December 22, 2021

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-3415-IFC
P.O. Box 8016
Baltimore, Maryland 21244-8016

Dear Administrator Brooks-LaSure:

LeadingAge appreciates the opportunity to comment on CMS *Omnibus COVID-19 Health Care Staff Vaccination*. As an association representing mission-driven providers across the aging services continuum, our comments represent providers across multiple settings impacted by the interim final rule including home health, hospice, intermediate care facilities for individuals with intellectual disabilities (ICF-IID), nursing homes, and programs of all-inclusive care for the elderly (PACE).

About LeadingAge: We represent more than 5,000 aging-focused organizations that touch millions of lives every day. Alongside our members and 38 state partners, we address critical issues by blending applied research, advocacy, education, and community-building. We bring together the most inventive minds in our field to support older adults as they age wherever they call home. We make America a better place to grow old. For more information: www.leadingage.org

Recognizing that COVID-19 vaccination is our most effective tool in protecting older adults and the individuals who serve them, many LeadingAge members proactively implemented vaccine requirements long before they were announced by the Biden Administration and Centers for Medicare & Medicaid Services (CMS). The comments below are based on feedback from providers who have real experience in implementing vaccine mandates, including educating staff on the importance of vaccination, coordinating staff vaccinations, tracking and securely documenting vaccination status, managing exemptions to vaccination, and implementing additional precautions for those who are not fully vaccinated.

Despite the current temporary injunctions on the federal mandate, our members have several months of experience from which to offer feedback thanks to their commitment to keeping older adults safe. We urge CMS to consider this expertise in re-evaluating the interim final rule.

## *Documentation of Vaccination Status of Non-Employee Staff*

CMS-3415-IFC requires providers to track and securely document the vaccination status of all staff, including those who are providing care, treatment, or services under contract or arrangement. The interim final rule states that acceptable forms of proof of vaccination include a COVID-19 vaccine record card, documentation of vaccination from a health care provider or electronic health record, or a state immunization information system record.

LeadingAge members report that while they have been able to maintain vaccination documentation for employees, collecting vaccination documentation for non-employee staff such as hospice staff in a nursing home, agency nursing staff, building contractors, individuals performing testing, inspection, and maintenance, and other individuals providing care, treatment, or services under contract or arrangement is infeasible.

In some circumstances, while the specific contracting organization remains constant, the individual contractors providing services may change frequently or unpredictably. For example, the driver assigned from a medical transport company will vary depending on the day, the route, or what appointments are scheduled for the day. This forces providers to attempt to collect vaccination information at the time of service, delaying or potentially even barring access to care.

In other circumstances, a contracting organization may be unwilling to provide documentation related to vaccination to the provider, forcing the provider to attempt to collect this information from the individual contractor either at the time of service or through ineffective attempts at direct contractor contact and collaboration. This causes undue burden on the provider and wastes time and resources that could be better utilized providing quality care and supporting infection prevention activities.

**LeadingAge advocates for flexibility in how providers ensure full vaccination of all staff.** Rather than requiring providers to maintain proof of vaccination for non-employee staff, providers will determine through organizational policy how to ensure that all staff are fully vaccinated. Providers may include a clause in the provider agreement that the contracting organization will provide only fully vaccinated staff to the organization. Providers may require a certified report of vaccination status from the contracting organization to cover all contractors. Providers may develop processes for ensuring that the contracting organization is adhering to the stipulations of the agreement, such as routine compliance audits. Giving providers the flexibility to determine processes for ensuring vaccination of all staff will ensure the safety of staff and residents in a reasonable manner.

## *Managing Exemptions for Non-Employee Staff*

CMS-3415-IFC requires providers to establish and implement a process by which staff may request exemptions to COVID-19 vaccination based on medical contraindications to vaccination or sincerely held religious beliefs, observances, or practices. The rule further requires that

providers have a process for collecting and evaluating such requests, including the tracking and secure documentation of information provided in support of the request, the provider's decision on the request, and any accommodations that are provided.

LeadingAge members report that while they have been able to manage exemptions for employees, managing exemptions for non-employee staff such as individuals providing care, treatment, or services under contract or arrangement is untenable. As noted above, individual contractors providing services may change and chasing this documentation is a waste of time and resources.

