

Surveying for the New Staff Vaccination Rule  
Acute and Continuing Care Surveyor Training  
January 2022  
Voice Over Script

**Slide 1**

Welcome to the surveyor training for the new interim final rule, Omnibus COVID-19 Health Care Staff Vaccination, known as IFC-6. This new rule establishes COVID-19 vaccination requirements for staff at various types of providers and suppliers, ranging from hospitals to hospices and rural health clinics to long term care providers.

**Slide 2**

On November 5, 2021, CMS published an interim final rule, CMS-3415-IFC entitled, “Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination,” to add requirements that most Medicare- and Medicaid-participating providers and suppliers must meet to participate in the Medicare and Medicaid programs.

The rule requires each provider develop and implement policies and procedures to ensure all staff, regardless of clinical responsibility or level of contact, are fully vaccinated for COVID-19. The requirements will be implemented in a two-phase approach.

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One of the key terms we’d like to highlight is “Staff”.

Staff Refers to individuals who provide any care, treatment, or other services for the provider and/or its residents/patients/clients

Includes provider employees, individuals under contract or arrangement, such as hospice and dialysis staff, therapists, mental health professionals, licensed practitioners, adult students, trainees or volunteers.

Staff would not include anyone who provides only telehealth or support services outside of the provider and does not have direct contact with residents/patients/clients and other staff.

Providers are not required to ensure the vaccination of individuals who very infrequently provide ad hoc, non-health care services (such as annual elevator inspection or services performed exclusively off-site).

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Providers must have policies and procedures that include processes for ensuring:

All staff have received at least a single-dose COVID-19 vaccine or the first dose of a multi-dose COVID-19 vaccine series prior to providing any care or services;

All staff, except those granted an exemption or for whom the vaccine must be temporarily delayed, are fully vaccinated for COVID-19.

Those staff who are not fully vaccinated adhere to additional precautions in order to mitigate the spread of COVID-19;

Staff are able to request an exemption from vaccination for medical or non-medical reasons;

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Policies and Procedures must include processes to ensure documentation for medical exemptions contain all necessary information, and tracks and securely documents the following:

Each staff member's vaccination status, including any boosters received;  
Each staff who has requested and been granted an exemption to vaccination; and  
Each staff for whom the vaccine must be temporarily delayed.

Policies and Procedures must also include processes for contingency plans for staff who are not fully vaccinated.

**Slide 6**

Additional precautions are intended to mitigate the transmission and spread of COVID-19 by staff who have not completed their primary vaccination series, been granted an exemption, or a temporary delay must adhere to additional precautions. There are a variety of actions or job modifications that can be implemented to reduce the risk of transmission by staff, including but not limited to:

Reassignment to non-patient care areas, duties performed remotely, or assignment to residents/patients/clients who are not immunocompromised or unvaccinated.

Additional precautions may also include testing at least weekly, regardless of community transmission;

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**Additional Precautions, continued:**

Additional Precautions may include: requiring staff to follow CDC recommended precautions such as: universal source control and physical distancing measures while in staff meeting rooms, and or the kitchen.

Requiring use of NIOSH-approved N95 or higher-level respirator for source control, at all times. Providers may also consult with their local health department for other actions to reduce transmission.

**Slide 8**

Within 30 days of issuance of QSO 22-07-All, the provider must implement the following:

All staff, prior to providing any care or services, must have received the first dose of a multi-dose COVID-19 vaccine, or a one-dose COVID-19 vaccine, or been granted or have a pending request for exemption, or been identified as having a temporary vaccination delay, **and**

The provider must have developed and implemented policies and procedures.

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Within 60 days of issuance of QSO 22-07-All, The provider must implement the following:

All staff, prior to providing any care or services, must have received all doses of a multi-dose COVID-19 vaccine, or a one-dose COVID-19 vaccine, or been granted a request for an exemption, or been identified as having a temporarily delayed vaccination, **and**

The provider must have developed and implemented policies and procedures.

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As required by the rule, providers must have a process for staff to request an exemption from vaccination that is based on recognized clinical contraindications or applicable federal laws which address religious exemptions. The process should:

Identify how an exemption is requested, and to whom the request must be made;

Address the collection and evaluation of each exemption request, and include secure documentation and tracking of exemption request information. Staff who are unable to furnish proper documentation must be vaccinated or the provider must follow the actions for unvaccinated staff.

