

CMS Vaccine Mandates: Compliance and Impact on Medicare Certified Healthcare Providers

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Over 30 years experience teaching and assisting hospitals and other healthcare facilities in understanding applicable Federal and State laws, rules, regulations and interpretative guidelines.

Previous experiences include:

- Director of Integrity & Compliance, Privacy Official at Mercy Medical Center, Des Moines
- Director of Regulatory Compliance, UnityPoint Health, West Des Moines
- Twenty years with Iowa Department of Inspections and Appeals

Learning Objectives

- Describe the new requirements
- Explain which individuals within organization the mandate applies to
- Describe reasonable accommodation process
- Explain consequences of non-compliance

Background

Regulations

- Published as interim final rule on November 4, 2021
 - CMS felt necessary to ensure safety and protection for anyone seeking healthcare and to protect health and safety of residents, clients, patients and staff
- Formal comments will be accepted for 60 days post publication.
- Comment period closed January 4, 2022
- Implementation was delayed pending various lawsuits
- First implementation date is February 14, 2022 based upon lawsuit dismissal

Who do the Requirements Apply
To?

Eligibility—Who is Included?

Requirements apply to facilities regulated under any Medicare Conditions of Participation

This includes:

- Hospitals
- Critical Access Hospitals
- Home Health Agencies
- Home Infusion Suppliers
- Hospices
- Rural Health Clinics
- Long Term Care Facilities
- End-State Renal Disease Facilities
- Rehabilitation Agencies, Community Mental Health Centers, CORF, ICF/ID, PACE and Psychiatric Residential Treatment Facilities

Eligibility—Who is excluded?

The following provider and supplier types **are not** included in this regulation:

- Religious Nonmedical Health Care Institutions
- Organ Procurement Organizations
- Portable X-Ray Supplies

Additionally the regulations **do not** apply to the following:

- Assisted Living Facilities (unless employees also work in long term care facility)
- Group Homes
- Home and Community based Services
- Physician Offices (unless provider based)

Key Fact to Remember: Only applies to providers and suppliers regulated under CMS COP (federal requirements).

Will discuss specific individuals required to be vaccinated later in presentation

CMS Definitions

Booster

- Per CDC, refers to a dose of vaccine administered when the initial sufficient immune response to the primary vaccination series is likely to have waned over time.

Clinical Contraindication

- Refers to conditions or risks that precludes the administration of a treatment or intervention.
- With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, facilities should refer to the CDC informational document, *Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States*, accessed at <http://.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>.
- For COVID-19 vaccines, according to the CDC, a vaccine is clinically contraindicated if an individual has a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the COVID-19 vaccine or an immediate (within 4 hours of exposure) allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine.

Fully Vaccinated

- Refers to staff who are two weeks or more from completion of their primary vaccination series for COVID-19.

Good Faith Effort

- Refers to a provider that has taken aggressive steps toward achieving compliance with staff vaccination requirement **and/or** the provider has no or has limited access to vaccine, and has documented attempts to access to the vaccine.

Primary Vaccination Series

- Refers to staff who have received a single-dose vaccine or all required doses of a multi-dose vaccine for COVID-19.

Staff

- Refers to individuals who provide any care, treatment, or other services for the hospital and/or its patients, including employees; licensed practitioners; adult students, trainees, and volunteers; and individuals who provide care, treatment, or other services for the hospital and/or its patients, under contract or by other arrangement. This also includes individuals under contract or arrangement with the hospital, including hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, licensed practitioners, or adult students, trainees or volunteers.
- **Staff would not include anyone who provides only telemedicine services or support services outside of the hospital and who does not have ANY direct contact with patients and other staff**

Temporarily Delayed Vaccination

- Refers to vaccination that must be temporarily postponed, as recommended by CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, or individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment in the last 90 days.
- <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>

What Must My Facility Do?

Minimum Written Policies and Procedures

- Develop overall written policy and procedure must address each required area by February 14
- Required policy and procedures include:
 - Process to ensure all staff receive least single dose COVID vaccine or first dose of multi-dose vaccine prior to staff providing any care, treatment or other services prior to February 14, 2022
 - Process to ensure all staff are fully vaccinated by March 15, 2022

How Does CMS Define Fully Vaccinated?

