**COVID-19 Vaccine**

**Implementation Checklist**

**Implementation Checklist: COVID Vaccination**

| **Regulation** | **Suggested Actions** |
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| **“F887: COVID-19 Immunization** **DEFINITIONS** “**Staff**” means those individuals who work in the facility on a regular (that is, at least once a week) basis, including individuals who may not be physically in the LTC facility for a period of time due to illness, disability, or scheduled time off, but who are expected to return to work. This also includes individuals under contract or arrangement, including hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, or volunteers, who are in the facility on a regular basis, as the vaccine is available. “**Emergency Use Authorization (EUA)”** is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. The EUA process is a way to ensure safety while still expediting approval in emergent situations. **GUIDANCE** In order to protect LTC residents from COVID-19, each facility must develop and implement policies and procedures that meet each resident’s, resident representative’s, and staff member’s information needs and provides vaccines to all residents and staff that elect them. **Education** All residents and/or resident representatives and staff must be educated on the COVID-19 vaccine they are offered, in a manner they can understand, and receive the FDA COVID-19 EUA Fact Sheet before being offered the vaccine. The Food and Drug Administration (FDA) requires that vaccine recipients or their representative are provided with certain vaccine-specific EUA information to help make an informed decision about vaccination. Fact Sheets can be found at the Center for Disease Control and Prevention’s (CDC) COVID-19 Vaccine Emergency Use Authorization (EUA) Fact Sheets for Recipients and Caregivers website. Education must cover the benefits and potential side effects of the vaccine. This should include common reactions, such as aches or fever, and rare reactions such as anaphylaxis. If the vaccination requires multiple doses of vaccine, the resident or resident representative and staff are again provided with education regarding the benefits and potential side effects of the vaccine and current information regarding those additional doses, including any changes in the benefits or potential side effects, before requesting consent for administration of any additional doses. The resident, resident representative, or staff member must be provided the opportunity to refuse the vaccine and to change their decision about vaccination at any time. The CDC, FDA, Immunization Action Coalition (IAC), and vaccine manufacturers have developed a variety of educational and training resources for healthcare professionals related to COVID-19 vaccines. CMS recommends that staff work with their LTC facility’s Medical Director and Infection Preventionist and use the CDC and FDA resources as the source of information for their vaccination education initiatives. The CDC’s LTC Facility Toolkit: Preparing for COVID-19 Vaccination at Your Facility has information and resources to build confidence among staff and residents.**Offering Vaccinations** LTC facilities must offer residents and staff vaccination against COVID-19 when vaccine supplies are available to the facility. Screening individuals prior to offering the vaccination for prior immunization, medical precautions and contraindications is necessary for determining whether they are appropriate candidates for vaccination at any given time. The vaccine may be offered and provided directly by the LTC facility or indirectly, such as through an arrangement with a pharmacy partner, local health department, or other appropriate health entity. The facility is not required to educate and offer COVID-19 vaccinations to individuals who enter the facility for specific purposes and for a limited amount of time, such as delivery and repair personnel or volunteers who may enter the LTC facility infrequently (meaning less than once weekly). However, if the facility has the availability, they may offer education and vaccination to these individuals. If a resident or staff member requests vaccination against COVID-19, but missed earlier opportunities for any reason (including recent residency or employment, changing health status, overcoming vaccine hesitancy, or any other reason), we expect the facility to offer the vaccine to that individual as soon as possible. If the vaccine is unavailable in the facility, the facility should provide information on obtaining vaccination opportunities (e.g. health department or local pharmacy) to the individual, however it is expected that the facility will provide evidence, upon request, of efforts made to make the vaccine available to its staff and residents. Similar to influenza vaccines, if there is a manufacturing delay, the facility should provide evidence of the delay, including efforts to acquire subsequent doses as necessary. Indications and contraindications for COVID-19 vaccination are evolving and facilities should be alert to any new or revised guidelines issued by the CDC, FDA, vaccine manufacturers, or other expert stakeholders.