

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ healthcare research and healthcare information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: October 27, 2011.

Carolyn M. Clancy,
Director.

[FR Doc. 2011-28402 Filed 11-1-11; 8:45 am]

BILLING CODE 4160-90-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket 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, Department of Health and Human Services.

ACTION: Final notice.

SUMMARY: The Ryan White HIV/AIDS Treatment Extension Act of 2009 (Pub. L. 111-87) addresses notification procedures for medical facilities and state public health officers and their designated 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. On December 13, 2010, CDC invited comment on a draft list of covered infectious diseases and both sets of guidelines (75 FR 77642). In consideration of the comments received, this notice sets forth CDC's final list of diseases, final guidelines describing circumstances under which exposure to listed diseases may occur, and final guidelines for determining whether an exposure to the listed diseases has occurred.

DATES: The list of diseases and guidelines in this notice will be effective December 2, 2011.

FOR FURTHER INFORMATION CONTACT:

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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 and 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, sec. 2695 [42 U.S.C. 300ff-131] requires the 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 sec. 2695B(d) [Evaluation and Response Regarding Request to Medical Facility, 42 U.S.C. 300ff-133(d)].

On July 7, 2010, the Secretary issued a PHS Act Delegation of Authority (Delegation of Authority), which assigned to the Director of CDC the authority vested in the Secretary of HHS (Secretary) under sec. 2695 of Title XXVI (42 U.S.C. 300ff-131) "as it pertains to the functions assigned to the [CDC]" (75 FR 40842, July 14, 2010). On December 13, 2010, CDC invited comment on a draft list of covered infectious diseases and two sets of guidelines developed pursuant to this Delegation of Authority and 42 U.S.C. 300ff-131 through a general notice and request for comments published in the **Federal Register** (75 FR 77642).

Response to Comments

In response to the December 2010 notice, CDC received a total of 83 comments from 22 individuals and/or organizations. The comments are addressed below.

Emergency Response Employees (EREs)

Comment: CDC received two comments regarding EREs. One commenter wanted to make it clear that police were included among the group of people considered EREs. The other commenter wanted there to be a specification that EREs included volunteer and paid emergency medical services.

CDC response: "Emergency response employee" is not defined in the PHS Act, and CDC's authority for purposes of this notice is limited to those duties set out in the Delegation of Authority (75 FR 40842). The duties of an individual considered an ERE are described in 42 U.S.C. 300ff-133(a):

[i]f an emergency response employee believes that the employee may have been exposed to an infectious disease by a victim of an emergency who was transported to a medical facility as a result of the emergency and if the employee attended, treated, assisted, or transported the victim pursuant to the emergency, then the designated officer of the employee shall, upon the request of the employee, carry out the duties described in subsection (b) regarding a determination of whether the employee may have been exposed to an infectious disease by the victim.

Non-compliance

Comment: CDC received one comment regarding non-compliance. The commenter noted that there was no mention of an administrative contact person or a process regarding non-compliance.

CDC response: The PHS Act addresses this issue in section 2695H [42 U.S.C. 300ff–139], which is outside the scope of this notice covering the Secretary's duties under sec. 2695 [42 U.S.C. 300ff–131]. The December 13, 2010, **Federal Register** notice was limited to those duties assigned to CDC through the Secretary's Delegation of Authority (75 FR 40842).

Designated officers

Comment: CDC received one comment regarding designated officers. The commenter noted that the designated officer position needs to be better developed.

CDC response: The PHS Act does not provide a definition of "designated officer," except that 42 U.S.C. 300ff–136 provides for selection of such officer by the public health officer of each state. The December 13, 2010, **Federal Register** notice was limited to those duties assigned to CDC through the Secretary's Delegation of Authority (75 FR 40842). Development of the designated officer position is beyond the scope of the Delegation and this notice.

Definitions

The December 13, 2010, general notice and request for comments provided definitions only where such were necessary for clarification of CDC's approach to developing the disease list and guidelines as assigned to CDC through the Secretary's Delegation of Authority (75 FR 40842). CDC received five comments regarding definitions. One commenter approved of the definitions.

Comment: Two commenters wanted to either use the word "communicable" instead of "infectious" or to add the word "communicable" in front of "infectious."

