May 31, 2021

Jeffrey A. Kraut
Chair, Public Health and Health Planning Council
Angel Gutierrrez, M.D.
Chair, Committee on Codes, Regulations, and Legislation
c/o Executive Secretary, Public Health and Health Planning Council
Empire State Plaza, Corning Tower, Room 1805
Albany, New York 12237

Re: Emergency Regulations 20-23 Amendment of Section 415.19 of Title 10 NYCRR (Nursing Home Personal Protective Equipment Requirements) and 21-06 Addition of Subpart 66-4 to Title 10 NYCRR (COVID-19 Vaccinations of Nursing Home and Adult Care Facility Residents and Personnel

Via E-Mail

Dear Mr. Kraut, Dr. Gutierrrez, and members of the Public Health and Health Planning Council,

I am writing on behalf of LeadingAge New York's non-profit and public nursing home and adult care facility-(ACF) members to offer comments on two emergency regulations on your agendas for discussion on June 3. In addition, I would like to bring to your attention ways in which guidance issued by the Department of Health governing visitation, social interaction, and staff testing in nursing homes and ACFs deviates from guidance issued by the Centers for Medicare and Medicaid Services (CMS), resulting in detrimental impacts on residents and staff.

LeadingAge NY urges you to take the following into consideration in your discussion of the below regulations and as you consider further actions in response to the COVID-19 pandemic:

- **20-23 Amendment of Section 415.19 of Title 10 NYCRR (Nursing Home Personal Protective Equipment (PPE) Requirements)**

While LeadingAge NY understands the importance of maintaining an adequate supply of PPE in preparation for current and future public health emergencies, this emergency regulation sets an arbitrary and wasteful benchmark for determining the necessary supply of PPE. It requires facilities to maintain a 60-day supply of PPE based on their *average daily use rates from April 19, 2020 to April 27, 2020*. Notably, this timeframe for measuring the size of the required stockpile does not appear to be required by statute. Public Health Law section 2803, which is cited as the legislative authority for the regulation, requires only that the residential health care facility implement "a plan to maintain or contract to have at least a two-month supply of personal protective equipment."

The reported April 2020 use rates are an unrealistic measure of current or anticipated PPE need for many facilities, and the use of this benchmark has forced many facilities to purchase excess supplies at exorbitant

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prices. Moreover, PPE comes with expiration dates, and in many cases facilities may never have the opportunity to use their excess PPE prior to its expiration.

Notably, the regulation and the associated DOH guidance require possession of sufficient PPE "consistent with federal Centers for Disease Control guidance." However, the CDC does not require facilities to apply a use rate from 13 months ago to determine the amount of PPE needed. Instead, its PPE burn rate calculator, used for determining how long supplies will last and projecting future needs, relies on the average daily use rate over the prior 5 days.[1] Nevertheless, DOH is enforcing compliance based on reported April *2020* rates that generally have little relation to current or expected rates.

We understand that the Department may have selected a benchmark date based on what it believed to be peak utilization. However, in many regions of the state, the peak of the pandemic occurred after April 2020. Many facilities outside of the New York City metro area had few if any COVID cases in April 2020. Some of these reported estimated PPE use based on projections that have proven to be excessive. Facilities in the New York City metro area had both higher COVID rates and higher censuses of residents in April 2020 than they do now, resulting in much higher April 2020 burn rates than the current rates. Accordingly, facilities' April 2020 burn rates often have little relation to their current or reasonably expected needs.

The Department of Health (DOH) should modify the emergency regulation to align with Centers for Disease Control (CDC) guidance and require nursing homes to use their current use rates or reasonably expected use rates. Facilities should not have to waste precious resources purchasing excess PPE that will have to be discarded based on its expiration date before it will be needed.

The regulations or associated guidance should also address how reusable PPE should be factored into calculating burn rates and required inventory. The method used by the Department to calculate the required supply of reusable PPE has never been explained. We suspect that reusable supplies are counted the same way as single-use supplies in the Department's analysis, leading to under-counting of inventories and the potential imposition of fines. Additionally, HERDS reports that are used to collect data on PPE inventories do not include goggles among the items reported, even though (according to the CDC) indirectly-vented goggles are preferable to face shields as eye protection under many circumstances.[2] Facilities that have used goggles in addition to face shields have been cited for an insufficient quantity of face shields, when they have an ample supply if goggles are also counted.

- **21-06 Addition of Subpart 66-4 to Title 10 NYCRR (COVID-19 Vaccinations of Nursing Home and Adult Care Facility Residents and Personnel)**

This emergency regulation, aimed at encouraging the vaccination of residents and personnel in nursing homes and ACFs, is similar to, but inconsistent with, recently-implemented federal regulations applicable to nursing homes which require ongoing education, offer of vaccines, documentation of efforts, and reporting

[1] Centers for Disease Control, Personal Protective Equipment (PPE) Burn Rate Calculator, *https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/burn-calculator.html*.

