

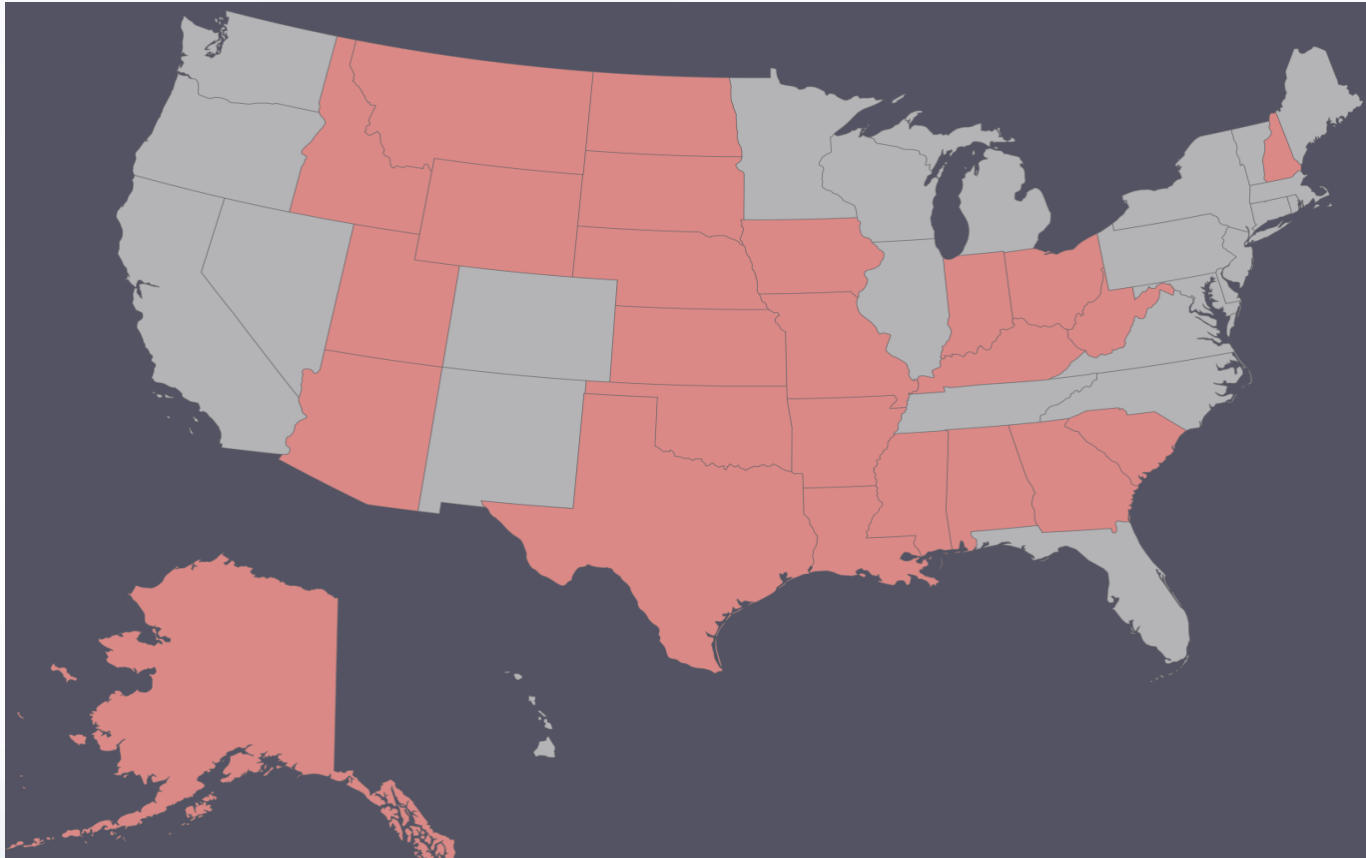
Vaccine Mandate Surveys

January 6, 2022
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VP Clinic Division



UPDATE

States NOT included at this time.



