



Vaccination Mandate Guidance Summary

Updated 1-18-2022

Overview

There were two vaccine mandates proposed in 2021:

- On November 4, 2021, the Centers for Medicare and Medicaid Services (CMS) issued an Interim Final Rule (IFR) establishing COVID-19 vaccination requirements for employees of Medicare and Medicaid-certified providers.
- On November 5, 2021, The Occupational Safety and Health Administration (OSHA) issued its COVID-19 Vaccination and Testing Emergency Temporary Standard (ETS) requirements for employers with 100 or more employees.

Both proposals were challenged in the court system and were ultimately taken to the U.S. Supreme Court. On January 13, 2022, the Supreme Court decided:

- To end the OSHA ETS for employers with 100 or more employees. Therefore, *the OSHA vaccination and testing mandate will not be enforced anywhere in the United States.*
- **To allow CMS to begin enforcing the components of the vaccination mandate in its IFR in all states except Texas. As of the January 13, 2022, ruling, Medicare and Medicaid-certified providers in Iowa are subject to the terms set forth in [QSO-22-09-ALL](#).** In addition, providers are subject to the following attachments relevant to their provider type:
 - **Nursing facilities and residential care facilities** that accept Medicaid funding should review and follow the guidance set forth in [Attachment A – LTC](#).
 - **Intermediate Care Facilities for Individuals with Intellectual Disabilities** should review and follow the guidance set forth in [Attachment F – ICF-IID](#).
 - **Home health agencies** should review and follow the guidance set forth in [Attachment G – HHA](#).
 - **Home Infusion Therapy providers** should review and follow the guidance set forth in [Attachment L-HIT](#).

CMS Interim Final Rule – Determining Applicability for Providers

IHCA/ICAL/ICHC encourages members to determine if the CMS vaccination mandate applies to their organization (see chart below) and begin preparing for enforcement actions immediately. Members are encouraged to download and print all available tools noted in this guidance to assist in their compliance efforts. The intent of this document is to provide comprehensive, up to date guidance and best practices to members. As CMS and the Iowa Department of Inspections and Appeals (DIA) provide more detailed information, IHCA will update this document accordingly.

Type of Organization	CMS Interim Final Rule
Medicare and/or Medicaid-Certified Nursing Facility or Skilled Nursing Facility	APPLIES
Licensed-Only Nursing Facility (Not Medicare/Medicaid-Certified)	DOES NOT APPLY
Hospital-Based Skilled Nursing Facility or Nursing Facility	APPLIES
Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF-ID)	APPLIES
Assisted Living Programs (including those accepting elderly waiver)	DOES NOT APPLY
Medicaid-Certified Residential Care Facility	APPLIES
Residential Care Facility (including those accepting elderly waiver)	DOES NOT APPLY
Medicare and/or Medicaid-Certified Home Health Agency	APPLIES
Non-Certified Home Health Agency/Home Care	DOES NOT APPLY

CMS states that their IFR only applies to those Medicare and Medicaid-certified provider and supplier types that are subject to CMS health and safety regulations. CMS’s health and safety regulations do not cover providers of Home- and Community-Based Services. Therefore, assisted living programs and residential care facilities that provide services through the Home- and Community- Based Services (HCBS) waiver are not included in the CMS Interim Rule.

IHCA/ICAL/ICHC recommends providers who house different levels of care under the same roof or on the same campus abide by the highest standard consistently across all levels of care.

CMS Interim Final Rule – Compliance Expectations

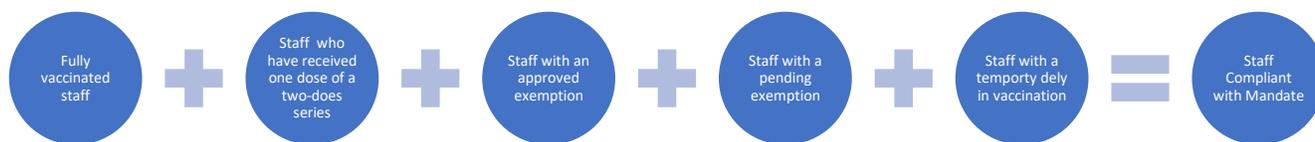
This rule went effect on January 13, 2022, for Iowa-based providers. The regulation requires health care providers to establish a process or policy to fulfill the staff vaccination requirement.

