



Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-21-19-NH

DATE: May 11, 2021

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Interim Final Rule - COVID-19 Vaccine Immunization Requirements for Residents and Staff

Memorandum Summary

- CMS is committed to continually taking critical steps to ensure America's healthcare facilities continue to respond effectively to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- On May 11, 2021, CMS published an interim final rule with comment period (IFC). This rule establishes **Long-Term Care (LTC) Facility Vaccine Immunization Requirements for Residents and Staff**. This includes new requirements for educating residents or resident representatives and staff regarding the benefits and potential side effects associated with the COVID-19 vaccine, and offering the vaccine. Furthermore, LTC facilities must report COVID-19 vaccine and therapeutics treatment information to the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN).
- **Transparency:** CMS will post the new information reported to the NHSN for viewing by facilities, stakeholders, or the general public on CMS's [COVID-19 Nursing Home Data](#) website.
- **Updated Survey Tools:** CMS has updated tools used by surveyors to assess compliance with these new requirements.

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 (Phase 1a).¹ Ensuring LTC residents receive COVID-19 vaccinations will help protect those who are most at risk of severe infection or death from COVID-19.

To support this, on May 11, 2021, CMS published an interim final rule with comment period (IFC), [CMS-3414-IFC](#), entitled "Medicare and Medicaid Programs; COVID-19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff." CMS added new requirements at §483.80(d)(3)(i)-(vii) for LTC facilities to develop policies and procedures

¹ <https://www.cdc.gov/mmwr/volumes/69/wr/mm6949e1.htm>

to educate residents or resident representatives and staff regarding the benefits and potential side effects associated with the COVID-19 vaccine and offer the vaccine unless it is medically contraindicated or the resident or staff member has already been immunized. Additionally, the facility must maintain appropriate documentation to reflect that the facility provided the required COVID-19 vaccine education, and whether the resident and staff member received the vaccine.

Furthermore, CMS added a new requirement at §483.80(g)(1)(viii)-(ix) for LTC facilities to report COVID-19 vaccine status of residents and staff, each dose of vaccine received, COVID-19 vaccination adverse events, and therapeutics administered to residents for treatment of COVID-19. As already required at §483.80(g)(2), this data also must be reported to CDC's NHSN system and CMS intends to post the new information collected on the [CMS COVID-19 Nursing Home Data website](#). This reporting will help public health agencies and stakeholders monitor the level of vaccinated residents and staff and target resources accordingly to improve vaccination rates. Additionally, reporting the use of therapeutics will help agencies and stakeholders monitor the prevalence of these treatments, their impact on reducing the effect of COVID-19 on nursing home residents, and support allocation efforts to ensure that nursing homes have access to supplies to meet their needs.

Noncompliance related to the new requirements for educating and offering COVID-19 vaccination to residents and staff will be cited at F-tag 887, and noncompliance related to COVID-19 vaccination reporting will be cited at F-tag 884.

§483.80 Infection control

(d) Influenza, pneumococcal, and COVID-19 immunizations. . .

(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, resident representative, or staff member 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 NHSN.

(g)(1)(viii) The COVID-19 vaccine status of residents and staff, including total numbers of residents and staff, numbers of residents and staff vaccinated, numbers of each dose of COVID-19 vaccine received, and COVID-19 vaccination adverse events; and

(ix) Therapeutics administered to residents for treatment of COVID-19.

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.

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>
- Long-Term Care Facilities COVID-19 Vaccination (landing page for LTC information, including the toolkit): <https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-home-long-term-care/vaccination.html>
- Understanding the Pharmacy Partnership for Long-Term Care Program: <https://www.cdc.gov/vaccines/covid-19/long-term-care/pharmacy-partnerships.html>
- COVID-19 Vaccine Emergency Use Authorization (EUA) Fact Sheets for Recipients and Caregivers <https://www.cdc.gov/vaccines/covid-19/eua/index.html#:~:text=For%20each%20COVID%2D19%20vaccine,an%20informed%20decision%20about%20vaccination>
- Post Vaccine Considerations for Residents and HCP: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-residents.html>, <https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-healthcare-personnel.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

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 COVID-19 vaccination of residents and staff.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

- F658: for concerns related to professional standards of practice for the provision of vaccines;
- F880: for concerns related to infection prevention and control;
- F660: for concerns related to provision of documentation of the resident's vaccination status to the next provider and follow-up vaccination instructions to the resident when the resident is transferred or discharged.

Updates to the Survey Process for F887

To determine compliance with §483.80(d)(3), surveyors will request a facility point of contact to provide information on how residents and staff are educated about and offered the COVID-19 vaccine, including samples of educational materials. Surveyors will also request a list of residents and staff and their COVID-19 vaccination status from which they will select a sample of residents and staff to review records and conduct interviews to confirm they were educated on and offered the COVID-19 vaccine in accordance with the new requirements. CMS will update the CMS-20054: “Infection Prevention, Control & Immunizations” Facility Task to include the new requirement at F887 for educating residents or resident representatives and staff and offering the COVID-19 vaccine. Additionally, CMS will update associated survey documents, which will be found under the “Survey Resources” link in the Downloads Section of the CMS Nursing Homes website. The updated documents will also be added to the Long-Term Care Survey Process software application.

