

Summary of CMS Emergency Temporary Rule & OSHA Emergency Temporary Standard Requirements November 2011

CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule	OSHA COVID-19 Vaccination and Testing Emergency Temporary Standard
Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services	Occupational Safety and Health Administration, U.S. Department of Labor
Published 11/5/2021 in the <u>Federal Register</u>	Published 11/5/2021 in the <u>Federal Register</u>
Effective 11/5/2021	Effective 11/5/2021 and anticipated to be in effect for six months
 Requires employee vaccination Applies only to Medicare and Medicaid-certified providers & suppliers Pre-empts any State law prohibiting mandatory vaccines 	 Requires employee vaccination OR weekly testing + face coverings Applies to private employers with ≥ 100 employees in all industries In states with OSHA-approved State Plans (NC), private employers + state and local-government employers with ≥ 100 employees will be covered by state occupational safety and health requirements.
Posted for a 60-day comment period until 1/4/2022 but this Emergency Rule is effective immediately	Posted for a 30-day public comment period until 12/6
11/10: first lawsuit filed in Eastern District of MO. Petition alleges that CMS has overreached its authority and that the rule is overly broad.	This Emergency Rule is under a stay (stalled judicial proceedings and enforcement) while several multi-state lawsuits are being consolidated in federal court.

CMS Rule	OSHA Rule
Provider employers subject to the Rule: Medicare and Medicaid-certified provider and supplier types (collectively, "facilities") that are regulated under the Medicare health and safety standards known as Conditions of Participation (CoPs), Conditions for Coverage (CfCs), or Requirements. • See the CMS list of providers & facilities here. • Physician offices are exempt. • Group Homes are exempt. • HCBS venues are exempt. • Assisted Living facilities are exempt. • Schools that receive Medicaid funding are exempt.	 Employers subject to the rule: Private employers with ≥ 100 employees Healthcare employers subject to the CMS Health Care Staff Vaccination Interim Final Rule should look to the CMS rule requirements first. If CMS Emergency Rule doesn't apply then the OSHA ETS applies. Healthcare employers in settings subject to the June 2021 OSHA Healthcare ETS are exempt from this ETS unless the Healthcare ETS is no longer in effect while this ETS in is in effect. These employers may not implement the Vaccination and Testing ETS in lieu of the Healthcare ETS; only in addition to the Healthcare ETS.
 Which provider employees are subject to the Rule? Staff working at a facility that participates in the Medicare and Medicaid programs, regardless of clinical responsibility or patient contact. Staff working off-site for home health, etc. if they are interacting with staff, clients, patients, residents. Existing and new staff who provide any care, treatment, or other services for the facility and/or its patients. Facility employees, licensed practitioners, admitted physicians, students, trainees, and volunteers. Individuals who provide care, treatment, or other services for the facility and/or its patients under contract or other arrangements. Work from home employees ("teleworkers") are exempt. 	 Who do employers include in their '100 employees' count? All employees across all U.S. workplaces at the employer level (firmor corporate-wide); not the individual location. Part-time employees are counted Work from home employees are not counted Independent contractors are not counted Temps from staffing agencies are not counted by the company using the temp staffers; only by the Temp company Other temporary and seasonal workers are counted

CMS Rule	OSHA Rule
Within 30 days of the effective date (12/6) employees subject to the Rule (including new employees) must have their first of two vaccinations (when applicable). Authorized vaccines may be those listed by the World Health Organization (WHO) for emergency use, those approve/licensed or authorized for emergency use by the U.S. Food and Drug Administration (FDA), or those received during an employee's participation in a clinical trial. Only a one- or two-shot primary vaccine series is required. Boosters are not mandatory; only the primary series. However, CMS recommends following CDC Guidelines regarding boosters.	Within 30 days of the effective date (12/6), employers subject to the Rule must: establish an employee vaccination policy; verify proof of employee vaccination status [excluding boosters] and maintain records [as confidential employee medical records that do NOT have to include COVID test or diagnosis results] and rosters [including unvaccinated employees]; require prompt employee notice of COVID-positive test or diagnosis; remove COVID-positive employees from environment; ensure employees who are not fully vaccinated [have received one or both injections, depending on brand] wear face coverings when indoors or when occupying a vehicle with another person for work purposes; provide each employee information about the ETS, workplace policies and procedures, vaccination efficacy, safety and benefits [in appropriate language and literacy level]; protections against retaliation and discrimination; and laws that provide for criminal penalties for knowingly supplying false documentation; Report work-related COVID-19 fatalities to OSHA within 8 hours and work-related COVID-19 in-patient hospitalizations within 24 hours; and make certain records available to OSHA and to individual employees and anyone with written, authorized consent upon request.
Within 60 days of the effective date (1/4/2022) employees subject to the Rule must have their second of two vaccinations (when applicable). Second shot by the deadline is acceptable even if the recommended 14 days after the second shot have not yet passed.	Within 60 days of effective date (1/4/2022) Ensure employees who are not fully vaccinated are tested for COVID-19 at least weekly (if in the workplace at least once a week) or within 7 days before returning to work (if away from the workplace for one week or longer). • Unvaccinated employees may not return to work with a face covering if they don't also have a weekly negative test result. • Pooled testing is allowed.