CDC response: To ensure consistency in interpretation of terms used in the

PHS Act and in the guidelines, CDC is mirroring the Act's language in its guidelines to the extent feasible. Title XXVI, Part G of the PHS Act refers only to the word "infectious" and not to the word "communicable." Furthermore, the ability of the infectious diseases included in the draft to be transmitted from person to person is addressed in their specification as "transmitted by contact or body fluid exposures," "transmitted through aerosolized airborne means," or "transmitted through aerosolized droplet means." In addition, Part III, "Guidelines Describing the Manner in Which Medical Facilities Should Make Determinations for Purpose of Section 2695B(d) [42 U.S.C. 300ff–133(d)]," in several places requires consideration of "infectious disease that was possibly contagious at the time of the potential exposure incident." Therefore the requested wording change was not made.

Comment: Two commenters requested that the word "exposed" be redefined as "any contact direct or indirect with a person in which there is a risk of transmission of an infectious agent to an ERE."

CDC response: CDC did not redefine "exposed." The existing definition is clear and there was concern that the word "contact" could lead to misinterpretations.

List of Potentially Life-Threatening Infectious Diseases (Part I)

Under sec. 2695 of Title XXVI (42 U.S.C. 300ff–131), CDC, through the Delegation of Authority by the Secretary of HHS, must 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). CDC received 45 comments regarding its proposed disease list.

CDC received a number of positive comments in support of the proposed disease list. For example, one commenter was pleased to see the addition of hepatitis C to the disease list. Another commenter supported finalization of the disease list. Two commenters stated that they agreed with the list of *Potentially Life-Threatening Infectious Diseases: Routinely Transmitted by Contact or Body Fluid Exposures* and the list of *Potentially Life-Threatening Infectious Diseases: Routinely Transmitted Through Aerosolized Airborne Means*. Two commenters appreciated the language in the document permitting amendments

to the list in the future as warranted by new scientific information or emerging diseases.

Comment: Two commenters felt that there should not be two separate lists, one listing diseases with aerosolized airborne transmission and the other listing diseases with aerosolized droplet transmission. They requested there be a single specification for the list of life-threatening infectious diseases that identifies disease routinely transmitted through airborne or aerosolized means. In contrast, others supported this approach. One commenter "agrees with these definitions [regarding aerosolized airborne and aerosolized droplet transmission and the corresponding lists] and appreciates the thoroughness and clarity in which they are written," and stated that "[t]his will permit our members to implement the revised requirements with accuracy and consistency." Two other commenters provided very similar supportive comments.

CDC response: CDC holds that having two separate lists most accurately represents the epidemiology of the diseases on the respective lists and mirrors usual infection control terminology, which will facilitate comprehension and optimal implementation of the Act. Therefore, the two separate lists (aerosolized airborne transmission and aerosolized droplet transmission) have been retained.

Commenters also asked CDC to consider amending the disease list by adding or removing conditions.

Comment: One commenter recommended that all multi-drug-resistant organisms (MDROs) be added to the disease list to establish documentation and surveillance for these organisms. Five other commenters specifically wanted methicillin-resistant *Staphylococcus aureus* (MRSA) and other resistant organisms [for example *E. coli* ST131 and vancomycin-resistant enterococci (VRE)] to be added to the disease list.

CDC response: Because documentation and surveillance activities are beyond the scope of 42 U.S.C. 300ff–131, the addition of MDROs for the purpose of documentation and surveillance to the disease list is not warranted. CDC's authority for purposes of this final notice is limited to those duties assigned to CDC through the Secretary's Delegation of Authority (75 FR 40842).

Regarding the addition of MRSA and other resistant organisms (ST131 and VRE) for the purposes of notification, exposure alone without clinical infection would not necessitate any type

of screening or prophylactic treatment.¹ MRSA, in particular, has become common and contemporary treatment of clinical conditions such as wound infections or cellulitis associated with abscesses, carbuncles, or furuncles routinely covers for MRSA until culture results allow for the narrowing of antibiotic coverage.² Therefore, CDC has not added MRSA, ST131, VRE, or MDROs in general to the list of diseases.

Comment: Five commenters wanted anthrax to be added to the disease list.

CDC response: Anthrax remains an endemic public health threat through annual epizootics in certain areas of the United States. Cutaneous anthrax can be transmitted human to human via drainage from lesions and is potentially fatal if left untreated;³ therefore, cutaneous anthrax has been added to the list of *Potentially Life-Threatening Infectious Diseases: Routinely Transmitted by Contact or Body Fluid Exposures*. Inhalation and gastrointestinal anthrax are not contagious from human to human and are not included in this list; they are, however, addressed in a newly added list of *Potentially Life-Threatening Infectious Diseases Caused by Agents Potentially Used for Bioterrorism or Biological Warfare*.

