

# **DRAFT**

Memo

ATTORNEY-CLIENT PRIVILEGED COMMUNICATION

Date: December 15, 2020

To: James R. Balda, President & CEO, Argentum

From: Thomas Barker, Foley Hoag LLP

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Regarding: State and Employer COVID-19 Vaccine Requirements

Argentum is the leading national association exclusively dedicated to supporting companies operating professionally managed, resident-centered senior living communities and the older adults and families they serve. Along with its state partners, Argentum's membership represents approximately 75 percent of the professionally managed communities in the senior living industry. Nearly 1 million older adults live in an estimated 28,000 assisted living facilities across the United States. ALFs and the population they serve are disproportionately impacted by the spread of COVID-19.

In late November 2020, pharmaceutical manufacturers Pfizer and Moderna announced their COVID-19 vaccine candidates prevented up to 95% of COVID-19 cases in their respective clinical trials.<sup>1</sup> On December 11<sup>th</sup>, The Department of Health and Human Services ("HHS") Food and Drug Administration ("FDA") issued an Emergency Use Authorization ("EUA") for Pfizer's vaccine candidate.<sup>2</sup> The FDA is also scheduled to review and issue an EUA for Moderna's vaccine

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<sup>&</sup>lt;sup>1</sup> D. Garde & M. Harper, *Pfizer and BioNTech to submit Covid-19 vaccine data to FDA as full results show 95% efficacy*, STAT (Nov. 18<sup>th</sup>, 2020), https://www.statnews.com/2020/11/18/pfizer-biontech-covid19-vaccine-fda-data/. <sup>2</sup> FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine, U.S. Food & Drug Administration (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.

candidate in the coming weeks.<sup>3</sup> The first doses of the vaccine are expected to be distributed to health care workers and residents of long-term care facilities.<sup>4</sup>

You have asked us to summarize and provide guidance on whether state governments and individual employers can implement COVID-19 vaccination requirements. In short, state governments generally have the authority under their power to promote public health and safety to impose vaccination requirements, subject to certain exemptions. Furthermore, employers such as health care providers and nursing homes that operate high-risk environments or with high-risk populations customarily can require mandatory vaccinations, subject to federal and state anti-discrimination laws.

## I. Discussion

#### A. State Governments

From the state perspective, it is likely that a state COVID-19 vaccination mandate would survive legal scrutiny. Historically, states' general police power to promote public health and safety has encompassed the authority to require mandatory vaccinations. In 1905, the Supreme Court in *Jacobson v. Commonwealth of 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 that the vaccination program had a "real and substantial relation to the protection of the public health and safety." In *Zucht v. King*, the Supreme Court again upheld a local ordinance requiring vaccinations for schoolchildren, concluding that "it is within the police power of a State to provide for compulsory vaccination" and that the ordinance did not bestow "arbitrary power, but only that *broad discretion required* for the protection of the public health." Today, all 50 states, as well as the District of Columbia, have laws requiring specified vaccines for students. Most states include certain exemptions for medical or religious reasons. That said, a number of recent lower court decisions have concluded that a state is not constitutionally required to provide a religious exemption to mandatory vaccinations.

It should be noted that the COVID-19 vaccine will differ from past vaccines in that it will be the first in history to be approved via Emergency Use Authorization ("EUA"). According to the FDA, an EUA "is a mechanism to facilitate the availability and use of medical countermeasures,

<sup>&</sup>lt;sup>3</sup> C. Johnson, *Two promising vaccines head to FDA review, setting scientific speed records*, The Washington Post (Nov. 30<sup>th</sup>, 2020), https://www.washingtonpost.com/health/2020/11/30/moderna-covid-vaccine-fda-approval/.

<sup>4</sup> *Id*.

<sup>&</sup>lt;sup>5</sup> W. Shen, *An Overview of State and Federal Authority to Impose Vaccination Requirements*, Congressional Research Service (May 22, 2019), https://fas.org/sgp/crs/misc/LSB10300.pdf. <sup>6</sup> 197 U.S. 11 (1905).

<sup>&</sup>lt;sup>7</sup> 260 U.S. 174, 177 (1922) (emphasis added).

<sup>&</sup>lt;sup>8</sup> States With Religious and Philosophical Exemptions From School Immunization Requirements, National Conference of State Legislatures (June 26, 2020), https://www.ncsl.org/research/health/school-immunization-exemption-state-laws.aspx

<sup>&</sup>lt;sup>9</sup> See Whitlow v. Cal. Dep't of Educ., 203 F. Supp. 3d 1079 (C.D. Cal. 2016); see also Middleton v. Pan, 2017 U.S. Dist. LEXIS 216203.

including vaccines, during public health emergencies, such as the current COVID-19 pandemic." <sup>10</sup> Under the EUA framework, the FDA may allow the use of unapproved medical products in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met. Thus, where past vaccines were *approved* or *licensed* by the FDA under statutory provisions of either the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act, the COVID-19 vaccination will likely be *authorized* to use for the entirety of the public health emergency.

Established in 2004, the EUA is a relatively recent phenomenon. <sup>11</sup> Thus, this sort of program was not before the Supreme Court in the seminal *Jacobson* and *Zucht* cases. That said, we believe the reasoning in those cases would nonetheless apply to a state program that would mandate the COVID-19 vaccine today. The Supreme Court has clarified that states must have broad discretion to protect the public health and safety of their respective citizens. A hypothetical state COVID-19 vaccination program would reasonably rely on authorization from the federal agency tasked with reviewing the safety and efficacy of potential vaccines, to curb the spread and ultimately eliminate a virus that has been the subject of an almost year-long public health emergency. This type of program seems to fall squarely within states' broad discretion to protect public health.

