



July 28, 2022

Katherine Ceroalo
NYS Department of Health
Bureau of Program Counsel
Reg. Affairs Unit
Corning Tower, Room 2438
Empire State Plaza
Albany, NY 12237

Re: COVID-19 Vaccinations of Nursing Home and Adult Care Facility Residents and Personnel, I.D. No. HLT-23-22-00002-P

Dear Ms. Ceroalo:

I am writing on behalf of the members of LeadingAge New York -- non-profit and public providers of long-term/post-acute care and aging services -- to offer comments on the above-referenced proposed regulation, requiring nursing homes and adult care facilities to offer or arrange for COVID-19 vaccinations of residents and staff.

As discussed in more detail below, our principal concerns are:

- The regulation requires nursing homes and adult care facilities (ACFs) to offer or arrange for vaccinations of residents, even if they know the vaccine is medically-contraindicated for that resident.
- The regulation is similar, but not identical, to federal regulations applicable to nursing homes. As a result, it has the potential to generate confusion and trigger duplicative penalties.
- The penalty provision for adult care facilities is disproportionately harsh.
- The requirement to post vaccination information in every resident hallway is excessive.
- The ACF language in the regulations is not entirely consistent with the vaccine mandate requirements outlined in a separate set of regulations.

Most of these concerns have been raised previously in the context of the reauthorization of this regulation on an emergency basis in written comments to the state's Public Health and Health Planning Council dated May 31, 2021, January 9, 2022, March 31, 2022 and May 31, 2022.

Under the regulation every nursing home must offer, and every ACF must make diligent efforts to arrange for, COVID-19 vaccinations for all consenting, unvaccinated existing personnel and residents. These offers and efforts must be documented and any decision to decline a vaccination must be documented by a signed affirmation. Nursing homes are also required to post conspicuous signage throughout the facility, *including at points of entry and exit and each residential hallway*, reminding personnel and residents that the facility offers COVID-19 vaccination.

The Requirement Should Not Apply When the Vaccine is Medically Contraindicated

This regulation does not include any provision that recognizes that the COVID-19 vaccine may be medically contraindicated for certain residents or personnel. As a result, it requires that all residents and staff must be offered the vaccine (even if medically-contraindicated). While we can expect a staff member to understand the blanket requirement, it may be confusing and disconcerting to residents and their representatives to be offered vaccines that are not medically appropriate and then be asked to sign an “affirmation” that they are declining it. The regulation should include a provision waiving the requirements with respect to residents who have medical conditions that make COVID-19 contraindicated.

The Regulation Duplicates a Federal Nursing Home Regulation

This regulation duplicates the substance of federal nursing home requirements, but uses slightly different terminology and documentation, creating the potential for confusion in the field and duplicative penalties. CMS regulations at 42 CFR 483.80(d) similarly require nursing homes to educate residents or resident representatives and staff regarding the benefits and potential side effects associated with the COVID-19 vaccine and to offer the vaccine unless it is medically contraindicated or the resident or staff member has already been immunized. Additionally, the facility must maintain appropriate documentation to reflect that the facility provided the required COVID-19 vaccine education, each dose of the vaccine offered to a resident, if the resident did not receive the COVID-19 vaccine due to medical contraindications or refusal, and the vaccination status of staff.

Nursing home staff have been working tirelessly for over two years to protect their residents and staff from COVID, under multiple layers (federal, state, and local) of often inconsistent operating and reporting requirements. Even when requirements are similar, but not identical, they cause confusion in the field for both surveyors and facility staff. Moreover, duplicative regulations can trigger duplicative penalties at a time when staff and financial resources are stretched very thin. We must begin to identify those requirements that are important to resident care and safety and eliminate those that are duplicative, obsolete, or inconsistent with federal standards. We cannot continue to drain facilities of resources through duplicative and punitive requirements, when those resources are needed for resident care.

ACF Penalties are Disproportionately Severe

The penalty provisions set forth in the regulation for ACFs are disproportionately severe, especially given the current staffing crisis. Notably, no other provider type, aside from nursing homes and ACFs, is subject to the requirements set forth in this regulation. For adult care facilities, the “failure to arrange for the vaccination of *every facility resident and personnel* . . . constitutes a “failure in systemic practices and procedures” – apparently, even if only one resident or staff member has not been scheduled for a vaccine within the requisite timeframe. The regulation also mentions referral for criminal investigation as a potential penalty. With staff in such short supply, nursing homes and adult care facilities must focus on meeting essential resident needs. To threaten harsh penalties and criminal prosecution for failure to provide (and document) an opportunity for *every* facility resident or staff member to receive a vaccine within an arbitrary timeframe is excessive.

The Requirement to Post Vaccine Availability Information in Nursing Homes is Over-Broad

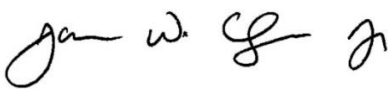
The regulation's requirement that nursing homes post "conspicuous signage throughout the facility, *including at points of entry and exit and each residential hallway*, reminding personnel and residents that the facility offers COVID-19 vaccination" is excessive and diminishes the homelike atmosphere that nursing homes strive to create and that is required by state and federal regulations (See 42 CFR 483.10). Requirements to post various types of information and notices in nursing homes are growing in number and scope. In addition to posting vaccination information in every resident hallway, nursing homes are required to post, among other items, residents rights (potentially in 10 languages), the facility's CMS Star Rating (which can change quarterly), nurse staffing information required by Public Health Law 2805-t, a summary of the minimum staffing statute provided by the Department of Health, and contact information for the state and regional offices of the LTC ombudsman program and nursing home complaint hotline. It is difficult to create a homelike environment with so many text-heavy, impersonal posters on the walls. We recommend that the requirement to post vaccination information be limited to staff break rooms and at the entrance to the facility.

The ACF Language is Somewhat Inconsistent with Vaccine Mandate Regulations

We understand that these regulations pre-dated the vaccine mandate for personnel working in nursing homes, ACFs and other settings, and thus were written in a way that does not address the mandate, aside from directing the reader to that regulation at the end of each respective section. We recommend, however, that the language in 66-4.2 *Requirements for Adult Care Facilities* be modified slightly to acknowledge the development of a mandate. Specifically, in 66-4.2(b)(2), the following language should be eliminated from the section on personnel: "...nothing in this paragraph shall be construed to require an adult care facility to make any hiring determination based upon the prospective personnel's COVID-19 vaccination status, history, or interest in COVID-19 vaccination;...". While it true that this section of regulation was not a mandate, a mandate was subsequently implemented and referenced later in that same section. Our suggestion to strike this language will eliminate the possibility of any confusion about the state's intent to require personnel working in these settings to be vaccinated.

Thank you very much for your consideration of these issues.

Sincerely yours,



James W. Clyne, Jr.
President and CEO

Cc: John Morley
Adam Herbst
Valerie Deetz
Heidi Hayes
Sheila McGarvey