March 31, 2022

Jeffrey A. Kraut
Chair, Public Health and Health Planning Council
Thomas Holt
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: 20-22 Amendment of Section 405.11 and 415.19 of Title 10 NYCRR (Hospital and Nursing Home Personal Protective Equipment Requirements); 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, Mr. Holt, and members of the Public Health and Health Planning Council:

I am writing on behalf of the members of LeadingAge New York -- non-profit and public providers of long-term and post-acute care services -- to offer comments on the above-referenced emergency extension and amendment of regulations relating to the COVID-19 public health emergency.

We would like to provide some feedback on the amendment to the Personal Protective Equipment regulation and briefly reiterate the issues we raised regarding these regulations in our January 9, 2022 comments.

I. 20-22 Amendment of Section 405.11 and 415.19 of Title 10 NYCRR (Hospital and Nursing Home Personal Protective Equipment Requirements)

The amended regulation adds a benign provision that requires providers to follow storage recommendations and dispose of expired supplies:

> In order to maximize the shelf life of stockpiled inventory, providers should follow the appropriate storage conditions as outlined by manufacturers and inventory should be rotated through regular usage and replace what has been used in order to ensure a consistent readiness level, and expired products should be disposed of when their expiration date has passed. Expired products shall not be used to comply with the stockpile requirement set forth in paragraph (1) of this subdivision.

We have no objection to this reminder. However, this amendment also highlights the fact that the regulation's formula for determining the quantities of each type of PPE is driving a substantial waste of precious resources (both financial and material). The formula is based on the highest COVID positivity rates over the past two years and bears no relation to actual or projected use rates. Thus, the regulation requires stockpiling of excessive amounts of PPE that may not be used prior to its expiration and must be discarded. These requirements also create a need for massive storage facilities for stockpiles that are likely to be excessive – many nursing homes are renting warehouse space for their stockpiles.

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The excess supply resulting from the formula's reliance on the highest possible positivity rates is exacerbated by its use of the number of licensed beds in a facility, not on staffed beds in operation or average census over a specified period. Many, if not most, nursing homes have closed units and limited admissions due to staffing constraints.

Thus, the required quantities of PPE may have no relationship to the amount of PPE being used today or in the foreseeable future. All of this wasted expense is being incurred at a time when facilities are struggling with skyrocketing costs and shrinking revenues. Instead, the regulation should require nursing homes to maintain a stockpile based on current and projected need that is periodically updated.

In addition to using metrics that require excessive stockpiles, this regulation requires facilities to "possess and maintain" the specified supply of each category of PPE without allowing them to use their reserves when regular supply chain resources run short. Under the regulation, the failure to "possess and maintain" the required supply may result in action against their license and fines. It does not include any provision that would allow facilities to drop below the 60-day supply in the event of widespread shortages. Facilities should not be subject to regulatory citations when, due to circumstances beyond their control, they need to use their PPE reserves and cannot immediately replenish their supply.

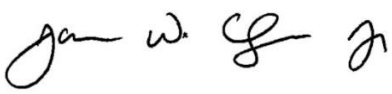
II. 21-06 Addition of Subpart 66-4 to Title 10 NYCRR (COVID-19 Vaccinations of Nursing Home and Adult Care Facility Residents and Personnel)

As previously noted, this regulation does not include any provision that recognizes that residents or personnel may not be eligible for a vaccine or booster due to recent COVID infection, treatment with monoclonal antibodies, or the timing of their initial vaccination series. Similarly, pediatric nursing facilities may serve individuals under age 5 who are ineligible for the vaccine. Thus, it may not make sense for these employees or residents to be offered an opportunity to receive their vaccination or booster within 14 days (or 7 days for adult care facilities) of admission or hiring.

Further, the penalty provisions set forth in the regulation seem disproportionately severe, especially given the current staffing crisis. Notably, no other provider type 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.

Thank you very much for your consideration of these issues.

Sincerely yours,



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