Let's Talk...

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Let's Talk ... QSO-22-07-ALL: Omnibus COVID-19 Health Care Staff Vaccination Guidance - LTC

(and QSO-22-09 and QSO-22-11)

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We'll Cover …

- Key points in these recent CMS QSO Memorandums including vaccination enforcement
- What to expect from enforcement and when
- Guidance for implementing and compliance with F888

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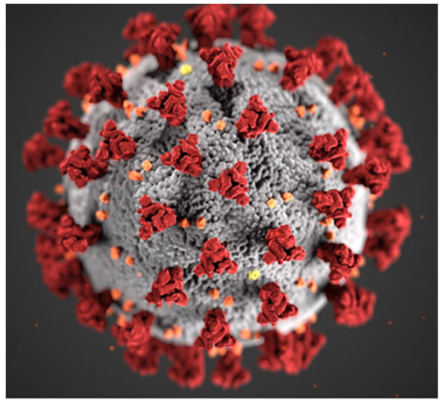

Status Check

- 1st U.S. case reported to CDC … January 22, 2020
- PHE Declared … January 31, 2020
- QSO-20-14-NH … March 13, 2020 (NH Lockdown/Visit Restriction)
- COVID-19 Emergency Declaration Blanket Waivers for HC Providers … March 13, 2020
- QSO-20-29-NH … May 6, 2020 (IFR: NHSN reporting; F884 & F885)
- U.S. COVID-19 death toll surpasses 100,000 … May 28, 2020
- CMS-3401-IFC … August 25, 2020 (IFR: routine testing NH residents & staff)
- U.S. COVID-19 death toll surpasses 200,000 … September 22, 2020
- 1st dose of vaccine given in U.S. … December 14, 2020
- Over 1 million people in U.S. vaccinated … December 24, 2020
- U.S COVID-19 death toll surpasses 400,000 … January 18, 2021
- U.S.COVID-19 death toll surpasses 500,000 … February 21, 2021
- QSO-21-19-NH … May 11, 2021 (IFR: Vaccine Immunization Requirements for NH Residents and Staff)
- CMS to issue new regulation requiring nursing homes to implement a requirement that all staff be vaccinated against COVID-19 … August 18, 2021
- U.S. death toll = 644,848 … September 3, 2021
- U.S. death toll = 864,203 … January 25, 2022

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What's at Stake

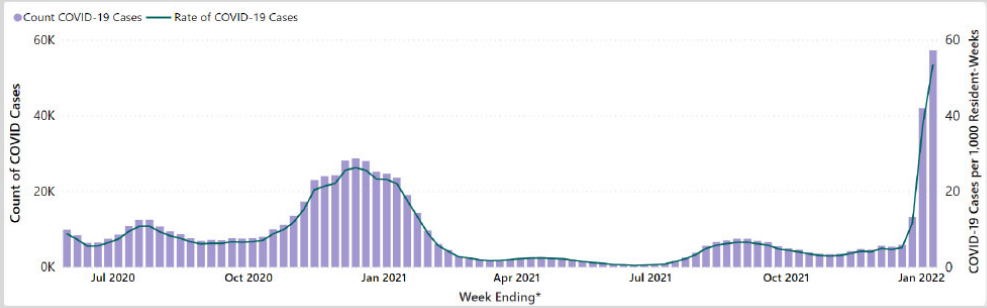
AHCA AMERICAN HEALTH CARE ASSOCIATION NCAL NATIONAL CENTER FOR ASSISTED LIVING

COVID-19 CASES IN NURSING HOMES ARE INCREASING AT ALARMING RATES DUE TO THE HIGHLY CONTAGIOUS OMICRON VARIANT

Weekly COVID Cases	Nursing Home Residents	Nursing Home Staff
Dec 19, 2021	4,361	5,919
Dec 26, 2021	6,406	13,257
Jan 2, 2022	18,186	42,004
Jan 9, 2022	32,061	57,243

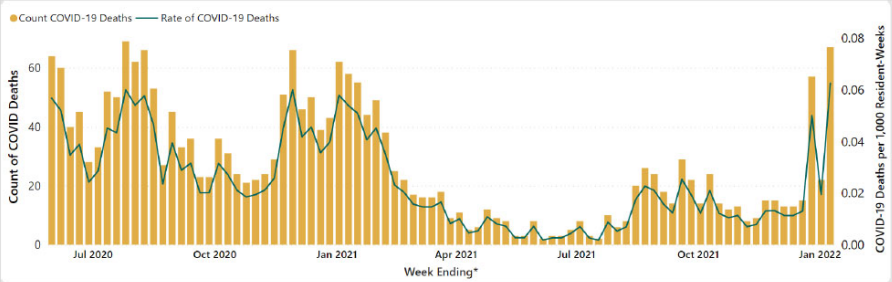
AHCA AMERICAN HEALTH CARE ASSOCIATION NCAL NATIONAL CENTER FOR ASSISTED LIVING

WEEKLY COVID CASES AMONG U.S. NURSING HOME STAFF
57,253 weekly staff cases as of January 9, 2022
53.41 staff cases per 1,000 residents



AHCA AMERICAN HEALTH CARE ASSOCIATION NCAL NATIONAL CENTER FOR ASSISTED LIVING

WEEKLY COVID DEATHS AMONG U.S. NURSING HOME STAFF
67 weekly staff deaths as of January 9, 2022
0.06 staff deaths per 1,000 residents



AHCA AMERICAN HEALTH CARE ASSOCIATION NCAL NATIONAL CENTER FOR ASSISTED LIVING

COVID-19 VACCINES ARE HELPING PREVENT NURSING HOME DEATHS
87.3% of residents are fully vaccinated
61.9% have received their booster
as of January 2, 2022

Week Ending	December 20, 2020	January 9, 2022
Weekly COVID Cases Among Nursing Home Residents	34,094	32,061
Weekly COVID Deaths Among Nursing Home Residents	6,219	645
Weekly COVID Death Rate per 1,000 Nursing Home Residents	5.68	0.60

