POPULATION, INTERVENTION, COMPARATOR, OUTCOME, TIMING, SETTING/STUDY DESIGN (PICOTS)—Continued

Element	Inclusion	Exclusion
Study design KQ1–3	• Randomized controlled trials (RCTs) • Non-randomized controlled trials, including quasi-experimental and controlled before-and-after studies. • Prospective cohort studies with or without comparison group with appropriate analytic technique. • Nested case-control studies.	• Narrative reviews. • Systematic reviews, meta-analyses, umbrella reviews, scoping reviews. • Systematic reviews or meta-analyses that exclusively include cross-sectional and/or uncontrolled studies. • Retrospective cohort studies. • All other study designs.
Language KQ1–3	English only (due to resource limitations)	
Geographic Location KQ1–3	Locations with food products or dietary supplements widely available to U.S. consumers, including those rated very high on the Human Development Index.	
Study size KQ1–3		Studies with N < 50 participants (for RCTs—25 participants analyzed per study arm), and without power calculation.
Publication date KQ1–3	2000 to present.	
Publication status KQ1–3	Articles published in peer-reviewed journals	Articles that have not been peer reviewed and are not published in peer-reviewed journals (*e.g.,* unpublished data, manuscripts, pre-prints, reports, abstracts, conference proceedings).

Abbreviations: AMDR = Acceptable macronutrient distribution range; GI = gastrointestinal; U.S. = United States; KQ = key question; CKD = chronic kidney disease; eGFR = estimated glomerular filtration rate; RCT = randomized controlled trial.

Dated: June 8, 2023.

Marquita Cullom,

Associate Director.

[FR Doc. 2023–12678 Filed 6–13–23; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Notice of Meeting

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) announces a Special Emphasis Panel (SEP) meeting on ''Implementing and Evaluating New Models for Delivering Comprehensive, Coordinated, Person-Centered Care to People with Long COVID (U18).'' This SEP meeting will be closed to the public.

DATES: July 27–28, 2023.

ADDRESSES: Agency for Healthcare Research and Quality, (Video Assisted Review), 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Jenny Griffith, Committee Management Officer, Office of Extramural Research, Education and Priority Populations, Agency for Healthcare Research and Quality, (AHRQ), 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 427–1557.

SUPPLEMENTARY INFORMATION: A Special Emphasis Panel is a group of experts in fields related to health care research who are invited by AHRQ, and agree to be available, to conduct on an as needed basis, scientific reviews of applications for AHRQ support. Individual members of the Panel do not attend regularly scheduled meetings and do not serve for fixed terms or a long period of time. Rather, they are asked to participate in a particular review meeting which requires their type of expertise.

The SEP meeting referenced above will be closed to the public in accordance with the provisions set forth in 5 U.S.C. 1009(d), 5 U.S.C. 552b(c)(4), and 5 U.S.C. 552b(c)(6). Grant applications for ''Implementing and Evaluating New Models for Delivering Comprehensive, Coordinated, Person-Centered Care to People with Long COVID (U18)'' are to be reviewed and discussed at this meeting. 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.

Agenda items for this meeting are subject to change as priorities dictate.

Dated: June 8, 2023.

Marquita Cullom,

Associate Director.

[FR Doc. 2023–12675 Filed 6–13–23; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

CDC Town Hall Meeting Concerning Future Directions for the Regional Centers for Public Health Preparedness and Response

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), announces a town hall meeting regarding the history and future of CDC-funded public health preparedness and response centers.

DATES: The town hall meeting will be held on Wednesday, June 28, 2023, from 1 p.m. to 5 p.m. EDT.

ADDRESSES: The town hall meeting is a virtual meeting and is open to the public, limited only by the webcast lines available. Registration is required. For information about accessing the webcast, visit *https://www.cdc.gov/orr/science/research.htm.*

FOR FURTHER INFORMATION CONTACT: Mary Leinhos, Ph.D., Office of Readiness and Response, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H21–5, Atlanta, Georgia 30329–4018; Phone: (770) 488–8619; Email: *CPROAR@CDC.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: The purpose of this town hall meeting is to provide an overview

and discussion of CDC-funded public health preparedness and response centers including the Centers for Public Health Preparedness and Response (CPHPs, 2004–2010), Preparedness and Response Learning Centers (PERLCs, 2010–2015), and Preparedness and Response Research Centers (PERRCs, 2008–2013). CDC seeks public input on opportunities and challenges for designing and implementing a network of regional centers for public health preparedness and response consistent with section 319F of the Public Health Service Act (42 U.S.C. 247d-6), as amended by the Consolidated Appropriations Act, 2023, sec. 2231 (*https://www.congress.gov/bill/117th-congress/house-bill/2617?r=1&s=3*).

