



Tips for Submitting Comments on Interim Final Rule CMS-3414-IFC (Vaccine Reporting)

An interim final rule with comment period was published on May 13, 2021 that requires nursing homes and intermediate care facilities for individuals with intellectual disabilities (ICF-IIDs) to provide education on and offer COVID-19 vaccination to residents/clients and staff. The rule additionally requires nursing homes to report COVID-19 vaccination of residents and staff and resident use of therapeutics through the National Healthcare Safety Network (NHSN).

LeadingAge will be submitting comments on the final rule and we encourage members to do so as well. We have compiled the following tips and links to help.

How to Write Your Comments

Begin by introducing yourself and telling why this rule matters to you. You might tell a little about the organization for which you work, the residents/clients you serve, or the job you do. Just remember to get appropriate permissions before sharing any identifying information.

Don't feel obligated to comment on every aspect of the rule. Choose what matters most to you, whether that is 1 issue or 4 issues. Identify the issue, tell why you support or oppose it, and offer an alternative to issues you oppose. Explain how your alternative will help meet the same objective more effectively.

Hit the sweet spot of concise and constructive. Provide enough information to make your point. Remember, you are shaping policy, not simply casting a vote.

How to Submit Your Comments

Comments must be received by CMS by **5pm ET on Monday, July 12, 2021**. Remember to reference file code CMS-3414-IFC in your comments. Comments can be submitted 1 of 3 ways:

Electronically: Comments can be submitted electronically via the Federal Register. Access the rule [here](#), then click on "Submit a Formal Comment" near the top of the page. You may type your comments directly into the text box, or you may attach a file containing your comments.

By regular mail: Comments may be submitted by mail and must be received before the close of the comment period. Mail written comments to:

Centers for Medicare & Medicaid Services

Department of Health and Human Services
Attn: CMS-3414-IFC
P.O. Box 8010
Baltimore, MD 21244-1850

By express or overnight mail: Comments may be submitted by express or overnight mail to:

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-3401-IFC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Main Points of the Rule

Nursing homes and ICF-IIDs are required to provide education on COVID-19 vaccination to residents/clients and staff as follows:

- Benefits on COVID-19 vaccination, including reduced risk of COVID-19 illness and serious outcomes such as hospitalization and death; and increased protection from completing all doses in a multi-dose vaccine regimen.
- Risks of COVID-19 vaccination, including both common side effects and rare side effects, while also noting the rare likelihood of serious reactions.
- Other topics such as the importance of staff vaccination in protecting the residents/clients the staff member serves, the staff member's personal health, and community health and notification that the COVID-19 vaccine is available to all residents in long-term care free of copays or out-of-pocket costs.

Nursing homes and ICF-IIDs are required to offer COVID-19 vaccination to resident/clients and staff who have not previously been vaccinated and for whom no contraindication to vaccination exists. If the nursing home or ICF-IID is unable to offer COVID-19 vaccination, the nursing home / ICF-IID must provide the resident/client or staff with information on how and where COVID-19 vaccination may be accessed, such as through a local pharmacy or public health.

Nursing homes (but not ICF-IIDs) are required to report COVID-19 vaccination data and resident use of therapeutics through the National Healthcare Safety Network (NHSN). Vaccination data includes rates of vaccination, numbers of doses, information on reasons for vaccine declination, vaccine access, and adverse events. For the purposes of NHSN reporting, "therapeutics" is defined as a treatment, therapy, or drug administered for the treatment of COVID-19. Monoclonal antibodies is one example of a therapeutic.

For the purposes of this rule, "staff" includes any individual who works in the nursing home or ICF-IID on a regular basis, at least once per week. This includes those working under contract or

arrangement, such as hospice workers or rehab therapist. It also includes individuals who may not have worked during the reporting week, such as those who were out sick or on leave.

Consistent with other required COVID-19 reporting, data will be posted publicly on the nursing home site at data.cms.gov and failure to report will result in citation and Civil Monetary Penalty (CMP).

Topics for Consideration

In discussion with our members, we are hearing common themes emerge. We have identified below points that you may wish to consider for inclusion in your comments.

- *There is too much room for interpretation in certain aspects of the rule.* One example is the education requirements. CMS states that they will direct surveyors to focus on education efforts toward unvaccinated residents and staff, but the rule indicates that education applies more broadly to both vaccinated and unvaccinated individuals. The rule offers several suggestions for what may be included in education, so how are providers to know what is considered sufficient?
- *The definition of staff for purposes of education, offering, and reporting is problematic.* In particular, the inclusion of contracted staff is challenging. While it may make sense to in situations where a dozen staff are exclusively working in one nursing home on a daily basis, such as dietary and food services, it makes less sense and is more challenging in situations where only 2-3 staff members are in a given building one day per week each, such as hospice workers.
- *More reporting requirements mean more time taken away from residents and resident care.* Since the beginning of required NHSN reporting in 2020 we have sounded the alarm that required reporting takes significant staff time, which is time that could be better spent caring for residents and focusing on quality improvement. Yet over the past year, we have continually seen more data elements added to reporting requirements. Are there other ways this data could be collected?

Resources to Assist You as You Write

Find the interim final rule [here](#). Provisions of the rule begin in Section II. Long-term care requirements are in Section II. A. and ICF-IID requirements are Section II. B.

Read the CMS memo on this rule [here](#).

Read the LeadingAge summary of provisions and analysis [here](#).

For more tips on writing comments, check out this resource: [Tips for Submitting Effective Comments](#)