ARGENTUM
EXPANDING SENIOR LIVING

July 12, 2021

VIA ELECTRONIC SUBMISSION

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3414-IFC
P.O. Box 8010
Baltimore, MD 21244-1850

RE: 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 (CMS-3414-IFC)

Dear Administrator Brooks-LaSure:

Argentum welcomes the opportunity to comment on this interim final rule with comment period (IFC) issued by the Centers for Medicare & Medicaid Services (CMS).[1] Argentum is the leading national association exclusively dedicated to supporting companies operating professionally managed, resident-centered senior living communities and the older adults and families they serve. Along with its state partners, Argentum's membership represents approximately 75 percent of the professionally managed communities in the senior living industry. Nearly 1 million older adults live in an estimated 28,000 assisted living facilities across the United States.

On May 13, 2021, CMS issued this IFC to revise the infection control requirements that certain long-term care (LTC) facilities (Medicaid nursing facilities and Medicare skilled nursing facilities, also collectively known as "nursing homes") must meet to participate in the Medicare and Medicaid programs. The IFC requires LTC facilities to: 1) offer the COVID-19 vaccine when available; 2) educate residents and staff on the COVID-19 vaccine; and 3) report COVID-19 vaccination status of residents and staff to the Center for Diseases Control and Prevention (CDC). The IFC became effective on May 21, 2021.

In the IFC, CMS states that it is considering whether to apply the IFC's requirements to "other Medicare/Medicaid participating shared residences" such as assisted living facilities (ALFs) that participate in the Medicaid program. CMS solicits comment on "the feasibility of adding appropriate COVID–19 vaccination requirements for residents and staff of all congregate living facilities where CMS has regulatory authority and pays for some portion of the care and services provided." Relatedly, CMS also solicits comment on any potential barriers facilities may face in meeting the requirements.

Argentum appreciates CMS's efforts to promote vaccination for COVID-19 and lower the risk of COVID-19 infection in congregate care settings. However, we do not believe the IFC's provisions should be extended to cover ALFs that participate in the Medicaid program. As

[1] 86 Fed. Reg. 26306.

explained in further detail below, there are many important differences between ALFs and nursing homes that would make it overly burdensome for the former to comply with this IFC's requirements. Indeed, we think that it is unnecessary to apply the provisions of the IFC to ALFs; although the assisted living community serves a resident population that is disproportionately at risk of COVID-19, ALFs have by and large successfully implemented policies to mitigate harm from COVID-19, and have implemented successful vaccination campaigns among both residents and staff.

Last, Argentum also requests that CMS clarify that the requirements laid out in this IFC would not apply to ALF's that do not participate in the Medicare and/or Medicaid programs, as these ALFs are not subject to CMS regulatory or oversight authority.

Background on Assisted Living

The IFC currently only applies to Medicaid nursing facilities and Medicare skilled nursing facilities, also collectively known as "nursing homes." However, in the IFC, CMS solicits public comment on the feasibility of implementing the vaccination requirements for other congregate living facilities where it has regulatory authority. CMS broadly describes "congregate living settings" as "shared residences of any size that provide services to clients and residents," and specifically mentions ALFs that participate in the Medicaid program.[2] These ALFs typically provide Medicaid services under state Home and Community Based Services (HCBS) programs and waivers.[3] However, there are material differences between the two care settings that lead to a significant divergence in each setting's ability to comply with the IFC's requirements.

Assisted living is a home and community based model that encompasses a wide range of care settings for older adults, combining housing, supportive services, and health care as needed. Assisted living communities are designed for older individuals (e.g., aged 55 and older) who can generally care for themselves without regular nursing or other routine medical assistance. Most assisted living residents come from their home and walk into an assisted living community looking for a congregate setting that provides assistance with daily activities of living. This is in contrast to nursing homes and skilled nursing facilities that offer routine medical assistance to individuals who require an increased level of medical attention and where most patients are admitted directly from a hospital or rehabilitation facility and need medical care.

