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Cal/OSHA issues problematic new COVID-19 interim guidance for health care facilities

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The California Division of Occupational Safety and Health ("DOSH") has issued new "guidance" for how health care employers must address "severe respirator shortages."[1] DOSH has not defined when respirator shortages are considered "severe."

Although DOSH has described this document as "guidance," it contains many mandatory requirements that are not contained in existing regulations, and DOSH has not attempted to adopt these new de-facto regulations through the proper rulemaking process. Unless and until the new "guidance" is either successfully challenged in court or modified by DOSH, employers will face citations and potentially other civil and criminal liability if they fail to follow these new requirements. As will be discussed below, compliance will be difficult.

Summary of the new guidance

The new guidance should be reviewed in full by health care employers as it is detailed, leaves many traps for unwary employers, and there are a number of new requirements that will need particular attention. Notable provisions include the following:

The new guidance requires that respirators must "always be *immediately* available to health care workers who *may* perform emergency aerosol generating procedures on confirmed or suspect COVID-19 patients." (Emphasis added.) Guidance p. 1. However, no definition of "immediately" is provided.

Engineering controls to minimize the number of employees exposed to confirmed or suspect cases must be used at *all times*, including barrier enclosures that cover a patient's head and upper body and that are authorized by the FDA. Guidance p. 1. No definition of "all times" is provided.

When there is no "*critical shortage,*" health care employers *must* provide and ensure the use of NIOSH-certified respirators by *all* employees occupationally exposed to novel pathogens including

[1] We discussed DOSH's previous guidance on the issue in our alert, "In the wake of severe respirator supply shortages, Cal/OSHA issues new guidance for health care facilities."

SARS-CoV-2 (the virus that causes COVID-19). However, as noted above, DOSH has provided no definition of "critical shortage." Guidance p. 1.

Even when there are shortages, respirators—not surgical masks—must always be used for "high hazard tasks," aerosol generating procedures, and any procedure requiring close interaction with patients such as collecting specimens by nasopharyngeal or oropharyngeal swabs. Guidance p. 5. This list appears broader than the ATD standard requirement for the use of respirators for "high-hazard procedures," which are defined as tasks in which exposure to aerosolized pathogens is reasonably anticipated to increase. 8 CCR 5199(b) and (g).

And critically, even when surgical masks can still be used, DOSH has imposed an onerous six (6) step process that must be completed before they can be utilized. Guidance pp. 2–5.

The new six-step process that must be followed before surgical masks can be utilized

Of particular concern, the guidance significantly limits the ability of health care employers to follow the common practice of using surgical masks for administrative or routine tasks with COVID-19-positive or -suspect cases. It does so by several of the requirements noted above, and perhaps most notably by imposing six (6) major steps employers must take in the following express numerical order to protect employees *before* surgical masks can be utilized:

1. Use reuseable NIOSH-certified respirators instead of disposable filtering facepiece respirators.
2. Use NIOSH-certified industrial filtering facepiece respirators pursuant to FDA Emergency Use Authorization (EUA).
3. Allow employees to wear their own respirator if it complies with Cal/OSHA requirements.
4. Use certain expired NIOSH-certified filtering facepiece respirators pursuant to NIOSH requirements.
5. Use specified methods to disinfect and extend the use of existing stocks of filtering facepiece respirators.
    5.1. Extended use of respirators.
    5.2. Reuse filtering facepiece respirators that have not been disinfected.
    5.3. Use approved methods to disinfect filtering facepiece respirators.
6. Use filtering facepiece respirators certified to a foreign standard pursuant to specific FDA EUAs.

    Guidance pp. 2–5.

However, the Aerosol Transmissible Diseases ("ATD") standard expressly *allows* the use of droplet precautions (which includes the use of surgical masks for routine tasks) when droplet precautions have been recommended by public health guidelines. 8 CCR 5199 Appendix A Droplet Precautions List. Such public health guidelines have been issued by WHO, the CDC, and others. The ATD standard contains no other limitations on the use of droplet precautions and thus this onerous six-step process certainly appears to directly contradict the ATD standard itself.

Moreover, this six-step process is made more onerous and confusing by DOSH's use of extreme and undefined terms. First, the six-step process only applies when severe respiratory shortages make it

"impossible" to provide NIOSH-certified filtering facepiece respirators. But what exactly does "impossible" mean? Does it mean absolutely no such respirators exist anywhere? Or in a facility's stockpiles? Or impossible without risking stockpiles? Or something else altogether? Further, DOSH is requiring that surgical masks cannot be used until *all* of the six (6) steps have been "*exhausted*." But when exactly are each of these steps "exhausted"? And how is that measured? Does it mean an employer must have taken the extremely risky step of having completely "exhausted" their current supply of respirators before turning to surgical masks for administrative or routine tasks? It remains unclear what DOSH means by this exhaustion requirement.

Specific comments on Step 5

Step 5 and its subparts also deserve particular attention. On the positive side, DOSH has now provided clarification and express approval for health care facilities to use a number of FDA-authorized systems for disinfecting and reusing certain N95s as well as procedures for respirator use during severe supply shortages. However, there are a number of significant problems with this guidance.

The CDC notes that such decontamination and reuse is part of a crisis strategy. However, DOSH is taking a radically different position and is now *requiring* that health care facilities engage in such decontamination and reuse during *any* "severe respirator shortages" before they can use surgical masks for occupational exposures to COVID-19. Guidance p. 2. As noted earlier, the ATD standard contains no such requirement, and no definition of "severe respirator shortage" is provided.

Instead of just approving the use of FDA-authorized systems, DOSH added its own set of onerous requirements, and some of the new DOSH requirements conflict with FDA-approved processes. As an example, the FDA-approved processes call for marking each respirator that is disinfected. The DOSH guidance does not allow such marking. Guidance p. 4.

The DOSH guidance also requires that beyond following the FDA-approved processes, health care facilities must also follow Cal/OSHA's 8 CCR Article 111 processes for fumigation when disinfecting respirators. This does not seem to make sense for fully enclosed systems, but will now require, among other things, that:

- Two or more trained employees be present, with respiratory protection during the disinfection process. 8 CCR 5221(a) and (b).
- Vaults or chambers used for fumigation must preclude any exposure to hazardous concentrations of fumigants. 8 CCR 5222(a).
- Warning notices on doors. 8 CCR 5222(b).
- Detailed procedures for post-fumigating purging must be followed. 8 CCR 5222(c) and (d).
- Rules regarding flammable gases must be followed. 8 CCR 5222(e).
- Extensive rules for fumigation in buildings without fumigation vaults or chambers must be followed. 8 CCR 5223.

The end result of these onerous rules may be that health care facilities may choose to outsource disinfection processes.

Following disinfection DOSH then also requires four (4) hours of aeration and recommends use of real-time monitors to confirm there is no off-gassing from respirators. No description of when and how often such monitoring is recommended. Guidance p. 4.

What should California health care employers do now?

We typically want to include practical compliance advice in our Alerts. However, we are having trouble doing so with this new guidance. It is just not clear how health care employers can fully comply.

We believe that health care employers may need to seek clarification and modification from DOSH. If such clarification and modification is not forthcoming, litigation may be the only remaining option for relief.

In the meanwhile, compliance is likely to be very difficult, and perhaps infeasible or even simply impossible. Employers can certainly try to meet the new requirements to the extent feasible, but it is not at all clear that this will protect them from citations. Given this, health care employers should consult with counsel with regard to any questions about compliance with these new requirements.

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