

## CMS COVID-19 Staff Vaccination Interim Final Rule FAQ

On November 4, 2021, the Centers for Medicare and Medicaid Services (CMS) issued the Omnibus COVID-19 Health Care Staff Vaccination [Interim Final Rule](#) requiring staff at Medicare and Medicaid-certified facilities to be vaccinated unless they have approved religious or medical exemptions. The responses below are based on the Interim Final Rule and [CMS FAQ](#).

On December 28, 2021, CMS [released new guidance on the implementation](#) of their IFR and [guidelines to assess and maintain compliance](#) with the COVID-19 vaccination requirements.

On January 13, 2021, the Supreme Court upheld the CMS COVID-19 Staff Vaccination Requirement IFR and lifted the preliminary injunctions. The CMS Staff Vaccination Requirement is enforceable in all States and US Territories. There are two compliance time frames for states under the IFR, known as Group 1 and Group 2. The compliance requirements under the IFR and FQHC guidance are the same.

**Group 1 states include:** California, Colorado, Connecticut, Delaware, Florida, Hawaii, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Tennessee, Vermont, Virginia, Washington and Wisconsin.

**Group 2 states include:** Alabama, Alaska, Arizona, Arkansas, Georgia, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, New Hampshire, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Texas, Utah, West Virginia and Wyoming.

We encourage health centers to review the information below and periodically check for updates on the [NACHC Employee COVID-19 Vaccination Mandate webpage](#). Attached to this FAQ is the FQHC CMS IFR Survey Guidelines and the EEOC Technical Assistance COVID-19 Vaccination Guidance.

### 1. Which Vaccine Mandate applies to FQHCs?

The [CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule](#) with Comment Period (the “Interim Final Rule”) applies to all FQHCs that 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 are expected to abide by the requirements established in the Interim Final Rule. **This rule takes priority above other federal vaccination requirements.**

Health Resources and Services Administration (HRSA) has established new programs to help FQHCs meet the needs of their communities and ensure continuity of health care services during the PHE. To implement these programs and to provide services and care, FQHC staff must interact with patients and members of the community at large. CMS recognized that

FQHCs have played an essential role in reaching the medically underserved communities that have been disproportionately affected by COVID-19.

CMS acknowledges that there may be rare occasions where a FQHC is subject to other COVID-19 vaccine requirement regulations, such as [OSHA's COVID-19 Vaccination and Testing Emergency Temporary Standard](#) (applicable to employers with greater than 100 employees) or the Executive Order on Ensuring Adequate COVID Safety Protocols for Federal Contractors (including the Safer Federal Workforce Task Force's [COVID-19 Workplace Safety: Guidance for Federal Contractors and Subcontractors](#)).

**2. Based on pending litigation, should health centers comply with other federal mandates like the OSHA COVID-19 Vaccination and Testing Emergency Temporary Standard?**  
*(12/28/21)*

As of December 15, 2021, following decisions by the United States Court of Appeals for the Fifth, Eighth, and Eleventh Circuits and the United States District Court for the Northern District of Texas, implementation and enforcement of the CMS IFR, is preliminarily enjoined in the following twenty-five states: Alabama, Alaska, Arizona, Arkansas, Georgia, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, New Hampshire, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Texas, Utah, West Virginia, and Wyoming. Medicare- and Medicaid-certified providers and suppliers in those states **are not required** to comply with the Interim Final Rule, and surveyors will not investigate compliance with the rule in facilities located in those states, pending future developments in the litigation.

According to the CMS Interim Final Rule FAQ, if a facility is not subject to the requirements of the IFR, then the Executive Order on Ensuring Adequate COVID Safety Protocols for Federal Contractors or OSHA COVID-19 Vaccination and Testing Emergency Temporary Standard (ETS) apply. Health centers could be subject to the OSHA ETS in the enjoined 25 states.

**NACHC advises health centers to wait for the Supreme Court's decision on the federal vaccine mandates, before adopting the OSHA ETS based on pending future developments.** Considering that the Supreme Court is evaluating the CMS IFR and OSHA ETS, there is no certainty either regulation will be upheld or how the government can proceed with enforcement. NACHC encourages health centers to prioritize the CMS IFR until there is legal clarity, in light of the tremendous effort health centers have invested in complying with the CMS IFR and the different compliance requirements under the OSHA ETS.

**3. What does the CMS Omnibus COVID-19 Staff Vaccination Interim Final Rule require?**  
*(12/28/21)*

All FQHCs achieve a 100% vaccination rate for their staff through the development of a policy to address vaccination applicable to all staff who provide any care, treatment, or other services for the FQHC and/or its patients.

As detailed at [42 CFR § 491.8\(d\)](#), CMS requires FQHCs to develop and implement policies and procedures to ensure their staff are vaccinated for COVID-19 and that appropriate documentation of those vaccinations are tracked and maintained. All staff includes employees; licensed practitioner; students, trainees, and volunteers; and other individuals who provide care, treatment, or other services for the provider or its patients.

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.

*Please review the [FOHC guidance](#) in detail for more information on the required policies and procedures.*

Please review: [NACHC Operational Resource Guide COVID-19 Vaccine Mandate](#)

### **3. What are the compliance deadlines? (1/19/21)**

The regulation requires CMS facilities, like FQHCs, to establish a process or policy to fulfill the staff vaccination requirements over two phases.

