

services is a key component of the HRSA mission. HRSA’s Maternal and Child Health Bureau (MCHB) provides funding to address some of the most urgent issues influencing the high rates of maternal mortality. Recent efforts to address persistent disparities in maternal, infant, and child health have employed a “life course” perspective and health equity lens focused on health promotion and disease prevention. The life course approach can be defined as analyzing people’s lives within structural, social, and cultural contexts through a defined sequence of age categories that people are normally expected to pass through as they progress from birth to death. Health equity is defined as the attainment of the highest level of health for all people.

Achieving health equity for pregnant and postpartum women will require attention to barriers in access to quality health services and promotion of equal opportunities to seek the highest possible level of health and well-being. Achieving health equity also requires a focus on social determinants of health.

With this emphasis on improving maternal health across the life course and promoting optimal health for all mothers, HRSA is employing a multipronged strategy to address maternal mortality and severe maternal morbidity through the following suite of programs:

1. The State Maternal Health Innovation Program,

2. The Alliance for Innovation on Maternal Health Program,
3. The Alliance for Innovation on Maternal Health—Community Care Initiative,
4. The Rural Maternity and Obstetrics Management Strategies Program, and
5. The Supporting Maternal Health Innovation Program.

MCHB is conducting a portfolio-wide evaluation of HRSA-supported Maternal Health Programs with a primary focus on reducing maternal mortality. Through this evaluation, HRSA seeks to identify individual and/or collective strategies, interrelated activities, and common themes within and across the Maternal Health Programs that may be contributing to or driving improvements in key maternal health outcomes. HRSA seeks to ascertain which components should be elevated and replicated to the national level, as well as inform future investments to reduce rates of maternal mortality and severe maternal morbidity.

*Need and Proposed Use of the Information:* HRSA seeks to understand the impact of HRSA’s investments into maternal health programs. These five HRSA maternal health programs represent a total of 12 state-based grantees and three grantees with the potential for national reach. In understanding the strategies that are most effective in reducing maternal morbidity and mortality, HRSA will be able to determine which program

elements could be replicated and/or scaled up nationally.

*Likely Respondents:* Likely respondents are recipients of the cooperative agreements mentioned above (State Maternal Health Innovation Program, Alliance for Innovation on Maternal Health Program, Alliance for Innovation on Maternal Health—Community Care Initiative, Rural Maternity and Obstetrics Management Strategies Program, and Supporting Maternal Health Innovation Program) which include 11 state health agencies, 2 national organizations, and 2 academic organizations.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Instrument 1: Interview guide for grantee staff .....	75	1	75	1.00	75.0
Instrument 2: Interview guide for HRSA POs .....	7	1	7	1.50	10.5
Instrument 3: Partnership Survey .....	290	1	290	0.25	72.5
Instrument 4: Web-based data collection tool .....	15	1	15	0.50	7.5
Total .....	387	.....	387	.....	165.5

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency’s functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information

technology to minimize the information collection burden.

**Maria G. Button,**

*Director, Executive Secretariat.*

[FR Doc. 2020–12308 Filed 6–5–20; 8:45 am]

BILLING CODE 4165–15–P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of the Secretary**

**Second Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19**

**ACTION:** Notice of amendment.

**SUMMARY:** The Secretary issues this amendment pursuant to section 319F–3 of the Public Health Service Act to clarify that Covered Countermeasures

under the Declaration include qualified pandemic and epidemic products that limit the harm COVID-19 might otherwise cause.

**DATES:** This amendment to the Declaration as published on March 17, 2020 (85 FR 15198) was effective as of February 4, 2020.

**FOR FURTHER INFORMATION CONTACT:** Robert P. Kadlec, MD, 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.

**SUPPLEMENTARY INFORMATION:** The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from, the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving “willful misconduct” as defined in the PREP Act. Under the PREP Act, a Declaration may be amended as circumstances warrant.