Comment: One commenter requested that syphilis be added to the disease list.

CDC response: While the transmission of syphilis via accidental needlestick injury may be a theoretical concern, there is only one case report of its occurrence in the medical literature, and even in that case, it is not clear whether active infection was due to a needlestick injury. Syphilis due to needlestick injury does not pose a significant public health risk to health care workers, and syphilis has not been added to the list.

Comment: Eight commenters desired that seasonal influenza and/or novel influenza be added to the disease list.

CDC response: CDC recognizes that influenza infections are potentially life-threatening. Therefore, CDC has

expanded the influenza viruses included on the list of *Potentially Life-Threatening Infectious Diseases: Routinely Transmitted Through Aerosolized Droplet Means* to broaden them beyond just avian influenza A viruses, but still avoid overburdening the reporting system. To achieve this, CDC has modified the list to specify novel influenza A viruses, as defined by the Council of State and Territorial Epidemiologists (CSTE).⁴ This specification includes avian influenza and adds other influenza A strains of animal origin and other new or unique reassortments. Regarding overburdening the reporting system, sec. 2695G(e) [42 U.S.C. 300ff-138(e)] states:

In any case in which the Secretary determines that, wholly or partially as a result of a public health emergency that has been determined pursuant to section 319(a), individuals or public or private entities are unable to comply with the requirements of this part, the Secretary may, notwithstanding any other provision of law, temporarily suspend, in whole or in part, the requirements of this part as the circumstances reasonably require.

Comment: Eight commenters suggested that pertussis be added to the disease list.

CDC response: CDC recognizes that pertussis is a highly communicable disease and is potentially life-threatening. Pertussis has been associated with significant adult morbidity.⁵ Additionally, an exposed and subsequently infected ERE might carry this highly contagious disease home to young children, and pertussis is associated with an increased number of fatalities in the very young.⁶ Therefore, CDC has added pertussis to the list of *Potentially Life-Threatening Infectious Diseases: Routinely Transmitted Through Aerosolized Droplet Means*.

Comment: One commenter noted that bioterrorist agents were not specifically mentioned in the disease list.

CDC response: The Select Agents list maintained by HHS⁷ lists biological agents that have the potential to pose a severe threat to human health and that may be used or adapted for bioterrorist attacks. Those agents on the list that are routinely transmitted human to human

are already listed in Part I "List of Potentially Life-Threatening Infectious Diseases to Which EREs Might be Exposed." CDC recognizes that the other agents on the Select Agents list would not typically exhibit human-to-human transmission or be considered contagious threats. However, in the setting of potential intentional modification to artificially increase transmissibility or lethality and deployment as bioweapons (potentially in quantities far greater than would naturally be encountered), atypical pathways of transmission may occur. In this case, EREs may be exposed by entering contaminated environments to care for victims and by exposure to contaminated individuals from those environments. Thus, CDC has added to the definition of exposed ("or, in the case of a select agent, from a surface or environment contaminated by the agent to an ERE.") and created the disease list category *Potentially Life-Threatening Infectious Diseases Caused by Agents Potentially Used for Bioterrorism or Biological Warfare*. This disease list category includes diseases caused by any transmissible agent included in the HHS Select Agents List including those that are not routinely transmitted human to human but may be transmitted via exposure to contaminated environments.⁸

Comment: One commenter requested rabies be removed from the disease list or that CDC add an explanation of its presence on the list.

CDC response: Rabies is an almost universally fatal viral disease that has no reliable treatment; therefore, if an exposure to the rabies virus has occurred, the best hope for prevention of the disease is timely post-exposure immunization (i.e., rabies vaccine with or without Human Rabies Immunoglobulin). Rabies virus is present in the saliva, nervous tissue, and spinal fluid of humans with the disease, and it is recommended protocol that a contact investigation be conducted and recommendations for any necessary post-exposure immunization be made any time there has been a diagnosis of rabies in a human patient.⁹ Thus, a brief explanation has been added regarding rabies exposure, and CDC will retain rabies on the list of *Potentially Life-Threatening Infectious Diseases*:

⁸ **Note:** 42 CFR 73 specifies special reporting requirements for Select Agents independent of these guidelines.

⁹ CDC. Human Rabies Prevention—United States, 2008: Recommendations of the Advisory Committee on Immunization Practices. MMWR 2008;57:1–26,28.

