



## COVID-19 Vaccination Policy and Procedures

**Date of Implementation:** [insert date]

### **Definitions:**

**Staff:** as used in the CMS Omnibus COVID-19 Health Care Staff Vaccination interim final rule, includes employees, licensed practitioners, students, trainees, volunteers, individuals who provide care, treatment, or other services for the provider and/or its residents under contract or by other arrangement. **This also includes individuals under contract or by arrangement with the nursing home, including hospice and dialysis staff, physical, occupational and speech therapists, and mental health professionals.** The term staff does not include those that exclusively provide telehealth or telemedicine services outside of the provider setting and who do not have any direct contact with residents and other staff. The term staff also does not include those 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 or other individuals considered as staff pursuant to this definition.

**Provider:** As used in the CMS Omnibus COVID-19 Health Care Staff Vaccination interim final rule, includes the following Medicare and Medicaid-certified provider and supplier types: Ambulatory Surgery Centers, 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, Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services, Psychiatric Residential Treatment Facilities (PRTFs), Programs for All-Inclusive Care for the Elderly Organizations (PACE), Rural Health Clinics/Federally Qualified Health Centers, and Long Term Care Facilities.

**Emergency Use Authorization (EUA):** is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during a public health emergency, such as the current COVID-19 pandemic. The EUA process is a way to ensure safety while still expediting approval in emergent situations.

**FDA Approved:** FDA-approved vaccines have undergone the agency's standard process for reviewing the quality, safety and effectiveness of medication products included in a manufacturer's submission of a BLA. A BLA is a comprehensive document that is submitted to the FDA providing very specific requirements. FDA conducts its own analyses of the information in the BLA to ensure the vaccine meets the FDA's standard for approval.

**Fully Vaccinated:** refers to an individual being 14 days post single-dose vaccine or 14 days post second vaccination in a two-dose series.

**Additional Dose:** an additional dose of vaccine administered when the immune response following a primary vaccine series is likely to be insufficient. An additional mRNA COVID-19 vaccine dose is recommended for moderately to severely immunocompromised individuals after an initial 2-dose primary mRNA vaccine series.

**Booster Dose:** an additional dose of vaccine administered when the initial sufficient immune response to a primary vaccine series is likely to have waned over time.

**Higher-risk Exposure:** generally involves exposure of HCP’s eyes, nose, or mouth to material potentially contained SARS-CoV-2, particularly if these HCP were present in the room for an aerosol-generating procedure.

**World Health Organization (WHO) List of Emergency Vaccines:** A list established by the WHO for vaccines that are authorized by the World Health Organization. The vaccines are not necessarily FDA authorized or approved.

**Clinical Contraindications:** Refers to conditions or risks that preclude the administration of a treatment or intervention. With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, nursing homes should refer to the CDC document [Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized or Approved in the United States](#).

**Primary Vaccination Series:** refers to staff who have received a single-dose vaccine or all required doses of a multi-dose vaccine for COVID-19.

**Temporary 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. Refer to the [Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized or Approved in the United States](#).

## **Background:**

On December 1, 2020, the Advisory Committee in Immunization Practices (ACIP) recommended that health care personnel (HCP) and long-term care (LTC) facility residents be offered COVID-19 vaccination first. Ensuring LTC residents receive COVID-19 vaccinations will help protect those who are most at risk of severe infection or death from COVID-19.

CMS released a “Center for Clinical Standards and Quality/Quality, Safety & Oversight Group” Memo (QSO-21-19-NH) on May 11, 2021 establishing regulatory requirements related to COVID-19 vaccination for residents and staff and establishing a reporting requirement to the CDC’s National Healthcare Safety Network (NHSN) LTCF COVID-19 module to allow for transparency of COVID-19 vaccination uptake among staff and residents in nursing homes across the United States.

In September 2021, the FDA provided an updated EUA for administering booster doses of Pfizer’s mRNA vaccine to certain individuals. On September 24, 2021, the CDC provided [guidance](#) for booster doses at least 6 months following the Pfizer primary dose in certain populations including anyone over the age of 65, live in a long-term care setting, people aged 50-64 years with underlying medical conditions, people aged 18-49 years with underlying medication conditions and people aged 18-64 years who are at an increased risk for COVID-19 exposure and transmission because of occupation or institutional setting.

