

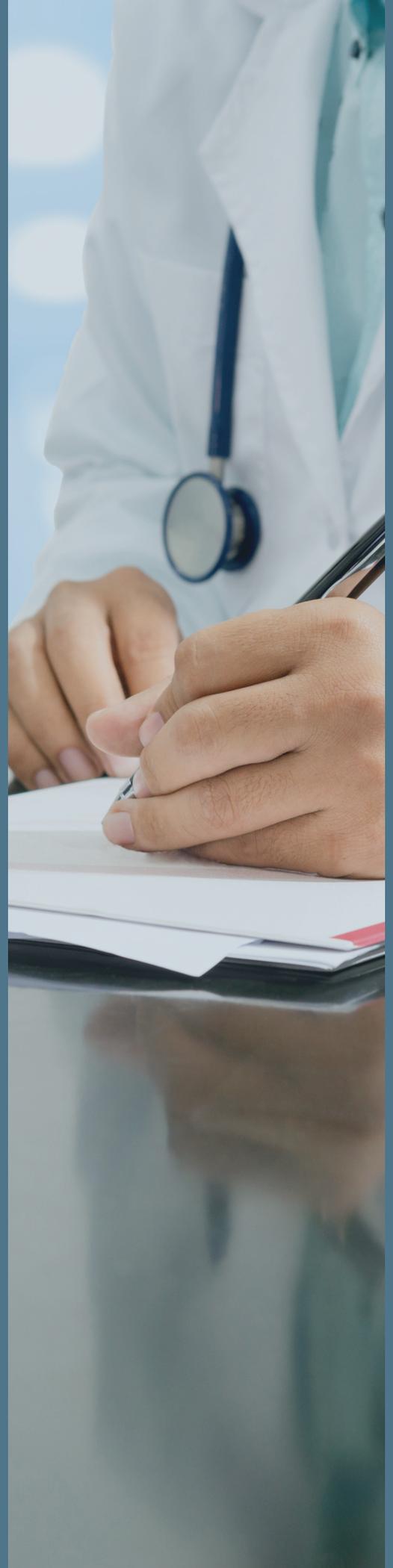
COVID-19 HEALTHCARE STAFF VACCINATION REQUIREMENT TOOLKIT

Resources to support
compliance with CMS
Interim Final Rule issued
November 4, 2021



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Background

The Centers for Medicare and Medicaid Services (“CMS”) issued an Interim Final Rule (“IFR”) requiring all CMS providers to fully vaccinate staff and other covered individuals by January 4, 2022. The IFR offers guidance to all healthcare facilities that qualify as CMS providers pertaining to the mandatory vaccination requirement. This requirement is pursuant to the Public Health Emergency declaration issued by the United States government on January 31, 2021, under the Public Health and Services Act. Both providers and suppliers are subject to CMS health and safety standards. If a facility participates in CMS’s standards of participation known as Conditions of Participation, Conditions of Coverage, or Requirements, facilities must have a policy in place for mandatory staff vaccination against COVID-19.

This toolkit includes: (1) a mandatory vaccination policy template; (2) a requested accommodation form for either religious or medical purposes; (3) a memo addressing the CMS policy and its interaction with other laws; and (4) common FAQs. The policy template includes information relating to the timeline for vaccination, with whom the vaccination mandate affects, accommodation requests, and an overview of reporting requirements. The CMS IFR does allow providers to use already adopted policies for other similar requirements. It also suggests appointing at least one Infection Preventionist to document vaccination status of all employees and covered individuals. Alternatively, the director of nursing, medical director, or other appointed administrative staff may be appointed to track employee vaccination records. The template policy also includes suggested timelines for reviewing accommodation applications, responding to applications, and a requirement for vaccination if accommodation application is denied. This is not specifically noted in the IFR; however, it may be helpful in carrying out compliance with the IFR.

Additionally, valid accommodation requests are listed on the accommodation template and apply only to religious or medical exemptions. Individuals with sincerely held religious beliefs and/or individuals who cannot be vaccinated due to valid medical conditions must be offered accommodations. Again, CMS facilities may use already existing policies and procedures to determine these exemptions.

