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December 30, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3415-IFC
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted electronically to http://www.regulations.gov

Re: **Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination; CMS-3415-IFC**

Dear Administrator Brooks-LaSure:

AARP, on behalf of our nearly 38 million members and all older Americans nationwide, appreciates the opportunity to comment on the interim final rule with request for comments (IFC) in which the Centers for Medicare & Medicaid Services (CMS) revises the requirements for participation for a number of types of Medicare- and Medicaid-certified providers and suppliers to ensure COVID-19 vaccination of health care staff and contractors.

AARP strongly commends CMS for establishing vaccination policies through this rule that protect the health and safety of Medicare and Medicaid provider and supplier staff and their many patients and residents. In particular, requiring Medicare and Medicaid facilities to ensure the vaccination of their staff is an important step to protect the health and safety of those working in, and those seeking treatment or care at, Medicare and Medicaid facilities, especially nursing homes. Residents and staff in nursing homes and other long-term care facilities have experienced unconscionable devastation with over 186,000 deaths due to COVID-19, an extremely high number, given that nursing home residents comprise less than one percent of the US population. This is a national disgrace and must never happen again. The rule brings critical protection not only to residents, but also to the health care professionals and other staff who have been on the front lines of the pandemic providing essential care to at-risk patient or resident populations including those experiencing a disproportionately high share of the infections, complications, and deaths nationwide caused by COVID-19. Health care staff have taken on increased risk during the pandemic, and in some types of facilities, often have COVID-19 case rates similar to those of their patients or residents.

Given the new variants that are emerging and the impact of COVID-19 on older adults, we strongly support the IFC as another important component of CMS' efforts to reduce the transmission and

spread of COVID-19, safeguard health care workers and the people they serve, and end the COVID-19 pandemic. Vaccines are an essential and effective tool in the fight against COVID-19. AARP's Nursing Home Dashboard has found that resident deaths in nursing homes dropped precipitously after vaccines became available and residents were fully vaccinated, and while still too high, are now just a fraction of what they were in the months prior to vaccine availability. Protecting the safety and well-being of people in long-term care and their families demands a strong response on vaccines.

Facilities (Providers and Suppliers) Subject to Requirements

The IFC revises the conditions of participation for Medicare- and Medicaid-certified providers and suppliers (mostly facilities) to establish COVID-19 vaccination requirements applicable to staff of 21 different types of such providers and suppliers. Existing health and safety requirements would be revised to require vaccination of staff of those facilities, as well as to require documentation of the vaccination status of each staff member, vaccine exemption requests, and their outcomes. Providers and suppliers impacted include ambulatory surgical centers, hospices, Programs for All-Inclusive Care for the Elderly (PACE), psychiatric residential treatment facilities, hospitals, nursing homes (skilled nursing facilities and nursing facilities), home health agencies, clinics, and community mental health centers, among others. CMS points out that the list of providers and suppliers subject to the rules are those over which CMS has regulatory authority to establish conditions of participation, conditions for coverage, or requirements for participation to certify as a Medicare or Medicaid provider.

AARP understands that the authority for CMS to require certification as a provider under Medicaid and Medicare conditions of participation does not exist with respect to assisted living facilities, home and community-based services providers, group homes, and other similar types of congregate living facilities or community-based care. We do urge, however, that CMS continue to explore opportunities to expand vaccination among staff in those facilities or arrangements. Medicare and Medicaid beneficiaries who are cared for in those types of settings are often among the most at-risk individuals in terms of health care needs, comorbidities, disabilities, and social determinants that negatively impact health care. Staff caring for those individuals are essential personnel whose health and safety should be a high priority and their health and well-being directly impacts those vulnerable individuals for whom they care.

A few examples of actions that CMS could take include working with states to develop state-based standards, identifying and disseminating best practices, providing technical assistance to facilities and staff, exploring federal matching payments for such vaccinations, and facilitating vaccination education. AARP stands ready to assist CMS in identifying and developing such policies.

