March 26, 2023

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)

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 regulation relating to the nursing home stockpiles of personal protective equipment (PPE).

The current iteration of the PPE stockpile regulation represents a significant improvement over the earlier version in that the required inventory for nursing homes is based on average annual census rather than certified nursing home beds. Nevertheless, additional changes in the regulation and in State policy are needed to avoid waste, pay for unreimbursed PPE stockpile costs, and ensure that adequate PPE is available and appropriately distributed during future pandemics. These concerns are detailed below.

Changes in Transmission Rates and Masking Guidance Justify Reducing Inventory Requirements in Order to Avoid Waste

The PPE stockpile formula continues to be based on the highest COVID positivity rates over the past three years and bears no relation current or reasonably projected use rates, given recent transmission rates and changes in state and federal health care masking guidance. As a result, it demands the purchase of amounts of PPE that are unlikely to be used before their expiration dates.

On February 10, 2023, the Department issued updated guidance on the use of face masks in health care facilities, aligning state masking requirements with the CDC's recommendations. Under the CDC guidance, source control (i.e., a well-fitting face mask) is recommended for everyone in a health care facility when COVID Community Transmission Levels are high. When Community Transmission Levels are *not* high, health care facilities may choose not to require universal source control, except for certain categories of individuals. With regard to the use of masks, ventilators, and other items as PPE (as opposed to source control), the CDC recommends Standard Precautions (and Transmission-Based Precautions) based on each patient's presentation and suspected diagnosis, rather than universal use. In counties where Community Transmission Levels are high, CDC recommends that facilities consider broader use of respirators and eye protection under certain circumstances.

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For the week of March 14-22, 2023 (the most current period available), the CDC's COVID data tracker shows that only 6 counties in New York State have high Community Transmission Levels. Thus, throughout most of New York State, health care facilities have the option of allowing their staff to unmask. We understand that staff have been clamoring for relief from mask requirements due to the discomfort they experience wearing masks for 8 to 12 hours per day. Given severe workforce shortages in facilities, it is important for employers to consider the perspectives of their staff.

Because the PPE stockpile regulation requires inventories based on peak periods of positivity, and current use rates of masks and other PPE are down due to changes in policy and Community Transmission Levels, the regulation's methodology is once again likely to result in the accumulation of inventory in stockpiles that will expire before they can be used. 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.

Instead of requiring the stockpiles based on peak periods of positivity in 2020 and 2021, the regulation should require nursing homes to maintain a stockpile based on current and projected need that is periodically updated. If stockpile inventories must be based on worst case scenarios in terms of infection rates, the regulations should provide for different formulas for calculating the required quantity of each type of PPE based on relative shelf lives. In other words, the formula should provide for lower quantities of PPE types that have short shelf lives in comparison with those types that have long shelf lives. This would reduce the likelihood that PPE will expire prior to use.

In addition, we recommend removing the reference to the specific peak periods in Section 415.19 defining the "applicable positivity rate." Instead, those reference dates should be provided through sub-regulatory guidance (e.g., "Dear Administrator Letter"). This would allow the regulations to be better aligned with the current conditions going forward.

Peak Positivity Rates Should Not be Used for Nursing Homes that Were Designated "COVID-Only"

In late 2020 and early 2021, a handful of nursing homes volunteered to become COVID-only facilities to accept discharges of COVID-positive patients from hospitals. The peak positivity rates for these facilities during the periods specified in the regulation approach 100 percent. Today, they are no longer designated "COVID-only," and their rates are much lower. These facilities should not be forced to waste resources on PPE that will expire before it can be used. The current methodology effectively penalizes these facilities for contributing to the pandemic response.

The Method of Calculating Annual Census Should be Specified

The methodology for calculating the 60-day inventory relies on a peak positivity rate, multiplied by the nursing homes "average census as determined annually by the Department," multiplied by a PPE-specific use multiplier. There are many ways to calculate a nursing home's average census. In an email to facilities, the Department indicated that "[t]he average census is the for the calendar year 2022 calculated from the facility level HERDS COVID 19 survey submissions." We are hopeful that the daily COVID-19 HERDS surveys will be eliminated. Moreover, nursing homes report occupancy via other data submissions. The regulation should specify the method for calculating average occupancy.

Requirement to "Possess and Maintain" the Specified Inventory Should be Modified to Allow Use of Stockpiles During Supply Chain Disruptions

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 the imposition of fines. The regulation 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.

Regulations Should Account for Reusable PPE

The State's formula for calculating the required quantities of PPE should take into account reusable supplies, such as gowns. It appears that at least some Department of Health surveyors require the same quantities of reusable gowns as disposable gowns. However, if the formula indicates a need for 5,000 gowns and the facility is using reusable gowns with a 50-wash lifecycle, then the facility would require 100 gowns in its stockpile to meet a 5,000 use requirement, not 5,000 gowns. If the Department requires the facilities to purchase the 5,000 gowns, whether or not they are reusable, facilities will buy disposables which are less expensive on a per item basis, notwithstanding the impact on the environment and the fact that reusables would be more cost-effective.

Medicaid Rates Must be Adjusted to Reimburse Nursing Homes for the Cost of their PPE Stockpiles

We support the aim of ensuring that sufficient PPE is readily available to nursing homes in the event of a surge in demand and supply chain failures. Historically, stockpiling PPE has been a government emergency preparedness function, and in many states and countries it remains one. We recognize that government PPE stockpiles fell short during the pandemic and that the allocation of limited public supplies did not prioritize nursing homes. Given the potential for shortfalls in the government supply of PPE, we understand the value of provider supplies in addition to government stockpiles.

However, it is important to recognize that *if providers are to assume the responsibility of stockpiling PPE, government payers must appropriately reimburse them for these expenditures.* Notwithstanding the Regulatory Impact Statement's conclusion that the stockpiles impose no long-term additional costs, the purchase, storage, and management of a 60-day stockpile of PPE is costly. In addition to the cost of the extra supplies, space must be acquired or dedicated, and staff must be retained and assigned to document, report, maintain, rotate, and dispose of the inventory. These expenses are not funded under the existing Medicaid rates. New York's nursing home Medicaid rates are based on *2007 costs, discounted by 9 percent.* According to the federal Medicaid and CHIP Access Commission, New York's gap between nursing home Medicaid rates and costs is among the largest in the country. With approximately 72 percent of New York's nursing home days paid for by Medicaid, the State bears a responsibility to pay for the new PPE stockpile requirement through the Medicaid rates. This cost was clearly not accounted for in 2007.

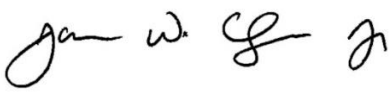
Initiate a Collaborative Effort to Right-Size the Government Stockpile and Develop an Appropriate Allocation Methodology for the Next Supply Chain Disruption

We urge the Department's Office of Primary Care and Health Systems Management, Office of Aging and Long-Term Care, and Office of Public Health to ensure that government stockpiles are appropriately sized and that an appropriate plan is developed, in consultation with all stakeholders, for distribution of supplies in the event of another pandemic or supply chain disruption, based on agreed-upon principles such as regional prevalence or incidence, vulnerability of the population served, and nature of services provided.

The State should also consult with clinical experts on an ongoing basis to determine which supplies are needed in facility stockpiles given evolving epidemiology and development of new equipment.

Thank you very much for your consideration of these issues.

Sincerely yours,



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