**Slide 11**

Certain allergies or medical conditions may provide grounds for a medical exemption. 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, an immediate allergic reaction of any severity to a previous dose, or known allergy to a component of the vaccine, to be a contraindication to COVID-19 vaccination. Staff who requests a medical exemption from COVID-19 vaccination must provide documentation containing all of the required information.

**Certain federal laws may provide grounds for a non-medical exemption**

Requests for non-medical exemptions, such as a religious exemption in accordance with Title VII, must be documented and evaluated in accordance with applicable federal law and each provider's policies and procedures. Surveyors will not evaluate the details of the non-medical exemption request, or the rationale for the provider's acceptance or denial of the request, rather only ensure there is a process for requesting such exemption.

**Slide 12**

CDC recommends temporarily delaying administration of a COVID-19 vaccination due to clinical precautions and considerations such as:

individuals with acute illness secondary to COVID-19 illness, or

individuals who received monoclonal antibodies, or convalescent plasma for COVID-19 treatment.

For more information you can go to the CDC website listed on the slide.

Providers must have a process to securely document and track the status of staff for whom vaccination is temporarily delayed.

**Slide 13**

Providers are required to have contingency plans for staff who are not fully vaccinated. These plans should:

Include actions that will be taken when staff decline vaccination and do not qualify for an exemption, such as:

- deadlines for staff to receive a single-dose vaccine or the first dose of a multi-dose vaccine,
- obtaining temporary vaccinated staff until permanent vaccinated staff can be hired,
- seeking vaccinated staff through advertising.

Contingency plans should address staff who are not fully vaccinated due to an exemption or temporary delay in vaccination, such as implementing additional precautions.

**Slide 14**

Surveyors should review records and **interview staff** to confirm the provider has implemented their contingency plan, if needed, by:

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verifying the actions taken for staff who would not get vaccinated and did not qualify for an exemption. asking when a deadline to receive the first dose of a vaccine was given? Confirm the date. identify what actions were taken, if the deadline has passed.

**Slide 15**

Surveyors will investigate for compliance with these requirements as part of initial, standard recertification, and complaint surveys, beginning 30-days after the issuance of QSO 22-07-All.

**Slide 16**

During the Entrance conference the surveyors will request the following:

COVID-19 policies and procedures for staff vaccination;

A list of all staff and their vaccination status, including:

- the percent of vaccinated staff, and
- the position or role of each staff member, including staff who are in direct contact with residents/patients/clients, regardless of frequency.

**Slide 17**

CMS expects all staff to have received the appropriate number of doses by the timeframes specified in QSO 22-07-All unless exempted as required by law.

Provider staff vaccination rates under 100% constitute non-compliance under the rule.

Non-compliance does not necessarily lead to termination and providers will generally be given opportunities to return to compliance.

**Slide 18**

Let's talk about surveys conducted from day 30 through day 59 following issuance of QSO-22-07-All. The provider is considered compliant if it demonstrates that all policies and procedures are developed and implemented, and, that 100% of staff have received **at least one dose of vaccine**, or have a pending request for, or have been granted an exemption, or has a temporarily delayed vaccination.

**Slide 19**

As we continue discussing surveys at day 30 through 59 following issuance of the memo, providers that have less than 100% of staff who have received at least one dose of a vaccine, or is pending or has been granted an exemption, or has a temporary delay, the provider is noncompliant and will be cited the appropriate tag. If the provider is above 80% and has a plan to achieve 100% vaccination rate within 60 days, they would not be subject to an enforcement action. However, States should work with their CMS location for cases that exceed the 80% threshold, yet pose a threat to resident health and safety.

Providers with less than 80% of staff who have received at least one dose of vaccine, or have a pending request for, or have been granted an exemption, or a temporary delayed vaccination, the provider is noncompliant and will be cited the appropriate tag and could be subject to additional enforcement actions.

**Slide 20**

This slide shows the 30-day staff vaccination formula. When calculating the staff vaccination rate, staff are considered vaccinated when they receive a COVID-19 vaccination. The 14-day waiting period does not have to occur to include the staff in the vaccination rate.

