



Tips for Submitting Comments on CMS Omnibus COVID-19 Health Care Staff Vaccination (CMS Vaccine Mandate Rule)

An interim final rule was published to the Federal Register on November 5 that requires COVID-19 vaccination for all staff working in CMS-certified settings that are subject to Conditions of Participation, Requirements of Participation, or Conditions for Coverage. Among the LeadingAge membership, this includes home health, hospice, intermediate care facilities for individuals with intellectual disabilities (ICFs-IID), nursing homes, and Programs of All-Inclusive Care for the Elderly (PACE).

While rulings in 2 separate court cases have resulted in a nationwide temporary stay of the rule, the 60-day comment period remains unchanged. LeadingAge will be submitting comments on the interim 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 individuals 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 Tuesday, January 4, 2022**. Remember to reference file code CMS-3415-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-3415-IFC
P.O. Box 8016
Baltimore, MD 21244-8016

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-3415-IFC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Main Points of the Rule

CMS-certified settings that are subject to Conditions of Participation, Requirements of Participation, or Conditions for Coverage would be subject to a vaccine mandate requiring COVID-19 vaccination of all staff. For purposes of this rule, staff would include “employees, licensed practitioners, students, trainees, volunteers and individuals who provide care, treatment, or services for the facility and/or its patients under contract or other arrangement.”

The organization must have policies in place outlining several processes including the process by which staff may request medical or religious exemptions, and a process to ensure that staff have at least one shot prior to providing any care. Those who are not fully vaccinated, including those who have requested or been granted a medical or religious exemption, should follow additional precautions outlined by the organization to mitigate the transmission and spread of COVID-19.

Compliance with the rule was initially scheduled for 2 phases. Phase 1 compliance, which included all policies and required all staff to have received at least one shot or have submitted an exemption request, was set for December 5, 2021. Phase 2, by which date staff must have completed a primary vaccination series, was set for January 4, 2022. However, legal challenges to the CMS rule have temporarily halted CMS from implementing and enforcing the rule, though the comment period remains unchanged.

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.

- *Collecting proof of vaccination for non-employee staff.* Providers are able to request proof of vaccination from their own employees, but have difficulty obtaining this documentation from non-employee staff such as vendors or contractors. Allowing providers to include a provision in the contract or provider agreement that only fully vaccinated individuals will provide services to the organization and obtain a certified list from the vendor or contractor of vaccination status is more easily managed.
- *Collecting and reviewing documentation for exemptions for non-employee staff.* Providers report concerns over the expectation that the organization would be responsible for reviewing exemption requests approved by the contractor or vendor to ensure requests meet CMS guidelines, particularly when the organization’s process for evaluating exemption requests differs from the contractor’s process. Allowing providers to obtain a certified list from the vendor or contractor of exemption status is more easily managed.
- *Defining additional precautions.* CMS states that staff who are not fully vaccinated must adhere to additional precautions outlined by the provider to mitigate the transmission and spread of COVID-19. CMS acknowledges that some providers are already subject to infection prevention requirements. Providers need clarification on whether “additional precautions” must go above and beyond current infection prevention requirements.
- *Clarifying if exempt individuals can provide care.* The rule states that staff must have, at a minimum, the first dose or single dose of a primary vaccine series prior to providing care. Recognizing that individuals who are granted medical or religious exemptions will not receive a first dose, providers need clarification on whether these individuals can be permitted to provide care at any time.
- *Defining “care”.* While provision of care is rather straight-forward for clinical staff, in settings that employ non-clinical staff such as housekeeping staff in a nursing home, providers need clarification on whether non-clinical staff can provide services without having received a first dose or single dose, recognizing that these non-clinical services may be provided in common areas or in the presence of other staff or residents.

Resources to Assist You as You Write

Read the interim final rule [here](#).

Access CMS’s Frequently Asked Questions document [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](#)