- CMS considers staff fully vaccinated if it has been two weeks or more since they completed a primary vaccination series for COVID-19
- **Important Note: Staff 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**
- Completion of primary vaccination series means
 - Received Single dose vaccine (J & J) Covid-19 vaccine
 - Received ALL required doses of multi-dose vaccine
 - Pfizer-BioNTech Covid-19 Vaccine (interchangeable with licensed Comirnaty Vaccine)
 - Moderna Covid 19 vaccine
 - Received vaccine listed by World Health Organization for emergency use (in accord with CDC guidelines)

Minimum Written Policies and Procedure

- Process for ensuring implementing additional precautions intended to mitigate transmission and spread of COVID-19 for all staff not fully vaccinated
- Process for tracking and securely documenting COVID-19 vaccination status of all staff
- Process for tracking and securely documenting staff who have obtained any booster doses as recommended by CDC

Minimum Written Policies and Procedures

- Exemption policies and procedures
 - Process must be documented in writing on how staff may request an exemption
 - Based on federal law
 - Written process for tracking and securely documenting information provided by staff who have requested an exemption AND for whom the hospital granted an exemption

Minimum Written Policies and Procedures

- Clinical Contraindications
 - Process to confirm recognized clinical contraindications for COVID-19 vaccination
 - Written process and procedure for staff who have requested exemption based upon contraindication
 - Written process for tracking and securely documenting information provided by staff with clinical contraindications
 - Appropriate licensed practitioner documentation which is signed and dated
 - Must include all information related to which of the COVID-19 vaccinations and the clinical contraindications for the staff member
 - Statement recommending the staff person be exempted

Minimum Policies and Procedures

- Temporary Vaccination Delays
 - Process for tracking and secure documentation of vaccination status for staff for whom COVID-19 must be delayed
 - Delay must be based upon CDC recommendations
 - Delay must be due to clinical precautions and considerations
 - Include:
 - Individuals with acute illness secondary to COVID-19
 - Individuals who have received monoclonal antibodies or convalescent plasma for COVID-19 treatment

Minimum Policies and Procedures

- Contingency Plans
 - Written policies and procedures for any staff who are not fully vaccinated for COVID-19
 - May include: physical distancing, source control
 - Does not require mandatory testing (Note: long term care has mandatory testing requirements)
 - Need to comply with EEOC requirements and minimize risk of transmission

When must my facility comply?

- Written policies and procedures in place for vaccinating staff, providing exemptions and accommodations, and documenting current staff vaccinations no later than February 14, 2022
- Process and plan for current staff vaccination must ensure all 100% eligible staff receive
 - 1st dose (Pfizer or Moderna) or one dose (J & J) vaccine by February 14, 2022
 - All doses for primary vaccination series by March 15, 2022

Are Boosters Required?

- Boosters are not required to be received in order to be considered fully vaccinated
- CMS strongly encourages facilities to review CDC Guidance for details on additional doses

What Staff do These Vaccination
Requirements Apply To?

Staff Covered

- All staff working at facility regardless of clinical responsibility or patient contact
- All current staff and any new staff who provide care, treatment or other services for the facility or patients
 - Facility employees
 - Licensed practitioners including all credentialed providers
 - Students
 - Trainees
 - Volunteers
 - Contracted staff

Existing vs New Employees

- Receive vaccine according to deadlines
- If hired between February 14, 2022 and March 15, 2022 must receive at least one dose prior to providing any care treatment or other services at facility or to patients
- If hired on or after March 15 2022, must be fully vaccinated—including all required doses PLUS 14 day waiting period

Do These Requirements Apply to Staff Working Off-Site

- Maybe—fact and circumstance based
- Required:
 - In-home Services
 - Home Infusion
 - Staff working who work or interact with other staff, patients, residents, clients in locations beyond formal clinical settings
 - Includes: homes, clinics, other sites of care, administrative offices, off-site meetings
- Staff who provide support services exclusively outside provider and who do not have ANY direct contact with patients or ANY other hospital staff

Do the Regulations Apply to Telehealth Employees?