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Here is an example. The Provider employs 98 staff. 55 staff received all doses of a multi-dose vaccine, 39 received one dose of a multi-dose vaccine, 1 has a pending medical exemption request, and 3 have pending requests for religious exemptions.

$55 + 39 + 1 + 3 = 98$     $98 \div 98 = 1 \times 100 = \mathbf{100\% \text{ of staff}}$  are vaccinated, or have a granted or pending exemption.

The Provider is compliant with the 100% vaccination requirement and will not be cited for non-compliance related to their staff vaccination rate.

The Provider may still be cited if non-compliance with the other requirements is identified (for example policies and procedures).

**Slide 22**

Let's look at another example. The Provider employs 165 staff. 122 staff received all doses of a multi-dose vaccine, 17 received only one dose of a multi-dose vaccine, 1 has a pending medical exemption request, 1 has a temporary delay, 3 staff have not received any doses of COVID-19 vaccine and do not have a pending request for an exemption or have been identified as having a temporary delay.

$122 + 17 + 1 + 1 = 141$     $141 \div 165 = 0.854 \times 100 = 85.4$  or **85% of staff** are vaccinated, or have a granted/pending exemption, or have a temporary delay.

The Provider is non-compliant with the 100% vaccination requirement and will be cited using the appropriate tag.

The provider may also be cited if non-compliance with the other requirements (e.g., policies and procedures) is identified.

**Slide 23**

Here is one more example. The Provider employs 100 staff. 58 have received all doses of a multi-dose vaccine, 5 have been granted medical exemptions, 5 have pending religious exemptions, 10 have a temporary delay, and 10 have not received any doses of COVID-19 vaccine and do not have a pending request for an exemption.

$58 + 5 + 5 + 10 = 78$     $78 \div 100 = 0.78 \times 100 = \mathbf{78\% \text{ of staff}}$  are vaccinated, or have a granted or pending exemption, or have a temporary delay.

The Provider is non-compliant with the 100% vaccination requirement and will be cited at the appropriate tag and could be subject to additional enforcement actions depending on the severity of the deficiency.

**Slide 24**

Let's talk about enforcement thresholds for surveys conducted between days 60 and 89 following issuance of QSO-22-07-All. Again, providers are expected to be 100% compliant with the requirements. A provider is compliant if all policies and procedures have been developed and implemented, and 100% of all staff have received the necessary doses to complete the primary vaccine series, or have been granted an exemption, or have been identified as having a temporary delay for vaccination.

**Slide 25**

For surveys at day 60 through 89, following issuance of the memo, providers that have less than 100% of staff who have completed their primary vaccination series, which means a single dose vaccine, or all doses of a multiple dose vaccine series, or has been granted an exemption, or a temporary delay, the provider is noncompliant and will be cited using the appropriate tag. If the provider is above 90% **and** has a plan to achieve 100% vaccination rate within 30 days, they would not be subject to an

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enforcement action. However, States should work with their CMS location for cases that exceed the 90% threshold, yet pose a threat to resident health and safety.

Providers with less than 90% of staff having completed their primary vaccination series, or have been granted an exemption, or a temporary delayed vaccination, the provider is noncompliant and will be cited at the appropriate tag and could be subject to additional enforcement actions.

**Slide 26**

This slide shows the 60 day and thereafter staff vaccination formula. Surveyors should note that for purposes of calculating the staff vaccination rate, staff are considered vaccinated when they receive a COVID-19 vaccination. The 14-day waiting period does not have to occur to include the staff in the vaccination rate. Please note for surveys at day 60 and beyond, if the provider's staff vaccination rate is below 100% because of newly hired staff, who are not yet eligible to receive the second dose in a two-dose series, the provider will be considered compliant with the 100% staff vaccination requirement.

**Slide 27**

On this slide we have an example of this enforcement threshold. The Provider employs 211 staff. 107 staff received all doses of a multi-dose vaccine, 99 staff received a single-dose vaccine, 3 have been granted medical exemptions, and 2 have a temporary delay.

$107 + 99 + 3 + 2 = 211$      $211 \div 211 = 1 \times 100 = \mathbf{100\%}$  of staff are vaccinated, have a granted exemption, or have a temporary delay.