Staff Impacted

CMS broadly defines staff who are required to be vaccinated under the IFC to include students, trainees, volunteers, and other contractors who are present in the facilities. Examples of contractors providing services under contract or arrangement who would be subject to the vaccine requirements include hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, social workers, and portable x-ray suppliers. In addition, administrative staff, facility leadership, volunteer or other fiduciary board members, housekeeping, and food services are

included in "staff" for whom COVID-19 vaccination is required as a condition of participation for the Medicare and Medicaid facilities.

AARP supports CMS' broad approach in defining the staff who must be vaccinated as the best possible approach to protect patients or residents, families, and staff. We believe that this approach will maximize the value of the protections by incorporating both direct health care providers as well as other support and administrative staff who may routinely be in contact with direct health care providers. Further, by including contract staff who provide health care services, even infrequently in a facility, the likelihood of those individuals unknowingly transmitting COVID-19 within and between facilities is reduced. Contract providers and other staff often work across facility types (for example, in a nursing home, a group home, and other settings within the employer's purview), and for different providers, which may contribute to
disease transmission. Having such staff vaccinated could also help provide protection for staff and residents in such other facilities not covered by Medicare and Medicaid. With respect to nursing homes alone, CMS has previously estimated that 50 percent of nursing home staff work in at least one additional facility. 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.

The broad applicability of the IFC will also have a positive impact on equity because Medicare and Medicaid facilities are likely to treat individuals who disproportionately experience health and social risk factors. While the rules increase safety for critical health care workers, they also reduce the risk that unvaccinated health care staff spread COVID-19 among those communities including among older adults, those with comorbidities, people of color, individuals with disabilities, individuals with limited English proficiency, individuals living in rural areas, and others adversely affected by persistent poverty or inequality.

We encourage CMS to track the application of these requirements over the coming months, if fully implemented, and adjust their applicability should gaps arise in the future that should be addressed. CMS should continue to evaluate its definition of staff, adjusting it as needed to maximize the rule's protections, particularly as more is learned about the available vaccines, treatments, emerging variants, and their transmissibility.

Exemptions

Under the IFC, limited exemptions from a facility's vaccination requirements are available. Exemptions may only be provided based on a recognized medical condition including certain allergies, or based on religious beliefs, observances, or practices. In addition, CMS acknowledges that there may be other federally required exemptions based on an applicable Federal law, such as the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of 1964, that must apply.

AARP encourages CMS to ensure that there is a meaningful process for exemptions to vaccination and that staff members and employees with disabilities are provided with appropriate accommodations to maximize the effectiveness of the requirements to improve the health and safety of health care providers, staff, and patients or residents. Some evidence exists that Americans with a disability have been having a harder time accessing vaccines compared to other people, despite

signaling interest in vaccination.[1] This points to a need for CMS and HHS to increase public awareness of those laws and to ensure their enforcement to increase the success of the vaccination policy. People with disabilities must also be able to get an appropriate exemption if they request one.

AARP supports the IFC's documentation requirements applicable to vaccine exemptions. Under the IFC, facilities must have a process in place for collecting and evaluating exemption requests, including the tracking and secure documentation of information provided by staff who have requested an exemption, the facility's decision on the request, and any accommodations that are provided. Requests for exemptions based on an applicable federal law, such as the ADA, must be documented and evaluated in accordance with applicable law and each facility's policies and procedures. AARP urges CMS to clarify that to the extent these rules continue to apply after the end of the Public Health Emergency (PHE), the documentation requirements also apply and are applicable with respect to all staff, including new hires onboarded after the end of the PHE.

Addressing Concerns About Staff Shortages

CMS addresses the concerns of stakeholders who fear that a required vaccination policy will create staff shortages among the facilities impacted by the IFC. CMS points out, and AARP agrees, that rather than vaccines creating staff shortages, the illnesses and deaths associated with COVID-19 are exacerbating what have been long-standing staffing shortages in certain health care fields. Further, the prolonged physical, mental, and emotional stress on health care providers of responding to the PHE is continuing to take a toll on these essential workers. We fully support CMS' efforts to improve the health and safety of the environments that Medicare and Medicaid health care providers work in, and in doing so, increase the safety of patients and residents.