¹ Liu C, et al. Clinical practice guidelines by the Infectious Diseases Society of America for the treatment of methicillin-resistant *Staphylococcus aureus* infections in adults and children. Infectious Disease Society of America Guidelines. January 4, 2011. <http://cid.oxfordjournals.org/content/early/2011/01/04/cid.ciq146.full.pdf+html>. Accessed July 14, 2011.

² Liu C, et al. Clinical practice guidelines by the Infectious Diseases Society of America for the treatment of methicillin-resistant *Staphylococcus aureus* infections in adults and children. Infectious Disease Society of America Guidelines. January 4, 2011. <http://cid.oxfordjournals.org/content/early/2011/01/04/cid.ciq146.full.pdf+html>. Accessed July 14, 2011.

³ Gold H. Anthrax: a report of 117 cases. AMA Arch Int Med 1955;96:387–96.

⁴ Council of State and Territorial Epidemiologists. Novel influenza A virus infections: 2010 Case Definition. CSTE Position Statement Number: 09-ID-43. http://www.cdc.gov/osels/ph_surveillance/nndss/casedef/novel_influenzaA.htm. Accessed July 18, 2011.

⁵ De Serres G, et al. Morbidity of pertussis in adolescents and adults. J Infect Dis 2000;182:174–9.

⁶ CDC. Pertussis—United States, 2001–2003. MMWR 2005;54:1283–6.

⁷ 42 CFR 73.3, 73.4.

Routinely Transmitted by Contact or Body Fluid Exposures.

Comment: Two commenters recommended that certain diseases such as SARS-CoV, smallpox, avian influenza, and aerosolizable spores (*i.e.*, anthrax) be listed on a separate list rather than on the main list.

CDC response: CDC appreciates this comment. Accordingly, anthrax (except for the cutaneous manifestation) and smallpox (Variola virus) have been placed in the disease list category *Potentially Life-Threatening Infectious Diseases Caused by Agents Potentially Used for Bioterrorism or Biological Warfare*. SARS-CoV and avian influenza (now included as a “novel influenza”) will remain under *Potentially Life-Threatening Infectious Diseases: Routinely Transmitted Through Aerosolized Droplet Means* because this accurately reflects their mode of transmission.

Guidelines Describing the Circumstances in Which Employees May Be Exposed (Part II).

In this final notice, “exposed” is defined as “to be in circumstances in which there is recognized risk for transmission of an infectious agent from a human source to an ERE¹⁰ or, in the case of a Select Agent, from a surface or environment contaminated by the agent to an ERE.” See discussion of the inclusion of Select Agents, above. CDC received three comments regarding this section.

One commenter supported the way that Part I “List of Potentially Life-Threatening Infectious Diseases to Which Emergency Response Employees May Be Exposed” clearly outlined the various methods of disease transmission (contact or body fluid exposures, aerosolized airborne, and aerosolized droplet) that are utilized in determining risk of exposure. The other two commenters made substantive requests.

Comment: One commenter requested that aerosolized airborne and aerosolized droplet means of transmission be addressed separately in Part II “Guidelines Describing the Circumstances in Which Such Employees May Be Exposed to Such Diseases” as they were in Part I.

CDC response: CDC determined that there was benefit in the current approach to discussing aerosolized airborne and aerosolized droplet transmission in the same section in Part

II, limiting redundancy by providing language common to the two modes of transmission only once.

Comment: The final commenter requested that CDC provide more information about exposures, but did not specify what additional information was desired.

CDC response: There was not enough specificity provided with this comment for CDC to formulate a response. Additionally, CDC believes that the current content of the exposures description is sufficient.

Guidelines Describing the Manner in Which Medical Facilities Should Make Determinations (Part III)

Section 2695B(d) [42 U.S.C. 300ff–133(d)] specifies that medical facilities shall evaluate the facts submitted in an ERE’s request to make a determination of whether, on the basis of the medical information possessed by the facility regarding the victim involved, the emergency response employee was exposed to an infectious disease included on the list issued pursuant to sec. 2695(a)(1) [42 U.S.C. 300ff–131(a)(1)] and sets certain parameters on these responses. CDC received six comments regarding medical facilities.

Two commenters were supportive of the medical facility guidelines. One supported making the proposed guidelines final. The other was in agreement with the proposed criteria for making determination of exposure when responding to appropriate requests by an employer; the individual felt such interaction would result in the best determination.

