

At A Glance: Ongoing Actions Required for New CMS Interim Rule on COVID-19 Vaccination Data Reporting

The Centers for Medicare & Medicaid Services (CMS) published an interim final rule for skilled nursing facilities, as well as intermediate care facilities for individuals with intellectual disabilities, containing new data reporting requirements and new requirements for educating residents, their representatives, and staff on the benefits and potential side effects associated with the COVID-19 vaccine.

Noncompliance related to the new requirements for providing education 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. Following are a few specific actions facilities are expected to take.

COVID-19 Immunization Policies and Procedures (F-tag 887)

- ✓ 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.
- ✓ Before offering the COVID-19 vaccine, each resident, resident representative, and staff member receives education regarding the benefits and risks and potential side effects associated with the COVID-19 vaccine.
- ✓ 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.
- ✓ The resident, resident representative, or staff member has the opportunity to accept or refuse a COVID-19 vaccine and change their decision.

Documentation (F-tag 887)

- ✓ Maintain documentation in the resident's medical record indicating, minimally:
 - The resident or resident representative was provided education regarding the benefits and potential risks associated with COVID-19 vaccine.
 - Each dose of COVID-19 vaccine administered to the resident.
 - If the resident did not receive the vaccine due to medical contraindications or refusal.
- ✓ Maintain documentation related to staff COVID-19 vaccination that includes, at a minimum, that staff were:
 - Provided education regarding the benefits and potential risks associated with COVID-19 vaccine.



- Offered the COVID-19 vaccine or information on obtaining COVID-19 vaccine.
 - COVID-19 vaccine status of staff and related information as indicated by the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN).
 - If a staff member is not eligible for COVID-19 vaccination because of previous immunization elsewhere, request vaccination documentation to confirm vaccination status.
- ✓ Adjust communication with residents and staff according to vaccination coverage in the facility, to help facilitate understanding and knowledge of the benefits of vaccination.

Education (F-tag 887)

- ✓ 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.
- They must also be given the FDA COVID-19 Emergency Use Authorization (EUA) Fact Sheet before being offered the vaccine.
- ✓ Provide vaccine-specific EUAs to recipients or their representatives, to help make an informed decision about vaccination.
- ✓ Repeat education regarding the benefits and potential side effects of the vaccine and current information regarding additional doses, including any changes in the benefits or potential side effects, before requesting consent for administration of any additional doses.

Vaccinations (Offering, Administration, Adverse Events)

- ✓ 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. (F-tag 578)
- ✓ Conduct vaccination in accordance with CDC, Advisory Committee on Immunization Practices (ACIP), Food & Drug Administration (FDA), and manufacturer guidelines.
- All facilities must adhere to current infection prevention and control recommendations when preparing and administering vaccines. (F-tag 887)
- ✓ Appropriately monitor recipients for adverse reactions after administration of any vaccine.
- Long-term care facilities must have strategies in place to appropriately evaluate and manage post-vaccination adverse reactions after vaccination. (F-tag 757).
- ✓ Report select adverse events for COVID-19 vaccines to the Vaccine Adverse Event Reporting System (VAERS) in accordance with FDA requirements.
- This may include but is not limited to vaccine administration errors, serious adverse events, multisystem inflammatory syndrome [MIS] in children or adults, and cases of COVID-19 that result in hospitalization or

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