

Cal/OSHA Interim Enforcement Policy on H1N1 and Section 5199 (Aerosol Transmissible Diseases)

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Background.

Cases of pandemic (H1N1) influenza A virus (previously called “swine flu” or “novel H1N1”) were first recognized in California in April 2009. The World Health Organization has declared a pandemic, with widespread human-to-human transmission in many countries.

The Centers for Disease Control and Prevention (CDC) has issued guidelines that recommend isolation of hospitalized cases and the use of respirators such as an N95 filtering facepiece respirator, by employees who must enter areas where people with suspected, probable, or confirmed H1N1 influenza are located. The federal Occupational Safety and Health Administration (OSHA) has stated that it will enforce these recommendations for the protection of employees, and has further called for the use of respirators such as the N95 to protect other health care employees against this disease.

California operates a “state plan” under the authority of the federal Occupational Safety and Health Act, and is required to be as effective as federal OSHA. Cal/OSHA has been addressing employee protection against H1N1 through guidance documents and enforcement of existing standards such as the Injury and Illness Prevention Program¹ and the Respiratory Protection² standards. This is consistent with the current recommendations of the California Department of Public Health (CDPH)

Applicability of the new Aerosol Transmissible Disease standard to H1N1 exposure control.

On August 5, 2009, the new Aerosol Transmissible Diseases (ATD) standard (Title 8 CCR Section 5199) took effect. This standard establishes a comprehensive approach to control of diseases identified as either requiring “droplet precautions” or “airborne infection isolation.” Among the controls required by the standard are written infection control procedures including source control measures such as providing surgical masks or other materials to symptomatic persons who enter the facility. The procedures should include how those patients can be placed in separate areas, to the extent feasible, to reduce exposure to employees. The standard can be found at: <http://www.dir.ca.gov/Title8/5199.html>.

¹ Title 8 California Code of Regulations, Section 3203

² Title 8 California Code of Regulations, Section 5144

The ATD standard also establishes certain requirements for “novel and unknown aerosol transmissible pathogens (ATPs).” A novel or unknown ATP is defined in the standard as follows: A pathogen capable of causing serious human disease meeting the following criteria:

- (1) There is credible evidence that the pathogen is transmissible to humans by aerosols; and
- (2) The disease agent is:
 - (a) A newly recognized pathogen, or
 - (b) A newly recognized variant of a known pathogen and there is reason to believe that the variant differs significantly from the known pathogen in virulence or transmissibility, or
 - (c) A recognized pathogen that has been recently introduced into the human population, or
 - (d) A not yet identified pathogen.

NOTE: Variants of the human influenza virus that typically occur from season to season are not considered novel or unknown ATPs if they do not differ significantly in virulence or transmissibility from existing seasonal variants. Pandemic influenza strains that have not been fully characterized are novel pathogens.

H1N1 influenza has been identified as a pandemic influenza strain. Neither the CDC nor CDPH has determined that this strain is “fully characterized.” In fact, the CDC has established a process for review of the status of H1N1 which includes evaluating the report prepared by a panel convened by the Institute of Medicine that was released on September 3. Meanwhile the CDC continues to recommend respirators for employees who must come into contact with suspected³, probable or confirmed H1N1 cases. CDPH continues to recommend that hospitalized H1N1 patients be placed in airborne infection isolation rooms (AIIR), if available,⁴ and to provide health care workers with respirators.

In addition to airborne infection isolation (AII) requirements for novel pathogens, the ATD Standard also requires AII when either the CDPH or the local health officer recommends airborne infection isolation for a pathogen. As noted above, the CDPH currently recommends AII and the use of respirators for hospitalized H1N1 suspected, probable, and confirmed cases. The ATD standard does not require the placement of

³ On August 20,2009 CDPH modified the definition for a suspect Pandemic Influenza H1N1 case to the following:

Any patient less than 60 years of age with a fever (>37.8 C or 100 F) and new onset of cough.

or

Any patient whom a healthcare provider believes, based upon information regarding the patient’s history and illness, to have a high likelihood of being infected with pandemic H1N1 influenza virus.