#### **GROUP 1**

##### **Phase 1: January 27, 2022, facilities are required to:**

- Develop and implement policies and procedures ensuring all facility staff are vaccinated for COVID-19, including tracking staff vaccinations and documenting exemptions; **and**
- Have 100% of staff receive at least one dose of COVID-19 vaccine or have a pending requests for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC.
  - A facility that is above 80% **and** has a plan to achieve a 100% staff vaccination rate within 60 days (by February 28, 2022) would not be subject to additional enforcement action but would be considered non-compliant under the IFR.

##### **Phase 2: February 28, 2022, facilities are required to:**

- Develop and implement policies and procedures ensuring all facility staff are vaccinated for COVID-19, including tracking staff vaccinations and documenting exemptions; **and**
- Have 100% of staff receive the necessary doses to complete the vaccine series or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC.
  - A facility that is above 90% **and** has a plan to achieve a 100% staff vaccination rate within 30 days (March 30, 2022) would not be subject to additional enforcement action but would be considered non-compliant under the IFR.

***By March 30, 2022, facilities failing to maintain compliance with the 100% standard may be subject to enforcement action.***

## **GROUP 2**

### **By February 14, 2022, facilities are required to:**

- Develop and implement policies and procedures ensuring all facility staff are vaccinated for COVID-19, including tracking staff vaccinations and documenting exemptions; and
- Have 100% of staff receive at least one dose of COVID-19 vaccine or have a pending requests for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC.
  - A facility that is above 80% and has a plan to achieve a 100% staff vaccination rate within 60 days (by March 15, 2022) would not be subject to additional enforcement action.

### **By March 15, 2022, facilities are required to:**

- Develop and implement policies and procedures ensuring all facility staff are vaccinated for COVID-19, including tracking staff vaccinations and documenting exemptions; and
- Have 100% of staff receive the necessary doses to complete the vaccine series (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.
  - A facility that is above 90% and has a plan to achieve a 100% staff vaccination rate within 30 days (April 14, 2022) would not be subject to additional enforcement action.

***By April 14, 2022, facilities failing to maintain compliance with the 100% standard may be subject to enforcement action.***

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 or the Moderna COVID-19 Vaccine).

For the purposes of compliance with the Interim Final Rule, staff who have completed the primary series for the vaccine by the required deadlines are considered to have met the requirements, even if they have not yet completed the 14-day waiting period required for full vaccination. As of now, the Interim Final Rule does not require booster shots; however, facilities must develop a process for tracking and securely documenting when staff obtain any booster doses as recommended by the CDC.

#### 4. Does this regulation apply to PCAs and HCCNs?

The CMS COVID-19 Vaccine requirement does not apply to PCAs nor HCCNs, unless the organization has contractual arrangements that require staff to visit FQHC sites.

PCAs and HCCNs may be subject to other COVID-19 vaccine requirement regulations, such as [OSHA's COVID-19 Vaccination and Testing Emergency Temporary Standard](#) (applicable to employers with greater than 100 employees) or the Executive Order on Ensuring Adequate COVID Safety Protocols for Federal Contractors (including the Safer Federal Workforce Task Force's [COVID-19 Workplace Safety: Guidance for Federal Contractors and Subcontractors](#)). Note that the vaccine requirements for Federal Contractors **do not apply** to federal grantees.

#### 5. What type of FQHC staff are required to comply with the CMS COVID-19 vaccine requirement?

The CMS COVID-19 vaccine requirement applies to current and new staff. The requirement is not based on the frequency of how often an individual is present in the facility or at the physical site of patient care. The policies and procedures must apply to all staff, including those providing services in home or community settings, who directly provide any care, treatment, or other services for the facility and/or its patients. This includes administrative staff, facility leadership, volunteer or other fiduciary board members, housekeeping and food services, and others. To ensure maximum patient protection, CMS extends the vaccination requirement to all staff who interact with other staff, patients, residents, or PACE program participants in any location beyond the formal clinical settings.

Under the Interim Final Rule “staff” includes:

- facility employees
- licensed practitioners
- students
- trainees
- volunteers\*
- board members
- individuals who provide care, treatment, or other services for the facility and/or its patients, under contract or other arrangement

When determining whether to require COVID-19 vaccination of individuals under contractual arrangements, facilities should consider frequency of presence, services provided, and proximity to patients and staff. In the preamble to the Interim Final Rule, CMS uses the example of a contractor who uses shared facilities (restrooms, cafeteria, break rooms) during their breaks and who visits the facility on a regular basis (versus a single, emergency visit to the facility) with CMS stating that such an individual would be subject to the requirements of the CMS Interim Final Rule.

The COVID-19 vaccination requirement does not apply to 100% fully remote staff that do not have contact with patients and other staff.

*\* The regulation does not define volunteer. Providers and suppliers are not required to ensure the vaccination of individuals who infrequently provide ad hoc non-health care services (such as annual elevator inspection), or services that are performed exclusively off-site, not at or adjacent to any site of patient care (such as accounting services), but they may choose to extend COVID-19 vaccination requirements to them if feasible.*

**6. What are facilities required to track and document under the Interim Final Rule? (12/28/21)**

Health centers must track and securely document:

- Each staff member's vaccination status (this should include the specific vaccine received, and the dates of each dose received, or the date of the next scheduled dose for a multi-dose vaccine);
- Any staff member who has obtained any booster doses (this should include the specific vaccine booster received and the date of the administration of the booster);
- Staff who have been granted an exemption from vaccination (this should include the type of exemption and supporting documentation); requirements by the RHC/FQHC; **and**
- Staff for whom COVID-19 vaccination must be temporarily delayed and should track when the identified staff can safely resume their vaccination.

