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FOR FURTHER INFORMATION CONTACT:

Elizabeth Martin, Program Manager, 267-455-8556 at arp.national.evaluation@gsa.gov.

SUPPLEMENTARY INFORMATION:

A. Purpose

The goal of this study is to look systematically across the selected subset of ARP programs, to provide an integrated account of whether, how, and to what extent their implementation served to achieve their intended outcomes, particularly with respect to advancing equity. More specifically, the study aims to learn how lessons from examination of ARP programs and interventions with shared outcomes, common approaches, or overlapping recipient communities may inform equitable program design and delivery across the Federal Government. The study aims to address these overarching evaluation questions:

- To what extent did ARP investments and policy interventions advance equitable outcomes for those they were designed to serve?
- What strategies contributed to the successes, and where are different strategies needed?
- Where multiple ARP programs aim to reach similar outcomes, especially among a shared population:
 - To what extent is there coordination across programs in their administration, customer experience strategies, or performance or outcome measurement practices?
 - To what extent are there collective impacts that could be attributed to more than one program? What kinds of impacts, if any, are observed?
 - What kinds of secondary effects are observed that may not be captured in targeted outcome measures?

The list of 32 programs covered in the May 2022 White House report “Advancing Equity through the American Rescue Plan” provided the scope of programs included in the National Evaluation. A partnership between the Office of Management and Budget Evidence Team and GSA’s Office of Evaluation Sciences, this study is also guided by leadership from the White House ARP Implementation Team, who participate on the Steering Committee, as well as a team of agency experts across the Federal Government.

To build evidence in support of the study goals, this project includes a

series of up to five in-depth, cross-cutting evaluations of selected ARP programs or recipient communities of multiple ARP program investments with shared outcomes, common approaches, or overlapping recipient groups. These evaluations will be selected based on program, population, place, community, or a combination of these factors. A mixed-methods approach is anticipated in order to ensure that appropriate attention is paid to context and that data collection and analysis methods reflect the complexity of program implementation and address the specific evaluation questions identified through the ongoing planning and consultation process.

The ARP National Evaluation will use a multiple-phased approach for this proposed information collection activity. In Phase 1 (current request) the research team seeks approval to carry out consultations with the relevant state and local agencies, community-based organizations, and program participants, including the formal recruitment process to establish community advisory boards for each of the planned in-depth evaluations.

Under subsequent phases of the request, the project will update the information collection request for the instruments tailored to each in-depth evaluation, to reflect the specific evaluation design, information collection methods and instruments, and associated burden. The proposed information collection activities cover mixed-method approaches to implement primarily outcome and process evaluations. Data collection activities for these studies may include: (1) interviews with program administrators and staff; (2) focus groups, (3) short surveys of program participants and/or eligible non-participants, and (4) data requests.

Respondents: State and local program administrators, program staff, community-based program partners, and individuals who participate or are eligible to participate in the relevant ARP programs.

B. Annual Burden Estimates

Currently, three cross-cutting in-depth evaluations are anticipated. The burden estimates below reflect the expectations for information collection and related activities associated with the conduct of those three studies, in addition to the anticipated burden for this initial, formative phase of the overall study. During Phase 1, we estimate the following: consultations with approximately 95 state and/or local program administrators or representatives from community-based

organizations, recruitment of up to 9 participants for each of up to seven Community Advisory Groups established across the three studies, and the initiation of the group meetings.

The anticipated information collections to be undertaken in Phase 2 are expected to vary in their approaches to data collection and sample size. The subsequent information collection requests will describe the specific study design and associated burden for each evaluation. The estimates below include our current expectations for the burden associated with these evaluations.

Total Respondents: 1,241.

Total Annual Responses: 15.

Average Burden Hours per Response: 1.9.

Total Burden Hours: 3,034.5.

C. Public Comments

A 60-day notice published in the **Federal Register** at 88 FR 85621 on December 8, 2023. Two comments were received, but neither provided substantive comments relevant to this specific information collection request.

Obtaining Copies: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division, by calling 202-501-4755 or emailing GSARegSec@gsa.gov. Please cite OMB Control No. 3090-XXXX, Data Collection for a National Evaluation of the American Rescue Plan.

Lois Mandell,

Director, Regulatory Secretariat Division, General Services Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Solicitation of Nominations for Appointment to the Communications and Public Engagement Workgroup of the Advisory Committee to the Director, CDC; Notice of Extension

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), is seeking nominations for membership on the Communications and Public Engagement Workgroup

(CPEW) of the Advisory Committee to the Director, CDC. The CPEW consists of approximately 15 members who are experts in fields associated with communications, including public relations, health communication, risk communication, communication research, and marketing; community and partner engagement; public health science and practice, including implementation; and behavioral science/behavior change campaigns.

DATES: The deadline for submission of nominations for membership on the CPEW published March 4, 2024, at 89 FR 15578, is extended. Nominations for membership on the CPEW must be received no later than April 26, 2024. Late nominations will not be considered for membership.

ADDRESSES: All nominations (cover letters, reference letters, and curriculum vitae/resumes) should be emailed to ACDDirector@cdc.gov with the subject line: "Nomination for CDC ACD Communications and Public Engagement Workgroup."

FOR FURTHER INFORMATION CONTACT: Kate Galatas, M.P.H., Senior Communications Specialist, Office of Communications, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H21-11, Atlanta, GA 30329-4027. Telephone: (404) 639-2064; Email: ACDDirector@cdc.gov.

The Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

SUPPLEMENTARY INFORMATION: The deadline for nominations for appointment to the Communications and Public Engagement Workgroup (CPEW) of the Advisory Committee to the Director, Centers for Disease Control and Prevention has been extended from March 28, 2024 to April 26, 2024. The original solicitation of nominations notice was published in the **Federal**

Register on March 4, 2024, Volume 89, Number 43, pages 15578-15579.

Kalwant Smagh,

Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-D-1173]

Electronic Submission of Expedited Safety Reports From Investigational New Drug-Exempt Bioavailability/Bioequivalence Studies; Guidance for Industry; 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 for industry entitled "Electronic Submission of Expedited Safety Reports From IND-Exempt BA/BE Studies." This guidance provides instructions for the electronic submission of expedited individual case safety reports (ICSRs) from investigational new drug (IND)-exempt bioavailability (BA)/bioequivalence (BE) studies to the FDA Adverse Event Reporting System (FAERS). This guidance finalizes the draft guidance entitled "Electronic Submission of Expedited Safety Reports From IND-Exempt BA/BE Studies" issued on August 3, 2022.

DATES: The announcement of the guidance is published in the **Federal Register** on April 2, 2024.

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 comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2022-D-1173 for "Electronic Submission of Expedited Safety Reports from IND-Exempt BA/BE Studies." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.