



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

Ref: QSO-21-21-ICFIID

DATE: August 23, 2021

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Interim Final Rule - COVID-19 Vaccine Immunization Requirements for Clients and Staff in Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs/IID)

Memorandum Summary

- CMS is committed to 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 clients or client representatives and staff regarding the benefits and potential side effects associated with the COVID-19 vaccine, and offering the vaccine. Furthermore, ICFs/IID are encouraged to report COVID-19 vaccine and therapeutics treatment information to the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN).

Background

On Dec. 1, 2020, the Advisory Committee in Immunization Practices (ACIP) recommended that health care personnel (HCP) and LTC facility residents be offered COVID-19 vaccination first (Phase 1a).¹ On May 13, 2021, CMS published an IFC codified at 42 CFR Part 483, CMS-3414-IFC, entitled "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" ([86 FR 26306](#)). The new requirements help ensure ICF/IID clients are offered COVID-19 vaccinations and education to help protect people most at risk of severe illness or death from COVID-19.

CMS added new requirements at 42 CFR 483.460(a)(4) directing ICF/IID to develop policies and procedures to educate clients, their representatives, and staff on the benefits and risks, and potential side effects of the COVID-19 vaccine. Further, the ICF/IID must offer the vaccine unless it is medically contraindicated or the client or staff member has already been immunized. Additionally, the facility must maintain appropriate documentation to reflect the provision of the required COVID-19 vaccine education and offering, and whether the client and staff member

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

received the vaccine or did not receive it due to [medical contraindications](#) or refusal. The education and offering of the vaccine only needed to be documented once the CMS-3414-IFC rule went into effect on May 21, 2021.

Further, CMS continues to encourage ICF/IID to voluntarily report COVID-19 incidence and vaccination status of clients and staff, each dose of vaccine received, COVID-19 vaccination adverse events, and therapeutics administered to clients to treat COVID-19 on the [CDC NHSN website](#). This reporting will help public health agencies and stakeholders monitor the percentage of clients and staff who are vaccinated 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 effectiveness, and support allocation efforts to ensure that the ICF/IID has access to the supplies (vaccines, personal protective equipment, and COVID-19 tests) they need.

Noncompliance related to the new requirements for educating and offering COVID-19 vaccination to clients and staff will be cited at W-tags 500-507.

§ 483.460 Condition of participation: Health care services.

“(a)(4) The intermediate care facility for individuals with intellectual disabilities (ICF/IID) must develop policies and procedures to ensure all of the following:

- (i) When the COVID-19 vaccine is available to the facility, each client and staff member is offered the COVID-19 vaccine unless the immunization is medically contraindicated or the client or staff member has already been immunized.
- (ii) Before offering the 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 the COVID-19 vaccine, each client or the client's representative receives education regarding the benefits and risks, and potential side effects associated with the COVID-19 vaccine.
- (iv) In situations where the COVID-19 vaccination requires multiple doses, the client, client's representative, or staff member is provided with current information regarding each additional dose, including any changes in the benefits or risks and potential side effects associated with the COVID-19 vaccine, before requesting consent for administration for each additional doses.
- (v) The client, client's representative, or staff member has the opportunity to accept or refuse the COVID-19 vaccine, and change their decision.
- (vi) The client's medical record includes documentation that indicates, at a minimum, the following:
 - (A) That the client or client's representative was provided education regarding the benefits and risks and potential side effects of COVID-19 vaccine; and
 - (B) Each dose of COVID-19 vaccine administered to the client; or
 - (C) If the client did not receive the COVID-19 vaccine due to medical contraindications or refusal.”

Guidance

In order to protect ICF/IID clients from COVID-19, there must be a robust vaccination program in each ICF/IID that meets each client's, client representative's, and staff member's information needs and provides vaccines to all clients and staff who elect to receive them.

Education

All clients, client representatives, and staff must be educated on the COVID-19 vaccine—the education should be done in a manner they can understand (including [different languages](#) and alternative formats)—and receive the FDA COVID-19 Emergency Use Authorization (EUA) Fact Sheet before being offered the vaccine. The CDC's [Toolkit for People with Disabilities](#) has information and resources to build confidence among staff and clients. All Medicare-participating providers offering the vaccine (public or private), are required by the National Vaccine Childhood Injury Act ([42 U.S.C. § 300aa-26 pdf icon\[2 pages\]external icon](#)) to give the appropriate Vaccine Information Statement (VIS) to the patient (or parent or legal representative), regardless of age, before every vaccine dose. The appropriate VIS must be given before each vaccination, including any multi-dose series. Fact sheets can be found at the CDC [COVID-19 Vaccine EUA Fact Sheets for Recipients and Caregivers](#) website.

