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Sent: Friday, February 11, 2011 11:15 AM
To: NIOSH Docket Office (CDC)
Cc: Meeks, Gail (CDPH-PS-DEODC); Materna, Barbara (CDC cdph.ca.gov)
Subject: Infectious Diseases; 42 U.S.C. 300ff-131
Attachments: CDPH Ryan White response 2-7-11 final.pdf

NIOSH Docket Officer:

The California Department of Public Health (CDPH) respectfully submits the attached comments in response to the NIOSH request for public comments on a proposed list of infectious diseases that may pose life-threatening health risks to emergency response employees through bloodborne or airborne transmission, and related proposed guidelines. This notice was issued pursuant to the Ryan White HIV/AIDS Treatment Extension Act of 2009 and was published in the December 13, 2010 Federal Register Notice. These comments were prepared collaboratively with the California Department of Industrial Relations, Division of Occupational Safety and Health (Cal/OSHA), and involved the input of staff from three programs within CDPH including:

- Occupational Health Branch, Division of Environmental and Occupational Disease Control, Center for Chronic Disease Prevention and Health Promotion;
- Healthcare Associated Infections Program, Center for Health Care Quality; and
- Immunization Branch, Division of Communicable Disease Control, Center for Infectious Diseases.

Thank you for the opportunity to comment.

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EDMUND G. BROWN JR.
Governor

RE: **Docket Number NIOSH-219**

Implementation of Section 2695 (42 U.S.C. 300ff-131) of Public Law 111-87: Infectious Diseases and Circumstances Relevant to Notification Requirements

General Notice and Request for Comments

Submitted February 7, 2011

California Department of Industrial Relations, Division of Occupational Safety and Health (Cal/OSHA), and California Department of Public Health (CDPH)

Cal/OSHA and CDPH have prepared these comments to the National Institute for Occupational Safety and Health (NIOSH) in response to Docket Number NIOSH-219, published December 13, 2010, Federal Register 75:238, page 77642-77644 (Notice). This Notice addresses certain aspects of implementation of the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Act). Cal/OSHA operates a state plan under the authority of the 1970 Occupational Safety and Health Act, and is responsible for protecting the health and safety of California's eighteen million workers. CDPH is the state agency with the lead responsibility for protecting the health of 37 million California residents and coordinates a network of 61 local health departments. The Director of CDPH is the State Public Health Official in whom the Act vests certain responsibilities and authority. The Occupational Health Branch of CDPH prevents occupational injury and illness through a non-regulatory program of public health surveillance, investigation, technical assistance, research, and education.

Cal/OSHA and CDPH have been very involved in the issue of notification of exposures to emergency response employees (EREs). During the development of Cal/OSHA's Aerosol Transmissible Diseases Standard (ATD Standard), paramedics, firefighters, and law enforcement officers and agencies raised the need for a reliable and timely system of communication between diagnosing health care providers and EREs exposed to infectious patients. As a result, the ATD Standard includes requirements regarding notification to employers of employees who may have had significant exposures.

In December 2009, a few months after the ATD Standard became effective, exposures of EREs and hospital staff to a patient with meningitis resulted in two secondary cases¹. The index case was found supine in an apartment on December 4 by police officers conducting a "welfare check". The patient's airway was partially obstructed, so the police officers rolled him onto his

¹ CDC. Occupational transmission of *Neisseria meningitidis* – California, 2009. MMWR 2010 59(45):1480-1483.

side while awaiting emergency medical personnel. The police officers had gloves but not respiratory protection. The emergency medical personnel from the fire department and ambulance companies used N95 respirators. The patient was transported to a hospital, where several health care workers provided life support, including intubation. One of the hospital workers used a surgical mask; none of them used a respirator. The day after the patient was hospitalized, bacteria consistent with *N. meningitidis* were detected in his cerebral spinal fluid and blood. The hospital did not report the suspected case to the local health department at that time, and also did not report the case until the day following laboratory confirmation of the *N. meningitidis* infection.

Two secondary cases resulted from this exposure. One of the cases, a police officer, was not aware of his exposure until he was informed by a co-worker who was notified six days after their exposure. By that time, the officer was off work, and sick enough to require hospitalization. The hospital did not investigate exposures to its staff until the following day, when the respiratory therapist who had assisted with the intubation was hospitalized.

This case illustrates the importance of timely notification to EREs. Although California regulations already address a number of the requirements of the Act, and Cal/OSHA citations were issued to the hospital in question, the Act will benefit California employees by establishing a structure that can be used to implement other requirements. The Act will also protect California employees in the federal sector, as well as employees in other states. We believe that full and broad implementation of this Act is important to protecting the health of EREs and their families, and urge NIOSH and the Secretary of Health and Human Services (Secretary) to move forward as quickly as possible to implement this law.

