

**Cal/OSHA Interim Enforcement Policy on H1N1 and Section 5199
(Aerosol Transmissible Diseases)
Issue Date: 10-22-09**

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.

On October 14, 2009 the Centers for Disease Control and Prevention (CDC) issued updated guidelines regarding infection control procedures for H1N1. This guidance continued the recommendation that employees who have direct exposure to H1N1 patients use respirators at least as protective as an N95 filtering facepiece respirator. Respirators are to be used by employees who must enter rooms or areas where people with suspected or confirmed H1N1 influenza¹ are located. Respirators are only one component of a hierarchy of controls that are recommended to protect employees from inhalation exposure to this disease. The California Department of Public Health (CDPH) has issued guidance that concurs with these recommendations.

The federal Occupational Safety and Health Administration (OSHA) has stated that it will enforce these recommendations for the protection of health care employees, including the use of respirators. 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.

On September 8, 2009, Cal/OSHA issued interim guidance for health care facilities regarding protecting employees from H1N1. This guidance was issued in anticipation of respirator supply shortages that would force employers into a respirator prioritization mode, in which some employees with patient contact would not be provided with respirators. However, in order to protect health care workers from H1N1, the State of California has begun to release stockpiled respirators through local health departments. Therefore the previous guidance regarding respirator prioritization is rescinded, and respirators are to be provided for contact with all potentially infectious patients, as discussed in detail below.

¹ 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>

Applicability of the California’s Aerosol Transmissible Disease standard to H1N1 exposure control

On August 5, 2009, California’s 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>.

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 addition, as stated above the CDPH continues to recommend that health care workers be protected against airborne transmission of H1N1 through the use of appropriate patient placement², engineering controls, and the use of respirators. The ATD standard therefore also requires these precautions for H1N1.

² The CDC and CDPH have recommended that aerosol generating procedures be conducted in airborne infection isolation rooms if available.

The impact of respirator supply on compliance with the ATD standard

Some hospitals have reported low inventories of respirators and ongoing difficulty in getting orders filled. As a result, and until further notice, the California Department of Public Health has determined that it will be working with local health authorities to ensure that the combined local and state respirator stockpiles will be used to fill supply gaps and allow compliance with the ATD Standards in exposure scenarios requiring respirator use.

The purpose of distributing these respirators is to ensure that every health care worker who is in direct contact with an H1N1 patient will be able to use to an appropriate respirator as required. Hospitals and other health care facilities and operations that are unable to obtain an adequate supply of respirators should request respirators through their local health department.

Measures to maximize and conserve respirator supplies

Given the increased demand for respirators created by the H1N1 pandemic and the finite supply, measures to conserve respirator supplies to the extent reasonably possible should be implemented. This will help 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 conservation measures are consistent with the ATD standards and the CDC Interim Infection Control guidance dated October 14 that delineates a hierarchy of controls to prevent influenza transmission in healthcare settings. 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.
2. Taking full advantage of opportunities to obtain respirators through non-medical supply chains, such as safety equipment suppliers. These respirators are of comparable quality and efficacy to those provided by medical distributors.
3. Taking full advantage of opportunities to use the variety of NIOSH-certified respirators available and appropriate for use in work involving close contact with H1N1 patients. For example, if an institution's policy has been to order only fluid-resistant or "surgical" N95 respirators, other N95 respirators not designated as "surgical" can be used in patient-care scenarios where contact with splashes or sprays of body fluids is not anticipated as long as they are NIOSH-certified. 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 are not required 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 or standard N95 respirator can be used. Employers should also consider using non-disposable elastomeric facepiece respirators or powered air

purifying respirators (PAPR) 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.

Extended use and re-donning as conservation measures

Cal/OSHA regulations require employers to develop policies for the use, cleaning, and decontamination and/or disposal of respirators as appropriate so that they remain effective in protecting employees and do not become a hazard. A respirator should always be removed and discarded if it becomes damaged or deformed, or it no longer forms an effective seal to the employee's face. A reusable respirator may be shared between users, but only if cleaned and disinfected between users. In addition, in health care settings, respirator use may be affected by infection control policies.

Disposable respirators should never be shared between users. A disposable respirator should always be discarded if (1) it becomes contaminated with a hazardous substance, (2) it becomes contaminated with blood, respiratory or nasal secretions, or other bodily fluids from patients, (3) it has been used during an aerosol generating procedure or during surgery, (4) it becomes wet or visibly dirty, or (5) breathing through it becomes more difficult.