Comment: Three commenters did not feel comfortable with the medical facilities’ authority to determine exposure. One commenter felt that the guidance should not allow a medical facility to overrule the designated officer’s determination that an exposure had occurred. Two commenters noted that Part III “Guidelines Describing the Manner in Which Medical Facilities Should Make Determination for Purposes of Section 2695B(d) [42 U.S.C. 300ff–133(d)]” appears to require medical facilities to conduct a second exposure evaluation, and they felt that the role of a medical facility should be solely to determine if a patient had a disease transmissible by aerosols, and if so, to provide information to the designated officer who would notify all potentially exposed EREs. One commenter stated that medical facility management and exposure guidelines are not adequate and will not work well.

CDC response: CDC notes that the role and responsibilities of medical facilities are specified in some detail in the

statute in sec. 2695B(d), (e), (f) [42 U.S.C. 300ff–133(d), (e), (f)]. In addition, sec. 2695B(g) [42 U.S.C. 300ff–133(g)] specifies the role of the public health officer in resolving differences of opinion between designated officers and medical facilities.

Notification

Under sec. 2695B(c)(2) [42 U.S.C. 300ff–133(c)(2)], a request for notification with respect to victims assisted shall be in writing and signed by the designated officer involved, and shall contain a statement of the facts collected pursuant to subsection (b)(1). Additionally, under sec. 2695B(e) [42 U.S.C. 300ff–133(e)], after receiving a request, a medical facility must make the applicable response as soon as is practicable, but not later than 48 hours after receiving the request. CDC received nine comments regarding notification.

Comment: Three commenters felt that the requirement for a written request was not practical. Of these commenters, two advocated for the use of modern technology allowing requests to be in a documented verbal or electronic form followed by a written communication. Three commenters felt that the 48-hour time frame for response by the medical facility is too long and that this time frame may unnecessarily restrict or delay notifications to EREs. One commenter felt there was a problem with medical facilities taking responsibility for notifying exposed EREs of lab results that were available a day or two after the victim arrived at the facility.

CDC response: Processes specified in the PHS Act cannot be altered through the guidelines published in this final notice. Moreover, the scope of this final notice is limited to those duties assigned to CDC through the Secretary’s Delegation of Authority (75 FR 40842).

Comment: One commenter requested additional clarification or emphasis that the statute requires medical facilities to notify EREs of possible exposure to TB and that the facilities notify the designated officers of the ERE agencies regarding the newly added airborne and droplet transmitted diseases.

CDC response: CDC has placed TB on the list of *Potentially Life-Threatening Infectious Diseases: Routinely Transmitted Through Aerosolized Airborne Means*; thus it will require routine notification. Additionally, sec. 2695(c) of Title XXVI [42 U.S.C. 300ff–131(c)] addresses dissemination by requiring that CDC, as delegated by the Secretary of HHS, shall transmit to State public health officers copies of the list and guidelines it developed with the request that the officers disseminate

¹⁰ 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.

such copies as appropriate throughout the State and make such copies available to the public.

Comment: One commenter felt that non-transporting emergency response employees should be included in notifications.

CDC response: As previously noted, “emergency response employee” is not defined in the PHS Act and CDC’s authority for purposes of this notice is limited to those duties set out in the Delegation of Authority (75 FR 40842). The duties of an individual considered an ERE are described in 42 U.S.C. 300ff-133(a) as having “attended, treated, assisted, or transported the victim pursuant to the emergency.”

HIPAA

CDC received three comments regarding the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which provides confidentiality for patients’ protected health information, including health conditions, treatments, or payment records. In general, HIPAA rules would apply to EREs and medical facilities caring for the victims of emergencies.

Comment: One commenter recommended the addition of a statement directing ERE companies to provide appropriate requests to medical facilities while also adhering to HIPAA rules in the process.

CDC response: CDC, in consultation with the HHS Office for Civil Rights, notes that the HIPAA rules regarding privacy of individually identifiable health information apply to HIPAA covered entities and, to some extent, to their business associates. Those ERE companies that are HIPAA covered entities or business associates must adhere to the relevant HIPAA rules. While ERE companies that are neither HIPAA covered entities nor their business associates are not subject to HIPAA, we expect that the designated officers of all ERE companies will only request relevant information of medical facilities; i.e., whether there was sufficient information to determine whether the emergency response employee involved had been exposed and, if so, what determination did the facility make. What information can be requested and reported can be found in sec. 2695C(a)(1), (2) [42 U.S.C. 300ff-134(a)(1), (2)] and sec. 2695D(a)(1), (2) and (b)(1)–(3) [42 U.S.C. 300ff-135(a)(1), (2) and (b)(1)–(3)]. Section 2695G(c) [42 U.S.C. 300ff-138(c)] states that “[t]his part may not be construed to authorize or require any medical facility, any designated officer of emergency response employees, or any such employee, to disclose identifying

information with respect to a victim of an emergency or with respect to an emergency response employee.”

