

Articles + Publications | November 10, 2021

CMS Mandates New Standards for COVID-19 Vaccine

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Who Needs to Know

All health care providers.

Why It Matters

Given the short timeframe required for CMS compliance, Facilities must act quickly to ensure they have, or can develop and implement, these new COVID-19 policies and procedures. Further, specific documentation standards and related internal processes must be developed and implemented, so the organization can demonstrate compliance when surveyed next year.

On November 5, the Centers for Medicare and Medicaid Services (CMS) published an [Interim Final Rule \(IFR\)](#), amending its conditions of participation, conditions of coverage, and requirements for participation. The new IFR requirements will impact 21 different types of providers and suppliers by mandating certain standards for the COVID-19 vaccine. These new requirements will apply, directly or indirectly, to most Medicare and Medicaid certified providers and suppliers, including, but not limited to, hospitals, ambulatory surgical centers, hospices, long-term care facilities, home health agencies, rehabilitation facilities, and others (together, the “Facilities”).^[1] Although 10 states^[2] have already filed a lawsuit against the COVID-19 mandates, Facilities should begin planning for implementation.

Implementation will be staggered and involve two phases. During Phase 1, 30 days following publication or by December 5, Facilities must (1) develop and implement COVID-19 vaccination policies and procedures and (2) require staff to receive one dose of the single dose vaccine or at least one dose of a primary series vaccine. During Phase 2, 60 days following publication or by January 4, 2022, staff must receive one dose of the single dose vaccine or have completed all doses required for a primary series vaccine to be considered “fully vaccinated.” As discussed in more detail below, staff granted an exception, or “for whom [a] COVID-19 vaccination must be temporarily delayed, as recommended by CDC, due to clinical precautions and considerations,” are exempted. Staff who receive the final dose of a primary series vaccine during the initial 60 days, but not 14 days out, will be considered fully vaccinated during the initial implementation period.

Below find a few key areas that a Facility’s COVID-19-related policies and procedures must address during the initial 60-day implementation phase.

What does it mean to be fully vaccinated? As discussed above, fully vaccinated means that staff must be at least two weeks out from when they “completed a primary vaccination series for COVID-19.” This is defined as “the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.” Interestingly, however, the rule allows staff who are not two-weeks out from their final dose to provide patient care

even after the initial 60-day implementation phase. To provide patient care or treatment, staff must only have a single-dose COVID-19 vaccine or “the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine” but the Facility must have a procedure for ensuring staff receive the second dose, when applicable.

Who is impacted? The revised rules apply to employees, licensed practitioners, students, trainees, volunteers, contracted employees, and others who provide patient care, treatment, or other services for a Facility and/or its patients. Staff who provide support services or telehealth or telemedicine services exclusively outside the Facility are not impacted if they do not have contact with patients or staff members who have contact with patients.

Are physician practices covered? Physician practices are not directly covered by the IFR because they are not regulated by CMS’ conditions of participation. However, individual practitioners who visit any of the covered Facilities (*i.e.*, a hospital, ASC, hospice, long-term care facility, etc.), or provide services under contract or another arrangement with any covered Facility, may find that they are required to be vaccinated (or request an exemption) as a result of their relationship with the Facility.

What documentation is required? The IFR requires Facilities to develop and document processes that ensure all staff are fully vaccinated (as defined above). Exceptions are made for staff members who are granted an exemption or whose vaccination must be temporarily delayed due to “clinical precautions and considerations” recommended by the CDC.

Specifically, the new rule requires covered Facilities to develop policies and procedures designed to implement processes that:

1. Ensure precautionary measures are taken to help mitigate the transition and spread of COVID-19 for staff who are not fully vaccinated;
2. Track and document the COVID-19 vaccination status of staff to include whether they have received any CDC-recommended boosters;[\[3\]](#)
3. Allow staff members to request an exemption based on applicable federal law;
4. Track and document information provided by staff who request and are granted an exemption;
5. Track and document the vaccination status of those for whom the COVID-19 vaccination must be temporarily delayed under CDC recommendations;[\[4\]](#) and
6. Include contingency plans for staff who are not fully vaccinated.

The IFR also requires that the documentation of a staff member’s medical exemption include a signed statement by a licensed practitioner practicing within his/her scope (and who is not the individual requesting the exemption) that contains the following:

1. Information specifying which vaccine is clinically contraindicated and the reasons for such contraindication; and

2. A recommendation from the authenticating practitioner to exempt the staff member based on the clinical contraindication.

What exemptions are allowed? In the IFR, CMS recognizes the obligation Facilities have to comply with antidiscrimination and civil rights laws — specifically, the Americans with Disabilities Act (ADA), Section 504 of the Rehabilitation Act (RA) Title VII of the Civil Rights Act of 1964 the Pregnancy Discrimination Act, the Genetic Information Nondiscrimination Act, and others. To this end, the IFR requires that a Facility's policies and procedures include a process for receiving and evaluating individual requests for an exemption to the COVID-19 vaccination mandate for a "disability, medical condition, or sincerely held religious belief, practice, or observance." The IFR also requires Facilities to adopt "additional precautions, ... to mitigate the transmission and spread of COVID-19, for all staff who are not fully vaccinated for COVID-19."

The OSHA emergency temporary standard announced on November 5 mandates that employee not fully vaccinated must (1) undergo regular COVID-19 testing (once every seven days, along with providing documentation of the most recent COVID-19 test result) and (2) wear a face covering at work. For more information, see Troutman Pepper's article, "[DOL-OSHA Announces New COVID-19 Vaccine ETS for Private-Sector Workers](#)." The IFR, however, stops short of mandating these additional procedures and seems to leave it to the Facility to impose appropriate "precautions."

What will enforcement look like? Consistent with how CMS handles other standards, it plans to issue interpretive guidelines and survey procedures addressing the new COVID-19 vaccine requirements. Once issued, we expect surveyors to pay particular attention to how Facilities have implemented these standards throughout their organization. If cited for noncompliance, Facilities may be subject to civil monetary penalties, denial of payment for new admissions, or termination of their Medicare/Medicaid provider agreement. "CMS will closely monitor the status of staff vaccination rates, provider compliance, and any other potential risks to patient, recent, client and PACE program participant health and safety."

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[1] The full list of providers impacted by these changes includes: ambulatory surgical centers, hospices, psychiatric residential treatment facilities, all-inclusive care programs for the elderly, hospitals, long-term care facilities, intermediate care facilities, home health agencies, comprehensive outpatient rehabilitation, critical care hospitals, clinics, rehabilitation agencies and public health agencies as providers of outpatient physical therapy and speech-language pathology services, community mental health centers, home infusion therapy suppliers, rural health clinics/federally qualified health centers, and end-stage renal disease facilities.

[2] Missouri filed its lawsuit first (at the publication of this alert), with nine states joining the lawsuit, including Alaska, Arkansas, Iowa, Kansas, Nebraska, New Hampshire, North Dakota, South Dakota, and Wyoming.

[3] Acceptable forms of proof of vaccination include (1) CDC COVID-19 vaccination card (or a legible photo of the

card), (2) documentation of vaccination from a health care provider or electronic health record, or (3) state immunization information system record.

[4] This can include those who have “an acute illness secondary to COVID-19 and those who received monoclonal antibodies or convalescent plasma for COVID-19 treatment . . .”

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