We further expect that the broad applicability of the vaccination requirements will help to reduce staff turnover since health care providers and other facility staff will have few alternative health care facilities to seek work that do not have similar requirements. Indeed, our understanding is that some health care providers support vaccination requirements. They wish to ensure they are working in safe circumstances, protecting their patients and residents, and minimizing their own exposure to COVID-19. We believe that the IFC will keep health care staff and providers healthier and happier, and that this will in turn reduce absenteeism due to the virus or need to quarantine, and reduce staff turnover as they view their workplaces as safer environments.

Vaccine Schedule and New Staff

Under the IFC, staff are considered to be fully vaccinated if it has been two weeks or more since they have completed the primary vaccination series for COVID-19. However, staff who have who have completed the primary series for the vaccine received by the Phase 2 implementation date are considered to have met these requirements, even if they have not yet completed the 14-day waiting period required for full vaccination. The completion of a primary vaccination series for COVID-19 is defined as the administration of a single-dose vaccine or the administration of all required doses of a multi-dose vaccine. At this time, CMS is not requiring that individuals receive boosters to be considered fully vaccinated. We are also learning on an ongoing basis the importance of boosters to protect individuals.

[1] CDC: Americans With Disabilities Have Harder Time Getting Covid Vaccine - The New York Times (nytimes.com)

AARP encourages CMS to update these requirements to ensure they remain consistent with any future CDC guidance to ensure they stay up to date with any advancing science and understanding of COVID-19, its variants, and the efficacy of vaccination. Vaccination requirements under these conditions of participation should incorporate such future changes to offer the maximum level of potential effectiveness of the policy to ensure the health and safety of health care providers, staff, residents, and patients.

The IFC requires existing staff to be fully vaccinated before the Phase 2 deadline (modified in subsequent guidance) and facilities to have in place policies and procedures that ensure that all staff have received, at a minimum, a single-dose COVID-19 vaccine, or the *first dose* of the primary vaccination series for a multi-dose COVID-19 vaccine *prior to providing care, treatment, or other services*. For new staff, however, the IFC does not establish a date certain upon which such staff must receive their final dose of a multi-dose protocol if they come on board near or after the Phase 2 deadline (modified in subsequent guidance). We encourage CMS to clarify the regulations to establish a timeline that ensures that new staff coming on board near or after the IFC's implementation and enforcement dates have completed their vaccination series in a timely manner in order to provide patient/resident care.

Clarification

CMS notes that while the IFC is in response to the PHE, its requirements may be retained as a permanent requirement for facilities, regardless of whether the PHE is extended beyond January 2022. Therefore, there is no sunset clause and the rules could remain in place for up to three years before CMS must either make them permanent or permit them to expire.[2] CMS also states that the costs of the vaccinations provided to staff at the affected facilities will be borne by the federal government. AARP requests that CMS clarify that the federal government will continue to bear the cost of the vaccines should the rule remain in effect after the end of the PHE.

Transparency

In May of 2021, CMS required nursing homes to 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.[3] That aggregated data, which may be used to identify facilities for whom a focused survey of infection control compliance is appropriate, has been compiled and made publicly available. AARP strongly supported those reporting requirements as part of a robust system for publicly reporting cases and deaths in long-term care (LTC) facilities due to COVID-19. We are also pleased that data on resident and staff vaccinations in nursing homes by individual facility, state, and nationally are available in a consumer-friendly format on Care Compare. We appreciate the CMS public release of COVID-19 booster data for nursing home residents and staff and urge the inclusion of these data on Care Compare, so they are more readily accessible to consumers and their families. Nursing homes' reporting of these data – including

[2] CMS states that Medicare interim final rules expire 3 years after issuance unless finalized. It expects to make a determination on whether to make the rules permanent at a later date based on public comments, incidence, disease outcomes, and other relevant factors.

[3] 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 (86 FR 26306)

booster data – and enforcement of this requirement is vital to having a more accurate understanding of the impact and potential impact of COVID-19 on residents and staff.

Likewise, AARP encourages CMS to extend the above CDC reporting requirement to other facilities that are required under the IFC to collect vaccination information as a condition of participation. We recommend that CMS compile the information to create consumer-friendly summary reports identifying vaccination status by facility and by state. We believe that collecting, reporting, and aggregating the data will help each facility better target its vaccine educational and outreach efforts, anticipate resource needs, and update health and safety policies. It would provide valuable information for current and future patients and their family caregivers to make better health care decisions and for staff to understand their workplace risk. Further, we urge public reporting of staff vaccination status by race and ethnicity nationally, as well as at the state and/or regional level where possible, while protecting individual privacy.

