



COVID-19 Vaccine Mandate FAQs for Employers (Updated 11-24-2021)

On Nov. 5, 2021, the Centers for Medicare and Medicaid Services (“CMS”) issued their interim final rule, 86 Federal Register 61555-61627 (“IRF”) on the COVID-19 Vaccine Mandate (“Mandate”). The Mandate applies to for health care facilities and providers that CMS regulates through its Conditions for Coverage/Requirements for Participation. Those covered range from hospitals to hospices and rural health clinics to long-term care facilities including skilled nursing homes.

See footnote 1 for a complete list.¹ Under Phase 1 of the IRF, all covered staff must have received a single-dose COVID-19 vaccine or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine by Dec. 5, 2021, unless such covered staff have requested an exemption or a request for a temporary delay.

Under Phase 2 of the IRF, covered staff must be fully vaccinated by Jan. 4, 2022, for COVID-19, except for those covered staff who have been granted exemptions to the Mandate or those covered staff whose request for a temporary delay in vaccination has been granted.

The following answers to frequently asked questions by hospital staff are based on the CMS FAQs and other guidance related to the IRF and will be updated periodically.

Q1. Does the vaccine mandate apply to my facility?

A1. Generally, if the Medicare Conditions of Participation regulate your facility, the IFR applies. See footnote 1 for a complete list of those entities and providers covered by the IFR.

¹ Ambulatory Surgical Centers (ASCs) (§ 416.51); Hospices (§ 418.60); Psychiatric residential treatment facilities (PRTFs) (§ 441.151); Programs of All-Inclusive Care for the Elderly (PACE) (§ 460.74); 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) (§ 482.42); Long Term Care (LTC) Facilities, including Skilled Nursing Facilities (SNFs) and Nursing Facilities (NFs), generally referred to as nursing homes (§ 483.80); Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF-IID) (§ 483.430); Home Health Agencies (HHAs) (§ 484.70); Comprehensive Outpatient Rehabilitation Facilities (CORFs) (§§ 485.58 and 485.70); Critical Access Hospitals (CAHs) (§ 485.640); Clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services (§ 485.725); Community Mental Health Centers (CMHCs) (§ 485.904); Home Infusion Therapy (HIT) suppliers (§ 486.525); Rural Health Clinics (RHCs)/Federally Qualified Health Centers (FQHCs) (§ 491.8); End-Stage Renal Disease (ESRD) Facilities (§ 494.30)(collectively, “**Facility**” or “**Facilities**”)

Q2: Which staff are covered under this requirement?

A2: The Mandate applies to staff working at a facility, regardless of clinical responsibility or patient contact, who provide care, treatment or other services for the facility or its patients. Specifically, the Mandate applies to a facility's employees, licensed practitioners, students, trainees and volunteers. Additionally, the Mandate applies to individuals who provide care, treatment, or other services for the facility and/or its patients under contract or other arrangements ("collectively, covered staff").

Q3: Does this requirement apply to staff who work offsite?

A3: Yes. Subject to certain exceptions for staff who exclusively provide services outside the facility setting and who do not have direct contact with patients or other staff, the mandate is not limited to those staff who perform their duties solely within a formal clinical setting, as many health care staff routinely care for patients and clients outside of such facilities (e.g. home health, home infusion therapy, etc.). To maximize patient protection, all staff who interact with other covered staff, patients, residents, clients, or PACE program participants in any location beyond the formal clinical setting (such as homes, clinics, other sites of care, administrative offices, off-site meetings, etc.) must be vaccinated.

Q4: Does this requirement apply to full time teleworkers?

A4: No. Individuals who provide services 100 percent remotely and who do not have any direct contact with patients and covered staff, such as fully remote telehealth or payroll services, are not subject to the vaccination requirements outlined in the mandate.

Q5: Would a physician with admitting privileges in a hospital be covered under this requirement?

A5: Yes, a physician admitting and/or treating patients in-person within a facility must be vaccinated so that the facility is compliant.

Q6: Does this requirement apply to board members?

A6: Yes. Unless the board member provides services as a board member exclusively outside the facility setting and without any direct contact with patients and covered staff or is otherwise exempt, the mandate requires the board member (and other administrative staff, facility leadership and volunteers) must be vaccinated for the facility to be compliant.

Q7: Why didn't CMS include all health care settings?

