

F888 COVID-19 Vaccination Requirements

Discussion Points for the Infection Control CE Pathway, COVID-19 Staff Vaccination Matrix, and the Scope and Severity Grid for F888



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What's New on the Infection Control CE Pathway (CMS-20054 – January 2022)

Critical Elements #1 - #12:

- ❑ Mostly deals with resident and staff interviews, observations, and record reviews to determine compliance with established infection control practices.
- ❑ Incorporated the term “**Source Control**” to replace the terms PPE, facemasks, etc.)

Critical Element #13 – Policy and Procedure for Staff COVID-19 Vaccinations:

- ❑ This is a **NEW** CE and applies to the **development** of STAFF COVID-19 policies and procedures.
- ❑ These P & Ps must include, as a minimum:
 - A process for ensuring that all staff are vaccinated or have been **granted** an exemption or temporary delay.
 - A process by which staff may **request** an exemption from the COVID-19 vaccination.
 - A process for **tracking** staff vaccine status.
 - A process for **securing** and **storing** vaccination documents.
 - A **contingency plan** for **unvaccinated** staff.

What's New on the Infection Control CE Pathway (CMS-20054 – January 2022)

Critical Element #14 – NHSN Data Compared to Facility Staff Matrix Data:

- ❑ This is a **NEW** CE and includes instructions for the survey team to **compare** the facility's **NHSN** staff vaccination weekly report data to the COVID-19 Staff Completely Vaccinated **Matrix** Data.
- ❑ Surveyors will **review** the facility's NHSN vaccination data **PRIOR** to entering the facility.
- ❑ If there is a **greater than 10%** difference **between** the **NHSN** data and the Staff **Matrix** data, the facility will be asked to **explain** the difference.
- ❑ If the **Matrix** information is **incorrect** (and the **NHSN** data is **correct**), or **IF both sources** are **incorrect**, the survey team will view this as the facility's **failure** to have a **process** for tracking and securely documenting COVID-19 vaccination status of the staff. Will consider citing **F888**.
- ❑ If the information reported to **NHSN** is **incorrect** (and the **Matrix** is **correct**), or there is **no** data present in **NHSN**, the survey team will **inform** the facility to **immediately correct** the information in the **NHSN** system.

What's New on the Infection Control CE Pathway (CMS-20054 – January 2022)

Critical Element #15 – Record Review, Staff Interviews, and Observations:

- ❑ This is a **NEW** CE and provides the surveyor with instructions on **which** staff to **select** to participate in the investigative process.
- ❑ **Two (2) VACCINATED** staff will be selected. **One** must be a **CNA** and the **other** must be an individual under **contract** or **other arrangements** (e.g., hospice and dialysis staff, therapists, licensed practitioners, etc.)
- ❑ The surveyor will **review** documents relative to these **individual's** vaccination status, screening and eligibility to receive the vaccine, and educational programs / materials relative to the COVID-19 vaccines.
- ❑ If **issues** are identified, the facility **may** be cited at survey tag **F887**.

What's New on the Infection Control CE Pathway

(CMS-20054 – January 2022)

Critical Element #15 – Record Review, Staff Interviews, and Observations – Continued:

- ❑ **Six (6) UNVACCINATED** staff must be selected (if available) as directed below.
 - ✓ **Three (3)** individuals **without** exemption or reason for being temporarily delayed must be selected. Two must be **CNAs** and the **other** may be any other staff member meeting the criteria. *(Names will be selected from **Column 11** of the **Matrix Form**.)*
 - ✓ **One (1) UNVACCINATED** staff with a **NON-MEDICAL** Exemption (such as a religious exemption) must be selected. *(Name will be selected from **Column 9** of the **Matrix Form**.)*
 - ✓ **One (1) UNVACCINATED** staff with a **MEDICAL** Exemption must be selected. *(Name will be selected from **Column 8** of the **Matrix Form**.)*
 - ✓ **One (1) UNVACCINATED** staff whose primary vaccine has been delayed must be selected. *(Name will be selected from **Column 10** of the **Matrix Form**.)*

What's New on the Infection Control CE Pathway (CMS-20054 – January 2022)

Critical Element #15 – Record Review, Staff Interviews, and Observations – Continued:

