Hello, and welcome to the Long-Term Care Surveyor Training for the new Staff Vaccination Requirement.
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,” revising the infection control requirements that most Medicare- and Medicaid-participating Facilities and suppliers must meet to participate in the Medicare and Medicaid programs.

The rule requires each facility develop and implement policies and procedures to ensure all staff, regardless of clinical responsibility or resident contact, are fully vaccinated for COVID-19.

The long-term care requirements will be located in the new federal tag F888 and will be implemented in a two-phase approach.
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 facility and/or its residents.

Includes facility 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 facility and does not have direct contact with residents and other staff.

Facilities 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).
Facilities 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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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;
Facilities must have policies and procedures that include processes for:

- Ensuring documentation for medical exemption requests contains all of the necessary information;
- Tracking and securely documenting:
  - each staff member’s vaccination status, including any booster doses received,
  - staff who have requested and were granted an exemption to vaccination,
  - staff for whom the vaccine must be temporarily delayed; and
- Contingency plans for staff who are not fully vaccinated.

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.
There are a variety of actions or job modifications a facility can implement to potentially reduce the risk of COVID-19 transmission by staff who have not completed their primary vaccination series, have a pending or granted exemption, or have a temporary delayed vaccination, including, but not limited to:

- Reassigning 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 residents who are not immunocompromised, unvaccinated).

- Requiring staff testing at least weekly, regardless of the community level of transmission;

Additional precautions must be consistent with the regulation, which states that these precautions are, “intended to mitigate the transmission and spread of COVID-19 for all staff who are not fully vaccinated (i.e., who have not completed their primary vaccination series, been granted an exemption, or a temporary delay must adhere to additional precautions). The guidance and this training provide examples 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 who are not immunocompromised or unvaccinated.

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

Note: Any precautions implemented must be consistent with the regulation, which states that these precautions are, “intended to mitigate the transmission and spread of COVID-19 for all staff who are not fully vaccinated.”
• Requiring staff to follow additional CDC-recommended precautions, even if the facility is located in a county with low to moderate community transmission, such as:
  • adhering to universal source control, and
  • physical distancing measures in areas that are restricted from resident access (e.g., staff meeting rooms, kitchen).
• Requiring staff to use a NIOSH-approved N95 or equivalent or higher-level respirator for source control, whether or not they are in contact with residents.
• Facilities may also consult with their local health department to identify other actions that can potentially reduce the risk of COVID-19 transmission by staff who are not fully vaccinated.

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.

Facilities may also consult with their local health department for other actions to reduce transmission.
Within 30 days of Issuance of QSO Memorandum

The facility 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 facility must have developed and implemented policies and procedures (except 483.80 (i)(3)(iii)).

Within 30 days of issuance of QSO-22-07-ALL-Revised, QSO-22-09-ALL-Revised, and QSO 22-11-ALL-Revised, The facility 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 facility must have developed and implemented policies and procedures (except 483.80 (i)(3)(iii)).
Within 60 days of issuance of QSO-22-07-ALL-Revised, QSO-22-09-ALL-Revised, and QSO 22-11-ALL-Revised, The facility 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 facility must have developed and implemented policies and procedures for §483.80 (i)(3)(ii).
Exemptions from Staff Vaccination Requirements

- Facilities must have a process for staff to request an exemption from COVID-19 vaccination based on recognized clinical contraindications or applicable Federal laws addressing religious exemptions.
- The process should:
  - identify how an exemption is requested;
  - identify to whom the request must be made;
  - include collection and evaluation of exemption requests; and
  - include secure documentation and tracking of exemption request information.