**7. Are facilities required to collect documentation for contractors and board members?**

CMS requires all facilities to track and securely document the vaccination status of each staff member (or information related to staff exemptions). This extends beyond the full-time health center staff to all individuals that fall under the Interim Final Rule's definition of "staff." (please see question 5 above).

Under this Interim Final Rule, CMS defines staff to include individuals who provide services directly, on a regular basis, under contract or arrangement. This including hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, social workers, and portable x-ray suppliers. The requirement is not limited to staff who perform their duties within a formal clinical setting and includes staff who routinely care for patients and clients outside of the facility.

**7. We just started a capital project, does the vaccination requirement include construction workers at a health center site?**

Any individual that performs their duties at any site of care, or has the potential to have contact with anyone at the site of care, **including staff or patients**, must be fully vaccinated or be granted an exemption. When determining whether to require COVID-19 vaccination of an individual who does not fall into the definition of staff established by this Interim Final Rule,

facilities **should consider frequency of presence, services provided, and proximity to patients and staff.**

When the vaccination requirement applies to construction workers or contractors:

- Individuals that use shared facilities (restrooms, cafeteria, break rooms) during breaks
- Individuals that use the same common areas used by staff, patients, and visitors.

When the vaccination requirement does not apply to construction workers or contractors:

- Individuals that provide infrequent services and tasks performed in or for a health care facility are conducted by “one off” vendors, volunteers, and professionals
- Individuals who infrequently provide ad hoc non-health care services (such as annual elevator inspection), or services that are performed exclusively off-site, not at or adjacent to any site of patient care, such as accounting services
- Individuals who may infrequently enter a facility or site of care for specific **limited purposes** and for a **limited amount of time**, but do not provide services by contract or under arrangement, may include delivery and repair personnel
- Individuals wears proper PPE and practices social distancing or works in isolation

CMS strongly encourage facilities, when the opportunity exists and resources allow, to facilitate the vaccination of all individuals who provide services infrequently and are not otherwise subject to the requirements of the Interim Final Rule.

#### **8. What if some of my staff are not fully vaccinated by the 90 day deadline? (12/28/21)**

For staff that are not fully vaccinated, the health center must develop contingency plans for staff who have not completed the primary vaccination series for COVID-19 and **will not** provide care, treatment, or other services for the provider or its patients until such time as such staff have completed the primary vaccination series for COVID-19. Health centers are required to have a plan to achieve 100% staff vaccination rates if they are not in compliance after phase one and phase two deadlines.

Contingency plans should include actions that the health center would take when staff have indicated that they will not get vaccinated and do not qualify for an exemption, but contingency plans should also address staff who are not fully vaccinated due to an exemption or temporary delay in vaccination, such as through the additional precautions.

**Facilities should prioritize contingency plans for those staff that have obtained no doses of any vaccine over staff that have received a single dose of a multi-dose vaccine.** For example, contingency plans could include a deadline for staff to have obtained their first dose of a multiple-dose vaccine. The plans should also indicate the actions the FQHC will take if the deadline is not met, such as actively seeking replacement staff through advertising or obtaining temporary vaccinated staff until permanent vaccinated replacements can be found.

It is to the health center's discretion on the details of the contingency plan and how they will handle unvaccinated staff. Facilities may already have contingency plans that meet the requirements of this Interim Final Rule in their existing Emergency Preparedness policies and procedures.

#### **9. Can staff members attest that they have been vaccinated?**

No, all staff COVID-19 vaccinations must be appropriately documented by the facility.

Examples of acceptable forms of proof of vaccination include:

- CDC COVID-19 vaccination record card (or a legible photo of the card),
- Documentation of vaccination from a health care provider or electronic health record, or
- State immunization information system record

All medical records, including vaccine documentation, must be kept confidential and stored separately from an employer's personnel files, pursuant to Americans with Disabilities Act (ADA) and the Rehabilitation Act. Examples of appropriate places for storing vaccine documentation include a facilities immunization record, health information files, or other relevant documents. Facilities have the flexibility to use the appropriate [tracking tools of their choice](#).

#### **10. Are exemptions allowed? (12/28/21)**

Yes, the Interim Final Rule **requires** facilities to allow exemptions for staff with recognized medical conditions for which vaccines are contraindicated (a medical exemption under the ADA) or for staff who are not vaccinated due to their strongly held religious beliefs, observances, or practices (a religious exemption under Title VII of the Civil Rights Act of 1964 (Title VII)). Employers following CDC guidelines and the new requirements in the Interim Final Rule are required to provide appropriate accommodations, to the extent required by Federal law, for staff who request and receive exemption from vaccination because of a disability, medical condition, or sincerely held religious belief, practice, or observance.

Facilities should establish exemptions as a part of their policies and procedures and in alignment with Federal law. Providers and suppliers must have a process for collecting and evaluating such requests, including tracking and securing documentation of information provided by those staff who have requested exemptions, the facility's decision on the requests, and any accommodations that are provided.

