

It's Worth a Shot

Updates About the
COVID-19 Vaccine Mandate

March 2, 2022



Housekeeping Items

- Add your webinar topics and clinician ideas or needs into chat!
- We will meet every Wednesday through April 13, 2022!



VACCINATION REQUIREMENTS

AN OVERVIEW OF CENTERS FOR MEDICARE &
MEDICAID SERVICES' (CMS) VACCINATION
REQUIREMENTS FOR LONG-TERM CARE FACILITIES



ALASKA STATE SURVEY AGENCY

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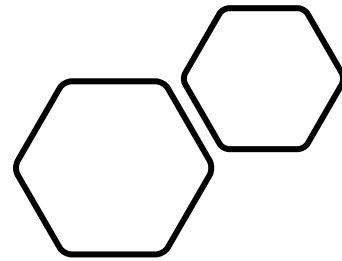
STATE SURVEY DIRECTOR

DISCLAIMER:

- This presentation does not reflect the opinion of CMS.
- This presentation **DOES NOT** replace any actual law, regulations or statutes set forth by CMS or the federal government.
- Please follow all regulations and QSO memos that directly come from CMS.
- This presentation is only informational and is not a tool for compliance.



RESOURCES



- QSO Memo 22-07-ALL
- QSO Memo 22-09-ALL
- QSO Memo 22-11-ALL

VACCINE TIMELINES – 90 DAY COMPLIANCE



- **December 28, 2021**, for all states except 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.
 - Full Compliance estimated March 28, 2022.
- **January 14, 2022**, for 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 except Texas.
 - Full Compliance estimated April 14, 2022.
- **January 20, 2022**, for Texas.
 - Full Compliance estimated April 20, 2022.

If compliance date falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day.

POLICES & PROCEDURES

The facility's policies and procedures must address each of the components specified in §483.80(i)(3).

Vaccine Administration - §483.80(i)(3)(i):

Requires the facility to have a process for ensuring all staff (as defined above) have received at least a single-dose, or the first dose of a multi-dose COVID-19 vaccine series, or have a pending, or have been granted a qualifying exemption, or identified as having a delay as recommended by the CDC, prior to providing any care, treatment, or other services for the facility and/or its residents.

Additional Precautions - §483.80(i)(3)(iii):

Requires facilities to ensure those staff who are not yet fully vaccinated, or who have a pending or been granted an exemption, or who have a temporary delay as recommended by the CDC, adhere to additional precautions that are intended to mitigate the spread of COVID-19. There are a variety of actions or job modifications a facility can implement to potentially reduce the risk of COVID-19 transmission including, but not limited to:

- Reassigning staff duties,
- Additional CDC-recommended precautions,
- Weekly testing,
- Use of N-95 mask.

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.

POLICES & PROCEDURES

The facility's policies and procedures must address each of the components specified in §483.80(i)(3).

Tracking Staff Vaccine Status – §483.80(i)(3)(iv)-(v) and (ix)

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.

POLICES & PROCEDURES

The facility's policies and procedures must address each of the components specified in §483.80(i)(3).

Vaccination Exemptions - §483.80(i)(3)(vi) - (viii)

Facilities 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.

Additionally, facilities 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.

MEDICAL EXEMPTIONS

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.

MEDICAL EXEMPTIONS

Facilities must have a process to track and secure documentation of the vaccine status of staff whose vaccine is temporarily delayed.

CDC recommends a temporary delay in administering the COVID-19 vaccination due to clinical precautions and considerations such as individuals with acute illness secondary to COVID-19 illness, and individuals who received monoclonal antibodies, or convalescent plasma for COVID-19 treatment.

“Temporarily delayed vaccination” refers to vaccination that must be temporarily postponed, as recommended by CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, or individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment in the last 90 days

NON-MEDICAL, INCLUDING 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.

CMS directs providers and suppliers to the Equal Employment Opportunity Commission (EEOC) Compliance Manual on Religious Discrimination for information on evaluating and responding to such requests.

NON-MEDICAL, INCLUDING 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.

POLICES & PROCEDURES

The facility's policies and procedures must address each of the components specified in §483.80(i)(3).

Contingency Plans - §483.80(i)(3)(x) 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

SEVERITY LEVELS

Level 4 – Immediate Jeopardy

Scenario #1

Noncompliance resulting in serious harm or death:

- Did not meet the requirement of staff vaccinated or has no policies and procedures developed or implemented; **and**
- Three or more resident infections in the last four weeks resulting in at least one resident experiencing hospitalization (i.e., serious harm) or death.

