May 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); 21-14 Addition of Section 2.61 to Title 10 NYCRR, Amendment of Sections 405.3, 415.19, 751.6, 763.13, 766.11, 794.3 & 1001.11 of Title 10 NYCRR & Sections 487.9, 488.9 and 490.9 of Title 18 NYCRR (Prevention of COVID-19 Transmission by Covered Entities)

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 regulations relating to the COVID-19 public health emergency. This letter principally reiterates concerns that have been raised previously in our November 14, 2021, January 9, 2022, and March 31, 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)

As previously noted, this 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. Not only does the formula lead to a waste of resources, the purchase and disposal of excess and unused PPE needlessly contributes to environmental pollutants.

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

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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 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.

III. Amendment of Sections 405.3, 415.19, 751.6, 763.13, 766.11, 794.3 & 1001.11 of Title 10 NYCRR & Sections 487.9, 488.9 and 490.9 of Title 18 NYCRR (Prevention of COVID-19 Transmission by Covered Entities)

We appreciate the Department's removal of the booster vaccine requirement, given the severe staffing shortages plaguing the entire health care continuum. We also appreciate the removal of a confusing reference to receipt of subsequent doses that was included in the March 17, 2022 version of the regulation presented to the Codes Committee.

However, we remain concerned that these regulations impose requirements that are duplicative of, but slightly inconsistent with, the CMS staff vaccination regulations applicable to hospitals, nursing homes, certified home health agencies, PACE programs, and certain other providers. Even minor inconsistencies in wording between the federal and state regulations cause added work and confusion for facilities and surveyors. One example of such an inconsistency is the description of exemptions from the vaccination requirement. While the state regulations reference only "exemptions," the federal regulations and guidance reference both exemptions and "temporarily delayed vaccination," "as recommended by the CDC, due to clinical considerations, including

known COVID-19 infection until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met. See CMS QSO 22-07-ALL, Long-Term Care and Skilled Nursing Facility Attachment A. In addition, according to CDC,

> people who recently had SARS-CoV-2 infection may consider delaying a primary series dose or their first or second COVID-19 vaccine booster dose by 3 months from symptom onset or positive test (if infection was asymptomatic). Studies have shown that increased time between infection and vaccination may result in an improved immune response to vaccination.

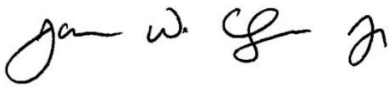
See CDC, Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States.

Moreover, for providers covered by both federal and state requirements, the state regulations also unnecessarily impose a second layer of penalties for non-compliance at a time when providers are coping with a staffing crisis and cash flow challenges and need to invest all available resources in delivering care. We have observed many cases, involving violations of other state and federal regulations, in which both federal and state penalties have been imposed for the same violation. For providers that are covered by the federal vaccination mandate, these regulations are unnecessary.

Finally, there appears to be a typographical error in paragraph (5) of subdivision (a) of Section 415.19. We believe the paragraph is intended to read: "collects documentation of COVID-19 vaccination or documentation of a valid medical exemption to such vaccination . . . .

Thank you very much for your consideration of these issues.

Sincerely yours,



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