



DOJ Approves Employers' COVID-19 Vaccine Requirements

Eliminating any remaining doubt as to whether the Emergency Use Authorization (or EUA) status of approved COVID-19 vaccines bars private employers from implementing mandatory COVID-19 vaccination policies, on July 6, 2021, the Office of Legal Counsel of the U.S. Department of Justice (OLC) issued a memorandum opinion stating that Section 564 of the Food, Drug, and Cosmetic Act (Section 564) imposes no such limitation. The memorandum opinion follows a decision, now on appeal, from the U.S. District Court for the Southern District of Texas dismissing a lawsuit in which employees challenged a mandatory COVID-19 vaccination policy. It also bolsters guidance issued by the U.S. Equal Employment Opportunity Commission (EEOC) stating that employers may require that employees be vaccinated against COVID-19 subject to the requirements that they provide reasonable accommodations for employees with disabilities or sincerely held religious beliefs that preclude vaccination.

Since December 2020, the U.S. Food and Drug Administration has granted EUA status to three COVID-19 vaccine products. In each authorization, the FDA imposed an "option to accept or refuse" condition by requiring the distribution to potential vaccine recipients of a fact sheet that states "It is your choice to receive or not receive [the vaccine]. Should you decide not to receive it, it will not change your standard medical care." In the Texas federal court lawsuit and elsewhere, some have argued that this language giving individuals an option to refuse to be vaccinated, in turn, operates to prevent public and private entities from imposing vaccination requirements.

OLC concluded that Section 564 "concerns only the provision of information to potential vaccine recipients and does not prohibit public or private entities from imposing vaccination requirements for vaccines that are subject to EUAs." At bottom, OLC found "[n]either the statutory conditions of authorization nor the Fact Sheet itself purports to restrict public or private entities from insisting upon vaccination in any context." Consequences imposed by employers and others for refusing vaccination constitute "secondary consequences" that fall outside the purview of Section 564.

Employers now have the approval of the U.S. Department of Justice, in addition to one federal court and the EEOC, in implementing a mandatory COVID-19 vaccination requirement. Employers must still provide for appropriate requests for accommodation based on disability or religion, and therefore should consult with legal coursel prior to deciding to implement such a policy.



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