AHCA/NCAL Report ... January 12, 2022

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January 9, 2022 Numbers

By the numbers

87.4%
National Percent of Vaccinated Residents per Facility

81.1%
National Percent of Vaccinated Staff per Facility

800,026
Total Resident COVID-19 Confirmed Cases

142,693
Total Resident COVID-19 Deaths

808,174
Total Staff COVID-19 Confirmed Cases

2,312
Total Staff COVID-19 Deaths

https://data.cms.gov/covid-19/covid-19-nursing-home-data

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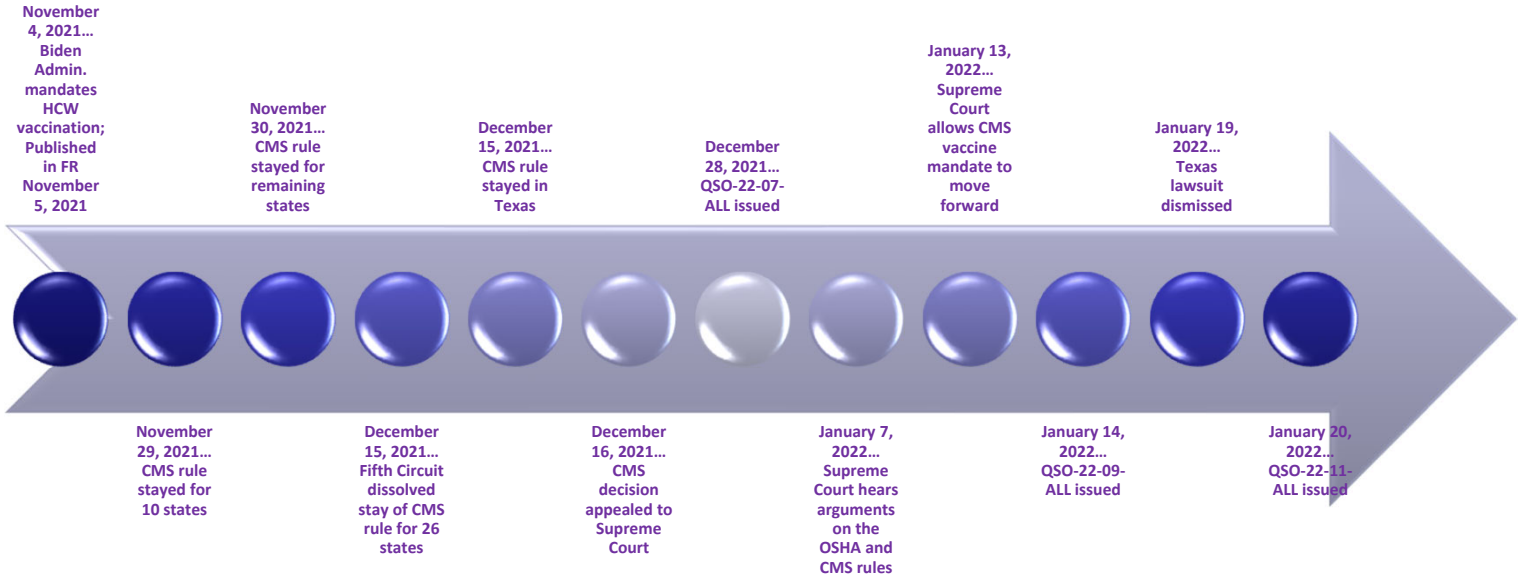
Challenges Timeline



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QSO Memorandums

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-22-07-ALL

DATE: December 28, 2021

TO: State Survey Agency Directors

FROM: Directors
Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG)

SUBJECT: Guidance for the Interim Final Rule - Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination

Memorandum Summary

- CMS is committed to ensuring America's healthcare facilities respond effectively in an evidence-based way to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- On November 05, 2021, CMS published an interim final rule with comment period (IFC). This rule establishes requirements regarding COVID-19 vaccine immunization of staff among Medicare- and Medicaid-certified providers and suppliers.
- CMS is providing guidance and survey procedures for assessing and maintaining compliance with these regulatory requirements.
- The guidance in this memorandum does not apply to the following states at this time: Alabama, Alaska, Arizona, Arkansas, Georgia, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, New Hampshire, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Texas, Utah, West Virginia and Wyoming. **Surveyors in these states should not undertake any efforts to implement or enforce the IFC.**

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-22-11-ALL

DATE: January 20, 2022

TO: State Survey Agency Directors

FROM: Directors
Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG)

SUBJECT: Guidance for the Interim Final Rule - Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination

Memorandum Summary

- CMS is committed to ensuring America's healthcare facilities respond effectively in an evidence-based way to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- On November 05, 2021, CMS published an interim final rule with comment period (IFC). This rule establishes requirements regarding COVID-19 vaccine immunization of staff among Medicare- and Medicaid-certified providers and suppliers.
- CMS is providing guidance and survey procedures for assessing and maintaining compliance with these regulatory requirements.
- The guidance in this memorandum specifically applies to the following state: **Texas**.
- States that are not identified above are expected to continue under the timeframes and parameters identified in either the December 28, 2021 or January 14, 2022 memoranda (QSO-22-07-ALL and QSO 22-09-ALL).

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-22-09-ALL

DATE: January 14, 2022

TO: State Survey Agency Directors

FROM: Directors
Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG)

SUBJECT: Guidance for the Interim Final Rule - Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination

Memorandum Summary

- CMS is committed to ensuring America's healthcare facilities respond effectively in an evidence-based way to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- On November 05, 2021, CMS published an interim final rule with comment period (IFC). This rule establishes requirements regarding COVID-19 vaccine immunization of staff among Medicare- and Medicaid-certified providers and suppliers.
- CMS is providing guidance and survey procedures for assessing and maintaining compliance with these regulatory requirements.
- The guidance in this memorandum specifically applies to the following states: Alabama, Alaska, Arizona, Arkansas, Georgia, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, New Hampshire, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Utah, West Virginia and Wyoming.
- The guidance in this memorandum does not apply to the following state at this time: Texas. **Surveyors in Texas should not undertake any efforts to implement or enforce the IFC.**
- States that are not identified above are expected to continue under the timeframes and parameters identified in the December 28, 2021 memorandum (QSO-22-07-ALL).

QSO-22-07-ALL

QSO-22-09-ALL

QSO-22-11-ALL

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Do the CMS staff vaccination requirements apply to my facility?

Are you one of the following Medicare- or Medicaid-certified facilities outside the 25 states listed above?

- Ambulatory Surgical Centers
- Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services
- Community Mental Health Centers
- Comprehensive Outpatient Rehabilitation Facilities
- Critical Access Hospitals
- End-Stage Renal Disease Facilities
- Home Health Agencies
- Home Infusion Therapy Suppliers
- Hospices
- Hospitals
- Intermediate Care Facilities for Individuals with Intellectual Disabilities
- Long Term Care Facilities
- Programs for All-Inclusive Care for the Elderly Organizations
- Psychiatric Residential Treatment Facilities
- Rural Health Clinics / Federally Qualified Health Centers

YES → ✓ Staff Vaccination Requirements Apply

No →

Do you provide services to certified facilities under contract or other arrangements? (Ex: EMS, physician w/ admitting privileges, pharmacies, etc.)

- YES → ✓ **Staff Vaccination Requirements Apply** *(Certified facilities must ensure individuals in this scenario are vaccinated)*
- NO → ✗ Staff Vaccination Requirements **Do Not Apply**

Do you have any staff who transition between your facility and a certified facility? (Ex: staff who transition between a nursing home and Assisted Living Facility)

- YES → ✓ **Staff Vaccination Requirements Apply** *(Certified facilities must ensure individuals in this scenario are vaccinated)*
- NO → ✗ Staff Vaccination Requirements **Do Not Apply**

How do I know if I'm a certified facility?

