

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](mailto: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.<sup>1</sup> 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.<sup>2</sup>

#### 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>).

<sup>1</sup> 75 FR 40842.

<sup>2</sup> 83 FR 50379 (October 4, 2018).

EREs 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

Services, 200 Independence Avenue SW, Washington, DC 20201, Telephone (202) 205-2882 (this is not a toll free number).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Under section 564 of the FD&C Act, 21 U.S.C. 360bbb-3, the Commissioner of the Food and Drug Administration (FDA), acting under delegated authority from the Secretary of HHS, may issue an Emergency Use Authorization (EUA) authorizing (1) the emergency use of an unapproved drug, an unapproved or uncleared device, or an unlicensed biological product; or (2) an unapproved use of an approved drug, approved or cleared device, or licensed biological product. Before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of four determinations: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a, chemical, biological, radiological, or nuclear (“CBRN”) agent or agents; (2) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F-2 of the Public Health Service (PHS) Act sufficient to affect national security or the health and security of United States citizens living abroad; (3) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of title 10 or title 50, of attack with (i) a biological, chemical, radiological, or nuclear agent or agents; or (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces; or (4) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent or agents.

Based on any of these four determinations, the Secretary of HHS may then declare that circumstances exist that justify the EUA, at which point the FDA Commissioner may issue an EUA if the criteria for issuance of an authorization under section 564 of the FD&C Act are met. The Office of the

Assistant Secretary for Preparedness and Response, HHS, requested that the FDA, HHS, issue an EUA for certain medical devices to allow the Department to take response measures based on information currently available about the virus that causes COVID-19. The determination of a public health emergency, and the declaration that circumstances exist justifying emergency use of certain medical devices by the Secretary of HHS, as described below, enable the FDA Commissioner to issue an EUA for these devices for emergency use under section 564 of the FD&C Act.

**II. Determination by the Secretary of Health and Human Services**

On February 4, 2020, pursuant to section 564 of the FD&C Act, I determined 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.

**III. Declaration of the Secretary of Health and Human Services**

On March 24, 2020, on the basis of my determination of 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 the novel (new) coronavirus, SARS-CoV-2, I 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.

Notice of the EUAs issued by the FDA Commissioner pursuant to this determination and declaration will be provided promptly in the **Federal Register** as required under section 564 of the FD&C Act.

Dated: March 24, 2020.

**Alex M. Azar II,**

*Secretary of Health and Human Services.*

[FR Doc. 2020-06541 Filed 3-25-20; 4:15 pm]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meetings**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel NIAAA Review Subcommittee Member Conflict Review Panel.

*Date:* April 7, 2020.

*Time:* 1:00 p.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Suite 2118, Bethesda, MD 20817 (Telephone Conference Call).

*Contact Person:* Philippe Marmillot, Ph.D., National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817 301-443-2861 [marmillotp@mail.nih.gov](mailto:marmillotp@mail.nih.gov).

*Name of Committee:* National Institute on Alcohol Abuse and Alcoholism Initial Review Group Epidemiology, Prevention and Behavior Research Review Subcommittee.

*Date:* June 8, 2020.

*Time:* 8:30 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Conference Room B, Bethesda, MD 20817.

*Contact Person:* Anna Ghambaryan, M.D., Ph.D., Scientific Review Officer, Extramural Project Review Branch Office of Extramural Activities National Institute on Alcohol Abuse and Alcoholism, 6700b Rockledge Drive, Room 2120, MSC 6902 Bethesda, MD 20892, 301-443-4032, [anna.ghambaryan@nih.gov](mailto:anna.ghambaryan@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research