**Vaccination Administration** For residents and staff who opt to receive the vaccine, vaccination must be conducted in accordance with CDC, ACIP, FDA, and manufacturer guidelines. All facilities must adhere to current infection prevention and control recommendations when preparing and administering vaccines.Administration of any vaccine includes appropriate monitoring of recipients for adverse reactions, and long-term care facilities must have strategies in place to appropriately evaluate and manage post-vaccination adverse reactions among their residents and staff, per 483.45(d), F757. Particularly for COVID-19 vaccines, safety monitoring is required under the associated EUAs.**Vaccination Adverse Event Reporting** In accordance with FDA requirements, select adverse events for COVID-19 vaccines must be reported to the Vaccine Adverse Event Reporting System (VAERS), (that is, vaccine administration errors, serious adverse events, multisystem inflammatory syndrome (MIS) in children or adults, and cases of COVID-19 that result in hospitalization or death). Any revised safety reporting requirements must also be followed. For additional information see VAERS – Vaccine Adverse Event Reporting System at <https://vaers.hhs.gov>.**Vaccination Refusal** Residents and their representatives have the right to refuse the COVID-19 vaccine in accordance with Resident Rights requirements at 42 CFR 483.10(c)(6) and tag F578. Additionally, the regulation at §483.10(b)(2) states “The resident has the right to be free of interference, coercion, discrimination, and reprisal from the facility in exercising his or her rights and to be supported by the facility in the exercise of his or her rights as required under this subpart.” Therefore, facilities cannot take any adverse action against a resident or representative who refuses the vaccine, including social isolation, denied visitation and involuntary discharge. Facilities should follow state law and facility policies with respect to staff refusal of vaccination.**Documentation** The resident's medical record must include documentation that indicates, at a minimum, that the resident or resident representative was provided education regarding the benefits and potential side effects of the COVID-19 vaccine, and that the resident (or representative) either accepted and received the COVID-19 vaccine or did not receive the vaccine due to medical contraindications, prior vaccination, or refusal. If there is a contraindication to the resident having the vaccination, the appropriate documentation must be made in the resident’s medical record. Documentation should include the date the education and offering took place, and the name of the representative that received the education and accepted or refused the vaccine, if the resident has a representative that makes decisions for them. Facilities should also provide samples of the educational materials that were used to educate residents.The facility must maintain documentation that each staff member was educated on the benefits and potential side effects of the COVID-19 vaccine and offered vaccination unless medically contraindicated or the staff member has already been immunized. Compliance can be demonstrated by providing a roster of staff that received education (e.g., a sign-in sheet), the date of the education, and samples of the educational materials that were used to educate staff. The facility must document the vaccination status of each staff member (i.e., immunized or not), including whether fully immunized (i.e., completed the series of multi-dose vaccines).If a staff member is not eligible for COVID-19 vaccination because of previous immunization at another location or outside of the facility, the facility should request vaccination documentation from the staff member to confirm vaccination status.LTC administrators and clinical leadership are encouraged to track vaccination coverage in their facilities and adjust communication with residents and staff accordingly to facilitate understanding and knowledge of the benefits of vaccination.”1 | The Interdisciplinary Leadership Team and Medical Director:* Develop and/or update policy and procedure for COVID-19 vaccination program
* Determine a process of record-keeping to audit that all residents and staff are offered the COVID-19 vaccine(s) unless it is documented that it is medically contraindicated or the individual has already been immunized
* Work with pharmacy provider to schedule ongoing COVID-19 vaccines when vaccines are needed for staff and/or residents
* The Infection Preventionist will obtain the most current COVID-19 Vaccine Emergency Use Authorization (EAU) Fact Sheets for recipients and caregivers for education on the benefits, risks and side effects of the vaccines ([Vaccine Information Statement | Current VISs | CDC](https://www.cdc.gov/vaccines/hcp/vis/current-vis.html)) under “COVID-19 Vaccine EUA Fact Sheets”
	+ For each dose of the vaccine, a current EAU fact sheet will be provided for education before consent
	+ Develop documentation process for refusals following education
* Develop or obtain a COVID-19 consent form
* Ongoing process to monitor compliance with National Healthcare Safety Network (NHSN) reporting
* Review and revise as necessary procedure and process for NHSN COVID-19 reporting with all updates