The Provider is compliant with the 100% vaccination requirement and will not be cited for non-compliance related to staff vaccination rate.

The Provider may still be cited if non-compliance with the other requirements (e.g., policies and procedures) is identified.

**Slide 28**

Lets' look at another example. The Provider employs 38 staff. 13 staff received all doses of a multi-dose vaccine, 17 received a single-dose vaccine, 5 have a temporary delay, and 3 have not received any doses of COVID-19 vaccine and have not been granted an exemption.

$13 + 17 + 5 = 35$      $35 \div 38 = 0.921 \times 100 = 92.1$  or **92%** of staff are vaccinated, have a granted exemption, or a temporary delay.

The Provider is non-compliant with the 100% vaccination requirement and will be cited using the appropriate tag.

The Provider may also be cited if non-compliance with the other requirements (e.g., policies and procedures) is identified.

**Slide 29**

Here is one more example of the 60day threshold. The Provider employs 83 staff. 30 staff received all doses of a multi-dose vaccine, 35 received a single-dose vaccine, 2 have a temporary delay and 16 have not received any doses of COVID-19 vaccine and do not have an exemption.

$30 + 35 + 2 = 67$      $67 \div 83 = 0.807 \times 100 = 80.7$  or **81%** of staff are vaccinated, have a granted exemption, or have a temporary delay.

The Provider is non-compliant with the 100% vaccination requirement and will be cited at the appropriate tag and could be subject to enforcement actions depending on the severity of the deficiency.

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**Slide 30**

And finally, the last enforcement threshold occurs 90 days following issuance of QSO-22-07-All. Providers are expected to be 100% compliant with the requirements. A provider is considered compliant if it demonstrates that all policies and procedures have been developed and implemented, and 100% of all staff have received the necessary doses to complete the primary vaccine series, which means a single dose vaccine, or all doses of a multiple dose vaccine series, or have been granted an exemption, or have been identified as having a temporary delay for vaccination.

**Slide 31**

Here is an example of calculating the percent of staff vaccinated at 90 days: The Provider employs 304 staff. 133 staff received all doses of a multi-dose vaccine, 167 received a single-dose vaccine, 1 has been granted a medical exemption, and 3 have been granted a non-medical exemption.

$133 + 167 + 1 + 3 = 304$   $304 \div 304 = 1 \times 100 = \mathbf{100\%}$  of staff are vaccinated, have a granted exemption, or have a temporary delay.

The Provider is compliant with the 100% vaccination requirement and will not be cited for non-compliance related to staff vaccination rate.

The Provider may still be cited if non-compliance with the other requirements (e.g., policies and procedures) is identified.

**Slide 32**

Another example of calculating the percentage of staff at 90 days: The Provider employs 156 staff. 119 staff received all doses of a multi-dose vaccine, 28 received a single-dose vaccine, and 9 received one dose of a multi-dose vaccine.

$119 + 28 = 147$   $147 \div 156 = 0.942 \times 100 = 94.2$  or **94% of staff** vaccinated, have a granted exemption, or have a temporary delay.

The Provider is non-compliant with the 100% vaccination requirement and will be cited using the appropriate tag.

The provider may also be subject to enforcement actions.

**Slide 33**

Now we are going to switch gears and talk about how surveyors will investigate for these requirements. Surveyors will review the provider's policies and procedures. You will use the appropriate survey process outlined and interpretive guidance to determine if the provider meets the requirements. Investigations should be focused on staff that provide services in the provider on a regular basis, for example weekly.

**Slide 34**

Surveyors will use their standard process for determining sample size based on provider type and the number of staff for each provider.

This sample should include - Vaccinated direct care staff, contracted staff, medical exemptions, non-medical exemptions, temporary delays and unvaccinated staff.

**Slide 35**

Surveyors should observe and interview sampled unvaccinated staff to determine if additional precautions are in place. Consider the following: Are unvaccinated staff using additional precautions,

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including universal source control (use a NIOSH-approved N95 or equivalent or higher-level respirator for source control) and physical distancing at all times while in the provider?

If reassigned, when were staff reassigned duties?