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

As required by the rule, facilities 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 facility must follow the actions for unvaccinated staff.
**Exemptions from Vaccination Requirements**

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<tr>
<th>Certain allergies or medical conditions may provide grounds for a medical exemption</th>
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<td>• 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, 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. See the CDC’s <a href="https://www.cdc.gov/vaccines/COVID-19/interim-considerations.html">Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States</a>.</td>
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<td>• Staff who requests a medical exemption from COVID-19 vaccination must provide documentation containing all of the required information.</td>
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<td>• 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 facility’s policies and procedures.</td>
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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 facility’s policies and procedures. Surveyors will not evaluate the details of the non-medical exemption request, or the rationale for the facility’s acceptance or denial of the request, rather only ensure there is a process for requesting such exemption.
In addition to medical contraindications, CDC recommends temporarily delaying administration of a COVID-19 vaccination due to clinical considerations such as: *known COVID-19 infection until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met.*

- See the CDC’s Summary Document for Interim Clinical Considerations for all clinical precautions. [https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf](https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf)
- Facilities must have a process to securely document and track the status of staff for whom vaccination is temporarily delayed.

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

individuals with known COVID-19 infection until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met.

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

Facilities must have a process to securely document and track the status of staff for whom vaccination is temporarily delayed.
Facilities are required to have contingency plans for staff who are not fully vaccinated and should:

- Include actions the facility will take when staff decline vaccination and do not qualify for an exemption, such as:
  - establishing a deadline 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,
  - actively seeking vaccinated staff through advertising.

- Address staff who are not fully vaccinated due to an exemption or temporary delay in vaccination, such as implementing additional precautions.

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

- 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.
- identifying what actions were taken, if the deadline has passed.
Surveying for the New Staff Vaccination Rule: Long Term Care Surveyor Training

Survey Process for Compliance *Revised*

- 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-Revised, QSO-22-09-ALL-Revised, and QSO 22-11-ALL-Revised.

- Updated survey tools include:
  - CMS 20054, Infection Prevention, Control & Immunizations.
  - LTCSP Procedure Guide,
  - COVID-19 Focused Infection Control (FIC) Survey Protocol, and
  - Entrance Conference Worksheets
  - COVID-19 Staff Vaccination Matrix

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Updated survey tools include:

- CMS 20054, Infection Prevention, Control & Immunizations,
- LTCSP Procedure Guide,
- COVID-19 Focused Infection Control (FIC) Survey Protocol, and
- Entrance Conference Worksheets
- COVID-19 Staff Vaccination Matrix
As part of Offsite Preparation, surveyors will begin by comparing the facility’s staff vaccination data provided to the surveyors with what is reported to NHSN. Instructions over the next several slides will describe this process. First, obtain the facility's staff COVID-19 vaccination data from NHSN. The data can be obtained through a link provided in the IPC Task and on the CMS COVID-19 Nursing Home Data webpage.

The facility’s vaccination rate is listed in the column titled, “Recent Percentage of Staff who are Fully Vaccinated.”

Record the percentage of staff from the column above in the IPC Task.
During the Entrance conference the surveyor Requests the following:

Policies and procedures for staff vaccination;

A numbered list of resident and staff COVID-19 cases over the last 4 weeks, indicating whether any residents were hospitalized or expired; and

A list of staff (refer to COVID-19 Staff Vaccination Matrix) and their vaccination status, including:

  o the title, position, and assigned work area of each staff member

Note: Facilities may use the COVID-19 Vaccination Matrix for Staff or provide their own list of all staff as long as all information requested by the surveyor is included.

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Facility staff who have been suspended or are on extended leave e.g., Family and Medical Leave Act (FMLA) leave, or Worker’s Compensation Leave, would not count as unvaccinated staff for the determining compliance.
During the Entrance conference the surveyor **Requests** the following:

Information on how the facility ensures that their contractor staff are compliant with the vaccination requirement.

A list of contract companies that provide services to the facility/residents which includes:

- The name of the contract company; and
- whether the company provides direct care or non-direct care; and
- how often services are provided (e.g., daily, weekly); and
- the approximate number of contract staff provided by the company.
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<th>Investigative Procedures</th>
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**Compare** the NHSN data retrieved during offsite prep to the staff vaccination information provided by the facility. The percent of staff vaccinated obtained from NHSN and provided by the facility should be reasonably consistent, but may not be exactly the same due to reporting lag time.

