

July 12, 2021

The Honorable Chiquita Brooks-LaSure Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Hubert H. Humphrey Building 200 Independence Avenue, S.W. Washington, DC 20201

Re: <u>CMS-3414-IFC</u>. Medicare and Medicaid Programs; COVID-19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF-IID) Residents, Clients, and Staff

Dear Administrator Brooks-LaSure:

AARP, on behalf of our nearly 38 million members and all older Americans nationwide, appreciates the opportunity to comment on this interim final rule with comment period in which the Centers for Medicare & Medicaid Services (CMS) revises the long-term care (LTC) facility requirements for nursing homes participating in Medicare and/or Medicaid to address issues surrounding COVID-19 vaccination of residents and staff. AARP commends CMS for giving much needed attention through this rule to facility residents, an extremely vulnerable population that experienced a disproportionately high share of the infections, complications, and deaths nationwide caused by COVID-19.

The rule also brings essential attention to facility staff who have been on the front lines of the pandemic providing essential care to residents. Staff took on increased risk during the pandemic, often having COVID-19 case rates similar to those of residents. The horrendous impact of COVID-19 on those in nursing homes is clearly reflected by the assignment of Phase 1a priority vaccination status, equivalent to that of front-line, acute care hospital health care workers, to LTC residents and staff by the Centers for Disease Control and Prevention (CDC) as soon as FDA authorized vaccines became publicly available.

Our comments will focus on the requirements for LTC facility (nursing home) resident and staff vaccination education and programs, public health data reporting, implications for assisted living facilities, sustained commitment to testing and vaccination, requirements for a vaccine booster, enforcement, streamlined vaccine policy, and termination of the waiver of certified nurse aide training.

COVID-19 VACCINE EDUCATION PROGRAM REQUIREMENTS

CMS is requiring that each nursing home provide COVID-19 vaccine education for all residents and staff, including information about the benefits, risks, and potential side effects of vaccination. AARP believes that the importance of this requirement cannot be overstated – it is essential. Also, we fully support that the resident educational program must include all residents and residents' representatives,

must be presented in a manner that is understandable to the entire audience, and must include an opportunity for follow-up questions.

AARP emphasizes that vaccine education should be a routine part of onboarding new staff members. AARP continues to be concerned with high staff turnover rates for nursing homes. The ongoing need to educate new staff about vaccines and offer them the opportunity to be vaccinated is important to maintaining staff vaccination rates.

We also believe that the educational program must remain readily available for the foreseeable future to be deployed promptly when new residents and staff arrive. It can also be a resource when residents and staff who have not yet been vaccinated have questions or are considering vaccination.

COVID-19 VACCINATION PROGRAM REQUIREMENTS

CMS is requiring that each nursing home have a program through which all residents and staff must be offered COVID-19 vaccination; AARP fully supports this essential requirement. We also concur with CMS that the program include 1) consent or assent for vaccination by the resident and/or the resident's representative, receipt of vaccine education; and documentation thereof; 2) right of vaccination refusal by the resident or the resident's representative and documentation of such refusal, and 3) documentation of resident vaccination elsewhere (e.g., as a hospital inpatient prior to nursing home arrival). AARP firmly believes that residents should not incur any co-pay or out-of-pocket expenses to be vaccinated.

It is also important for nursing homes to accurately document and be able to retrieve the vaccination status of staff to enable accurate reporting of this information to the CDC. AARP asks CMS to clarify the entity to be held responsible for the costs of staff member vaccinations (e.g., the facility, staff members and/or their health care insurers).

Defining LTC Facility Staff

CMS states that for the purposes of COVID–19 vaccine education, offering, and reporting, LTC facility staff are those individuals who work in the facility on a regular basis at least once a week (this also includes individuals under contract or arrangement who are in the facility on a regular basis, as the vaccine is available). CMS clarifies that individuals who may not be physically in the facility for a period of time (e.g., due to illness, disability, or scheduled time off), but who are expected to return to work, are considered staff. LTC facilities are not required to educate and offer vaccination to individuals who provide services less frequently, but facilities are permitted and encouraged by CMS to offer vaccination to those infrequent workers (e.g., a plumber or delivery driver) as opportunity and resources allow.

AARP notes that contractual staff of all types who visit multiple work sites (including other LTC facilities) were found to be a significant source of community spread of COVID-19 in some regions and we are concerned about the potential for infrequent workers (on-site less than once weekly) for ongoing COVID-19 transmission. We further note that in this IFC's regulatory impact analysis, CMS

assumes that 50 percent of nursing home staff work in at least one additional facility. Therefore, given the potential risk, a once weekly threshold for defining staff may not be sufficiently broad.

