

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Infant and Maternal Mortality (Formerly the Advisory Committee on Infant Mortality)

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Infant and Maternal Mortality (ACIMM) has scheduled a public meeting. Information about ACIMM and the agenda for this meeting can be found on the ACIMM website at <https://www.hrsa.gov/advisory-committees/infant-mortality/index.html>.

DATES:

- September 13, 2022, 9 a.m.–4 p.m. Central Time (CT);
- September 14, 2022, 9 a.m.–5 p.m. CT; and
- September 15, 2022, 9 a.m.–12 p.m. CT.

ADDRESSES: This meeting will be conducted in-person at Mystic Lake Center, 2400 Mystic Lake Blvd. NW, Prior Lake, MN 55372. The meeting will also be held via webinar. *The webinar link and log-in information will be available at ACIMM's website before the meeting: <https://www.hrsa.gov/advisory-committees/infant-mortality/index.html>.* Refer to the ACIMM website for any updated information concerning the meeting, including the potential for the meeting to be held virtually only via webinar. If the meeting is changed to virtual only, an update will be posted on the website listed above on or about August 30, 2022.

FOR FURTHER INFORMATION CONTACT: Vanessa Lee, MPH, Designated Federal Official, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room 18N84, Rockville, Maryland 20857; 301-443-0543; or SACIM@hrsa.gov.

SUPPLEMENTARY INFORMATION: The ACIMM is authorized by section 222 of the Public Health Service Act (42 U.S.C. 217a), as amended. The Committee is governed by provisions of Public Law 92-463, as amended, (5 U.S.C. App. 2), which sets forth standards for the formation and use of Advisory Committees.

The ACIMM advises the Secretary of HHS on department activities,

partnerships, policies, and programs directed at reducing infant mortality, maternal mortality and severe maternal morbidity, and improving the health status of infants and women before, during, and after pregnancy. The Committee provides advice on how to coordinate federal, state, local, tribal, and territorial governmental efforts designed to improve these outcomes, as well as influence similar efforts in the private and voluntary sectors. With its focus on underlying causes of the disparities and inequities seen in birth outcomes for women and infants, the Committee also advises the Secretary of HHS on the health, social, economic, and environmental factors contributing to the inequities and proposes structural, policy, and/or systems level changes.

The agenda for the September 13–15, 2022, meeting is being finalized and may include the following topics: infant and maternal mortality among American Indian/Alaska Native (AI/AN) women and infants; indigenous health; and federal program updates. In addition to these topics, it is expected that there will be a discussion of recommendations by the ACIMM to the Secretary of HHS on improving birth outcomes among AI/AN mothers and infants, and then a vote on whether to send the recommendations forward to the Secretary of HHS. Agenda items are subject to change as priorities dictate.

Members of the public will have the opportunity to provide written or oral comments. Requests to submit a written statement or make oral comments to the ACIMM should be sent to Vanessa Lee, using the email address above, at least 3 business days prior to the meeting. Public participants may submit written statements in advance of the scheduled meeting by emailing SACIM@hrsa.gov. Oral comments will be honored in the order they are requested and may be limited as time allows.

Individuals who plan to attend and need special assistance or some reasonable accommodation should notify Vanessa Lee at the contact information listed above at least 10 business days prior to the meeting.

Maria G. Button,

Director, Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Department of Health and Human Services

Office of the Secretary; Emergency Use Authorization; Monkeypox Virus Vaccine

ACTION: Notice.

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 August 9, 2022, the Secretary determined pursuant to his authority under section 564 of the FD&C Act 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 that involves monkeypox virus.

On the basis of this determination, he also declared that circumstances exist justifying the authorization of emergency use of vaccines for use against monkeypox virus pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

DATES: The determination and declaration are valid August 9, 2022.

FOR FURTHER INFORMATION CONTACT: Dawn O'Connell, Assistant Secretary for Preparedness and Response, Administration for Strategic Preparedness and Response, 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, the Commissioner of Food and Drugs of the U.S. 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