

F887

(Rev.)

§483.80 Infection control

§483.80(d)(3) COVID-19 immunizations. *The LTC facility must develop and implement policies and procedures to ensure all the following:*

- (i) When COVID-19 vaccine is available to the facility, each resident and staff member is offered the COVID-19 vaccine unless the immunization is medically contraindicated or the resident or staff member has already been immunized;*
- (ii) Before offering COVID-19 vaccine, all staff members are provided with education regarding the benefits and risks and potential side effects associated with the vaccine;*
- (iii) Before offering COVID-19 vaccine, each resident or the resident representative receives education regarding the benefits and risks and potential side effects associated with the COVID-19 vaccine;*
- (iv) In situations where COVID-19 vaccination requires multiple doses, the resident, resident representative, or staff member is provided with current information regarding those additional doses, including any changes in the benefits or risks and potential side effects, associated with the COVID-19 vaccine, before requesting consent for administration of any additional doses.*
- (v) The resident or resident representative, has the opportunity to accept or refuse a COVID-19 vaccine, and change their decision; and*
- (vi) The resident's medical record includes documentation that indicates, at a minimum, the following:*
 - (A) That the resident or resident representative was provided education regarding the benefits and potential risks associated with COVID-19 vaccine; and*
 - (B) Each dose of COVID-19 vaccine administered to the resident, or*
 - (C) If the resident did not receive the COVID-19 vaccine due to medical contraindications or refusal.*
- (vii) The facility maintains documentation related to staff COVID-19 vaccination that includes at a minimum, the following:*
 - (A) That staff were provided education regarding the benefits and potential risks associated with COVID-19 vaccine;*
 - (B) Staff were offered the COVID-19 vaccine or information on obtaining COVID-19 vaccine; and*
 - (C) The COVID-19 vaccine status of staff and related information as indicated by the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN).*

DEFINITIONS

“Staff” refers to 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)” refers to a mechanism to facilitate the

availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the 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 should receive the Food and Drug Administration (FDA) COVID-19 EUA Fact Sheet for vaccines under an EUA or the CDC Vaccine Information Statement (VIS) for FDA approved vaccines, before being offered the vaccine. The FDA requires that vaccine recipients or their representative are provided with certain vaccine-specific EUA information to help make an informed decision about vaccination. EUA Fact Sheets can be found at the FDA's [COVID-19 Vaccines](#) and the CDC's [COVID-19 Vaccine Emergency Use Authorization \(EUA\) Fact Sheets for Recipients and Caregivers](#) website. CDC Vaccine Information Statements can be found at the CDC's [Current VISs](#) 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, or resident representative, 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 [Promoting COVID-19 Vaccine in Long-term Care Settings](#) webpage 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 or provided information on obtaining the vaccine 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).

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.

INVESTIGATIVE PROCEDURES

Use the Infection Prevention, Control & Immunizations Facility Task, along with the above interpretive guidance, when determining if the facility meets the requirements for, or investigating concerns related to educating and offering COVID-19 vaccines to residents and staff.

If noncompliance is identified with educating and offering residents and staff of COVID-19 vaccine, surveyors may need to expand their sample to evaluate the scope of the noncompliance. Once the review is complete, use the following to determine the scope of noncompliance:

- One or two individuals = Isolated*
- Three or more individuals, but not pervasive throughout the facility (e.g., less than 50% of residents and/or staff) = Pattern*
- A large number (e.g., greater than 50%) of residents and/or staff = Widespread.*

Resources for COVID-19 Vaccines

- *COVID-19 Vaccination Training Programs and Reference Materials for Healthcare Professionals: <https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-Clinical-Training-and-Resources-for-HCPs.pdf>*
- *Immunization Action Coalition - for education and implementation materials <https://www.immunize.org/handouts/covid19-vaccines.asp>*
- *CDC's Clinical Resources for COVID-19 Vaccine <https://www.cdc.gov/vaccines/covid-19/index.html>*
- *General Best Practice Guidelines for Immunization: Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP) www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html*

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