Enforcement Thresholds:

CMS identifies that 100% facility staff vaccination rates are required for compliance with the rule. To calculate the percentage of staff that contribute to compliance, all individuals who meet one of the following criteria will be included:

- Individuals who have received the required vaccination dose(s)
- Individuals who have requested and been approved for a medical or religious exemption
- Individuals who are unable to be vaccinated due to temporary circumstances as recommended by Centers for Disease Prevention and Control (CDC)

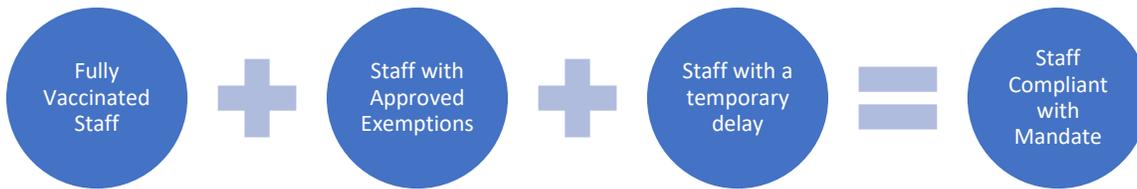
Within 30 days of issuance of [QSO-22-09-ALL](#), (February 14, 2022):



- **A facility is considered compliant if:**
 - Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or patient or resident contact are vaccinated for COVID-19; **and**
 - 100% of staff have received at least one dose of COVID-19 vaccine, or have a pending request for, or have been granted qualifying exemption, or identified as having a temporary delay as recommended by the CDC,
- **A facility is considered NOT compliant if:**
 - Less than 100% of all staff have received at least one dose of COVID-19 vaccine, or have a pending request for, or have been granted a qualifying exemption, or identified as having a temporary delay as recommended by the CDC.
 - *The facility will receive notice of their non-compliance with the 100% standard. A facility that is above 80% and has a plan to achieve a 100% staff vaccination rate within 60 days would not be subject to additional enforcement action.*

Note: Newly hired staff who are not yet eligible to receive the second dose in a two-dose series will be considered compliant with the requirement.

Within 60 days after the issuance of this memorandum, (March 15, 2022):



- **A facility is considered compliant if:**
 - Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or patient or resident contact are vaccinated for COVID-19; **and**
 - 100% of staff have received the necessary doses to complete the vaccine series (i.e., one dose of a single-dose vaccine or all doses of a multiple-dose vaccine series), or have been granted a qualifying exemption, or identified as having a temporary delay as recommended by the CDC.
- **A facility is considered NOT compliant if:**
 - Less than 100% of all staff have received at least one dose of a single-dose vaccine, or all doses of a multiple-dose vaccine series, or have been granted a qualifying exemption, or identified as having a temporary delay as recommended by the CDC.
 - *The facility will receive notice of their non-compliance with the 100% standard. A facility that is above 90% and has a plan to achieve a 100% staff vaccination rate within 30 days would not be subject to additional enforcement action.*

Note: Newly hired staff who are not yet eligible to receive the second dose in a two-dose series will be considered compliant with the requirement.

Within 90 days and thereafter following issuance of the QSO (May 15, 2022, and thereafter), facilities failing to maintain compliance with the 100% standard may be subject to enforcement action.

Included Employees

This vaccination requirement applies to eligible staff working at a facility that participates in the Medicare and Medicaid programs, regardless of clinical responsibility or patient contact. The requirement includes all current staff as well as any new staff who provide any care, treatment, or other services for the facility and/or its patients. This includes facility employees, licensed practitioners, students, trainees, and volunteers. Additionally, this also includes individuals who provide care, treatment, or other services for the facility and/or its patients under contract or other arrangements, such as agency personnel, dieticians, mental health professionals, social workers, physicians, or contracted therapy staff.

