



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 Occupational 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 OSHA 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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