The Interdisciplinary Leadership Team and Medical Director:* Review and update as necessary policy and procedure for COVID-19 vaccination program for staff and residents
* Work with pharmacy provider to identify ongoing COVID-19 vaccine supply needs when vaccines are needed for staff and/or residents
* If ability to access COVID-19 vaccine from pharmacy, develop a plan to work with local public health department and pharmacies to identify locations for staff and resident vaccinations. Document all efforts.
* Review and revise as necessary policies and procedures for:
	+ Acquiring/ordering Vaccine
	+ Storage and Handling
	+ Inventory Management
	+ Training and Education
	+ Competency
	+ Administration
	+ Vaccine wastage/spoilage
	+ Documentation
	+ Review V-safe information from CDC
	+ Reporting
* Develop a process to document all attempts to obtain opportunities for COVID-19 vaccinations for residents and staff if unable to access vaccine clinics, sites or vaccine
* The Infection Preventionist will obtain the most current COVID-19 Vaccine Emergency Use Authorization (EAU) Fact Sheets for recipients and caregivers for education on the benefits, risks and side effects of the vaccines: <https://www.cdc.gov/vaccines/covid-19/eua/index.html>
* Review and revise as necessary COVID-19 consent form
* Develop documentation process for refusals following education
* Develop procedures to offer any resident who initially refused or
	+ did not receive a vaccine for another reason (i.e. health status, etc.) as soon as possible.
* Develop a protocol for reporting to the Vaccine Adverse Event Reporting System (VAERS):
	+ “Vaccine administration errors, whether or not associated with an adverse event (AE)
		- If the incorrect mRNA COVID-19 vaccine product was inadvertently administered for a second dose in a 2-dose series, **VAERS reporting is required**.
		- If a different product from the primary series is inadvertently administered for the additional or booster (third dose), **VAERS reporting is required**.
		- **VAERS reporting is not required for the following situations:**
			* If a mixed series is given intentionally (e.g., due to hypersensitivity to a vaccine ingredient)
			* Mixing and matching of booster doses (as of October 21, 2021, mixing and matching of booster doses is allowed)
	+ Serious AEs regardless of causality. Serious AEs per FDA are defined as:
		- Death;
		- A life-threatening AE;
		- Inpatient hospitalization or prolongation of existing hospitalization;
		- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
		- A congenital anomaly/birth defect;
		- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.
	+ Cases of myocarditis after a Pfizer-BioNTech, Moderna, or Novovax Vaccine
	+ Cases of pericarditis after a Pfizer-BioNTech, Moderna, or Novovax Vaccine
	+ Cases of Multisystem Inflammatory Syndrome
	+ Cases of COVID-19 that result in hospitalization or death.

