CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

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Doug Parker
Chief
Cal/OSHA / Division of Occupational Safety and Health
1515 Clay Street, Suite 1901
Oakland, CA 94612

Dear Doug,

I am writing, at the suggestion of Deputy Cabinet Secretary Richard Figueroa, to provide feedback on the June 12 Cal/OSHA Guidance as well as some changes under consideration. As emphasized during recent discussions, California's hospitals are committed to employee and patient health and safety. That's why hospitals are concerned about the June 12 Guidance, which would destabilize rather than enhance employee safety. Details and recommendations follow; concerns fall into four categories:

- Clarity of definitions of terms and processes
- Clarity of guidance for alternative options
- Need to address operational/patient safety challenges
- Supply shortages

Background

On March 28, Cal/OSHA adopted guidance to address severe respirator shortages. While there were concerns with that guidance, hospitals appreciated that it accounted for the reality that there were not enough respirators, and there was a global shortage preventing hospitals from obtaining a sufficient supply to meet demand based on expected patient surge. It also appeared to take into account the fluid nature of the pandemic and the fact that hospitals vary by bed size, community, patient type, employee and medical staff relations, labor representation, COVID-19 community spread, research activities, supply chain, clinical complexities, and regional demographics, among other differences.

Although there has been progress in securing PPE — including N95 respirators — manufacturing and the supply chain are not yet fully operational, and the demand across the country is increasing. From the onset of this pandemic, hospitals' ability to secure dependable sources of National Institute for Occupational Safety and Health (NIOSH) and Food and Drug Administration (FDA)-compliant PPE has been inconsistent and unpredictable. For a short period, as the state flattened the COVID-19 curve, hospitals were briefly able to begin to build their inventory. But now, hospitalizations are rising again, and PPE burn rates are accelerating. Testing delays also increase PPE burn rate, as full PPE is used to care for persons under investigation (PUI) to ensure worker safety. These factors inhibit hospitals' ability to maintain a stable inventory or predict future PPE needs.

In addition, the state's emergency management system process for hospitals to request additional PPE has not always resulted in receipt of product. While the stockpile has been somewhat replenished, the ongoing and significant increase in cases will quickly deplete it if hospitals are not able to continue to

employ current conservation strategies. These strategies have enabled most hospitals to provide N95 respirators to staff (rather than simple facemasks) for care of COVID-19 positive patients or PUI.

As you consider this feedback, we hope you will do so with the recognition that the science around COVID-19, including PPE usage and strategies, continues to evolve and in some cases guidance is conflicting. Cal/OSHA itself changed its position on respirator decontamination four times in the past five weeks. Given this, it is unfair and impractical to expect hospitals to immediately pivot whenever Cal/OSHA guidance changes.

Detailed Concerns and Recommendations

I. Definitions and Processes:

A. "Severe" and "critical" are not defined. Do they have the same meaning? Who makes this determination, and what is the metric? Same issue with respect to the requirement to return to "full compliance with the ATD Standard once respirator supply chains are restored." It may be that supply chains are "restored" but that a hospital must still conserve PPE, given the number of current and anticipated COVID-19 patients, as well as patients experiencing other aerosol transmissible diseases. **These terms and processes should be clearly defined.**

B. Guidance focuses on "surgical masks." The industry uses that term in a generic sense as referring to both surgical masks and procedure masks. **This term should be clearly defined as both "surgical masks" (which are in short supply) as well as "procedure masks," which are more readily available.**

II. Alternatives:

A. It is unclear how alternatives to the options expressly identified will be handled. For example, one hospital has developed but not yet implemented a respirator disinfection process that complies with all standard-setting government agencies' requirements, including 1) being consistent with practices accepted by the National Institutes of Health, Centers for Disease Control and Prevention (CDC), and FDA, 2) having been presented in published literature (University of Nebraska), and 3) having passed internal testing. Another hospital modified a scuba mask with full face seal and added a HEPA filter on the breathing tube apparatus, which passed the fit test. **The guidance should be clarified so hospitals can continue to use safety measures that meet or exceed these standards.**