- ❑ Surveyors will **interview** and **observe** the **six (6) UNVACCINATED** staff to determine if they are following additional precautions to prevent the spread of COVID-19.
- ❑ Surveyors will **request** and **review** COVID-19 vaccine documentation to **ensure** the facility is in compliance with such recordkeeping requirements. (As outlined in CE #13).
- ❑ **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) will most likely be **added** to the sample.
- ❑ Surveyors will **review** the facility records of the six (6) selected **UNVACCINATED** staff to **confirm** that the facility has implemented its **Contingency Plan** to **verify** the actions taken by the facility for **any** staff who indicated they would **not** get vaccinated and were **not** qualified for an exemption (e.g., vaccination deadlines, action to take if the deadline has passed, etc.)

What's New on the Infection Control CE Pathway

(CMS-20054 – January 2022)

Critical Element #16 – Education and Offering COVID-19 Immunization to Staff:

- ❑ Surveyors are to use the **SAME** eight (8) staff **selected** for the investigative process outlined in **CE #15**.
- ❑ Surveyors will **review** the facility's COVID-19 policies and procedures and **ask** the facility:
 - ✓ What **efforts** has the facility made to **obtain** the COVID-19 vaccine?
 - ✓ How was information **provided** to staff on **obtaining** the vaccine if **not** available at the facility?
 - ✓ How are staff **educated** about the COVID-19 vaccine?
 - ✓ How are staff **screened** for eligibility, **documentation** to support the **offering** of the vaccine, **consenting** or **refusal** of the vaccine, etc.?
 - ✓ If **issues** are **identified** at this critical element, the facility **may** be cited at survey tag **F887**.

The COVID-19 Staff Vaccination Matrix

- ❑ During the **Entrance Conference**, the survey team coordinator will provide the facility with a copy of the **COVID-19 Staff Vaccination Matrix Form**.
- ❑ Facilities are **permitted** to use other documents **IF** they contain the **SAME** information as required on the **Matrix**.
- ❑ The facility **must** provide the **completed** form to the survey team within **four (4)** hours of their entry into the facility.
- ❑ Surveyors will use the **completed Matrix** data to **compare** the facility's **percentage of completely vaccinated staff** to the **NHSN** weekly staff vaccination report.
- ❑ The survey team **reviews** the facility **NHSN** data **PRIOR** to the survey entry date. This usually occurs **1 – 5 days** PRIOR to the scheduled survey date.
- ❑ **If** the facility's **completely vaccinated rate** is **greater** than **10%** of the **NHSN** staff vaccination data, the facility will be **asked** to **explain** why there is such a significant difference.

Calculating Percentage of Completely Vaccinated Staff

COVID-19 Staff Vaccination Status for Providers

Complete this form or provide a list containing the same information required in this form. Section I: Complete based on the Day 1 of the survey: Total # of staff: 150 # partially vaccinated staff (5): 10 # completely vaccinated staff (6): 130 # pending exemption (8 and 9): 3 # granted exemption (8 and 9): 1 # temporary delay/new hire (10): 0 # not vaccinated without exemption/delay (11): 6 Note: The sum of the #'s for columns 5, 6, 8 through 11 should equal the total # of staff.	Direct facility hire (DH), Contracted hire (C), Other (O)	Title	Position	Assigned work area	Vaccinated			Not Vaccinated			
					Partially vaccinated	Completely vaccinated	Booster dose	Pending (P) or Granted (G) medical exemption	Pending (PN) or Granted (GN) non-medical exemption	Temporary delay per CDC/ new hire	Not vaccinated without exemption/delay
Staff Name	1	2	3	4	5	6	7	8	9	10	11
Thom Thumb	DH	RN	Nurse	East Wing		x					
Martha Steward	C	RPH	Pharm	West Wing					x		

Example

Total Completely Vaccinated (Column 6)	Divided By TOTAL # of Staff	X 100 = % Completely Vaccinated
130	150	86.6%

Do NOT round

Obtaining and Comparing NHSN Vaccination Data

- ❑ Surveyors will obtain the facility's **weekly** NHSN Data **prior** to facility entry.