Healthcare providers are encouraged to report to VAERS any additional clinically significant AEs following vaccination, even if they are not sure if vaccination caused the event.Also, healthcare providers must report any additional selected AEs and/or any revised safety reporting requirements per FDA's conditions of authorized use of vaccine(s) throughout the duration of any COVID-19 vaccine's Emergency Use Authorization (EUA) or any approved COVID-19 vaccine as outlined in [the Fact Sheet for Healthcare Providers](https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization).”2 |
| **F888 COVID-19 Vaccination of Facility Staff**The facility must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine. (1) 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: (i) Facility employees; (ii) Licensed practitioners; (iii) Students, trainees, and volunteers; and (iv) Individuals who provide care, treatment, or other services for the facility and/or its residents, under contract or by other arrangement. (2) The policies and procedures of this section do not apply to the following facility staff: (i) 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 specified in paragraph (i)(1) of this section; and (ii) 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 and other staff specified in paragraph (i)(1) of this section. (3) The policies and procedures must include, at a minimum, the following components: (i) A process for ensuring all staff specified in paragraph (i)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multidose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the facility and/or its residents; (ii) A process for ensuring that all staff specified in paragraph (i)(1) of this section are fully vaccinated for COVID-19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations; (iii)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; (iv)A process for tracking and securely documenting the COVID-19 vaccination status of all staff specified in paragraph (i)(1) of this section; (v) A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC; (vi)A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law; (vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the facility has granted, an exemption from the staff COVID-19 vaccination requirements; (viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains: (A) All information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and (B) A statement by the authenticating practitioner recommending that the staff member be exempted from the facility’s COVID-19 vaccination requirements for staff based on the recognized clinical contraindications; (ix)A process for ensuring the tracking and secure documentation of the vaccination status of 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 COVID19 treatment; and (x) Contingency plans for staff who are not fully vaccinated for COVID-19.”3 | * Review and revise as necessary, facility policy and procedure for vaccination of facility staff to include:
	+ Definitions
		- Booster
		- Clinical contraindications
		- Fully vaccinated
		- Primary Vaccination Series
		- Staff
		- Temporarily Delayed vaccination
	+ Process to ensure all staff have received at lease a single-dose, or the first dose of a multi-dose COVID-19 vaccine series or have a pending or granted a qualifying exemption or a recommended delay
	+ Additional precautions to mitigate the spread of COVID-19 for all staff not fully vaccinated
	+ Exemptions
		- Medical
		- Non-Medical includingReligious
	+ Temporary Delays
	+ Process for tracking staff vaccine status
	+ Accommodations (if any)
	+ Contingency plans for staff who are not fully vaccinated
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| **Resources for Review** |  |
| Centers for Disease Control and Prevention. Immunization Education & Training. COVID-19 Vaccine Training Modules, Updated May 18, 2021: <https://www2.cdc.gov/vaccines/ed/covid19/>  | * Infection Preventionist, DON or designee to review
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**References and Resources**

1Centers for Medicare & Medicaid Services. QSO-21-19-NH. Interim Final Rule – COVID-19 Vaccine Immunization Requirements for Residents and Staff. May 11, 2021: <https://www.cms.gov/files/document/qso-21-19-nh.pdf>

2 Vaccine Adverse Event Reporting System (VAERS). Frequently Asked Questions (FAQs): <https://vaers.hhs.gov/faq.html>

3 Centers for Medicare & Medicaid Services. QSO-23-02-ALL, Revised Guidance for Staff Vaccination Requirements. October 26, 2022: <https://www.cms.gov/files/document/qs0-23-02-all.pdf>

Centers for Disease Control and Prevention. COVID-19 Vaccines for Long-term Care Residents, Updated Nov. 18, 2022: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/LTCF-residents.html>

Centers for Disease Control and Prevention. Overview of COVID-19 Vaccines, Updated Nov. 1, 2022: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/overview-COVID-19-vaccines.html>

Centers for Disease Control and Prevention. Stay Up to Date with COVID-19 Vaccines Including Boosters, Updated Nov. 1, 2022: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html>

Centers for Disease Control and Prevention. Vaccine Storage and Handling Toolkit, Updated April 12, 2022: <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

AMDA COVID-19 Vaccine Education Toolkit can be accessed at:

<https://paltc.org/newsroom/amda-releases-covid-19-vaccine-education-toolkit>

Centers for Medicare & Medicaid Services State Operations Manual, Appendix PP – Guidance to Surveyors for Long Term Care Facilities (Rev. 208, 10/21/22): <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf>

Centers for Medicare & Medicaid Services, “Nursing Home Reopening Guidelines for State and Local Officials”, May 18, 2020, Revised 03/10/21:

<https://www.cms.gov/files/document/qso-20-30-nh.pdf-0>

Centers for Medicare and Medicaid Services (CMS) Infection Prevention Critical Element Pathway, Form CMS 20054 (10/26/2022): <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Nursing-Homes>

Centers for Disease Control and Prevention. National Healthcare Safety Network (NHSN) LTCF COVID-19 Module: <https://www.cdc.gov/nhsn/ltc/covid19/index.html>

Vaccine Adverse Event Reporting System (VAERS): <https://vaers.hhs.gov/>

U.S. Food & Drug Administration (FDA). Emergency Use Authorization, Content current as of: 12/05/2022: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>