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Director, Division of Investigative Oversight, Office of Research Integrity.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Priority Setting for the Children's Health Insurance Program Reauthorization Act (CHIPRA) Pediatric Quality Measures Program—Notice of Correction

On pages 75469 and 75470, Volume 75, Number 232, **Federal Register** notice publication dated December 3, 2010, under **DATES** section, the correct date is: January 14, 2011. Also, on pages 75470 and 75471, under section

SUPPLEMENTARY INFORMATION all Web links that include the word: "ahrg" should be changed to: "AHRQ".

Dated: December 7, 2010.

Carolyn M. Clancy,

Director, AHRQ.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[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

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services.

ACTION: General Notice and Request for Comments.

SUMMARY: The Ryan White HIV/AIDS Treatment Extension Act of 2009 (Pub. L. 111-87) addresses notification procedures for designated officers, medical facilities, and State and community public health officers regarding exposure of emergency response employees (EREs) to potentially life-threatening infectious diseases. The Secretary of Health and Human Services (Secretary) has delegated authority to the Director of the

Centers for Disease Control and Prevention (CDC) to issue a list of potentially life-threatening infectious diseases, including emerging infectious diseases, to which EREs may be exposed in responding to emergencies (including a specification of those infectious diseases that are routinely transmitted through airborne or aerosolized means); guidelines describing circumstances in which employees may be exposed to these diseases; and guidelines describing the manner in which medical facilities should make determinations about exposures. CDC is seeking comment on the list of diseases and guidelines contained in this notice.

DATES: Comments must be received by February 11, 2011.

ADDRESSES: Comments on the content of this Notice should be in writing and addressed to:

- *E-mail:* NIOSH Docket Officer, nioshdocket@cdc.gov. Include "Infectious Diseases" and "42 U.S.C. 300ff-131" in the subject line of the message.
- *Mail:* NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 4676 Columbia Parkway, Cincinnati, OH 45226.
- *Internet:* Federal e-rulemaking portal, <http://www.regulations.gov>. Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name and docket number for this Notice. All comments will be posted without change to <http://www.cdc.gov/niosh/docket/archive/docket219.html>, including any personal information provided. For detailed instructions on submitting comments and additional information about this process, see the "Public Participation" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.cdc.gov/niosh/docket/archive/docket219.html>.

FOR FURTHER INFORMATION CONTACT:

Centers for Disease Control and Prevention, Attention: James Spahr, Associate Director, Emergency Preparedness & Response, Office of the Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Mailstop E20, Atlanta, GA 30333. Telephone (404) 498-6185 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

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Public Participation

Interested persons or organizations are invited to participate in this request for public comments by submitting written views, arguments, recommendations, and data. Comments are invited on any topic related to this proposal. In particular, CDC invites comment on the list of infectious diseases and both sets of guidelines discussed herein.

Comments submitted by e-mail or mail should be titled "Docket #219 Public Comments," addressed to the "NIOSH Docket Officer," and identify the author(s), return address, and a phone number, in case clarification is needed. Comments can be submitted by e-mail to nioshdocket@cdc.gov as e-mail text or as a Microsoft Word file attachment. Printed comments can be sent to the NIOSH Docket Office at the address above. All communications received on or before the closing date for comments will be fully considered by CDC in developing a final list of infectious diseases and guidelines which will be published in the **Federal Register**.

Introduction

The Ryan White HIV/AIDS Treatment Extension Act of 2009 (Pub. L. 111-87) amended the Public Health Service Act (PHS Act, 42 U.S.C. 201-300ii), including the addition of a Part G to Title XXVI, which addresses notification procedures and requirements for medical facilities, State public health officers and their designated officers regarding exposure of EREs to potentially life-threatening infectious diseases. (See Title XXVI, Part G of the PHS Act, codified as amended at 42 U.S.C. 300ff-131 to 300ff-140.)

For purposes of these notification requirements, Section 2695 [42 U.S.C. 300ff-131] requires the Secretary of Health and Human Services (Secretary) to develop and disseminate:

- (1) A list of potentially life-threatening infectious diseases,

including emerging infectious diseases, to which EREs may be exposed in responding to emergencies (including a specification of those infectious diseases on the list that are routinely transmitted through airborne or aerosolized means);

(2) Guidelines describing the circumstances in which such employees may be exposed to such diseases, taking into account the conditions under which emergency response is provided; and

(3) Guidelines describing the manner in which medical facilities should make determinations for purposes of section 2695B(d) [42 U.S.C. 300ff-133(d)].¹

On July 7, 2010, the Secretary delegated authority for Section 2695 [42 U.S.C. 300ff-131] to the Director of the CDC (75 FR 40842). This Notice includes the proposed list of diseases and guidelines developed by CDC pursuant to this delegation and in accordance with Section 2695 [42 U.S.C. 300ff-131]. CDC invites comment on the list of infectious diseases and both sets of guidelines.