In granting an accommodation, employers must ensure that they minimize the risk of transmission of COVID-19 to at-risk individuals, in keeping with their obligation to protect the health and safety of patients. Employers must also follow Federal laws protecting staff from retaliation for requesting an exemption on account of religious belief or disability status. Please review [the EEOC's FAQ on Religious Objections and Medical Exemptions to COVID-19 Vaccine Mandates](#). (see attachment on page 16)



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. **Staff who are unable to furnish proper exemption documentation must be vaccinated or the facility must follow the actions for unvaccinated staff.**

Staff who have previously contracted COVID-19 **are not** exempt from these vaccination requirements. The regulation permits a “temporary delay” in vaccination, for individuals who recently received monoclonal antibodies, convalescent plasma, or other recommendations due to clinical precautions.

*Note: Surveyors will **not** evaluate the details of the request for a religious exemption, **nor** the rationale for the RHC/FQHC’s acceptance or denial of the request. Rather, surveyors will review to ensure the RHC/FQHC has an effective process for staff to request a religious exemption for a sincerely held religious belief.*

Resource: [Sample Request for Religious Exemption Form](#)

#### **11. What type of policies can I implement for staff who are not yet fully vaccinated or have been granted an exemption? (12/28/21)**

Actions or job modifications a facility can implement to meet this interim requirement include, but are not limited to:

- Reassigning 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);
- Requiring 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.

#### **12. How will this new requirement be enforced on FQHCs? (1/19/22)**

Under the [FQHC guidelines](#), CMS will begin surveying for compliance after January 27, 2022 (Group 1) or February 14, 2022 (Group 2). Compliance will be assessed through observation, interview, and record review as part of the survey process. Surveyors will be guided to focus on the vaccination status and FQHC policies to address vaccination for staff that regularly work in the FQHC.

CMS will follow current enforcement procedures based on the level of deficiency cited during the survey. For instances of non-compliance identified through the survey process, the level of deficiency will be determined based on the following criteria: From 30-60 days following issuance of the guidance, the expected minimum threshold for use in these determinations will be 80%. From 60-90 days following issuance of the guidance, the expected minimum threshold will be 90%. From 90 days on, the expected minimum threshold will be 100%.

Accrediting organizations will be required to update their survey processes to assess facilities they accredit for compliance with applicable vaccination regulations. FQHCs should monitor survey policy changes for other related accrediting organizations.

**Please review CMS IFR Survey Guidance for FQHCs starting on page 12 of this document for more detailed information.**

## **12. Will HRSA enforce the CMS COVID-19 Staff Vaccination Requirement?**

CMS will enforce the requirements under the Interim Final Rule. This regulation is outside of HRSA's jurisdiction and is not currently a requirement under the Health Center Program Compliance Manual. As of now, HRSA will not include requirements under this Interim Final Rule into operational site visits (OSV).

As mentioned above, accrediting organizations will be required to update their survey processes to assess facilities they accredit for compliance with vaccination regulations. FQHCs should monitor survey policy changes for other related accrediting organizations.

## **13. How does the CMS COVID-19 Staff Vaccination Requirement interact with OSHA ETS for Health Care Staff Requirements? (12/29/21)**

[On December 27, 2021](#), OSHA announced the withdrawal of the COVID-19 Healthcare ETS. Under the OSH Act, the Agency was required to issue a final rule as a permanent standard within 6 months of the ETS promulgation. OSHA intends to continue to work expeditiously to issue a final standard that will protect healthcare workers from COVID-19 hazards and strongly encourages all healthcare employers to continue to implement the ETS requirements to protect employees from COVID-19 hazards. As OSHA works towards a permanent regulatory solution, OSHA will vigorously enforce the general duty clause and its general standards, including the Personal Protective Equipment (PPE) and Respiratory Protection Standards, to help protect healthcare employees from the hazard of COVID-19.

CMS believes this Interim Final Rule is complementary to the [OSHA COVID-19 Healthcare ETS](#), which generally applies to all workplace settings where any staff provides health care services or health care support services. Because the OSHA COVID-19 Healthcare ETS targets settings where care is provided for individuals with known or suspected COVID-19, FQHCs are subject to the OSHA COVID-19 Healthcare ETS requirements, unless an exception applies.

The OSHA COVID-19 Healthcare ETS, incorporated into OSHA’s regulations at [29 CFR 1910.502](#), requires covered health care employers to develop and implement a COVID-19 plan to identify and control COVID-19 hazards in the workplace and implement requirements to reduce transmission of COVID-19 in their workplaces related to the following: patient screening and management, standard and transmission-based precautions, personal protective equipment (facemasks, respirators), controls for aerosol-generating procedures, physical distancing of at least six feet when feasible, physical barriers, cleaning and disinfection, ventilation, health screening and medical management, training, anti-retaliation, recordkeeping, and reporting. The OSHA ETS encourages vaccination by requiring employers to provide reasonable time and paid leave for staff vaccinations and any side effects.

A COVID-19 vaccination requirement reduces the likelihood of medical removal of health care staff from the workplace, as required by the OSHA COVID-19 Healthcare ETS. This is yet another way in which the CMS Interim Final Rule protects the individuals who receive services from the providers and suppliers to whom the rule applies by minimizing unpredictable disruptions to operations and care.