In October, 2021, the CDC endorsed booster doses of Moderna and Johnson & Johnson COVID-19 vaccines. **As of January 17, 2022, the CDC has endorsed booster doses for all individuals aged 12 and older.**

On November 5, 2021, CMS issued the Omnibus COVID-19 Health Care Staff Vaccination interim final rule, mandating the COVID-19 vaccine for staff at participating health care providers in the Medicare and Medicaid program as a condition of participation. [The Supreme Court ruled on the Injunction in place prohibiting enforcement of the Interim Final Rule on January 13, 2022. CMS issued QSO-22-09-All establishing timelines and interpretive guidance for the Interim Final Rule.](#)

## **Policy:**

### **Residents:**

This policy and related procedures are intended to assist **[Facility name]** in ensuring resident protection against the SARS-CoV-2 or COVID-19 virus. **[Facility name]** understands the best protection against the COVID-19 virus is vaccination. **[Facility name]** is committed to providing the highest level of protection possible to the residents/tenants, while complying with Federal and State regulations and laws in relation to vaccination, protected health information, and civil rights laws such as the Americans with Disabilities Act and Title VII Civil Rights Act of 1964.

This policy provides guidelines for **[Facility name]** in relation to assessing vaccination status of all residents. If residents are unvaccinated, **[Facility name]** will provide education as outlined in the procedures section of this policy and obtain a consent or declination for vaccination. Upon consent for vaccination **[Facility name]** will coordinate vaccination for the resident. If a resident indicates that they've previously been vaccinated for COVID-19 **[Facility name]** will request documentation to confirm vaccination status.

### **Staff:**

All staff working at **[Facility name]** will be fully vaccinated for COVID-19, **unless** they've requested and received approval for a medical or religious exemption. **(See definition of staff for this policy and procedure.)**

### **Reporting:**

**[Facility name]** will report information required to the CDC's NHSN LTCF COVID-19 module.

## **Procedures:**

### **Residents:**

Upon admission to the nursing home each resident will be assessed for vaccination status for COVID-19. If through assessment it is determined that the resident hasn't previously been vaccinated against COVID-19 and the resident is medically able to receive the COVID-19 vaccine **[Facility name]** will educate and offer vaccination to the resident and/or their representative. Vaccination status assessment will include individuals that have received their primary series and eligibility for an additional dose or booster dose per current CDC guidance.

Prior to consenting for the vaccination, each resident and/or representative will receive education regarding the current COVID-19 vaccinations approved or authorized by the FDA. Education will include the benefits of the COVID-19 vaccination, the potential risks including possible side effects and common and rare reactions to the COVID-19 vaccination. In addition to educational information, resident and/or representative will receive the FDA approval or EUA as appropriate for the vaccine that will be

administered. Educational information for nursing homes residents can be found at [www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html](http://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html). Emergency Use Authorization information can be found at [www.cdc.gov/vaccines/covid-19/eua/index.html](http://www.cdc.gov/vaccines/covid-19/eua/index.html).

Once residents and/or representatives receive information and have an opportunity to ask questions regarding vaccination the resident and/or their representative will either consent or decline the COVID-19 vaccine. If the vaccine is declined, residents and/or their representatives have the right to change their decision at any time and will notify **[enter title of position]** that they would like to receive the vaccine. The **[enter title of position]** will provide the resident and/or their representative with educational information and the opportunity to consent to the vaccine again.

Upon consenting to the vaccine, the nursing home will coordinate administration of the vaccine via the Federal Retail Pharmacy Program, local public health, or other means of obtaining the vaccine.

The resident will be provided the educational information at the time of the first dose as well as subsequent doses as well as the opportunity to decline subsequent doses.

### **Resident Documentation:**

**[Facility name]** will maintain an original copy of educational information disseminated to all residents and/or their representatives.

If a resident has been fully vaccinated **[Facility name]** will obtain documentation to confirm vaccination status.

If the resident has not been fully vaccinated, the resident's consent/declination form or information on administration, including vaccination dates and follow up assessments will be maintained in the resident's medical record.

In the event that **[Facility name]** is unable to coordinate vaccination on-site, information on obtaining vaccination opportunities off-site will be provided to residents and/or representatives. Documentation by **[Facility name]** will be maintained of efforts made to make the vaccine available on-site to the residents. In the event there is manufacturing delays, evidence of this delay will be maintained.