Definitions

The following definitions are used in the list of diseases and guidelines developed pursuant to Section 2695[42 U.S.C. 300ff-131]:

Aerosol means tiny particles or droplets suspended in air. These range in diameter from about 0.001 to 100 μm (Baron P, accessed 2010) (Baron PA and Willeke K, 2001; 1065).

Aerosolized transmission means person-to-person transmission of an infectious agent through the air by an aerosol. See “aerosolized airborne transmission” and “aerosolized droplet transmission.”

Aerosolized airborne transmission means person-to-person transmission of an infectious agent by an aerosol of small particles able to remain airborne for long periods of time. These are able to transmit diseases on air currents over long distances, to cause prolonged airspace contamination, and to be inhaled into the trachea and lung (Baron P, accessed 2010) (Seigel *et al.*, 2007; 18).

Aerosolized droplet transmission means person-to-person transmission of an infectious agent by large particles only able to remain airborne for short periods of time. These generally transmit diseases through the air over short distances (approximately 6 feet), do not cause prolonged airspace contamination, and are too large to be inhaled into the trachea and lung (Baron

P, accessed 2010) (Seigel *et al.*, 2007; 17).

Contact or body fluid transmission means person-to-person transmission of an infectious agent through direct or indirect contact with an infected person's blood or other body fluids (Seigel *et al.*, 2007; 15).

Exposed means to be in circumstances in which there is recognized risk for transmission of an infectious agent from a human source to an ERE (Seigel *et al.*, 2007; 14).

Potentially life-threatening infectious disease means an infectious disease to which EREs may be exposed and that has reasonable potential to cause death or fetal mortality in either healthy EREs or EREs who are able to work but take medications or are living with conditions that might impair host defense mechanisms.

Part I. List of Potentially Life-Threatening Infectious Diseases to Which Emergency Response Employees May Be Exposed

A. Potentially Life-Threatening Infectious Diseases: Routinely Transmitted by Contact or Body Fluid Exposures

- Hepatitis B (HBV).
- Hepatitis C (HCV).
- Human immunodeficiency virus (HIV) infection.
- Rabies (Rabies virus).
- Vaccinia (Vaccinia virus).

B. Potentially Life-Threatening Infectious Diseases: Routinely Transmitted Through Aerosolized Airborne Means

These diseases are included within “* * * those infectious diseases on the list that are routinely transmitted through airborne or aerosolized means.” Section 2695(b) [42 U.S.C. 300ff-131(b)]

- Measles (Rubeola virus).
- Tuberculosis (*Mycobacterium tuberculosis*)—infectious pulmonary or laryngeal disease; or extrapulmonary (draining lesion).
- Varicella disease—chickenpox, disseminated zoster (*Varicella zoster* virus).

C. Potentially Life-Threatening Infectious Diseases: Routinely Transmitted Through Aerosolized Droplet Means

These diseases are included within “* * * those infectious diseases on the list that are routinely transmitted through airborne or aerosolized means.” Section 2695(b) [42 U.S.C. 300ff-131(b)]

- Avian Influenza (Avian influenza A virus).
- Diphtheria (*Corynebacterium diphtheriae*).
- Meningococcal disease (*Neisseria meningitidis*).

- Mumps (Mumps virus).
- Plague, pneumonic (*Yersinia pestis*).
- Rubella (German measles; Rubella virus).
- SARS-CoV.
- Smallpox (Variola virus).
- Viral hemorrhagic fevers (Lassa, Marburg, Ebola, Crimean-Congo, and other viruses yet to be identified).

CDC will continue to monitor the scientific literature on infectious diseases. In the event that CDC determines that a newly emerged infectious disease fits criteria for inclusion in the list of potentially life-threatening infectious diseases required by the Ryan White HIV/AIDS Treatment Extension Act of 2009, CDC will amend the list and add the disease.

Part II. Guidelines Describing the Circumstances in Which Such Employees May Be Exposed to Such Diseases

A. Exposure to Diseases Routinely Transmitted Through Contact or Body Fluid Exposures

Contact transmission is divided into two subgroups: Direct and indirect. Direct transmission occurs when microorganisms are transferred from an infected person to another person without a contaminated intermediate object or person. Indirect transmission involves the transfer of an infectious agent through a contaminated intermediate object or person.

Contact with blood and other body fluids may transmit the bloodborne pathogens HIV, HBV, and HCV. When EREs have contact circumstances in which differentiation between fluid types is difficult, if not impossible, all body fluids are considered potentially hazardous. In the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard, an exposure incident is defined as a “specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties” (29 CFR 1910.1030).

Occupational exposure to rabies would include exposure incidents similar to those described for bloodborne pathogens, with special concern for contact of mucous membranes (eyes, nose, mouth, *etc.*) or non-intact skin to the saliva [rather than blood] of infected individuals. Occupational exposures of concern to vaccinia would include contact of mucous membranes (eyes, nose, mouth, *etc.*) or non-intact skin with drainage from a vaccinia vaccination site.

¹ Evaluation and Response Regarding Request to Medical Facility.

