Long-Term Care Facilities Must Educate, Offer, and Report on COVID-19 Vaccinations for Residents and Staff, According to CMS Interim Rule

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On May 11, 2021, the Centers for Medicare & Medicaid Services (CMS) of the U.S. Department of Health & Human Services published an interim final rule/guidance to establish COVID-19 vaccination requirements for Long-Term Care (LTC) facilities. The requirements are applicable to both residents and staff. LTC facilities have already been managing COVID-19 vaccination requirements both at the federal and state levels. CMS’ interim final rule, however, adds new requirements for educating residents (or resident representatives) and staff regarding the benefits and potential side effects associated with the COVID-19 vaccine, offering the vaccine, and reporting COVID-19 vaccine and therapeutics treatment information to the Center for Disease Control’s (CDC’s) National Healthcare Safety Network (NHSN)

An important definition in the guidance is of the term “staff.” This includes 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. The term 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.

The chart below provides an outline of the requirements in the interim final rule.

### Residents/Staff

**Education**

Education should be provided in a manner that is easily understood and in advance of each vaccination dose, which should include (i) FDA EUA Fact Sheet, (ii) benefits and side effects (e.g., fever, aches, rare reactions) for each dose needed.

LTC facilities must have policies and procedures to oversee that vaccines are offered when supplies are available (unless contraindicated or already immunized). Facilities also need to be screening for prior immunization, and medical precautions, contraindications necessary to determine eligibility.

Residents and staff must have opportunity to accept or decline the vaccine, and change their decisions. Note, residents may decline vaccines and LTC facilities may not take any adverse action, including social isolation, denied visitation, and involuntary discharge. However, staff may not be able to decline vaccination, as LTC facilities will need to review state law and organizational policies.

If a resident or staff member requested vaccination and missed prior opportunity for any reason, the LTC facility must offer vaccine as soon as possible.

**Vaccination**

Vaccinations 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, including monitoring for adverse reactions. This includes monitoring of indications and contraindications for COVID-19 vaccination, including new or revised guidelines issued by the CDC, FDA, vaccine manufacturers, or other expert stakeholders.

If the vaccine is unavailable, LTC facilities should provide information on obtaining vaccination opportunities (e.g.,
Vaccine education and offer requirements do not apply to individuals entering the LTC facility for a specific purpose, or limited amount of time – e.g., delivery, repair persons, volunteers, entering facility less than once per week.

**Residents**

Residents’ medical record must document:

- that resident or resident representative was provided education regarding the benefits and potential risks associated with COVID-19 vaccine;
- each dose of vaccine administered, or that the resident did not receive the COVID-19 vaccine due to refusal or medical contraindications;
- date education and offer of vaccine took place;
- name of representative that received education and accepted/refused vaccine, if applicable; and
- Samples of educational materials used.

**Staff**

Documentation concerning staff includes:

- that staff was provided education regarding the benefits and potential risks associated with COVID-19 vaccine;
- that staff were offered the vaccine or information on obtaining-19 vaccine, unless contraindicated or already vaccinated; and
- vaccine status of staff and related information as indicated by NHSN.

LTC facilities need to document vaccine status, including total numbers of staff, number of staff vaccinated, numbers of each dose of COVID-19 vaccine received, and any vaccination adverse events.

This could be accomplished with a staff roster noting education (e.g., sign-in sheets), date of education, samples of educational materials. Additionally, for staff that have already been vaccinated or received the vaccination outside the LTC facility, the facility should request staff to substantiate...

LTC facilities must be able to provide evidence, upon request, of efforts made to make the vaccine available.

If there is manufacturing delay, LTC facility must be able to provide evidence of the delay, and efforts to acquire subsequent doses as necessary.

Adverse reactions must be reported to the Vaccine Adverse Event Reporting System (VAERS)

**Reporting**

Through the National Healthcare Safety Network (NHSN) LTC facilities are required to report, on a weekly basis, the COVID-19 vaccination status of residents and staff, total numbers of residents and staff vaccinated, each dose of vaccine received, COVID-19 vaccination adverse events, and therapeutics administered to residents for treatment of COVID-19.

These new requirements will raise additional data privacy and security requirements for LTC facilities involving the collection, storage, transmission, and potential recordkeeping of resident and employee health information. LTC facilities should review their policies and procedures and how they will be applied these new requirements.

CMS will begin reviewing for compliance with the new vaccination reporting requirements beginning Monday, June 14, 2021.

Surveyors will engage in efforts to ensure compliance. Surveyors will be looking for a facility representative to provide information on how residents and staff are educated about and offered the COVID-19 vaccine. They will want to see educational materials. Surveyors will request a list of residents and staff and their COVID-19 vaccination status, further review their records and even conduct interviews to confirm residents and staff were educated on and offered the COVID-19 vaccine, in accordance with the new requirements.

According to the guidance, failure to meet reporting requirements will result in a Civil Monetary Penalty (CMP) starting at $1,000 for the first occurrence. For each subsequent week that the facility fails to submit the required report, noncompliance will result in an additional CMP imposed at an amount increased by $500 and added to the previously imposed CMP amount for each subsequent occurrence.