

New Covid-19 Vaccination and Mask Guidance has Employers Rethinking Safety Protocols

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Yesterday, on July 27, 2021, the U.S. Center for Disease Control (CDC) issued new COVID-19 guidance, including recommending face masks even for vaccinated people when they are in indoor public settings in geographic areas with substantial or high COVID-19 transmission rates, as mapped from time to time by the CDC. The CDC:

- Updated guidance for fully vaccinated people given new evidence on the degree to which the B.1.617.2 (Delta) variant is currently circulating in the United States and its high contagion factor.
- Recommended that fully vaccinated people wear a mask in public indoor settings in areas of substantial or high transmission.
- Recommended that fully vaccinated people might choose to wear a mask regardless of the level of transmission in their location, particularly if they are immunocompromised or at increased risk for severe disease from COVID-19, or if they have someone in their household who is immunocompromised, at increased risk of severe disease or not fully vaccinated.
- Recommended that fully vaccinated people who have a known exposure to someone with suspected or confirmed COVID-19 be tested 3-5 days after exposure and wear a mask in public indoor settings for 14 days after exposure or until they receive a negative test result.
- Recommended universal indoor masking for all teachers, staff, students, and visitors to schools, regardless of vaccination status.

In other news, earlier this month the U.S. Department of Justice's Office of Legal Counsel (DOJ) issued an opinion that the FDA emergency use authorization (EUA) status of the current COVID-19 vaccines available in the U.S. does not preclude private or public employers from mandating vaccines. Some employers have questioned the impact of the EUA status, because federal law provides that individuals must be provided with information on their right to decline a drug with EUA rather than full FDA approval status. EUA authorization from the FDA permits a product to be introduced into interstate commerce and to be administered to individuals even when the FDA has not approved the product for general distribution through its standard review process. The DOJ's opinion states that the Food, Drug, and Cosmetic Act (FDCA) EUA provision "concerns only the provision of information to potential vaccine recipients and does not prohibit public or private entities from imposing vaccination requirements" even for a vaccine that is subject to an emergency use authorization. In other words, the FDCA provisions require that certain information be



conveyed to the potential recipient of the vaccination or product, but do not limit an entity from requiring vaccinations.

Lawsuits have been filed challenging public and private organizations' vaccination requirements on the basis that potential vaccine recipients need to be informed that they have the right to accept or refuse the vaccine, but thus far no such challenge has succeeded. The DOJ's opinion provides ammunition for fighting such challenges by arguing that current vaccines can be mandated despite EUA status. Organizations should, however, consult with legal counsel about mandatory vaccine policies to ensure that any mandate does not run afoul of other laws.

For more information, please contact Rosalee McNamara or your regular Lathrop GPM contact.