

## REMINDER TO LTC PROVIDERS: CMS INTERIM RULE ON VACCINATIONS IN LONG-TERM CARE FACILITIES

June 9, 2021

On May 11, 2021, the Centers for Medicare & Medicaid Services (“CMS”) published an interim final rule, [CMS-3414-IFC](#) (the “Final Rule”), along with interpretive guidance, [QSO-21-19-NH](#), outlining new requirements for long-term care (“LTC”) providers and Intermediate Care Facilities for Individuals with Intellectual Disabilities to develop policies and procedures for educating staff and residents regarding COVID-19 vaccinations and to report resident and staff COVID-19 vaccination status. The LTC requirements can be found at 42 C.F.R. § 483.80(d)(3) and (g)(1), and noncompliance will be cited under F-Tags F884 (Reporting – National Healthcare Safety Network (“NHSN”)) and F887 (COVID-19 Immunization).

### OFFERING VACCINES TO RESIDENTS/STAFF: EDUCATION AND DOCUMENTATION REQUIREMENTS

Under the Final Rule, LTC facilities must develop policies and procedures to ensure that residents/representatives and staff are offered COVID-19 vaccinations when such vaccinations are available to the facility, unless the immunization is medically contraindicated or the resident or staff member has already been immunized. “Staff” under the Final Rule refers to those individuals who work in the facility on a regular (that is, at least once a week) basis, including individuals under contract or other arrangement, such as hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, or volunteers. Before being offered the vaccine, each staff member or resident/representative must be educated regarding the vaccine’s benefits, risks, and potential side effects. This includes providing updated information, as appropriate, for subsequent vaccine doses where more than one vaccine dose is required (e.g., Moderna and Pfizer). The Food and Drug Administration requires that vaccine recipients or their representative be provided certain vaccine-specific Emergency Use Authorization (“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.

Staff and residents must be given an opportunity to accept or refuse the COVID-19 vaccine. For residents, LTC facilities are required to document in each resident’s medical record the education provided regarding vaccine benefits/risks and each dose administered, or whether the vaccine was not administered due to medical contraindications or refusal. Likewise, facilities must also maintain documentation of the education provided to each staff member and that they were offered the vaccine, as well as the vaccination status of staff as indicated by the NHSN.

To determine compliance with the education and documentation requirements, 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.

## VACCINE REPORTING REQUIREMENTS

Beyond education and documentation, LTC facilities must also report the COVID-19 vaccination status of residents and staff through [NHSN's LTCF COVID-19 Module](#), 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, as well as therapeutics administered to residents for treatment of COVID-19.

CMS will begin reviewing for compliance with the new vaccination reporting requirements Monday, June 14, 2021. Failure to meet reporting requirements will result in a civil monetary penalty (“CMP”) starting at \$1,000 for the first occurrence of a failure to report. For each subsequent week that a 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.

## WHAT THIS MEANS FOR PROVIDERS

Providers are encouraged to review QSO-21-19-NH and the Final Rule thoroughly and ensure they have developed policies, procedures, and materials sufficient to ensure residents and staff can be properly educated regarding available COVID-19 vaccines, and that such education, as well as updated vaccination status for residents and staff, is properly documented. As above, providers must ensure that they account for all “staff,” including those volunteers, contractors, and others who, though they are not employed or present in the facility on a full-time basis, nonetheless meet the definition of “staff” under QSO-21-19-NH. Providers should consult with their internal compliance and risk management stakeholders and counsel, as applicable, to determine how their policies and procedures may account for vaccinations administered to staff through outside third parties. Additionally, facilities must ensure that they have updated their COVID-19 reporting processes to ensure they are properly reporting the vaccination status of residents and staff, including total numbers of residents and staff through [NHSN's LTCF COVID-19 Module](#).

If you have any questions or need further guidance regarding the Final Rule or QSO-21-19-NH, please contact a member of Hancock Daniel's [Long-Term Care & Post-Acute Care](#) team.

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