Biden Administration Issues Two COVID-19 Vaccine-Mandate Policies

November 11, 2021

Summary
- The Department of Labor (DOL) and the Department of Health and Human Services (HHS) issued emergency employee-vaccine mandates for COVID-19.
- Although 60-day comment periods accompany these rules, both are effective immediately.
- The DOL and HHS require full compliance within 60 days of November 5, 2021 (January 4, 2022).
- Both rules face legal challenges, which may affect implementation and enforcement.

OSHA Employee Vaccine Mandate
The DOL’s Occupations Safety and Health Administration (OSHA) issued an emergency temporary standard (ETS) that instructs companies with over 100 employees to require each employee be fully vaccinated, or confirm a negative COVID-19 test result every seven days, by January 4, 2022. This rule applies to over 84-million workers.

OSHA can issue an ETS if it determines that: 1) “employees are exposed to grave danger” from toxic or harmful agents or “from new hazards,” 2) the measure is “necessary to protect employees from danger.”

Employer Vaccination and Testing ETS
- OSHA’s ETS applies to a company’s total workforce—not the number of employees at specific sites.
- Full-time teleworkers count toward the 100-worker threshold, but are exempt from this mandate.
- The ETS sets criteria for confirming employee-vaccination status and defines “fully vaccinated” in accordance with CDC guidance.
- The ETS neither requires employers to offer, nor pay for, weekly COVID-19 testing.
- Employers may offer exemption provisions for workers who cannot receive the vaccination for medical or religious reasons; employers must provide this option if they do not offer weekly testing.
- The ETS requires employers to provide reasonable PTO to receive the vaccinations, respond to any vaccine-related side effects, and/or undergo weekly COVID-19 testing.

Steps to Ensure Compliance
To help facilitate compliance, Smithbucklin clients with members potentially affected by this rule should:
- Determine whether the OSHA ETS applies to their clients (as employers or employees).
- Develop compliance protocol for onsite contractors.
- Develop a data-collection and tracking mechanism to categorize vaccinated and unvaccinated employees, and, if necessary, weekly test results.
- Consider vaccination and testing facilitation—either onsite or through vetted, accessible locations.
- Determine if the employer or employees will pay for weekly COVID tests, if offered.
- Establish PTO-reporting protocol for receiving the vaccine, vaccine-related reactions, and/or weekly tests.

OSHA Compliance
- OSHA considers ETS-noncompliance violations as either “serious” or “willful” and can issue a maximum penalty of $13,653 for a “serious” violation and $136,532 for a “willful” violation.
- The DOL provides more information about OHSA penalties Under 29 C.F.R. § 1903.15.
COVID-19 Healthcare Staff Vaccination Interim Final Rule

Effective November 5, 2021, the Department of Health & Human Service’s (HHS) interim final rule requires that all staff at Medicare- or Medicaid-certified healthcare facilities be fully vaccinated against COVID-19 by January 4, 2022. This mandate applies to the following entities, which includes approximately 76,000 healthcare practitioners, and 17-million personnel:

- Hospitals and Critical-Access Hospitals
- Ambulatory Surgical Centers
- Hospices
- Programs of All-Inclusive Care for the Elderly
- Long-Term Care facilities
- Psychiatric Residential Treatment Facilities
- Intermediate Care Facilities for Individuals with Intellectual Disabilities
- Home Health Agencies
- Comprehensive Outpatient Rehabilitation Facilities
- Clinics (rehab and public-health agencies that provide outpatient physical therapy and speech-language pathology services)
- Community Mental Health Centers
- Home-Infusion Therapy suppliers
- Rural-Health Clinics and Federally Qualified Health Centers
- End-Stage Renal Disease Facilities.

The rule does not apply to physician and dentist offices that Medicare/Medicaid does not regulate, nor does it apply to Organ-Procurement Organizations or Portable X-Ray suppliers.

Important Dates

- **November 4, 2021:** HHS issued a 60-day comment period for its interim rule.
- **November 5, 2021:** HHS begins enforcing the interim rule.
- **December 5, 2021:** HHS will require that personnel employed at applicable facilities have received the first dose of the Moderna or Pfizer vaccines or the Johnson & Johnson vaccine before providing any “care, treatment, or other services.”
- **January 4, 2022:** HHS will require that all personnel employed at applicable facilities be fully vaccinated against COVID-19.

Compliance

CMS will use established survey and enforcement processes to ensure compliance and work with accrediting organizations, as well as State Survey Agencies that assess compliance with Medicare/Medicaid regulations.

These Agencies will conduct onsite-compliance reviews by:

- Assessing all facilities for these requirements during the standard recertification survey.
- Assessing staff-vaccination statuses on all complaint surveys.

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