- You have gone through the Medicare enrollment process
- Have received a survey by State Survey Agency or CMS approved Accrediting Organization
- Received a National Provider Identifier (NPI) and CMS Certification Number (CCN)
- Can bill Medicare for services
- Medicare pays for services

You can verify whether you are certified via QCOR

If the staff vaccination requirements apply, your facility must:

For Phase 1:

- Facilities must have all policies and procedures in place for ensuring staff are fully vaccinated, providing exemptions, and tracking staff vaccinations.
- Staff at all health care facilities included within the regulation must have received, at a minimum, the first dose of a primary series or a single dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the facility and/or its patients.

For Phase 2:

- Staff must be fully vaccinated (with the exception of those who have been granted exemptions from the COVID-19 vaccine or for those staff for whom the COVID-19 vaccination must be temporarily delayed, as recommended by CDC.

Note: The staff vaccination requirement does not apply to full time telework staff.

CMS

https://www.cms.gov/files/document/covid-19-health-care-staff-vaccination-requirements-decision-tree-graphic.pdf

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COVID-19 Vaccination Requirements for Health Care Providers and Suppliers

I'M A COMMUNITY CHAMPION

If you are one of the following Medicare or Medicaid providers or suppliers, the CMS staff vaccination requirement applies to you:

- Ambulatory Surgery Centers
- Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services
- Community Mental Health Centers
- Comprehensive Outpatient Rehabilitation Facilities
- Critical Access Hospitals
- End-Stage Renal Disease Facilities
- Home Health Agencies
- Home Infusion Therapy Suppliers
- Hospices
- Hospitals
- Intermediate Care Facilities for Individuals with Intellectual Disabilities
- Long Term Care facilities
- Programs for All-Inclusive Care for the Elderly Organizations (PACE)
- Psychiatric Residential Treatment Facilities (PRTFs)
- Rural Health Clinics/Federally Qualified Health Centers

How do I meet this requirement?

Phase 1 Requirements	Phase 2 Requirements
Facilities must have **all policies and procedures in place** for ensuring staff are fully vaccinated, providing exemptions, and tracking staff vaccinations. Staff at all health care facilities included within the regulation must have received, at a minimum, **the first dose of a primary series or a single dose COVID-19 vaccine** prior to staff providing any care, treatment, or other services for the facility and/or its patients.	**Staff must be fully vaccinated** (with the exception of those who have been granted exemptions from the COVID-19 vaccine or for those staff for whom the COVID-19 vaccination must be temporarily delayed, as recommended by CDC).

How is this requirement enforced?

Onsite Survey Reviews for:

- ☑ Plan for vaccinating all eligible staff to meet thresholds listed above
- ☑ Plan to provide accommodations to those who are exempt
- ☑ Plan for tracking and documenting staff vaccinations
- ☒ Facility is out of compliance and subject to citations if the above is not met

Facility Citations
Based on severity of deficiency

Opportunity to come into compliance

If facility does not return to compliance, it is at risk for additional enforcement actions, including losing Medicare or Medicaid payment

CMS

https://www.cms.gov/files/document/covid-19-health-care-staff-vaccination-requirements-infographic.pdf

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Vaccine Mandate Timelines

CMS Omnibus COVID-19 Health Care Staff Vaccination Rule – Implementation Timeline

State		Phase 1 Deadline	Phase 2 Deadline
Alabama	QSO-22-09	February 14, 2022	March 15, 2022
Alaska	QSO-22-09	February 14, 2022	March 15, 2022
Arizona	QSO-22-09	February 14, 2022	March 15, 2022
Arkansas	QSO-22-09	February 14, 2022	March 15, 2022
California	QSO-22-07	January 27, 2022	February 28, 2022
Colorado	QSO-22-07	January 27, 2022	February 28, 2022
Connecticut	QSO-22-07	January 27, 2022	February 28, 2022
Delaware	QSO-22-07	January 27, 2022	February 28, 2022
Distinct of Columbia	QSO-22-07	January 27, 2022	February 28, 2022
Florida	QSO-22-07	January 27, 2022	February 28, 2022
Georgia	QSO-22-09	February 14, 2022	March 15, 2022
Hawaii	QSO-22-07	January 27, 2022	February 28, 2022
Idaho	QSO-22-09	February 14, 2022	March 15, 2022
Illinois	QSO-22-07	January 27, 2022	February 28, 2022
Indiana	QSO-22-09	February 14, 2022	March 15, 2022
Iowa	QSO-22-09	February 14, 2022	March 15, 2022
Kansas	QSO-22-09	February 14, 2022	March 15, 2022
Kentucky	QSO-22-09	February 14, 2022	March 15, 2022
Louisiana	QSO-22-09	February 14, 2022	March 15, 2022
Maine	QSO-22-07	January 27, 2022	February 28, 2022
Maryland	QSO-22-07	January 27, 2022	February 28, 2022
Massachusetts	QSO-22-07	January 27, 2022	February 28, 2022
Michigan	QSO-22-07	January 27, 2022	February 28, 2022
Minnesota	QSO-22-07	January 27, 2022	February 28, 2022
Mississippi	QSO-22-09	February 14, 2022	March 15, 2022
Missouri	QSO-22-09	February 14, 2022	March 15, 2022
Montana	QSO-22-09	February 14, 2022	March 15, 2022
Nebraska	QSO-22-09	February 14, 2022	March 15, 2022
Nevada	QSO-22-07	January 27, 2022	February 28, 2022
New Hampshire	QSO-22-09	February 14, 2022	March 15, 2022
New Jersey	QSO-22-07	January 27, 2022	February 28, 2022
New Mexico	QSO-22-07	January 27, 2022	February 28, 2022
New York	QSO-22-07	January 27, 2022	February 28, 2022
North Carolina	QSO-22-07	January 27, 2022	February 28, 2022
North Dakota	QSO-22-09	February 14, 2022	March 15, 2022
Ohio	QSO-22-09	February 14, 2022	March 15, 2022
Oklahoma	QSO-22-09	February 14, 2022	March 15, 2022
Oregon	QSO-22-07	January 27, 2022	February 28, 2022
Pennsylvania	QSO-22-07	January 27, 2022	February 28, 2022
Rhode Island	QSO-22-07	January 27, 2022	February 28, 2022
South Carolina	QSO-22-09	February 14, 2022	March 15, 2022
South Dakota	QSO-22-09	February 14, 2022	March 15, 2022
Tennessee	QSO-22-07	January 27, 2022	February 28, 2022
Texas	QSO-22-11	February 22, 2022	March 21, 2022
Utah	QSO-22-09	February 14, 2022	March 15, 2022
Vermont	QSO-22-07	January 27, 2022	February 28, 2022
Virginia	QSO-22-07	January 27, 2022	February 28, 2022
Washington	QSO-22-07	January 27, 2022	February 28, 2022
West Virginia	QSO-22-09	February 14, 2022	March 15, 2022
Wisconsin	QSO-22-07	January 27, 2022	February 28, 2022
Wyoming	QSO-22-09	February 14, 2022	March 15, 2022

Phase 1 Requirements:

- Facilities must have all policies and procedures in place for ensuring staff are fully vaccinated, providing exemptions, and tracking staff vaccinations.
- Staff at all health care facilities included within the regulation must have received, at a minimum, the first dose of a primary series or a single dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the facility and/or its patients.