We do, however, have several significant concerns (described below) about the guidance as published in the Notice. Our primary concern is that this guidance, if implemented as stated, may unnecessarily restrict or delay notifications to EREs.

The Ryan White Act establishes two pathways for notification:

1. A medical facility, or facility that ascertains the cause of death, (facility) that determines that EREs transported a patient that it determined to have a disease listed by the Secretary of Health and Human Services as an "airborne infectious disease" must notify the designated officer (DO) for the EREs.
2. An ERE who believes that he or she may have been exposed to a person with an infectious disease may request information from the medical facility through the ERE's DO.

In relation to this notification system, the Secretary was tasked with developing a list of potentially life-threatening infectious diseases, and a list specifying which of those diseases are "Airborne Infectious Diseases." The Act defines airborne infectious diseases as those that are "routinely transmitted through airborne or aerosolized means." The Secretary was also directed to provide guidelines describing the circumstances in which EREs may be exposed to such diseases.

We have three specific concerns and one additional recommendation:

1. The Notice does not provide clear guidance regarding assessment of exposures to EREs.

It is important that the guidance recognize that emergency medical response typically involves near-range exposures in uncontrolled environments. Responders are very mobile and, as illustrated by the police officer who contracted meningitis, may perform short duration tasks that are not easily recognized as creating a high risk for transmission. EREs may not even recall specific tasks or exposures, particularly if they are not performing medical tasks that are required to be recorded. Unlike hospitals, there are no airborne infection isolation rooms and few, if any, other engineering controls. It is therefore important that a broad interpretation be given to the term “exposed” so that notifications can be provided. Once notified, the employee’s exposure and personal health factors can be evaluated, and appropriate follow-up provided. Without notification, the employee may develop symptoms that are unrecognized, and treatment may be delayed.

In this context, we are particularly concerned about the definition statement “Exposed means to be in circumstances in which there is a recognized risk for transmission of an infectious agent from a human source to an ERE. (Siegel et al. 2007; 14)” This definition provides little useful guidance for evaluating ERE exposures. The referenced document contains few mentions of emergency response, and no specific guidance for evaluating exposures to EREs. We suggest that the Notice define exposure as “any contact, direct or indirect, with a person in which there is a risk for transmission of an infectious agent to an ERE.”

2. The Notice may mislead facilities regarding how to evaluate exposures by unnecessarily distinguishing between types of aerosol transmission.

As stated above, the Act defines “airborne infectious diseases” for the purposes of the Act, as “diseases routinely transmitted through airborne or aerosolized means.” Unlike the Act, the Notice separates these diseases into two categories “aerosolized airborne transmission” and “aerosolized droplet transmission.” This unnecessary distinction is also included in Part 1 B. of the Notice, which lists a few diseases it defines as transmitted through “Aerosolized Airborne Means,” and lists a number of other diseases transmitted through “Aerosolized Droplet Means.” It is again repeated in Part II of the Notice.

The Act does not make this distinction, and the Notice does not give any purpose for separating diseases “routinely transmitted through airborne or aerosolized means” into these two categories. In emergency response, many short-range exposures are to be expected. These exposures may be supplemented with uncontrolled contact transmission. The message to ERE employers and health care professionals should be clear: if a patient is determined to have a disease spread through airborne or aerosolized means, exposure should be assumed for EREs who provided care, transport, or otherwise attended the patient. Distinctions based on the assumed size or deposition of aerosols are not relevant in most cases. These unnecessary distinctions, which are inconsistent with the language of the Act, can lead to under-estimation of employee exposures, as was done in the meningitis cases mentioned above, and result in under-notification and delays in prophylaxis or treatment.²

² California’s ATD Standard requires health care providers who diagnose a reportable ATD to automatically notify all employers whose EREs were exposed to an infectious patient, to the extent that that information can be found in

It is also important that the list of diseases that the Notice identifies as transmitted by “airborne aerosolized means” does not include SARS-CoV, Smallpox, Avian Influenza, and aerosolizable spores (such as Anthrax) prior to decontamination. This is inconsistent with the referenced document which recommends airborne isolation for these diseases, as well as the three diseases listed in the Notice -- Measles, Tuberculosis, and Varicella disease (chicken pox and disseminated varicella).

We believe that EREs would be better served by clarifying that, in an emergency response context, short-range aerosol transmission should be assumed. Therefore the Notice should provide a single specification for the list of life-threatening infectious diseases that identifies diseases routinely transmitted through airborne or aerosolized means, as the Act directs.

3. The process provided in the notice for facilities from whom a DO requests information on behalf of an exposed ERE appears to require the facility to conduct a second exposure evaluation. This unnecessarily limits and delays notification.

