



November 9, 2021

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Administrator Brooks-LaSure:

LeadingAge welcomes the interim final rule requiring COVID-19 vaccination in CMS-certified settings to protect the residents/patients/participants in those settings and the staff who serve them. We recognize that COVID-19 vaccination is the most effective tool at protecting vulnerable individuals and helping to move our country past the public health emergency.

The Frequently Asked Questions document has proven valuable in answering early questions on the rule. We assume that further interpretive guidance for state survey agencies is forthcoming in the form of a Quality, Safety, and Oversight memo. As LeadingAge members work toward compliance, a number of questions have arisen that are not adequately addressed in either the rule or the Frequently Asked Questions. We would like to meet with you to discuss these questions and hope CMS will address them in further guidance.

Does the CMS rule apply to an entire setting or organization or only the entity that is CMS-certified?

Increasingly, aging services providers offer many different types of services and settings. Interim final rule CMS-3415-IFC states that CMS-certified providers are subject to the provisions of this rule. The accompanying Frequently Asked Questions document further clarifies that the rule does not apply to settings such as assisted living, group homes, home care, or other home and community based services (HCBS) settings, despite the receipt by these settings and providers of Medicaid dollars. **In circumstances where a single provider offers multiple service lines both inclusive and exclusive of CMS certification and in which staff are clearly delineated between service lines, is the entire organization subject to the CMS rule or only staff working in the CMS-certified service lines?**

For example, if an organization operates both a CMS-certified home health agency and non-certified home care, are only home health staff subject to the mandate? Or would both home health and home care staff be subject despite home care staff operating exclusively under a state home care license? Similarly, in life plan communities (also called continuing care retirement communities) that typically offer independent living, assisted living, memory care, and skilled nursing care on one campus, would all employees of the community be required to be vaccinated, or only those working in the skilled nursing unit?

Can CMS provide more detail about expectations for additional precautions for unvaccinated staff in settings already subject to specific infection prevention and control guidelines?

Interim final rule CMS-3415-IFC states that providers must have a process for ensuring the implementation of additional precautions intended to mitigate the transmission and spread of COVID-19 for staff who are not fully vaccinated. Recognizing that certain providers are already subject to infection prevention and control guidelines, must providers in these settings develop additional guidelines that extend beyond current guidelines?

For example, nursing home staff are required to implement universal source control and social distancing. Specific personal protective equipment including respirators is required based on the type of care being provided. Per [CMS-3401-IFC](#) released in August 2020 with [interpretive revisions](#) issued most recently in September 2021, unvaccinated staff are subject to routine screening testing based on community transmission rates. **Would the nursing home be expected to develop additional precautions for unvaccinated staff beyond the current requirements for source control, personal protective equipment, social distancing, and routine testing?**

When must providers begin to implement contingency plans, including additional precautions, for unvaccinated staff?

As noted above, interim final rule CMS-3415-IFC states that providers must have a process for ensuring the implementation of additional precautions for staff who are not fully vaccinated. The rule further states that providers must make contingency plans in consideration of staff who are not fully vaccinated to ensure that they do not provide care, treatment, or services until they have completed a primary vaccination series and are considered fully vaccinated or have, at a minimum, received the first dose of a multi-dose COVID-19 vaccine. **During the initial implementation period of phase 1 and phase 2, how and when would these additional precautions and contingency plans be implemented?**

For example, if a staff member working for a home health agency has received only a single dose in a multi-dose primary vaccination series by December 5, would this individual be subject to additional precautions and the contingency plan until he or she is fully vaccinated? Or would additional precautions and contingency plans be implemented only for those who, due to unforeseen circumstances such as monoclonal antibody treatment for COVID-19 infection, are not fully vaccinated by the January 4, 2022 phase 2 compliance date?

Must additional precautions include staffing re-assignment or care restrictions?

Interim final rule CMS-3415-IFC states that providers must have a process in place to ensure that staff have received, at a minimum, a single-dose COVID-19 vaccine or the first dose of a multi-dose COVID-19 vaccine prior to providing care, treatment, or services for the facility and/or its patients. The rule further requires providers to develop contingency plans to ensure that staff who are not fully vaccinated will not provide care, treatment, or other services for the provider or patients.

Recognizing that staff who are not fully vaccinated, including those who have been granted exemptions or whose completion of a primary vaccine series has been temporarily delayed due to unforeseen circumstances, are subject to additional precautions, **must the additional precautions taken by the provider for these staff include reassigning or restricting from resident or patient care all staff who are not fully vaccinated, regardless of exemption or exception status?**

For example, if a certified nurse aide (CNA) in a nursing home is granted a medical exemption, is the CNA restricted from providing care, treatment, or services for the facility, including caring for residents? Or do the requirements not to provide services prior to a minimum of one dose of COVID-19 vaccine apply on to those for whom exemptions have not been granted?

