August 10, 2023

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

Re: Hospital and Nursing Home Personal Protective Equipment (PPE) Requirements, I.D. No. HLT-23-22-00001-RP

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 revised proposed regulation, requiring nursing homes and hospitals to maintain a 60-day supply of personal protective equipment (PPE). This letter addresses the revised proposed regulation (henceforth "the regulation") as it applies to nursing homes.

The current iteration of the PPE stockpile regulation represents a significant improvement over the earlier version, although we continue to have concerns with several aspects of the regulation as detailed below. Additional changes in the regulation and in State policy are needed to avoid waste, pay for unreimbursed PPE stockpile costs, avoid detrimental environmental impacts, ensure transparency, and ensure that adequate PPE is available and appropriately distributed during future pandemics.

Required Inventory Should be Modified and Formula Should be More Transparent

We welcome the changes in the methodology for calculating the required inventory set forth in the revised proposed regulation. Specifically, we support the shift to using average census, in lieu of certified beds, as a factor in the formula, given reductions in nursing home occupancy. Likewise, the proposed change in the regulation's methodology for calculating the PPE inventory to be maintained by facilities previously designated as "COVID-only" nursing homes represents an improvement over the prior version. While we recognize that these changes are steps in the right direction and mitigate the waste of resources driven by the prior methodology, they do not go far enough.

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

The formula set forth in the regulation for calculating the required inventory for nursing homes continues to be based on periods with the highest COVID positivity rates over the past three years. We are concerned that given current PPE use rates, items within the required inventories run the risk of expiring before they can feasibly be used. This will waste precious resources and contribute to environmental pollutants.

- **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 and different sources of data that could be used. 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." In order to ensure consistency and transparency, the regulation, or at a minimum sub-regulatory guidance, should specify the method for calculating average occupancy and the source of the data used.

Requirement to "Possess and Maintain" the Specified Inventory Should be Modified

Section 415.19(f) of the regulation requires facilities to "possess and maintain" the specified supply of each category of PPE and provides for "revocation, limitation, or suspension of the nursing home's license" if it fails to possess and maintain the required supply. As acknowledged in the regulatory impact statement, the purpose of the regulation is to provide a reliable source of PPE when regular supply chain resources run short. However, the regulation does not include any provision that would allow facilities to use their stockpiles and drop below the 60-day supply in the event of widespread shortages. Facilities should not be subject to regulatory citations or actions against their licenses when, due to circumstances beyond their control, they need to use their PPE reserves and cannot immediately replenish their supply. Section 415.19(f) should be amended to provide an exception to the requirement to "possess and maintain" the 60-day inventory, in the event of an emergency or widespread supply chain interruptions.

Regulations Should Account for Reusable PPE

As we've previously noted, the State's formula for calculating the required quantities of PPE should take into account reusable supplies, such as gowns. If reusable PPE is counted the same way as disposable PPE, there is a disincentive to purchase reusable supplies which are more expensive on a per unit basis. Based on a review of the literature, researchers from Stanford University concluded that "reusable gowns are safer, more cost-effective, and more sustainable than disposable gowns."[1] The researchers view reusable gowns as "a means to lower health care costs, address climate change, and improve resilience while preserving the safety of health care workers."

In its response to public comment, the Department states that, due to variation among products and manufacturers, there is no valid way to calculate a required inventory of reusable PPE. We disagree.

[1] Baker, N., et al., "COVID-19 Solutions Are Climate Solutions: Lessons From Reusable Gowns," *Frontiers in Public Health*, Nov. 25, 2020, available at https://www.frontiersin.org/articles/10.3389/fpubh.2020.590275/full. Similarly, a study published in the *AORN (Assoc. of Perioperative Registered Nurses) Journal* concluded that "selection of reusable gowns rather than disposable gowns reduced natural resource energy consumption (64%), greenhouse gas emissions (66%), blue water consumption (83%), and solid waste generation (84%)." Vozzola, E., et al., "An Environmental Analysis of Reusable and Disposable Surgical Gowns," *AORN Journal*, Mar. 2020.

The Department could simply require providers to follow the manufacturers' instructions, just as it does for expiration dates. The Department also noted in its response to public comments that "facilities have inaccurately reported their reusable PPE amounts when the Department employed a standard adjustor to account for reusability." We are unaware of the Department's use of a standard adjustor to account for reusability. We suspect that any inaccurate reporting among nursing homes may be attributed to the lack of information provided by the Department to nursing homes and their associations concerning its method of accounting for reusable PPE and its use of such an adjustor.

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.

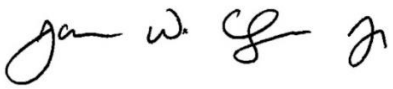
Initiate a Collaborative Effort to Right-Size the Government Stockpile and Develop an Appropriate Allocation Methodology for the Next Supply Chain Disruption

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,



James W. Clyne, Jr.
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