Comment: Two commenters recommended a clear statement that notification of source patient test results or other information is not a HIPAA violation.

CDC response: CDC, in consultation with the HHS Office for Civil Rights, notes that under the HIPAA Privacy Rule, if a law requires the disclosure of individually identifiable health information, a covered entity (such as a medical facility) may comply with such statute provided that the disclosure complies with and is limited to the relevant requirements of such law. Public Law 111-87 requires medical facilities that make determinations as to whether EREs have been exposed to an infectious disease to notify the designated officer who submitted the request. If the determination is that the employee has been exposed, the medical facility shall provide the name of the infectious disease involved and the date on which the victim of the emergency was transported by EREs to the facility. Other than this information, Public Law 111-87 does not authorize medical facilities to disclose identifying information with respect to either a victim of an emergency or an ERE. A medical facility would not violate HIPAA by complying with this requirement of the PHS Act.

Patient Testing

CDC received four comments regarding testing victims of emergencies for potentially life-threatening infectious diseases. Results of such tests are generally needed for medical facilities to make definitive determinations about potential ERE exposures.

Comment: Three commenters noted that there are state laws allowing for the testing of victims if an ERE can document an exposure; one of these three commenters recommended it be stated that State and local laws be used when they are more expansive than the Federal law.

CDC response: CDC has not added that specific statement to this final notice, because it is outside the scope of this notice, which is limited to those duties assigned to CDC through the Secretary’s Delegation of Authority. However, Section 2695G(f) [42 U.S.C. 300ff-138(f)] states that “[n]othing in this part shall be construed to limit the application of State or local laws that require the provision of data to public health authorities.”

Comment: One commenter requested that CDC strongly recommend patient testing.

CDC response: Patient testing is not authorized under sec. 2695G(b) [42 U.S.C. 300ff-138(b)], which specifically states that “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 an infectious disease.”

General

CDC received 7 general comments not focused on a specific part of the December 13, 2010, **Federal Register** notice.

Comment: Two commenters stated that the Act is important and urged CDC to move as quickly as possible to implement.

CDC response: CDC agrees and is working toward that end.

Comment: Two commenters recommended that more research is needed regarding how to protect EREs, and encouraged the National Institute for Occupational Safety and Health (NIOSH) to conduct more research.

CDC response: CDC agrees that this remains an important area of investigation.

Comment: One commenter recommended that Title XXVI, Part G of the PHS Act be a standalone Public Law.

CDC response: The requested action is outside the scope of this final notice and Delegation of Authority.

Comment: One commenter recommended that CDC/NIOSH facilitate a structured process to engage key stakeholders in development of any regulation and guidance materials related to the Ryan White HIV/AIDS Treatment Extension Act.

CDC response: CDC appreciates this comment and agrees that transparency and stakeholder involvement are extremely important. This is why CDC published its draft guidance in the **Federal Register** and requested public comments to assist in development of the final guidance. Even after this final notice is issued, CDC will encourage stakeholders to continue to provide comments and intends to establish a Web site to facilitate ongoing communication.

Comment: One commenter stated that he or she supports and would be willing to participate in pre-rabies vaccination for wildlife rehabilitators and others who volunteer or are employed working with animals.

CDC response: Although CDC appreciates this response, this topic is outside the scope of this notice and the Delegation of Authority.

Final Notice

For the reasons discussed in the preamble, CDC amends Implementation of Section 2695 (42 U.S.C. 300ff–131) Public Law 111–87: Infectious Diseases and Circumstances Relevant to Notification Requirements as follows:

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

The Ryan White HIV/AIDS Treatment Extension Act of 2009¹¹ (Pub. L. 111–87) amended the Public Health Service Act (PHS Act, 42 U.S.C. 201–300ii) and addresses notification procedures and requirements for medical facilities and state public health officers and their designated officers regarding exposure of emergency response employees (EREs) to potentially life-threatening infectious diseases.¹² (See Title XXVI, Part G of the PHS Act, codified as amended at 42 U.S.C. 300ff–131 to 300ff–140). This document sets forth the final list of diseases to which these provisions apply; final guidelines describing circumstances under which exposure to listed diseases may occur, and final guidelines for determining whether an exposure to the listed diseases has occurred, as required by the Act. The final list of diseases and guidelines incorporate comments received by CDC on a draft list and guidelines (75 FR 77642, December 13, 2010).

