



New CMS Rule – Medicare and Medicaid COPs Require COVID-19 Vaccinations

November 4, 2021

Overview

Today the Administration released two Interim Final Rules with Comment mandating vaccines for COVID-19. The CMS rule (click [here](#)) applies to approximately 76,000 health care facilities, including hospitals and long-term care facilities, that are required to ensure its workers are fully vaccinated. The OSHA rule (click [here](#)) applies to employers with 100 or more employees who are required to ensure each of their workers is fully vaccinated to tests for COVID-19 on at least a weekly basis. In general, the CMS rule takes priority for health systems.

The CMS rule is effective on November 5, 2021; comments are due within 60 days.

Click [here](#) for the screenshots from the CMS presentation earlier today. Click here for the [FAQ](#) on the CMS rule, [here](#) for the CMS Press Release, [here](#) for the White House Fact Sheet and [here](#) for the background press briefing.

The text of the Conditions of Participation for Hospitals begins on page 182 of the CMS rule (click [here](#)).

CMS Rule - General Requirements

According to the Fact Sheet provided by CMS, if facilities participate in and are certified under the Medicare and Medicaid programs and are regulated by the CMS health and safety standards known as the Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation, then they are expected to abide by the requirements established in the CMS Omnibus Staff Vaccination Rule. This rule takes priority above other federal vaccination requirements. CMS's oversight and enforcement will exclusively monitor and address compliance for the provisions outlined in the CMS Omnibus Staff Vaccination Rule, while also continuing to monitor for proper infection control procedures as established under previous regulations.

There are rare situations where the Executive Order on Ensuring Adequate COVID Safety Protocols for Federal Contractors or the OSHA COVID-19 Healthcare Emergency Temporary Standard may also apply to staff who are not subject to the vaccination requirements outlined in

the CMS Omnibus Staff Vaccination Rule. Facilities should review these regulations and comply with any other federal requirements as necessary.

Note that this interim final rule is complementary to the COVID-19 Healthcare Emergency Temporary Standard issued on June 21, 2021 by OSHA (click [here](#)). Providers and suppliers may be covered by both rules.

The new OSHA rule released today applies to employees with 100+ employees not subject to the Medicare/Medicaid COPs.

Federal Preemption: These federal rules preempt state laws as well as any state restrictions against vaccine mandates.

Deadline for Vaccination: Either 2 doses of Pfizer or Moderna or one dose of Johnson & Johnson are required by January 4, 2022. Staff who have completed a primary vaccination series by this 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 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).

Additional doses or boosters are not required to comply with this rule.

Applies to: Health care workers at facilities participating in Medicare and Medicaid – whether clinical or non-clinical and includes employees, students, trainees and volunteers at the following: Ambulatory Surgical Centers (ASCs), Hospices, Psychiatric residential treatment facilities (PRTFs), Programs of All-Inclusive Care for the Elderly (PACE), Hospitals (acute care hospitals, psychiatric hospitals, hospital swing beds, long term care hospitals, children’s hospitals, transplant centers, cancer hospitals, and rehabilitation hospitals/inpatient rehabilitation facilities), Long Term Care (LTC) Facilities, including Skilled Nursing Facilities (SNFs) and Nursing Facilities (NFs), generally referred to as nursing homes, Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID), Home Health Agencies (HHAs), Comprehensive Outpatient Rehabilitation Facilities (CORFs), Critical Access Hospitals (CAHs), Clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services, Community Mental Health Centers (CMHCs),

Home Infusion Therapy (HIT) suppliers, Rural Health Clinics (RHCs)/Federally Qualified Health Centers (FQHCs) and End-Stage Renal Disease (ESRD) Facilities.

CMS recognizes that “early indications are that rural hospitals are having greater problems with employee vaccination refusals than urban hospitals, and we welcome comments on ways to ameliorate this problem.”

Exceptions:

Staff who telework 100% of the time are not required to be vaccinated.

Religious Nonmedical Health Care Institutions (RNHCIs), Organ Procurement Organizations (OPOs) and Portable X-Ray Suppliers are not included in the vaccination requirements. The rule does not apply to physician offices. Entities not covered by the CMS rule may still be subject to other state or Federal COVID-19 vaccination requirements, such as those issued by OSHA for certain employers.

Exemptions: See pages 53-55 of the rule. Certain allergies, recognized medical conditions, or religious beliefs, observances, or practices, may provide grounds for exemption.

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 <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>.

Federal laws, including the ADA, section 504 of the Rehabilitation Act, section 1557 of the ACA, and Title VII of the Civil Rights Act, that prohibit discrimination based on race, color, national origin, religion, disability and/or sex, including pregnancy. In some circumstances, employers may be required by law to offer accommodations for some individual staff members. Accommodations can be addressed in the provider or supplier’s policies and procedures.

CMS encourages facilities to review the Equal Employment Opportunity Commission’s Compliance Manual on Religious Discrimination for more information on religious exemptions. Click [here](#).

Staff who previously had COVID-19 are NOT exempt on those grounds alone.

Facilities have the flexibility to put their own processes in place for requesting exemptions.

For Employees Granted an Exemption: Facilities must develop a process for implementing additional precautions for any staff who are not vaccinated. Potential accommodations could include testing, physical distancing and/or source control.

Enforcement: Compliance will be ensured through established surveys and enforcement process; facilities will have an opportunity to return to compliance before additional actions occur. Range of remedies from fines to payment denials to termination from Medicare/Medicaid

program depending upon the facility. The remedy for non-compliance among hospitals and certain other acute and continuing care providers is termination from the Medicare/Medicaid program. Termination would generally occur only after providing a facility with an opportunity to make corrections and come into compliance.

CMS will issue interpretive guidelines, which will include survey procedures and will advise and train state surveyors on how to assess compliance. See page 59.

Documentation: See page 52-53 for suggestions on where to keep documentation and acceptable forms of proof.

Reporting Requirements: No new requirements.

Duration: This rule is not tied to the Public Health Emergency and there is no sunset clause. Interim Final Rules expire 3 years after issuance unless finalized following final rulemaking.

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