### B. Employers

Although state governments likely can implement COVID-19 vaccination requirements, whether individual employers can implement mandatory employee COVID-19 vaccination policies is a separate legal question. Generally, health care providers, schools, nursing homes, and other employers that work in high-risk environments or with high-risk populations customarily can require mandatory vaccinations. <sup>12</sup> However, facilities considering such policies must still comply with both federal and state-level laws and policies regulating discrimination in the workplace.

**EEOC.** The Equal Employment Opportunity Commission ("EEOC") is responsible for enforcing federal anti-discrimination laws in the employment context. The EEOC first tackled mandatory vaccination programs in 2009 in response to the H1N1 ("swine flu") pandemic, and addressed the issue in its guidance document Pandemic Preparedness for the Workplace. <sup>13</sup> As part of its initial guidance, the EEOC stressed that an employer considering a mandatory vaccine policy must comply with Title VII of the Civil Rights Act of 1964 and the Americans with Disabilities Act ("ADA"). Specifically, the EEOC stated:

An employee may be entitled to an exemption from a mandatory vaccination requirement based on an ADA disability that prevents him from taking the influenza vaccine. This would be a reasonable

<sup>&</sup>lt;sup>10</sup> Emergency Use Authorization for Vaccines Explained, U.S. Food & Drug Administration (November 20, 2020), https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained.

<sup>&</sup>lt;sup>11</sup> The EUA program was established in 2004, when the Project BioShield Act, among other measures, amended Section 564 of the *Federal Food, Drug, and Cosmetic Act*.

<sup>&</sup>lt;sup>12</sup> See e.g., Hustvet v. Allina Health Sys., 910 F.3d 399 (8th Cir. 2018) (upholding a healthcare system's requirement that its employees immunize against rubella as a condition of employment).

<sup>&</sup>lt;sup>13</sup> https://www.eeoc.gov/laws/guidance/pandemic-preparedness-workplace-and-americans-disabilities-act

accommodation barring undue hardship (significant difficulty or expense). Similarly, under Title VII of the Civil Rights Act of 1964, once an employer receives notice that an employee's sincerely held religious belief, practice, or observance prevents him from taking the influenza vaccine, the employer must provide a reasonable accommodation unless it would pose an undue hardship as defined by Title VII ("more than de minimis cost" to the operation of the employer's business, which is a lower standard than under the ADA).<sup>14</sup>

The EEOC updated this guidance document on March 21<sup>st</sup> of this year. However, because at the time vaccine development efforts were still in their infancy, the EEOC did not address the specific question of whether employers could also require employees to take a COVID-19 vaccine, authorized under an EUA. That said, given recent developments on the vaccine front, we expect additional EEOC guidance regarding COVID-19 vaccines to be forthcoming. Given the extent to which the vaccine issue has become politically charged, and the fact that the COVID-19 vaccine will be unique in its authorization under an EUA, we find it unlikely EEOC's guidance regarding the COVID-19 vaccine will depart in any material respect from its past guidance on vaccine mandates.

State-Level Laws and Regulations. Given the current lack of definitive guidance from the EEOC on the COVID-19 vaccine issue, and the fact that states can always pass laws that are more protective of employees than federal law, the legal framework governing whether an employer can impose a COVID-19 vaccination requirement on employees will ultimately be a state-by-state determination. Accordingly, we conducted a multi-state survey for state laws that would prevent an employer from requiring that its employees receive a COVID-19 vaccination authorized under an EUA as a condition of employment. Based on our search, there are no such laws currently in effect. That said, states generally also require employers to provide exemptions for employees with medical restrictions or religious objections. Thus, facilities considering a vaccine requirement must be sure to provide workers who do not wish to be vaccinated for medical reasons an opportunity to request an exemption under the ADA, and workers for whom taking a vaccine would violate their religious beliefs an opportunity to request an exemption under Title VII of the Civil Rights Act of 1964.

In the same vein, facilities considering implementing programs that encourage employee vaccinations should proceed with caution. The same anti-discrimination laws that apply to vaccine requirements also apply to vaccine incentive programs. Thus, a program that incentivizes employees to take the COVID-19 vaccination through monetary or similar rewards arguably discriminates against employees that cannot or will not take the vaccine due to a protected reason under the ADA or Title VII. A general educational campaign encouraging employees to take the COVID-19 vaccine would likely be preferable and allow the employer to avoid potential liability.

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<sup>&</sup>lt;sup>14</sup> *Id.*; *see also* Equal Employment Opportunity Comm'n, EEOC Compliance Manual Section 12: Religious Discrimination 56-65 (2008), https://www.eeoc.gov/policy/docs/religion.pdf.

## II. Conclusion

To conclude, facilities can likely require their employees to take the COVID-19 vaccine, when it becomes available. However, any mandatory vaccination program must comply with federal and state anti-discrimination laws. In the context of the H1N1 vaccine, the EEOC has made clear that any such program must allow for exemptions for medical or religious reasons, in order to comply with the ADA and Title VII of the Civil Rights Act, respectively. Although the COVID-19 vaccine will be authorized via an unprecedented EUA pathway, the same legal framework will likely apply. Furthermore, our multi-state survey did not find any state-level employer discrimination laws that would alter this framework.