Studies have consistently found that materials that are captured in a respirator filter will not be released, even if the user coughs or sneezes,³ or if the respirator is dropped. However, materials that may be on the outside of the respirator can be transferred to the employee's hands, just as materials that are on the employee's face or clothing can be transferred. Therefore employees should be instructed to perform hand hygiene whenever their hands touch the outside of the respirator.⁴ Respirators can be continuously worn between patients without removal ("extended use") without creating a hazard for the patients or the employees, so long as hand hygiene and other standard precautions are maintained. Respirators should not be worn between patients after high hazard procedures or surgery, or if the respirator has become contaminated with bodily fluids.

Disposable filtering facepiece respirators may be removed, stored, and re-donned by an employee if the employer has established procedures for this type of use, provided

³ "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

⁴ The October 14, 2009 CDC Guidance discontinued the recommendation that contact precautions be taken with H1N1 patients. However, standard precautions include the performance of hand hygiene after touching contaminated surfaces.

appropriate facilities for storage, and trained employees in how to remove, store, inspect, and re-don the respirator. Employees must also be trained in how to recognize a respirator that must be discarded. Employer re-donning policies cannot include an absolute limit on the number of respirators that will be furnished to an exposed employee during a given period of time.

Protecting the outside surfaces of the respirator

It may be possible to prolong the useful life of the respirator by protecting the outer surface from sprays with a face shield, but a face shield may be used only if it does 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 also make it more difficult to breathe through.

Respirator doffing, storage and re-donning procedures

When an employee removes a respirator in the context of re-donning practices, the employee should lift the respirator straps from the back of the head. The respirator should be handled as little as possible, and the employee should avoid touching the inside surfaces of the respirator. If the respirator is visibly contaminated with blood or other bodily fluids, if it is wet, dirty or deformed, it should be discarded. If it is in good condition, the respirator should be placed in a clean container labeled with the employee's name or other identifier.

The respirator container should be located in an area free from chemical contamination, and it should be sufficient to protect the respirator against contamination or crushing, but it need not be "airtight." Prior to re-donning, the employee should inspect the respirator, including straps, clips, sealing surfaces and general condition. If it is in good condition, the employee should don the respirator according to instructions provided for the specific respirator, and perform the user seal check. After handling the respirator, the employee should perform hand hygiene.⁵

Use of stockpiled respirators

Many of the respirators that will be provided from the State stockpile are not the same respirators that have been in use in some health care facilities. OSHA and Cal/OSHA regulations require that a fit-test be provided for each model of respirator used.⁶ Fit-tests

⁵ Additional information about donning and taking off (doffing) personal protective equipment, including respirators, is available from the CDC at <http://www.cdc.gov/ncidod/dhqp/ppe.html>.

⁶ 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, an additional fit-test is not required.

are important in ensuring that the respirator will provide an employee with the required level of protection.

It may take some time to provide fit-tests to every respirator user when an employer is forced to switch to the stockpiled respirators. Employers can limit the number of employees needing fit-testing by strategies such as assigning existing stock of respirator models that may be in short supply to certain units, while rolling out the new models to a limited number of employees.

Employers should not fail to provide a respirator because the employee to use it has not yet been fit-tested for the respirator, since even a respirator that has not been fit-tested will offer better protection than a surgical mask, and almost all users will achieve some level of protection from any given respirator. Where all users cannot be immediately fit-tested, employers should first target employees who perform aerosol generating procedures or are otherwise at higher risk of exposure. Employers may also seek help in performing fit-testing from workers' compensation carriers, respirator suppliers, occupational medicine service providers, trade associations, the local health departments, industrial hygiene consultants, and the Cal/OSHA Consultation Service.

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.

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. However, in the case of a novel pathogen, the ATD standard does not require referral or transfer where such actions are not feasible. Employees who are exposed to the patient are required to be protected by respirators. This is consistent with current CDC and CDPH guidance, which does not require airborne infection isolation rooms for routine patient care of H1N1 patients.

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. The CDC and CDPH have recommended that employees providing care to these patients use a respirator at least as effective as an N95 respirator.

Under Cal/OSHA's ATD standard, 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 or examination of the mouth or throat are not considered high hazard procedures

under this standard, employees who perform these activities or similar activities should use a respirator, since the procedures cannot be performed with the patient's mouth and nose covered and they 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. CDPH and CDC now recommend that these patients be managed in individual rooms, and need not be transferred to an airborne infection isolation room for routine patient care. AIIRs are recommended for high hazard procedures.

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.

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 re-donning procedures are to be implemented, employees must receive 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 ensure that their written respiratory protection program or ATD exposure control plan reflects current respirator use policies and procedures in the facility. Records of plan implementation must be maintained 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.