The current CDPH guidance can be found at:

<http://www.cdph.ca.gov/HealthInfo/discond/Documents/H1N1UpdatedRecforHealthCareSettings.pdf>

⁴ If AIIR are not available, then CDPH recommends that H1N1 patients are to be placed in single rooms with the door closed.

patients in AIIR who are suspected or confirmed cases of a novel pathogen (such as H1N1), where that use is not feasible. However, employees must use respirators when entering or working in areas where those patients are located.

The impact of respirator shortages on compliance with the ATD standard.

As of August 1, some hospitals have been reporting shortages in their supplies of respirators and difficulty in getting orders filled. Where an employer's ability to maintain an adequate respirator supply becomes uncertain, measures to conserve respirator supplies to the extent reasonably possible should be implemented to ensure that a sufficient supply of respirators will remain on hand to treat patients with H1N1, tuberculosis, or any other disease requiring respiratory protection. These policies should include:

1. Reviewing patient flow and work organization to determine whether unnecessary employee contact with suspected or confirmed H1N1 cases can be reduced. This may reduce the use of respirators.
2. Ordering respirators through non-medical supply chains, such as safety equipment suppliers.
3. Switching some respirator users to alternate respirators, some of which may not be "surgical N95", meaning N95's that are fluid-resistant. Surgical N95s are required when needed to protect against splashes or sprays of bodily fluids, and may also be required for infection control during surgery, but not in situations where fluid contact is not an issue.

For most patient-care activities, including support activities such as housekeeping in patient rooms, a non-surgical N95 respirator (standard N95) can be used. OSHA and Cal/OSHA regulations require that a fit test be provided for each model of respirator used. However, if a respirator manufacturer provides documentation that a standard N95 is identical in construction, size, and shape to a surgical N95 respirator the employee has been using, Cal/OSHA will not require an additional fit test prior to the employer providing the standard respirator to the employee.⁵

Employers should also consider using non-disposable elastomeric facepiece respirators or powered air purifying respirators which can be reused and disinfected. All respirators must be approved by the National Institute for Occupational Safety and Health (NIOSH), must be used in compliance with the conditions of their approval, and must function at a level of protection equal to or greater than an N95 respirator.

⁵ Cal/OSHA standards require that respirators be fit-tested at least annually. Section 5199 permits employers to lengthen the fit-test interval for non-high hazard uses, to up to two years until January 1, 2014.

Re-donning as a conservation measure.

Filtering facepiece respirators such as N95's, when used to protect against infectious aerosols, should generally be disposed of each time they are removed. However, if the employer is unable to assure a sufficient supply of respirators through the above methods, then the employer should implement and document in writing the attempts to obtain respirators and measures the employer is implementing to conserve the respirator supply, which may include re-donning.

Respirator conservation can be accomplished by training employees to remove, safely store, inspect, and re-don the respirator, and by protecting the outside surface of the respirator. Please see below for a more detailed discussion of respirator supply conserving strategies. Employers should also contact their state or local emergency planning agency to request assistance in maintaining a sufficient supply of respirators.

Prioritized respirator use.

Where an extreme shortage of respirators exists despite all reasonable efforts to maintain a sufficient reliable supply, the employer may shift to a prioritized respirator use mode in which respirator use is assured for employees exposed to H1N1 in connection with high hazard procedures. In this mode, respirator use may be temporarily discontinued for employees in H1N1 exposure scenarios considered less likely to cause disease transmission as necessary to maintain the supply for employees exposed to high-hazard procedures.