A7: CMS is using the authority established by Congress under the Social Security Act to regulate Medicare and Medicaid-certified health facilities. Sections 1102 and 1871 of the Social Security Act (the Act) grant the Secretary of Health and Human Services authority to make and publish such rules and regulations, not inconsistent with the Act, as may be necessary to the efficient administration of the functions with which the Secretary is charged under this Act. Citations to the relevant statutory authorities for each specific type of provider and supplier is set out in the discussion of each provider- and supplier-specific provision of the mandate. The mandate does not extend to certain facilities or to independent physicians/clinicians who do not provide services for a facility or its patients.

Q8. How does CMS define “fully vaccinated” for the purposes of this requirement?

A8. For purposes of the mandate, covered staff are considered fully vaccinated if it has been two weeks or more since they completed a primary vaccination series for COVID-19. However, covered staff who have who have completed the primary vaccination series by Jan. 4, 2022, are considered to have met these requirements, even if they have not yet completed the 14-day waiting period required for full vaccination, but such individual would still need to meet the facility’s additional precautions for unvaccinated staff. 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 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.

Q9. Which vaccines count toward the requirement?

A9. CMS expects that staff will receive a vaccine licensed or authorized for emergency use by the Food and Drug Administration, which currently includes:

- Pfizer-BioNTech COVID-19 Vaccine (interchangeable with the licensed Comirnaty vaccine),
- Moderna COVID-19 Vaccine, and
- Janssen (Johnson & Johnson) COVID-19 Vaccine.

Facilities will also be in compliance if they allow covered staff to work who received a vaccine listed by the WHO for emergency use that is not approved or authorized by the FDA, or who received a vaccine during their participation in a clinical trial.

Q10: What if one of my staff participated in a clinical trial?

A10: According to the CDC, no additional doses are needed for covered staff who participated in a clinical trial at a site in the U.S. and received the full series of an “active” vaccine candidate (not placebo) and vaccine efficacy has been independently confirmed (by a data and safety monitoring board). Staff should consult with their doctor or other health care provider if they have questions about their vaccination.

Q11: Does the regulation include testing requirements for unvaccinated staff?

A11: No, the mandate requires covered staff obtain vaccination only. While CMS considered requiring daily or weekly testing of unvaccinated individuals, scientific evidence on testing found that vaccination is a more effective infection control measure.

Q12: Is there provision for certain individuals for whom a vaccination should be delayed, for example, because of a recent COVID-19 diagnosis?

A12: Yes. The Mandate addresses staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations.

Q13: Are exemptions allowed?

A13: CMS requires facilities to allow for exemptions to covered staff with recognized medical conditions for which vaccines are contraindicated (as a reasonable accommodation under the Americans with Disabilities Act) or religious beliefs, observances, or practices (established under Title VII of the Civil Rights Act of 1964). Facilities should establish exemption request and evaluation processes as a part of its policies and procedures and in alignment with Federal law. CMS believes that exemptions could be appropriate in certain limited circumstances, but no exemption should be provided to any staff for whom it is not legally required (under the ADA or Title VII of the Civil Rights Act of 1964).

Q14: Does the regulation include exemptions for staff that show they have COVID-19 antibodies?

A14: No. covered staff who have previously had COVID-19 are not exempt from these vaccination requirements.

Q15: How will facilities determine if an individual's request for a religious exemption is valid?

A15: CMS encourages facilities to review the [Equal Employment Opportunity Commission's Compliance Manual on Religious Discrimination](#) for more information on religious exemptions.

Q16: What is the process for staff to seek a religious exemption?

A16: 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.

Q17: What is the process for staff to seek a medical exemption?

A17: Similar to religious exemptions, facilities have the flexibility to establish their own processes that permit covered staff to request a medical exemption from the COVID-19 vaccination requirements, so long as the processes include the required element for the medical exemption set forth in the Mandate. Facilities must ensure that all documentation confirming recognized clinical contraindications to COVID-19 vaccinations for covered 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 required.

Q18. How do accommodations work for staff members who meet the requirements for an exemption and are not vaccinated?

A18. The mandate requires that facilities develop a process for implementing additional precautions for any staff who are not vaccinated, in order to mitigate the transmission and spread of COVID-19. 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. CMS encourages facilities to review the Equal Employment Opportunity Commission’s website for additional information about situations that may warrant accommodations. In granting such exemptions or accommodations, employers must minimize the risk of transmission of COVID-19 to at-risk individuals as they work to protect the health and safety of patients. Accommodations may include testing, social distancing, and other source control measures.

Q19: How will this new requirement be enforced on facilities?

A19: CMS works directly with the 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 four 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.

Q20. What penalties will be applied by CMS if our facility is out of compliance?

A20: CMS may use enforcement remedies such as civil monetary penalties, denial of payment and even termination from the Medicare and Medicaid program as a final measure.