### **Additional Doses/Booster Doses:**

All residents and staff will be assessed for an additional dose or booster dose. If the CDC recommendation for an additional dose or booster dose is pertinent to a staff member or a resident, **[Facility name]** will assist with coordinating the vaccine. Additional dose/booster dose records will be maintained in the resident's medical record and staff records will be maintained in their health file. Any vaccination records for staff, included in the definition above, but are not actually employed with the provider, will be maintained in **[enter facility specific details]**. Vaccinations will be reported to NHSN, per CMS requirements.

### **Staff Vaccination:**

All staff shall be vaccinated consistent with the CMS regulatory requirements. All staff working at **[Facility name]** must receive the first-dose of a primary series or a single-dose COVID-19 vaccine prior to ~~December 6, 2021~~, **February 13, 2022** unless the staff member has **requested or been approved** for an exemption as outlined below. All staff must receive the second-dose of a two-dose primary series

COVID-19 vaccine prior to ~~January 4, 2022~~, **March 15, 2022** unless approved for an exemption outlined below. The CMS rule allows for a temporary ~~exception~~ **delay in vaccination for employees that meet criteria as recommended by the CDC, which includes, but is not limited to, individuals with an acute illness secondary to COVID-19, or individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment in the last 90-days.** ~~recommendations by the CDC for delaying COVID-19 vaccination, such as testing positive for COVID-19 and monoclonal antibody receipt within the last 90 days.~~

Any new staff hired ~~January 4, 2022~~ **February 13, 2022 or later** must have received at least the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine or a single-dose COVID-19 vaccine, prior to providing any care, treatment, or other services for the nursing home and/or its residents.

### **Staff Exemptions:**

Staff may request an exemption from vaccine requirements based on a medical contraindication or religious belief or practice. Exemptions must be requested from **[enter position or title]** utilizing a form authorized by **[enter Organization name]**. Consistent with the CMS vaccine requirement, **[enter Organization name]**, will review submitted exemption requests and only authorize exemptions based on applicable Federal regulations under the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of 1964. Exemptions will not be granted solely based on an employee's desire to not receive the vaccine.

### **Medical Exemptions:**

Medical exemptions require certification of a clinical contraindication for the vaccine by a licensed practitioner (who is able to perform this duty as part of the State Scope of Practice Laws). Staff seeking a medical exemption must submit a completed, authorized medical exemption form to **[enter position or title]** for review.

Medical exemption form submissions must include the clinical contraindications that the staff has, the vaccines that are excluded from administration based on the clinical contraindications, and a statement from the licensed practitioner completing the form indicating that they recommend the staff be excluded from the vaccine requirements must be included. **The licensed practitioner cannot be the same person that is requesting the medical exemption.**

Consistent with the CMS vaccine requirement, **[enter Organization name]** will review submitted exemption requests and only authorize exemptions based on applicable Federal regulations under the Americans with Disabilities Act (ADA). Exemptions will not be granted solely based on an employee's desire to not receive the vaccine.

### **Religious Exemptions:**

Staff may request an exemption from vaccine requirements based on a sincerely held religious belief or practice. Religious exemptions must be requested from **[enter position or title]** utilizing a form authorized by **[enter Organization name]**. Consistent with the CMS vaccine requirement and guidance from the Equal Employment Opportunity Commission (EEOC), **[enter Organization name]** will review submitted religious exemption requests on a case-by-case basis and only authorize exemptions based on applicable Federal regulations such as Title VII of the Civil Rights Act of 1964. Exemptions will not be granted solely based on an employee's desire to not receive the vaccine.

### **Additional Mitigation Measures for Exemptions:**

Because unvaccinated staff pose a greater risk of contracting and transmitting COVID-19 to vulnerable residents, [enter facility name] has implemented additional measures that unvaccinated staff will be required to adhere to while at work. Per the [CMS QSO-22-09-All](#), this may include but is not limited to additional personal protective equipment (PPE) once the nursing home has entered a low to moderate community transmission level, additional testing for the presence of COVID-19, relocation of the employee or reassignment of duties, and/or the use of an N95, equivalent or higher-level respirator for universal source control while in the building.

The additional measures [enter Organization name] has instructed unvaccinated staff to follow include:

[Enter individual provider procedures for additional measures for employees that have exemptions]

### **Documentation:**

Staff vaccination records will be maintained in the staff member's medical record for the duration of their employment. If a medical or religious exemption is approved, the corresponding exemption form will be maintained in the staff member's file for the duration of their employment.