High hazard procedures include bronchoscopy, sputum induction, intubation, and open circuit suctioning. For enforcement purposes, the Division considers that an extreme shortage exists if the hospital's respirator supply **will fall below what the hospital in good faith projects to be the amount that will last for 30 days** with the application of respirator conserving methods such as cohorting and other forms of work re-organization and re-donning as described below. When the supply of respirators falls **below this amount**, then hospitals and other employers may prioritize respirator use so that respirator use is ensured for each of the following activities:

1. protection of health care workers performing high hazard procedures on suspected or confirmed cases of H1N1, tuberculosis, or other diseases requiring airborne infection isolation.
2. protection of health care workers exposed to suspected or confirmed cases of tuberculosis or other diseases other than pandemic H1N1 that require airborne infection isolation⁶; and
3. protection of immunocompromised patients.

⁶ Section 5199, Appendix A, contains a list of diseases as requiring airborne infection isolation.
<http://www.dir.ca.gov/Title8/5199-a.html>

Because this policy may result in increased unprotected employee exposures to patients with H1N1, employers must take all reasonable steps available to procure an adequate supply of respirators. Cal/OSHA will recognize such prioritized respirator use as compliant if the hospital documents in writing, on at least a weekly basis, the level of its existing supply, contacts made with alternate suppliers and suppliers of alternate respirators, and contacts made to obtain respirators through local and state emergency stockpiles. Appendix A provides guidance on how efforts to address respirator supplies can be documented.

Surgical masks for employees who are not provided a respirator due to the implementation of prioritized respirator use.

If the employer is unable to provide a respirator to employees who provide care to H1N1 suspected and confirmed cases, the employer should provide those employees with surgical masks. While surgical masks are not designed or certified to prevent the inhalation of small airborne contaminants, it is likely they will provide some droplet protection and should therefore be chosen over no protection at all. They do not seal tightly to the user's face and therefore infectious particles can pass through gaps between the face and the surgical mask. In addition the ability of the mask to filter small particles varies significantly based upon the type of material used to make the surgical mask.

Surgical masks that have been cleared for marketing by the U.S. Food and Drug Administration have been tested for their ability to resist blood and body fluids, and generally provide a physical barrier to droplets that are expelled directly at the user. Employers who provide surgical masks to employees in lieu of respirators during a respirator shortage must inform the employees that the surgical mask is not a respirator, and is not certified by NIOSH to protect against inhalation exposures.

Non-hospital health care facilities, services and operations.

Under the ATD Standard, health care employers are required to determine which services they can provide safely to patients with airborne infectious diseases. At this time, for the reasons stated above, airborne infectious diseases include H1N1. Those employers who do not have the facilities to protect employees by providing airborne infection isolation may provide initial screening and treatment.

This category of employer is generally required to refer patients who need continuing care to a facility that can provide airborne infection isolation, unless the transfer is not appropriate for medical reasons, or unless there are no airborne infection isolation rooms (AIIRs) available in another facility. In the case of a novel pathogen, the ATD standard does not require referral or transfer where such actions are not feasible. However, employees who are exposed to the patient are required to be protected by respirators.

Under subsection (c) of the ATD Standard, referring employers must have infection control procedures that include early identification of patients who may have an airborne infectious disease, including H1N1. These patients should be provided with source control materials such as surgical masks or tissues and hand hygiene materials, and to the extent feasible, these patients should be placed in a separate room or area with separate ventilation.

Employees who enter that room or area must use an approved respirator, such as an N95 filtering facepiece respirator, unless either the patient uses source control measures (i.e., the patient wears a surgical mask to cover their cough) or respirator use by the employee is not feasible. Although obtaining a nasopharyngeal swab is not considered a high hazard procedure under this standard, employees who perform that activity or similar activities should use a respirator, since the procedure cannot be performed with the patient's mouth and nose covered and it may stimulate coughing, thereby exposing the employee to infectious aerosols. Title 8 of the California Code of Regulations Section 5199(c)(5) contains these and other requirements applicable to referring employers during periods when people requiring referral are in the facility.