How town hall meeting input will be used: As appropriate, future funding opportunities will use input from town hall participants, including the following: (1) examples of past successful activities and strategies; (2) potential partnership opportunities between CDC and awardees; and (3) types of technical assistance that would benefit funded projects.

Matters to be considered: The agenda will include presentations and discussions on three topic areas: (1) strengths and limitations of past CPHP, PERLC, PERRC and similar programs; (2) new program priorities as directed by sec. 2231 of the Consolidated Appropriations Act, 2023; and (3) discussion of how best to meet state, territorial, local, and tribal public health preparedness and response needs in the design, implementation, and coordination of regional centers under the new Consolidated Appropriations Act, 2023, sec. 2231 language. There will be prepared presentations, discussions among presenters and panelists, and a period for questions and public comments. Agenda items are subject to change as priorities dictate.

Specific questions for the public to consider: The goal of the new Consolidated Appropriations Act, 2023, sec. 2231 language is to implement a network of regional centers for public health preparedness and response for the purpose of increasing uptake of evidence-based preparedness and response programs. What have we learned from past CPHP, PERLC, PERRC and similar programs that will increase opportunities to reach this goal? How might CDC and funded regional centers leverage other initiatives and partners to enhance the evidence base and its implementation? Section 319F requires award recipients to coordinate with state, local, and tribal health departments and officials, health care facilities, and health care coalitions. Are there other entities that could be engaged at the regional level that members of the public recommend be included or informed about this work? What are the greatest public health preparedness and response needs that should be addressed to support the goals of section 319F in the regions?

Background: CDC's Office of Readiness and Response is hosting the town hall meeting with invited speakers representing public health and healthcare preparedness partners nationwide including from academia, government, and national associations to address new authorization language requiring the establishment and maintenance of a network of regional centers for public health preparedness and response.

CDC commissioned the National Academies of Sciences, Engineering, and Medicine to address a longstanding need for a comprehensive, systematic review and grading of public health emergency preparedness and response (PHEPR) evidence for practice. The resulting 2020 consensus study report, *Evidence-Based Practice for Public Health Emergency Preparedness and Response* (*https://doi.org/10.17226/25650*), reviews the status of evidence on PHEPR practices and the improvements needed to advance the field and strengthen the PHEPR system. The report provides recommendations seeking to strengthen PHEPR research and support effective and sound evidence-based PHEPR practice.

Section 2231 of the Consolidated Appropriations Act, 2023 amended section 319F to incorporate new requirements and priorities for establishing or maintaining a network of Centers for Public Health Preparedness and Response, including coordination of activities with partners and implementation of evidence-informed or evidence-based PHEPR practices.

The discussion and feedback generated during the town hall will assist CDC in developing program guidance related to workplan development and overall structure of regional coordinating bodies. Ultimately, feedback will be used to inform the establishment and maintenance of a network of regional centers. Participants may provide individual feedback or perspectives. CDC is not seeking consensus advice or recommendations from participants.

Dated: June 9, 2023.

Tiffany Brown,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2023–12741 Filed 6–13–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0775]

Content of Premarket Submissions for Device Software Functions; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Content of Premarket Submissions for Device Software Functions.'' This guidance document is intended to provide information regarding the recommended documentation sponsors should include in premarket submissions for FDA's evaluation of safety and effectiveness of device software functions, which are functions that meet the definition of a device under the Federal Food, Drug, and Cosmetic Act (FD&C Act). This document replaces FDA's ''Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices'' issued on May 11, 2005, and updates FDA's thinking related to the documentation FDA recommends sponsors include for the review of device software functions in premarket submissions.

DATES: The announcement of the guidance is published in the **Federal Register** on June 14, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your