Resource: [OSHA ETS for Healthcare Workers FAQ](#), [NACHC OSHA ETS FAQ](#)

#### **14. How does the CMS COVID-19 staff vaccination requirement interact with State and Local laws?**

This rule would preempt some State laws that prohibit employers from requiring their staff to be vaccinated for COVID-19. CMS finds that State and local laws that forbid employers in the State or locality from imposing vaccine requirements on staff directly conflict with the exercise of CMS’ statutory health and safety authority to require vaccinations for staff of the providers and suppliers subject to the Interim Final Rule.

To the extent that State-run facilities that receive Medicare and Medicaid funding are prohibited by State or local law from imposing vaccine mandates on their staff, there is direct conflict between the provisions of this Interim Final Rule (requiring such mandates) and the State or local law (forbidding them). As is relevant here, **this regulation preempts the applicability of any State or local law providing for exemptions to the extent such law provides broader grounds for exemptions than provided for by Federal law and are inconsistent with this regulation.** In these cases, consistent with the Supremacy Clause of the Constitution, CMS intends that the Final Interim Rule preempts State and local laws to the extent the State and local laws conflict with the Final Interim Rule/

**(Updated 1/19/22)**

For questions, please contact [regulatoryaffairs@nachc.org](mailto:regulatoryaffairs@nachc.org)

## **FQHC CMS Omnibus COVID-19 Health Care Staff Vaccination IFR Survey Process**

Below are excerpts from the [CMS FQHC Supplemental Guidance](#) for the Interim Final Rule – Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination. Health centers should review the entire document, which is periodically updated by the EEOC.

### **Survey Process**

Compliance will be assessed through observation, interview, and record review as part of the survey process.

#### 1. Entrance Conference

- Surveyors will ask RHCs/FQHCs to provide vaccination policies and procedures.
  - At a minimum, the policy and procedures must provide:
  - A process for ensuring all required staff have received, at a minimum, the
  - first dose of a multi-dose COVID-19 vaccine, or a one-dose COVID-19 vaccine, before staff provide any care, treatment, or other services for the RHC/FQHC and/or its patients;
  - A process for ensuring that all required staff are fully vaccinated; o A process for ensuring that the RHC/FQHC continues to follow all
  - standards of infection prevention and control practice, for reducing the transmission and spread of COVID-19 in the RHC/FQHC especially by those staff who are unvaccinated or who are not yet fully vaccinated;
  - A process for tracking and securely documenting the COVID-19 vaccination status for all required staff;
  - A process for ensuring all staff obtain any recommended booster doses, and any recommended additional doses for individuals who are immunocompromised, in accordance with the recommended timing of such doses;
  - A process by which staff may request a vaccine exemption from the COVID-19 vaccination requirements based on recognized clinical contraindications or applicable Federal laws, such as religious beliefs or other accommodations
- A process for tracking and securely documenting information confirming recognized clinical contraindications to COVID-19 vaccines provided by those staff who have requested and have been granted a medical exemption to vaccination;
- A process for ensuring that all documentation, which confirms recognized
- clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their

respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains-

- 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; and
- a statement by the authenticating practitioner recommending that the staff member be exempted from the RHC/FQHC's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;
- A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the 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; and
- Contingency plans for staff that are not yet vaccinated for COVID-19 (and without an exemption for medical contraindications or without a temporary delay in vaccination due to clinical considerations as recommended by the CDC and as specified in paragraph (id(3)(x)), including deadlines for staff to be vaccinated.
- The RHC/FQHC will provide a list of all staff and their vaccine status.
  - Including the percentage of unvaccinated staff, excluding those staff that have approved exemptions
  - If any concerns are identified with the staff vaccine status list, surveyors should verify the percentage of vaccinated staff.
  - The RHC/FQHC must identify any staff member remaining unvaccinated because it's medically contraindicated or has a religious exemption.
  - The RHC/FQHC must also identify newly hired staff (hired in the last 60 days).
  - The RHC/FQHC must indicate the position or role of each staff member

## 2. Record Review, interview, and observations:

- Surveyors will review the policy and procedure to ensure all components are present.
- Surveyors will review any contingency plan developed to mitigate the spread of COVID-19 infections by the RHC/FQHC that may include:
  - Requiring unvaccinated staff 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.
  - Reassigning unvaccinated staff 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);



- Requiring at least weekly testing for unvaccinated staff, regardless of whether the facility or service site is located in a county with low to moderate community transmission
- Requiring unvaccinated staff 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
  
- Surveyors will select a sample of staff based on current staff sample selection guidelines. Surveyors should also examine the documentation of each staff identified as unvaccinated due to medical contraindication. The sample should include (as applicable):
  - Direct care staff (vaccinated and unvaccinated)
  - Contracted staff
  - Direct care staff with an exemption
- For each individual identified by the RHC/FQHC as vaccinated, surveyors will:
  - Review RHC/FQHC records to verify vaccination status. Examples of acceptable forms of proof of vaccination include:
    - CDC COVID-19 vaccination record card (or a legible photo of the card),
    - Documentation of vaccination from a health care provider or electronic health record, or
    - State immunization information system record.
  - Conduct follow-up interviews with staff and administration if any discrepancies are identified. If applicable, determine if any additional doses were provided.
  - For each individual identified by the RHC/FQHC as unvaccinated, surveyors will
    - Review RHC/FQHC records
    - Determine, if they have been educated and offered vaccination
    - Interview staff and ask if they plan to get vaccinated, if they have declined to get vaccinated, and if they have a medical contraindication or religious exemption.
      - Request and review documentation of medical contraindication.
      - Request to see employee record of the staff education of the RHC/FQHC policy and procedure regarding unvaccinated individuals.
    - Observe staff providing care to determine compliance with current standards of practice with infection control and prevention.
  