This packet also serves to answer questions regarding the direct conflicts between Montana’s state law, House Bill 702, and the federal implementation of the vaccine requirement. The included memo will contain more information about the policy and its relationship with other laws. In addition, the FAQs included in this packet will address numerous questions regarding CMS mandates and other impacts on providers.

If you have any questions, please contact us.

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MEMORANDUM

TO: Rich Rasmussen, MHA
FROM: Daniel J. Auerbach
DATE: November 5, 2021
RE: CMS Vaccine Mandate

CMS issued an Interim Final Rule (IFR) with comment period to create regulations in furtherance of President Biden's September 2021 proclamation concerning a vaccine mandate for all health care workers. The IFR states that on or before January 4, 2022, all health care employees must either (1) be fully vaccinated against COVID-19, as defined by the FDA and/or CDC; or (2) have been exempted from the vaccine requirement based on either an ADA disability (medical condition) exemption or due to a "sincerely held" religious belief, practice or observance. Additional information regarding accommodations for both disabilities and religious beliefs is provided by the EEOC: <https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws>.

The IFR applies to essentially all health care entities that receive Medicare or Medicaid funding, including IHS facilities based on the application of the Conditions of Participation. The IFR does not apply to physician's offices, assisted living facilities, or group homes, all of which are not subject to CMS's regulatory authority.

All affected health care entities must develop a policy ensuring all eligible staff have received either the first dose of the Moderna or Pfizer vaccine or the Johnson & Johnson vaccine by December 5, 2021, prior to providing any care, treatment, or other services. Employees that do not request an exemption must be fully vaccinated by the January 4, 2022 deadline. Failure to comply with the IFR could result in termination of a facility's participation in CMS reimbursement program. The implementation of such a policy will potentially result in concerns for violating Mont. Code Ann. § 49-2-312, the codification of HB 702 as employers must receive an employee's vaccination status to comply with the requirements of the IFR.

There are currently at least two pending lawsuits in Montana that are seeking to challenge the constitutionality of HB 702. While the case pending in US District Court, Missoula Division appears to be progressing fairly quickly, it is unclear whether the Court will be in a

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position to decide the substantive issues prior to the December 5, 2021 deadline to commence requiring vaccines.

Given the uncertainty of the potentially competing state law and federal regulations, facilities are encouraged to take the following steps in the immediate future:

- Conduct a review of facility policies addressing vaccine requirements.
- Review accommodation protocols for those employees that are currently unvaccinated for any reason or for whom vaccination status has not been confirmed.
- Develop a draft policy to be implemented prior to the December 5, 2021 deadline for initial vaccination shots.
- Ensure supply availability for vaccines to be offered on-site for employees.
- Prepare forms for employees to complete prior to December 5, 2021 confirming (1) vaccination status with proof of vaccination; and (2) exemption requests.

COVID-19 Staff Vaccination Requirements FAQs

Q. When does this take effect?

A. The emergency regulation is effective November 5, 2021.

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 is 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.

November 4, 2021

CMS Issues Interim Final Rule Requiring Mandatory COVID-19 Vaccinations for Workers in Hospitals and Most Health Care Settings

See details on applicability, enforcement, exemptions and other key policies

The Centers for Medicare & Medicaid Services (CMS) today issued an [interim final rule](#) requiring COVID-19 vaccinations for workers in most health care settings, including hospitals and health systems, that participate in the Medicare and Medicaid programs. The rule is effective as of Nov. 5. Under the regulation, all eligible workers must be fully vaccinated by Jan. 4, 2022.

Also this morning, the Occupational Safety and Health Administration (OSHA) issued an [emergency temporary standard](#) requiring all employees at private businesses with 100 or more workers to be vaccinated by Jan. 4 or get tested for COVID-19 weekly.

In addition to preempting state and local law, CMS asserts that its rule takes priority above other federal vaccination requirements.