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- Part II. Guidelines Describing the Circumstances in Which Emergency Response Employees May Be Exposed to Such Diseases.
- 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)].

Definitions

The following definitions are used in the list of diseases and guidelines:

Aerosol means tiny particles or droplets suspended in air. These range

in diameter from about 0.001 to 100 μm .¹³

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.¹⁴

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.¹⁵

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.¹⁶

¹³ 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 22, 2011.

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

¹⁴ 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 22, 2011.

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 22, 2011.

¹⁵ 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 22, 2011.

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 22, 2011.

¹⁶ Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee. 2007 Guideline for Isolation

Exposed means to be in circumstances in which there is recognized risk for transmission of an infectious agent from a human source to an ERE¹⁷ or, in the case of a Select Agent, from a surface or environment contaminated by the agent to an ERE.

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 in 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

The *List of Potentially Life-Threatening Infectious Diseases to Which Emergency Response Employees May Be Exposed* is divided into four sections: Diseases routinely transmitted by contact or body fluid exposures, those routinely transmitted through aerosolized airborne means, those routinely transmitted through aerosolized droplet means, and those caused by agents potentially used for bioterrorism or biological warfare. Diseases often have multiple transmission pathways. However, for purposes of this classification, diseases routinely transmitted via the aerosol airborne or aerosol droplet routes are so classified, even if other routes, such as contact transmission, also occur. CDC will continue to monitor the scientific literature on these and other 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.

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

- Anthrax, cutaneous (*Bacillus anthracis*)
- Hepatitis B (HBV)
- Hepatitis C (HCV)

Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. <http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf>. Accessed September 22, 2011.

¹⁷ 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 22, 2011.

¹¹ The Ryan White Act (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.

¹² See Title XXVI, Part G of the PHS Act, codified as amended at 42 U.S.C. 300ff–131 to 300ff–140.

- Human immunodeficiency virus (HIV)
- Rabies (Rabies virus)
- Vaccinia (Vaccinia virus)
- Viral hemorrhagic fevers (Lassa, Marburg, Ebola, Crimean-Congo, and other viruses yet to be identified)¹⁸

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.”¹⁹

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

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.”²⁰

- Diphtheria (*Corynebacterium diphtheriae*)
- Novel influenza A viruses as defined by the Council of State and Territorial Epidemiologists (CSTE)²¹
- Meningococcal disease (*Neisseria meningitidis*)
- Mumps (Mumps virus)
- Pertussis (*Bordetella pertussis*)
- Plague, pneumonic (*Yersinia pestis*)
- Rubella (German measles; Rubella virus)
- SARS-CoV

D. Potentially Life-Threatening Infectious Diseases Caused by Agents Potentially Used for Bioterrorism or Biological Warfare

These diseases include those caused by any transmissible agent included in the HHS Select Agents List.²² Many are

¹⁸ For most viral hemorrhagic fevers (VHFs), routine transmission is limited to transmission from a zoonotic reservoir or direct contact with an infected person (e.g. Ebola virus, Marburg virus) or through arthropod-borne transmission (e.g. Nipah virus), however prolonged close contact is likely necessary. Aerosol transmission does not occur in natural (non-laboratory) settings.

¹⁹ Section 2695(b) [42 U.S.C. 300ff–131(b)].

²⁰ Section 2695(b) [42 U.S.C. 300ff–131(b)].

²¹ Council of State and Territorial Epidemiologists, Position Statement Number: 09–ID–43. Available at http://www.cdc.gov/osels/ph_surveillance/nndss/casedef/novel_influenzaA.htm (Accessed July 18, 2011).

²² 42 CFR 73.3, 73.4.

not routinely transmitted human to human but may be transmitted via exposure to contaminated environments. (See the special note in Part II.C for further explanation.) The HHS Select Agents List is updated regularly and can be found on the National Select Agent Registry Web site: <http://www.selectagent.gov/>.