Long-Term Health Care Settings

Most long-term health care facilities do not have AIIRs and function as referring employers under the ATD Standard. Generally, referring employers must transfer patients who require airborne infection isolation to a hospital or other appropriate facility.

However, the standard provides an exception for novel pathogens, such as H1N1, recognizing that AIIRs may not be available. CDPH has recommended that decisions to transfer H1N1 suspected or confirmed cases be based on clinical considerations and not solely on the need for isolation.

To the extent feasible, H1N1 suspected and confirmed cases not in AIIRs should be placed in a single room or cohorted, with the door closed, unless closing of the door would jeopardize patient safety or patient's rights. Employees who enter rooms where H1N1 suspected or confirmed cases are located or who otherwise are exposed to those patients must be protected with an N95 respirator (or higher level of respiratory protection). In addition, the employer should place signs or use other effective means to communicate that isolation precautions are to be followed in the room.

Respirator Conserving Strategies.

Cal/OSHA regulations require employers to develop policies for the use, cleaning, and decontamination and/or disposal of respirators so that they remain effective in protecting employees and do not become a hazard. In addition, in health care settings, respirator use may be affected by infection control policies. Reusable respirators should never be

shared between employees unless the respirator has been cleaned and disinfected between users.

There are no accepted methods to disinfect N95 filtering facepiece respirators. Under normal conditions, filtering facepiece respirators should therefore be discarded after they have been used to protect against infectious aerosols. However, in regards to pandemic influenza, the federal Occupational Safety and Health Administration (OSHA) has stated:

If a sufficient supply of respirators is not available during a pandemic, employers and employees may consider reuse as long as the device has not been obviously soiled or damaged (e.g., creased or torn), and it retains its ability to function properly. This practice is not acceptable under normal circumstances and should only be considered under the most dire⁷ of conditions. Data on decontamination and/or reuse of respirators for infectious diseases are not available. Reuse may increase the potential for contamination; however, this risk must be balanced against the need to provide respiratory protection. When preparing for a pandemic, employers who anticipate providing respiratory protection to employees for the duration of the pandemic should consider using reusable or elastomeric respirators that are designed to be cleaned, repaired and reused.⁸

Regardless of supply circumstances, a filtering facepiece respirator should always be removed and discarded if (1) it becomes damaged or deformed, (2) it no longer forms an effective seal to the employee's face, (3) it becomes contaminated with hazardous substances, (4) it becomes wet or visibly dirty, or (5) breathing through it becomes more difficult. In addition, the respirator should always be discarded if it becomes contaminated with blood, respiratory or nasal secretions, or other bodily fluids from patients.

Filtering facepiece respirators used for surgery or aerosol generating procedures should always be discarded at the end of each procedure. Filtering facepiece respirators generally should be discarded at the end of a work shift.⁹ Respirators may be used for more than one shift if the respirator manufacturer provides data demonstrating that the performance of the specific respirator does not degrade when used for more than one shift under the conditions in which it is used.

⁷ Cal/OSHA interprets this phrase to mean that the employer has ordered a supply of respirators sufficient to assure that a respirator may be disposed of each time it is taken off, and that despite efforts to procure such a supply, there is less than a sixty day supply available.

⁸ Guidance on Preparing Workplaces for an Influenza Pandemic OSHA 3327-02N 2007

⁹ Some N95 respirators may be labeled, in accordance with FDA regulations, as "single use", disposable devices. The FDA has clarified this labeling to mean that "if your respirator is damaged or soiled, or if breathing becomes difficult, you should remove the respirator, discard it properly, and replace it with a new one." <http://www.fda.gov/cdrh/ppe/masksrespirators.html#4>

A respirator that is worn continuously while caring for different patients, i.e., not removed between patients, does not pose an infection hazard to the wearer. A 2006 report by the Institute of Medicine¹⁰ found that materials captured by a filter are unlikely to be released even if the wearer sneezes or coughs.

