

NEW RULES ON MANDATORY VACCINATIONS: APPLICABILITY TO PHARMACIES

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New Rules on Mandatory Vaccinations: Applicability to Pharmacies

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CMS Interim Final Rule (“IFR”)

On Thursday, November 4, 2021, CMS issued its IFR (effective November 5, 2021) regarding mandatory COVID-19 vaccinations for “all facilities” participating in Medicare and Medicaid. The “Background” section of the IFR states its applicability to “21 types of providers and suppliers, ranging from hospitals and hospices to rural health clinics to long term care facilities.”

Pharmacies are not included in the list of “providers and suppliers” to which the vaccine mandate applies. Therefore, the IFR does not impact retail (customer walk-in) pharmacies that do not work with facilities that participate in Medicare or Medicaid programs. However, the IFR potentially impacts pharmacies that provide services under a contract or arrangement with a facility that participates in Medicare or Medicaid programs. The IFR requires “staff” at facilities (that participate in Medicare or Medicaid) to be vaccinated. The initial dose must be received by December 6, 2021 and the second dose by January 4, 2021.

The IFR states that the vaccination requirements must apply to all staff who directly provide any care, treatment or other services for the facility or its patients. For such staff, the COVID-19 vaccination is required as a condition for continued provision of services for the facility or its patients. In addition to a facility’s employees, practitioners and volunteers, the IFR broadly includes anyone who (i) provides services to the facility under a contract or an arrangement and (ii) potentially comes in contact with the facility staff or patients. Thus, if a pharmacy delivers drugs to hospitals, SNFs and other facilities, the delivery employee will likely need to be vaccinated. The CMS Rule does not apply to “one off” vendors, volunteers or professionals who infrequently provide ad-hoc, non-health care services. Examples include individuals who infrequently enter a facility for specific limited purposes and for a limited amount of time, and do not provide services by contract or under an arrangement.

The IFR does not prohibit facilities from extending the vaccination requirements beyond their staff. Pharmacies should check with facilities to which they deliver products. It is likely that the facilities will require the pharmacy’s delivery employee to be vaccinated.

OSHA Emergency Temporary Standard (“ETS”)

On Thursday, November 4, 2021, OSHA issued its ETS regarding mandatory COVID-19 vaccinations for all private sector employers with 100 or more employees. Under the ETS, covered employers must implement and enforce a mandatory COVID-19 vaccination policy under which employees may either (1) become vaccinated or (2) undergo regular COVID-19 testing (at least once every seven days for employees in the office each week) and wear a face covering. Exceptions for medical (or disability) and sincerely held religious beliefs apply to the OSHA ETS. OSHA will begin enforcing the ETS on December 5, 2021. This is the date by which unvaccinated workers need to begin wearing masks. Employers must begin collecting tests from their unvaccinated workforce on January 5, 2022.

Defining 100 Employees

Employers must count all employees, including part-time workers, remote workers, minors, and temporary employees in determining its threshold compliance responsibility. Employers cannot consider separate locations as separate “workforces;” the 100-employee threshold includes all employees in all locations. For example, if Corporation A owns three pharmacies (i.e., under a single tax ID number), each with 40 employees, then Corporation A is subject to the OSHA ETS because it has a total of 120 employees. On the other hand, if John Smith owns three pharmacies under separate corporate entities (i.e., three different tax ID numbers) and each pharmacy has 40 employees, then none of the pharmacies are subject to the OSHA ETS. A pharmacy that has fewer than 100 employees at the start of the OSHA ETS effective date is not subject to the ETS. However, if that pharmacy then hits the 100-employee threshold, the pharmacy becomes subject to the ETS for the duration of the standard, even if the employee count drops back under 100 employees.

The 100-employee threshold does not include independent contractors or workers provided by staffing agencies. Employers should be very careful when classifying workers as independent contractors, as the Department of Labor (“DOL”) and state agencies critically review these classifications and make determinations that workers are actually employees and not independent contractors.

PTO to Receive Vaccine

Employees are entitled to PTO for the time necessary to receive the COVID-19 vaccine. The amount of vaccine PTO available is defined as a “reasonable” amount of time, not to exceed four hours. Employees are also entitled to PTO for the time necessary for recovery due to the side effects of a COVID-19 vaccination. The OSHA ETS instructs that employers may not force employees to use vacation pay to cover an absence period arising due to side effects from receipt of the vaccine.

Verification of Vaccination Status

Employers must require employees to provide acceptable proof of vaccination, which includes: (1) a record of immunization from a health care provider or pharmacy; (2) a copy of the employee’s COVID-19 Vaccination Record card; (3) a copy of medical records documenting the vaccination; or (4) a copy of an immunization record from a public health, state, or tribal immunization system, or a copy of any other official documentation that contains the type of vaccine administered, date(s) of administration, and the name of the health care professional or clinic site that/who administered the vaccine. These records are considered “medical records” and should be stored in employees’ medical files (separate from their HR or disciplinary files).

