

Cal/OSHA Interim Enforcement Policy on H1N1 and Section 5199 (Aerosol Transmissible Diseases) Issue Date: February 16, 2010

Background

Cases of pandemic 2009 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 N95 filtering facepiece respirators. 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 released stockpiled respirators through local health departments. Therefore the previous Cal/OSHA guidance regarding respirator prioritization was rescinded on [October 22, 2009](#) and respirators were to be provided for contact with all potentially infectious patients, as discussed in detail below.

As the state stockpile began to be deployed some concerns regarding one of the respirators in the stockpile arose. It was determined that the 3M 8000 respirator, which constitutes over 60 percent of the state stockpile, did not reliably fit some health care workers. At this time, CDPH is distributing other models contained within the stockpile. Because there are concerns regarding maintaining a reliable respirator supply facilities

¹ The current CDPH case definition can be found at:
<http://www.cdph.ca.gov/HealthInfo/discond/Documents/H1N1-IC-CaseDefinitions.pdf>

should adopt respirator conserving measures, as described below, in order to ensure that respirators remain available. For more information on this respirator, please see the Cal/OSHA alert at: http://www.dir.ca.gov/DOSH/CalOSHA_3M.pdf

On November 20, 2009, federal OSHA issued "[Instruction 02-02-075, "Enforcement Procedures for High to Very High Occupational Exposure Risk to 2009 H1N1 Influenza."](#) State programs, including Cal/OSHA are required to take equivalent action. Therefore, Cal/OSHA is issuing this updated guidance. The changes in this guidance include:

1. Clarification of policies regarding redonning/reuse and extended use of filtering facepiece respirators, and documentation of shortages, to be consistent with the OSHA Instruction
2. Information about use of respirators provided from state and federal stockpiles
3. Recordkeeping requirements for work-related H1N1 infections
4. Clarification of vaccination requirements for health care workers as they apply to influenza this year.

Applicability of the California 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,” at this time. 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 placement,² engineering controls, administrative controls, and the use of respirators. The ATD standard therefore also currently requires these precautions for H1N1. The CDC and CDPH are continuing to evaluate this pandemic virus. Cal/OSHA will update this advice if CDPH recommendations change.

Vaccination Requirements

The ATD standard requires that employers provide the seasonal influenza vaccine to all employees who are covered by this standard. This requirement is in effect at the present time. A declination statement must be completed for each employee who declines the vaccine.

On November 12, 2009 CDPH recommended that H1N1 vaccine be provided to all health care personnel in licensed facilities.

“Health and Safety Code (HSC) section 1288.7(a) provides that each General Acute Care Hospital (GACH) licensed pursuant to HSC Section 1250 must annually offer onsite influenza vaccinations, upon availability, to all hospital employees at no cost to the employee. That HSC section mandates that each GACH must require its employees to be vaccinated, or, if the employee elects not to be vaccinated, to obtain a written declaration that the employee declined the vaccination. HSC section 1288.7(a) applies to the newly developed Novel H1N1 vaccine. The Novel H1N1 vaccination is mandated to be offered by all GACHs, in addition to the seasonal influenza vaccination.

Due to the anticipated extensive spread and the severity of the illness caused by this virus, and in an effort to maintain the workforce and reduce the likelihood of healthcare workers transmitting the virus to patients, the California Department of Public Health (CDPH) recommends all other facility types to offer the Novel H1N1 vaccine to all of their employees free of charge. CDPH also asks that facilities maintain written records of the employees who have received the vaccination, and requests that facilities obtain written declinations from any

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

employee who chooses not to be vaccinated.”

<http://www.cdph.ca.gov/certlic/facilities/Pages/LnCAFL09.aspx>

As of September 1, 2010, additional Section 5199 requirements regarding vaccinations of health care workers and laboratory workers will become effective. For health care workers, these requirements will include “influenza” vaccine, including the monovalent H1N1 vaccine, if it is still available and recommended. Cal/OSHA joins with CDPH in encouraging health care employers to implement the H1N1 vaccine for all exposed employees as soon as it becomes available.

Although the H1N1 vaccine is anticipated to be as effective as seasonal influenza vaccine, the ATD standard’s requirements for the use of other control measures, including respirators, remain in effect for vaccinated employees. No vaccine is 100 percent effective, and experience with seasonal influenza vaccine indicates that some individuals do not develop immunity after vaccination. The requirement that all employees with direct exposure to H1N1 patients use respiratory protection is consistent with CDC and CDPH recommendations, and the OSHA Instruction.

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 CDPH 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 Standard 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 supply issues, measures should be taken to maximize respirator supplies and to reduce the need for respirator use, to the extent reasonably possible. 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 standard, the CDC Interim Infection Control guidance dated October 14 that delineates a hierarchy of controls to prevent influenza transmission in healthcare settings, and the OSHA Instruction. 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 the respirators 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 redonning to reduce respirator demand

Although the release of stockpiled respirators is expected to mitigate immediate respirator shortages, there is still no assurance that an adequate supply of respirators will be available throughout the coming months. 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.

In the October 14 guidance, the CDC discontinued the recommendation for contact precautions for H1N1. Therefore, for routine patient care, health care workers are no longer required to wear gowns and other protective coverings and remove them upon

exiting the patient room. Hand hygiene, and protection against bodily fluids is required by standard precautions, which are to be implemented for all patients.