- For each individual identified by the RHC/FQHC as unvaccinated due to a medical contraindication:
  - Review and verify all required documentation.
    - Signed and dated by physician or advanced practice provider

- States the specific vaccine that is contraindicated. The recognized clinical reason for the contraindication with a statement recommending exemption.

General Information: [https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC\\_AA\\_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html)

### **Level of Deficiency**

For instances of non-compliance identified through the survey process, the level of deficiency will be determined based on the following criteria: From 30-60 days following issuance of this memorandum, the expected minimum threshold for use in these determinations will be 80%. From 60-90 days following issuance of this memorandum, the expected minimum threshold will be 90%. From 90 days on, the expected minimum threshold will be 100%. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety not otherwise addressed by the criteria below:

- **Immediate Jeopardy:**

- 40% or more of staff remain unvaccinated creating a likelihood of serious harm

**OR**

- Did not meet the 100% staff vaccination rate standard; observations of noncompliant infection control practices by staff, (e.g., staff failed to properly don PPE) **and** 1 or more components of the policies and procedures were not developed or implemented.

- **Condition Level-**

- Did not meet the 100% staff vaccination rate standard; **and**

- 1 or more components of the policies and procedures were not developed and implemented

**OR,**

- 21-39% of staff remain unvaccinated creating a likelihood of serious harm.

- **Standard Level:**

1. 100% of staff vaccinated and all new staff have received at least one dose; **and**

- 1 or more components of the policies and procedures were not developed and implemented

**OR,**

- Did not meet the 100% staff vaccination rate standard of staff are not vaccinated, but are making good faith efforts toward vaccine compliance.



## **Plan of Correction**

To Qualify for Substantial Compliance and Clear the Citation:

- The RHC/FQHC has met the requirement of staff fully vaccinated (either by staff obtaining additional doses, or replacing unvaccinated staff with vaccinated staff).
- OR,**
- The combined number of staff that are vaccinated (have received a single dose of a vaccine or all of the doses in the multiple dose vaccine series or have received at least one dose of a multiple vaccine series) meet the requirement.

o Staff that has received at least one dose must also have their second dose scheduled.

To Qualify for Substantial Compliance, but the Citation Remains at Standard Level:

- The RHC/FQHC has not met the requirement of staff vaccinated, but has provided

evidence of the unvaccinated staff that have obtained their first dose, AND the remainder of the unvaccinated staff are scheduled for their first dose.

### **Components of a Plan of Correction AND/OR Actions Required for IJ Removal**

Plans of correction or Immediate Jeopardy removal plans for noncompliance should be reviewed to ensure they include the following:

- Correcting any gaps in the facility's policies and procedures.
- Implementation of the facility's contingency plan, that should include a deadline for each unvaccinated staff to have received their first dose of a vaccine.
- Implementation of additional precautions to mitigate the spread of COVID-19 by unvaccinated staff.

### **Good-Faith Effort:**

Surveyors and CMS may lower the citation level and/or enforcement action if they identify that any of the following have occurred **prior to the survey** (note: noncompliance is still cited, only the citation level and enforcement is adjusted).

1. If the RHC/FQHC has no or has limited access to vaccine, and the RHC/FQHC has documented attempts to obtain vaccine access (e.g., contact with health department and pharmacies).



2. If the RHC/FQHC provides evidence that they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc.

**Enforcement Actions**

CMS will follow current enforcement procedures based on the level of deficiency cited during the survey.

## **EEOC Technical Assistance Question and Answers for COVID-19 Vaccinations**

Below are excerpts of relevant Q&As from the EEOC’s “[What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws.](#)” Health centers should review the entire document, which is periodically updated by the EEOC.

### **Title VII and COVID-19 Vaccinations**

**K.12. Under Title VII, how should an employer respond to an employee who communicates that he or she is unable to be vaccinated for COVID-19 (or provide documentation or other confirmation of vaccination) because of a sincerely held religious belief, practice, or observance? (Updated 5/28/21)**

Once an employer is on notice that an employee’s sincerely held religious belief, practice, or observance prevents the employee from getting a COVID-19 vaccine, the employer must provide a reasonable accommodation unless it would pose an undue hardship. Employers also may receive religious accommodation requests from individuals who wish to wait until an alternative version or specific brand of COVID-19 vaccine is available to the employee. Such requests should be processed according to the same standards that apply to other accommodation requests. For more information on requests for religious accommodations related to COVID-19 vaccination requirements, see [Section L, Vaccinations – Title VII and Religious Objections to COVID-19 Vaccine Mandates](#).

EEOC guidance explains that the definition of religion is broad and protects beliefs, practices, and observances with which the employer may be unfamiliar. Therefore, the employer should ordinarily assume that an employee’s request for religious accommodation is based on a sincerely held religious belief, practice, or observance. However, if an employee requests a religious accommodation, and an employer is aware of facts that provide an objective basis for questioning either the religious nature or the sincerity of a particular belief, practice, or observance, the employer would be justified in requesting additional supporting information. See also 29 CFR 1605.