The PREP Act was enacted on December 30, 2005, as Public Law 109-148, Division C, § 2. It amended the Public Health Service (PHS) Act, adding section 319F-3, which addresses liability immunity, and section 319F-4, which creates a compensation program. These sections are codified at 42 U.S.C. 247d-6d and 42 U.S.C. 247d-6e, respectively. Section 319F-3 of the PHS Act has been amended by the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113-5, enacted on March 13, 2013, and the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law 116-136, enacted on March 27, 2020, to expand Covered Countermeasures under the PREP Act.

On January 31, 2020, the Secretary declared a public health emergency pursuant to section 319 of the PHS Act, 42 U.S.C. 247d, effective January 27, 2020, for the entire United States to aid in the response of the nation’s health care community to the COVID-19 outbreak. Pursuant to section 319 of the PHS Act, the Secretary renewed that Declaration on April 26, 2020. On March 10, 2020, the Secretary issued a Declaration under the PREP Act for medical countermeasures against COVID-19 (85 FR 15198, Mar. 17, 2020). On April 10, the Secretary amended the

March 10, 2020 Declaration under the PREP Act to extend liability immunity to covered countermeasures authorized under the CARES Act (85 FR 21012, Apr. 15, 2020).

The Secretary now amends the March 10, 2020, Declaration to clarify that covered countermeasures under the Declaration include qualified products that limit the harm COVID-19 might otherwise cause. 42 U.S.C. 247d-6d(i)(7)(A)(i)(II). This amendment is made in accordance with section 319F-3(b)(4) of the PHS Act, which authorizes the Secretary to amend a PREP Act Declaration at any time.

### **Description of This Amendment by Section**

#### *Section VI. Covered Countermeasures*

Section VI of the Declaration identifies the Covered Countermeasures for which the Secretary has recommended activities under section III of the Declaration. The PREP Act, as amended, states that a “Covered Countermeasure” must be a “qualified pandemic or epidemic product,” a “security countermeasure,” a drug, biological product, or device authorized for emergency use in accordance with sections 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic (FD&C) Act, or a respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, that the Secretary determines to be a priority for use during a public health emergency declared under section 319 of the PHS Act.

As described in section VI of the preamble to the March 10, 2020 Declaration, the PREP Act further defines a “qualified pandemic or epidemic product” to mean a drug or device, as defined in the FD&C Act or a biological product, as defined in the PHS Act that is (i) manufactured, used, designed, developed, modified, licensed or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or limit the harm such a pandemic or epidemic might otherwise cause; (ii) manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by such a drug, biological product, or device; or (iii) a product or technology intended to enhance the use or effect of such a drug, biological product, or device. A qualified pandemic or epidemic product must also be approved, cleared, licensed, or authorized for investigational or emergency use under the FD&C Act or

PHS Act. The Coronavirus Aid, Relief, and Economic Security (CARES) Act section 3103, Public Law 116-136 (Mar. 27, 2020), amended the PREP Act to add respiratory protective devices to the list of covered countermeasures so long as they are NIOSH approved and determined by the Secretary to be a priority for use during a public health emergency declared by the Secretary under section 319 of the Public Health Service Act. 85 FR 21012 (Apr. 15, 2020) (amending the Declaration effective March 27, 2020 to address this statutory change).

The Secretary intended section VI of the March 10, 2020 Declaration to include all qualified pandemic and epidemic products defined under the PREP Act and described in the preamble to the Declaration. But section VI of the March 10, 2020 Declaration identified Covered Countermeasures under the Declaration as “any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product.” 85 FR 15202. That description omitted the phrase from the statutory definition that qualified pandemic and epidemic products may also include products that “limit the harm such a pandemic or epidemic might otherwise cause.” The Secretary intended to identify the full range of qualified countermeasures in the March 10, 2020 Declaration. The Secretary accordingly amends section VI of the Declaration to clarify that intent.