Prior to the emergence of H1N1, health care institutions have had different policies regarding the disposal of N95 respirators used to protect against TB and other diseases. In some institutions, these respirators were removed, stored and put back on (redonned) by the same health care worker, when caring for the same, or for different patients. In some facilities, N95 respirators have been worn continuously by the same health care worker when caring for different patients (extended use), and then disposed of when the respirator is taken off. In other facilities, respirators have been discarded after each patient contact.

Although there is little data available regarding whether any of these policies reduce the protection provided by the respirator, 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 There may be some potential for contact transmission whenever the outside of a respirator (or any clothing item or exposed body area) is touched, in that materials that may be on the outside of the respirator can be transferred to the employee's hands. Whether or not respirators are to be redonned or reused, employees should be instructed to perform hand hygiene whenever their hands touch the outside of the respirator or any other potentially contaminated surface, in accordance with standard precautions.

Another potential concern with redonning of filtering facepiece respirators is that the respirator may be structurally compromised with repeated donning and doffing. If employers implement redonning procedures, employees must be instructed to inspect the respirator prior to putting it back on, and to discard any respirators that are damaged, wet or dirty, or that fail to seal to the face. Employees should perform a user seal check every time a respirator is put on. If air is felt leaking around the respirator, the respirator should be adjusted or discarded. Because the user seal check involves touching the outside of the respirator, hand hygiene should be performed after the user seal check on a redonned respirator.

Because materials that are captured in respirator filters are not released, wearing a respirator between patients without removal ("extended use") will not expose either the employee or the patient to any pathogens that are in particles captured by filter fibers. Respirators should not be worn between patients after high hazard procedures or surgery, or if the respirator has become contaminated with bodily fluids, due to the increased risk of contact transmission from materials on the outside surface of the respirator. The CDC has recommended that facilities facing supply shortages consider extended use in

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

preference to reuse/redonning, because the respirator is handled less. The CDC's recommendations regarding respirator use can be found at:
http://www.cdc.gov/h1n1flu/guidance/ill-hcp_qa.htm#reuse

If redonning of disposable filtering facepiece respirators is necessary, the employer must establish procedures for this type of use, provide appropriate facilities for storage, and train employees in how to remove, store, inspect, and redon the respirator. Employees must also be trained in how to recognize a respirator that must be discarded. Employer redonning 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.

Extended use and redonning should be adopted only when necessary to address respirator shortages. Therefore, facilities that adopt these policies, as well as facilities that access state or local stockpiles of respirators, should document their attempts to address respirators shortages through reviewing work organization, minimizing exposures, and attempting to maximize the respirator supply as described above. [Appendix A](#) can be used for this purpose.

Protecting the outside surfaces of the respirator

It may be possible to prolong the useful life of the respirator and reduce surface contamination 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 redonning procedures

When an employee removes a respirator in the context of redonning 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, damaged 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 redonning, 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.⁴

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.⁵ Fit-tests are important in ensuring that the respirator will provide an employee with the required level of protection. [Section 5144, Appendix A](#), describes the fit-test methods that are required to be used.

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 who will 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. These requirements are consistent with current CDC and CDPH guidance, which does

⁴ 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>.

⁵ 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.

not require AIIRs for routine patient care of H1N1 patients, but does recommend the use of respirators by employees who have direct contact with 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 redonning or extended use procedures are to be implemented, employees must receive training in how to recognize when a respirator must be discarded. For redonning, training must also include how to safely remove, store, inspect, and redon or discard the respirators as well as specific training on the employer's redonning policies.

Recording of work-related H1N1 infections

The OSHA Instruction states that work-related H1N1 infections in workplaces at high or very high risk of H1N1 transmission (which includes most health care facilities) must be recorded on the Log 300 (Log of Work Related Injuries and Illnesses).

“For purposes of OSHA injury and illness recordkeeping, illnesses due to the 2009 H1N1 influenza is not considered a common cold or seasonal flu. The work-relatedness exception for the common cold or flu at 29 CFR 1904.5(b)(2)(viii) does not apply to these cases. Employers are responsible for recording cases of 2009 H1N1 illness if all of the following requirements are met: (1) the case is a confirmed case of 2009 H1N1 illness as defined by CDC; (2) the case is work-related as defined by 1904.5; and (3) the case involves one or more of the recording criteria set forth in 1904.7 (e.g., medical treatment, days away from work).”

Physicians' offices and some other health care employers are not required to maintain a Log 300. A complete list of those establishments, by Standard Industrial Classification code, can be found at: http://www.dir.ca.gov/T8/14300_2.html. However, all employers must report to the Division of Occupational Safety and Health any workplace incident that results in a serious injury or illness or death, as required by [Title 8 Section 342](#). All employers must also complete other forms (such as workers compensation forms) to document individual cases of occupational injuries and illnesses. Hospitals and long-term care facilities are among the categories of employers that are required to maintain a Log 300.

Recordkeeping

The employer should ensure that the written respiratory protection program or ATD exposure control plan reflects current respirator use policies and procedures in the facility. Records of plan implementation should include documentation of control measures taken to reduce employee exposure. These records also include actions taken to obtain adequate supplies of respiratory protection, including attempts made to obtain respirators through alternate suppliers, and through public stockpiles. [Appendix A](#), Respirator Supply Documentation, can be used for this purpose. 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.