AHA Take: In a [statement shared with the media](#) today, AHA President and CEO Rick Pollack said, “Today’s vaccine mandate regulations set clear expectations, and streamline and simplify compliance requirements for health care providers. Importantly, they clarify that hospitals will need to comply with only the CMS rule, eliminating unnecessary complexity in implementing vaccine mandates. Additionally, we welcome that the CMS regulation provides time to come into compliance, offers guidance on medical and religious exemptions, clarifies interactions with state and local laws, and provides a level playing field across healthcare facilities. AHA has been supportive of hospitals that call for mandated vaccination of health care workers in order to better protect patients and

Key Takeaways

In the interim final rule, CMS establishes a Condition of Participation that:

- Requires workers in health care settings to be fully vaccinated by Jan. 4.
- Applies to all employees, including volunteers and students, in health care settings regardless of whether their positions are clinical or non-clinical.
- Requires processes to be established for medical and religious exemptions.
- Takes priority over other federal vaccine requirements in an effort to eliminate the unnecessary confusion and contradiction of multiple standards.
- Preempts state law that would otherwise prevent a facility from complying with this rule.

the communities we serve. We will further review today's regulations and assist our members in coming into compliance."

While CMS' interim final rule provides many important details about this new requirement, the AHA expects the agency soon will supplement this rule with interpretive guidance aimed at providing more information on how it will assess compliance. In addition, CMS provided a number of [frequently asked questions](#) on the rule.

Highlights of CMS' interim final rule follow. The AHA will provide additional details in a future communication on the OSHA ETS for organizations that may be subject to those regulations.

HIGHLIGHTS OF CMS' INTERIM FINAL RULE

Applicability: The interim final rule establishes a Condition of Participation that applies to most health care settings, including hospitals, critical access hospitals, ambulatory surgery centers, comprehensive outpatient rehabilitation facilities, home health agencies, rural health clinics, federally qualified health centers and long term care facilities. The vaccination requirement applies to all eligible staff working at a facility that participates in the Medicare and Medicaid programs, regardless of clinical responsibility or patient care, including staff who work in offsite locations, such as homes, clinics or administrative offices. The requirement does not apply to individuals who provide services 100% remotely and have no direct contact with patients and other staff.

Vaccination Process and Requirements: The regulation requires health care providers to establish a process or policy to ensure staff, except for those individuals who are granted an exemption, are fully vaccinated over two phases:

- Phase 1: Within 30 days of the rule's publication, **or by Dec 5**, staff at all health care facilities where the regulation applies must have received their first dose of a 2-shot series (Moderna or Pfizer, currently) or a single dose of a 1-shot vaccine (Johnson and Johnson, currently). **Staff must complete this step before they can provide any care, treatment or other services for the facility and/or its patients.**
- Phase 2: Within 60 days of the rule's publication, **or by Jan 4**, all staff must complete the primary vaccination series.

Under the vaccination requirement, staff at health care facilities **must be fully vaccinated**. Fully vaccinated is defined by CMS as two weeks or more since the individual completed a primary vaccination series for COVID-19. Staff who complete their primary vaccination series by the Phase 2 implementation date will be considered fully vaccinated even if they have yet to complete the two-week post-series waiting period. In addition to the three vaccines currently approved in the U.S. (Pfizer, Moderna and Johnson and Johnson), the agency will recognize as fully vaccinated those staff who received vaccines listed by the World Health Organization for emergency use, but

not yet approved by the Food and Drug Administration. The vaccination requirement **applies only to the primary series. It does NOT include booster shots.**

In a situation where state law prohibits the implementation of a vaccine mandate, CMS clearly states **the federal vaccination requirement pre-empts any state law that is contrary to the federal requirement.**

Vaccination Exemptions: The rule requires health care facilities to allow for exemptions to staff with recognized medical conditions or religious beliefs, observances or practices. Facilities must establish a process for staff to request either exemption and ensure that the requests are appropriately documented and evaluated. In instances of medical exemption requests, providers must ensure that all documentation confirming recognized clinical contraindications are signed and dated by a licensed practitioner other than the individual requesting the exemption. **Staff who previously had COVID-19 are NOT exempt from the vaccination requirements.**

In instances where a staff member meets the requirements for an exemption and is therefore unvaccinated, the facility must develop a process for implementing additional precautions to mitigate transmission and spread of COVID-19. This could include reassigning the non-vaccinated staff to non-patient care settings. Further, when granting an exemption or accommodation, providers must take steps to minimize the risk of COVID-19 transmission to at-risk individuals.

While the regulation does not require testing for unvaccinated staff, the agency indicates it is considering such a requirement in the future. For now, providers may voluntarily institute testing alongside other infection prevention measures to mitigate any risk of COVID-19 transmission.