- If there is a 10% or less difference between the NHSN data and data obtained onsite, no further investigation is required.
- If there is a 10% or greater difference, interview facility staff and review the documentation to determine which source is incorrect and the explanation for the discrepancy.

Once onsite, after the facility has provided the staff vaccination status, the survey team will compare the NHSN data retrieved during offsite prep to the staff vaccination information provided by the facility. The percent of staff vaccinated obtained from NHSN and provided by the facility should be reasonably consistent, but may not be exactly the same due to reporting lag time.

If there is a 10% or less difference between the NHSN data and data obtained onsite, no further investigation is required.

If there is a 10% or greater difference, determine which source is incorrect and the explanation for the discrepancy.
If the facility information is incorrect and NHSN is correct, or both sources are incorrect, it is likely the facility has failed to have a process for tracking and securely documenting, consider citing F888.

If the information reported to NHSN is incorrect, and information reviewed onsite is correct, instruct the facility to immediately correct the NHSN information.

If the surveyor identifies that a data field is blank, instruct facilities to obtain additional information on submitting data to NHSN by emailing NH_COVID_Data@cms.hhs.gov.

**Note:** The determination that one source is incorrect does not automatically infer that the other source is correct.
CMS expects all staff to have received the appropriate number of doses by the timeframes specified in QSO-22-07-ALL-Revised, QSO-22-09-ALL-Revised, and QSO 22-11-ALL-Revised unless exempted as required by law.

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

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

NOTE: Failure of contract staff to provide evidence of vaccination status reflects noncompliance and should be cited at F888 under the requirement to have policies and procedures for ensuring that all staff are fully vaccinated, except for those staff who have been granted exemptions or a temporary delay at 483.80(i)(3)(ii).
Let’s talk about surveys conducted from day 30 through day 59 following issuance of QSO-22-07-ALL-Revised, QSO-22-09-ALL-Revised, and QSO 22-11-ALL-Revised. The facility 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 COVID-19 vaccine, have a pending request for or have been granted an exemption, or has a temporarily delayed vaccination.
Temporary Enforcement Thresholds - 30-days(cont.)

For surveys conducted days 30 – 59 (cont.)

If a facility demonstrates 80% - 99% of staff received at least one dose of a COVID-19 vaccine, have a pending request for or have been granted an exemption, or have a temporarily delayed vaccination, the facility is non-compliant with the 100% vaccination requirement.

• The facility will be cited using tag F888 on the CMS-2567.
• If the facility is above 80% and has a plan to achieve a 100% staff vaccination rate within 60 days they would not be subject to an enforcement action.

States should work with their CMS location for cases that exceed the 80% threshold, yet pose a threat to resident health and safety.

If a facility demonstrates less than 80% of staff received at least one dose of COVID-19 vaccine, have a pending request for or have been granted an exemption, or have a temporarily delayed vaccination, the facility is non-compliant with the 100% vaccination requirement.

• The facility will be cited at tag F888 and could be subject to additional enforcement actions.

Note: Use the Phase 1 staff vaccination formula to calculate vaccination rates days 30-59.

As we continue discussing surveys at day 30 through 59 following issuance of the memo, facilities 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 facility is noncompliant and will be cited using F888. If the facility 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.

Facilities 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 facility is noncompliant and will be cited at F888 and could be subject to additional enforcement actions.
For the purpose of calculating the staff vaccination rate, staff are considered vaccinated when they receive a COVID-19 vaccination. The 14-day waiting period, as defined by the CDC, does not have to occur for the staff to be included in the vaccination rate.