These requirements are not limited to those staff who perform their duties solely within a formal clinical setting, as many health care staff routinely care for patients and clients outside of such facilities (e.g., home health). To ensure maximum patient protection, all staff who interact with other staff, patients, residents, or clients in any location beyond the formal clinical setting (such as homes, clinics, other sites of care, administrative offices, off-site meetings, etc.) must be vaccinated. Employees of a health care entity who work solely in an off-site or non-clinical location, such as a corporate office, may **not** be subject to vaccination requirements if they do not have resident interaction or contact with staff who have resident interaction.

It is important to note that hospice agencies, clinics, dialysis centers, rehabilitation agencies, hospitals, emergency medical services, and many other Medicare and Medicaid-certified entities that interact with long-term care (LTC) facilities, assisted living programs, residential care facilities, and home health agencies also fall under this rule. Therefore, the staff of those organizations will be required to comply with vaccination requirements through their employment. Conversations with service providers and partners in care should be initiated to determine compliance efforts within those organizations.

For other services suppliers (such as portable x-ray services, non-medical transport services, or durable medical equipment providers), it is important to note that the staff of these entities are indirectly included in the vaccination requirements through their service arrangements with LTC facilities and other providers and suppliers included under this rule. A service arrangement is when these providers have a contract with other providers to furnish services. That contract may require individuals from these organizations to be vaccinated. It is important to note that many of these suppliers may be subject to the other state or federal COVID-19 vaccination requirements.

IHCA/ICAL/ICHC recognizes that most members have contracted employees, such as therapists, dietitians, consultants, and staff provided through a temporary agency. Members are encouraged to review current contracts held with these partners to ensure the expectations of both parties for vaccination-related information (vaccination status, approved exemptions, etc.) sharing is clear. IHCA has drafted an [addendum template](#) that members can use at their discretion to accommodate communication of such expectations. Additionally, CMS has been clear in their direction that facilities covered under the mandate are responsible for having a process to access and review vaccine-related documents for all staff, including contracted employees. Members should also be reminded that they are not required to accept an exemption that was previously approved by the contracting agency and can choose to allow or deny access to their facility based upon what is provided.

Newly Hired Staff

Employees hired by the facility are subject to vaccination requirements. Facilities should identify in their policies and procedures how they will educate new staff about vaccination risks and benefits, identify eligibility for vaccination, obtain and secure vaccination information, and communicate the process for requesting a medical or religious exemptions. Newly hired staff who are not fully vaccinated must obtain the first dose of a two-dose series or obtain an approved exemption prior to resident contact. Newly hired staff who are not yet fully vaccinated should follow the guidelines for additional precautions until they are fully vaccinated.

Employees who are NOT included

Individuals who provide services 100% remotely and who do not have any direct contact with patients and other staff, such as fully remote telehealth or payroll services, are not subject to the vaccination requirements outlined in this regulation.

Contractors who visit the facility to provide services on a one-time basis (such as a plumber entering to complete repairs) will not be subject to vaccination requirements.

Qualified Vaccination Types

CMS expects that staff will receive a vaccine licensed or authorized for emergency use by the Food and Drug Administration (FDA), which currently includes the Pfizer-BioNTech COVID-19 Vaccine (interchangeable with the licensed Comirnaty vaccine), Moderna COVID-19 Vaccine, and the Janssen (Johnson & Johnson) COVID-19 Vaccine. Facilities will also be in compliance if they allow staff to work who received a vaccine listed by the World Health Organization (WHO) for emergency use that is not approved or authorized by the FDA, or who received a vaccine during their participation in a clinical trial.

CMS expects that vaccine administration will occur within the United States for most staff and that individuals will receive a COVID-19 vaccine authorized for emergency use or licensed by the FDA. However, it is permissible to receive a COVID-19 vaccine outside of the United States. Eligible COVID-19 vaccinations administered to staff outside of the United States include those that are FDA licensed or authorized for emergency use or those that are listed by the WHO for emergency use.