Enforcement: CMS will expect state survey agencies to conduct onsite compliance reviews of the vaccination requirements in two ways:

- Standard recertification surveys
- Assessment of vaccination status of staff on all complaint surveys

In instances where a surveyor is onsite at a facility, they will review:

- The provider's COVID-19 vaccination policies and procedures;
- The number of resident and staff COVID-19 cases over the previous four weeks; and
- A list of all staff and their vaccination status.

In addition to the state survey agencies, CMS will require all Accrediting Organizations to update their survey processes to assess compliance with the new vaccination requirements.

If a provider is deemed to be noncompliant with the requirement, CMS has a number of enforcement tools at its disposal. For nursing homes, home health agencies and hospice, the agency can enforce civil monetary penalties, denial of payment and termination from the Medicare and Medicaid program as a last resort. For hospitals and health systems, noncompliance with the requirement can lead to termination; **however, the agency expresses its intent to work with noncompliant health care facilities to bring them into compliance.**

CMS Vaccination Requirement’s Interaction with OSHA Requirements: CMS asserts its rule takes priority above other federal vaccination requirements. In instances where a facility is not regulated by the Conditions of Participation because of nonparticipation in the Medicare and Medicaid programs, then the Executive Order on Ensuring Adequate COVID Safety Protocols for Federal Contractors or the OSHA COVID-19 Vaccination and Testing Emergency Temporary Standard (ETS), also issued today, apply. It should be noted that OSHA differently asserts that its new ETS does not apply in settings where employees provide health care services or health care support services subject to the requirements of the [OSHA Healthcare ETS](#) (29 CFR 1910.502), or in workplaces covered under the “Safer Federal Workforce Task Force COVID-19 Workplace Safety: Guidance for Federal Contractors and Subcontractors.” This could leave some organizations worried about whether they are subject to more than one rule, so AHA is seeking clarification from the agencies.

NEXT STEPS

- Please share this document with your organization’s leadership, quality and patient safety team, and compliance team.
- Ensure that your organization has a process in place to implement this requirement, including a process by which to grant medical and religious exemptions.
- Even though it is effective immediately, formal comments on the emergency regulation can be submitted by Jan. 4.

If you have further questions, please contact Akin Demehin, director of policy, at ademehin@aha.org, or Mark Howell, senior associate director of policy, at mhowell@aha.org.

Compliance Checklist

Plan of Compliance with CMS Vaccine Mandate

Pursuant to CMS Interim Final Rule on Omnibus COVID-19 Health Care Staff Vaccination under modified 42 CFR 416, 418, 441, 460,482-486, 491,494, all healthcare facilities must establish a plan to comply with mandatory vaccination requirements. Toward that end, the facility has adopted this plan and the accompanying documents to include:

_____ Company policy regarding vaccines and accommodations

_____ Form for employees to confirm vaccination status and any requests for exemptions

_____ Attestation form for contractors and vendors

_____ Process or plan for tracking and documenting staff vaccinations

XX Coordinator Signature

COVID-19 Vaccination Policy (Template)

[Download](#) and customize as needed.

[INSERT FACILITY NAME] COVID-19 Vaccination Policy

Effective **[INSERT DATE]**

This policy is being implemented by **[INSERT FACILITY NAME]** (“Employer”) and is effective and applicable to all employees as of the date listed above.

In accordance with the CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule (42 CFR 416, 418,441,460,482,483,484,485,486,491,494) Employer is issuing the following employee policy.

This is done to protect the health of employees, their families, our clients and members, and the community at large. As a CMS qualifying health care provider, Employer must adhere to requirements including the requirement that all employees be fully vaccinated or granted a reasonable accommodation due to disability (medical condition) or sincerely held religious belief.