B. Exposure to Diseases Routinely Transmitted Through Aerosolized Airborne or Aerosolized Droplet Means

Occupational exposure to pathogens routinely transmitted through aerosolized airborne transmission may occur when an ERE shares air space with a contagious individual who has an infectious disease caused by these pathogens. Such an individual can expel small droplets into the air through activities such as coughing, sneezing and talking. After water evaporates from the airborne droplets, the dried out remnants can remain airborne as droplet nuclei. Occupational exposure to pathogens routinely transmitted through aerosolized droplet transmission may occur when an ERE comes within about 6 feet of a contagious individual who has an infectious disease caused by these pathogens and who creates large respiratory droplets through activities such as sneezing, coughing, and talking.

Part III. Guidelines Describing the Manner in Which Medical Facilities Should Make Determinations for Purposes of Section 2695B(d) [42 U.S.C. 300ff-133(d)]

Section 2695B(d) [42 U.S.C. 300ff-133(d)] specifies that medical facilities must respond to appropriate requests by making determinations about whether EREs have been exposed to infectious diseases included on the list issued pursuant to Section 2695(a)(1) [42 U.S.C. 300ff-131(a)(1)].

A medical facility has access to two types of information related to a potential exposure incident to use in making a determination. First, the request submitted to the medical facility contains a "statement of the facts collected" about the ERE's potential exposure incident. Section 2695B [42 U.S.C. 300ff-133]. Information about infectious disease transmission provided in relevant CDC guidance documents (such as Siegel *et al.*, 2007) or in current medical literature should be considered in assessing whether there is a realistic possibility 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) [42 U.S.C. 300ff-131(a)(1)].

Second, the medical facility possesses medical information about the victim of an emergency transported and/or treated by the ERE. This is the medical information that the medical facility would normally obtain according to its usual standards of care to diagnose or treat the victim, since the Act does not require special testing in response to a

request for a determination. As stated in Section 2695G(b) [42 U.S.C. 300ff-138(b)], "this part may not, with respect to victims of emergencies, be construed to authorize or require a medical facility to test any such victim for any infectious disease."

Information about the potential exposure incident and medical information about the victim should be used in the following manner to make one of the four possible determinations as required by Section 2695B(d) [42 U.S.C. 300ff-133(d)].

(1) The ERE involved has been exposed to an infectious disease included on the list issued pursuant to Section 2695(a)(1) [42 U.S.C. 300ff-131(a)(1)]:

—Facts provided in the request document a realistic possibility that an exposure incident occurred with potential for transmitting a listed infectious disease from the victim of an emergency to the involved ERE; and
 —The medical facility possesses sufficient medical information allowing it to determine that the victim of an emergency treated and/or transported by the involved ERE had a listed infectious disease that was possibly contagious at the time of the potential exposure incident.

(2) The ERE involved has not been exposed to an infectious disease included on the list issued pursuant to Section 2695(a)(1) [42 U.S.C. 300ff-131(a)(1)]:

—Facts provided in the request rule out a realistic possibility that an exposure incident occurred with potential for transmitting a listed infectious disease from the victim of an emergency to the involved ERE; or
 —The medical facility possesses sufficient medical information allowing it to determine that the victim of an emergency treated and/or transported by the involved ERE did not have a listed infectious disease that was possibly contagious at the time of the potential exposure incident.

(3) The medical facility possesses no information on whether the victim involved has an infectious disease included on the list issued pursuant to Section 2695(a)(1) [42 U.S.C. 300ff-131(a)(1)]:

—The medical facility lacks sufficient medical information allowing it to determine whether the victim of an emergency treated and/or transported by the involved ERE had, or did not have, a listed infectious disease at the time of the potential exposure incident.

—If the medical facility subsequently acquires sufficient medical information allowing it to determine that the victim of an emergency treated and/or transported by the involved ERE had a listed infectious disease that was possibly contagious at the time of the potential exposure incident, then it should revise its determination to reflect the new information.

(4) The facts submitted in the request are insufficient to make the determination about whether the ERE was exposed to an infectious disease included on the list issued pursuant to Section 2695(a)(1) [42 U.S.C. 300ff-131(a)(1)]:

—Facts provided in the request insufficiently document the exposure incident, making it impossible to determine if there was a realistic possibility that an exposure incident occurred with potential for transmitting an infectious disease included on the list issued pursuant to Section 2695(a)(1) [42 U.S.C. 300ff-131(a)(1)] from the victim of an emergency to the involved ERE.

Addendum

References

Baron P. *Generation and Behavior of Airborne Particles (Aerosols)*. PowerPoint Presentation. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, Division of Applied Technology. http://www.cdc.gov/niosh/topics/aerosols/pdfs/Aerosol_101.pdf. Accessed September 23, 2010.

Baron PA, Willeke K, eds. *Aerosol measurement: Principles, Techniques, and Applications*. Second edition. New York: John Wiley & Sons, Inc. 2001.

OSHA Standards, Bloodborne Pathogens, 29 CFR 1910.1030 (2009).

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Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee. *2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings*. <http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf>. Accessed September 23, 2010.

Dated: December 2, 2010.

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