

## **COVID-19 Staff Vaccination Requirements Q&A**

### **Q. When does this take effect?**

A. The emergency regulation is effective January 14, 2022.

### **Q. Which facilities will this rule apply to?**

A. Any Medicare and Medicaid- certified provider and supplier types that are regulated under the Medicare health and safety standards known as Conditions of Participation (CoPs), Conditions for Coverage (CfCs), or Requirements. Indian Health Services also is subject to this rule.

### **Q. Which provider and supplier type does this apply to?**

A. Ambulatory Surgery Centers, Community Mental Health Centers, Comprehensive Outpatient Rehabilitation Facilities, Critical Access Hospitals, End-Stage Renal Disease Facilities, Home Health Agencies, Home Infusion Therapy Services, Hospices, Hospitals, Intermediate Care Facilities for Individuals with Intellectual Disabilities, Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services, Psychiatric Residential Treatment Facilities Programs for All-Inclusive Care for the Elderly Organizations (PACE), Rural Health Clinics/Federally Qualified Health Centers and Long Term Care facilities.

### **Q. Which staff are covered under this requirement?**

A. The vaccination requirement applies to eligible staff regardless of clinical responsibility or patient contact. This includes employees, licensed practitioners, students, trainees, and volunteers. It also includes individuals who provide care, treatment or other services for the facility and/or its patients under contract or other arrangements. It includes off-site employees including home health, home infusion therapy etc.

### **Q. Does this requirement apply to full time teleworkers?**

A. If an employee is 100 percent remote and does not have direct contact with patients and other staff, then the requirement does not apply.

### **Q. Are physicians with admitting privileges in a hospital covered under this requirement?**

A. Yes, a physician admitting and/or treating patients in-person within a facility subject to the CMS health and safety regulations and included as a part of this requirement must be vaccinated so that the facility is compliant.

### **Q. How quickly must staff be vaccinated in order for the facility to remain compliant with the regulation?**

A: The regulation requires health care providers to establish a process or policy to fulfill the staff vaccination requirements over two phases. For Phase 1, within 30 days after the regulation is published, staff at all health care facilities included within the regulation must have received, at a minimum, the first dose of a primary series or a single dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the facility and/or its patients. For Phase 2, within 60 days after the regulation is published, staff at all health care provider and supplier types included in the regulation must complete the primary vaccination series (except for those who have been granted exemptions from the COVID-19 vaccine or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by CDC).

### **Q. How does CMS define “fully vaccinated” for the purposes of this requirement?**

A. For purposes of this regulation, CMS currently considers staff fully vaccinated if it has been two weeks or more since they completed a primary vaccination series for COVID-19. However, staff who have who have completed the primary series for the vaccine received by the Phase 2 implementation date are considered to

have met these requirements, even if they have not yet completed the 14-day waiting period required for full vaccination. The completion of a primary vaccination series for COVID-19 is defined in the rule as the administration of a single-dose vaccine (such as the Janssen (Johnson & Johnson) COVID-19 Vaccine), or the administration of all required doses of a multi-dose vaccine (such as the Pfizer-BioNTech COVID-19 Vaccine (interchangeable with the licensed Comirnaty Vaccine) or the Moderna COVID-19 Vaccine). Additionally, staff who receive vaccines listed by the World Health Organization (WHO) for emergency use that are not approved or authorized by the FDA or as a part of a clinical trial are also considered to have completed the vaccination series in accordance with CDC guidelines.

**Q. Will there be different requirements for existing staff versus new staff?**

A. No. Staff at all health care facilities included within the regulation must have received, at a minimum, the first dose of a two-dose COVID-19 vaccine or a one-dose COVID-19 vaccine by the regulatory deadline, or prior to providing any care, treatment, or other services for the facility and/or its patients. After the deadline, new hires will need to be vaccinated prior to beginning work.

**Q: Does this regulation establish any new data reporting requirements?**

A: No, this regulation does not establish any new data reporting requirements. However, hospitals and Long-Term Care facilities (nursing homes) are expected to continue complying with their facility-specific data reporting requirements set forth in the emergency regulations issued by CMS in May 2020, August 2020, and May 2021, respectively. Additionally, facilities participating in the Inpatient, PPS-Exempt Cancer, Long Term Care Hospital, Inpatient Rehabilitation, and Inpatient Psychiatric Quality Reporting Programs must collect data on the new COVID-19 Vaccination Coverage among Health Care Professionals measure from October 1, 2021 to December 31, 2021 and quarterly thereafter.