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.
Here is an example. The Facility 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.

\[55 + 39 + 1 + 3 = 98\]
\[98 \div 98 = 1 \times 100 = 100\% \text{ of staff are vaccinated, have a granted/pending exemption, or a temporary delay.}\]

- The Facility is compliant with the 100% vaccination requirement and will not be cited for non-compliance related to their staff vaccination rate.
- The Facility may still be cited if non-compliance with the other requirements (e.g., policies and procedures) is identified.
Let’s look at another example. The Facility 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.

\[ 122 + 17 + 1 + 1 = 141 \quad 141 \div 165 = 0.854 \times 100 = 85.4 \text{ or } 85\% \text{ of staff are vaccinated, have a granted/pending exemption, or have a temporary delay.} \]

The Facility is non-compliant with the 100% vaccination requirement and will be cited using tag F888.

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

- $58 + 5 + 5 + 10 = 78$  
  - $78 \div 100 = 0.78 \times 100 = \textbf{78\% of staff}$ are vaccinated, have a granted/pending exemption, or have a temporary delay.
  
- The Facility is non-compliant with the 100% vaccination requirement and will be cited at F888 and could be subject to additional enforcement actions depending on the severity of the deficiency.

Here is one more example. The Facility 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.

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

The Facility is non-compliant with the 100% vaccination requirement and will be cited at F888 and could be subject to additional enforcement actions depending on the severity of the deficiency.
Let’s talk about enforcement thresholds for surveys conducted between days 60 and 89 following issuance of QSO-22-07-ALL-Revised, QSO-22-09-ALL-Revised, and QSO 22-11-ALL-Revised. Again, facilities are expected to be 100% compliant with the requirements. A facility 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.
For surveys conducted days 60 – 89 (cont.)

If a facility demonstrates 90% - 99% of staff have received a single-dose vaccine, all doses of a multi-dose vaccine, or have been granted an exemption, or identified as having a temporary delay, the facility is non-compliant with the 100% vaccination requirement.

- The facility will be cited using tag F888 on the CMS-2567.
- If the facility has a plan to achieve a 100% staff vaccination rate within 30 days they would not be subject to an enforcement action.

States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to resident health and safety.

If a facility demonstrates less than 90% of staff have received a single-dose vaccine, all doses of a multi-dose vaccine, have been granted an exemption, or identified as having a temporary delay, the facility is non-compliant with the 100% vaccination requirement.

- The facility will be cited using tag F888 and could be subject to additional enforcement actions.

Note: Use the Phase 2 staff vaccination formula to calculate vaccination rates days 60 and beyond.

For surveys at day 60 through 89, following issuance of the memo, facilities 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 facility is noncompliant and will be cited using F888. If the facility is above 90% and has a plan to achieve 100% vaccination rate within 30 days, they would not be subject to an 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.

Facilities with less than 90% of staff having completed their primary vaccination series, or have been granted an exemption, or a temporary delayed vaccination, the facility is noncompliant and will be cited at F888 and could be subject to additional enforcement actions.
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 facility’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 facility will be considered compliant with the 100% staff vaccination requirement.
The Facility 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.

\[ 107 + 99 + 3 + 2 = 211 \quad \frac{211}{211} = 1 \times 100 = 100\% \text{ of staff} \]

- 107 + 99 + 3 + 2 = 211  \quad 211 \div 211 = 1 \times 100 = 100\% \text{ of staff}

- The Facility is compliant with the 100% vaccination requirement and will not be cited for non-compliance related to staff vaccination rate.
- The Facility may still be cited if non-compliance with the other requirements (e.g., policies and procedures) is identified.

On this slide we have an example of this enforcement threshold. The Facility 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.

\[ 107 + 99 + 3 + 2 = 211 \quad \frac{211}{211} = 1 \times 100 = 100\% \text{ of staff} \]

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

The Facility may still be cited if non-compliance with the other requirements (e.g., policies and procedures) is identified.
The Facility 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 Facility is non-compliant with the 100% vaccination requirement and will be cited using tag F888.
- The Facility may also be cited if non-compliance with the other requirements (e.g., policies and procedures) is identified.

Let's look at another example. The Facility 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.