Part II. Guidelines Describing the Circumstances in Which Emergency Response 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.”²³

Occupational exposure to cutaneous anthrax would include exposure of an ERE’s nonintact skin or mucous membrane to drainage from a cutaneous anthrax lesion; percutaneous injuries with sharp instruments potentially contaminated with lesion drainage should also be considered exposures. Contact with blood or other bodily fluids is not thought to pose a significant risk for anthrax transmission. Occupational exposure to rabies would include exposure of an ERE’s wound, nonintact skin, or mucous membrane to saliva, nerve tissue, or cerebral spinal fluid from an infected individual. Percutaneous injuries with contaminated sharp instruments should be considered exposures because of potential contact with infected nervous tissue. Intact skin contact with infectious materials or contact only with

blood, urine, or feces is not thought to pose a significant risk for rabies transmission. 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 or other mucopurulent lesion caused by vaccinia infection.

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

C. Special Note on Exposure to Diseases Transmitted by Agents Potentially Used for Bioterrorism or Biological Warfare

The Select Agents list²⁴ maintained by HHS, lists biological agents and

²⁴ Notwithstanding any notification procedures specified here, all reporting requirements that are required under 42 CFR part 73 remain applicable. The HHS Select Agents list is updated regularly and can be found on the National Select Agent Registry Web site: <http://www.selectagent.gov/>. Agents on the HHS select agents list at the time of publication of this notice include the following:

42 CFR 73.3:

Botulinum neurotoxin producing species of Clostridium; Cercarial dermatitis (Swimmer’s itch); Herpes B virus; *Coccidioides posadasii*/*Coccidioides immitis*; *Coxiella burnetii*; Crimean-Congo haemorrhagic fever virus; Eastern Equine Encephalitis virus; Ebola viruses; *Francisella tularensis*; Lassa fever virus; Marburg virus; Monkeypox virus; Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus); *Rickettsia prowazekii*; *Rickettsia rickettsii*; South American Haemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito); Tick-borne encephalitis complex (flavi) viruses (Central European Tick-borne encephalitis, Far Eastern Tick-borne encephalitis [Russian Spring and Summer encephalitis, Kyasanur Forest disease, Omsk Hemorrhagic Fever]); Variola major virus (Smallpox virus) and Variola minor virus (Alastrim); *Yersinia pestis*.

42 CFR 73.4:

Bacillus anthracis; *Brucella abortus*; *Brucella melitensis*; *Brucella suis*; *Burkholderia mallei* (formerly *Pseudomonas mallei*); *Burkholderia*

²³ 29 CFR 1910.1030.

toxins that have the potential to pose a severe threat to human health and that may be used for or adapted for bioterrorist attacks. There are special reporting requirements for Select Agents, as detailed in 42 CFR part 73. Those agents included on the HHS Select Agents List that are routinely transmitted person to person and for which natural transmission remains a significant concern are categorized in the "List of Potentially Life-Threatening Infectious Diseases to Which Emergency Response Employees May be Exposed," Part I above, according to their modes of transmission. The remaining agents on the Select Agent List would not typically exhibit human-to-human transmission or be considered contemporary contagious threats. However, in the setting of potential intentional modification to artificially increase transmissibility and/or lethality ("weaponization") and deployment as bio-weapons (potentially in quantities far greater than would naturally be encountered), atypical pathways of transmission may occur. In this case, EREs may be exposed by entering contaminated environments to care for victims and by exposure to contaminated individuals from those environments.

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 sec. 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.²⁵ Information about infectious disease transmission provided in relevant CDC guidance documents²⁶ 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 sec. 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 sec. 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 sec. 2695B(d) [42 U.S.C. 300ff-133(d)]:

- (1) The ERE involved has been exposed to an infectious disease included on the list:
 - 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:
 - 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:

- 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:

- 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.

Dated: October 26, 2011.

James W. Stephens,
Director, Office of Science Quality, Office of the Associate Director for Science, Centers for Disease Control and Prevention.

[FR Doc. 2011-28234 Filed 11-1-11; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-6049-N]

Medicare, Medicaid, and Children's Health Insurance Programs; Provider Enrollment Application Fee Amount for Calendar Year 2012

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the \$523 calendar year (CY) 2012

pseudomallei (formerly *Pseudomonas pseudomallei*); Hendra virus; Nipah virus; Rift Valley fever virus; Venezuelan Equine Encephalitis virus.

²⁵ Section 2695B [42 U.S.C. 300ff-133].

²⁶ For example:

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.

CDC. Updated U.S. Public Health Service Guidelines for the Management of Occupational

Exposures to HIV and Recommendations for Postexposure Prophylaxis. MMWR 2005;54 (No. RR-9):1-17.