Under Title VII, an employer should thoroughly consider all possible reasonable accommodations, including telework and reassignment. For suggestions about types of reasonable accommodation for unvaccinated employees, see [question and answer K.6.](#), above. In many circumstances, it may be possible to accommodate those seeking reasonable accommodations for their religious beliefs, practices, or observances.



Under Title VII, courts define “undue hardship” as having more than minimal cost or burden on the employer. This is an easier standard for employers to meet than the ADA’s undue hardship standard, which applies to requests for accommodations due to a disability. Considerations relevant to undue hardship can include, among other things, the proportion of employees in the workplace who already are partially or fully vaccinated against COVID-19 and the extent of employee contact with non-employees, whose vaccination status could be unknown or who may be ineligible for the vaccine. Ultimately, if an employee cannot be accommodated, employers should determine if any other rights apply under the EEO laws or other federal, state, and local authorities before taking adverse employment action against an unvaccinated employee

**K.13. Under Title VII, what should an employer do if an employee chooses not to receive a COVID-19 vaccination due to pregnancy? (Updated 10/13/21)**

[CDC recommends](#) COVID-19 vaccinations for everyone aged 12 years and older, including people who are pregnant, breastfeeding, trying to get pregnant now, or planning to become pregnant in the future. Despite these recommendations, some pregnant employees may seek job adjustments or may request exemption from a COVID-19 vaccination requirement.

If an employee seeks an exemption from a vaccination requirement due to pregnancy, the employer must ensure that the employee is not being discriminated against compared to other employees similar in their ability or inability to work. This means that a pregnant employee may be entitled to job modifications, including telework, changes to work schedules or assignments, and leave to the extent such modifications are provided for other employees who are similar in their ability or inability to work. Employers should ensure that supervisors, managers, and human resources personnel know how to handle such requests to avoid [disparate treatment in violation of Title VII](#).

**L. Vaccinations – Title VII and Religious Objections to COVID-19 Vaccine Mandates**

*The EEOC enforces Title VII of the Civil Rights Act of 1964 (Title VII), which prohibits employment discrimination based on religion. This includes a right for job applicants and employees to request an exception, called a religious or reasonable accommodation, from an employer requirement that conflicts with their sincerely held religious beliefs, practices, or observances. If an employer shows that it cannot reasonably accommodate an employee’s religious beliefs, practices, or observances without undue hardship on its operations, the employer is not required to grant the accommodation. See generally [Section 12: Religious Discrimination](#); [EEOC Guidelines on Discrimination Because of Religion](#). Although other laws, such as the Religious Freedom Restoration Act (RFRA), may also protect religious freedom in some circumstances, this technical assistance only describes employment rights and obligations under Title VII.*

**L.1. Do employees who have a religious objection to receiving a COVID-19 vaccination need to tell their employer? If so, is there specific language that must be used under Title VII? (10/28/21)**

Employees must tell their employer if they are requesting an exception to a COVID-19 vaccination requirement because of a conflict between that requirement and their sincerely held



religious beliefs, practices, or observances (hereafter called “religious beliefs”). Under Title VII, this is called a request for a “religious accommodation” or a “reasonable accommodation.”

When making the request, employees do not need to use any “magic words,” such as “religious accommodation” or “Title VII.” 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.

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.

*As an example, here is how [EEOC designed its own form for its own workplace](#). Although the EEOC’s internal forms typically are not made public, it is included here given the extraordinary circumstances facing employers and employees due to the COVID-19 pandemic. (Note: Persons not employed by the EEOC should not submit this form to the EEOC to request a religious accommodation.)*

## **L.2. Does an employer have to accept an employee’s assertion of a religious objection to a COVID-19 vaccination at face value? May the employer ask for additional information? (10/25/21)**

Generally, under Title VII, an employer should assume that a request for religious accommodation is based on sincerely held religious beliefs. However, if an employer has an objective basis for questioning either the religious nature or the sincerity of a particular belief, the employer would be justified in making a limited factual inquiry and seeking additional supporting information. An employee who fails to cooperate with an employer’s reasonable request for verification of the sincerity or religious nature of a professed belief risks losing any subsequent claim that the employer improperly denied an accommodation. *See generally* [Section 12-IV.A.2: Religious Discrimination](#).

The definition of “religion” under Title VII protects nontraditional religious beliefs that may be unfamiliar to employers. While the employer should not assume that a request is invalid simply because it is based on unfamiliar religious beliefs, employees may be asked to explain the religious nature of their belief and should not assume that the employer already knows or understands it. By contrast, Title VII does not protect social, political, or economic views, or personal preferences. [Section 12-I.A.1: Religious Discrimination \(definition of religion\)](#). Thus, objections to COVID-19 vaccination that are based on social, political, or personal preferences, or on nonreligious concerns about the possible effects of the vaccine, do not qualify as “religious beliefs” under Title VII.

The sincerity of an employee’s stated religious beliefs also is not usually in dispute. The employee’s sincerity in holding a religious belief is “largely a matter of individual credibility.” [Section 12-I.A.2: Religious Discrimination \(credibility and sincerity\)](#). Factors that – either alone or in combination – might undermine an employee’s credibility include: whether the employee has acted in a manner inconsistent with the professed belief (although employees



need not be scrupulous in their observance); whether the accommodation sought is a particularly desirable benefit that is likely to be sought for nonreligious reasons; whether the timing of the request renders it suspect (e.g., it follows an earlier request by the employee for the same benefit for secular reasons); and whether the employer otherwise has reason to believe the accommodation is not sought for religious reasons.