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

The Facility is non-compliant with the 100% vaccination requirement and will be cited using tag F888.

The Facility may also be cited if non-compliance with the other requirements (e.g., policies and procedures) is identified.
The Facility 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 ÷ 83 = 0.807 x 100 = 80.7 or 81% of staff are vaccinated, have a granted exemption, or have a temporary delay.

• The Facility is non-compliant with the 100% vaccination requirement and will be cited at F888 and could be subject to enforcement actions depending on the severity of the deficiency.

Here is one more example of the 60-day threshold. The Facility 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 ÷ 83 = 0.807 x 100 = 80.7 or 81% of staff are vaccinated, have a granted exemption, or have a temporary delay.

The Facility is non-compliant with the 100% vaccination requirement and will be cited at F888 and could be subject to enforcement actions depending on the severity of the deficiency.
For surveys conducted on or after day 90, following the issuance of QSO-22-07-ALL-Revised, QSO-22-09-ALL-Revised, and QSO 22-11-ALL-Revised.

The facility is compliant if it demonstrates:

- All policies and procedures have been developed and implemented, and
- 100% of staff have received a single-dose vaccine, all doses of a multi-dose vaccine, have been granted an exemption, or have a temporary delay.

And finally, the last enforcement threshold occurs 90 days following issuance of QSO-22-07-ALL-Revised, QSO-22-09-ALL-Revised, and QSO 22-11-ALL-Revised. Facilities are expected to be 100% compliant with the requirements. A facility 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.
The Facility 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 ÷ 304 = 1 x 100 = **100% of staff** are vaccinated, have a granted exemption, or have a temporary delay.

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

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

Here is an example of calculating the percent of staff vaccinated at 90 days: The Facility 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.

\[
133 + 167 + 1 + 3 = 304 \quad 304 ÷ 304 = 1 \times 100 = **100% of staff** \text{ are vaccinated, have a granted exemption, or have a temporary delay.}
\]

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

The Facility may still be cited if non-compliance with the other requirements (e.g., policies and procedures) is identified.
The Facility 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 ÷ 156 = 0.942 x 100 = 94.2 or 94% of staff vaccinated, have a granted exemption, or have a temporary delay.

- The Facility is non-compliant with the 100% vaccination requirement and will be cited using tag F888.

- The facility may also be subject to enforcement actions.

Another example of calculating the percentage of staff at 90 days: The Facility 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 ÷ 156 = 0.942 x 100 = 94.2 or 94% of staff vaccinated, have a granted exemption, or have a temporary delay.

The Facility is non-compliant with the 100% vaccination requirement and will be cited using tag F888.

The facility may also be subject to enforcement actions.
Now we are going to switch gears and talk about how surveyors will investigate for these requirements. Surveyors will review the facility’s policies and procedures. You will use the infection prevention, control and Immunizations facility task and interpretive guidance and determine if the facility meets the requirements. Investigations should be focused on staff that provide services in the facility on a regular basis, for example weekly.
Randomly select 4 staff from the completed COVID-19 Staff Vaccination Matrix, as described below, unless concerns exist for specific staff (e.g., complaints, infection control practice observations).

- 2 vaccinated direct care staff
  - 1 certified nurse aide (CNA)
  - 1 additional direct care staff
- 2 unvaccinated staff (if available)
  - 1 unvaccinated staff without exemption or temporary delay
  - 1 unvaccinated staff with a medical exemption

Note: If there are no staff who meet one of the above unvaccinated criteria, you do not need to increase the sample size for another category. If the surveyor identifies any staff that were not vaccinated and were not granted a qualifying exemption or have a temporary delay (and weren’t marked as such on the staff matrix), that individual(s) should be added to the sample.

The sample selection will include a total of 8 staff for COVID-19 immunization review, which will include 4 staff and 4 contractor staff. Sample selection of staff will include 2 vaccinated direct care staff (1 must be a CNA and the other will be a direct care staff) and 2 unvaccinated staff (1 unvaccinated staff without an exemption or temporary delay and 1 unvaccinated staff with a medical exemption).