Phase 2 Requirements:

- Staff must be fully vaccinated (with the exception of those who have been granted exemptions from the COVID-19 vaccine or for those staff for whom the COVID-19 vaccination must be temporarily delayed, as recommended by CDC).

https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/guidance-interim-final-rule-medicare-and-medicaid-programs-omnibus-covid-19-health-care-staff-0

https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/guidance-interim-final-rule-medicare-and-medicaid-programs-omnibus-covid-19-health-care-staff-1

https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/guidance-interim-final-rule-medicare-and-medicaid-programs-omnibus-covid-19-health-care-staff-2

CMS

https://www.cms.gov/files/document/health-care-staff-vaccination-rule-implementation-timeline.pdf

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QSO Contents

Downloads

QSO-22-07-ALL (PDF)
QSO-22-07 ALL Attachment A - LTC (PDF)
QSO-22-07-ALL Attachment B ASC (PDF)
QSO-22-07 ALL Attachment C Hospice (PDF)
QSO-22-07 ALL Attachment D Hospital (PDF)
QSO-22-07-ALL Attachment E PRTF (PDF)
QSO-22-07 ALL Attachment F ICF-IID (PDF)
QSO-22-07 ALL Attachment G HHA (PDF)
QSO-22-07 ALL Attachment H CORF (PDF)
QSO-22-07 ALL Attachment I CAH (PDF)
QSO-22-07 ALL Attachment J OPT (PDF)
QSO-22-07 ALL Attachment K CMHC (PDF)
QSO-22-07 ALL Attachment L HIT (PDF)
QSO-22-07 ALL Attachment M RHCFQHC (PDF)
QSO-22-07 Attachment N ESRD (PDF)

Use both

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FAQ Document

External FAQ: CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule

These frequently asked questions (FAQs) were initially issued on November 5, 2021 and have been updated as of January 20, 2022 as discussed below.

Basics

Q: When does this take effect?
A: The emergency regulation is effective as of November 5, 2021.

New as of 1/20/22 - **Q: Now that the guidance is issued, when will enforcement of the IFC begin?**
A: CMS, as an exercise of enforcement discretion, will begin monitoring and enforcing compliance on the following modified timeline:

https://www.cms.gov/files/document/cms-omnibus-covid-19-health-care-staff-vaccination-requirements-2021.pdf

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In Short, You Must…

- ✓ Have a plan and process in place for vaccinating all your staff by the required CMS deadlines
- ✓ Have a plan and process for providing exemptions and accommodations for those staff who are exempt from the vaccination requirement (medical or religious) as well as temporary delay for vaccination
- ✓ Have a plan and process for tracking and documenting staff vaccinations
- ✓ Have a process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all staff who are not fully vaccinated for COVID-19
- ✓ Follow your plan and process

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General Comments - Enforcement

- 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, home health agencies, and hospice (beginning in 2022), this includes civil monetary penalties, denial of payments, and—as a final measure—termination of participation from the Medicare and Medicaid programs.
- CMS's primary goal is to bring health care facilities into compliance. Facility staff vaccination rates under 100% constitute noncompliance under the rule.
- The sole enforcement remedy for non-compliance for hospitals and certain other acute and continuing care providers is termination. Termination would generally occur only after providing a facility with an opportunity to make corrections and come into compliance.
- CMS expects all providers' and suppliers' staff to have received the appropriate number of doses by the timeframes specified in the QSO-22-07/09/11 unless exempted as required by law or delayed as recommended by CDC.
- Consistent with CMS's existing enforcement processes, this guidance will help surveyors determine the severity of a noncompliance deficiency finding at a facility when assigning a citation level.

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Phase 1 Deadline

Within 30 days after issuance of this memorandum[2], if a facility demonstrates that:

- 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, the **facility is compliant under the rule; or**
- 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 is non-compliant under the rule.** The facility will receive notice[3] 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. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction, civil monetary penalties, denial of payment, termination, etc.).

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Phase 2 Deadline

Within 60 days after the issuance of this memorandum[4], if the facility demonstrates that:

- 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, the **facility is compliant under the rule; or**
- 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 is non-compliant under the rule.** The facility will receive notice[5] 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. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction, civil monetary penalties, denial of payment, termination, etc.).

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Phase 3 Deadline

Within 90 days and thereafter following issuance of this memorandum, facilities failing to maintain compliance with the 100% standard may be subject to enforcement action.

Federal, state, Accreditation Organization, and CMS-contracted surveyors will begin surveying for compliance with these requirements as part of initial certification, standard recertification or reaccreditation, and complaint surveys 30 days following the issuance of this memorandum. Additional information and expectations for compliance can be found at the provider-specific guidance attached to this memorandum.

[2] If 30 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day.
[3] This information will be communicated through the CMS Form-2567, using the applicable Automated Survey Process Environment (ASPEN) federal tag.
[4] If 60 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day.

[5] This information will be communicated through the CMS Form-2567, using the applicable Automated Survey Process Environment (ASPEN) tag.

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Survey Process

- Surveyors will request the facility's COVID-19 vaccination policies and procedures, the number of resident and staff COVID-19 cases over the last 4 weeks, and a list of all staff and their vaccination status. The staff list must include the percentage of vaccinated staff, using the vaccine matrix provided by the survey team, and the position or role of each staff member, including staff (facility staff, contracted staff, volunteers, or students) who are or are likely to be in contact with residents or other staff, regardless of frequency.
- CMS updated CMS-20054…Infection Prevention Control and Immunization Critical Element Pathway on January 25, 2022 to provide for F888 compliance.

Effective Date	Document/File Name	Description of Change
01/24/2022	1. Survey Resources Folder 2. Survey Resources-January 2022 Folder (NEW)	Updated: 1. Survey Resources Folder • LTC Survey Pathways • Entrance Conference form • LTCSP Procedure Guide 2. Added Survey Resources-January 2022 Folder (**for States NOT affected by injunction**) Effective as a result of QSO-22-07-ALL and QSO-22-09-ALL and QSO-22-11-ALL

- https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Nursing-Homes

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Entrance Conference WSheet…1/25/2022

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

COVID-19 Focused Infection Control (FIC) Survey with Staff Vaccination Mandate
Entrance Conference Worksheet

(Note: Surveyors in a state that is subject to QSO-22-07-ALL should start using this protocol on 1/27/2022. Surveyors in a state that is subject to QSO-22-09-ALL should start using this protocol on 2/14/2022. Surveyors in a state that is subject to QSO-22-11-ALL should start using this protocol on 2/22/2022).