Inclusion of Additional Doses or Booster Shots

For purposes of this regulation, CMS currently considers staff fully vaccinated if it has been two weeks or more since they completed a primary vaccination series for COVID-19. However, staff who have completed the primary series for the vaccine by the Phase 2 (January 4, 2022) implementation date are considered to have met these requirements, even if they have not yet completed the 14-day waiting period required for full vaccination. The completion of a primary vaccination series for COVID-19 is defined in the rule as the administration of a single-dose vaccine (such as the Janssen (Johnson & Johnson) COVID-19 Vaccine), or the administration of all required doses of a multi-dose vaccine (such as the Pfizer-BioNTech COVID-19 Vaccine (interchangeable with the licensed Comirnaty Vaccine) or the Moderna COVID-19 Vaccine).

The FDA has approved, and CDC has recommended, boosters for certain groups that previously completed a primary vaccination series. Because the science and clinical recommendations around additional doses and boosters is evolving rapidly, members should refer to CDC's [Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States](#) for additional details about the inclusion of booster shots in the definition of fully vaccinated staff.

Staff who have previously had COVID-19 are not exempt from these vaccination requirements. Staff with previous COVID-19 infection should receive the vaccine according to the [recommendations](#) set forth by the CDC. Additionally, staff who have received treatments for COVID-19 (monoclonal antibodies or convalescent plasma) may not be eligible to receive the vaccination for a period following the administration of the treatment. Staff become subject to the vaccine requirement once the designated period has elapsed.

The CDC's preference is that individuals should generally avoid receiving doses of different vaccines to complete a primary COVID-19 vaccination series. Nevertheless, CDC does recognize that, in certain exceptional circumstances (e.g., when the vaccine product given for the first dose cannot be determined or is no longer available), a different vaccine may be used to complete the primary COVID-19 vaccination series. Accordingly, staff may be considered compliant with the requirements within this regulation if they have received any combination of two doses of a vaccine licensed or authorized by the FDA or listed on the WHO emergency use list as part of a two-dose series. Of note, the recommended interval between the first and second doses of a vaccine licensed or authorized by FDA, or listed on the WHO emergency use list, varies by vaccine type. To be compliant with this requirement, the second dose in a two-dose mixed vaccine series must have been received no earlier than 28 days after the first dose.

Staff who have received a COVID-19 vaccination neither licensed or authorized by the FDA nor listed on the WHO emergency use list should receive an FDA licensed or authorized vaccination series. Per CDC guidelines, staff in this category should wait at least 28 days following the last dose of a non-FDA approved or authorized and non-WHO-listed vaccination to begin a new series. Staff should consult with their doctor or other health care provider if they have questions about their vaccination.

According to the CDC, no additional doses are needed for staff who participated in a clinical trial at a site in the U.S. and received the full series of an "active" vaccine candidate (not placebo) and vaccine efficacy has been independently confirmed (by a data and safety monitoring board).

Staff who were hired before December 5, 2021, should have received their first dose of a two-dose series or a dose of the single-dose vaccine before December 5, 2021. Staff who were hired after December 5, 2021, must have received their first dose of a two-dose series or a dose of the single-dose vaccine before they have resident contact. If necessary, the second dose should be administered according to recommendations to maintain compliance.

Is there a testing option for unvaccinated staff?

No. Vaccination is required for all employees unless they meet the requirements for a medical or religious exemption. Nursing facilities should continue to test based upon the requirements outlined in [QSO-20-38-NH](#).

Reporting Vaccination Status of Employees

No new reporting requirements were released with the IFR. Reporting staff and resident vaccination status to NHSN in nursing facilities remains unchanged. Members are required to track and securely

document the vaccination status of each staff member, including those for whom there is a temporary delay in vaccination.

Examples of acceptable forms of vaccine documents include:

- CDC COVID-19 Vaccination record card (or a legible copy of the card)
- Documentation of vaccine administration from a health care provider or electronic medical record
- State immunization information system record (IRIS)
- If vaccinated outside of the U.S., an equivalent to these examples is acceptable

Exemptions

IHCA/ICAL/ICHC has developed a comprehensive [toolkit](#) for member use when managing vaccine exemptions. This toolkit includes a sample policy, medical and religious exemption forms, and suggested verbiage for employee handbooks or other organizational policies.