CMS Rule	OSHA Rule
CMS encourages but does not require providers and suppliers to consider on-site vaccination programs to avoid, e.g., transportation barriers, a need to take time off from work, and scheduling.	 Employers must support employee COVID-19 vaccination with "reasonable time" during work hours for each vaccination dose. Pay up to 4 hours at regular rate of pay per dose; may be fewer hours if employer offers on-site vaccination. May not require employees to use accrued leave of any kind [distinct from Healthcare ETS]. Do not have to pay employees for non-workday hours if employee voluntarily uses day off. Do not have to reimburse employees for related travel. Do not have to reimburse unvaccinated employees for testing or face coverings.
	Employers must offer reasonable time and paid sick leave to employees to recover from side effects experienced following a primary vaccination dose regardless of vaccination venue. • May cap the paid sick leave to, e.g., 2 days. Employers are not required to monitor for or detect fraudulent proof of vaccination. • Both employees and employers are subject to civil penalties under the OSH Act of 1970 if they knowingly submit or accept, respectively, false statements or documentation.
 Acceptable document for proof of vaccination: CDC COVID-19 vaccination record card (or a legible photo of the card); Documentation of vaccination from a health care provider or electronic health record; State immunization information system record; or If vaccinated outside of the U.S., a reasonable equivalent of any of the previous examples. Medical record files must be stored separately and remain confidential. 	Acceptable documentation for proof of vaccination: record of immunization from health care provider or pharmacy; copy of U.S. COVID-19 Vaccination Record Card; copy of medical records documenting the vaccination; copy of immunization records from a public health, state, or tribal immunization information system; or 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(s) or clinic site(s) administering the vaccine(s). If none of the above are available, a signed and dated attestation (see FAQs section 4.G. for required content).

CMS Rule	OSHA Rule
Facilities are required to have a process or policy in place ensuring that all applicable staff are vaccinated against COVID-19.	The employer plan/vaccination policy should be made readily accessible to all employees through the employer's normal methods of distributing information to employees.
See 42 C.F.R. 483.430(f)(3) for minimum required vaccination policy content and related documentation requirements (including primary vaccinations, boosters, and provider-signed medical exemption forms) for facility Conditions of Participation. Employers must have a contingency plan for implementing additional precautions for any staff who are not vaccinated to mitigate the transmission and spread of COVID-19.	 See FAQs section 3.C. for required plan/policy content. The ETS establishes minimum requirements and employers may implement additional measures. Employers may develop and implement partial mandatory vaccination policies for only employees who provide services directly to members of the public. Employers are not required to submit their written policies to OSHA unless requested. The Assistant Secretary may request employers' written plans for examination and copying.
 Allowable exemptions from the mandatory vaccination policy: Employees for whom a vaccine is medically contraindicated Employees for whom medical necessity requires a delay in vaccination Employees who are legally entitled to a reasonable accommodation under federal civil rights laws because they have a disability or sincerely held religious beliefs, practices, or observances that conflict with the vaccination requirement The rule incorporates by reference anti-discrimination laws and EEOC Guidance regarding religious objections The rule authorizes employers to establish their own exemption request policies & procedures, but employers must meet federal documentation requirements. 	Allowable exemptions from the mandatory vaccination policy:
Sanctions for Non-Compliant Providers, Facilities	Sanctions for Non-Compliant Employers
Provider and supplier compliance with the rule are mandatory for participation in the Medicare and Medicaid programs. CMS remedies upon	OSHA has authority to issue a separate penalty for each instance of noncompliance with an OSHA standard.
State Survey Agency assessment:	 Per serious violation: max penalty of \$13,653
Plan of correction	Failure to abate: max \$13,653 per day beyond abatement date
Civil monetary penalties	Willful or repeated: max \$136,532 per violation
Denial of payment	
 Termination from Medicare and/or Medicaid programs 	