Education must cover the benefits and risks and potential side effects of the vaccine. The education should include common reactions, such as body aches or fever, and rare reactions, such as anaphylaxis. ICF/IID administrators and clinical leadership are encouraged to track vaccination coverage in their facilities and adjust communication with clients, their representatives, and staff accordingly to facilitate understanding and knowledge of the benefits of vaccination.

If the vaccination requires multiple doses of vaccine, the client or their representative and staff must be offered the necessary COVID-19 education before administering each dose of the COVID-19 vaccine if indicated. The COVID-19 education should include the benefits and risks and potential side effects of the vaccine and any additional relevant information about those additional doses, including any changes in the benefits and risks or possible side effects, before requesting consent for administration of any additional doses.

The CDC, FDA, Immunization Action Coalition, and vaccine manufacturers have developed various educational and training resources for healthcare professionals related to COVID-19 vaccines. CMS recommends that staff work with their ICF/IID's medical director and infection control professionals and use the CDC and FDA resources as the source of information for their vaccination education initiatives.

Offering Vaccinations

The ICF/IID must offer clients and staff vaccination against COVID-19 when vaccine supplies are available to the facility. Screening people before 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 ICF/IID or indirectly, such as through an arrangement with a pharmacy partner, local health department, or other appropriate health entity.

The facility is required to educate and offer COVID-19 vaccination to staff who work at the facility regularly (regular is defined as working at the facility at least once a week). The facility is not required to educate and offer COVID-19 vaccinations to people 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 ICF/IID infrequently (less than once weekly). However, if the facility has the necessary resources, they may offer education and vaccination to these people.

If a client or staff member requests to receive a COVID-19 vaccination but missed earlier

opportunities for any reason (including recent residency or employment, changing health status, vaccine hesitancy), we expect the facility to offer the vaccine to that person as soon as possible. If the vaccine is unavailable in the facility, the facility should provide information on local vaccination opportunities (e.g., health department or local pharmacy) to the person. If a client or staff member already received the vaccine before the CMS-3414-IFC rule, then the facility does not need to provide education after the fact.

If a facility does not have access to the vaccine, we expect the facility to provide evidence, upon request, that efforts have been made to make the vaccine available to its staff and clients. Similar to influenza vaccines, if for example there is a manufacturing delay, the facility should provide evidence of the delay, including efforts to acquire subsequent doses as necessary. While Pharmacy Partnership clinics are currently one avenue for delivering COVID-19 vaccines to ICFs/IID, we expect facilities to be prepared to participate in other distribution programs (possibly through local health departments or traditional pharmacies) as the situation evolves.

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.

Note: In addition to the topics addressed above, education of ICF/IID staff, clients, and clients' representatives should cover the fact that nearly all ICF/IID clients can receive the vaccine without any copays or out-of-pocket costs. Medicare and Medicaid pay for the administration of the COVID-19 vaccine to beneficiaries, and other public and private insurance providers are required to cover it as well.

Vaccination Administration

For clients and staff who opt to receive the vaccine, vaccination should be conducted following CDC, ACIP, FDA, and manufacturer guidelines. When preparing and administering vaccines, facilities should adhere to current FDA and Medicare infection prevention and control recommendations. Safety monitoring is required under the associated EUAs.

Vaccination Adverse Event Reporting

Per FDA requirements, select adverse events for COVID-19 vaccines should be reported to the Vaccine Adverse Event Reporting System (VAERS). These include 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 after the recipient has received the COVID-19 vaccine. Any revised safety reporting requirements should also be followed. For additional information see VAERS at <https://vaers.hhs.gov>.

Staff and clients who use smartphones may wish to use CDC's new smartphone-based tool called V-safe to self-report on their health after receiving a COVID-19 vaccine as a second reporting mechanism, which would be considered above and beyond required facility reporting. This is not required. Enrollment in V-safe allows clients and staff to directly report any problems or adverse reactions after receiving the vaccine. When a person receives the vaccine, they should also receive a V-safe information sheet telling them how to enroll in V-safe. People who enroll will receive regular text messages directing them to surveys where they can report any problems or adverse reactions. Reporting to V-safe does not take the place of clients and staff reporting adverse events and side effects to facility staff or mandatory facility reporting of adverse effects.

For additional information on V-safe, see <https://www.ccondc.gov/coronavirus/2019-ncov/vaccines/safety/faq.html>.