F884: Reporting – National Healthcare Safety Network (NHSN)

42 CFR 483.80(g)(1)(viii)-(ix) requires LTC facilities 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 through [NHSN's LTCF COVID-19 Module](#).

LTC facility administrators and clinical leadership are encouraged to track vaccination coverage in their facility, which can help them target efforts to improve vaccination coverage. Facilities may use the COVID-19 Vaccination module in NHSN to track aggregate vaccination coverage.

Refer to CMS memorandum [QSO-20-29-NH](#) for additional NHSN reporting requirements under F884 as well as instructions on registering, enrolling, and reporting to NHSN. For NHSN questions, please email: NHSN@cdc.gov and add “Weekly COVID-19 Vaccination” in the subject header.

Facilities must continue submitting their COVID-19 data to NHSN at least weekly, but no later than Sunday at 11:59 p.m., each week. Facilities must begin including vaccination and therapeutic data reporting in facility NHSN submissions by 11:59 p.m. Sunday, June 13, 2021. To be compliant with the new reporting requirements, facilities must submit the data through the NHSN reporting system at least once every seven days. Facilities may choose to submit multiple times a week.

Enforcement for F884

Compliance with F884 requires facilities to continue to report COVID-19 data through NHSN’s LTCF COVID-19 Module, and now, with finalization of the new reporting requirements at §483.80(g)(viii) and (ix), they must begin reporting vaccination data for residents and staff and the use of therapeutics for residents. **CMS will begin reviewing for compliance with the new vaccination reporting requirements Monday, June 14, 2021.**

As has been done since June 2020, CMS will continue to receive the CDC NHSN reported data and review for timely and complete reporting of **all** data elements. Facilities identified as not meeting the all reporting requirements under the provisions at §483.80(g)(1), including the new vaccination reporting requirements, will receive a deficiency citation at F884 on the CMS 2567, Statement of Deficiencies, at a scope and severity level of F (no actual harm with a potential for more than minimal harm that is not an Immediate Jeopardy [IJ] and that is widespread).

Failure to report the required elements to NHSN (including the new vaccination reporting requirements) will result in a single deficiency at F884 for that reporting week. In accordance with §488.447, a determination that a facility has failed to comply with the requirements to report weekly to the CDC pursuant to §483.80(g)(1)-(2) (tag F884) will result in a civil money penalty (CMP) imposition. Enforcement for F884 follows a progressive pattern, which leads to an increase of the CMP amount for each subsequent occurrence of noncompliance, not to exceed the maximum amount set forth in §488.408(d)(1)(iii), as specified in §488.447(a)(2).² The amount of the CMP imposed is incrementally increased based on the provider's history of noncompliance with F884 since June 2020 when providers were first required to start reporting COVID-19 related data to the CDC.

Per enforcement requirements at §488.447, failure to meet reporting requirements at §483.80(g)(1) will result in a CMP starting at \$1,000 for the first occurrence of a failure to report. For each subsequent week that the facility fails to submit the required report, the 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. Please refer to [QSO 20-29-NH](#), which detailed how CMS will enforce the new reporting requirement.

CMS will continue to provide notification of noncompliance and imposition of a CMP, along with the CMS 2567 to facilities via their CASPER shared folders.

NHSN Resources for Providers

- LTCF COVID19 Module webpage (<https://www.cdc.gov/nhsn/ltc/covid19/index.html>): Visit this website before submitting questions to the NHSN help desk.
- Enrollment help: <https://www.cdc.gov/nhsn/pdfs/covid19/ltc/covid19-enrollment-508.pdf> or <https://www.cdc.gov/nhsn/ltc/covid19/enroll.html>. If you still need help with enrollment/data submission, contact NHSN@cdc.gov "LTCF" in the subject line.
- To correct facility type: <https://www.cdc.gov/nhsn/pdfs/covid19/ltc/change-ltc-508.pdf>.
- To change/update your NHSN facility administrator: <https://www.cdc.gov/nhsn/facadmin/index.html>
- For enforcement-related questions, please email: DNH_Enforcement@cms.hhs.gov

Contact: For questions or concerns regarding this memo, please contact DNH_TriageTeam@cms.hhs.gov.

Effective Date: This policy should be communicated with all survey and certification staff, their managers and the State/CMS Location training coordinators immediately. The effective dates of the specific actions are specified above.

² See Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, Interim Final Rule, 85 FR 54820, at 54823-54825 (Sept. 2, 2020).

/s/
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cc: Survey and Operations Group Management