

delegated herein prior to the effective date of this delegation.

Robert McGowan,
Chief of Staff, CDC.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Ryan White HIV/AIDS Treatment Extension Act of 2009: Update to the List of Potentially Life-Threatening Infectious Diseases to Which Emergency Response Employees May Be Exposed To Include Coronavirus Disease 2019 (COVID-19), the Disease Caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Notice.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH), of the Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), is adding coronavirus disease 2019 (COVID-19), the disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), to the *List of Potentially Life-Threatening Infectious Diseases to Which Emergency Response Employees May Be Exposed*. The list and companion guidelines are published by NIOSH pursuant to the Ryan White HIV/AIDS Treatment Extension Act of 2009. NIOSH encourages medical facilities to review the agency's guidelines describing the manner in which medical facilities should make determinations on whether an emergency response employee was exposed to COVID-19, the disease caused by SARS-CoV-2.

FOR FURTHER INFORMATION CONTACT: Rachel Weiss, Office of the Director, NIOSH; 1090 Tusculum Avenue, MS:C-48, Cincinnati, OH 45226; telephone (855) 818-1629 (this is a toll-free number); email NIOSHregs@cdc.gov.

SUPPLEMENTARY INFORMATION:

Statutory Authority

The Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990 (Pub. L. 101-381) was reauthorized in 1996, 2000, 2006, and 2009. The most recent reauthorization, 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) and, pursuant to Section 2695, requires the HHS Secretary to establish the following: A list of potentially life-threatening infectious diseases, including emerging infectious diseases, to which emergency response employees (ERE) may be exposed while responding to emergencies; guidelines describing circumstances in which EREs may be exposed to these diseases, taking into account the conditions under which emergency response is provided; and guidelines describing the manner in which medical facilities should make determinations about exposures to EREs.

In a **Federal Register** notice published on July 14, 2010, the HHS Secretary delegated this responsibility to the CDC Director.¹ The CDC Director further assigned the responsibility to the NIOSH Director and formally re-delegated the authority to develop the list and guidelines to NIOSH on August 27, 2018.²

Addition of COVID-19, the Disease Caused by the Virus SARS-CoV-2, to the List of Potentially Life-Threatening Infectious Diseases to Which Emergency Response Employees May Be Exposed

The list of potentially life-threatening infectious diseases maintained by NIOSH is available in a **Federal Register** notice published on November 2, 2011 (76 FR 67736), available on the NIOSH website at <https://www.cdc.gov/niosh/topics/ryanwhite/default.html>. With this notice the NIOSH *List of Potentially Life-Threatening Infectious Diseases to Which Emergency Response Employees May Be Exposed* is updated by the addition of the following:

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

■ COVID-19 (the disease caused by the virus SARS-CoV-2)

COVID-19, the disease caused by the virus SARS-CoV-2, is being added to the existing list. COVID-19, the disease caused by the virus SARS-CoV-2, is a potentially life-threatening emerging infectious disease that is thought to be spread primarily by respiratory droplets generated by an infectious person through events such as coughing or sneezing (<https://www.cdc.gov/coronavirus/2019-ncov/index.html>).

¹ 75 FR 40842.

² 83 FR 50379 (October 4, 2018).

ERE may be exposed to COVID-19, the disease caused by the virus SARS-CoV-2, by a victim of an emergency who may be infected with SARS-CoV-2 while attending to, treating, assisting, or transporting the victim to a medical facility. Medical facilities should review the NIOSH guidelines describing the manner in which medical facilities should make determinations about exposures to life-threatening infectious diseases, including COVID-19, available on the NIOSH website at <https://www.cdc.gov/niosh/topics/ryanwhite/default.html>.

John J. Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Emergency Use Authorization Declaration

ACTION: Notice of Emergency Use Authorization Declaration.

SUMMARY: The Secretary of Health and Human Services (HHS) is issuing this notice pursuant to section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act. On February 4, 2020, the Secretary determined pursuant to his authority under section 564 of the FD&C Act that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019-nCoV). The virus is now named SARS-CoV-2, which causes the illness COVID-19. On the basis of this determination, he also declared that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

DATES: The determination was effective February 4, 2020, and this declaration is effective March 24, 2020.

FOR FURTHER INFORMATION CONTACT:

Robert P. Kadlec, M.D., MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human