Qualified pandemic and epidemic products that limit the harm that COVID-19 might otherwise cause are those that would not have been manufactured, administered, used, designed, developed, modified, licensed, or procured but for the COVID-19 pandemic, even when the products are manufactured, administered, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure health threats or conditions other than COVID-19. For example, the COVID-19 pandemic has resulted in shortages of certain drugs and devices that the FDA has authorized. These drugs and devices may be used for COVID-19 and other health conditions. Those shortages are “harm[s] [COVID-19] might otherwise cause.” Filling those shortages caused by COVID-19 reduces the strain on the American healthcare system by mitigating the escalation of adverse

health conditions from COVID-19 and non-COVID-19 causes. And mitigating that escalation conserves limited healthcare resources—from personal protective equipment to healthcare providers—which are essential in the whole-of-Nation response to the COVID-19 pandemic.

#### Amendments to Declaration

Amended Declaration for Public Readiness and Emergency Preparedness Act Coverage for medical countermeasures against COVID-19.

Section VI of the March 10, 2020, Declaration under the PREP Act for medical countermeasures against COVID-19, as amended April 10, 2020, is further amended pursuant to section 319F-3(b)(4) of the PHS Act, as described below. All other sections of the Declaration remain in effect as published at 85 FR 15198 (Mar. 17, 2020) and amended at 85 FR 21012 (Apr. 15, 2020).

Covered Countermeasures, section VI, delete in full and replace with:

#### VI. Covered Countermeasures

42 U.S.C. 247d-6b(c)(1)(B), 42 U.S.C. 247d-6d(i)(1) and (7)

Covered Countermeasures are

(1) any antiviral, any other drug, any biologic, any diagnostic, any other device, any respiratory protective device, or any vaccine, used

a. to treat, diagnose, cure, prevent, mitigate or limit the harm from COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or

b. to limit the harm that COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, might otherwise cause; or

(2) any device used in the administration of any such product, and all components and constituent materials of any such product.

Covered Countermeasures must be “qualified pandemic or epidemic products,” or “security countermeasures,” or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act, or a respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, that the Secretary determines to be a priority for use during a public health emergency declared under section 319 of the PHS Act.

**Authority:** 42 U.S.C. 247d-6d.

Dated: June 4, 2020.

**Alex M. Azar II,**

*Secretary of Health and Human Services.*

[FR Doc. 2020-12465 Filed 6-4-20; 4:15 pm]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Minority Health and Health Disparities; Notice of Closed Meeting

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

The meeting 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 Minority Health and Health Disparities Special Emphasis Panel; Addressing Racial Disparities in Maternal Mortality and Morbidity (R01 Clinical Trial Optional).

*Date:* July 29–30, 2020.

*Time:* 10:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Gateway Plaza, 7201 Wisconsin Avenue, Bethesda, MD 20817 (Virtual Meeting).

*Contact Person:* Deborah Ismond, Ph.D., Scientific Review Officer, Division of Scientific Programs, NIMHD, National Institutes of Health, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892, (301) 402-1366, [ismondldr@mail.nih.gov](mailto:ismondldr@mail.nih.gov).

Dated: June 2, 2020.

**Miguelina Perez,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2020-12335 Filed 6-5-20; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as

amended, notice is hereby given of the following meeting.

The meeting 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 of Allergy and Infectious Diseases Special Emphasis Panel, NIAID Resource Related Research Projects (R24 Clinical Trial Not Allowed).

*Date:* June 30, 2020.

*Time:* 3:00 p.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G49, Rockville, MD 20892 (Virtual Meeting).

*Contact Person:* Tara Capece, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health, 5601 Fishers Lane, Room 3G49, Rockville, MD 20852, 240-191-4281, [capecet2@niaid.nih.gov](mailto:capecet2@niaid.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: June 2, 2020.

**Tyeshia M. Roberson,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2020-12332 Filed 6-5-20; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of General Medical Sciences; Notice of Closed Meeting

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

The meeting 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