SEVERITY LEVELS

Level 4 – Immediate Jeopardy

Scenario #2

Noncompliance resulting in a likelihood for serious harm or death:

- Did not meet the requirement of staff vaccinated; and
- Three or more resident infections in the last four 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.

SEVERITY LEVELS

Level 4 – Immediate Jeopardy

Scenario #3

More than 40% of staff are unvaccinated and there is evidence of a lack of effort to increase staff vaccination rates.

SEVERITY LEVELS

Level 3 – Actual harm that is not
an immediate jeopardy

Did not meet the requirement of staff
vaccinated; **and**

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

1 or more components of the policies and
procedures were not developed and
implemented

SEVERITY LEVELS

Level 2 – No actual harm
with potential for
more than minimal harm

Scenario #1:

Did not meet the requirement of staff
vaccinated; and

No resident outbreaks

-OR-

Scenario #2

Did not meet the requirement of staff
vaccinated; and

One or more components of the policies and
procedures were not developed and
implemented

SEVERITY LEVELS

Level 1

Met the requirement of staff vaccinated;

and

One or more components of the policies and procedures to ensure staff vaccination were not developed and implemented (must be cited as widespread (“C”).

SCOPE

Background Study:

Nursing homes where vaccination coverage of staff is 75% or lower experienced higher rates of preventable COVID infection;

The COVID-19 resident case rate in nursing homes with 45-59% of staff vaccinated was approximately twice as high as facilities with over 60% of staff vaccinated.

In other words, for facilities with few staff unvaccinated, CMS expects the facility to be at a lower risk for an isolated number of resident infections

SCOPE

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 required components of the policies and procedures were not developed and implemented.

NONCOMPLIANCE AND CONCERNS IN THE FIELD

Subjective and Objective Observations from Surveys

- Less than 75% vaccination rate without exemption process.
- Lack of access to employee files to establish compliance with requirements.
- Lack of required components related to the vaccine policy and procedure (P&P)
 - Missing one or more of the P&P components can cause a citation
 - Process for exemptions
 - Additional precautions for exempted or unvaccinated staff
 - Tracking failures
- Vaccinated versus Exemption Ratio
 - Though there is not guidance on this ratio – if surveyors see an exemption rate higher than vaccination rate, this could result in further investigation of the process not the exemptions themselves. This does not mean the facility is out of compliance with current guidance.
 - Example: 80% exempted with 20% vaccination

HOW TO PREPARE FOR SURVEY

- Maintain a list of all COVID-19 cases for residents and staff (we will review the last 4 weeks at minimum)
- Provide a list of all staff and their vaccination status using the vaccine matrix provided by the survey team.
- Ensure NHSN data is being submitted timely and correctly.
- Ensure your vaccine P&P meets all the requirements established by CMS
- Ensure your vaccine P&P is being implemented.
- Be prepared to provide all required information for each initial, standard recert and complaint survey.



THANK YOU!



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COVID-19 Testing in Nursing Homes



Why Test



Administer a COVID-19 test to:

- Determine if your symptoms are from COVID-19 (as opposed to influenza, RSV, rhino virus, etc.)
- Know if you are still contagious after having COVID-19
- Satisfy a requirement for work, travel, event or school

Types of Tests: PCR and Rapid Antigen



Polymerase Chain Reaction (PCR)

- Detects small amount of RNA from virus and amplifies it millions of times
- Very sensitive and accurate, very few false negatives, unlikely to miss a positive
- Takes a lab and highly trained tech, may take several days for result
- Expensive, approximately \$100
- May be positive weeks after your symptoms resolve and you are no longer contagious
- Best to confirm symptoms are from COVID-19

Rapid Antigen



Rapid Antigen (rapid test)

- Detects a protein from the virus
- Uses an antibody strip, looks like a home pregnancy test
- Less accurate, needs a lot of protein to be positive, more false negatives, but few false positives, if positive, you likely have it and are contagious
- Rapid and cheap, 30 minutes, approximately \$15, can be done at home
- If it is negative, you are likely not contagious