CMS requires facilities to allow for exemptions to staff with recognized medical conditions for which vaccines are contraindicated (as a reasonable accommodation under the Americans with Disabilities Act (ADA) or religious beliefs, observances, or practices (established under Title VII of the Civil Rights Act of 1964). Providers and suppliers should establish exceptions as a part of their policies and procedures and in alignment with federal law. CMS believes that exemptions could be appropriate in certain limited circumstances, but no exemption should be provided to any staff for whom it is not legally required (under the ADA or Title VII of the Civil Rights Act of 1964) or who requests an exemption solely to evade vaccination.

Iowa recently passed a bill stating that employers must accept medical and religious exemptions without question. The CMS Interim Final Rule takes precedence over state rule due to the Supremacy Clause of the U.S. Constitution. Therefore, any facility or program that is subject to CMS Interim Final Rule is expected to comply with its requirements.

Medical exemptions

Facilities have the flexibility to establish their own processes that permit staff to request a medical exemption from the COVID-19 vaccination requirements. Facilities must ensure that all documentation confirming recognized [clinical contraindications](#) to COVID-19 vaccinations for staff seeking a medical exemption are signed and dated by a licensed practitioner, who is not the individual requesting the exemption and is acting within their respective scope of practice based on applicable state and local laws. This documentation must contain all information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications. Additionally, a statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID-19 vaccination requirements is also expected.

Religious exemptions

Facilities have the flexibility to establish their own processes that permit staff to request a religious exemption from the COVID-19 vaccination requirements. CMS requires facilities to ensure that requests for religious exemptions are documented and evaluated in accordance with applicable federal law and as a part of a facility's policies and procedures. CMS encourages facilities to review the [Equal Employment Opportunity Commission's Compliance Manual on Religious Discrimination](#) for more information on religious exemptions.

*Note: Surveyors will not evaluate the details of the request for a religious exemption, nor the rationale for the facility's acceptance or denial of the request. Rather, surveyors will review to ensure the facility has an effective process for staff to request a religious exemption for a sincerely held religious belief.

Related to religious exemptions, consideration of the following items as outlined in the Civil Rights Act of 1964 (Title VII) should be given when writing the organization's policy:

- Religion is very broadly defined for purposes of Title VII. The presence of a deity (god) or deities (gods) is not necessary for a religion to receive protection under Title VII. Religious beliefs can include unique beliefs held by a few or even one individual; however, mere personal preferences are not religious beliefs. Individuals who do not practice any religion are also protected from discrimination based on religion or lack thereof. Title VII requires employers to accommodate religious beliefs, practices and observances if the beliefs are "sincerely held" and the reasonable accommodation poses no undue hardship on the employer.
- Social, political, or economic philosophies, as well as mere personal preferences, are not religious beliefs protected by Title VII.
- Undue hardship is defined as 'something greater than hardship.' This hardship can be found in monetary cost to the employer or in indirect cost to the employer's business, such as the infringement on others' rights or benefits, impairment of workplace safety, or causing other workers to carry the accommodated worker's share of the burdensome work.

Members are encouraged to consult with an attorney when considering how to approach exemptions.

Additional Measures Required for Any Unvaccinated Individual with a Qualifying Exemption or Prior to Being Fully Vaccinated

The regulation requires that facilities develop a process for implementing additional precautions for any staff who are not fully vaccinated to mitigate the transmission and spread of COVID-19. Accommodations should be addressed in the organization's policies and procedures. Under federal law, including the ADA and Title VII of the Civil Rights Act of 1964, individuals who cannot be vaccinated because of medical conditions or sincerely held religious beliefs, practice, or observance may be entitled to an accommodation. Members are encouraged to review the Equal Employment Opportunity Commission's website for additional information about situations that may warrant accommodations. In granting such exemptions or accommodations, employers must ensure that they

minimize the risk of transmission of COVID-19 to at-risk individuals, in keeping with their obligation to protect the health and safety of patients.