- No
- Individuals who provide services **100%** remotely and have no direct contact with patients or other staff are not subject to the regulations
- **HOWEVER**-if staff come onsite for any type of staff meetings or interact with any staff in person, the telehealth employee would need vaccination

Who Else Is Covered?

- Board Members –CMS considers these individuals to be providing services to patients or residents and they are in direct contact with other staff who provide direct care
- Construction Workers-if they utilize common spaces such as bathrooms, dining rooms or if they are completing construction in areas where they may encounter patients/residents
 - Will need to evaluate what level of contact and frequency
- Vendor Representatives—those who participate in surgery. For example: Ortho representatives
- Staff who accompany providers on rounds or in surgery
- Anyone who has a contract with facility who provides care, treatment or other services (think consultants)

Who Else May Be Covered?

- EMS—does provider have contract with service? If so-regulation covers. If not, most likely organization covered by June OSHA ETS
- Police/Sheriff—does provider have contract for security? Or just dropping off patients?
- Community Pastors- do they have contract with facility to provide services or are they visiting individual patients
- Hopeful CMS will further define in interpretative guidelines

Considerations in Determining Who is Employee

- Frequency of presence in facility
- What services are being provided
- Amount of control over individual
- Proximity to patients and staff
- Federal Register example:
 - Outside plumber enters empty patient room to provide services and wears mask
 - Not considered employee for vaccination
- Facilities encouraged to facilitate vaccinations

Contracted Employees

- Not required to accept another employer's exemption determination
 - Some staffing agencies have indicated they are going to issue exemptions to all employees
- Remember staffing agency itself is not governed by Conditions of Participation
- Remains provider responsibility to ensure compliance

Who is Not Required to be Vaccinated?

- Visitors
- Ad-hoc non health-care contracted staff such as elevator inspector

Applicability to State or Accrediting Body Surveyors

- Required to be vaccinated per CMS
- **HOWEVER:** Providers/suppliers are not allowed to ask surveyors for proof of vaccination per CMS. CMS states it is state or accrediting body responsibility to enforce

Allowable Exemptions

Exemptions

- CMS requires facilities to allow exemptions in accord with federal law
 - Recognized medical conditions for which vaccines are contraindicated
 - Religious beliefs, observances or practices
- 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.

Medical Exemption Basics

- Must develop a written procedure for permitting staff to request a medical exemption
- Must ensure all documentation is signed and dated by a licensed practitioner
- Must contain all information specifying **why** the COVID-19 vaccines are clinically contraindicated for the staff person
- Documentation must include a statement by the authenticating practitioner recommending the staff person be exempted

CMS Clarifications on Medical Exemptions

- Dr. David Nilasena-CMS Regional Medical Officer provided additional clarification on acceptable medical contraindications to vaccine (beyond allergies) including:
 - Example given was myocarditis
 - Must be based upon individual person and their patient specific medical contraindications.
- If there are concerns about a particular physician issuing numerous medical exemptions, should report concerns to Board of Medicine

Temporary Delay in Vaccination

- Conditions should be addressed in policy/procedure
- CMS is allowing a temporary delay in vaccination for staff meeting criteria established by the CDC.
- <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>
- Example – someone that has active COVID-19 infection
- Following temporary delay, it is expected that employees will be vaccinated.

Is Pregnancy a Contraindication for Vaccination Delay?

- Not on CDC list of clinical conditions that could temporarily delay vaccination
- CDC recommends COVID vaccination for people who are pregnant, breastfeeding, trying to get pregnant now, or who may become pregnant in future
- May be considered protected or exempt under EEOC due to pregnancy being considered protected class under Title VII

Religious Exemptions

- Must develop a written procedure for permitting staff to request a religious exemption
 - Flexibility allowed in process design
- Must ensure all requests for religious exemptions are documented and evaluated in accordance with applicable federal law and as a part of the facility's existing policies and procedures

Religious Exceptions

- When making the request, employees do not need to use any “magic words,” such as “religious accommodation” or “Title VII” or even specific Bible (or other religious document) verses or information. However, they need to notify the employer that there is a conflict between their sincerely held religious beliefs and the employer’s COVID-19 vaccination requirement.
 - Must describe how vaccination conflicts with religious beliefs
- The same principles apply if employees have a religious conflict with getting a particular vaccine and wish to wait until an alternative version or specific brand of COVID-19 vaccine is available.
- As a best practice, an employer should provide employees and applicants with information about whom to contact, and the procedures (if any) to use, to request a religious accommodation.