	INFORMATION NEEDED FROM THE FACILITY IMMEDIATELY UPON ENTRANCE*
❑	1. Census number
❑	2. An alphabetical list of all residents and room numbers (note any resident out of the facility).
❑	3. A list of residents who are confirmed or suspected cases of COVID-19
❑	4. Name of facility staff responsible for Infection Prevention and Control Program.
❑	5. Name of facility staff responsible for overseeing the COVID-19 vaccination effort.
	ENTRANCE CONFERENCE
❑	6. Conduct a brief Entrance Conference with the Administrator.
❑	7. Signs announcing the survey that are posted in high-visibility areas.
❑	8. A copy of an updated facility floor plan, if changes have been made, including observation and COVID-19 units.
❑	*9.Complete the COVID-19 Staff Vaccination Matrix or provide a list containing the same information as soon as possible.*
	INFORMATION NEEDED FROM FACILITY WITHIN ONE HOUR OF ENTRANCE*
❑	10. The actual working schedules for all staff, separated by departments, for the survey time period.
❑	11. List of key personnel location, and phone numbers. Note contract staff (e.g., rehab services). Also include the staff responsible for notifying all residents, representatives, and families of confirmed or suspected COVID-19 cases in the facility.
❑	12. Provide each surveyor with access to all resident electronic health records (EHRs) – do not exclude any information that should be a part of the resident's medical record. Provide instructions on how surveyors can access the EHRs outside of the conference room. Please complete the attached form on page 3 which is titled "Electronic Health Record Information."
❑	13. Facility Policies and Procedures: • Infection Prevention and Control Program Policies and Procedures, to include the Surveillance Plan • Procedures to address residents and staff who refuse testing or are unable to be tested • Emergency Preparedness Policy and Procedure to include Emergency Staffing Strategies • Influenza, Pneumococcal, and COVID-19 Vaccination Policy & Procedures • *COVID-19 Healthcare Staff Vaccination Policies and Procedures*
❑	14. The facility's mechanism(s) used to inform residents, their representatives, and families of confirmed or suspected COVID-19 cases in the facility and mitigating actions taken by the facility to prevent or reduce the risk of transmission, including if normal operations in the nursing home will be altered (e.g., supply the newsletter, email, website, etc.). If the system is dependent on the resident or representative to obtain the information themselves (e.g., website), provide the notification/information given to residents, their representatives, and families informing them of how to obtain COVID-19 updates.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

COVID-19 Focused Infection Control (FIC) Survey with Staff Vaccination Mandate
Entrance Conference Worksheet

❑	15. Documentation related to COVID-19 testing, which may include the facility's testing plan, logs of county level positivity rates (before 09-10-2021) and the level of community transmission (after 09-10-2021), testing schedules, list of staff who have confirmed or suspected cases of COVID-19 over the last 4 weeks, and, if there were testing issues, contact with state and local health departments.
❑	16. A list of residents and their COVID-19 vaccination status.
❑	*17. Numbered list of resident cases of confirmed COVID-19 over the last 4 weeks. Indicate whether any resident cases resulted in hospitalization or death.*

*The timelines for requested information in the table are based on normal circumstances. Surveyors should be flexible on the time to receive information based on the conditions in the facility. For example, do not require paperwork within an hour if it interrupts critical activities that are occurring to prevent the transmission of COVID-19.

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Staff Formulas for F888…1/2022

Comparison to NHSN data		
Total number of staff completely vaccinated (6)	Total staff	% Current staff received completed vaccination
		#DIV/0!

Within 30-59 days following issuance of memo						
Total number of staff partially vaccinated (5)	Total number of staff completely vaccinated (6)	Granted or pending medical exemption (8)	Granted or pending non-medical exemption (9)	Temporary delay per CDC (10)	Total staff	% Current staff vaccinated
						#DIV/0!

After 60 days following issuance of memo					
Total number of staff completely vaccinated (6)	Granted Medical exemption (8)	Granted Non-medical exemption (9)	Temporary delay per CDC (10)	Total staff	% Current staff vaccinated
					#DIV/0!

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COVID-19 Staff Vaccination Matrix Instructions for Providers…1/2022

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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OMB Exempt

COVID-19 STAFF VACCINATION MATRIX INSTRUCTIONS FOR PROVIDERS

The Matrix is used to identify the vaccination status for all staff. The facility completes this form, including section I, staff name, and columns 1–11, which are described in detail below, or provide a list containing the same information required in the matrix.

Unless stated otherwise, for each staff mark an X for all columns that are pertinent.

1. **Direct facility hire (DH), Contracted hire (C), or Other (O):** Direct facility hires (DH) are employees who are directly hired by the facility. Contracted hires (C) provide care, treatment, or other services for the facility and/or its residents under contract or by other arrangements. Other (O) includes adult students, trainees, and volunteers.
2. **Title:** Identify the staff's title (e.g., RN, LPN, CNA, PA, RD).
3. **Position:** Identify the staff's position (e.g., staff nurse, charge nurse, infection preventionist, restorative aide).
4. **Assigned work area:** The physical location in the facility (e.g., laundry room, kitchen, unit, ward, wing). If the staff is PRN/floater/agency, indicate their assigned work area on the first day of the survey.
5. **Partially vaccinated:** Staff who have received one dose of a multi-dose vaccine.
6. **Completely vaccinated:** Staff who have received one dose of a single dose vaccine or all doses of a multi-dose vaccine. (For the purpose of this document, fully vaccinated and completely vaccinated are the same)
7. **Booster dose:** A dose of vaccine administered when the initial sufficient immune response to the primary vaccination series is likely to have waned over time.
8. **Pending (P) or Granted (G) medical exemption:** Per CDC certain allergies or recognized medical conditions, which may provide grounds for a medical exemption (Please refer to the CDC).
9. **Pending (PN) or Granted (GN) non-medical exemption:** May be a religious exemption in accordance with Title VII.
10. **Temporary delay per CDC/new hire:** Vaccination that must be temporarily postponed, as recommended by the CDC, due to clinical precautions and considerations. Newly hired staff, who are not completely vaccinated due to timing requirements between doses.
11. **Not vaccinated without exemption or delay:** Any staff who have not received any doses of a vaccine and do not qualify for any of the exemptions or delays.

Section I

Total number of staff: All staff that work in the facility. Staff includes facility employees (regardless of clinical responsibilities or resident contact), licensed practitioners, adult students, trainees, and volunteers; and individuals who provide care, treatment, or other services for the facility and/or its residents, under contract or by other arrangement.

Number partially vaccinated staff (column 5): Number of current staff who received partial vaccination at any time as defined as, current staff who have received at a minimum, the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine.

Number completely vaccinated staff (column 6): Number of current staff who completed vaccination at any time is defined as, current staff with administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine

Number of staff with pending exemption (columns 8 and 9): Number of current staff with a request (pending) a medical or non-medical exemption.

Number of staff with granted exemption (columns 8 and 9): Number of current staff who was granted a qualifying medical or non-medical exemption.

Number of staff with temporary delay (column 11): Number of current staff whose COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations.

Number of staff not vaccinated without exemption or delay: Number of current staff who have not received any doses of a vaccine and do not qualify for an exemption or temporary delay.

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:
partially vaccinated staff (5):
completely vaccinated staff (6):
pending exemption (8 and 9):
granted exemption (8 and 9):
temporary delay/new hire (10):
not vaccinated without exemption/delay (11):

Note: The sum of the #'s for columns 5, 6, 8 through 11 should equal the total # of staff.