Assisted living communities are regulated in all 50 states plus the District of Columbia.[4] These regulations direct the level of care and services that an ALF can provide within a particular state. Generally, assisted living regulations allow for the provision of activities of daily living and

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[2] *Id.* at 26307.
[3] Centers for Medicare & Medicaid Services, Home & Community Based Services Authorities, https://www.medicaid.gov/medicaid/home-community-based-services/home-community-based-services-authorities/index.html.
[4] While the licensing terminology for senior living communities and facilities varies from state to state, for ease of reference, the term "assisted living community" or "ALF" is used herein to globally refer to retirement and assisted living communities for individuals age 55 and older that require a state license or are otherwise regulated in order to operate.

coordination of care and services, as opposed to the provision of skilled nursing or other medical services. When ALFs do provide nursing services, this is not the primary function of an ALF; these services are minimal, and are provided based upon the ability of licensed practical nurses (LPNs) or registered nurses (RNs) to delegate pursuant to state nurse practice laws. The majority of ALFs staff minimal nursing hours based upon the delivery of services that are provided by staff through this delegation authority.

In other words, ALFs primarily focus on promoting an independent lifestyle with assistance customized pursuant to each resident's needs and limited medical care, whereas nursing homes prioritize the provision of medical care.

Feasibility of Compliance with the Interim Final Rule's Requirements

The distinction between ALFs and nursing homes leads to material differences in each setting's ability to comply with requirements such as those set forth in the IFC. Because ALFs are not primarily focused on the provision of medical care, most facilities simply do not have the infrastructure necessary to comply with the IFC's requirements. For example, the management of the COVID-19 vaccine supply for ALFs is burdensome and costly due to short expirations of the life of the vaccine and the associated storage requirements mandated by the FDA's emergency use authorization for the available vaccines. In addition, certain states limit the practice of nursing in the assisted living setting, and administration of the vaccine may not be an option for a given assisted living community.

In states where the vaccine can be administered by ALFs, staffing, education and skills capabilities must be considered. Moreover, administration of the vaccine places additional burden on assisted living communities. Procurement of the vaccine, supply chain management, and reporting requirements are burdensome and costly, and federal requirements are not easily met by assisted living providers. In addition to the direct difficulties with imposing these requirements (such as the limited nursing practices permitted by states, minimal nursing availability, etc.), the addition of nontraditional staffing and provision of services would increase additional risk exposures evaluated by insurance underwriters that could impact general and liability insurance costs in an already difficult insurance market for ALFs.

Although currently there is an option for COVID-19 vaccine administration to be delegated by the pharmacy to ALFs through Federal Pharmacy Partnership, this option requires contracting with the pharmacy who retains chain of custody and recordkeeping, and there are fees and additional costs associated with this option. Furthermore, certain ALFs that specialize in "independent living" were left out of the Federal pharmacy program entirely.

It should also be noted that ALFs are already tasked with complying with various comprehensive state-level requirements, including reporting requirements on COVID-19 cases and vaccination rates. Some of these requirements may be duplicative with those set out in the IFC. Furthermore, assisted living communities participating in Medicaid also must comply with reporting under the respective state's HCBS program.

The issues described above are compounded by the precarious financial situation of many ALFs across the country due to the COVID-19 pandemic. For over a year, assisted living communities

have been serving on the front lines of the COVID-19 pandemic, working tirelessly to keep safe and engaged the residents who call senior living home as well as the employees who care for them. This population is among the most vulnerable to the harmful effects of the virus, with nearly 80 percent of all COVID-19 deaths in the U.S. having occurred in people over the age of 65. For older adults living in senior living communities—whose average age is 85—the risk is even higher. Despite this, assisted living communities have not received anywhere near close to the same level of federal and state relief as other types of providers. ALFs have suffered over $30 billion in losses due to PPE, testing, cleaning, staffing needs and heroes pay, as well as record-low occupancy rates. Despite these great costs, to date, assisted living caregivers have received only about $1 billion in relief from the Provider Relief Fund (PRF), which represents less than 1 percent of the overall fund. Many are still waiting for relief, and others have been inexplicably denied. As a result, nearly half are operating at a loss, and over half report that closures are imminent.

Extending the IFC's requirements to the assisted living industry, with serious penalties for noncompliance, would only exacerbate these problems for an industry that has been at the front lines caring for those most vulnerable to this deadly disease.