- 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
- Wyoming

Surveyors in these states should not undertake any efforts to implement or enforce the Interim Final Rule with Comment (IFC)

491.8 (d)



The clinic's COVID vaccination policies and procedures apply to the following clinic staff who provide any care, treatment, or other services for the clinic and/or its patients: (491.8(d)(1))

- RHC employees (491.8(d)(1)(i))

- Licensed practitioners (491.8(d)(1)(ii))

- Students, trainees, and volunteers and (491.8(d)(1)(iii))

- Individuals who provide care, treatment, or other services for the clinic and/or its patients under contract or by other arrangement. (491.8(d)(1)(iv))

The RHC COVID vaccination policies and procedures do not apply to the following clinic staff: (491.8(d)(2))

- Staff who exclusively provide telehealth or telemedicine services outside of the clinic setting and do not have any direct contact with patients or provide any care, treatment, or other services in the clinic. (491.8(d)(2)(i))

- Staff who provide support services for the clinic that are performed exclusively outside the clinic and who do not have any direct contact with patients with other staff of the clinic. (491.8(d)(2)(ii))

491.8 (d)



The RHC COVID vaccination policies and procedures must include, at a minimum (491.8(d)(3))

- a. A process that ensures all staff have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the clinic or center and/or its patients. (Cite 491.8(d)(3)(i) if the clinic does not have a process) (Cite 491.8(d)(3)(ii) if all staff are not vaccinated)

***Note:** Except for those staff who have pending requests for, or who have been granted exemptions to the vaccination requirements or those staff for whom COVID1-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations.

491.8 (d)



A process for ensuring that the clinic follows nationally recognized infection prevention and control guidelines intended to mitigate the transmission and spread of COVID-19, and which must include the implementation of additional precautions for all staff who are not fully vaccinated for COVID-19. (491.8(d)(3)(iii))

A process for tracking and securely documenting the COVID-19 vaccination status for all staff. (491.8(d)(3)(iv))

A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC.
(491.8(d)(3)(iv))

A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal Law. (491.8(d)(3)(vi))

491.8 (d)



A process for tracking and securely documenting information provided by those staff who have requested, and for whom the facility has granted, an exemption from the staff COVID-19 vaccination requirements.(491.8(d)(3)(vii))

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: (491.8(d)(3)(viii))

i. All information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognize clinical reasons for the contraindications; and (491.8(d)(3)(viii)(A))

ii. A statement by the authenticating practitioner recommending that the staff member be exempted from the clinic's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications. (491.8(d)(3)(viii)(B))

491.8 (d)