					Vaccinated			Not Vaccinated			
Staff Name	**Direct facility hire (DH), Contracted hire (C), Other (O)** 1	**Title** 2	**Position** 3	**Assigned work area** 4	**Partially vaccinated** 5	**Completely vaccinated** 6	**Booster dose** 7	**Pending (P) or Granted (G) medical exemption** 8	**Pending (PN) or Granted (GN) non-medical exemption** 9	**Temporary delay per CDC/ new hire** 10	**Not vaccinated without exemption/delay** 11

Instructions for Surveyors to Determine Compliance at

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Matrix Instructions Cont'd

§483.80(i) COVID-19 Vaccination of Facility Staff

Note: A Staff Formula spreadsheet is available in the Survey Resources folder that can be used to calculate the formulas listed below. **Please attach the completed spreadsheet to the LTCSP software or the survey shell.**

Section II – Verification of National Health Care Safety Network (NHSN) data

- Please fill in the blanks with data directly from this link.
- NHSN as reported for week ending on (report header):
- Recent Percentage of Staff who are Fully Vaccinated: If there is no data present in NHSN, please ask the facility staff the rationale while onsite. (For the purpose of this document, fully vaccinated and completely vaccinated are the same)
- Review the staff matrix or the facility's list of all staff and their vaccination status, which is obtained on the first day of the survey. Calculate the percentage of the current staff who have completed vaccinations using the formula listed in Figure 1 (do not round). Compare the facility's data with the above NHSN data.

Figure 1: Formula to calculate percentage of current vaccinated staff to compare with NHSN data

$$\text{\% current staff received completed vaccination} = \frac{\text{\# Completely vaccinated (6)}}{\text{\# of total staff}} \times 100$$

- If there is a 10% or less difference between the facility documentation and the NHSN data, no further investigation is required.
- If there is a greater than 10% difference, ask the facility to verify and explain why there is a significant variation.
- If the information presented to the surveyor is incorrect (and NHSN is correct), or if both sources are incorrect, this likely demonstrates the facility's failure to have a process for tracking and securely documenting the COVID-19 vaccination status for all staff [per §483.80(i)(3)(iv)], consider citing F888.
- If the information reported to NHSN is incorrect (and the information reviewed onsite is correct) or data is not present, inform the facility to immediately correct the information in the NHSN system.

Section III – Determine when to cite F888

Determine the percentage of staff vaccinated: (Follow the data in Section I provided on the facility matrix)

- **When surveying between 30 - 59 days following issuance of the QSO-22-07-ALL (effective 1/27/2022–2/27/2022) / QSO-22-09-ALL (effective 2/14/2022-3/14/2022)/ QSO-22-11-ALL (effective 02/22/2022-03/20/2022) :** Use the formula below (or in the Staff Formula spreadsheet) to calculate the percentage (round to the whole number) of staff that received a COVID-19 vaccination using the information the facility completed in Section I above.

Formula for surveys conducted between 30 - 59 days following issuance of the QSO memo

$$\text{\%Vaccinated} = \frac{\text{\# Partially vaccinated (5)} + \text{\# Completely vaccinated (6)} + \text{\# Pending exemption (8 and 9)} + \text{\# Granted exemption (8 and 9)} + \text{\# Temporarily delayed (10)}}{\text{\# of total staff}} \times 100$$

  - If the percent vaccinated is less than 100%, cite F888.

- **When surveying 60 days following issuance of the QSO-22-07-ALL (effective 2/28/22 and thereafter) / QSO-22-09-ALL (effective 3-15-2022 and thereafter) / QSO-22-11-ALL (effective 03/21/2022 and thereafter):** Use the formula below (or in the Staff Formula spreadsheet) to calculate the percentage (round to the whole number) of staff that received a completed COVID-19 vaccination series.

Formula for surveys conducted 60 following issuance of the QSO memo

$$\text{\%Vaccinated} = \frac{\text{\# Completely vaccinated (6)} + \text{\# Granted exemption (8 and 9)} + \text{\# Temporarily delayed (10)}}{\text{\# of total staff}} \times 100$$

  - If the percent vaccinated is less than 100%, cite F888.
  - Note: 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 would need to be incompliance with §483.80(i)(3)(iii), including adhering to additional precautions that are intended to mitigate the spread of COVID-19.

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13. Did the facility develop policies and procedures that address the above components? ☐ Yes ☐ **No F888**

Verification of National Healthcare Safety Network (NHSN) data: Please fill in the blanks with data directly from this link.

NHSN as reported for week ending on (report header): ☐

https://download.cms.gov/covid_nhsn/covid-19%20nursing%20home%20resident%20and%20staff%20vaccination%20rates.xlsx

Recent Percentage of Staff who are Fully Vaccinated: ☐

Note: if there is no data present in NHSN, please ask the facility staff the rationale while onsite.

☐ Review the COVID-19 Staff Vaccination Matrix or the facility's list of all staff and their vaccination status, which is obtained on the first day of the survey. Calculate the percentage of the current staff who received completed vaccinations using the formula listed in Figure 1 on the Surveyor Instructions on the COVID-19 Staff Vaccination Matrix (do not round). Compare the facility's data with the above NHSN data.

- If there is a 10% or less difference between the facility documentation and the NHSN data, no further investigation is required.
- If there is a greater than 10% difference, ask the facility to verify and explain why there is a significant variation.
  - If the information presented to the surveyor is incorrect (and NHSN is correct), or if both sources are incorrect, this likely demonstrates the facility's failure to have a process for tracking and securely documenting the COVID-19 vaccination status for all staff [per §483.80(i)(3)(iv)], consider citing F888.
  - If the information reported to NHSN is incorrect (and the information reviewed onsite is correct) or there is no data present in NHSN, inform the facility to immediately correct the information in the NHSN system.

14. Did the facility implement their policy and have a process to track and securely document the COVID-19 vaccination status for all staff (per 483.80(i)(3)(iv))? ☐ Yes ☐ **No F888**

Determine the percentage of staff vaccinated and when to cite F888 in ASE-Q or LTCSP: (Refer to the surveyor instructions section III on the COVID-19 Staff Vaccination Matrix)

☐ Surveys conducted per QSO Memo 22-07-ALL (effective 01/27/2022–2/27/2022) / QSO-22-09-ALL (effective 02/14/2022-03/14/2022)/QSO-22-11-ALL (effective 02/22/2022-03/20/2022)

- If the percent vaccinated is 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, cite F888.

☐ Surveys conducted per QSO-22-07-ALL (effective on 02/28/2022 and thereafter) / QSO-22-09-ALL (effective 03/15/2022 and thereafter) / QSO-22-11-ALL (effective 03/21/2022 and thereafter)

- If the percent vaccinated is less than 100% of all staff have received at least **one dose of a single-dose vaccine**, or **all doses of a multiple vaccine series**, or have been **granted** a qualifying exemption, or identified as having a temporary delay recommended by the CDC, cite F888.