Weekly Testing for Unvaccinated Employees

Employers are allowed to mandate their entire workforce to be vaccinated (except for any employees with disability, medical, or religious accommodations). However, under OSHA’s

ETS, covered employers may provide a “soft” compliance option for unvaccinated employees in lieu of mandatory vaccination. Under this approach, unvaccinated employees must provide the employer with a negative test result every seven days for continuing access to the workplace. Unvaccinated employees who come into the workplace less than once every seven days must only obtain a negative test result within seven days prior to their return to the workplace.

Unvaccinated employees who work exclusively from home, or exclusively outside, are not required to submit to testing. Employees granted a religious, disability, or medical accommodation from the COVID-19 vaccination must still submit weekly negative COVID-19 tests, even though granted an accommodation from receiving the COVID-19 vaccine. The testing requirement may be satisfied through a negative NAAT (nucleic acid amplification test), a rapid-result antigen test, or through other testing options approved by the FDA. Employees may not rely upon tests that are both self-administered and self-read. Instead, an authorized health care provider must administer the test (which likely includes pharmacists, though this is not explicitly stated in the regulations).

Employees who submit weekly negative COVID-19 tests in lieu of vaccination must wear masks in the workplace. Employers who allow for weekly COVID-19 testing in lieu of mandatory COVID-19 vaccinations are not required to pay for the cost of weekly COVID-19 testing. However, OSHA reminds employers: “. . . Payment for testing may be required by other laws, regulations, or collective bargaining agreements or other collectively negotiated agreements.” For example, Wisconsin has a potentially applicable statute disallowing employers from requiring their employees to pay for the cost of a “medical examination” required by the employer as a condition of employment (Wis. Stat. Section 103.37(2m)).

Face Covering Obligation

Unvaccinated employees must wear approved face coverings (beginning December 5, 2021) when indoors and when occupying a vehicle with others for work purposes. This policy must be enforced at all times, except: (1) when the employee is alone in a room with floor-to-ceiling walls and a closed door; (2) for a limited time period to allow the employee to drink and/or eat; (3) when the employee is wearing a respirator; or (4) where the employer can show that the use of face coverings is infeasible or creates a greater hazard. The fourth reason listed will likely be difficult to prove and should not be relied on with frequency.

Enforcement Dates

OSHA will begin enforcing the ETS on December 5, 2021. This is the date by which unvaccinated workers need to begin wearing masks. Employers must begin collecting tests from their unvaccinated workforce on January 5, 2022.

Penalties for Non-Compliance

If an employer with 100 or more employees does not comply with the OSHA ETS, OSHA can penalize the employer for each individual violation. Each individual violation could lead to a fine of up to \$14,000. OSHA intends to penalize employers for each employee who is negatively

impacted by the employer's failure to comply and for each instance of "failing to protect" an employee. OSHA has stated it anticipates that the penalties will be large in order to achieve a deterrent effect.

Temporary Stay of Enforcement

On Saturday, November 6, 2021, the Fifth Circuit Court of Appeals (the Federal Court of Appeals governing Louisiana, Mississippi, and Texas) issued a stay temporarily blocking OSHA's ETS. The Fifth Circuit granted an emergency stay stopping enforcement of the new policy, saying it raises "grave statutory and constitutional issues," and added that the rule was suspended "pending further action by this court." The stay appears to apply nationally, though the stay does not specifically state it is national in application. The DOL responded quickly by stating, "The Occupational Safety and Health Act explicitly gives OSHA the authority to act quickly in an emergency where the agency finds that workers are subjected to grave danger and a new standard is necessary to protect them."

The DOL's Chief Legal officer, Seema Nanda, stated that the DOL is "fully prepared to defend this standard in court." The Fifth Circuit ordered the Biden Administration to file initial legal papers by November 8, 2021, and requested responsive filings by November 9, 2021. The court is expected to move quickly to issue a final ruling on whether the new policy can be enforced. We recommend that employers with 100 or more employees prepare for compliance with the ETS, even though it is currently stayed, especially given the short compliance deadlines in the rule. Further, even though it appears as though the stay applies nationwide, the Fifth Circuit may later clarify that its applicability is only to Texas, Mississippi, and Louisiana.

THIS WHITE PAPER DOES NOT CONSTITUTE LEGAL ADVICE. THIS WHITE PAPER WAS PREPARED ON A SPECIFIC DATE. THE LAW MAY HAVE CHANGED SINCE THIS WHITE PAPER WAS WRITTEN. THE READER SHOULD CONSULT AN ATTORNEY REGARDING THE ISSUES DISCUSSED IN THIS WHITE PAPER.

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