**Q. Does this regulation include testing requirements?**

A. No, facilities may voluntarily institute testing with other infection prevention measures. For Long Term Care facilities, CMS still requires compliance with previous emergency regulations that have passed.

**Q. Are exemptions allowed?**

A. Yes, medical and religious exemptions are allowed. No other exemptions are allowed including for staff who previously had COVID-19 and have remaining antibodies.

**Q. How do facilities determine whether a religious exemption is valid?**

A. Review the Equal Employment Opportunity Commission's Compliance Manual on Religious Discrimination. The EEOC provides more information at: <https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws>.

**Q: What is the process for staff to seek a religious exemption?**

A: Facilities have the flexibility to establish their own processes that permit staff to request a religious exemption from the COVID-19 vaccination requirements. CMS requires facilities to ensure that requests for religious exemptions are documented and evaluated in accordance with applicable federal law and as a part of a facility's policies and procedures.

**Q: What is the process for staff to seek a medical exemption?**

A: Similar to religious exemptions, facilities have the flexibility to establish their own processes that permit staff to request a medical exemption from the COVID-19 vaccination requirements. Facilities must ensure that all documentation confirming recognized clinical contraindications to COVID-19 vaccinations for staff seeking a medical exemption are signed and dated by a licensed practitioner, who is not the individual requesting the

exemption and is acting within their respective scope of practice based on applicable state and local laws. This documentation must contain all information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications. Additionally, a statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID-19 vaccination requirements is also expected.

**Q. What are the requirements for employers when staff seek medical exemptions?**

A. Employers must ensure all documents which support staff requests for medical exemptions are signed and dated by a licensed practitioner, who is not the individual representing the exemption, and who is acting within their respective scope of practice. The employer must also have a process for tracking and securing documentation of the vaccination status of staff that must be temporarily delayed and employer must have contingency plans for staff who are not fully vaccinated.

**Q. Are employers at risk for requiring above the minimum requirements for exemptions?**

A. Employers have flexibility to establish their own processes for both religious and medical exemptions.

**Q. How does the federal vaccine mandate interact with HB 702?**

A. The federal regulation preempts any state law when in direct conflict, per CMS. However, in order to comply with both CMS and HB 702, is to inform employees that HB 702 allows employers to ask whether an employee is vaccinated but gives employees the right to refuse to answer. If an employee refuses to answer about vaccination status prior to December 5, the employer should remind the employee that beginning December 5, the employee must answer that question and confirm that they have received their first (or only) dose of the vaccine or have requested an exemption. If they have done neither by December 5, the employer may be obligated by federal regulation to terminate the employee to ensure the facility does not lose its CMS certification.

**Q: How will this new requirement be enforced on facilities?**

A: CMS works directly with the accrediting bodies with deeming authority such as State Survey Agencies to regularly review compliance with Medicare/Medicaid regulations across multiple health care settings. CMS expects state survey agencies to conduct onsite compliance reviews of these requirements in two ways:

- State survey agencies would assess all facilities for these requirements during the standard recertification survey.
- State survey agencies would assess vaccination status of staff on all complaint surveys.

While onsite, surveyors will review the facility's COVID-19 vaccination policies and procedures, the number of resident and staff COVID-19 cases over the last 4 weeks, and a list of all staff and their vaccination status. This information, in addition to interviews and observations, will be used to determine the compliance of the provider or supplier with these requirements.

Additionally, Accrediting Organizations will be required to update their survey processes to assess facilities they accredit for compliance with vaccination regulations.

Montana's State Survey Bureau has not yet released information on implementation; however, it will be required to follow the above criteria.

**Q: How do the penalties work/are providers immediately denied payment?**

A: Medicare and Medicaid-certified facilities are expected to comply with all regulatory requirements, and CMS

has a variety of established enforcement remedies. For nursing homes, home health agencies, and hospice (beginning in 2022), this includes civil monetary penalties, denial of payment, and even termination from the Medicare and Medicaid program as a final measure. The remedy for non-compliance among hospitals and certain other acute and continuing care providers is termination; however, CMS's goal is to bring health care facilities into compliance. Termination would generally occur only after providing a facility with an opportunity to make corrections and come into compliance.