- **[Insert Designee]** is designated COVID-19 infection preventionist coordinator (“Coordinator”).
- On or before January 4, 2022, all employees including students, trainees, and volunteers must either: (1) be fully vaccinated against COVID 19 as defined by the FDA or CDC; or (2) have submitted a written request for accommodation to the Coordinator.
- Under current CMS guidelines, CMS considers staff fully vaccinated two weeks or more since they have completed a primary COVID-19 vaccination series. A primary vaccination series means either: (1) a single dose Johnson & Johnson vaccine; or (2) administration of two required doses for Pfizer or Moderna. The regulation is broken into two phases: (1) Phase 1 which requires staff to receive their first dose 30 days after the regulation takes effect on November 5,2021; and (2) Phase 2 which requires staff to complete their vaccination series 60 days after the regulation takes effect on November 5,2021. Staff who have completed Phase 2 requirements but have not yet completed the 14-day waiting period for the vaccine are still considered to have met these requirements.
- Employees hired after January 4, 2022, will be required to either: (1) be fully vaccinated according to the FDA/CDC definition at their hire date; or (2) have obtained a valid accommodation prior to their start date.

- Individuals are considered fully vaccinated two weeks following their last required dose. Employees who have completed their primary vaccination series by the Phase 2 implementation date are considered to have met the requirements. Employees should arrange their vaccination schedule, so they will comply with this policy.
- Employees shall document their vaccination status by submitting a copy of their current COVID-19 Vaccination Record Card (CDC Form MLS-319813-r) or by providing other documentation from a vaccine or healthcare provider to the Coordinator.
- Employees may request an accommodation from the vaccine requirement by submitting a request for accommodation to the Coordinator. Accommodations may be granted for either disability (medical condition) or a sincerely held religious belief. Per the CMS, [Insert Facility] must make contingency plans while the request is pending. This includes not being able to give care or provide treatment until the primary series of vaccination is complete or request is approved.
 - All accommodation requests must be submitted in writing and must include all supporting documentation. Accommodation requests shall be made available upon a request to the Coordinator. All accommodation requests must be submitted on or before December 5, 2021.
 - The Coordinator shall, within 14 days, review each request and respond to the accommodation request in writing as to whether the accommodation request is approved or denied.
 - If an accommodation request is denied, the employee must receive a first dose of the COVID 19 vaccine within 14 days of receiving the denial letter and, if applicable, must receive the second dose of COVID 19 vaccine within 40 days of receiving the denial letter. Individuals that have not received their Phase 2 vaccination by January 4, 2022, will not be able to provide care or other services until completing their primary series vaccination.
 - The Coordinator will make each accommodation decision based upon the request, any supporting documents or information provided by the applicant, and any applicable guidance from federal entities. The Coordinator may request additional information. The Coordinator may grant an accommodation if the request and supporting documents tend to show the applicant: (1) suffers from a disability (medical condition) for which all COVID 19 vaccines are contraindicated according to guidance; or (2) has a sincerely held religious belief.
 - Accommodation will be granted in all cases where the criteria for compliance is met; however, Employer may deny an accommodation request where the accommodation would cause the Employer undue hardship or where the accommodation may pose a threat to the health and safety of others.
 - Accommodation may include the requirement that the accommodated employee wear a face mask, socially distance in all work-related circumstances,

perform work that is significantly different from an employee's normal tasks, or other measures.

- All employees that fail to show proof of being fully vaccinated or be granted an accommodation as provided herein may have their employment terminated.

If necessary, this policy may be changed or modified at any time as circumstances warrant.

Name

Print

Have you received the COVID-19 vaccine?

Yes No

(Both shots from Pfizer/Moderna. One shot from Johnson & Johnson)

Signature

** If you are fully vaccinated, you must provide documentation showing that you are fully vaccinated ** All medical records, including vaccine documentation, must be kept confidential and stored separately from an employer's personnel files, pursuant to ADA and the Rehabilitation Act. CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule

COVID-19 Employee Vaccination Verification and Accommodation Request Form

[Download](#) and customize as needed.