If no staff meet one of the unvaccinated criteria, do not increase the sample size for another area to make the total number of facility staff equal 4. Additionally, if the surveyor identifies any staff who are not vaccinated, were not granted an exemption or have a temporary delay, and weren’t identified as such on the staff matrix, add the individual(s) to the sample.
Sample selection of contracted staff will include 2 direct care contracted staff and 2 non-direct care contracted staff for a total of up to 4 contracted staff.

Select 2 contract companies (1 direct care and 1 non-direct care) from the list of contracted companies provided by the facility during the entrance conference. Ask the facility for a list of contracted staff from each of the two companies selected who are scheduled to provide services during the survey.

Randomly select 2 contracted staff from each list to make up a total of 4 contracted staff:
- 2 non-direct care contracted staff
- 2 direct care contracted staff

Note: If there are no contracted staff scheduled to be onsite during the survey, you do not need to increase the sample size for another category.

If there are no contracted staff scheduled during the survey time period, surveyors do not need to increase the sample size of the contracted staff to equal 4.
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, 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 facility?

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.

NOTE: The examples above are not all inclusive, and represent actions that can be implemented, however, facilities can choose other precautions that align with the intent of the regulation which is intended to “mitigate the transmission and spread of COVID-19 for all staff who are not fully vaccinated.”
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. Additional information can be found at F887 for verification and maintenance of documentation related to staff COVID-19 vaccination.
### Record Review for Medical Exemption Requests

Review documentation for staff who requested a medical exemption to determine if the requests are secure, tracked and contains:

- which COVID-19 vaccine is clinically contraindicated;
- the recognized clinical reason for the contraindication;
- a statement recommending the staff member be exempted from the COVID-19 vaccination requirement; and
- a signature and date by a licensed practitioner, who is not the individual requesting the exemption.

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.
## Unvaccinated Staff Who Do Not Have an Exemption or Temporary Delay

**Interview** staff and **Review** documentation for unvaccinated staff without an exemption or temporarily delayed vaccination:

- Are you scheduled to receive a COVID-19 vaccine? If so, confirm it is scheduled.
- If the staff isn’t scheduled to receive a vaccine: Did you request an exemption?
- When did the facility become aware staff did not have an exemption or a reason for temporary delay?
- What actions did the facility take to educate and offer COVID-19 vaccines to staff?
- What actions did the facility take when staff indicated that they will not get vaccinated and do not qualify for an exemption?

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 facility become aware staff did not have an exemption or a reason for temporary delay?
- What actions did the facility take to educate and offer COVID-19 vaccines to staff?
- What actions did the facility take when staff indicated that they will not get vaccinated and do not qualify for an exemption?
After investigating using the Infection Prevention, Control and Immunizations Facility Task, determine compliance with the requirements using the critical element questions.

If the facility is non-compliant with the 100% vaccination requirement and/or has not developed and implemented the required policies and procedures, cite F888.

The level of severity will be cited based on the level of harm, or likelihood of harm for residents.

Failure of contract staff to provide evidence of vaccination status reflects noncompliance and should be cited at F888 under the requirement to have policies and procedures for ensuring that all staff are fully vaccinated, except for those staff who have been granted exemptions or a temporary delay at 483.80(i)(3)(ii).

Compliance Determination for F888 Revised

• After investigating using the Infection Prevention, Control and Immunizations Facility Task, determine compliance with the requirements using the critical element questions.

• If the facility is non-compliant with the 100% vaccination requirement and/or has not developed and implemented the required policies and procedures, cite F888.

• The level of severity will be cited based on the level of harm, or likelihood of harm for residents.

• Failure of contract staff to provide evidence of vaccination status reflects noncompliance and should be cited at F888 under the requirement to have policies and procedures for ensuring that all staff are fully vaccinated, except for those staff who have been granted exemptions or a temporary delay at 483.80(i)(3)(ii).