[2] *Centers for Disease Control, National Institute for Occupational Safety and Health, Eye Safety Infection Control, available at https://www.cdc.gov/niosh/topics/eye/eye-infectious.html*.

of vaccine status of residents and staff. It is critical to understand that ACFs and nursing homes have been working tirelessly for past 15 months to protect their residents and staff from COVID, under multiple layers (federal, state, and local) of often inconsistent operating and reporting requirements. 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 must support providers in focusing their resources on resident care and quality of life. DOH should rely on the federal vaccination regulation with respect to nursing homes and abandon or modify the comparable state regulation.

There are other more technical concerns with this regulation. The regulation implies that nursing homes must supply vaccine on-site, when it is often faster for staff to get vaccine off-site. Logistically, facilities still need to aggregate 5-10 people to receive the vaccine due to the number of doses in each vial, and this sometimes cannot happen within the short timeframe provided. In addition, the regulation requires nursing homes to "offer all consenting, unvaccinated existing personnel and residents" the opportunity to be vaccinated, without regard for eligibility. It does not contain any explicit exemptions for pediatric residents under age 12 or those who are medically ineligible. There should be an explicit exemption from offering the vaccine to these individuals. Lastly, the regulations should recognize the guidance regarding tuberculosis testing for new employees in these settings. The state has adopted CDC guidance which recommends that COVID vaccination and TB testing be conducted separate from one another. If baseline TB testing is a prerequisite for employment, the COVID vaccination may have to be deferred several weeks as a result. The regulations must reflect these nuances, particularly given the harsh penalties for non-compliance.

- **Visitation, Social Interaction and Serial COVID Testing**

LeadingAge NY appreciates that New York was among the earliest and hardest hit by COVID, and as a result had to pave the way and develop state-specific policies. Now, it is time to align the state's policies with those of the federal government. We urge the state to follow the CDC and CMS policies governing nursing home and ACF visitation, social interaction, and staff testing.

Eighty-five percent of New York's nursing home residents and 61 percent of nursing home staff, as well as 94 percent of ACF residents and 69 percent of ACF staff, are vaccinated. Our nursing home and ACF residents and staff deserve to enjoy the benefits of vaccination that other New Yorkers are enjoying. New York should allow fully-vaccinated residents to unmask and hug their fully-vaccinated visitors, as allowed by CMS and CDC guidance.[3] It should allow fully-vaccinated residents to sit within 6 feet of other fully-vaccinated residents and unmask for meals and activities so that they can communicate effectively and enjoy each other's company.[4] New York should also work with CMS to expand visitation for vaccinated residents during contained COVID outbreaks in nursing homes. It is extremely confusing and distressing for residents, family members, and staff to grapple with the discrepancies between conflicting state and federal guidance. Moreover, following CMS guidance would encourage vaccination for residents and their visitors.

[3] CMS, QSO 20-39-NH, 4/27/2021, https://www.cms.gov/files/document/qso-20-39-nh-revised.pdf (accessed 5/31/2021); CDC, Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination, https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-after-vaccination.html (accessed 5/31/2021).
[4] *Ibid.*

In addition, New York should follow CDC and CMS guidance[5] and eliminate routine COVID testing for fully-vaccinated and recently-recovered staff in nursing homes and assisted living settings (twice weekly in nursing homes and weekly in ACFs). New York's requirements far exceed CMS requirements, and no other health care setting in New York is subject to serial screening testing. Eliminating the weekly and twice weekly testing for vaccinated staff would encourage vaccination, while removing an uncomfortable, ongoing test that serves as a barrier to recruitment and retention of staff. Eliminating testing for recently-recovered staff would also reduce unnecessary furloughs of non-infectious staff who persistently test positive.

With widespread vaccination within nursing homes and ACFs, the risks associated with social isolation are greater than the risks of COVID infection among residents. A recent study of over 18,000 nursing home residents conducted by Brown University found that the incidence of COVID declined to 0.3 percent among both vaccinated and unvaccinated residents, after more than 14 days elapsed either from their second vaccine dose or, for unvaccinated residents, after more than 42 days from the first vaccination clinic.[6] Of the very small number of infections, most were asymptomatic.

New York should allow nursing home and ACF residents and staff to experience the joy of reconnecting and the relaxation of some restrictions after vaccination. We need to allow nursing homes and ACFs to focus on care of their residents and recovery of their staff. We must support them as they strive to rebuild their staff and revitalize social life within their facilities.

Thank you very much for your consideration of these issues.

Sincerely yours,

Karen Lipson
Executive Vice President for Innovation Strategies

Cc: Colleen Leonard
Lisa Thomson
Jaclyn Sheltry

[5] CMS, QSO 28-38-NH 4/27/2021, https://www.cms.gov/files/document/qso-20-38-nh.pdf (accessed 5/31/2021).

[6] White E.M, "Incident SARS-CoV-2 Infection among mRNA-Vaccinated and Unvaccinated Nursing Home Residents," Letter, *NEJM,* May 19, 2021, https://www.nejm.org/doi/full/10.1056/NEJMc2104849.