Any vaccination records for staff, included in the definition above, but are not actually employed with the provider, will be maintained in [enter facility specific details].

[Enter position or title] will maintain a list of current staff and their vaccination status, including the vaccine the staff member received, the dates of vaccination, additional or booster doses, to provide to State or Federal Surveyors upon request. If a staff member has requested or been approved for a medical or religious exemption, this information will be documented on the tracking form including the type of exemption that was requested or approved and additional mitigation measures the staff is expected to adhere to.

If a staff qualifies for a temporary delay in vaccination this will be documented on the tracking form, including the reason for temporary delay and the date the staff will be eligible to resume their vaccination series.

Acceptable forms of proof of vaccination include:

- A COVID-19 vaccination card
- State immunization information system record
- Documentation of vaccination from a health care provider or electronic health record

### **~~Disciplinary Process~~ Contingency Plan:**

[enter Organization name] will develop a contingency plan for staff members that decline vaccination and do not qualify for a medical or religious exemption. Prioritization for contingency planning should be made for those staff members that decline vaccination over those that are awaiting additional doses of a primary series. Contingency plans may include, but are not limited to, temporary replacement of unvaccinated staff members with fully-vaccinated staff members until a permanent replacement can be found and advertising for fully-vaccinated staff members to replace the unvaccinated staff members with.

Any staff member that does not comply with the staff vaccination requirements set forth above will be:

[enter specific procedures for contingency plans ~~disciplinary/termination of current staff that are unvaccinated or refuse to be vaccinated. ; note that discipline cannot include the staff remaining on premises or having resident contact~~]

### **Reporting:**

Prior to June 13, 2021 at 11:59 p.m., [Facility name] will initiate weekly reporting on resident and staff vaccination status and any therapeutic COVID-19 agents (such as monoclonal antibodies) to the CDC's NHSN LTCF module. Reporting on resident and staff vaccination status will continue to be reported weekly on [enter day of the week].

[Facility name] will assist residents and provide staff with reporting any adverse events to the COVID-19 vaccine to the Vaccine Adverse Event Reporting System (VAERS). This includes administration errors, serious adverse events such as multisystem inflammatory syndrome (MIS) and any cases of COVID-19 that result in hospitalization or death.

### **Emergency Planning/~~Contingency Planning:~~**

Any contracted temporary staff shall follow the definition of staff as noted at the beginning of this document. This includes temporary staff as part of an emergency staffing plan.

In the event of an emergency, as determined in our Emergency Preparedness Plan, the volunteers that may assist during an emergency may not meet the criteria of fully vaccinated as determined by the CDC. Due to the emergency nature of the circumstances, it is in the resident's best interest to be removed from the imminent danger situation so unvaccinated volunteers may assist with emergency evacuation needs.



## References:

CMS. *QSO-21-19-NH Interim Final Rule - COVID-19 Vaccine Immunization Requirements for Residents and Staff*. (2021, May 11). <https://www.cms.gov/files/document/qso-21-19-nh.pdf>

CDC. (2022, Jan. 7). *Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States*. <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>

CDC. (2021, Sept. 24). *CDC Statement on ACIP Booster Recommendations*. <https://www.cdc.gov/media/releases/2021/p0924-booster-recommendations.html>

CDC. (2021, Sept. 10). *Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2*. <https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assessment-hcp.html>

CMS. (2021, Nov. 4) *CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule FAQ Document*. <https://www.cms.gov/files/document/cms-omnibus-staff-vax-requirements-2021.pdf>

Federal Register. (2021, Nov. 4) *Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination*. <https://www.federalregister.gov/public-inspection/2021-23831/medicare-and-medicaid-programs-omnibus-covid-19-health-care-staff-vaccination>

CMS. (2022, Jan. 14). *Guidance for the Interim Final Rule- Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination*. <https://www.cms.gov/medicareprovider-enrollment-and-certificationsurvey/certificationgeninfo/policy-and-memos-states-and/guidance-interim-final-rule-medicare-and-medicaid-programs-omnibus-covid-19-health-care-staff-1>.

CDC. (2021, Dec. 21). *Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized or Approved in the United States*. <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>

CDC. (2021, Dec. 23). *Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2*. [https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html?CDC\\_AA\\_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhcp%2Freturn-to-work.html](https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhcp%2Freturn-to-work.html)