Part III of the Notice addresses notifications that are generated in response to a request by an ERE, pursuant to Section 2695B of the Act. The Act directs that an ERE who believes that he or she may have been exposed to an infectious disease by a victim of an emergency may initiate a request for information through the employee’s DO. The DO is then required to collect and evaluate facts relating to the circumstances of exposure. If the DO determines that the employee would have been exposed to the disease if the victim had such a disease, then the DO must submit a written request to the facility. The Act then requires the facility to evaluate the facts submitted in the request, and in conjunction with those facts, and the medical information it holds, respond to the request. The facility must either notify the DO that the ERE was or was not exposed to an infectious disease, or must notify the DO that there is insufficient information to make that determination. In cases where there is insufficient information, the DO may request assistance from the public health officer.

The Act tasks the Secretary to provide guidance for medical facilities to use in making determinations for the purpose of responding to DO requests. The Notice appears to task medical facilities with the responsibility to determine whether EREs involved in the care of a victim with an infectious disease listed in Part I have had an exposure that could transmit a listed disease. The Notice states, “First the request submitted to the medical facility contains a “statement of the facts collected” about the ERE’s potential exposure incident...Information about infectious disease transmission provided in relevant CDC guidance documents (such as Siegel et al, 2007) of in current medical literature should be considered in assessing whether there is a **realistic possibility** [emphasis added] that the exposure incident described in the “statement of the facts” could potentially transmit an infectious disease included on the list issued pursuant to Section 2695(a)(1).”

This statement, including the use of the term “realistic possibility,” may give the impression that the medical facility is supposed to reevaluate the exposure determination already made by the

the providers’ records. A proactive system that routinely notifies all exposed EREs, not just transport personnel, would result in more inclusive and timely notification, and should be considered in future rulemaking.

ERE's DO. This second exposure evaluation is unnecessary and may result in under-notification and/or delay in notification. Employers of EREs, not the medical facility, are in the best position to collect the type of information needed to determine if an exposure has occurred. The DO knows what control measures are available to the employees, the types of procedures they perform, and the protocols employees follow. The DO can question the ERE directly about his or her activities in regards to the patient. The role of the medical facility should be to determine whether the disease in question may be transmitted through the activities described in the statement of fact, or whether the known routes for transmission of the victim's disease do not include those exposures. For example, if there was no exposure to blood or bodily fluids, then a notification for HIV would not be required. It is hard to envision a situation where a medical facility could rule out notification for aerosol transmission where an ERE had near-field exposure to that patient.

In the exposure incident described above, meningococcal disease was transmitted to a police officer involved in an emergency response to an infected victim. The medical facility that received the victim did not notify other employers whose employees were involved in the emergency response (police, fire, EMT).

The investigation of the meningitis cases illustrates two relevant points. First, the ERE may have no reason to suspect that an exposure occurred given his limited contact and therefore would not request notification. So it is important that DOs and facilities be pro-active in initiating notification. Secondly, if the police officer had been notified of possible exposure he could have sought early diagnosis and treatment when he started experiencing symptoms, which may have mitigated his disease course.

Broad and timely notification could have prevented disease in the police officer, or resulted in early treatment that could have modified the disease course. Therefore, we would argue that broad notification of possibly exposed EREs is necessary to prevent underreporting of exposures. The role of the medical facility should be solely to determine if the patient had a disease transmissible by aerosols, and if so, to provide information to the DO who would then notify all potentially exposed EREs.

4. More research is needed regarding how to protect EREs.

The major reference incorporated in this notice has very little information or guidance regarding emergency responders, and we have found few others that specifically address these exposures. Yet it can not be disputed that EREs are at risk. Paramedics and EMTs were significantly impacted during the SARS outbreak in Toronto^{3,4}. As discussed above, even police officers with brief exposures may contract serious and life-threatening infections. We therefore encourage NIOSH to conduct further research in this area to provide guidance on applicable control measures in this critical area.

³ Silverman A, Loutfy MR, Simor A. Toronto emergency medical services and SARS [letter]. *Emerg Infect Dis* [serial on the Internet]. 2004 Sep [date cited]. Available from: <http://www.cdc.gov/ncidod/EID/vol11no9/04-0170.htm>.

⁴ Verbeek PR et al. Loss of Paramedic Availability in an Urban Emergency Medical Services System. *Academic Emergency Medicine*; Sep 2004; 11, 9.

In summary, Cal/OSHA and CDPH support the immediate implementation of notification protocols with the changes we have suggested. Emergency response employees, and their families and friends, deserve the reasonable protections provided by this Act.

Thank you for the opportunity to provide input on this important matter. If you have any further questions, please contact Deborah Gold, Cal/OSHA, at (510) 286-7006, dgold@dir.ca.gov or Barbara Materna, CDPH, at (510) 620-5730, Barbara.Materna@cdph.ca.gov.

Sincerely,



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