CMS Rule FAQs: CMS Omnibus Staff Vax Requirements - External FAQ (508 Compliant)

Related U.S. Department of Labor Equal Employment Opportunity Commission (EEOC) Guidance

The CMS Rule incorporates by reference COVID-19 U.S. Department of Labor / EEOC Guidance ["Under federal law, including the ADA and Title VII of the Civil Rights Act of 1964, individuals who cannot be vaccinated because of medical conditions or sincerely held religious beliefs, practice, or observance may be entitled to an accommodation. CMS encourages facilities to review the Equal Employment Opportunity Commission's website for additional information about situations that may warrant accommodations."] You can access that guidance here: What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws | U.S. Equal Employment Opportunity Commission (eeoc.gov)

Applicable federal anti-discrimination laws and civil rights protections include but are not limited to:

- The Americans with Disabilities Act (ADA)
 Section 504 of the Rehabilitation Act
- Title VII of the Civil Rights Act of 1964
- The Pregnancy Discrimination Act
- The Genetic Information Nondiscrimination Act

CMS list of health care organizations that are subject to being regulated under the Conditions for Coverage and Conditions of Participation Conditions for Coverage (CfCs) & Conditions of Participation (CoPs) | CMS [This list is mirrored in the Emergency Rule]

Brief **CMS** description of ICF-IID functions and responsibilities: Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs/IID) | CMS

CMS Regulatory definitions of ICF-IIDs including the qualifying number of beds (≥ 4), services provided ("in a protected residential setting, ongoing evaluation, planning, 24-hour supervision, coordination, and integration of health or rehabilitative services to help each individual function at his greatest ability"), etc.: ICF/MR Glossary (cms.gov)

OSHA Rule FAQs: COVID-19 Vaccination and Testing ETS - Frequently Asked Questions | Occupational Safety and Health Administration (osha.gov)

OSHA Vaccination and Testing ETS Fact Sheet: COVID-19 Vaccination and Testing ETS (osha.gov)

OSHA Vaccination and Testing Under Review with NC Department of Labor

- NC is one of 22 states with a State-level OSHA office and State Plan.
- The North Carolina State Plan exercises jurisdiction over all private and public sector employers and employees within the state, with the exception of federal employees, United States Postal Service, private sector maritime activities, employment on Indian reservations, railroad employment, enforcement on military bases, and the American National Red Cross.
- See this <u>11/4 NC DOL press release</u> regarding Labor Commissioner Dobson's review period and the pending decision to adopt, amend, or not adopt the federal OSHA Vaccination and Testing ETS. [NC fully adopted OSHA's June Healthcare ETS]

Can the NC Department of Labor "Not Adopt" the OSHA Vaccination and Testing ETS?

- This ETS preempts States, and political subdivisions of States, from adopting and enforcing workplace requirements relating to the occupational safety and health issues of vaccination, wearing face coverings, and testing for COVID-19, except under the authority of a Federally-approved State Plan. . . OSHA intends for the ETS to preempt and invalidate any State or local requirements that ban or limit an employer's authority to require vaccination, face covering, or testing.
- State Plans are required to adopt and enforce occupational safety and health standards that are at least as effective as Federal OSHA's requirements (29 U.S.C. 667(c)(2)).
- OSHA will work with the State Plans on adopting an emergency standard that is at least as effective as the ETS within the 30-day timeframe required by 29 CFR 1953.5(b).
- In the event that a State Plan fails to adopt this ETS or a comparable standard, such failure to act will result in a determination by Federal OSHA that the State Plan is not at least as effective as Federal OSHA.
- When OSHA determines that a State Plan is no longer fulfilling its statutory responsibilities under the OSH Act by failing to meet Federal requirements under Section 18 for continued approval, Federal OSHA may commence proceedings to ensure adequate protections for covered workers within the state.
- For State Plans covering the private sector that have final approval, this may include OSHA's reconsideration and possible revocation of the State Plan's final approval status in order to reinstate concurrent federal enforcement authority as necessary.

OSHA June 2021 Healthcare ETS Fact Sheet: Subpart U—COVID-19 Healthcare ETS (osha.gov)

OSHA June 2021 Healthcare ETS Flow Chart: Is Your Workplace Covered? <u>Is your workplace covered by the COVID 19 Healthcare ETS? (osha.gov)</u>

OSHA Healthcare ETS Checklist and Employee Job Hazard Analysis: COVID-19 Healthcare Worksite Checklist & Employee Job Hazard Analysis (osha.gov)