COVID 19 VACCINE REQUIREMENT VERIFICATION AND ACCOMMODATION REQUEST	
<p>NAME: _____</p> <p>DATE SUBMITTED: _____</p> <p>Check all that apply:</p> <p><input type="checkbox"/> CURRENTLY VACCINATED: Please check the box if you have been vaccinated for COVID-19. Documentation of your vaccination is required and must be attached to this verification accommodation request.</p> <p><input type="checkbox"/> RELIGIOUS ACCOMMODATION: Please check the box if you wish to exercise your right to a religious accommodation. [optional-facilities may require a written statement explaining religious exemption. Keep/ Delete based on facility approach]</p> <p>The CMS Vaccination Rule permits an exception to the requirement for religious beliefs, observances, or practices (established under Title VII of the Civil Rights Act of 1964). By attesting to this exemption, you acknowledge that your personal and deeply held religious beliefs are in conflict with the requirements of 42 CFR 416, 418, 441, 460,482-486, 491,494.</p> <p>OPTIONAL</p> <p>Please describe your sincerely held religious belief and the reason you cannot receive any of the available COVID-19 vaccinations pursuant to 42 CFR 416, 418, 441, 460,482-486, 491,494. Please provide a letter from your religious or spiritual advisor, if applicable.</p> <p>_____</p>	<p><input type="checkbox"/> MEDICAL ACCOMMODATION: Please check the box if you wish to exercise your right to a medical exemption.</p> <p>Please describe your disability (medical condition) and the reason you cannot receive any of the available COVID 19 vaccinations pursuant to 42 CFR 416, 418, 441, 460,482-486, 491,494. Please provide a letter from your medical provider containing: (1) signature and date of a practitioner acting within their scope of practice that is not the person seeking the exemption; (2) all information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive; (3) recognized clinical reasons for the contraindications; and (4) a statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID-19 vaccination requirements.</p> <p>_____</p> <p>I verify that the information I am submitting in support of my request for an accommodation is complete and accurate to the best of my knowledge, and I understand that any intentional misrepresentation contained in this request may result in disciplinary action. I also understand that my request for an accommodation may not be granted if it is not reasonable, if it poses a direct threat to the health and/or safety of others in the workplace and/or to me, or if it creates an undue hardship on the facility.</p> <p>Signature: _____</p> <p>Date: _____</p> <p>Print Name: _____</p>

COVID-19 Vendor (Company) Vaccination Status Attestation Form

[Download](#) and customize as needed.

Vendor / Contractor Vaccination Status Attestation

Pursuant to 42 CFR 416, 418, 441, 460,482-486, 491,494, any employees of [Vendor Company], will either be vaccinated or their exempt status will be communicated. Any unvaccinated employee that provides services in the facility will comply with the facility's policies regarding Personal Protective Equipment. By signing below, I hereby affirm that [Vendor Company] has requested and received all documentation necessary to confirm the vaccination or exemption of all employees that may be providing services at the facility.

NAME: _____

TITLE: _____

DATE SUBMITTED: _____

Name of Employee	Vaccinated?	Exemption?

COVID-19 Vendor (Individual) Vaccination Status Attestation Form

[Download](#) and customize as needed.

Individual Vendors/ Contractors Vaccination Status Attestation

Pursuant to 42 CFR 416, 418, 441, 460,482-486, 491,494, any individual that performs their duties at any site of care, or has the potential to have contact with anyone at the site of care, including staff or patients, must be fully vaccinated to reduce the risks of transmission of SARS-CoV-2 and spread of COVID-19. This includes any ad hoc non-health care service persons that frequently provide services, visit the facility, and are around staff and/or patients. If an individual frequently uses shared facilities, they are subject to the mandatory vaccination requirement.

NAME: _____

DATE SUBMITTED: _____

Check all that apply:

Fully Vaccinated (Please provide proof of vaccination)

COVID 19 VACCINE REQUIREMENT ACCOMMODATION REQUEST

Disability (Medical Condition) Accommodation

Pursuant to 42 CFR 416, 418, 441, 460,482-486, 491,494, please provide a letter from your medical provider containing: (1) signature and date of a practitioner acting within their scope of practice that is not the person seeking the exemption; (2) all information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive; (3) recognized clinical reasons for the contraindications; and (4) a statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID-19 vaccination requirements. Please attach to this form.

Religious Accommodation

Pursuant to 42 CFR 416, 418, 441, 460,482-486, 491,494, do you have a sincerely held religious belief that prevents you from receiving a COVID-19 vaccination?

Yes

No

I verify that the information I am submitting in support of my request for an accommodation is complete and accurate to the best of my knowledge, and I understand that any intentional misrepresentation contained in this request may result in disciplinary action.

I also understand that my request for an accommodation may not be granted if it is not reasonable, if it poses a direct threat to the health and/or safety of others in the workplace and/or to me, or if it creates an undue hardship on the facility.

Signature: _____

Date: _____

Print Name: _____

COVID-19 Staff Vaccination Requirements FAQs

[Download](#) and customize as needed.

