early consultation on the use of new surrogate endpoints, and exploring the use of real world evidence for use in regulatory decision-making, among other enhancements. This iteration includes commitments to enhance the use of regulatory tools to support drug development and review through incorporation of the patient's voice in drug development, expanded use of a benefit-risk framework in drug reviews, and advancing the use of complex innovative trial designs and model informed drug development. More information on these commitments can be found in the PDUFA VI commitment letter at: *https://www.fda.gov/media/99140/download.*

As part of the current authorization, FDA also modernized the user fee structure to improve program funding predictability, stability, and administrative efficiency. The new structure eliminated the supplement fees, replaced the establishment and product fees with a program fee, and shifted a greater proportion of the target revenue to the new more predictable and stable annual program fee. The agreement also included commitments to enhance management of user fee resources through the development of a resource capacity planning capability and third-party evaluation of program resource management, along with the publication and annual update of a 5-year financial plan.

Recognizing the challenges with hiring in PDUFA V, the current authorization also includes several commitments to improve the hiring and retention of critical review staff through modernization of FDA's hiring system, augmentation of hiring staff capacity and capabilities, creation of a dedicated function focused on staffing the program, reporting on hiring metrics, and a comprehensive and continuous assessment of hiring and retention. A list of the deliverables developed to meet PDUFA VI commitments is available on the FDA web page at: *https://www.fda.gov/industry/prescription-drug-user-fee-amendments/completed-pdufa-vi-deliverables.*

III. Public Meeting Information

A. Purpose and Scope of the Meeting

In general, the meeting format will include presentations by FDA and a series of panels representing different stakeholder groups. We will also provide an opportunity for other stakeholders to provide public comment at the meeting. FDA policy issues are beyond the scope of these reauthorization discussions. Accordingly, the presentations should focus on process enhancements and funding issues, and not focus on policy issues.

B. Participating in the Public Meeting

Registration: Persons interested in attending this virtual public meeting should register online by 11:59 p.m. Eastern Time on June 23, 2020, at *http://pdufavii-publicmeeting.eventbrite.com.* Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone.

Opportunity for Public Comment: Those who register online by June 23, 2020, will receive a notification about an opportunity to participate in the public comment session of the meeting. If you wish to speak during the public comment session, follow the instructions in the notification and identify which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their comments and request time jointly. All requests to make a public comment during the meeting must be received by July 9, 2020, 11:59 p.m. Eastern Time. We will determine the amount of time allotted to each commenter, the approximate time each comment is to begin, and will select and notify participants by July 16, 2020. No commercial or promotional material will be permitted to be presented at the public meeting.

Streaming Webcast of the Public Meeting: The webcast for this public meeting is available at *https://collaboration.fda.gov/pdufajuly2020/.*

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/industry/fda-user-fee-programs/prescription-drug-user-fee-amendments.*

Dated: June 2, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–12317 Filed 6–5–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Maternal Health Portfolio Evaluation Design, OMB No. 0906–xxxx—NEW

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than August 7, 2020.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Maternal Health Portfolio Evaluation Design OMB No. 0906–xxxx—NEW.

Abstract: HRSA programs provide health care to people who are geographically isolated, economically, or medically vulnerable. HRSA programs help those in need of high quality primary health care, such as pregnant women and mothers. Improving maternal health outcomes and access to quality maternity care

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