Q: Are volunteer Board of Director required to comply with the mandate?
A: Yes, they must be fully vaccinated or apply and be granted an exemption. If they are 100% remote, they would be exempt. As with all staff, volunteers, contractors, etc. your process for documentation and maintained documentation should reflect this.

Q: How does the mandate apply to EMS staff?
A: Per the CMS FAQs: “EMS providers are not regulated by CMS health and safety standards; therefore, they are not directly subject to these requirements. Some EMS providers may be subject to the vaccination requirements by virtue of their professional relationship with a health care entity that is regulated by CMS. For example, a hospital may contract with EMS providers and therefore these staff would be included in the requirement.”

Q: What about someone who cleans after hours who has no contact with staff or patients?
A: They are subject to the mandate if they are employees of your RHC. Per the Interim Final Rule (IFR), “Regardless of frequency of patient contact, 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, including employees; licensed practitioners; students, trainees, and volunteers; and individuals who provide care, treatment, or other services for the facility and/or its patients, under contract or other arrangement. This includes administrative staff, facility leadership, volunteer or other fiduciary board members, housekeeping and food services, and others...”

If these individuals are contractors, “facilities should consider frequency of presence, services provided, and proximity to patients and staff.”

Q: Are boosters necessary to be considered “fully vaccinated”?
A: No, boosters are not required in order to meet the definition of “fully vaccinated.” However, booster status must be documented in a staff member’s records along with proof of other COVID-19 vaccinations, if they receive their booster.

Q: With the delay on the rule, what are the relevant effective dates? Have they been postponed?
A: The original dates were December 6 (P&P in place and first shot) and January 4 (fully vaccinated). Currently, the policy cannot be enforced so these dates will change; however, it’s unclear what dates will be established. This will be shared when a decision is made in the courts, but we encourage you to have your COVID-19 Vaccine P&P prepared if necessary.
Q: Do we need to offer exemptions?

A: RHCs are required to establish a process for and offer medical and religious exemptions. There are many templates that you can find for both. Some states have specific forms you must use for these exemptions.

- New staff must also be offered religious and medical exemptions and are subject to the same mandate. Staff at all health care facilities included within the regulation must have received, at a minimum, the first dose of a two-dose COVID-19 vaccine or a one-dose COVID-19 vaccine by the regulatory deadline, or prior to providing any care, treatment, or other services for the facility and/or its patients.

Q: Is it the employer’s responsibility to pay for COVID-19 tests if, for example, weekly testing, is established as an additional precaution for vaccine-exempt staff?

A: The CMS mandate has no language addressing this question. The OSHA guidance says that their mandate "Places no obligation on the employer to pay for costs associated with the regular testing of unvaccinated workers for COVID-19 or their use of face coverings, which will provide a financial incentive for some employees to be fully vaccinated." However, we have heard other perspectives that explain that for employees who are granted a legitimate medical or religious exemption and that testing is incorporated as a requirement (Condition of Employment) to maintain their job that the employer would be obligated to pay. Ultimately, without explicit guidance it may depend on state guidance or Employment Law surrounding conditions of employment. You do also have the option to not include testing as an additional precaution taken for your exempted employees, but we know this is an "easy" option to include in your P&P...

Q: Can Provider-Based RHCs operate under their parent organization’s P&P?

A: This is an area that is not entirely clear and where we are seeking clarification from CMS. The only reference to integrated healthcare systems in current RHC regulation and guidance from Appendix Z relates to emergency preparedness. Regarding survey procedures in this case, the guidance explains:

Survey Procedures
- Verify whether or not the facility has opted to be part of its healthcare system’s unified and integrated emergency preparedness program. Verify that they are by asking to see documentation of its inclusion in the program.
- Ask to see documentation that verifies the facility within the system was actively involved in the development of the unified emergency preparedness program.
- Ask to see documentation that verifies the facility was actively involved in the annual reviews of the program requirements and any program updates.
- Ask to see a copy of the entire integrated and unified emergency preparedness program and all required components (emergency plan, policies and procedures, communication plan, training and testing program).
- Ask facility leadership to describe how the unified and integrated emergency preparedness program is updated based on changes within the healthcare system such as when facilities enter or leave the system.
Q: Will this rule expire at the end of the Public Health Emergency (PHE)?

A: No, per the IFR, “We note that although this IFC is being issued in response to the PHE for COVID-19, we expect it to remain relevant for some time beyond the end of the formal PHE. Depending on the future nature of the COVID-19 pandemic, we may retain these provisions as a permanent requirement for facilities, regardless of whether the Secretary continues the ongoing PHE declarations. Therefore, this rulemaking’s effectiveness is not associated with or tied to the PHE declarations, nor is there a sunset clause. Pursuant to section 1871(a)(3) of the Act, Medicare interim final rules expire 3 years after issuance unless finalized. We expect to make a determination based on public comments, incidence, disease outcomes, and other factors regarding whether it will be necessary to conduct final rulemaking and make this rule permanent.”

Q: What are the additional precautions that must be in place for unvaccinated staff who have been granted an exemption? Can staff take a weekly COVID-19 test or have results showing COVID antibodies?

A: Firstly, per the IFR, documented natural immunity is not a substitute for staff being fully vaccinated. The additional precautions put in place for unvaccinated, exempt staff are at the discretion and enforcement of each RHC and must be included in your P&P. Options include weekly testing, additional PPE, temperature checks, etc. but these must be in addition to normal infection control practices in place in your RHC.

Q: Regarding surveying and enforcement, if the mandate does go into effect and the clinic during the state RHC inspection is found to be out of compliance with the vaccine mandate can the RHC prepare a plan of correction and vaccinate everyone within the 45 days to clear a Condition level deficiency and maintain their RHC status? What are surveyors allowed to ask employees during interviews?

A: CMS will issue interpretive guidelines, which include survey procedures, and will advise and train State surveyors on how to assess compliance with the new requirements among providers and suppliers. Specific levels of deficiencies based on the degree of non-compliance will be established; however, it is our expectation that surveyors will seek to assist RHCs in becoming compliant whenever possible. The interviews with employees will be intended to verify vaccination status and ensure that each RHCS P&P are being followed as written.

Q: If my state has a COVID vaccine requirement already am I required to follow it or is it also on hold?

A: The delay on this rule does not impact your existing mandates. If this rule does go into effect, “this IFC 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 IFC. In these cases, consistent with the Supremacy Clause of the Constitution, the agency intends that this rule preempts State and local laws to the extent the State and local laws conflict with this rule.”

If you are choosing to implement a vaccine mandate prior to the final decision on this Interim Final Rule, we recommend establishing and following your P&P prior to enacting the mandate.
If you have any additional questions please visit the CMS Vaccine Mandate FAQ or contact Sarah Hohman, Deputy Director of Government Affairs at Sarah.Hohman@narhc.org.