However, AARP also recognizes that a broader definition of staff would precipitate multiple logistical issues, such as second dose scheduling for some vaccines and coordinating dose delivery from a long-term care pharmacy and impose an additional burden on facilities. We understand the necessity for CMS to balance the potential benefits of requiring facilities to offer vaccination of infrequent workers (e.g., decreased viral exposure risk for facility staff and residents) with the practicalities of identifying, fully immunizing, and documenting vaccine outreach and administration of those same workers. AARP encourages CMS to consider defining staff in ways that would capture infrequent workers for vaccination, or simply to voluntarily undertake outreach to them. It is important to vaccinate individuals who work in many facilities, even if infrequently in each facility, because they could unknowingly transmit COVID-19 within and between facilities. It is important to have a strategy to reach such individuals. We encourage CMS to continue considering other options for defining staff, particularly as more is learned about the available vaccines, the release of new ones, and the transmissibility of emerging virus variants.

AARP also notes that, in addition to staff, there is a need for guidance for nursing home volunteers, particularly as facilities begin to return to more normal operations beyond residents and staff. Volunteers bring tangible and intangible value to residents and facilities in myriad ways but comprise a diverse group that may create even greater outreach and tracking challenges than infrequent workers. We urge CMS to give thought to sensible guidance for facilities, again striving to balance protection of nursing home residents with demands on finite facility resources. Modifying the once weekly threshold for application to volunteers who regularly come into contact with residents could be one approach.

For both resident and staff vaccination programs, nursing homes are permitted but not required to provide the vaccine directly. Inability to acquire the vaccine, directly or indirectly, must be documented by the facility. AARP supports this flexibility for each facility to determine how best to meet the needs of its residents and staff but urges CMS to closely monitor availability of sufficient quantities of vaccine doses for nursing homes. It is vital that these facilities have consistent access to COVID-19 vaccines, given the ongoing turnover among staff and residents. CMS states that vaccines must be administered in a safe and sanitary manner and recipients must be monitored appropriately for adverse reactions; AARP also supports these essential safety requirements.

COVID-19 VACCINATION DATA COLLECTION AND REPORTING

CMS is requiring that each facility report data weekly regarding vaccination and COVID-19 therapeutic treatments to CDC's National Healthcare Safety Network, including the vaccination status of all residents and staff and which, if any, COVID-19 therapeutics (e.g., monoclonal antibodies) have been administered to any residents. In the IFC, CMS indicates that aggregated data will be made publicly available "in the future", which CMS has already done. CMS also notes that vaccination status results combined with other COVID-related data already being collected will allow identification of facilities for whom a focused survey of infection control compliance is appropriate.

AARP strongly supports this reporting requirement as part of a robust system for publicly reporting cases and deaths in LTC facilities due to COVID-19. Publicly reported data should be provided in a format that is accessible, available, and understandable to consumers and their families. We appreciate that resident and staff vaccination status data is now public. While this public use file dataset is comprehensive, it is not accompanied by consumer-friendly summary reports. A compressed file folder listing all facilities with 75 percent or more completed staff vaccinations can be downloaded.

AARP has previously called for transparent data collection and reporting of the number and percentage of residents and staff who have been vaccinated by facility and state. We strongly urge CMS to proceed more rapidly with releasing user-friendly aggregated information. We concur with CMS that the required data reported when tracked internally will help each facility better target its vaccine educational and outreach efforts, anticipate resource needs, and update cohorting and visitation policies. Finally, we urge the public reporting of resident and staff vaccination status by race and ethnicity nationally, as well as at the state and/or regional level where possible, while protecting individual privacy.

VACCINE POLICIES FOR OTHER CONGREGATE LIVING SETTINGS: REQUEST FOR COMMENTS

CMS poses a lengthy set of questions for comment, with plans to use responses to guide its future efforts to support reasonable and effective COVID-19 vaccination programs in congregate living facilities. AARP agrees with CMS that the substantial diversity of congregate living arrangements presents policymaking challenges for the group as a whole. Several of the congregate living facility types cited by CMS have past or current experience with public health reporting and managing infectious disease issues (e.g., influenza). Assisted living facilities, however, may have little such familiarity and have only recently begun to house a substantive number of Medicaid recipients. We therefore urge CMS to look carefully at the needs of residents and staff and consider how assisted living facilities and some other congregate long-term care facilities may require more technical assistance than other congregate living entities to undertake public health reporting and resident health education. CMS encourages the congregate living community to voluntarily engage in COVID-19 education and vaccination; AARP concurs with CMS, with the caveat that facilities are likely to vary widely in their capabilities to do so.

