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**Vizient Office of Public Policy and Government Relations**

## Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination

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## Background & Summary

On November 4, 2021, the Centers for Medicare & Medicaid Services (CMS) released the interim final rule with comment period, "Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination" (hereinafter "IFC"). The IFC establishes a COVID-19 vaccination requirement (e.g., Condition of Participation) that most Medicare- and Medicaid-certified providers and suppliers (collectively "facilities") must satisfy to participate in the Medicare and Medicaid programs.

Although the IFC went into effect November 5, 2021, there are two phases for implementation. Generally, for Phase 1, by December 6, 2021, staff at all health care facilities included within the IFC must have received at least the first dose of the primary series (or a single dose) of an authorized for emergency use or approved COVID-19 vaccine.[1] For Phase 2, by January 4, 2022, staff at health care facilities must complete the primary vaccination series, unless they have been granted an exemption or the vaccine must be delayed due to clinical precautions and considerations.

Additional information regarding the IFC is available in CMS FAQs. Comments on the IFC are due on January 4, 2022 by 5pm. CMS will consider and respond to comments as a part of potential future rulemaking, if needed.

## Vaccination Requirements

Through the IFC, CMS requires that most Medicare- and Medicaid-certified providers and suppliers ensure that all applicable staff are vaccinated for COVID-19. Facilities included in the IFC are ambulatory surgical centers, hospitals (acute care hospitals, psychiatric hospitals, long-term care hospitals, children's hospital, hospital swing beds, transplant centers, cancer hospitals, and rehabilitation hospitals), critical access hospitals, and home infusions therapy (HIT) suppliers, among others. In the IFC, CMS groups these facilities into four categories: residential congregate care facilities; acute care settings (i.e., hospitals, critical access hospitals (CAHs) and ambulatory surgical centers); outpatient clinical care and services; and home-based care. This summary will focus on requirements for acute care settings, although most of the requirements are consistent among facilities. The requirements do not apply directly to physician offices not regulated by CMS, organ

[1] As of November 4, 2021, this would include the authorized Pfizer-BioNTech (interchangeable with the licensed Comirnaty vaccine made by Pfizer for BioNTech), Moderna, and Janssen (Johnson & Johnson) COVID-19 vaccines. CMS will defer to CDC guidance for COVID-19 vaccination when staff received vaccines outside of the United States or during participation in a clinical trial at a site in the United States.

procurement organizations and portable x-ray suppliers, however, staff working for these organization may need to adhere to the requirements based on their contract with other health care entities subject to CMS vaccine requirements.

The IFC does not require testing for unvaccinated staff, but CMS notes it may consider this requirement in the future.

### Staff Subject to COVID-19 Vaccination Requirements

CMS specifies that the vaccination policy applies to the following facility staff who provide any care, treatment or other services for the facility and/or its patients: facility 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.[2] In the IFC, CMS emphasizes that it believes it is necessary to require vaccination for all staff that interact with other staff, patients, residents, clients, or PACE program participants in any location, beyond those that physically enter facilities, clinics, homes, or other sites of care.

For individuals who provide services 100 percent remotely (e.g., fully remote telehealth or payroll services), CMS provides that they are not subject to the IFC's vaccination requirements. For these employees, CMS specifies that facilities should include in their policies and procedures mechanisms to identify and monitor these individuals, including documenting and tracking overall vaccination status. Notably, these individuals may be subject to other Federal requirements for COVID-19 vaccination (e.g., the Occupational Safety and Health Administration (OSHA) Emergency Temporary Standard on Vaccination and Testing). However, at the time of the IFC's publication, the OSHA Emergency Temporary Standard exempts employees who work remotely 100 percent of the time from the vaccination or testing requirement.

To help facilities identify whether to require COVID-19 vaccination of an individual who does not fall into the categories noted above, CMS provides that facilities should consider frequency of presence, services provided and proximity to patients and staff.

CMS acknowledges current staffing shortages in the IFC. The agency estimates disruptions to staffing and services in the first year would cost $600 million but notes major uncertainties associated with its estimate. **The agency seeks feedback from stakeholders regarding staff turnover.**

### Determining When Staff are Considered Fully Vaccinated

CMS requires that facilities' staff be "fully vaccinated" for COVID-19. For purposes of the IFC, "fully vaccinated" is defined as being two weeks or more since the completion of a

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[2] CMS further specifies that this includes "administrative staff, facility leadership, volunteer or other fiduciary board members, housekeeping and food services, and others. We considered excluding individual staff members who are present at the site of care less frequently than once per week from these vaccination requirements but were concerned that this might lead to confusion or fragmented care." Also, facilities "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."

primary vaccination series. Notably, staff do not need to be “fully vaccinated” by the Phase 2 January 4, 2022 deadline, but they must have completed a primary vaccination series. For example, if an individual receives the first dose of the Moderna mRNA COVID-19 Vaccine 2 or 3 days prior to the Phase 1 deadline, they must wait at least 28 days before receiving the second dose. This second dose must be administered prior to January 4, 2022 and, in the meantime, the individual would be subject to the IFC’s additional precautions until two weeks has passed.

