



July 9, 2021

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-3414-IFC
PO Box 8010
Baltimore, Maryland 21244-1850

Dear Administrator Brooks-LaSure:

LeadingAge appreciates the opportunity to comment on *CMS-3414-IFC Medicare and Medicaid Programs; 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*.

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

Acknowledging the many challenges our nursing home and ICF-IID members have experienced implementing this rule, it is our desire that consideration of this feedback will drive changes to the existing rule, while informing future policy making to avoid these unnecessary hardships for the other provider types that we are honored to serve. In our comments below, we address the issues related to the interim final rule. LeadingAge submits a separate set of comments to address the specific information requests for application of related policies to home and community-based services and assisted living providers.

Educating on and Offering COVID-19 Vaccination to Residents and Staff

Our members have expressed frustration that the requirement to provide education on COVID-19 vaccination to residents and staff is too vague and open to interpretation. The requirement states that nursing homes and ICFs-IID must provide education on the benefits and risks, including potential side effects, of COVID-19 vaccination. CMS includes several resources in the interim final rule and CMS memo QSO-21-19-NH. While these suggestions are helpful in directing providers toward appropriate content, questions remain about how much education is enough. **LeadingAge recommends that CMS state a minimum standard for compliance with the education requirement of this rule**, such as providing the emergency use authorization (EUA) fact sheet to residents and staff.

Additionally, requirements around offering the COVID-19 vaccination are equally broad. While CMS officials from the Division of Nursing Homes have clarified that one episode of educating on and offering the COVID-19 vaccine is sufficient for meeting compliance, they have stressed that, as stated in the interim final rule, the goal of this requirement is to ensure access to COVID-19 vaccination, address

issues of equity, and ultimately increase the safety of residents and staff. In keeping with this goal, CMS officials have stated that providers should continue to work with residents and staff as much as needed to address vaccine hesitance. The interim final rule references “ongoing education and informational updates for all staff” and states that staff should be informed about ongoing opportunities for vaccination. This dual narrative once again begs the question of how much is enough? **LeadingAge recommends that CMS develop a framework, available to both surveyors and providers, to help determine sufficient education on and offering of COVID-19 vaccination to residents and staff.** The framework should be clear, logical, and easy to follow, such as a critical element pathway or other survey tool.

Reporting on COVID-19 Vaccination of Residents and Staff

Reporting Burden. Since May 2020, nursing home providers have reported COVID-19 data to the Centers for Disease Control & Prevention (CDC) through the National Healthcare Safety Network (NHSN) system. This data began with reporting multiple data elements related to COVID-19 cases and deaths, personal protective equipment supplies, and access to testing, and was grossly underestimated by the agency to require approximately 20 minutes per response for a total of 1 hour 20 minutes of staff time required to comply with reporting requirements in 4 distinct data pathways.

Since that time, data elements have been refined according to the changing landscape of the pandemic and the data needs of public health officials and policy makers. While some data elements have been removed, far more have been added, increasing the burden on providers who are already stretched thin after 16 months of constant vigilance, changing guidance, and agile response on a shoestring budget of resources.

In fact, according to NHSN data, nursing home providers continue to struggle with staffing shortages while the latest revisions to the same NHSN data reporting are now estimated at 2 hours 15 minutes of staff time required for reporting. The interim final rule reports time estimates of an additional 30 minutes to complete the newly required reporting on therapeutics and vaccinations for a conservative total of 2 hours 45 minutes each week spent on data collection and reporting.

LeadingAge urges CMS and CDC to reconsider the data collection requests and requirements placed on long-term care providers. While we recognize the importance of data for evaluating the course of this pandemic and informing best practices and policy decisions, the burden of data collection can be assumed by the agencies who will be utilizing the data, leaving long-term care providers more time to continue the important work of providing quality care and ensuring the safety of residents and staff.

Definition of Staff. Another way to address reporting burden would be to re-evaluate the definition of staff on which vaccination data must be reported. The rule states that nursing homes must report vaccination data each week on all staff who regularly work, at least once per week, in the nursing home. This includes contracted staff and staff working under an arrangement. Additionally, this definition means that nursing homes must include in reporting any individual who normally would have worked in the nursing home during the week but may have been out sick or on leave. While this definition of staff is less burdensome than the definition employed for requirements around COVID-19 testing, it still requires a significant amount of tracking and data collection on behalf of the nursing home provider. Is the cost of this burden outweighed by the benefit afforded by the data?

