

• *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-2023-N-4806 for "Implementing Interoperable Systems and Processes for Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act." 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.

• *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS

CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Sarah Venti, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4258, Silver Spring, MD 20993, 301-796-3130, drugtrackandtrace@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 20, 2023 (88 FR 80726), FDA established a public docket to solicit comments on "Implementing Interoperable Systems and Processes for Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act." The request for information highlights areas for consideration and policy development identified by the Center for Drug Evaluation and Research (CDER). The notice includes a series of questions to stimulate feedback from the public, including CDER and the Center for Biologics Evaluation and Research stakeholders.

Interested persons were originally given until February 20, 2024, to comment on the docket.

Following publication of the November 20, 2023, notice, and in consideration of the joint public

meeting organized by FDA and Partnership for DSCSA Governance (PDG): "PDG-FDA Joint Public Meeting: DSCSA Stabilization Period Midway Checkpoint" scheduled for June 17-18, 2024 (<https://www.fda.gov/news-events/partnership-dscsa-governance-pdg-fda-joint-public-meeting-dscsa-stabilization-period-midway>), FDA has decided to reopen the public docket to allow interested persons additional time to comment.

Dated: June 7, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-12857 Filed 6-11-24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Development of Public Health Vaccine and Prevention Educational Campaigns Involving Community Health Workers

AGENCY: Office of Minority Health, U.S. Department of Health and Human Services (HHS).

ACTION: Request for information.

SUMMARY: The U.S. Department of Health and Human Services (HHS) Office of Minority Health (OMH) seeks input on involving community health workers (CHWs) to increase "cultural competency in educational campaigns on public health vaccines and prevention, including but not limited to influenza and COVID-19."

DATES: Written comments must be received electronically at the email address provided below, no later than 11:59 p.m. on July 11, 2024.

ADDRESSES: OMH invites the submission of the requested information through one of the following methods:

• *Preferred method:* Submit information through the Federal eRulemaking Portal at <http://www.regulations.gov>. Follow the online instructions for submissions.

• *Email:* Send comments to MinorityHealthInfo@hhs.gov with the subject line "OMH RFI: Development of Public Health Vaccine and Prevention Educational Campaigns Involving Community Health Workers."

Submissions received after the deadline will not be reviewed. Respond concisely and in plain language. You may use any structure or layout that presents your information well. You may respond to some or all of our questions, and you can suggest other factors or relevant questions. You may also include links to online material or

interactive presentations. Clearly mark any proprietary information and place it in its own section or file. Your response will become government property, and we may publish some of its non-proprietary content.

FOR FURTHER INFORMATION CONTACT:

Norris Agnew, (240) 268–0665, norris.agnew@hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background Information

The Office of Minority Health (OMH)

Authorized under section 1707 of the Public Health Service Act, 42 U.S.C. 300u–6, as amended, the mission of OMH is to improve the health of racial and ethnic minority populations through the development of health policies and programs that help eliminate health disparities. OMH grant awards and other activities are intended to support the identification of effective policies, programs, and practices for improving health outcomes and to promote sustainability and dissemination of these approaches.

Role of Community Health Workers in COVID–19 Vaccination and Prevention

The COVID–19 pandemic magnified disparities within the United States healthcare system, notably in access to culturally competent health information and services for racial and ethnic minority populations. CHWs emerged as key figures in addressing COVID–19 vaccine confidence concerns and supporting other prevention strategies.

The Congressional report accompanying the FY 2023 appropriations law requested that OMH focus on involving CHWs to increase “cultural competency in educational campaigns on public health vaccines and prevention, including but not limited to influenza and COVID–19.”¹

II. Request for Information

Through this RFI, OMH seeks to obtain information from CHWs, recipients of CHW services, and organizations representing and/or communities using CHWs to guide the development of an educational campaign focused on increasing the cultural and linguistic competency efforts related to public health vaccines (e.g., influenza and COVID–19) and other prevention strategies.

Please Note: This request for information (RFI) is for planning purposes only. It is not a notice for a

proposal and does not commit the federal government to issue a solicitation, make an award, or pay any costs associated with responding to this announcement. All submitted information shall remain with the federal government and will not be returned. All responses will become part of the public record and will not be held confidential. The federal government reserves the right to use information provided by respondents for purposes deemed necessary and legally appropriate. Respondents are advised that the federal government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted. Responses will not be accepted after the due date.

III. Questions

Note: *We understand that not all questions may apply to each respondent's experience or capacity. Small organizations, individuals, or groups of recipients who may not have access to comprehensive data or resources are still encouraged to share their valuable insights and experiences.*

1. What specific methods or practices (i.e., discussing vaccines as part of a prevention program, prioritizing social determinants of health (SDOH), being a member of the cultural group being engaged, etc.) are required to build trust around vaccinations within the communities you serve?

2. What innovative culturally competent practices have resulted in increasing vaccine uptake or vaccine confidence in your communities?

3. What training programs have been effective in engaging CHWs to enhance cultural and linguistic competency to support vaccine confidence and other prevention efforts?

4. What training, coaching, or learning collaborations would improve the ability of CHWs to improve vaccine confidence or vaccine uptake in their communities?

IV. Definitions

For the purposes of this RFI, the following working definitions apply:

Community Health Worker—a frontline public health worker who promotes wellness by helping people adopt healthy behaviors. They implement programs and advocate for people who may have limited access to health resources and social services. Community health workers are employed in a variety of settings, including hospitals, public health departments, and community-based organizations. Community health

workers act as intermediaries between their clients and providers of healthcare and social services. They identify health-related issues, collect data, and discuss clients' health concerns within the community. For example, community health workers might identify barriers preventing clients from accessing transportation and provide referrals to resources that provide transportation. Community health workers work closely with other healthcare and social service providers, including registered nurses, social workers, and substance abuse, behavioral disorder, and mental health counselors.

Cultural and Linguistic Competence—encompasses the ability of providers and organizations to deliver services that are respectful of and responsive to the health beliefs, practices, and cultural and linguistic needs of diverse patients. It involves recognizing and addressing biases, facilitating communication across cultural boundaries, and tailoring health delivery to meet patients' social, cultural, and linguistic expectations. This competency is critical in ensuring equitable healthcare access, enhancing patient-provider relationships, and improving health outcomes in diverse patient populations.

Social Determinants of Health (SDOH)—these are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks. The five domains of SDOH are *Economic Stability*, *Education Access and Quality*, *Health Care Access and Quality*, *Neighborhood and Built Environment*, and *Social and Community Context*.

Vaccine Confidence—refers to the trust that individuals or communities have in the safety and efficacy of vaccines and in the systems that deliver them. This includes beliefs about the development, testing, approval, and policies that lead to vaccine distribution and administration. High levels of vaccine confidence contribute to higher vaccination uptake, which is crucial for the success of immunization programs.

Dated: April 19, 2024.

Norris Agnew,

Lead Public Affairs Specialist, Division of Information and Education, HHS Office of Minority Health.

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¹ <https://docs.house.gov/meetings/AP/AP00/20220630/114968/HMKP-117-AP00-20220630-SD003.PDF>.