What are the requirements for new hires after the phase 2 compliance date?

The Frequently Asked Questions document states that new hires and existing staff are to be treated in the same way and providers must ensure new hires have received, at a minimum, a single-dose COVID-19 vaccine or the first dose in a multi-dose primary vaccination series by the regulatory deadline or prior to providing any care, treatment, or services.

This answer seems to clearly address new hires who begin prior to the phase 2 compliance date: Individuals hired between December 5, 2021 and January 4, 2022 must have at least one dose of COVID-19 vaccine prior to providing care, treatment, or services and must be fully vaccinated by January 4, 2022.

However, interim final rule CMS-3415-IFC states that timing flexibility applies only to initial compliance and has no bearing on ongoing compliance. **Must all new hires after January 4, 2022 be fully vaccinated prior to beginning work?** Meaning must all new hires have completed one dose of a single-dose primary vaccination series or all doses of a multi-dose primary vaccination series, plus 2 weeks, before beginning work in a CMS-certified setting?

What are considered “recognized clinical contraindications” for determining medical exemptions?

Interim final rule CMS-3415-IFC states that disability, certain allergies, or recognized medical conditions may provide grounds for exemption. The rule further refers to [guidance from the Centers for Disease Control & Prevention](#) (CDC) regarding “recognized clinical contraindications.” Vaccination reporting in the National Healthcare Safety Network (NHSN) system references the same guidance, stating that these are the only acceptable medical contraindications to COVID-19 vaccination.

Notably, this guidance lists only severe or immediate allergic reactions to COVID-19 vaccines or components of vaccines as contraindications to COVID-19 vaccination and does not include any disability of recognized medical condition as a contraindication. **Are medical exemptions to be granted only for severe or immediate allergic reactions as recognized by CDC to be a contraindication?**

How should providers handle staff who are unable to consent to vaccination and for whom a parent/guardian withholds consent?

Interim final rule CMS-3415-IFC states that providers must have a process to ensure that all staff are fully vaccinated against COVID-19. Staff includes employees, licensed practitioners, students, trainees, volunteers, and individuals providing care, treatments, or services under contract or arrangement. While the majority of staff working in CMS-certified settings are able to self-consent for vaccination, there are circumstances under which a staff member may be legally unable to self-consent such as due to age or adjudication. In these circumstances, a parent or legal guardian must consent to vaccination on the individual’s behalf. Should the parent or guardian withhold consent for vaccination of these individuals, **can a provider grant**

an exemption based on these special circumstances to allow the individual to continue to work while adhering to additional precautions and contingency plans?

Can CMS provide more detail on the types of services or contractors that would be considered ad hoc and eligible for an exception to vaccine mandates?

Interim final rule CMS-3415-IFC states that providers are not required to ensure vaccination for certain individuals and contractors providing infrequent, ad hoc services who enter a CMS-certified setting for specific limited purposes for limited amounts of time. Examples in the rule include annual elevator inspectors and delivery or repair persons. **Are there further guidelines for determining these exceptions?**

For example, prior to the public health emergency, activities and special events may have been provided within these guidelines in a nursing home. A musician might be hired for a one-time concert or a local expert might volunteer to provide a guest lecture. Would these individuals constitute an exception to the vaccine mandate?

Does this requirement apply to Medicaid home care services, such as Home and Community-based Services (HCBS), since these providers receive Medicaid funding but are not regulated as certified facilities?

The Frequently Asked Questions document states that CMS does not have the regulatory authority to establish COVID-19 vaccination requirements in assisted livings, group homes, or other non-Medicare and Medicaid-certified settings where HCBS may be provided. However, CMS does require that State Medicaid Agencies establish adequate provider qualifications and standards to assure the health and welfare of HCBS program participants. **Will CMS be reviewing the HCBS provider qualifications for vaccination requirements in any pending or newly submitted HCBS waiver or state plan actions?**

LeadingAge recognizes that CMS is unable to provide guidance on individual, one-off scenarios. The questions outlined above have been received several times from providers across settings and across the country in the days since the rule was released, indicating that these are more common scenarios that bear addressing.

Thank you for your consideration of these questions. We would appreciate the opportunity to meet to discuss in greater detail. Please reach out to Senior Vice President of Policy and Advocacy Ruth Katz rkatz@leadingage.org.

Sincerely,



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