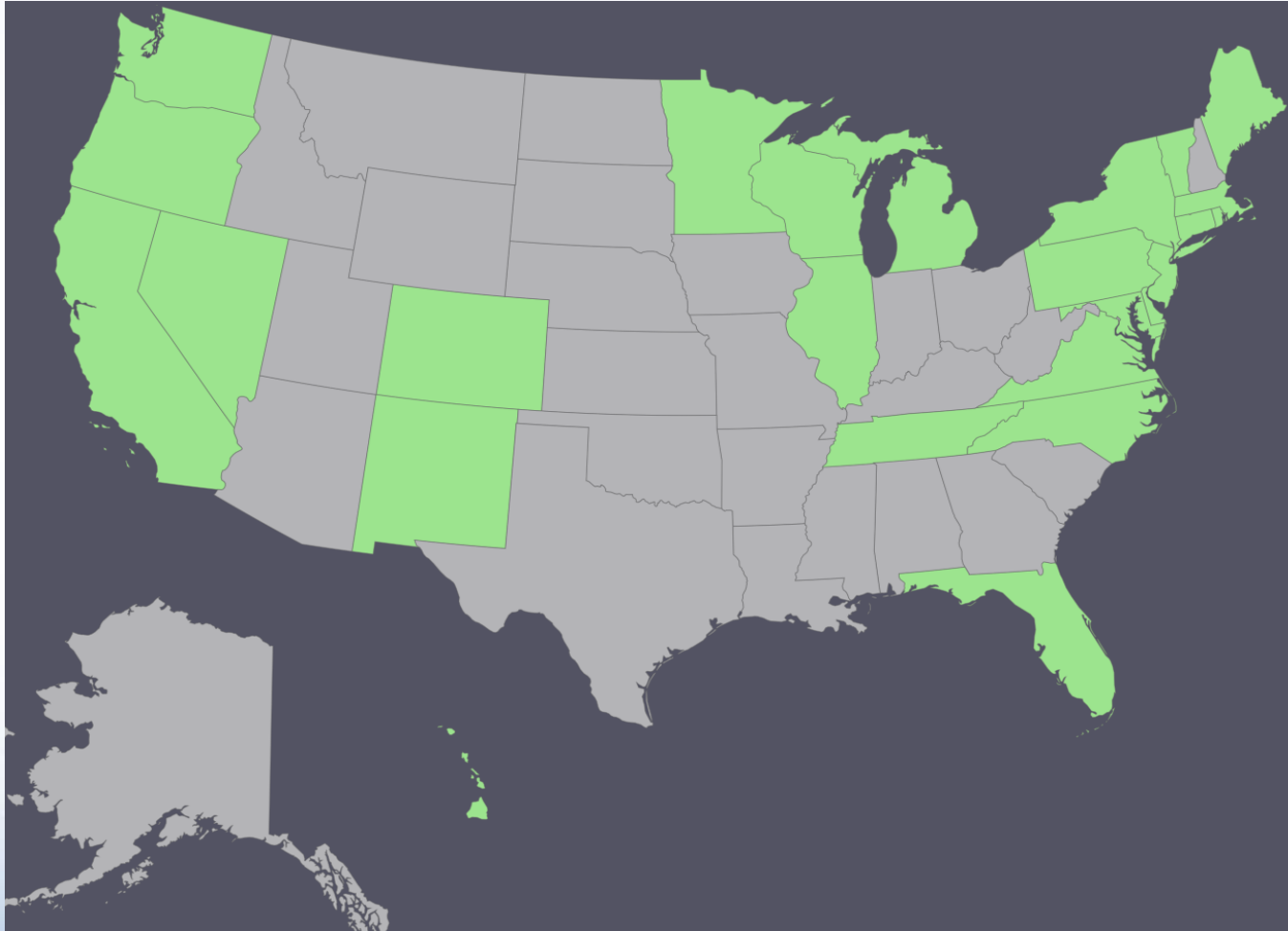


A process for ensuring the tracking and secure documentation of the vaccinations status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19 and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment, and (491.8(d)(3)(ix))

Contingency plans for staff who are not fully vaccinated for COVID-19. (491.8(d)(3)(x))

Note: The term staff in refers to RHC employees, licensed practitioners, students, trainees, volunteers, individuals who provide care, treatment, or other services for the clinic and/or its patients under contract or by other arrangement.

States to be surveyed as of Jan 27, 2021



- 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
- Wisconsin

Key Dates



January 27, 2022: 60 days to come into compliance

February 27, 2022: 30 days to come into compliance

March 27, 2022: **100% Compliance**

By January 27, 2022



Compliant:

- Policies and procedures are developed and implemented for ensuring all facility staff are vaccinated **and** 100% of staff have received at least one dose of COVID-19 vaccine or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule;**

OR

Non-compliant:

- Less than 100% of all staff have received at least one dose of COVID-19 vaccine, or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant under the rule.**
- The facility will receive notice of their non-compliance with the 100% standard. A facility that is above 80% **and** has a plan to achieve a 100% staff vaccination rate within **60** days of January 27, 2022 would not be subject to additional enforcement action. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction and termination.).

By February 28, 2022



Compliant:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or resident contact are vaccinated for COVID-19, including all required components of the policies and procedures specified below (e.g., related to tracking staff vaccinations, documenting medical and religious exemptions, etc.); **and**
- 100% of staff have received the necessary doses to complete the vaccine series (i.e., 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, the **facility is compliant under the rule; or**

Non-Compliant:

- Less than 100% of all staff have received at least one dose of COVID-19 vaccine, or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant under the rule.**
- The facility will receive notice of their non-compliance with the 100% standard. A facility that is above 90% **and** has a plan to achieve a 100% staff vaccination rate within **30** days of February 28, 2022 would not be subject to additional enforcement action.

March 28, 2022



By March 28, 2022 facilities failing to maintain compliance with the 100% standard may be subject to enforcement action.

Within 90 days and thereafter following issuance of the memorandum, facilities failing to maintain compliance with the 100% standard may be subject to enforcement action.

Note: The requirements described above do not include the 14-day waiting period as identified by CDC for full vaccination. Rather these requirements are considered met with the completed vaccine series (i.e., one dose of a single dose vaccine, or final dose of a multi-dose vaccine series).

Policies



The RHC/FQHC policies and procedures must be implemented within **30 days** of the publication of this regulation and address each of the following components:

RHCs/FQHCs must have a process for ensuring all staff (as defined above) have received at least a single-dose, or the first dose of a multi-dose COVID-19 vaccine series prior to providing any care, treatment, or other services for the facility and/or its patients.

Policies



- The policy must also ensure those staff who are not yet fully vaccinated, or who have been granted an exemption or accommodation as authorized by law, or who have a temporary delay, adhere to additional precautions that are intended to mitigate the spread of COVID-19.
- 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.
 - 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)
 - Requiring at **least weekly testing for exempted staff**, and staff who have not completed their primary vaccination series, until the regulatory requirement is met,
 - 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.

Tracking



The RHC/FQHC 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.

