



FAQs on CMS COVID-19 Health Care Staff Vaccination Rule

The Texas Hospital Association offers answers to member hospitals' questions about the Centers for Medicare and Medicaid Services' (CMS) interim final rule ("IFR"), published on November 5, 2021.

1. Where can I find the IFR?

The IFR may be accessed [here](#).

2. What is the IFR's effective date?

The IFR took effect on November 5, 2021. However, the IFR's implementation dates are divided into two phases.

Phase 1 requires facilities to comply with all requirements, except for the requirement for staff to be *fully* vaccinated, by December 5, 2021.

Phase 2 requires facilities to comply with all the rule's requirements, including the requirement for staff to receive all doses of a vaccine regimen (subject to exemptions), by January 4, 2022.

3. What does the IFR require?

Broadly, the IFR requires most of the entities covered by applicable Conditions of Participation, Conditions for Coverage, or Requirements for Participation to establish a policy requiring eligible staff to receive at least one dose of a COVID-19 vaccine by December 5, 2021 and complete a primary vaccination series by January 4, 2022.

4. Are there exceptions to the IFR's requirement?

Yes, staff who have applied for or are granted an exemption are not subject to this requirement.

CMS further clarified that it:

requires facilities to allow for exemptions to staff with recognized medical conditions for which vaccines are contraindicated (as a reasonable accommodation under the Americans with Disabilities Act (ADA)) or religious beliefs, observances, or practices (established under Title VII of the Civil Rights Act of 1964). Providers and suppliers should establish exceptions 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) or who requests an exemption solely to evade vaccination.

THA believes the IFR is drafted so facilities should interpret and apply these exemptions narrowly, but additional and specific considerations should be discussed with your legal counsel. Facilities should consider the creation of a small committee to review any exemptions requested by staff. Any policies and procedures related to exemptions should be enforced uniformly amongst the staff requests.

5. Can facilities test staff, as an alternative to the vaccine requirement?

No. The IFR indicates that testing is not available as an alternative to vaccination. Although testing was considered, vaccination was determined the best and most effective infection control measure. CMS will accept comments on testing as an alternative.

The stated purpose of the IFR is to protect patients first and to prevent COVID-19 transmission.

6. Does the IFR's requirements apply despite local and state orders, such as the Governor's Executive Order GA 40?

Executive Order GA 40 remains in effect and generally prohibits any requirement by any employer regarding vaccinations. However, according to CMS, and pursuant to the Supremacy Clause of the U.S. Constitution, the IRF preempts any contradicting state law or order. THA believes the IFR will control, unless otherwise mandated by a court order.

7. Which facilities must comply with the IFR?

The IFR has broad scope and applicability. CMS intends the IFR to apply to entities, providers, and suppliers that participate in Medicare or Medicaid, including, but not limited to: Hospitals, Community Mental Health Centers, Comprehensive Outpatient Rehabilitation Facilities, Critical Access Hospitals, End-Stage Renal Disease Facilities, Ambulatory Surgery Centers (ASCs), Dialysis Facilities, Home Health Agencies, Home Infusion Therapy Suppliers, Hospices, Intermediate Care Facilities for Individuals with Intellectual Disabilities, Clinics, Rehabilitation Agencies, Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services, Psychiatric Residential Treatment Facilities (PRTFs), Programs for All-Inclusive Care for the Elderly Organizations (PACE), Rural Health Clinics/Federally Qualified Health Centers, Long-Term Care Facilities, and Indian Health Service (IHS) Facilities.

CMS does not believe the IRF applies to: Physician's Offices, Dental Offices, Assisted Living Facilities, Group Homes, Religious Nonmedical Health Care Institutions (RNHCIs), Organ Procurement Organizations (OPOs), Portable X-Ray Suppliers, Providers of Home and Community-Based Services (HCBC) that receive Medicaid funding but are not regulated by CMS, or schools that receive Medicaid funding but are not regulated by CMS.

8. Are all staff required to comply with the IFR?

Most likely. The IFR's requirements apply to staff working at a facility that participates in the CMS programs, regardless of the level of clinical responsibility or patient contact.

These requirements are not limited to staff who perform their duties in a formal clinical setting; they also apply to staff that work offsite – unless an individual provides services 100% remotely and does not have any direct contact with patients or other staff who do. The requirements are not limited to employed staff, and apply to any individuals who provide any care, treatment, or other services for the hospital and/or its patients including licensed practitioners; 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.

The IFR includes a broad definition of “staff” (e.g., volunteer and fiduciary board members are included). THA believes a facility's policy should encompass a broad definition of staff, with clear delineation of individuals not required to comply with the vaccination requirement. For example, a delivery person spending a few minutes a day within the facility might not trigger the IFR's requirements, but should wear a mask within the facility, while a maintenance person visiting the facility on a weekly basis to check on equipment might. These particulars should be considered (e.g., how much time does an individual spend within the facility and in the vicinity of patients?) and related policies should be consistent in their enforcement.

9. How does the IFR define “fully vaccinated?”

The IFR deems staff “fully vaccinated” pursuant to CDC definitions, which currently require at least two weeks since the completion of a primary vaccination series. This requires either both doses of a 2-dose regimen, or one dose of a 1-dose regimen.

Booster doses are not currently required by CMS or the IFR.

10. What if staff does not receive a vaccination?

Under the IFR, facilities must implement contingency plans in consideration of staff that are not fully vaccinated, to be sure they will be vaccinated and do not provide care or treatment to patients until they are fully vaccinated or, at a minimum, received at least one dose of a multi-dose vaccine.

THA reads this requirement to mean that, as of December 5, 2021, staff that have not received at least one dose of a vaccine or requested/received an exemption should not provide treatment to patients.

11. What is the penalty for violating the IFR?

CMS will issue further interpretive guidelines regarding enforcement of the rule, which will include survey procedures and guidance on how surveyors should cite noncompliance. Noncompliance may be subject to any of the available remedies under federal law. According to CMS, the remedy for non-compliance among hospitals and certain other acute and continuing care providers is termination from the Medicare

and Medicaid programs. However, CMS indicates that its goal is to bring health care facilities into compliance, and termination would generally occur only after providing a facility with an opportunity to make corrections and come into compliance.

12. How can a facility document staff vaccination status?

Proof of vaccination may include a CDC COVID-19 vaccination card or a legible photo of the card, documentation from a health care provider or an electronic health record, or an entry in a state immunization information system record. If vaccinated outside of the US, a reasonable equivalent of this document will suffice.

THA suggests that facilities obtain copies of such proof, to adequately meet the IFR's documentation requirements. However, facilities must also consider applicable HIPAA, confidentiality and other privacy laws when accessing medical records and state immunization information systems.

13. Should hospitals alter policies and procedures in response to the IFR?

Yes. In addition to the requirements set forth above, the IFR requires that facilities implement a process for ensuring the implementation of additional precautions intended to mitigate the transmission and spread of COVID-19 for those not fully vaccinated. At a minimum, facilities should comply with infection control and prevention measures recommended by the CDC.

Facilities must also track and securely document the vaccination status of staff members, including those for whom there is a temporary delay in vaccination (e.g., receipt of antibodies or plasma) and those for whom an exemption applies. All documentation relating to staff vaccinations that includes medical records (including vaccine documentation) must be kept confidential and stored separately from an employee's personnel file.

Contact a member of THA's advocacy & legal teams for additional information:

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