



June 30, 2022

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-P.

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 proposed regulation, requiring nursing homes and hospitals to maintain a 60-day supply of personal protective equipment (PPE).

This letter addresses the proposed regulation as it applies to nursing homes. As discussed in more detail below, our principal concerns are:

- The formula used to determine the size of the required stockpile is unlikely to bear any relation to the supplies of PPE that could reasonably be needed by a nursing home within a 60-day period, resulting in a waste of precious health care resources; and
- The text of the regulation requires facilities to maintain the 60-day supply at all times or face penalties. It does not include any provision that would allow facilities to use their stockpile, even in the event of widespread shortages, without violating the terms of the regulation and risking the imposition of penalties.

These concerns have been raised previously in the context of the reauthorization of this regulation on an emergency basis in written comments to the state's Public Health and Health Planning Council dated June 5, 2021, January 9, 2022, March 31, 2022 and May 31, 2022.

As previously noted, the regulation's formula for determining the quantities of each type of PPE to be stockpiled is driving a substantial waste of precious resources (both financial and material). The formula is based on the periods with the highest COVID positivity rates over the past two years and bears no relation to actual or projected use rates. The excess supply resulting from the formula's reliance on the highest possible positivity rates is exacerbated by its use of the number of certified beds in a nursing home, 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 since the onset of the pandemic. Statewide, there are approximately 17,250 certified nursing home beds that are not in use.¹

¹ The statewide median occupancy of nursing homes is approximately 89.8 percent, down from 95 percent before the pandemic, with regional medians ranging from 84.5 percent to 93.6 percent. LeadingAge NY analysis of NYS DOH June 2022 data. © 2022 British American Bldg. | Suite 2 | Latham, NY 12110

As a result of the formula's reliance on periods of highest prevalence of COVID and on certified beds, the regulation requires stockpiling of excessive amounts of PPE that may not be used prior to its expiration and must be discarded. The formula also creates 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.

Notably, the regulation requires possession of sufficient PPE “consistent with federal Centers for Disease Control guidance,” but imposes a standard that is inconsistent with CDC guidance. The CDC does not require facilities to determine their PPE inventory based on use rates or disease rates that existed 28 months ago or 18 months ago. Nor does it use certified beds to calculate need. Instead, it speaks to “surge capacity” and notes that “there are no commonly accepted measurements or triggers to distinguish surge capacity from daily patient care capacity.” To help healthcare facilities determine how long PPE supplies will last and project future needs in response to COVID-19, CDC developed a [Personal Protective Equipment \(PPE\) Burn Rate Calculator](#). The PPE burn rate calculator computes a facility's average burn rate over the prior five days and tracks average rates for up to 90 days.² It does not rely on use rates from over a year ago.

Instead of relying on outdated disease rates and certified beds, New York's regulation should follow CDC guidance and require nursing homes to maintain a stockpile based on current and reasonably expected projected need that is periodically updated. 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, such as gowns, should be factored into calculating the required inventory. The method used by the Department to calculate the required supply of reusable gowns 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. The failure to provide guidance on the required quantities of reusable gowns discourages facilities from using them, even though they are more economical and better for the environment.

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. Although the “Costs” section of the Regulatory Impact Statement accompanying the regulation recognizes that “in the event of an emergency need, hospitals and nursing homes are expected to tap into their stockpiles,” nothing in the

2022 HERDS Data, accessed on 6/29/2022 at <https://health.data.ny.gov/Health/New-York-State-Statewide-Nursing-Home-and-Adult-Ca/6bi9-fsqm>.

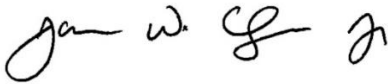
² Centers for Disease Control, Personal Protective Equipment (PPE) Burn Rate Calculator, <https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/burn-calculator.html>.

actual text of the regulations allows facility stockpiles to fall below required levels without triggering penalties.

The regulation should clearly state that facilities will not be penalized if their stockpiles drop below the required levels in the event of widespread shortages. The absence of such a provision may defeat the purpose of the regulation by forcing facilities to wait for Department of Health permission to use their supplies when shortages arise. 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.

Thank you very much for your consideration of these issues.

Sincerely yours,

A handwritten signature in black ink, appearing to read "James W. Clyne, Jr.", written in a cursive style.

James W. Clyne, Jr.
President and CEO