Contract or off-site staff



- Facilities that employ or contract staff who telework full-time (e.g., 100 percent of their time is remote from sites of patient care and staff who do work at sites of care) should identify these individuals as a part of implementing the facility's policies and procedures, but those individuals are not subject to the vaccination requirements.
- Note, however, that these individuals may be subject to other federal requirements for COVID-19 vaccination.
- Facilities have the flexibility to use the tracking tools of their choice; however, they must provide evidence of this tracking for surveyor review.
- Additionally, facilities' tracking mechanism should clearly identify each staff's role, assigned work area, and how they interact with patients. This includes staff who are contracted, volunteers, or students.

Vaccination Exemptions



- Facilities must have a process by which staff may request an exemption from COVID-19 vaccination based on an applicable Federal law. This process should clearly identify how an exemption is requested, and to whom the request must be made. Additionally, facilities must have a process for collecting and evaluating such requests, including the tracking and secure documentation of information provided by those staff who have requested exemption, the facility's determination of the request, and any accommodations that are granted.

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

Medical Exemptions



- Certain allergies, or recognized medical conditions may provide grounds for an exemption.
- With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, RHC/FQHCs should refer to the CDC informational document, *Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States*, accessed at <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>.
- In general, CDC considers a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine, or an immediate allergic reaction of any severity to a previous dose, or known (diagnosed) allergy to a component of the COVID-19 vaccine, to be a contraindication to vaccination with COVID-19 vaccines.
- Medical exemption documentation must specify which authorized or licensed COVID-19 vaccine is clinically contraindicated for the staff member and the recognized clinical reasons for the contraindication. The documentation must also include a statement recommending that the staff member be exempted from the RHC/FQHC's COVID-19 vaccination requirements based on the medical contraindications.

Medical Exemptions



- A staff member who requests a medical exemption from vaccination must provide documentation signed and dated by a licensed practitioner acting within their respective scope of practice and in accordance with all applicable State and local laws. The individual who signs the exemption documentation cannot be the same individual requesting the exemption.
- RHC/FQHCs must have a process to track and secure documentation of the vaccine status of staff whose vaccine is temporarily delayed. In addition to medical contraindications, CDC recommends a temporary delay in administering the COVID-19 vaccination due to clinical precautions and considerations such as individuals with acute illness secondary to COVID-19 illness, and individuals who received monoclonal antibodies, or convalescent plasma for COVID-19 treatment.

Non-Medical Exemptions



- Requests for non-medical exemptions, such as a religious exemption in accordance with Title VII, must be documented and evaluated in accordance with each RHC/FQHC's policies and procedures. We direct RHC/FQHC to the Equal Employment Opportunity Commission (EEOC) Compliance Manual on Religious Discrimination (<https://www.eeoc.gov/laws/guidance/section-12-religious-discrimination>) for information on evaluating and responding to such requests.

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.

Accommodations of Unvaccinated Staff with a Qualifying Exemption



- While accommodations could be appropriate under certain limited circumstances, no accommodation should be provided to staff that is not legally required. For individual staff members that have valid reasons for exemption, facility can address those individually. An example of an accommodation for an unvaccinated employee with a qualifying exemption could include mandatory routine COVID-19 testing in accordance with OSHA and CDC guidelines, physical distancing from co-workers and patients, re-assignment or modification of duties, teleworking, or a combination of these actions. Accommodations can be addressed in the RHC/FQHC's policies and procedures.
- Staff who have been granted an exemption to COVID-19 vaccination requirements should adhere to national infection prevention and control standards for unvaccinated health care personnel. For additional information see CDC's Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic webpage.

Contingency Plan



- For staff that are not fully vaccinated, the RHC/FQHC must develop contingency plans for staff who have not completed the primary vaccination series for COVID-19.
- Contingency plans should include actions that the RHC/FQHC 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 RHC/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.

Survey Procedure



- 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.

Survey Procedure



For each individual identified by the RHC as unvaccinated, surveyors will:

- Review RHC 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 or if they have a medical contraindication or religious exemption.
- Request to see employee record of the staff education of the RHC 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.

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%.

Note: If the provider or supplier is a home health agency, hospice or skilled nursing facility, the facility could be subject to civil monetary penalties. This does not apply to Rural Health Clinics.

Level of Deficiency by March 28, 2022



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:

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.

Background



All RHCs/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 RHC/FQHC and/or its patients.

There may be many infrequent services and tasks performed in or for a RHC/FQHC that is conducted by “one-off” vendors, volunteers, and professionals. RHCs/FQHCs are not required to ensure the vaccination of individuals who very infrequently provide ad hoc non-healthcare services (such as annual elevator inspection), 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.

RHCs/FQHCs should consider the frequency of presence, services provided, and proximity to patients and staff.



Thank you for all that you do!

Questions? Email me
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