DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2022–0137]

Proposed Update to the CDC Framework for Program Evaluation in Public Health

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

ACTION: Request for information.

SUMMARY: The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) announces the opening of a docket to obtain comments and suggestions to update the CDC Framework for Program Evaluation in Public Health (CDC Evaluation Framework) and associated resources (*e.g.,* checklists, self-study guide). Updates to the CDC Evaluation Framework are needed to continue its valuable use and service to the evaluation field and public health.

DATES: Written comments must be received on or before January 30, 2023.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2022–0137 by either of the methods listed below. Do not submit comments by email. CDC does not accept comments by email.

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Centers for Disease Control and Prevention, Program Performance and Evaluation Office, 1600 Clifton Road NE, Mailstop H21–10, Atlanta, GA 30329–4027

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *http://regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Daniel Kidder, CDC Chief Evaluation Officer, Centers for Disease Control and Prevention, Program Performance and Evaluation Office, 1600 Clifton Road NE, Mailstop H21–10, Atlanta, GA 30329–4027; Telephone: 404.639.6270; Email: *CDCeval@cdc.gov.*

SUPPLEMENTARY INFORMATION: The flexibility and simplicity of the CDC Evaluation Framework have led to its wide adoption and use beyond CDC and public health. The CDC Evaluation Framework has guided CDC and other evaluators over two decades, as evidenced by more than 300 citations in peer-reviewed articles and use in projects reaching more than 50 countries on six continents. However, evaluation has evolved since publication of the framework in 1999; [1] therefore, CDC seeks to update the framework to align with changes in evaluation, public health, and federal policies and practices.

The comments from this Request for Information, along with input gathered through other mechanisms (*e.g.,* townhall with CDC, interviews with key federal evaluators, surveys with federal evaluation staff and leaders), will help identify how the framework may have been adapted and used in different settings, what aspects of the framework have been useful, any challenges in using the framework across different contexts, and gaps that may need to be addressed. CDC is gathering input from a variety of audiences, such as federal evaluators, CDC staff, and CDC funded partners. Feedback from these sources will be considered in determining priority areas to update and revise in the CDC Evaluation Framework to continue its valuable use and service to the evaluation field and public health. The relevant feedback along with tools, evidence, and resources in the field and literature will also be considered in determining whether to update, revise, or create new content for the CDC Evaluation Framework and supporting resources (*e.g.,* checklists, tools).

Request for Information

Interested persons or organizations are invited to submit written views, information, and recommendations. CDC invites comments specifically on the following questions, along with suggestions for improving the CDC Evaluation Framework:

1. How has the current CDC Evaluation Framework assisted or not assisted the public health community in planning and conducting high-quality program evaluations? What specifically helped or did not help?
2. Which contexts has the current CDC Evaluation Framework worked well for and for which contexts has it not worked well? What specifically did or did not work and why?
3. How does the current CDC Evaluation Framework promote or inhibit the conduct of evaluations that are culturally responsive and address health equity? What opportunities for improvement exist?

Please be clear and specific in the comments so that CDC can consider the feedback provided in determining whether to change or keep specific aspects of the CDC Evaluation Framework. The CDC Evaluation Framework and associated resources can be found here in the Supporting Materials tab of the docket and at *https://www.cdc.gov/evaluation/framework/index.htm.*

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on *https://www.regulations.gov.* Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign.

Dated: November 23, 2022.

Angela K. Oliver,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2022–25997 Filed 11–28–22; 8:45 am]

BILLING CODE 4163–18–P

[1] Centers for Disease Control and Prevention. Framework for program evaluation in public health. MMWR 1999;48(No. RR–11).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30-Day–23–22BC]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''Enhancing Data-driven Disease Detection in Newborns (ED3N)'' to the Office of Management and Budget (OMB) for

review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on December 6, 2021 to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Enhancing Data-driven Disease Detection in Newborns (ED3N)—New—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Newborn Screening and Molecular Biology Branch (NSMBB), in the National Center for Environmental Health (NCEH) Division of Laboratory Science (DLS), has the only laboratory in the world devoted to ensuring the accuracy of newborn screening (NBS) tests in every state and more than 78 countries. NSMBB supports NBS programs by conducting research, developing methods, and performing analyses by using complex, state-of-the-art molecular and biochemical techniques for identifying risk factors for diseases of public health importance.