Additionally, exemptions are a complex and potentially subjective issue. A contracting organization that is not subject to CMS requirements may develop an exemption process that does not align with the interim final rule. Individual contractors would be required to submit additional exemption requests directly to the provider for evaluation and determination. Not only is this a waste of time and resources that could be better spent providing care, but the unnecessary bureaucracy may serve as a deterrent to individual contractors or contracting organizations from working with certified settings subject to the interim final rule.

**LeadingAge advocates for flexibility in how providers manage exemptions for non-employee staff.** Rather than requiring providers to collect, evaluate, and maintain documentation for exemptions of these individuals, providers will determine through organization policy how to manage these exemptions. Providers may include a clause in the provider agreement that the contracting organization will be responsible for providing only exempted staff whose exemption requests align with requirements of the interim final rule. Providers may develop processes for ensuring that the contracting organization is adhering to the stipulations of the agreement. These flexibilities alleviate providers of the responsibility and vulnerability of managing potentially conflicting exemption policies.

## *Additional Precautions for Those Who Are Not Fully Vaccinated*

CMS-3415-IFC requires providers to follow nationally recognized infection prevention and control guidelines intended to mitigate the transmission and spread of COVID-19. CMS acknowledges in interim final rule that some providers, such as nursing homes, are already subject to specific infection prevention and control requirements and further requires that all providers develop a process for ensuring the implementation of additional precautions for staff who are not fully vaccinated.

**LeadingAge requests clarification on the implementation of additional precautions.** Infection prevention and control requirements include adherence to nationally recognized standards. Relative to COVID-19, the Centers for Disease Control & Prevention (CDC) has developed specific recommendations for source control measures, physical distancing, the use of personal protective equipment, and administrative and engineering controls to mitigate transmission

and spread of COVID-19. Additionally, nursing homes are subject to routine screening testing of unvaccinated staff.

It seems unreasonable to require providers to implement precautions that extend beyond the CMS requirements and the nationally recognized standards recommended by the CDC. Clarifying requirements to state that providers must adopt nationally recognized infection prevention and control guidelines to include setting-specific COVID-19 recommendations from CDC will ensure consistent, safe care across settings without unduly ostracizing and burdening nursing home providers to implement additional precautions beyond these standards.

## *Requirements for New Hires*

CMS-3415-IFC requires, as noted above, that all staff, at a minimum, have received the first dose of a primary vaccine series or a single-dose COVID-19 vaccine prior to providing any care, treatment, or services. A Frequently Asked Questions document on the interim final rule released by CMS clarifies that new hires are subject to the same requirements as existing staff. New hires are required to have received at least the first dose of a primary vaccine series prior to providing care, treatment, or services and must comply with compliance deadlines as stated in the rule.

However, CMS has failed to explicitly address what is required of staff who are hired after the compliance deadlines. For example, a staff member hired prior to the phase 2 compliance deadline would be required to be fully vaccinated by the phase 2 deadline, but CMS has not stated whether a staff member hired after the phase 2 compliance deadline must be fully vaccinated to begin work, or whether the staff member may begin work after receiving, at a minimum, the first dose of a primary vaccine series.

**LeadingAge advocates for allowing partially vaccinated staff to begin work immediately.** Requiring staff to be fully vaccinated prior to beginning work will cause unnecessary delays in on-boarding that could be a deterrent to recruitment. Any barriers to recruitment are barriers to quality care and must be eliminated. Staff who are hired after the phase 2 compliance deadline should be permitted to provide care, treatment, or services after receiving at least the first shot of a primary vaccine series with a plan in place to complete the primary vaccine series according to recommendations.

## *Consider Workforce in Policy-Making*

Existing workforce shortages in aging services have only been intensified by the pandemic. Shortages now extend into nearly every sector of the national workforce. Challenging, exhausting, and exacting work with low pay, punitive oversight, and harsh public criticism threaten our ability to attract workers to this field.

**LeadingAge strongly urges CMS to consider the workforce crisis in evaluating these and other existing or future policies.** Protecting older adults in the settings in which they live and receive

care is our top priority. However, providers simply cannot provide quality care without staff and existing staff cannot afford to be over-taxed by checking boxes for regulatory compliance. CMS must work with stakeholders to effectively address challenges to recruitment and retention that are exacerbated by federal policies.

LeadingAge appreciates your time and attention to these issues. Should you wish to discuss these concerns further or have any questions, please contact Jodi Eyigor jeyigor@leadingage.org. We value CMS's commitment to collaboration and look forward to continued work together to ensure the safety of older adults and the staff who serve them.

Sincerely,

Jodi Eyigor
Director, Nursing Home Quality & Policy