	E	F	G	H	I	J	K	L	M	N
Recent Facility Resident and Staff Vaccination Rates and Other Data, as reported for week ending 01/23/22										
Vaccination percentages are for the current week if present, otherwise the prior week if present										
	Provider State	Provider Zip Code	Provider Phone Number	County	Submitted Data	Passed Quality Assurance Check	Recent Percentage of Residents who are Fully Vaccinated ¹	Recent Percentage of Fully Vaccinated Residents who Received a Booster Dose ²	Recent Percentage of Staff who are Fully Vaccinated ³	Recent Percentage of Fully Vaccinated Staff who Received a Booster Dose ⁴
	AL	35653	2.563E+09	Franklin	Y	Y	98.0	71.4	81.4	40.0

NHSN as reported for week ending: 01/23/2022

NHSN Percentage of Staff Fully Vaccinated = 81.4%

Matrix Percentage of Staff Completely Vaccinated = 86.6%

Percentage **Difference** Between **NHSN** Data and **Matrix** Data = **5.2%**

- ❑ If there is **10% or LESS difference** between the Matrix Data and NHSN Data, **no further action is needed**.
- ❑ If there is **GREATER** than a **10% difference**, the facility will be asked to **explain** the difference.

Formulas for Calculating % of Vaccinated Staff for Surveys Conducted Between 30 and 59 Days from the QSO Memo Date

- ❑ This formula is **NOT** used in determining the **completely vaccinated percentage** difference between the **NHSN** data and the staff **Matrix** data.
- ❑ The **purpose** of this calculation is for the survey team to **determine WHEN** to **cite** survey tag **F888**.
- ❑ To **determine** the **percentage** of facility staff vaccinated the survey team will use the **following formula** to **calculate** the COVID-19 vaccination **percentage** rate:

Total Partially Vaccinated (Column 5)	+	Total Completely Vaccinated (Column 6)	+	Total Pending Exemption (Columns 8 & 9)	+	Total Granted Exemption (Columns 8 & 9)	+	Total Temporarily Delayed (Column 10)	Totals for Columns 5, 6, 8, 9 & 10	Divided By TOTAL # of Staff	X 100 = % Vaccinated for citing F888
4		124		1		1		3	= 133	÷ 150	= 88.6%* 89%

* Round to Whole Number

- ❑ If the staff **vaccinated** rate is **LESS** than **100%**, the survey team is instructed to **CITE** tag **F888**.
- ❑ Refer to QSO Memo **Attachment A**, beginning on page 4, for enforcement **guidance**.

Vaccination Enforcement – Surveying for Compliance

Within **30 Days AFTER** Issuance of the QSO Memo

- ❑ If policies and procedures **are** developed **and** implemented for COVID-19 vaccination, **AND**
- ❑ **100%** of the facility staff have **received** at least **one** dose of COVID-19 vaccine, **or** have a pending, granted, or temporary delay exemption --
- ❑ The facility **will** be considered to be **in compliance** with the rule.
- ❑ If **LESS than 100%** of the facility have received **at least one dose** of COVID-19 vaccine, **or** have a pending, granted, or temporary delay exemption, the facility is considered to be in **non-compliance** with the rule.
- ❑ The facility **will** receive a **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** will **not** be subject to additional **enforcement** action.
- ❑ Facilities that do **not** meet the parameters **could** be subject to additional **enforcement actions** depending on the **severity** of the deficiency (e.g., plans of correction, CMPs, DPNA, termination, etc.).

Formulas for Calculating % of Vaccinated Staff for Surveys Conducted 60 Days and thereafter from the QSO Memo Date

- ❑ This formula is **NOT** used in determining the **completely vaccinated percentage difference** between the **NHSN** data and the staff **Matrix** data.
- ❑ The **purpose** of this calculation is for the survey team to **determine WHEN** to **cite** survey tag **F888**.
- ❑ To **determine** the **percentage** of facility staff vaccinated the survey team will use the **following formula** to **calculate** the COVID-19 vaccination **percentage** rate:

Total Completely Vaccinated (Column 6)	+ Total Granted Exemption (Columns 8 & 9)	+ Total Temporarily Delayed (Column 10)	Totals for Columns 6, 8, 9 & 10	Divided By TOTAL # of Staff	X 100 = % Vaccinated for F888 (85.3%*)
124	1	3	= 128	÷ 150	= 85% *

* Round to Whole #

- ❑ If the staff **vaccinated** rate is **LESS** than **100%**, the survey team is instructed to **CITE** tag **F888**.
- ❑ If the 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.
- ❑ Refer to QSO Memo **Attachment A**, beginning on page 4, for enforcement **guidance**.