Assisted Living Communities Have Successfully Implemented Infection Control and Vaccination Campaigns

In addition to the practical and financial barriers established above, it should be noted that the assisted living community has successfully implemented infection control protocols and vaccination campaigns. Since the beginning of the COVID-19 pandemic in the U.S., senior living providers have implemented enhanced protocols to prevent COVID-19 from entering the community, mitigate the spread of, and otherwise limit the harm from COVID-19. For example, assisted living communities implemented a number of changes and protocols in order to reduce the spread of COVID-19, including: staff workflow changes; visitor restrictions; enhanced infection control protocols; restriction or cessation of move-ins; and health screenings and COVID-19 testing as available and appropriate for residents and staff. [5] These steps led to a significant mitigation of harm - while 39 percent of skilled nursing facilities experienced no COVID-19-related deaths, about two-thirds of independent living (67 percent); assisted living (64 percent); and memory care (61 percent) properties have had no COVID-19-related deaths.

CMS states that the IFC's requirements are necessary given the slow uptake of vaccination in long-term care facilities, noting that not all residents and staff were able to access the vaccine through the initial Pharmacy Partnerships, and that some individuals have declined the vaccine.[6] However, these concerns are not as salient in the assisted living community. A high number of assisted living facilities participated in the Pharmacy Partnerships program. Since the beginning of the vaccine distribution rollout, a high percentage of assisted living resident *and* staff have

[5] A. C. Pearson et al., *The Impact of COVID-19 on Seniors Housing*, NORC at the University of Chicago (June 3, 2021), p. 18, https://info.nic.org/hubfs/Outreach/2021_NORC/20210601NICFinalReportand20ExecutiveSummary20FINAL.pdf. (hereinafter "the NORC Report").
[6] 86 Fed. Reg. at 26320.

been vaccinated for COVID-19.[7] Although initial staff vaccine uptake was lower than resident vaccine uptake, ALFs around the country have successfully increased staff vaccination rates through a variety of education campaigns, vaccine mandates and incentive programs.

CMS also states that it is concerned the IFC's requirements are necessary because of high turnover rates of residents and staff in long-term care facilities. But again, these concerns are not as heightened in the assisted living setting. Currently, assisted living communities have several options available to assist with the provision of the COVID-19 vaccination for new team members and residents, including: physician and independent pharmacy provider arrangements; large pharmacy providers who have established programs that make it convenient and easy for residents and new team members to set up an appointment and go to their setting to receive the vaccine; and the provision of transportation services. Furthermore, many ALFs have implemented COVID-19 vaccine provision during employment hiring processes through third party arrangements.

CMS Can Accomplish the Interim Final Rule's Goals through a Voluntary Compliance Program

Argentum is supportive of CMS efforts to promote vaccination against COVID-19 and allocate vaccination resources to those communities most in need. However, we believe this goal can be accomplished without subjecting Medicaid participating ALFs already in difficult financial situations caused by the COVID-19 pandemic to penalties for noncompliance with this IFC's requirements. Instead, CMS can make compliance with the IFC's provisions voluntary. This framework would allow facilities most in need of vaccination resources to notify CMS of such a need, without subjecting all Medicaid participating ALFs to penalties for potential noncompliance with weekly reporting requirements. Argentum welcomes the opportunity to work with CMS to establish such a voluntary program.

CMS Should Clarify the Scope of the Interim Final Rule

Argentum appreciates CMS's efforts to contain the spread of COVID-19 in congregate care settings. However, we are concerned that some language in the IFC may be misinterpreted by some stakeholders as CMS extending its regulatory and oversight authority to assisted living facilities generally, even those that do not participate in the Medicare and/or Medicaid programs. Only 17% of ALFs receive funding from the Medicaid program. The remaining 83% of ALFs are funded solely on a private pay basis, with no affiliation with, or reimbursement from CMS or affiliated federal programs. It is well understood that CMS generally does not have the authority to impose oversight and other regulatory requirements on facilities that do not participate in CMS programs. However, given some ambiguity in the IFC, we respectfully ask CMS to clarify that these requirements will not, and cannot be extended to ALFs where CMS

[7] *See* National Investment Center for Seniors Housing & Care, *Executive Survey Insights Wave 29: May 17 to June 13, 2021* (June 24, 2021), https://blog.nic.org/executive-survey-insights-wave-29-. (finding vaccination rates at long-term care facilities to be 9 out of 10 for residents, and 2 out of 3 for staff).

does not have regulatory authority and does not "pay[] for some portion of the care and services provided."[8]

Thank you for your consideration of these comments. Please contact me with any questions or requests for additional information.

Sincerely,

James Balda
President & CEO
Argentum

[8] 86 Fed. Reg. at 26307.