Vaccination Refusal

Clients and their representatives have the right to refuse the COVID-19 vaccine per Protection of Client Rights requirements at 42 CFR 483.420(a)(2) in tag W124. Additionally, the regulation at § 483.420(a)(2) states, “Inform each client, parent (if the client is a minor), or legal guardian, of the client’s medical condition, developmental and behavioral status, attendant risks of treatment, and of the right to refuse treatment.” Therefore, facilities cannot take any adverse action against a client or representative who refuses the vaccine, including social isolation, denied visitation, or involuntary discharge. Once a client or their representative refuses and all education and offering meets the regulation, the facility does not need to continue to educate and offer repeatedly, and there is not a requirement to offer again. If at any time after having refused the vaccine a client and their representative decide that the client does want to receive the vaccine, the ICF/IID should help them with receiving the vaccine directly through the ICF/IID or indirectly, such as through an arrangement with a pharmacy partner, local health department, or other appropriate health entity.

Under 42 CFR 483.460(a)(4)(v), staff may refuse the COVID-19 vaccine, per EEOC guidance: <https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws>. Once a staff member refuses the vaccine and all education (under their discretion, as set out in the regulation), the facility does not need to continue to educate, and there is not a requirement to offer again. If at any time after having refused the vaccine a staff member decides they do want to receive the vaccine, the ICF/IID should help them receive the vaccine directly through the ICF/IID or indirectly, such as through an arrangement with a pharmacy partner, local health department, or other appropriate health entity. The requiring of staff to be vaccinated for COVID-19 will be subject to state or local law, some facilities might have different requirements with regards to offering or requiring vaccines for staff.

For guidance on how a facility should manage staff, clients, and visitors who are unvaccinated and/or clients who may struggle with infection prevention and control compliance, refer to CMS guidance [QSO-21-14-ICF/IID & PRTF Revised](#) and [QSO-21-07-Psych-Hospital-PRTF-ICFIID.pdf](#).

Documentation

The client’s medical record must include documentation that indicates, at a minimum, that the client or client’s representative was educated about the benefits and risks and potential side effects of the COVID-19 vaccine, and that the client (or representative) either accepted and received the vaccine or did not receive the vaccine because of medical contraindications, prior vaccination, or refusal. If there is a contraindication to the client having the vaccination, the appropriate documentation must be made in the client’s medical record. Documentation should include the date the education and offering took place and the name of the representative who received the education and accepted or refused the vaccine if the client has a representative who makes decisions for them. Facilities should also provide samples of the educational materials that were used to educate clients.

The facility must maintain documentation that each staff member was educated on the benefits and risks 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 who 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. Facilities are not expected to maintain this documentation (e.g., vaccine records from other locations) for surveyors, but they are expected to record the fact that the staff member has been vaccinated.

Investigative Procedures

Use the above guidance when determining if the facility meets the requirements for, or investigating concerns related to COVID-19 vaccination and education of clients, client representatives, and staff.

Potential Tags for Additional Investigation

- W318: Condition of Participation: Health Care Services (a) Standard: Physician services;
- W324: for concerns related to immunizations following the Public Health Service ACIP of the Committee on the Control of Infectious Diseases of the American Academy of Pediatrics;
- W341: for concerns related to nursing services instructing staff in the methods of infection control;
- W454–W458: for concerns related to the facility’s overall infection control environment and program.

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>
- Toolkit for People with Disabilities COVID-19 Vaccination Toolkit:
<https://www.cdc.gov/coronavirus/2019-ncov/communication/toolkits/people-with-disabilities.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 Health Care Personnel:
<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
www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html

- HHS Office for Civil Rights Guidance on Federal Legal Standards Prohibiting Disability Discrimination in COVID-19 Vaccination Programs. Found on the OCR website here: <https://www.hhs.gov/sites/default/files/federal-legal-standards-prohibiting-disability-discrimination-covid-19-vaccination.pdf>.

NHSN Resources for Providers

- LTCF COVID-19 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>

Updates to the Survey

To determine compliance with these new requirements, surveyors will request a facility point of contact to provide information on how clients, client representatives, and staff are educated about and offered the COVID-19 vaccine, including samples of educational materials. Surveyors will also request a list of clients and staff and their COVID-19 status. They will select a sample of clients and staff to review records and conduct interviews to confirm they were educated on and offered the COVID-19 vaccine following the new requirements.

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

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers, and the State/Regional Office training coordinators immediately.

/s/

David R. Wright

cc: Survey and Operations Group Management