Religious Exemptions

- EEOC issued new guidance

<https://www.eeoc.gov/newsroom/eeoc-issues-updated-covid-19-technical-assistance-0>

- Must be a sincerely held religious belief, practice, or observance.
- Title VII requires employers to consider requests for religious accommodations but does not protect social, political, or economic views, or personal preferences of employees who seek exceptions to a COVID-19 vaccination requirement.
- Employers that demonstrate “undue hardship” are not required to accommodate an employee’s request for a religious accommodation.

How do Accommodations Work?

- Must have process for implementing additional precautions for any staff who are not vaccinated
 - Additional precautions must comply with EEOC accommodations
- Must describe accommodations in policies and procedures
- Accommodations must ensure facility minimizes risk of transmission of COVID-19 to at risk individuals (patients, other staff, visitors)
- June 2021 OSHA Healthcare Emergency Temporary Standards provides guidance as to potential accommodations

Possible Manners to Reduce Risk

- Reassign staff who have not completed their primary vaccination series to non-patient care areas, to duties that can be performed remotely (i.e., telework), or to duties which limit exposure to those most at risk (e.g., assign to patients who are not immunocompromised, unvaccinated);
- Require staff who have not completed their primary vaccination series to follow additional, CDC-recommended precautions, such as adhering to universal source control and physical distancing measures in areas that are restricted from patient access (e.g., staff meeting rooms, kitchen), even if the facility or service site is located in a county with low to moderate community transmission.
- Requiring at least weekly testing for exempted staff and staff who have not completed their primary vaccination series, until the regulatory requirement is met, regardless of whether the facility or service site is located in a county with low to moderate community transmission, in addition to following CDC recommendations for testing unvaccinated in facilities located in counties with substantial to high community transmission.
- Requiring staff who have not completed their primary vaccination series to use a NIOSH-approved N95 or equivalent or higher-level respirator for source control, regardless of whether they are providing direct care to or otherwise interacting with patients

What Vaccination
Documentation is Acceptable?

Documentation

- COVID-19 Vaccination Card (or legible photocopy)
- Documentation from a healthcare provider
- Documentation from electronic health record
- State Immunization information system record
- If vaccinated outside US, reasonable equivalent

Vaccine Record Maintenance

- All COVID-19 vaccinations must be appropriately documented by the facility, which could be in a facility's immunization record, health information files, or other relevant documents.
- All medical records, including vaccine documentation, must be kept confidential and stored separately from an employer's personnel files.

Documentation Requirements

Employee Tracking

- Must clearly identify :
 - Each staff's role,
 - Assigned work area,
 - How they interact with patients.
- This includes staff who are contracted, volunteers, or students.
- Staff who telework full-time (e.g., 100 percent of their time is remote from sites of patient care and staff who do work at sites of care) should identify these individuals as a part of implementing the facility's policies and procedures, but those individuals are not subject to the vaccination requirements.
- Flexibility to track in any manner but subject to surveyor review

Review by Surveyor

- Surveyors will **not** evaluate the details of the request for a religious exemption, **nor** the rationale for the hospital's acceptance or denial of the request.
- Surveyors will review to ensure the hospital has an effective process for staff to request a religious exemption for a sincerely held religious belief.

Enforcement

How Will CMS Check for Compliance?

