

CMS to Require COVID-19 Vaccinations for Medicare and Medicaid Providers

- *CMS is requiring that all staff of certain providers and suppliers participating in the Medicare or Medicaid programs receive the COVID-19 vaccine.*
- *The IFR does not allow for weekly testing in lieu of vaccination.*
- *The agency expressly preserves an employer's right to require its employees to be fully vaccinated, regardless of the exemptions provided by the IFC.*

Today, the **Centers for Medicare and Medicaid Services (CMS)** issued an interim final rule with comment (IFC), establishing COVID-19 vaccination requirements for staff at specified Medicare- and Medicaid-certified providers and suppliers. The IFC, entitled, "**Medicare and Medicaid Programs: Omnibus COVID-19 Health Care Staff Vaccination**" ([rule](#); [press release](#); [FAQ](#)) stipulates that all staff members, **including those who perform their duties outside of a formal clinical setting**, of certain providers and suppliers participating in the Medicare and Medicaid programs must be fully vaccinated against COVID-19 unless exempt. The IFC provides that individuals who **provide services 100 percent remotely are not subject to the vaccination requirements**; however, staff that primarily provide services remotely via telework who occasionally encounter fellow staff are still bound by the IFC's provisions.

- **Background:** On September 9, 2021 President Biden issued an [executive order](#) (EO) entitled "Path out of the Pandemic," a multifaceted COVID-19 response plan that seeks to boost vaccinations and testing amid the surge in the delta variant. The President's new plan focuses on six core components, including: (1) "Vaccinating the Unvaccinated;" (2) "Further Protection for the Vaccinated;" (3) "Keeping Schools Safely Open;" (4) "Increased Testing and Requiring Masking;" (5) "Protecting Our Economic Recovery"; and (6) "Improving Care for Those with COVID-19." To further the mission of this EO, CMS and the Occupational Health Services Administration (OSHA) issued regulations requiring certain individuals in the workforce to be vaccinated against COVID-19. In today's IFC, CMS indicates that providers and suppliers may be covered by both the OSHA rules and the CMS IFC.

CMS is providing **two implementation phases** for the IFC in order to ensure efficiency in carrying out these requirements — effective 30 and 60 days after publication of this IFC in the *Federal Register* for Phases 1 and 2, respectively. The IFC notes that **non-compliant facilities** may be subject to civil money

penalties, denial of payment for new admissions, or termination of their Medicare and Medicaid provider agreement. The agency also stated that it **intends to retain these provisions** beyond the conclusion of the public health emergency (PHE) as relevant, adding that it may deem these provisions permanent for facilities. To this end, CMS highlighted that this rulemaking is not associated with or tied to the PHE declarations, nor is there a sunset clause.

- **What's Next?** The final rule is expected to be published in the *Federal Register* on November 5, 2021, with an expected effective date of January 4, 2022. Comments to the IFC must be received no later than 60 days after the publication of the IFC in the *Federal Register*. While legal challenges to these guidelines are expected, CMS has already notably indicated in today's IFC that, to the extent a court may enjoin any part of the rule, it intends that all other provisions or parts of provisions are to remain in effect.

Key policy items outlined in the IFC include:

- **Applicable Entities** — The IFC provides that Medicare- and Medicaid-certified providers and suppliers must require that all applicable staff are fully vaccinated for COVID-19. Specifically, the entities subject to these requirements include:
 - (1) ambulatory surgical centers (ASCs);
 - (2) hospices;
 - (3) psychiatric residential treatment facilities (PRTFs);
 - (4) programs of all-inclusive care for the elderly (PACE);
 - (5) hospitals, including acute care hospitals, psychiatric hospitals, long term care hospitals, children's hospitals, hospital swing beds, transplant centers, cancer hospitals, and rehabilitation hospitals;
 - (6) long term care (LTC) facilities, including skilled nursing facilities (SNFs) and nursing facilities (NFs);
 - (7) intermediate care facilities for individuals with intellectual disabilities (ICFs-IID);
 - (8) home health agencies (HHAs);
 - (9) comprehensive outpatient rehabilitation facilities (CORFs);
 - (10) critical access hospitals (CAHs);
 - (11) clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services;
 - (12) community mental health centers (CMHCs);
 - (13) home infusion therapy (HIT) suppliers;
 - (14) rural health clinics (RHCs)/federally qualified health centers (FQHCs); and
 - (15) end-stage renal disease (ESRD) facilities.
- In the IFC, CMS refers to the above facilities as residential congregate-care facilities, acute care settings, outpatient clinical care and services, and home-based care, generally. Notably, the requirements outlined in the IFC do not apply to assisted living facilities, group homes, or physician's offices because they are not regulated by CMS health and safety standards.
- **Applicable Staff** — CMS is requiring that all staff, regardless of patient contact or clinical responsibility, be fully vaccinated against COVID-19. The IFC stipulates that