While CDC contends that most outbreaks continue to originate with infected staff, recall that an outbreak is defined as a single positive case and, with significant numbers of nursing home residents now fully vaccinated, even outbreaks of multiple cases may be contained exclusively among staff. Additionally, recalling that unvaccinated staff continue to be routinely tested, one wonders how much protection is afforded by weekly reporting of vaccination rates on staff who do not have direct contact with residents. **LeadingAge recommends that CMS revise the definition of staff for reporting purposes to include direct care staff only.**

Alternative Reporting Methods. Additionally, **LeadingAge recommends implementing alternative methods for reporting.** Reporting vaccination data through NHSN has been extremely challenging, as outlined below. Nursing homes currently report flu and pneumonia vaccination for residents through the Minimum Data Set (MDS). Adding a data element on the MDS to capture residents' COVID-19 vaccination status is a logical step that is supported by many stakeholders. Though MDS data is generally reported only quarterly for long-term care residents, COVID-19 vaccination data, like flu vaccination data, is likely to remain stable and any variance through admission or discharge would be captured in the admitting/discharging resident's MDS assessment.

For staff, COVID-19 vaccination data could be reported through the payroll-based journal (PBJ). While also reported only quarterly, staff vaccination going forward will likely also follow a more predictable pattern similar to flu vaccines, and variances caused by new or terminated staff would be captured in the individual staff member's data. LeadingAge notes that current requirements for PBJ reporting do not cover all staff included in the staff definition employed by this interim final rule; however, adjusting the definition of staff as outlined above would make PBJ an appropriate platform for vaccination reporting without changing requirements related to which staff are reported on PBJ.

Penalties for a Confusing System. Although nursing homes have been reporting COVID-19 data through NHSN since May 2020 as noted above, the addition of vaccination reporting requirements has not been a smooth implementation. In working with our members since enforcement of this interim final rule, LeadingAge has identified themes of misunderstanding among those who have been identified as non-compliant with reporting requirements.

One common issue is that the method for calculating data for the newly required vaccination reporting is the exact opposite of methods for calculating previously required COVID-19 data. For all previously required COVID-19 data, nursing homes report only new cases, new deaths, and other new occurrences since the previous week's reporting. Vaccination reporting elements require nursing homes to switch to reporting on aggregate, cumulative numbers of vaccination rates of all eligible residents and staff each reporting week. Missing the distinction in the new reporting, some providers are reporting only numbers of residents and staff who are newly vaccinated in a given week. This misunderstanding results in inaccurate or incomplete data.

Additionally, the methods for reporting relative to dates differs between the vaccination data and other required data. When reporting positive cases, providers have been encouraged to enter the data for the date on which the positive case was identified. With this practice firmly established, we have observed some nursing home providers erroneously reporting vaccinations on the dates on which vaccination occurred. Like the cumulative reporting error, this also results in inaccurate or incomplete data.

Another common theme of misunderstanding relates to the very module in which nursing homes must report. The NHSN system contains 2 separate but extremely similar modules for reporting COVID-19 vaccination rates. The Healthcare Personnel (HCP) COVID-19 vaccination module in the Healthcare Personnel Safety Component is intended for hospital staff, while the Healthcare Personnel (HCP) COVID-19 vaccination module in the Long-Term Care Facility component is intended for nursing homes. Depending on how a nursing home provider accesses a vaccination reporting module, the provider may mistakenly report vaccination data through the Healthcare Personnel Safety Component module rather than the Long-Term Care Facility module. Data reported through the Healthcare Personnel Safety Component module is not captured in the transfer of data from NHSN to CMS each week. Nursing home providers have reported the required data but because it was unknowingly reported in the wrong module, they find themselves at a loss to understand why they have been enforced citation and a CMP.

These issues demonstrate that the problem is not noncompliance, but the very system by which providers must comply. **LeadingAge recommends that CMS impose citations for non-reporting under F884 as written, but delay imposition of CMPs for a period of 60 days from the original enforcement date.** Any CMPs already imposed during the period of June 21, 2021 to August 12, 2021 would be forgiven. Additionally, during this time, CMS, CDC, and the Quality Improvement Organizations should provide targeted outreach and assistance to nursing homes identified as noncompliant to improve understanding of requirements and associated processes.

No opportunity to correct. As of the original June 13, 2021 reporting deadline, nearly 2,500 nursing homes were missing required data. Providers were notified through a warning letter from CMS; however, June 13 data was not publicly available until June 24. Without access to this data, LeadingAge, state Departments of Health, and even the Quality Improvement Organizations were limited in their ability to assist providers to identify and address issues. Providers who were unable to independently identify and correct reporting issues subsequently repeated the same mistakes the following week, receiving citations and Civil Money Penalties (CMPs) for issues they were only later able to gain assistance to correct. **LeadingAge urges CMS to work with CDC to implement a process by which providers have an opportunity to identify and correct erroneous or missing data prior to the enforcement of citations and penalties.**

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 quality care for all older adults wherever they call home.

Sincerely,

A handwritten signature in black ink that reads "Jodi Eyigor". The signature is written in a cursive, flowing style.

Jodi Eyigor
Director, Nursing Home Quality & Policy