. 26, 2021), <https://www.nytimes.com/2021/07/26/nyregion/new-york-vaccinations-workers.html>.

<sup>7</sup> Jennifer Steinhauer, V.A. *Issues Vaccine Mandate for Health Care Workers, a First for a Federal Agency*, N.Y. TIMES (Jul. 26, 2021), <https://www.nytimes.com/2021/07/26/us/politics/veterans-affairs-coronavirus-covid-19.html>.

<sup>8</sup> James G. Hodge, Jr., *Preventing & Treating Communicable Conditions* 107, in PUBLIC HEALTH LAW IN A NUTSHELL (3rd ed. 2018).

<sup>9</sup> *Id.* at 108.

<sup>10</sup> *Id.*

<sup>11</sup> *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

<sup>12</sup> *Id.* at 12.

<sup>13</sup> *Id.* at 25.

<sup>14</sup> KATHLEEN S. SWENDIMAN, CONG. RESEARCH SERV., RS21414, MANDATORY VACCINATIONS: PRECEDENT AND CURRENT LAWS 2, 4 (2011).

<sup>15</sup> *Id.* at 3, 4.

<sup>16</sup> Alexandra Ellerbeck, *The Health 202: States Propose Bills to Ban Employers from Mandating Coronavirus Vaccines*, WASH. POST (Mar. 8, 2021), <https://www.washingtonpost.com/politics/2021/03/08/health-202-states-propose-bills-ban-employers-mandating-coronavirus-vaccines/>.

<sup>17</sup> *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).

<sup>18</sup> 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).

<sup>19</sup> 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>.

<sup>20</sup> 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>.

<sup>21</sup> 29 U.S.C.A. § 654(a)(1).

<sup>22</sup> 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>.

<sup>23</sup> OSHA.gov, Subpart U — COVID-19 Emergency Temporary Standard, available at <https://www.osha.gov/sites/default/files/covid-19-healthcare-ets-reg-text.pdf> (last visited June 11, 2021).

<sup>24</sup> *Supra* note 19.

<sup>25</sup> 42 U.S.C.A. §§ 12112, 12113.

<sup>26</sup> *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=](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).

<sup>27</sup> 42 U.S.C.A. §§ 2000e(j), 2000e-2(a)(1).

<sup>28</sup> *Supra* note 20.

<sup>29</sup> *Va. Mason Hosp. v. Wash. State Nurses Ass’n*, 511 F.3d 908 (9th Cir. 2007).

<sup>30</sup> 21 U.S.C.A. § 360bbb-3(e)(1)(A)(ii)(III).

<sup>31</sup> 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).

<sup>32</sup> See also Dorit Reiss, *Can Employers Mandate a Vaccine Under Emergency Use Authorization?*, BILL OF HEALTH (Feb. 24, 2021), <https://blog.petrieflom.law.harvard.edu/2021/02/24/employer-mandate-covid-vaccine-eua/#more-29801> (“Arguing that the act can overturn a legal reality by implication alone, that employers are now prohibited from doing something they have done for decades, is a tall order. Especially when the statute is not clear: by suggesting there could be consequences for refusing the vaccine, it clearly sees that the right to refuse is not absolute.”).

<sup>33</sup> U.S. Food & Drug Admin., *Pfizer-BioNTech COVID-19 Vaccine EUA Letter of Authorization* (Dec. 11, 2020), <https://www.fda.gov/media/144412/download>.

<sup>34</sup> U.S. Food & Drug Admin., *Moderna COVID-19 Vaccine EUA Letter of Authorization* (Feb. 25, 2021), <https://www.fda.gov/media/144636/download>.

<sup>35</sup> Isaac Stanley-Becker, *Resistance to Vaccine Mandates is Building. A Powerful Network is Helping.*, WASH. POST (May 26, 2021), <https://www.washingtonpost.com/health/2021/05/26/vaccine-mandate-litigation-siri-glimstad-ican/>; Susan Montoya Bryan, *New Mexico Corrections Officer Sues over Vaccination Mandate*, U.S. NEWS (Mar. 4, 2021), <https://www.usnews.com/news/politics/articles/2021-03-03/new-mexico-corrections-officer-sues-over-vaccination-mandate>.

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<sup>36</sup> Bridges v. Houston Methodist Hosp., No. 4:21-cv-01774, 2021 WL 2399994, at \*1–2 (S.D. Tex. June 12, 2021), appeal docketed, No. 21-20311 (5th Cir. June 14, 2021).

<sup>37</sup> Klaassen v. Trustees of Indiana University, No. 1:21-CV-238, 2021 WL 3073926 (N.D. Ind. July 18, 2021), appeal docketed, No. 21-2326 (7th Cir. July 20, 2021).

<sup>38</sup> 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=](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 May 28, 2021).

<sup>39</sup> Whether Section 564 of the Food, Drug, and Cosm. Act Prohibits Entities from Requiring the Use of a Vaccine Subject to an Emergency Use Authorization, 45 Op. O.L.C., July 6, 2021, at 1.

<sup>40</sup> *Id.* at 18.

<sup>41</sup> *Id.* at 2.

<sup>42</sup> Mary S. Holland, *Liability for Vaccine Injury: The United States, The European Union, and the Developing World* 67 EMORY L.J. 415, 418-19 (2018).

<sup>43</sup> Jan Hoffman, *C.D.C. Panel Recommends Pfizer Vaccine for Patients as Young as 16*, N.Y. TIMES (Dec. 12, 2020), <https://www.nytimes.com/2020/12/12/health/covid-vaccine-teens-cdc.html>.

<sup>44</sup> CDC, *The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine in Adolescents Aged 12-15 Years – United States, May 2021*, MORBIDITY & MORTALITY WEEKLY REPORT (May 21, 2021), <https://www.cdc.gov/mmwr/volumes/70/wr/mm7020e1.htm>.

<sup>45</sup> CDC, *The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Moderna COVID-19 Vaccine – United States, December 2020*, MORBIDITY & MORTALITY WEEKLY REPORT (Jan. 1, 2021), [https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e1.htm?s\\_cid=mm695152e1\\_w](https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e1.htm?s_cid=mm695152e1_w).

<sup>46</sup> CDC, *The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Janssen COVID-19 Vaccine – United States, February 2021*, MORBIDITY & MORTALITY WEEKLY REPORT (Mar. 5, 2021), <https://www.cdc.gov/mmwr/volumes/70/wr/mm7009e4.htm>.