**Q. What opportunities are available to return to compliance for hospitals and other acute and continuing care providers?**

A. CMS surveyors will sight severity of deficiency in three levels: "Immediate Jeopardy", "Condition", and "Standard." Immediate Jeopardy citations indicate a "serious scope of non-compliance, failure of the provider to address deficiencies, and close interaction with patients of unvaccinated staff. Termination of the provider type will occur within 23-days following the citation if not immediately addressed." Condition level citations indicate substantial non-compliance that needs to be addressed to avoid termination. Standard level citations indicate minor non-compliance where (with respect to this rule) almost all staff are vaccinated, the provider has a reasonable policy in place to educate staff on the vaccinations, and the provider has procedures for tracking and monitoring vaccination rates. CMS generally allows for continued operation subject to the facility's agreement to a CMS-approved plan of correction.

**Q. Are health care employers responsible for the cost of testing as it relates to accommodations for staff with religious or medical exemptions?**

A. At this time, it is unclear whether an employer is required to pay for the cost of testing. The CMS IFR does not directly address the issue, but it does state that testing is voluntary. Under the OSHA Emergency Temporary Standards, OSHA states that employers are not required to cover the cost of testing; however, employer payment may be required based on other laws. Montana laws do not directly address employer required payment for COVID testing; however, other Montana laws do require employers to pay for the cost of testing. For example, MCA § 39-2-207, a statute involving drug and alcohol testing, states testing must be at the employer's expense.

**Q. If there are conflicts between OSHA and CMS requirements, which take priority over health care facilities?**

A. Although the CMS Interim Final Rule and OSHA Emergency Temporary Standard are different, the CMS IFR is meant to be complimentary to the OSHA ETS. A providers and suppliers may be covered by both the OSHA ETS and the IFR. OSHA's ETS was directed to ensure safe and healthy working conditions. The ETS primarily required employers to develop a plan to protect employees from COVID-19 hazards in the workplace and implement requirements to reduce transmission. OSHA's ETS did not mandate employee vaccination. As such, the IFR is considered complementary to the ETS rule in its vaccine mandate. CMS and OSHA worked to ensure that the requirements were not overly duplicative; however, if a Medicare or Medicaid certified provider or supplier falls under the CMS IFR, then it should look to those requirements first.

**Q. How must we handle vendors that deliver and/or work on-site? How do we evaluate patient contact? What are the criteria for contained spaces/sites?**

A. When determining whether to require COVID-19 vaccination of an individual who does not fall into the categories established by the IFC, facilities should consider frequency of presence, services provided, proximity to patients and staff. One example the IFC states is a plumber who makes an emergency repair in an empty bathroom wearing a mask the whole time would not be a good candidate for vaccination. If on the other hand, there is a construction crew working in the building and they share bathrooms, break room etc., and they are using the same common areas as staff, patients and visitor would be subject to these requirements. Providers and suppliers are not required to ensure vaccination of individuals who provide ad hoc non-health care services

such as an annual elevator inspection. In addition, services performed exclusively off-site like accounting services are not required to be vaccinated. Other individuals that do not fall under the mandate are delivery or repair personnel that enter the building for a limited purpose and for a limited amount of time. If feasible, facilities may choose to extend vaccine requirements to these individuals but are not required to.

**Q. What documentation must a health care provider secure and/or maintain for non-employed individuals?**

A. Employers must maintain a copy of the COVID-19 vaccination record card, documentation of vaccination from a health care provider or state immunization information system record. The CDC provides a staff vaccination tracking tool at <https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html>. Employers must ensure confidentiality in vaccine documentation.

**Q. How does the rule apply to traveling staff? Will the agency or the health care facility need to validate?**

A. The policies and procedures implemented by a facility will apply to traveling staff. Health care facilities will be required to track and document this information.

**Q. Are off-site and separate and distinct buildings that do not provide health services subject to CMS rules if they are owned by a hospital?**

A. No, the staff vaccination requirements apply to CMS certified providers (see above FAQ on qualifying facilities). The requirement only applies to staff who are providing care, treatment, or other services for the facility and or/its patients. However, OSHA requirements may pertain to facilities with over 100 employees.

**Q. Will hospital board members be required to be vaccinated?**

A. Yes, the IFC is not limited to individuals who are present in the facility or physical site of patient care based on frequency. Policies and procedures must include all staff including administrative staff, facility leadership, volunteers or other fiduciary board members. However, if the Board member is not around other members, patients, or is not present in the facility i.e. is 100% remote then they need not be subject to vaccination requirements.

**Q. Can an employee that refuses to comply with the hospital's vaccine policy receive unemployment benefits if they are terminated for non-compliance or otherwise voluntarily quit?**

A: Under current rules, an employee or former employee would not be eligible for unemployment benefits if they are terminated for failing to comply with employer policies, whether they are terminated or voluntarily quit.