Additionally, the completion of a primary vaccination series for COVID-19 is defined in the requirements as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine. Notably, CMS indicates that for the IFC, and if permitted by CDC, COVID-19 vaccine doses from different manufacturers may be combined to meet the requirements for a primary vaccination series.

Regarding booster doses, CMS requires that facilities have 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. However, staff are not required to receive booster doses.

Since two of the three vaccines licensed or authorized for use in the United States consist of a defined number of doses administered a certain number of weeks apart, CMS has provided two phases for implementation. Each phase is further detailed below.

### Infection Prevention and Control

In the IFC, CMS provides that all facilities must have a process for ensuring the implementation of additional mitigation precautions for all staff who are not fully vaccinated for COVID-19. CMS clarifies that even though several facilities included in this IFC must already meet specific infection prevention and control requirements, these facilities must have a process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all staff who are not fully vaccinated for COVID-19.

As noted above, CMS did not include testing requirements in the IFC. In the IFC, CMS notes it considered requiring daily or weekly testing of unvaccinated individuals but, based on the agency’s review, found vaccination to be a more effective infection control measure. The agency notes that nothing in the IFC removes the obligation on providers and supplier to meet existing requirements to prevent the spread of infection (e.g., entities may conduct regular testing, in addition to source control and physical distancing). **CMS welcomes comment on testing requirements, infection prevention and control cost estimates and alternative approaches.**

### Documentation of Staff Vaccinations

To ensure that facilities are complying with the vaccination requirements of the IFC, CMS requires that they track and securely document the vaccination status of each staff member, including those for whom there is a temporary delay in vaccination (e.g., recent receipt of monoclonal antibodies or convalescent plasma). Vaccine exemption requests and outcomes must also be documented, and these documentation requirements should be part of an ongoing process as new staff are onboarded.

Facilities are required to appropriately document COVID-19 vaccines for all staff. Examples of appropriate places for vaccine documentation include a facility's immunization record, health information files or other relevant documents. All medical records, including vaccine documentation, must be kept confidential and stored separately from an employer's personnel files, pursuant to the Americans with Disabilities Act (ADA) and the Rehabilitation Act. CMS clarifies that facilities have flexibility to use the appropriate tracking tools of their choice and notes that the CDC provides a free staff vaccination tracking tool.

### Vaccine Exemptions

In implementing the IFC, CMS recognizes that some individuals may be eligible for exemptions from the IFC's vaccination requirements under existing Federal law.[3] Therefore, CMS requires facilities to establish and implement a process by which staff may request a vaccination exemption based on an applicable Federal law. CMS notes circumstances that may provide grounds for an exemption (e.g., certain allergies, recognized medical conditions, or religious beliefs, observances or practices).

Applicable staff must be able to request an exemption, and facilities must have a process for collecting and evaluating such requests. For example, the facility's process for collection and evaluation should consider the tracking and secure documentation of information provided by those staff who have requested exemption, the facility's decision on the request and any accommodations that are provided. In the IFC, CMS clarifies that the documentation and evaluation of exemption requests must be done in accordance with applicable Federal law and each facility's policies and procedures.

With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, facilities 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. For staff members who request a medical exemption from vaccination, all documentation – which confirms recognized clinical contraindications to COVID-19 vaccines and supports the staff member's request – must be signed and dated by a licensed practitioner. The licensed practitioner must not be the individual requesting the exemption and must be acting within their respective scope of practice.
Such documentation must specify which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member and the recognized clinical reasons for the contraindications and include a statement by the authenticating practitioner recommending that the staff member be exempted from the vaccination requirements based on the clinical contraindications.

Under Federal law (e.g., ADA and Title VII of the Civil Rights Act of 1964), workers who cannot be vaccinated or tested because of an ADA disability, medical condition, or sincerely

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[3] In the IFC, CMS notes that federal laws, including the ADA, section 504 of the Rehabilitation Act, section 1557 of the Affordable Care Act, and Title VII of the Civil Rights Act, that prohibit discrimination based on race, color, national origin, religion, disability and/or sex, including pregnancy are relevant to consider when providing vaccine exemptions. CMS recognizes that, in some circumstances, employers may be required by law to offer accommodations for some individual staff members. Accommodations can be addressed in the provider or supplier's policies and procedures.

held religious beliefs, practice, or observance may in some circumstances be granted an exemption from their employer. In granting such exemptions, employers must ensure that they minimize the risk of transmission of COVID-19 to at-risk individuals.

Employers must also follow Federal laws protecting employees from retaliation for requesting an exemption on account of religious belief or disability status. For more information about these situations, employers can consult the Equal Employment Opportunity Commission's website.

Notably, CMS states that the IFC preempts the applicability of any State or local law to the extent such law provides broader exemptions than provided for by Federal law and are inconsistent with this IFC.