RELATED AND ADDITIONAL ISSUES

Sustained Commitment to Testing and Vaccination of Residents and Staff

The COVID-19 pandemic is not over, and the increasing rates of vaccination nationwide should not spur complacency about future effects, especially for vulnerable populations like LTC facility residents. AARP urges CMS to ensure that nursing homes and other long-term care facilities have adequate access to prompt, affordable, and accurate testing on an ongoing basis for a substantial time after the declared public health emergency (PHE) ends. Similarly, it is also vital that long-term care

¹ https://dev.socrata.com/foundry/data.cms.gov/s2uc-8wxp June 10, 2021 data refresh.

facilities have consistent long-term access to COVID-19 vaccines, given the ongoing turnover among staff and residents and the unanswered questions about duration of immunity and booster dose requirements. We strongly recommend that the federal government commit to working with states, LTC facilities, and other entities, as needed, to ensure that those facilities can access and administer vaccines on a continuing basis for the foreseeable future. AARP is aware of innovative best/practices already being adopted by facilities to maintain their momentum regarding staff vaccination such as facility-wide staff bonuses for reaching and sustaining high vaccination rates.

Applicability of the IFC Requirements to Vaccine Booster Doses

AARP notes that uncertainty continues as to whether booster doses of vaccines will be required. We ask CMS to clarify the meaning of the following statement from the IFC's preamble with respect to booster doses: "The requirements for LTC facilities and ICFs–IID established by this IFC can be met by offering current and future COVID–19 vaccines authorized by FDA under EUA, or any COVID–19 vaccines licensed by FDA, as well as any COVID–19 vaccine boosters if authorized or licensed" (86 FR 26312). While this blanket authorization may provide regulatory assurance that future authorization is not delayed, in the event that boosters are deemed necessary, AARP recommends that CMS commit to developing and issuing specific LTC facility requirements regarding booster doses when the necessity of such shots is established.

Enforcement

Consistent with enforcement policies for influenza and pneumococcal vaccination in LTC facilities, nursing homes that fail to meet the public health reporting requirements laid out in this IFC will be subject to citation by surveyors and application of civil money penalties (CMP). AARP strongly supports the ability of CMS to apply penalties to facilities who are not in compliance with these important reporting requirements. We commend CMS for promptly updating the tools used by LTC facility surveyors to reflect the requirements of this IFC.² For repeated instances of non-compliance, AARP urges CMS to allow imposition of a CMP with a larger dollar amount or a per-diem CMP for each day the facility has not complied. In such instances, CMS should also eliminate the cap on the number of occurrences of non-compliance.

Streamlined Single Vaccine Policy

CMS states COVID-19 vaccination policies and requirements in this IFC are based on those for influenza and pneumococcal vaccination, including enforcement. AARP asks CMS to consider whether a single policy or specific alignments should be created for COVID-19, influenza, and pneumococcal vaccination requirements for LTC facilities. A single policy could add administrative simplification, facilitate compliance, clarify understanding of multiple immunizations among residents and staff, and offer a streamlined pathway for expansion to vaccination against additional diseases, if needed.

 $^{^2}$ See CMS Center for Clinical Standards and Quality. QSO-21-29-NH, May 11, 2021. $\underline{\text{https://www.cms.gov/files/document/qso-21-19-nh.pdf}}$

Proposed Health Care Personnel Vaccination Rate Measure

AARP notes that CMS has proposed adding a measure of health care personnel COVID-19 vaccination rates to several of its quality programs (e.g., skilled nursing facilities, inpatient psychiatric facilities, long-term care hospitals), and we recommended adoption of this measure in our recent comment letter about skilled nursing facilities. If this measure is finalized in one or more programs, AARP strongly supports the public display of its performance results on Care Compare. We believe residents and their family caregivers would find this information very useful in their health care decision making processes. We also urge the publication of similar data for residents on Care Compare, plus the number and percentage of residents and staff who have been vaccinated by facility and state.

<u>Termination of Waiver of Certified Nurse Aide Training</u>

AARP urges CMS to reinstate as soon as possible the provisions previously waived by CMS regarding training of certified nurse aides (CNAs) in nursing homes. These provisions are important to the quality of care in our nation's nursing homes. We are also concerned about CMS guidance to states to consider allowing some of the time worked by the nurse aides during the PHE to count towards the 75-hour training requirement. While in general we encourage individuals who became CNAs during the PHE to continue as CNAs, their training requirements should be the same as other CNAs. States and these CNAs can also work to complete all training and certification requirements sooner rather than later, including before the temporary waiver is lifted.

AARP appreciates the opportunity to comment on the CMS revised long-term care facility requirements on COVID-19 vaccination of residents and staff. Our members and all older Americans living in these facilities have been greatly impacted by this virus. We urge CMS to ensure the safety and well-being of nursing home residents and that the ongoing availability of COVID-19 vaccine to facility residents and staff is a priority. If you have questions, please contact me or Rhonda Richards (rrichards@aarp.org) on our Government Affairs staff at (202) 434-3770.

Sincerely,

David Certner

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