facility employees; licensed practitioners; students, trainees, and volunteers; and individuals who provide care, treatment, or other services for the facility and/or its patients, under contract or other arrangement, are subject to this requirement. The agency notes that staff who perform their duties outside of a formal clinical setting — such as home health, home infusion therapy, hospice, PACE programs, and therapy staff — are not precluded from the rule. Further, CMS asserts that individuals who provide services 100 percent remotely — including fully remote telehealth or payroll services — are not subject to the vaccination requirements. However, staff that primarily provide services remotely via telework who occasionally encounter fellow staff are still bound by the rulemaking.

- **Definition of “Fully Vaccinated”** — Under the IFC, an individual is considered to be “fully vaccinated” if it has been two weeks or more since such individual completed a primary vaccination series defined as a single-dose or all doses of a multi-dose vaccine approved by the Food and Drug Administration (FDA). Importantly, individuals who receive vaccines listed by the World Health Organization (WHO) for emergency use but have not been approved or authorized by the FDA will also be counted as fully vaccinated for the purposes of the rulemaking. Additionally, individuals are not required to receive a booster or third dose of a vaccine in order to be considered fully vaccinated. However, providers and suppliers covered by the IFC must have a process for tracking and securely documenting the vaccination status of individuals who have obtained any booster.
- **Exceptions** — CMS is requiring that applicable providers and suppliers establish and implement a process to allow staff to request an exemption from COVID-19 vaccination requirements based on applicable Federal law. The agency cites certain allergies; recognized medical conditions; or religious beliefs, observances, or practices as possible grounds for exemption. Providers and suppliers covered by the IFC are also required to document exemption requests from the vaccine requirements as well as the outcomes of those requests. Further, the agency is requiring that all applicable providers and suppliers establish a process to ensure the implementation of additional precautions to mitigate the transmission of COVID-19 for all staff who are not fully vaccinated. Notably, CMS expressly preserves an employer’s right to require that employees be fully vaccinated, regardless of the exemptions provided by the IFC.
- **Implementation** — CMS is providing two implementation phases for the IFC in order to ensure efficiency in carrying out these requirements.
 - **Phase 1.** This phase includes a large majority of provisions in the IFC, including requirements that: (1) all staff have received at least the first dose of the COVID-19 vaccine, or a single dose COVID-19 vaccine, or have requested and/or been granted a lawful exemption to the requirement and (2) facilities have developed and implemented the aforementioned policies and procedures. **Phase 1 is effective 30 days after the publication of this IFC in the *Federal Register*.**
 - **Phase 2.** This phase requires that all applicable staff are fully vaccinated for COVID-19, unless granted an exception, which must be fully approved at this

phase. Staff who have completed a primary vaccination series by this date are considered to have met these requirements, even if they have yet to complete the 14-day waiting period required for full vaccination. **Phase 2 is effective 60 days after the publication of this IFC in the *Federal Register*.**

- **Enforcement** — CMS plans to issue interpretive guidelines, which include state survey procedures, to aid in assessing compliance with the new requirements among providers and suppliers following the publication of this IFC. The agency provides that non-compliant facilities may be subject to civil money penalties, denial of payment for new admissions, or termination of their Medicare and Medicaid provider agreement.
- **Other Provisions** — This rule does not provide any prevention and control requirements for PRTFs, RHCs/FQHCs, and HIT suppliers. However, it does require that these entities create procedures in accordance with nationally recognized guidelines to limit the spread of COVID-19. Further, this IFC requires that providers and suppliers retain proper documentation of the vaccination status of each staff member, such as: (1) CDC COVID-19 vaccination card or legible photo of the card; (2) documentation of vaccination from a health care provider or electronic health record; or (3) a state immunization information system record.