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Record Review, Staff Interviews, and Observations:

☐ Randomly select 8 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 staff
  - One certified nurse aide (CNA).
  - One individual who provides care, treatment, or other services for the facility and/or its residents under contract or by other arrangements (e.g., hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, licensed practitioners).
- 6 unvaccinated staff (if available)
  - Three unvaccinated staff (two of whom are CNAs, if available) without exemption or reason for being temporarily delayed.
  - One unvaccinated staff with a non-medical exemption such as religious exemption.
  - One unvaccinated staff with a medical exemption. (Note: If there are 2 or more staff with medical exemptions listed on the COVID-19 Staff Vaccination Matrix, select 50% of the facility staff from this category for review).
  - One unvaccinated staff whose primary vaccine series has been delayed.

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.

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☐ Observe and interview sampled staff who are not vaccinated to ensure additional precautions are in place to help prevent the spread of COVID-19.

- If reassigned: When were you reassigned duties?
- Are you being tested for COVID-19? If so, how often?
- Observe staff to determine whether they are using additional CDC-recommended precautions, including universal source control (use a NIOSH-approved N95 or equivalent or higher-level respirator for source control) and maintaining physical distance including areas that are restricted from resident access (e.g., staff meeting rooms, kitchen). at all times while in the facility.
- Determine whether other additional precautions are in place to mitigate the transmission of COVID-19.

☐ For all sampled staff, determine whether the COVID-19 vaccination documentation includes the following:

- Screening and eligibility to receive the vaccine(s); and
- The provision of education related to the COVID-19 vaccines such as the benefits and potential side effects; and offering of the COVID-19 vaccines to staff by the facility per requirements at 42 CFR 483.80(d)(3), F887.

Note: These provisions do not apply to sampled staff that received their vaccination outside of the facility.

☐ For sampled **vaccinated staff**, determine whether the facility documented the vaccination status for:

- a single-dose COVID-19 vaccine, or
- all required doses for a multi-dose COVID-19 vaccine, and
- a booster dose.

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☐ For the sampled **unvaccinated staff**:

- For staff who **do not have an exemption or reason for temporary delay,** ask the following:
  - Are you scheduled to receive a COVID-19 vaccine? If so, confirm the staff is scheduled.
  - If the staff isn't scheduled to receive a vaccine: Do you have a request for exemption pending?
  - When did the facility become aware staff did not have an exemption or 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?
- For staff who have requested and/or are granted **non-medical exemption**, verify facility records are tracked and secure, and interview staff to determine the following:
  - What is the process to request a non-medical exemption, such as a religious exemption?
  - How are staff informed about the process to request a non-medical exemption?
  - Ensure the facility has an effective process for staff to request a non-medical exemption. Surveyors will not focus on the details of the request, approval, or denial of non-medical exemptions.
- For staff who have requested and/or are granted **medical exemption,** verify facility records are tracked, secure, and include the following:
  - Which COVID-19 vaccine is clinically contraindicated;
  - The recognized clinical reasons for the contraindication;
  - A statement by the practitioner 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.
- For staff whose primary vaccine series is **temporarily delayed,** verify facility records are tracked, secure, and include the following:
  - An explanation for delay as per CDC clinical precautions and considerations;
  - How long the delay is planned; and
  - A plan for vaccination when the temporary delay is over (date when vaccination can resume).
- Review facility records and interview staff to confirm the facility has instituted the contingency plan, if needed:
  - Verify the actions taken by the facility for any staff who indicated they would not get vaccinated and were not qualified for an exemption?
  - When was staff given a deadline to receive the first dose of a vaccine? Confirm the date.
  - If the deadline has passed: What actions were taken?

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15. Did the facility implement their policy and procedures to ensure:
a) all staff are vaccinated for COVID-19;
b) there is a process to request an exemption;
c) vaccination status is tracked, and documentation is secure for staff with an exemption or temporary delay; and
d) contingency plans are developed and followed?
☐ Yes ☐ **No F888**

Educate and Offer COVID-19 Immunizations for Staff at Requirement 483.80(d)(3)

☐ Use the same staff sample used for CE #15 to determine compliance with CE #16.
☐ Review the facility's policies and procedures related to COVID-19 vaccination 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 it was not available?
- How are staff educated on the benefits and potential side effects before being offered a vaccine including any additional dose?
- How are staff vaccination status tracked or documented?
- How are staff screened for eligibility (e.g., medical contraindications, previous vaccination), that the vaccines are offered, and consent or refusal is obtained?

16. Did the facility maintain staff documentation of screening, education, offering, and current COVID-19 vaccination status?
☐ Yes ☐ **No F887**

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Table 1: Scope and Severity Grid

Severity & Scope for F888	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 P&Ps were not developed and implemented.
Level 4 - Immediate Jeopardy: Noncompliance resulting in **serious harm or death**: • 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. **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; **or** ○ 1 or more components of the policies and procedures were not developed or implemented. **OR,** ○ More than 40% of staff are unvaccinated **and** there is evidence of a lack of effort to increase staff vaccination rates.	**J**	**K**	**L**
Level 3 – Actual Harm: ○ 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**
Level 2: No actual harm w/potential for more than minimal harm that is not IJ: • Did not meet the requirement of staff vaccinated; **and** • No resident infections **OR,** • 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**
Level 1: No actual harm w/potential for minimal harm: • 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**

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F888 - §483.80 Infection Control Policies & Procedures

- The facility must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19:
  - 2 weeks or more since they completed a primary vaccination series for COVID-19
  - administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine
- Regardless of clinical responsibility or resident contact, the policies and procedures must apply to the following facility staff, who provide any care, treatment, or other services for the facility and/or its residents:
  - Facility employees – housekeeping, laundry, administrative, fiduciary board members, food service, etc.
  - Licensed practitioners
  - Students, trainees and volunteers
  - Individuals who provide care, treatment, or other services for the facility and/or its residents, under contract or by other arrangement

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Staff/Individuals Not Included

- Exempt from P&P:
  - Staff who exclusively provide telehealth or telemedicine services outside of the facility setting and who do not have any direct contact with residents and other staff
  - Staff who provide support services for the facility that are performed exclusively outside of the facility setting and who do not have any direct contact with residents
- Vendors who provide infrequent and ad-hoc non-health care services - delivery personnel, repair personnel and others
- Staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations - including, but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment
- Residents and their visitors

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Process for Tracking Staff Vaccine Status

The facility must track and securely document:

- each staff member's vaccination status (this should include the specific vaccine received, and the dates of each dose received, or the date of the next scheduled dose for a multi-dose vaccine);
- any staff member who has obtained any booster doses (this should include the specific vaccine booster received and the date of the administration of the booster);
- staff who have been granted an exemption from vaccination (this should include the type of exemption and supporting documentation);
- requirements by the facility; and
- staff for whom COVID-19 vaccination must be temporarily delayed. For temporary delays, facilities should track when the identified staff can safely resume their vaccination.