However, the outside of the respirator may contain infectious particles that may be transferred from the outside of the respirator onto the employee's hands during the process of taking off the respirator or putting it back on.

If respirators are to be re-donned, employees must be trained on procedures such as those in the CDC guidelines for donning and taking off (doffing) personal protective equipment, including respirators. See <http://www.cdc.gov/ncidod/dhqp/ppe.html>.

Employees should be instructed not to touch the inside surface of the respirator they are donning in order to avoid contaminating the inside surface, and also because the inside of the respirator may be contaminated with the health care worker's own secretions. Employees should perform hand hygiene if they touch the outside surface of a respirator that may be contaminated.¹¹

If a respirator user must put on and take off a filtering facepiece respirator multiple times during a shift, the respirator should be stored during periods it is not worn, in a clean container¹² labeled with the employee's name, and in a manner that protects the inside of the respirator from contamination. If the respirator is stored in a bag, the bag should be disposed of after the respirator is re-donned to prevent contamination of the inside of the respirator when it is again stored.

Filtering facepiece respirators should be discarded as frequently as necessary and at the end of the employee's shift.

Protecting the Outside of the Respirator.

It may be possible to prolong the useful life of the respirator by protecting the outer surface from sprays by wearing a face shield, but a face shield may only be used if it does

¹⁰ "Filter contamination refers, in particular, to the collection of organisms on filters (in the case of aerosol exposures). Laboratory loading tests of inert bacterial particles have found that while filters will capture particles throughout the extent of the media, particles are held with considerable attractive force and are quite difficult to remove, even when the filter is subjected to high bursts of air similar to coughs and sneezes or when dropped onto a hard surface (Qian et al., 1997a; Qian et al., 1997b; Kennedy and Hinds, 2004). As a result, the filter material in respirators and medical masks does not present a hazard during use." Reusability of Facemasks During an Influenza Pandemic: Facing the Flu. Institute of Medicine, 2006

¹¹ Contact procedures have been recommended for H1N1 influenza.

¹² Some health care professionals recommend storing the respirator in a container such as a paper bag or other container that is not airtight, in order to permit the respirator to "dry out." In this context, "drying out" refers to the moisture captured by the respirator from the employee's exhaled breath. This is different from respirators that are wet, which should be discarded and not re-used.

not interfere with the function of the respirator. Cal/OSHA regulations require that respirators be used as approved by the National Institute for Occupational Safety and Health (NIOSH) and must not be altered. Therefore surgical masks should not be placed over the respirator, as they may unseat or deform the respirator and may make it more difficult to breathe through.

Training for Respirator Users.

Cal/OSHA regulations require that employees who use respirators be trained initially and annually. The required training elements are:

- (A) Why the respirator is necessary and how improper fit, usage, or maintenance can compromise the protective effect of the respirator;
- (B) What the limitations and capabilities of the respirator are;
- (C) How to use the respirator effectively in emergency situations, including situations in which the respirator malfunctions;
- (D) How to inspect, put on and remove, use, and check the seals of the respirator;
- (E) What the procedures are for maintenance and storage of the respirator;
- (F) How to recognize medical signs and symptoms that may limit or prevent the effective use of respirators; and
- (G) The general requirements of Title 8, Section 5144.

If an employer determines that supply limitations make it necessary for employees to re-don filtering facepiece respirators, employees must receive additional training in how to safely remove, store, inspect, and re-don or discard the respirators as well as specific training on the employer's re-donning policies.

Recordkeeping.

The employer should include their re-donning policies in their respiratory protection program or ATD exposure control plan. Appendix A may be used to document respirator shortages and the employer's actions taken to obtain a sufficient supply of respirators, in order to support the use of respirator conserving strategies or prioritization. These records must be maintained as records of implementation of the ATD exposure control plan, in accordance with subsection 5199(j)(3). These records must be made available, in accordance with subsection 5199(j)(4) to Cal/OSHA, NIOSH, the local health officer, employees and employee representatives.