Potential accommodations can include the following:

- COVID-19 testing (in accordance with CMS and CDC guidelines)
 - At least weekly testing should be required for exempted or those who are not fully vaccinated regardless of community transmission levels.
- Physical distancing from co-workers and patients/residents
- Reassignment or modification of duties
- Teleworking
- Any combination of the above

Staff who have not completed their primary vaccination series should be required to use a NIOSH-approved N95 or equivalent or higher-level respirator for source control, regardless of whether they are providing direct care to or otherwise interacting with patients.

Staff who have been granted an exemption to COVID-19 vaccination requirements should adhere to national infection prevention and control standards for unvaccinated health care personnel. For additional information, see CDC's [Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 \(COVID-19\) Pandemic](#) webpage.

Enforcement

State survey agencies will integrate compliance measures into complaint and standard (initial certification and recertification/annual) surveys. **Surveying for compliance with the vaccination rule will begin in Iowa on February 14, 2022.** While onsite, surveyors will review the facility's COVID-19 vaccination policies and procedures, the number of resident and staff COVID-19 cases over the last four weeks, and a list of all staff and their vaccination status. This information, in addition to interviews and observations, will be used to determine the compliance of the provider or supplier with these requirements.

Surveyors will specifically be looking for the following items:

1. The facility's plan to vaccinate all employees, both current and new.
2. The facility's plan to approach exemptions and the accommodations made for those who cannot be vaccinated due to exemption.
3. The facility's plan to track and document staff vaccination status.

Medicare- and Medicaid-certified facilities are expected to comply with all regulatory requirements, and CMS has a variety of established enforcement remedies. For nursing homes and home health agencies this includes civil monetary penalties, denial of payment, and even termination from the Medicare and Medicaid program as a final measure. Termination would generally occur only after providing a facility with an opportunity to make corrections and come into compliance.

Citing Noncompliance — Scope and Severity:

Facility staff vaccination rates under 100% constitute non-compliance under the rule. The level of severity will be cited 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.

Good-Faith Effort:

Surveyors and CMS may lower the scope and severity of a citation and/or enforcement action if they identify that any of the following have occurred prior to the survey (note: noncompliance is still cited, only the scope, severity, and/or enforcement is adjusted).

- a) If the facility has no or has limited access to the vaccine, and the facility has documented attempts to obtain vaccine access (e.g., contact with health department and pharmacies).
- b) If the facility provides evidence that they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc.

Scope and severity will be determined in the following table:

Table 1: Scope and Severity Grid

Severity & Scope for F888	<u>ISOLATED</u> 1% or more, but less than 25% of staff are unvaccinated (76% – 99% of staff are vaccinated).	<u>PATTERN</u> 25% or more, but less than 40% of staff are unvaccinated (61% – 75% of staff are vaccinated).	<u>WIDESPREAD</u> 40% or more of staff are unvaccinated (0% - 60% of staff are vaccinated), OR 1 or more components of the P&Ps were not developed and implemented.
<p>Level 4 - Immediate Jeopardy: Noncompliance resulting in serious harm or death:</p> <ul style="list-style-type: none"> • Did not meet the requirement of staff vaccinated; 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. <p>OR,</p> <p>Noncompliance resulting in a likelihood for serious harm or death:</p> <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ○ Any observations of noncompliant infection control practices by staff; or ○ 1 or more components of the policies and procedures were not developed or implemented. <p>OR,</p> <ul style="list-style-type: none"> ○ More than 40% of staff are unvaccinated and there is evidence of a lack of effort to increase staff vaccination rates. 	J	K	L
<p>Level 3 – Actual Harm:</p> <ul style="list-style-type: none"> ○ 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. 	G	H	I
<p>Level 2: No actual harm w/potential for more than minimal harm that is not IJ:</p> <ul style="list-style-type: none"> • Did not meet the requirement of staff vaccinated; and • No resident infections <p>OR,</p> <ul style="list-style-type: none"> • Did not meet the expected minimum threshold of staff vaccinated; and • 1 or more components of the policies and procedures were not developed and implemented. 	D	E	F
<p>Level 1: No actual harm w/potential for minimal harm:</p> <ul style="list-style-type: none"> • Met the requirement of staff vaccinated; and • 1 or more components of the P&Ps were not developed and implemented (cited as widespread (“C”). 	A	B	C