We also encourage CMS to consider adding a measure of health care personnel COVID-19 vaccination rates to applicable quality programs in which this may not have been done already. AARP also strongly supports the public display of performance results of such measures. We believe patients, residents, staff, and family caregivers would find this information very useful in their health care decision-making processes.

Vaccine Shortages

CMS states, in the preamble to the IFC, that there is widespread availability of vaccines and cites CDC information to support the assertion.[4] Nonetheless, AARP urges CMS to closely monitor availability of sufficient quantities of vaccine doses for Medicare and Medicaid participating facilities and to work with others and take any necessary action to ensure that facilities have access to sufficient supplies to meet these requirements. It is vital that facilities have consistent access to COVID-19 vaccines, especially considering the ongoing turnover among staff and residents/patients of many of the types of facilities subject to the vaccination requirements. In addition, we urge CMS and the Administration more broadly to ensure the availability of COVID-19 tests for nursing home and other long-term care facility residents and staff and to promptly address any testing shortages. Testing is crucial to detecting COVID-19 and helping to prevent its spread.

Enforcement

Medicare and Medicaid providers and suppliers that fail to meet the vaccination and documentation requirements laid out in the IFC may be subject to citation by surveyors, sanctions, and application of civil money penalties (CMPs). AARP encourages CMS to take enforcement action, including the application of penalties when facilities are not in compliance with these important vaccination and documentation requirements when such penalties are available. For facilities demonstrating a pattern of non-compliance, CMS should consider increasing penalties such as by imposing a per-diem CMP for each day the facility has not complied. Enforcement is an important part of the effectiveness of vaccination requirements.

[4] COVID-19 Vaccination Federal Retail Pharmacy Partnership Program | CDC

Refusals

CMS seeks comments on ways to minimize staff refusals of vaccination. It states that, for example, in certain rural areas, hospitals are having greater problems with employee vaccination refusals than hospitals in urban locations.

AARP recognizes that there will be individuals who refuse to accept vaccination, but we urge CMS to ensure that policies of facilities for reviewing and granting such exemptions are not so freely applied as to render those processes meaningless. To avoid such outcomes, we encourage CMS to identify and share best practices among Medicare and Medicaid providers regarding providing vaccine education and support for continuing achievement in this area.

We expect that, over time, staff hesitancy likely will decline as the benefits of vaccination become clear to increasing numbers of individuals working in health care settings. As staff begin to understand that the vaccination policy will make their workplace safer and healthier, any potential turnover is likely to decline and the ability for facilities to retain essential health staff is likely to increase.

Infection Prevention Control Process

AARP strongly supports the requirement in the IFC that facilities must have a process to ensure additional precautions are in place to mitigate the transmission and spread of COVID-19 for those who are not fully vaccinated. AARP believes that process should minimize to the extent possible unvaccinated health care staff providing direct patient or resident care, especially in nursing homes. We recognize this may not always be feasible due to staff shortages. Facilities may also want to consider unvaccinated staff minimizing contact with staff that do provide direct patient or resident care, especially in nursing homes where residents and staff have experienced such high rates of COVID-19 cases and deaths. CMS' survey and certification processes must ensure that the facility's policies are operational, including items such as masks and physical distancing, and enforcement tools must be available to ensure their continued application. Survey tools should be modified to include review of such processes to prevent the spread of the virus by those remaining unvaccinated. We urge CMS to closely monitor provider compliance with these important health and safety requirements and note CMS has issued relevant guidance.

AARP appreciates the opportunity to comment on the Omnibus COVID-19 Health Care Staff Vaccination IFC. Our members and all older Americans receiving care and services in these facilities have been greatly impacted by this virus. We strongly support the actions of CMS to ensure the safety and well-being of Medicare and Medicaid providers and beneficiaries and that universal access to COVID-19 vaccination of health care 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
Legislative Counsel and Legislative Policy Director
Government Affairs