III. Operational Challenges:

A. There is concern with the guidance around "first warning:" That respirators must always be immediately available to health care workers who may be called upon to perform emergency aerosol-generating procedures on suspected or confirmed COVID-19 patients. Hospitals have adopted inventory control protocols given the continued shortage of N95s and other PPE. For example, crash carts contain many supplies for emergency situations, including N95s. Thus, when a crash cart is used, all supplies are available. Further, a minor delay in obtaining appropriate PPE is inherent in the requirement to move to a higher level of protection when performing aerosol-

generating procedures. Even assuming hospitals have a sufficient supply of N95s for routine care, the ATD standard dictates switching to a PAPR for an aerosol-generating procedure. That too takes some time under normal circumstances. **The guidance should be clarified to permit hospitals to maintain their inventory control processes, given the continuing challenges with obtaining PPE.**

B. The guidance identifies barrier enclosures that cover a patient's head and upper body as one of the engineering controls. This is of concern for two reasons: 1) Several hospitals have explored this option and report that medical staff would not authorize use of such barriers due to patient safety concerns. In fact, the CDC developed a fact sheet that illustrates the serious risks for patients. 2) The FDA has issued an emergency use authorization (EUA), but it is unclear whether any products have actually been produced that comply with the EUA. **The guidance should make it clear that use of barrier enclosures as an engineering control is optional.**

IV. Supply Shortages:

A. The June 12 guidance is overly prescriptive as hospitals continue to face the challenge of securing sufficient PPE. Of greatest concern, the guidance fails to account for a hospital's obligation to prepare for anticipated surge. Hospitals must maintain an inventory of N95 respirators to ensure they are available for high-hazard procedures involving any patient with a communicable disease. With the current increase in hospitalizations, this is not hypothetical. The restrictive framework of this guidance will likely preclude hospitals from using respirator conservation strategies, leading to more shortages that will drive employees to perform aerosol-generating procedures without N95 respiratory protection.

1. The guidance fails to recognize shortages beyond N95s. For example, the guidance reminds employers that powered air-purifying respirators (PAPRs) are an alternative to N95s. However, turning to PAPRs is not a realistic solution at this time because there are significant shortages of replacement parts and liners; some hospitals are being told by vendors, suppliers, and manufacturers that they may have to wait over two months for parts or additional PAPRs. Additionally, although hospitals can obtain replacement shields, they weigh twice as much as original shields and thus place a heavy load on an employee. That is likely to cause other problems, such as employee injury, which could result in staff shortages. **The guidance should be modified to acknowledge other PPE shortages beyond N95s.**
2. The guidance requires each hospital to exhaust each of the conservation strategies before moving to the next one. Simply put, this is not feasible as it prohibits the use of surgical masks until all other respiratory protection options have been exhausted. Among the concerns raised by this guidance: a) What does it mean to "exhaust" all of the other options? b) Some unions object to many of the options. How can a hospital exhaust all options in this circumstance? c) It does not allow hospitals to prioritize when N95s are used, as directed by the governor's Executive Order N-33-20, which *requires* hospitals to do so. **The guidance should be modified to remove the "exhaustion" mandate.**

3. The warning contained in this section allows for use of a respirator with a valve covered by a mask as an acceptable option. During the June 30 CDPH provider call, you indicated that may not be appropriate and the guidance would be revised. The structure of this warning also raises concerns for hospital infection preventionists. It is unclear why there is a reference to "sterile fields." The majority of respiratory protection issues arise in areas that are not considered "sterile fields." **This guidance should be clarified to clearly state whether this is an acceptable option in a patient care environment and to remove reference to "sterile fields."**

4. The guidance calls for "allowing employees to wear their own respirator if it complies with Cal/OSHA requirements." Practically, this is impossible to operationalize on a large scale. How can a hospital validate what hundreds (or thousands) of employees might bring in, particularly as there are so many counterfeit respirators on the market? Even if that were possible, a hospital could not fit test each employee who brought in their own respirator every shift. How does the employer know whether the respirator was "properly maintained?" How does an employer "exhaust" this option before moving to the next one? While we recognize an employee's right to bring in their own PPE if an employer cannot provide it, **this alternative should be removed from the guidance for the reasons set forth above.**

5. There is a lack of clarity around extended use and re-use strategies. For example, CDPH has directed one hospital to discard N-95s after five donnings. This has resulted in a burn rate five times faster than before. At this rate, hospitals will run out of supply far faster.

