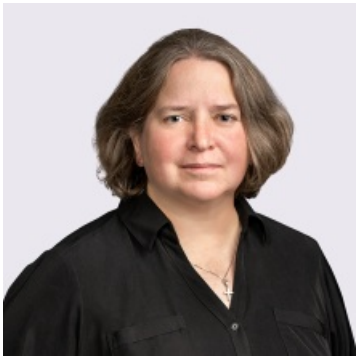


To Mandate or Not To Mandate: Department of Justice Weighs In on Vaccination Mandates

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Meet the Authors



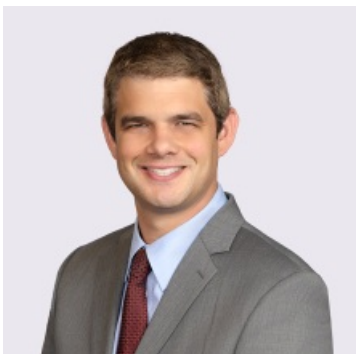
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Can employers mandate vaccines? The Department of Justice’s Office of Legal Counsel (OLC) says they can, but before employers do, they should consider the many legal and practical risks.

On July 26, 2021, the OLC issued an opinion (dated July 6, 2021) stating that the COVID-19 vaccinations’ Emergency Use Authorization (EUA) status under the Food, Drug, and Cosmetics Act (FDCA) does not prevent public and private entities from imposing vaccine requirements. However, the OLC expressly states that the opinion does not address whether any other federal, state, or local laws or regulations might restrict the ability of an entity to mandate the vaccine or adopt any particular vaccination policy.

Background of OLC

OLC is the part of the Department of Justice that has been given the legal authority to issue the Department’s definitive legal interpretations of statutory and constitutional issues. Due to the Department’s status as the chief legal agency within the federal government, OLC’s opinions are effectively binding on agencies within the Executive Branch (although some “independent” agencies may argue they can take positions contrary to OLC opinions). An opinion from OLC on any matter will have a significant effect on the legal positions taken throughout the federal government as OLC’s position is often the final word within the federal government on a legal issue.

Furthermore, while OLC opinions are not binding on courts, they can carry significant weight with judges due to the office’s reputation and status within the federal government.

OLC Opinion on EUA Status

Section 564 of the FDCA states that the Food and Drug Administration (FDA), when approving an EUA, “to the extent practicable,” must impose appropriate conditions on the EUA. One such condition mentioned in section 564(e)(1)(A)(ii)(III) is that recipients of the EUA product “are informed” of “the option to accept or refuse administration of the product.” To satisfy this requirement, the FDA, when approving the EUAs for the COVID-19 vaccines, required that the recipient receive a Fact Sheet. The Fact Sheet notifies the individual that it is the individual’s choice whether to receive the vaccine.

According to the OLC, although recipients of the EUA product must be informed of their option to refuse, this does not prevent public or private entities from requiring the vaccine as a condition of employment, to attend a university, or to participate in events (as several entities have done). OLC noted that it did not consider these types of mandates to be “direct legal requirements.”

OLC noted that allowing public and private entities to require the vaccines was permissible under the FDCA’s EUA provisions because the individual still has the option

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to refuse the vaccination, but will simply have to face the consequences of refusal, including finding new employment. OLC also noted that the FDA agrees with its interpretation of section 564 of the FDCA.

Considerations

OLC's opinion provides employers considering mandating the vaccine support defending claims that such a mandate is prohibited because the vaccine is in EUA status. It is not a clear green light for employers on this subject, however. Although various state and federal agencies and other entities have been encouraging employers to require vaccination, employers considering mandatory vaccination policies still face a host of legal and practical challenges and considerations. Employers still must consider (among other things):

1. Bargaining obligations that may exist in unionized workforces;
2. Accommodation obligations that may exist for individuals who cannot receive the vaccine due to disability, pregnancy, or religious reasons;
3. Disparate impact risk, and whether the employer can show the requirement is job-related and consistent with business necessity;
4. Impact on diversity efforts if the vaccination rates of some groups are disproportionate;
5. Employee relations considerations and whether a mandate will cause an employer to lose employees or limit the pool for new hires (which may be particularly difficult in the current labor market);
6. The entity's overall risk tolerance, as legal challenges to mandatory programs continue (regardless of whether employers are ultimately successful in these, there may be legal costs and publicity associated with them);
7. Compliance with state and local requirements (*e.g.*, Montana prohibits mandatory programs in most settings, similar bills are pending in other jurisdictions);
8. Whether and how the employer will confirm vaccination status and the coordination of related recordkeeping;
9. The impact such a mandate will have on wage and hour compliance; and
10. Other risks associated with requiring a vaccine still in EUA status, including possible liability risk if the vaccine causes an adverse reaction in an employee who only receives because it is mandated.

If you have questions about the OLC opinion or your vaccination policy for employees, please contact your Jackson Lewis attorney.

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