Bottom Line

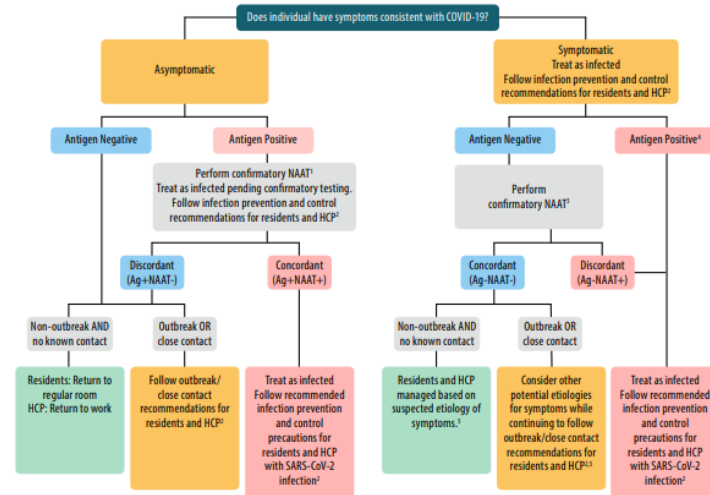


- To confirm symptoms are COVID-19, use a PCR test
- To know if you are contagious, use a rapid test
- If you think you may have been exposed, wait three days, then take a Rapid Antigen test, retest on days five and seven if no symptoms develop
- If you have symptoms PCR test will be best to diagnose COVID-19

Resources



CONSIDERATIONS FOR INTERPRETATION OF SARS-COV-2 ANTIGEN TESTS IN LONG-TERM CARE FACILITIES



NAAT: nucleic acid amplification test, including reverse-transcriptase polymerase chain reaction (RT-PCR). **Ag:** antigen. **HCP:** healthcare personnel. This algorithm should be used as a guide, but clinical decisions may deviate from this guide, if indicated. Contextual factors, including community incidence, characteristics of different antigen testing platforms, and availability and turnaround times of NAAT, further inform interpretation of antigen test results. Confirmatory tests may be considered at any time if concerns about false negative or positive results arise (e.g., multiple unexpected positive results). If confirmatory tests are performed, facilities should perform the test within 1 to 2 days of the initial test and optimize sensitivity of the confirmatory test by choosing a platform (e.g., NAAT) and specimen source (e.g., nasopharyngeal swab) with high sensitivity. Facilities may consider discussing discordant results with health department to determine the most appropriate action. Facilities should routinely review operation of antigen test to ensure optimization and minimize cross-contamination of samples.

¹Asymptomatic people who test antigen positive may not need confirmatory testing if they have high pre-test probability (e.g., persons in a facility with a large outbreak) and the individual should be treated as infected.

²Currently recommended infection prevention and control precautions for residents and HCP are available in the following guidance documents. These include recommendations for those who: 1) have SARS-CoV-2 infection; 2) had close contact

(residents) or a higher-risk exposure (HCP) with someone with SARS-CoV-2 infection; 3) reside or work in a facility experiencing an outbreak.

- [Interim Infection Prevention and Control Recommendations to Prevent SARS-CoV-2 Spread in Nursing Homes](#)
- [Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2](#) | CDC

³Some antigen platforms have higher sensitivity when testing individuals soon after symptom onset (e.g., within 5 days). Clinical discretion may be used when determining if people who test negative should be retested with NAAT. Confirmatory testing may not be necessary if the individual has a low likelihood of SARS-CoV-2 infection. Factors that might indicate a lower likelihood of infection include: low to moderate levels of community transmission, no known or suspected close contact with someone infected with SARS-CoV-2 infection, and/or the person is up to date with COVID-19 vaccination.

⁴For symptomatic people who test antigen positive, confirmatory testing is generally not necessary. It might be considered in some circumstances (e.g., other unexpected positive results from testing that day in low-incidence community).

⁵Management decisions will be based on other suspected etiologies for symptoms. For example, influenza testing should also have been performed if influenza is circulating in the community.



319625-01

[cdc.gov/coronavirus](https://www.cdc.gov/coronavirus)

SARS-CoV-2 Antigen Testing in Long Term Care Facilities | CDC

Click the image or the following link to view larger:
www.cdc.gov/coronavirus/2019-ncov/downloads/hcp/Considerations-for-Interpretation-of-SARS-CoV-2-Antigen-Tests-in-Long-Term-Care-Facilities.pdf

Thank you!

Join us next week on
Wednesday, March 9, 2022.

This material was prepared by Mountain-Pacific Quality Health, a Medicare Quality Innovation Network-Quality Improvement Organization (QIN-QIO), under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services (HHS). Views expressed in this material do not necessarily reflect the official views or policy of CMS or HHS, and any reference to a specific product or entity herein does not constitute endorsement of that product or entity by CMS or HHS. 12SOW-MPQHF-AS-NH-03/22-112