Vaccination Enforcement – Surveying for Compliance

Within **60 Days AFTER** Issuance of the QSO Memo

- If policies and procedures **are** developed **and** implemented for COVID-19 vaccination, **AND**
- 100%** of the facility staff have **received** at least **one** dose of COVID-19 vaccine, **or** have a pending, granted, or temporary delay exemption --
- The facility **will** be considered to be **in compliance** with the rule.
- If **LESS than 100%** of the facility have received **at least one dose** of COVID-19 vaccine, **or** have a pending, granted, or temporary delay exemption, the facility is considered to be in **non-compliance** with the rule.
- The facility **will** receive a **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** will **not** be subject to additional **enforcement** action.
- Facilities that do **not** meet the parameters **could** be subject to additional **enforcement actions** depending on the **severity** of the deficiency (e.g., plans of correction, CMPs, DPNA, termination, etc.).
- Within 90 days and thereafter** following the issuance of the QSO Memo, facilities **failing to maintain compliance** with the **100%** standard **may** be subject to **enforcement** actions.

Determining the Severity Level of an F888 Citation

- ❑ The **severity grid** outlined in the QSO Memo Attachment A is used **ONLY** for determining the severity level of an **F888** citation.
- ❑ **Severity** will be **based** on the **following** criteria.
- ❑ **Level 4 - Immediate Jeopardy (IJ) – Noncompliance** resulting in **serious** harm or death.
 - ✓ Did **not** meet the **requirement** (less than 100%) 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

Determining the Severity Level of an F888 Citation

Level 4 - Immediate Jeopardy (IJ) – Noncompliance resulting in a **likelihood** for serious harm or death.

- ✓ Did **not** meet the requirement (less than 100%) 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 to ensure staff vaccination were **not** developed **or** implemented.

OR

- ❑ **More than 40%** of staff are **unvaccinated** and there is **evidence** of a lack of the facility's **effort to increase** staff vaccination rates.

Determining the Severity Level of an F888 Citation

Level 3: Actual Harm that is not IJ

- Did **not** meet the requirement (less than 100%) 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.

Level 2: No Actual Harm with Potential for More than Minimal harm that is not IJ

- Did **not** meet the requirement (less than 100%) of staff vaccinated; **and**
- No** resident outbreaks. **OR**
- Did **not** meet the requirement of staff vaccinated; **and**
- 1 or more components** of the policies and procedures were **not** developed **and** implemented.

Determining the Severity Level of an F888 Citation

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 to ensure staff vaccination were **not developed and implemented** (must be **cited** as widespread (“**C**”).

Using the Scope Grid for F888

- ❑ The **scope** outlined in the QSO Memo Attachment A is used **ONLY** for determining the scope of an **F888** citation.
- ❑ The **SCOPE** of an **F888 citation** is based on the **percent** of staff **vaccinated** because lower vaccination rates are associated with higher number of COVID-19 resident cases.
- ❑ The **scope** will be based on the **following** criteria:
 - ✓ **Isolated: 76% - 99%** of staff **are** vaccinated.
 - ✓ **Pattern: 61% - 75%** of staff **are** vaccinated.
 - ✓ **Widespread: 0% - 60%** of staff **are** vaccinated **OR** **1 or more components** of the policies and procedures are **not** developed and implemented. (See also CE #13).
- ❑ Facilities that have met the requirement for staff vaccination will **not** be cited **UNLESS** there is **noncompliance** with the **development** or **implementation** of policies and procedures. However, the facility **may** still be cited for **noncompliance** with **other** requirements, such as failure to implement an effective infection prevention and control program (**F880**).

Question and Answer Session

Interested in the Complete COVID-19 Health Care Staff Vaccination In-Service Training Program?

You can provide your management team with ready-to-use training materials referenced in this webinar that will enhance the team's knowledge, understanding and support of the regulations and guidelines governing COVID-19 Staff Vaccinations.

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