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Medical Exemptions

- Certain allergies or recognized medical conditions may provide grounds for a medical exemption:
  - history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
  - immediate (within 4 hours of exposure) allergic reaction of any severity to a previous dose
  - known (diagnosed) allergy to a component of the COVID-19 vaccine
- Medical exemption documentation must specify which authorized or licensed COVID-19 vaccine is clinically contraindicated for the staff member and the recognized clinical reasons for the contraindication. The documentation must also include a statement recommending that the staff member be exempted from the facility's COVID-19 vaccination requirements based on the medical contraindications.
- A staff member who requests a medical exemption from vaccination must provide documentation signed and dated by a licensed practitioner acting within their respective scope of practice and in accordance with all applicable State and local laws. The individual who signs the exemption documentation cannot be the same individual requesting the exemption.

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Religious Exemptions

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. We direct providers and suppliers to the Equal Employment Opportunity Commission (EEOC) Compliance Manual on Religious Discrimination (https://www.eeoc.gov/laws/guidance/section-12-religious-discrimination) for information on evaluating and responding to such requests.

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.

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More on Exemptions

- Facility must have a process by which staff may request exemption from COVID-19 vaccination based on an applicable Federal law.
- This process should clearly identify how an exemption is requested, and to whom the request must be made.
- Facility must have a process for collecting and evaluating such requests, including the tracking and secure documentation of information provided by those staff who have requested exemption, the facility's determination of the request, and any accommodations that are granted.
- Note: Staff who are unable to furnish proper exemption documentation must be vaccinated or the facility must follow the actions for unvaccinated staff.

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Accommodations of Unvaccinated Staff with a Qualifying Exemption

While accommodations could be appropriate under certain limited circumstances, no accommodation should be provided that is not legally required or if it is requested solely to evade vaccination. For individual staff members that have valid reasons for exemption, the facility can address those individually. An example of an accommodation for an unvaccinated employee with a qualifying exemption could include mandatory routine COVID-19 testing in accordance with OSHA and CDC guidelines, physical distancing from co-workers and patients, re-assignment or modification of duties, teleworking, or a combination of these actions. Accommodations can be addressed in the facility's policies and procedures. 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.

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Contingency Plans

Facilities are required to have contingency plans for staff who are not fully vaccinated. Contingency plans should include actions that the facility would take when staff have indicated that they will not get vaccinated and do not qualify for an exemption. Contingency plans should also address staff who are not fully vaccinated due to an exemption or temporary delay in vaccination, such as through the additional precautions required at §483.80(i)(3)(iii). Facilities should prioritize contingency plans for those staff that have obtained no doses of any vaccine over staff that have received a single dose of a multi-dose vaccine. For example, contingency plans could include a deadline for staff to have obtained their first dose of a multi-dose vaccine. The plans should also indicate the actions the facility will take if the deadline is not met, such as actively seeking replacement staff through advertising or obtaining temporary vaccinated staff until permanent vaccinated replacements can be found.

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Contingency Plans Include

- Reassigning staff who have not completed their primary vaccination series to non-patient care areas, to duties that can be performed remotely (e.g., telework), or to duties which limit exposure to those most at risk (e.g., assigning to residents who are not immunocompromised, unvaccinated).
- Requiring staff who have not completed their primary vaccination series to follow additional CDC-recommended precautions, such as adhering to universal source control and physical distancing measures in areas that are restricted from patient access (e.g., staff meeting rooms, kitchen), even if the facility or service site is located in a county with low to moderate community transmission.
- Requiring at least weekly testing for exempted staff, and staff who have not completed their primary vaccination series for until the regulatory requirement is met, regardless of whether the facility or service site is located in a county with low to moderate community transmission, in addition to following CDC recommendations for testing unvaccinated staff in facilities located in counties with substantial to high community transmission.
- Requiring staff who have not completed their primary vaccination series 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.
- Facilities may also consult with their local health departments to identify other actions that can potentially reduce the risk of COVID-19 transmission from unvaccinated staff.

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What Do I Do Now?

- Review the QSO, LTC attachment and this handout for compliance guidance.
- Work with your team to use the tools provided during this webinar (and from CMS) to achieve compliance as well as protection for residents, staff, visitors, etc. living and working in your facility.
- Continue to educate staff, residents, visitors, contractors, etc. on the benefits of vaccination for protection against COVID-19.
- Be a role model for everyone you interact with. Show them the way.
- Document everything you do for compliance with F888. In God we trust, all others must document. Submit required data – timely.
- Remember to thank your staff for all they do every day! Find meaningful ways to thank/reward them for their service. Everyone's work is important. It takes a team – make yours the greatest.

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Let's Talk...

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Our Next Webinar

Let's Talk ... QSO-22-08-NH: Nursing Home Staff Turnover and Weekend Staffing Levels | **February 10, 2022 10:00 AM CST**

We'll cover the key points in this recent CMS QSO Memorandum including why nursing home staffing and weekend staffing is being published *now*, what happened in January and what will happen in July, inclusion of data on Care Compare and the Five Star Quality Rating System, weekend nurse staffing and staff turnover as well as linking employer identifiers.

Register here

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Upcoming Webinar

If you'd like to listen to another presentation on the F888/QSO Memorandums for HC Staff Vaccination, you'll want to attend this webinar:

F888 COVID-19 Health Care Staff Vaccination Requirements – An Overview

February 17, 2022 … 10-11am CST

This webinar will review the current COVID-19 Vaccination of Facility Staff Requirements as implemented in the newly released F888 survey tag, its accompanying scope and severity grid as well as solutions for compliance with this regulation.

Register here

Briggs Healthcare is proud to welcome Hugh Heaton as our guest speaker for this webinar!

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Hugh Heaton was Founder, Chairman and CEO of Heaton Publications and The Compliance Store until he sold the product line in March 2010. In 2015, Hugh launched Regs-In-A-Flash - a new website that provides automated and digital regulatory and compliance resources. Hugh attended the University of Alabama majoring in Business Administration. Hugh began his LTC career in 1969 and has worked in the long-term care field for 46 years. He spent 12 years as a nursing home administrator and the last 40 years researching and writing policy manuals, training programs, and regulatory compliance resource guides. Hugh has authored/edited over 50 health-related manuals and training publications. Hugh has conducted educational seminars nationwide on topics such as the Survey Process, Regulatory Compliance, Identifying MDS Facility Rate Indicators, IDR/IIDRs, Health Care Staff Vaccination Requirements, and OSHA Regulations.

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Mary Madison
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Today's Presenter

Mary Madison is a registered nurse with 48 years of experience in the healthcare field – 45+ years in the long-term care industry. Mary has held positions of Director of Nursing in a 330-bed SNF, DON in two 60-bed SNFs, Reviewer with Telligen (Iowa QIO), Director of Continuing Education, Manager of Clinical Software Support, Clinical Software Implementer and Clinical Educator. Mary is a Certified Resident Assessment Coordinator (AAPACN) and a Certified Dementia Practitioner (NCCDP). Mary has conducted numerous MDS trainings and other LTC educational sessions across the country in the past 2+ decades. She joined Briggs Healthcare® as their LTC/Senior Care Clinical Consultant in July 2014.

Mary's contact information is: Madison.Mary@BriggsCorp.com

Briggs Healthcare® website: https://www.briggshealthcare.com/

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Thank you for attending today!

We're looking forward to seeing you again soon.

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