Are unvaccinated staff being tested for COVID-19? If so, how often?

Determine whether other additional precautions are in place to mitigate the transmission of COVID-19.

**Slide 36**

In addition to Observation and interview, surveyors must review documentation to verify staff vaccination status. Documentation must demonstrate administration of a single dose vaccine, or all required doses for a multi-dose vaccination series, and any booster doses received.

**Slide 37**

Surveyors will review documentation to determine if medical exemption requests are secure, tracked and contain:

which COVID-19 vaccine is clinically contraindicated;

the recognized clinical reason for the contraindication;

a statement recommending the staff be exempted from vaccination requirement; and

a signature and date by a licensed practitioner, who is not the individual requesting the exemption.

**Slide 38**

Surveyors will review non-medical exemption documentation to determine if the requests are secure and tracked, and to determine what the process is to request a non-medical exemption, and how staff are informed about the process to request a non-medical exemption. Please note, surveyors do not evaluate the details of the request for a non-medical (e.g., religious) exemption **or** the rationale for the provider's acceptance or denial of the request.

**Slide 39**

For staff whose vaccination has been temporarily delayed, surveyors will determine if the documentation is secure, tracked and includes:

- the reason for delaying COVID-19 vaccination;
- how long the delay is expected; and
- a plan for vaccination when the delay is over.

If the timeframe for the temporary delay has passed, evaluate whether the staff member was vaccinated.

**Slide 40**

Surveyors should interview staff and review documentation for unvaccinated staff without an exemption or temporarily delayed vaccination to determine:

If the staff is scheduled to receive a COVID-19 vaccine? If so, confirm it is scheduled.

If the staff isn't scheduled to receive a vaccine: Did the staff request an exemption?

When did the provider become aware staff did not have an exemption or a reason for temporary delay?

What actions did the provider take to educate and offer COVID-19 vaccines to staff?

What actions did the provider take when staff indicated that they will not get vaccinated and do not qualify for an exemption?

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If the provider is non-compliant with the 100% vaccination requirement and/or has not developed and implemented the required policies and procedures, cite the appropriate federal tag.

The level of deficiency for noncompliance is based on the level of harm, or likelihood of harm. For example, providers with a high percentage of unvaccinated staff, breeches in infection control processes, and gaps in their policy and procedures, represent a higher risk of harm. Therefore, these providers would be cited at a higher level of severity than providers with few unvaccinated staff, no COVID-19 infections, and compliant policy and procedures.

**Slide 42**

CMS may use discretion to lower level of deficiency of a citation and/or enforcement action if the following occurred prior to the survey:

The provider has limited or no access to vaccines, and/or

The provider provides evidence that they have taken aggressive steps to have all staff vaccinated.

**Slide 43**

Surveyors will assign severity based on the criteria listed in Attachment B-N. Let's look Immediate Jeopardy. Noncompliance resulting in serious harm or death exists when the provider:

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.

**Slide 44**

Condition Level Deficiency - 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.

**Slide 45**

Standard Level Deficiency - 100% of staff are 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, but are making good faith efforts toward vaccine compliance.

**Slide 46**

To qualify for substantial compliance and clear the citation:

The provider has met the requirement of staff vaccinated or

The combined number of staff that are vaccinated or have received at least one dose of a multiple dose vaccine series meet the expected minimum threshold of staff vaccinated.

- Staff who have received at least one dose of a multiple vaccine series must also have their second dose scheduled.

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**Slide 47**

To qualify for substantial compliance, but the citation remains at Standard Level

The provider has not met the expected minimum threshold of staff vaccinated, but has provided evidence that some of the unvaccinated staff have obtained their first dose, AND other unvaccinated staff are scheduled for their first dose.

For example, the citation would continue if there is evidence that 50% of staff who were identified as unvaccinated have received one dose of a multiple vaccine series with their second dose scheduled, or are scheduled to receive one dose of a single-dose vaccine series.

**Slide 48**

Components of POC and/or actions required for IJ removal:

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

Correcting any gaps in the provider's policies and procedures.

Implementation of the provider'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.

**Slide 49**

For questions regarding requirements, please email: [DCACP@CMS.HHS.GOV](mailto:DCACP@CMS.HHS.GOV)