OSHA Issues Long-Awaited COVID-19 Vaccination and Testing Requirements

- *OSHA is requiring that all private-sector employers with 100 or more employees to institute a mandatory COVID-19 vaccination policy.*
- *The ETS allows unvaccinated workers to be tested weekly in lieu of vaccination.*
- *The agency stipulates that employers are required to provide employees with paid time off for vaccination and recovery.*
- *State and local governments in 28 states with OSHA-approved State Plans must also adhere to the ETS.*

Today, the **Occupational Safety and Health Administration (OSHA)** issued an highly-anticipated **Emergency Temporary Standard (ETS)** for **COVID-19 vaccination and testing** ([rule](#); [fact sheet](#); [press release](#)) in the workplace. The ETS requires employees — who are employed by private-sector employers with 100 or more employees — to get vaccinated or test negative for the virus once per week. Under the ETS, private sector employers with 100 or more employees must develop, implement, and enforce a mandatory COVID-19 vaccination policy. In lieu of vaccination, OSHA’s rule stipulates that employees who choose not to get inoculated are subject to weekly testing and indoor masking requirements. OSHA has **published a series of [resources](#)** with respect to this ETS, including: [frequently asked questions](#); [guidance materials](#); and [reporting requirements](#).

- **What’s Next?** While the testing requirement for unvaccinated workers is slated to begin on January 4, 2022, employers must be in compliance with all other requirements — such as providing paid time off for employees to get vaccinated and masking for unvaccinated workers — by December 5, 2021. Employees falling under the ETS rules will need to have their final vaccination dose by January 4, 2022, according to the administration. Given some of the widespread opposition to new vaccine-related mandates, it is likely that the ETS could face legal challenges from certain business and GOP-led groups. In September, a group of GOP State Attorneys General penned a [letter](#) to the President stating they will seek “every available legal option” with respect to challenging the administration’s vaccine requirement policies. The Biden administration spelled out its legal authority within the ETS announcement,

citing OSHA's statutory authorities to provide workers with safe and healthy working conditions as its justification.

With respect to **state and local governments**, the agency requires that states with OSHA-approved [State Plans](#) adhere to any new ETS developed by OSHA. To this end:

- Of the 28 states and territories with OSHA-approved State Plans, 22 cover both public and private-sector employees: Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington, and Wyoming.
- The remaining six states and territories cover only state and local government employees: Connecticut, Illinois, Maine, New Jersey, New York, and the Virgin Islands.
- Unless state action or lawsuits invalidate the OSHA ETS, these 28 states and their local governments will be expected to adhere to the vaccine and testing ETS.

Key requirements for covered employers contained in the ETS include:

- **Developing a COVID-19 Vaccination Policy** — The standard requires covered employers to develop, implement, and enforce a written COVID-19 vaccination policy that requires the vaccination of all employees, except those: (1) for whom a vaccine is medically unsafe; (2) for whom medical necessity requires a delay in vaccination; or (3) who are legally entitled to a reasonable accommodation due to a conflicting disability or sincerely held religious beliefs, practices, or observances that conflict with the vaccination requirement.
- **Testing & Masking Requirements** — Employers must ensure that each worker who is not fully vaccinated is tested for COVID-19 at least weekly if the worker is in the workplace at least once a week, or within seven days before returning to the workplace if the employee is away from the setting for a week or longer. Under the ETS, this rule also requires unvaccinated employees to wear a face covering when indoors or when occupying a vehicle with another person for work purposes. Additionally, employers are not responsible for covering the costs of testing for unvaccinated employees, as OSHA emphasized that it is leaving the decision regarding who pays for testing to the employer. The agency does point out that employers may be required to cover testing under other laws, regulations, or collective bargaining agreements.
- **Paid Time Off** — Employers must provide paid time off for employees to get vaccinated and/or recover from any side effects. This should include up to four hours of paid time off to receive each primary vaccination dose, as well as “reasonable time and paid sick leave” in the event of any side effects, OSHA explains.
- **Documentation** — The ETS mandates that employers determine the vaccination status of each employee, obtain acceptable proof of vaccination status from vaccinated employees, and maintain records and a roster of each employee's vaccination status. Acceptable proof of vaccination includes: (1) the record of immunization from a health care provider or pharmacy; (2) a copy of the COVID-19 vaccination card; (3) a copy of immunization records from a public health, state, or tribal immunization information

system; or (4) a copy of any other documentation that contains vaccination information. Further, employers are subject to requirements for reporting and recordkeeping with respect to vaccine documentation, testing results, as well as work-related COVID-19 hospitalizations and fatalities.

- **Required Notice of Positive Test** — Employers must require employees to provide prompt notice when they test positive for COVID-19 or receive a COVID-19 diagnosis. Once noticed, employers must then remove the employee from the workplace, regardless of vaccination status. The employee is not permitted to return to the workplace until they meet the required criteria outlined in the employer’s policy.
- **Penalties** — This rule states that the standard penalty for a single violation is roughly \$14,000, and this figure could increase if there are multiple violations in a workplace. Employees will also be subject to criminal penalties for knowingly providing false information.