Compliance determination for F888.

Long-term care surveyors will use the Infection Prevention, Control and Immunizations Facility Task, to determine compliance with the requirements using the critical element questions.

If the facility is non-compliant with the 100% vaccination requirement and/or has not developed and implemented the required policies and procedures, cite F888.

The severity level for noncompliance at F888 is based on the level of harm, or likelihood of harm for residents. For example, facilities with a high percentage of unvaccinated staff, several COVID-19 infections, and gaps in their policy and procedures, represent a higher risk of harm to residents. Therefore, these facilities would be cited at a higher level of severity than facilities with few unvaccinated staff, no COVID-19 infections, and compliant policy and procedures.

Failure for contract staff to provide evidence of vaccination status reflects noncompliance and should be cited at F888 under the requirement to have policies and procedures for ensuring that all staff are fully vaccinated, except for those staff who have been granted exemptions or a temporary delay at 483.80(i)(3)(ii).
**Surveying for the New Staff Vaccination Rule: Long Term Care Surveyor Training**

<table>
<thead>
<tr>
<th>Good Faith Effort Revised</th>
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<tbody>
<tr>
<td>Surveyors and CMS may use discretion to lower the scope and severity of a citation and/or enforcement action if they identify that any of the following have occurred <strong>prior to the survey</strong> (note: noncompliance is still cited, only the scope, severity, and/or enforcement is adjusted):</td>
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<tr>
<td>• If the facility has limited or no access to vaccines and has documented attempts to obtain vaccine access (e.g., contact with health department and pharmacies) and/or</td>
</tr>
<tr>
<td>• If the facility provides evidence they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc. For example, if the facility staff vaccination rate is 90% or more, there is no resident outbreak in the previous 4 weeks, and all policies and procedures were developed and implemented, per Table 1 this would be cited at “D”. However, if the facility provides evidence that it has made a good faith effort by taking aggressive steps to get all staff vaccinated, surveyors may lower the citation to “A”.</td>
</tr>
</tbody>
</table>

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

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

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

For example, if the facility staff vaccination rate is 90% or more, there is no resident outbreak in the previous 4 weeks, and all policies and procedures were developed and implemented, per Table 1 this would be cited at “D”. However, if the facility provides evidence that it has made a good faith effort by taking aggressive steps to get all staff vaccinated, surveyors may lower the citation to “A”. 
Citing Non-Compliance – Level 4 Immediate Jeopardy

- Noncompliance resulting in serious harm or death:
  - Did not meet the requirement of staff vaccinated or has no policies and procedures developed or implemented; and
  - 3 or more resident infections in the last 4 weeks resulting in at least one resident experiencing hospitalization (i.e., serious harm) or death.
  OR
- Noncompliance resulting in a likelihood for serious harm or death:
  - Did not meet the requirement of staff vaccinated; and
  - 3 or more resident infections in the last 4 weeks that did not result in serious harm or death; and
  - One of the following:
    - Any observations of noncompliant infection control practices by staff, (e.g., staff failed to properly don PPE so F880 would also be cited); or
    - 1 or more components of the policies and procedures was not developed or implemented.
  OR
- More than 40% staff are unvaccinated and there is evidence of a lack of effort to increase staff vaccination rates.

Surveyors will assign severity based on the criteria listed in Attachment A. Let’s look at Severity level 4, or Immediate Jeopardy. Noncompliance resulting in serious harm or death exists when the facility:

Did not meet the required percent of staff vaccinated, or has no policies or procedures developed or implemented, AND

3 or more resident COVID-19 infections have occurred in the last 4 weeks with at least one resident being hospitalized or dying.

Noncompliance resulting in a likelihood for serious harm or death exists when:

Did not meet the required percent of staff vaccinated, or has no policies or procedures developed or implemented, AND

3 or more resident COVID-19 infections have occurred in the last 4 weeks which did not result in serious harm or death, AND one of the following:

Any observations on noncompliant infection control practices, or 1 or more components of the policies and procedures was not developed or implemented.