### Contingency Planning

Since the course of the COVID-19 pandemic remains unpredictable, CMS requires that providers and suppliers make contingency plans to ensure that staff who are not fully vaccinated soon become vaccinated. Staff who are not fully vaccinated are not to provide care, treatment, or other services for the provider or its patients until they have completed the primary vaccination series, or at minimum, have received a single-dose COVID-19 vaccine.

Facility planning should also address the safe provision of services by individuals who have requested an exemption from vaccination while their request is being considered and by those staff for whom COVID-19 vaccination must be temporarily delayed (e.g., per CDC recommendations due to clinical precautions and considerations).

CMS notes that contingency plans could also address special precautions to be taken when there is a regional or local emergency declaration (e.g., hurricane or flooding), which necessitates the temporary utilization of unvaccinated staff to better ensure patient safety.

## Implementation Timeline

CMS reiterates that due to the urgent nature of the vaccination requirements provided in in the IFC, it decided not to issue a proposed rule. Although the IFC was issued as an interim final rule, which generally go into effect immediately, the agency recognizes that compliance with the IFC takes time. As a result, the agency is establishing two implementation phases for the IFC, as further detailed below and in the following table.

Also, the agency notes that even though the IFC is being issued in response to the public health emergency (PHE), its effectiveness is not tied to the PHE declaration and there is not a sunset clause. Under law[4], Medicare interim final rules expire three years after issuance unless finalized. CMS will decide whether to conduct final rulemaking and make

[4] Social Security Act, section 1871(a)(3)

this rule permanent based on public comments, incidence, disease outcomes, and other factors.

### Implementation Phases

By the end of Phase 1 (December 6, 2021), nearly all provisions of the IFC must be met, including requirements that all staff have received, at a minimum, the first dose of the primary series or a single dose COVID-19 vaccine, or requested and/or been granted a lawful exemption, prior to staff providing any care, or other services. Phase 1 also includes the requirements for facilities to have appropriate policies and procedures developed and implemented related to the COVID-19 vaccine as described in the IFC (e.g., policies and procedures to ensure staff are vaccinated for COVID-19, documentation of vaccinations are tracked and maintained, contingency plan for all staff not fully vaccinated).

By the end of Phase 2 (January 4, 2022), all applicable staff must be fully vaccinated for COVID-19, except for those who have been granted exemptions from COVID-19 vaccination or those staff for whom COVID-19 vaccination must be temporarily delayed (i.e., due to clinical precautions and considerations). CMS clarifies that staff who have received the final dose of a primary vaccination series by the Phase 2 effective date (i.e., January 4, 2022) are considered to have met the vaccination requirement, even if the vaccine was administered within two weeks of the deadline and therefore, the employee is not yet "fully vaccinated".

| | Effective Date | New Regulatory Provisions for All Facilities included in the IFC |
|---|---|---|
| Phase 1 | December 6, 2021<br>*(30 days after Federal Register publication)* | All requirements except the requirement for completion of a primary vaccination series for COVID-19. |
| Phase 2 | January 4, 2022<br>*(60 days after Federal Register publication)* | All the requirements for ensuring that all staff have completed the primary vaccination series for COVID-19, except for those staff who have:<br>- Been granted exemptions to the vaccination requirements of this section, or<br>- Not completed the primary series for the vaccine received (including those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations). |

### Enforcement

Consistent with its practice for new or revised requirements, CMS will soon issue interpretive guidelines, which include survey procedures. Also, CMS will advise and train State surveyors on how to assess compliance with the new requirements among facilities. CMS anticipates state survey agencies to perform onsite compliance reviews through standard recertification surveys and assessment of vaccination status on staff on all

complaint surveys. Also, CMS will require accrediting organizations to update survey processes in light of the new vaccination requirements.

Facilities that are cited for noncompliance may be subject to enforcement remedies imposed by CMS depending on the level of noncompliance and the remedies available under Federal law (e.g., civil money penalties, denial of payment for new admissions, or termination of the Medicare/Medicaid provider agreement). CMS will closely monitor the status of staff vaccination rates, provider compliance, and any other potential risks to patient, resident, client, and PACE program participant health and safety.

## Regulatory Changes

To implement the IFC's requirements, CMS provides new regulations for each facility type (as determined by CMS) that must comply (e.g., residential congregate care facilities, acute care facilities, outpatient clinical care and services, and home-based care). These regulations are generally included alongside other regulations that must be met to participate in Medicare. For example, CMS adds a new regulatory text to the hospital "Condition of Participation: Infection prevention and control and antibiotic stewardship programs."[5]

## What's Next?

Although requirements go into effect through a two-phase approach, CMS is accepting comments on the IFC until January 4, 2022.

Vizient's Office of Public Policy and Government Relations looks forward to hearing member feedback on this Interim Final Rule. Stakeholder input plays a major role in shaping future changes to policy. We encourage you to reach out to our office if you have any questions or regarding any aspects of this IFC – both positive reactions and provisions that cause you concern. Please direct your feedback to Jenna Stern, Sr. Regulatory Affairs and Public Policy Director in Vizient's Washington, D.C. office.

[5] 42 CFR 482.42(g)