Both NSMBB and state NBS programs are experiencing increased data analytic challenges associated with continued expansion of the number of newborn screening diseases, increased complexity of disease detection, and difficulties in correlating disease markers with disease risk. Further, the addition of late-onset diseases to NBS panels necessitates a better way to routinely capture clinical information and outcomes so that NBS programs can fully appreciate the spectrum of disease they are detecting.

The NSMBB is requesting a three-year Paperwork Reduction Act (PRA) clearance for Enhancing Data-driven Disease Detection in Newborns (ED3N), a new national NBS data platform, that will address these analytic and post-analytic challenges and promote sharing of molecular, biochemical, and clinical information amongst NBS partners. The information will better equip NSMBB and newborn screening partners to assess disease risk and will help harmonize approaches for disease detection in newborns. Given the rarity of newborn screening diseases, it is imperative that data be collected and analyzed at a national level in order to glean useful insights and to analyze trends. The NSMBB is best suited to oversee this work given its role in providing technical assistance to NBS programs nationally. Numerous studies along with presentations by NBS programs suggest that gaps in programmatic resources and expertise are hampering the ability to perform more complex data analytics resulting in low positive predictive values for a number of conditions (which subsequently results in higher false positive and negative rates and downstream burden to families and the medical system). Smaller-scale work on the use of post-analytical tools such as machine learning algorithms have shown that incorporation of these elements into newborn screening can improve detection rates, while reducing false positives. These studies, however, have been limited to single sites and have not been integrated into the daily workflow of high-throughput NBS programs. Without this project, NBS programs will continue to be unable to keep up with the increasing complexity and future demands of screening, perpetuating inequities in screening across the nation.

There are 53 domestic NBS programs in the United States. A ''respondent'' refers to a single NBS program. Given that data submission will ultimately be accomplished through automatic electronic data transfer, each respondent's burden hours were split into two estimates: (1) the one-time need to set-up, test, and implement the electronic data transfer mechanism; and (2) the ongoing automatic electronic data transfer occurring after initial set-up. Initial set-up time burden was estimated based on analysis of similar data transfer projects embarked upon by NBS programs as well as brief discussions with NBS Program Laboratory Information Management System vendors. The one-time burden to set-up the data transfer interface was estimated to be 40 hours total. For purposes of annualizing this component of burden over the three-year period of this request, the 53 respondents are represented as 18 respondents in the table below (53/3 = 17.67, rounded to 18). Ongoing daily data submission burden was estimated assuming automatic transfer thereafter, 365 days per year. The estimated burden per response is one minute.

CDC requests OMB approval for an estimated 1,042 annualized burden hours. There are no costs to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr)
Newborn Screening Programs	Set-up of ED3N Data Elements	18	1	40
	Ongoing transfer of ED3N Data Elements	53	365	1/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2022–25992 Filed 11–28–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0811]

Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation To Treat *Clostridioides difficile* Infection Not Responsive to Standard Therapies; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance entitled ''Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation to Treat *Clostridioides difficile* Infection Not Responsive to Standard Therapies; Guidance for Industry.'' The guidance document informs members of the medical and scientific community and other interested persons notice that, at this time, we intend to exercise enforcement discretion with respect to the investigational new drug application (IND) requirements for the use of fecal microbiota for transplantation (FMT) to treat *Clostridioides difficile* (*C. difficile*) infection not responding to standard therapies under limited circumstances described in the guidance. The guidance announced in this notice finalizes the draft guidance entitled ''Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation to Treat *Clostridium difficile* Infection Not Responsive to Standard Therapies'' dated March 2016, and supersedes the guidance entitled ''Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation to Treat *Clostridium difficile* Infection Not Responsive to Standard Therapies'' dated July 2013.

DATES: The announcement of the guidance is published in the **Federal Register** on November 29, 2022.

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–2013–D–0811 for ''Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation to Treat *Clostridium difficile* Infection Not Responsive to Standard Therapies; Final Guidance for Industry.'' 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.*