OR

More than 40% of staff are unvaccinated and a lack of effort to increase staff vaccination rates.
Let’s talk about Severity Level 3 – Actual Harm that is not Immediate Jeopardy

Actual Harm exists when a facility did not meet the requirement of staff vaccinated, AND

3 or more resident infections in the last 4 weeks which did not result in hospitalization (i.e., serious harm) or death, or the likelihood for IJ for one or more residents; and

1 or more components of the policies and procedures were not developed and implemented.
### Citing Non-Compliance – Level 2

Citing Level 2: No actual harm with potential for more than minimal harm that is not immediate jeopardy

- Did not meet the requirement of staff vaccinated; **and**
- No resident infections

OR

- Did not meet the requirement of staff vaccinated; **and**
- 1 or more components of the policies and procedures were not developed and implemented

Severity Level 2, Potential for more than minimal harm exists when a facility Did not meet the requirement of staff vaccinated; and

No resident infections

**OR**

Did not meet the requirement of staff vaccinated; and

1 or more components of the policies and procedures were not developed and implemented
Citing Non-Compliance – Level 1

Citing Level 1: No actual harm with potential for minimal harm:
• Met the requirement of staff vaccinated; and
• 1 or more components of the policies and procedures were not developed and implemented (cite as widespread (“C”)).

Severity level 1 – potential for minimal harm exists when a facility Met the requirement of staff vaccinated; and

1 or more components of the policies and procedures were not developed and implemented (cite as widespread (“C”)).
Determining Scope

Scope is based on the percent of staff vaccinated, therefore, the scope will be based on the following criteria:

- **Isolated**: 1% or more, but less than 25% of staff are unvaccinated (76% – 99% of staff are vaccinated).

- **Pattern**: 25% or more, but less than 40% of staff are unvaccinated (61% – 75% of staff are vaccinated).

- **Widespread**: 40% or more of staff are unvaccinated (0% - 60% of staff are vaccinated), OR
  1 or more components of the policies and Procedures were not developed and implemented.

Scope is based on the percent of staff vaccinated. Scope is isolated when 1% or more, but less than 25% of staff are unvaccinated. Scope is a pattern when 25% or more, but less than 40% of staff are vaccinated, and scope is widespread when 40% or more of staff are unvaccinated, or 1 or more components of the policies or procedures were not developed or implemented.
To qualify for substantial compliance and clear the citation:

The facility has met the requirement of staff vaccinated or

The combined number of staff that are vaccinated (have received a single-dose vaccine or all doses of a multiple vaccine series) 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.
To qualify for substantial compliance but citation remains at level 1 (“C”)

- The facility has not met the requirement 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 at Level 1 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 a single-dose vaccine series.

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To qualify for substantial compliance but citation remains at level 1 or a scope and severity of C:

The facility has not met the requirement of staff vaccinated, but has 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 at Level 1 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 a single-dose vaccine series.
Components of POC and/or actions required for IJ removal:

Plans of correction or Immediate Jeopardy removal plans for non-compliance at F888 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; and
- Implementation of additional precautions to mitigate the spread of COVID-19 by unvaccinated staff.

Plans of correction should include:

Correction of any gaps in policies and procedures;

Implementation of the contingency plan, including a deadline for each unvaccinated staff to get first dose of vaccine,

Implementation of additional precautions.
Note: If the facility was determined to be in substantial compliance with F888 within the previous six weeks for staff COVID-19 vaccinations, it is not necessary to conduct a full compliance review of Critical Element (CE) questions pertaining to F888.
Updated survey documents, may be found under the “Survey Resources” link, in the Downloads section, of the CMS Nursing Homes website.

The updated documents will also be added to the Long-Term Care Survey Process software application.

For questions regarding LTC requirements, email: DNH_TriageTeam@cms.hhs.gov.