- CMS expects State Survey Agencies to conduct onsite compliance reviews for the requirements:
 - Recertification Surveys
 - Complaint Investigations
- Surveyors will check to see if three basic requirements met:
 - Process for vaccinating all eligible staff in place
 - Written policy and procedure
 - List of all staff and vaccination status
 - Will review the number of staff COVID-19 cases over the last 4 weeks
 - Will review the number of resident cases (in long term care) over the last 4 weeks
 - Have process or plan for providing exemptions and accommodations for those who are exempt
 - Have process or plan for tracking and documenting staff vaccinations
- This information, in addition to interviews and observations, will be used to determine the compliance of the provider or supplier with these requirements.
- Accrediting Organizations will also be required to assess for compliance

What If My Facility is Out of Compliance?

Will cite facilities based upon level or severity of the non-compliance

Facility staff vaccination rates under 100% constitute non-compliance under the rule. Non-compliance does not necessarily lead to termination, and facilities will generally be given opportunities to return to compliance.

Facilities that are out of compliance will be cited and provided an opportunity to return to compliance

IF not? CMS may use enforcement remedies such as civil monetary penalties, denial of payment, loss of accreditation or even potential termination from Medicare/Medicaid as a final measure

By February 14, 2022

- All Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or patient contact are vaccinated for COVID-19, including all required components of the policies and procedures specified below **and**
- 100% of staff have received at least one dose of COVID-19 vaccine or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule.**
- **IF** less than 100% of all staff have received at least one dose of COVID-19 vaccine, or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant under the rule.** The facility will receive notice of their non-compliance with the 100% standard.
 - A facility that is above 80% **and** has a plan to achieve a 100% staff vaccination rate within 60 days would not be subject to an enforcement action.
 - Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction and/or termination).

By March 15, 2022

- 100% of staff have received the necessary doses to complete the vaccine series (i.e., one dose of a single-dose vaccine or all doses of a multiple vaccine series) or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule.**
- Less than 100% of all staff have received at least one dose of a single-dose vaccine, or all doses of a multiple vaccine series, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant under the rule.**
 - The facility will receive notice of their non-compliance with the 100% standard. A facility that is above 90% **and** has a plan to achieve a 100% staff vaccination rate within 30 days would not be subject to an enforcement action.

After April 14, 2022

- **Within 90 days and thereafter following issuance of the memorandum, facilities failing to maintain compliance with the 100% standard may be subject to enforcement action.**
- **Note:** The requirements described above do not include the 14-day waiting period as identified by CDC for full vaccination. Rather these requirements are considered met with the completed vaccine series (i.e., one dose of a single dose vaccine, or final dose of a multi-dose vaccine series).

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
- CMS will provide opportunities to comply

Opportunities to Return to Compliance

- Based upon severity of deficiencies
- “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.

Anything Else Facility Should
Know?

Vaccination-ONLY Options

- Regulation do not include a testing option for unvaccinated staff
- Facilities encourage to voluntarily implement testing **in addition to** other infection prevention measures such as physical distancing and source control (masks)

Data Reporting Requirements

- **NO NEW requirements**
- Hospitals and nursing homes must still comply with facility specific data reporting requirements set forth in CMS regulations of May, 2020, August 2020 and May 2021.

How Will CMS use new COVID-19 Vaccination Quality Measure?

- Not going to be used to measure compliance
- Providers participating in the Inpatient, PPS-Exempt Cancer Hospital, Long Term Care Hospital, Inpatient Psychiatric, and Inpatient Rehabilitation Quality Reporting Programs are expected to report on the new COVID-19 Vaccination Coverage among Health Care Personnel quality measure from October 1, 2021 to December 31, 2021 as established in the various Fiscal Year 2022 payment rules.

Interactions with Other Regulations

- This regulation pre-empts any state law
- If your facility participates in Medicare/Medicaid which is regulated by Conditions of Participation or Conditions for Coverage (rural health clinics), these regulations take priority
- Other Considerations:
 - If not certified in Medicare/Medicaid programs, then the OSHA Covid-19 ETS applies (physician offices) or the Executive Order on Ensuring Adequate COVID Safety Protocols for Federal Contractors

OSHA COVID-19 June 2021 Emergency Temporary Standards (Healthcare)

- This regulation only encouraged vaccination -- did not mandate
- Described methods to reduce transmission
- CMS worked closely to ensure these regulations were complementary, ensured maximum coverage of staff and were not overly duplicative

QUESTIONS?



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