COVID-19 Staff Vaccination Requirements Q&A

Q. When does this take effect?

A. The emergency regulation is effective November 5, 2021.

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).

PowerPoint Presentation Deck

Download and customize as needed.

The image displays a grid of 23 PowerPoint slides, numbered 1 through 23, each with a navigation icon (back, forward, search, etc.) and a star icon. The slides are organized as follows:

- Slide 1:** Federal COVID-19 Vaccine Requirement for Health Care Staff
- Slide 2:** Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule
- Slide 3:** Overview
- Slide 4:** Eligibility
- Slide 5:** Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule
- Slide 6:** Which organizations must comply?
- Slide 7:** Who must be vaccinated?
- Slide 8:** Requirements
- Slide 9:** Requirements for Facilities
- Slide 10:** How do exemptions work?
- Slide 11:** How do accommodations work?
- Slide 12:** Enforcement
- Slide 13:** Enforcement
- Slide 14:** Interactions with other regulations, state law (HB 702)
- Slide 15:** Conflict with State Law: HB 702
- Slide 16:** Potential results of noncompliance
- Slide 17:** Medicare & Medicaid in Montana
- Slide 18:** Key Dates
- Slide 19:** Key Dates (Timeline from Dec 6, 2021 to Jan 6, 2022)
- Slide 20:** Recommended Actions
- Slide 21:** Action Items
- Slide 22:** Action Items: Sample Templates
- Slide 23:** (Blank slide with MHA logo)

Sample Language

Customize as needed for staff communications.

NEW FEDERAL COVID-19 VACCINE REQUIREMENT:

Vaccine Verification and Accommodations Request Form due 12/5

The Centers for Medicare and Medicaid Services (“CMS”) issued an Interim Final Rule (“IFR”) requiring all CMS providers to fully vaccinate staff and other covered individuals by January 4, 2022. As a facility providing care to Medicare and Medicaid patients, our organization is required to comply. According to CMS, this federal regulation preempts any state or local law (such as HB 702 passed by the Montana Legislature earlier this year).

The requirement applies to all staff, volunteers (including board members) and students who set foot inside our facilities. It also applies to many contractors and some other service providers who work in a healthcare provider site.

Exemptions are allowed for:

- Recognized medical conditions for which vaccines are contraindicated; and
- Religious beliefs, observances or practices.

In order to remain in compliance, all staff are required to complete and return the COVID-19 Employee Vaccination Verification and Accommodation Request Form to [CONTACT/DEPT] no later than December 6, 2021. This form will document one of the following for each staff member:

- Received first of two-shot vaccine series (Moderna or Pfizer) by 12/5/21; or
- Received the one-shot vaccine series (Johnson & Johnson) by 12/5/21; or
- Requested accommodations due to medical reasons; or
- Requested accommodations due to sincerely held religious beliefs.

Staff who require a second shot to complete their vaccination series must provide proof of their second shot no later than January 4, 2022.

For more information, please review COVID-19 Staff Vaccination Requirement FAQs. For questions or assistance, please reach out to your supervisor or [HR contact].

Please complete and return your COVID-19 Employee Vaccination Verification and Accommodation Request Form to [CONTACT/DEPT] no later than December 5, 2021.

Other Communication Considerations

- Promote the dates/times of your employee vaccination clinics, if available
- Promote other sites administering the COVID-19 vaccine
- Offer an employee forum in which you provide an overview of the new rule and its implications for your organization
 - Include a vaccination station for employees
 - Include/designate an HR staff member to provide forms and answer questions
- Hold a leadership meeting with supervisors to provide an overview of the new rule and its implications for your organization
 - Distribute talk sheet for supervisors
 - Distribute FAQs
 - Distribute flyers for employee areas
 - Include Vaccine Verification and Accommodations Request form

Flyer

[Download](#) and customize as needed.

FEDERAL COVID-19 VACCINE REQUIREMENT

Forms Due 12/5/21

All staff must complete and return the COVID-19 Vaccine Verification and Accommodation Request Form to [CONTACT/DEPT] no later than **December 5, 2021**.

For more information, including FAQs and forms, please contact [CONTACT] at [PHONE/EXT] or [Email].

YOUR LOGO HERE