The employer may ask for an explanation of how the employee's religious belief conflicts with the employer's COVID-19 vaccination requirement. Although prior inconsistent conduct is relevant to the question of sincerity, an individual's beliefs – or degree of adherence – may change over time and, therefore, an employee's newly adopted or inconsistently observed practices may nevertheless be sincerely held. An employer should not assume that an employee is insincere simply because some of the employee's practices deviate from the commonly followed tenets of the employee's religion, or because the employee adheres to some common practices but not others. No one factor or consideration is determinative, and employers should evaluate religious objections on an individual basis.

When an employee's objection to a COVID-19 vaccination requirement is not religious in nature, or is not sincerely held, Title VII does not require the employer to provide an exception to the vaccination requirement as a religious accommodation.

### **L.3. How does an employer show that it would be an “undue hardship” to accommodate an employee's request for religious accommodation? (10/25/21)**

Under Title VII, an employer should thoroughly consider all possible reasonable accommodations, including telework and reassignment. For suggestions about types of reasonable accommodations for unvaccinated employees, *see* K.6, above. In many circumstances, it may be possible to accommodate those seeking reasonable accommodations for their religious beliefs, practices, or observances without imposing an undue hardship.

If an employer demonstrates that it is unable to reasonably accommodate an employee's religious belief without an “undue hardship” on its operations, then Title VII does not require the employer to provide the accommodation. 42 U.S.C. § 2000e(j). The Supreme Court has held that requiring an employer to bear more than a “de minimis,” or a minimal, cost to accommodate an employee's religious belief is an undue hardship. Costs to be considered include not only direct monetary costs but also the burden on the conduct of the employer's business – including, in this instance, the risk of the spread of COVID-19 to other employees or to the public.

Courts have found Title VII undue hardship where, for example, the religious accommodation would impair workplace safety, diminish efficiency in other jobs, or cause coworkers to carry the accommodated employee's share of potentially hazardous or burdensome work. For a more detailed discussion, *see* [Section 12-IV.B: Religious Discrimination \(discussing undue hardship\)](#).

An employer will need to assess undue hardship by considering the particular facts of each situation and will need to demonstrate how much cost or disruption the employee's proposed accommodation would involve. An employer cannot rely on speculative hardships when faced with an employee's religious objection but, rather, should rely on objective information. Certain common and relevant considerations during the COVID-19 pandemic include, for example,



whether the employee requesting a religious accommodation to a COVID-19 vaccination requirement works outdoors or indoors, works in a solitary or group work setting, or has close contact with other employees or members of the public (especially medically vulnerable individuals). Another relevant consideration is the number of employees who are seeking a similar accommodation (i.e., the cumulative cost or burden on the employer).

**L.4. If an employer grants some employees a religious accommodation from a COVID-19 vaccination requirement because of sincerely held religious beliefs, does it have to grant the requests of all employees who seek an accommodation because of sincerely held religious beliefs? (10/25/21)**

No. The determination of whether a particular proposed accommodation imposes an undue hardship on the conduct of the employer's business depends on its specific factual context. When an employer is assessing whether exempting an employee from getting a vaccination would impair workplace safety, it may consider, for example, the type of workplace, the nature of the employee's duties, the number of employees who are fully vaccinated, how many employees and nonemployees physically enter the workplace, and the number of employees who will in fact need a particular accommodation. A mere assumption that many more employees might seek a religious accommodation to the vaccination requirement in the future is not evidence of undue hardship, but the employer may take into account the cumulative cost or burden of granting accommodations to other employees.

**L.5. Must an employer provide the religious accommodation preferred by an employee if there are other possible accommodations that also are effective in eliminating the religious conflict and do not cause an undue hardship under Title VII? (10/25/21)**

No. If there is more than one reasonable accommodation that would resolve the conflict between the vaccination requirement and the sincerely held religious belief without causing an undue hardship under Title VII, the employer may choose which accommodation to offer. If more than one accommodation would be effective in eliminating the religious conflict, the employer should consider the employee's preference but is not obligated to provide the reasonable accommodation preferred by the employee. If the employer denies the employee's proposed accommodation, the employer should explain to the employee why the preferred accommodation is not being granted.

An employer should consider all possible alternatives to determine whether exempting an employee from a vaccination requirement would impose an undue hardship. *See, e.g.*, K.2. Employers may rely on [CDC recommendations](#) when deciding whether an effective accommodation is available that would not pose an undue hardship.

**L.6. If an employer grants a religious accommodation to an employee, can the employer later reconsider it? (10/25/21)**

The obligation to provide religious accommodations absent undue hardship is a continuing obligation that takes into account changing circumstances. Employees' religious beliefs and practices may evolve or change over time and may result in requests for additional or different religious accommodations. Similarly, an employer has the right to discontinue a previously



granted accommodation if it is no longer utilized for religious purposes, or if a provided accommodation subsequently poses an undue hardship on the employer's operations due to changed circumstances. As a best practice, an employer should discuss with the employee any concerns it has about continuing a religious accommodation before revoking it and consider whether there are alternative accommodations that would not impose an undue hardship.