   For re-use, the CDC recommends five days between usage while the guidance requires seven. A change in this protocol will also increase the burn rate. The guidance states that N95s should be discarded after use during an aerosol-generating procedure or surgery. If the respirator is not damaged, why shouldn't it be available for respirator conservation strategies such as re-use, de-contamination, etc.? **The guidance should be modified to slow down the PPE burn rate, rather than accelerate it.**

6. The guidance prohibits writing on a respirator, generating significant confusion. CDPH has been encouraging hospitals to participate in the Battelle decontamination program, which includes use of a marker for identification purposes. Prior to the June 12 Guidance, it appeared that Cal/OSHA did not have any concerns with this process. However, in the June 12 Guidance, hospitals were advised they could only use a decontamination process if they did not write on the N95. Subsequently, during a June 30 CDPH Provider call, Cal/OSHA stated it came to this conclusion based on a 2007 NIOSH study, although the Battelle EUA issued earlier this year clearly permitted the use of a marker. Hospitals were also advised to use labels instead of markers, but acknowledged Cal/OSHA had not tested any labels and was not aware whether any labels were appropriate.

The use of labels is also inconsistent with Employee Health and Safety training and principles. More recently, on the July 21 CDPH Provider call, Cal/OSHA advised hospitals that it had come to the conclusion that the use of markers does not degrade the N95 and they will be permitted. **The guidance should remove the restriction of marker use on N95 respirators that will be decontaminated.**

7. Requiring a decontaminated respirator only be used by the person who previously used it also goes beyond the CDPH/CDC guidance and in many cases is impractical because those protocols were not previously adopted. As noted above, without the ability to clearly identify the previous user, this is simply not possible. **The guidance should remove this requirement.**

8. According to Mr. Figueroa, Cal/OSHA is considering prohibiting the use of decontaminated N95s. This is confusing as CDPH is encouraging use of the Battelle system. And while most hospitals using the Battelle system are not putting them into use now, some may, as that is preferred by staff over other conservation strategies. Further, it is unclear when those decontaminated N95s should be used before seeking additional supplies from the MHOAC or only after the MHOAC cannot fulfill a request. **Cal/OSHA should not prohibit the use of decontaminated N95 masks.**

9. The section addressing use of respirators certified to a foreign standard prohibits a hospital from using FDA-approved N95 respirators with ear loops. The basis for this prohibition is unclear. At least one hospital purchased such respirators and has fit-tested them with success. To require a hospital to abandon use when it may be the best way to provide respiratory protection does not further the goal of employee safety. **This prohibition should be removed.**

10. The guidance does not address respirators made in United States that are not yet NIOSH certified. One system has been purchasing N95s produced in Oregon. The manufacturer has not obtained NIOSH certification yet, but the product passed the OSHA fit test. If the hospital runs out of NIOSH-approved respirators, shouldn't these respirators be an option? **The guidance should explicitly allow for use of any respirators that pass the OSHA fit test.**

11. The guidance mandates the use of surgical masks only when all other attempts to provide respiratory protection *have been exhausted.* Adopting a new conservation strategy takes time to develop a policy and train employees. Hospitals may need to use facemasks as they transition from one strategy to another. **The guidance should allow for a grace period to adopt new strategies.**

12. The statement prohibiting discipline or layoff of employees for exercising their health and safety rights suggests that an employee must be provided the requested PPE if the employee demands it, even when a hospital is in a "severe" shortage situation. Again, this is inconsistent with the governor's direction to "prioritize resources, including personal protective equipment, for the providers providing direct care" to the sickest patients (E.O. N-33-20 (2). In some situations, an employee may be provided an N95 rather than a PAPR due to shortages or may be provided a facemask rather than an N95 for routine care. **The guidance should recognize hospitals' need to conserve PPE in addition to**

recognizing an employee's rights, to remain in accord with the governor's executive order.

Hospitals remain deeply committed to the health and safety of patients, employees, and communities. We continue to stand ready to care for all Californians and are working tirelessly to care for an increasing number of patients while facing significant staffing and personal protective equipment shortages. We urge Cal/OSHA to adopt an approach that allows hospital teams, including infection preventionists, front-line staff, and materials management experts to work together to protect their colleagues and the patients entrusted to them. I would welcome the opportunity to connect you with hospital teams to provide more detail on current infection prevention protocols and supply chain challenges.

/S/
Gail Blanchard-Saiger
Vice President & Counsel, Labor & Employment
California Hospital Association

cc: Richard Figueroa, Deputy Cabinet Secretary
Carmela Coyle, CEO California Hospital Association