Jeffrey M. Zirger,

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[FR Doc. 2025–01154 Filed 1–16–25; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–25–25CQ; Docket No. CDC–2025–0004]

Proposed Data Collection Submitted for Public Comment and Recommendations

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

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Healthcare Prevention and Response Workforce Development for Health Departments. The proposed workforce development evaluations will be used to assess whether the CDC-developed workforce development activities are reaching the intended audience and achieving the intended goal of strengthening public health workforce capacity to prevent and respond to Healthcare-Associated Infection and Antibiotic Resistance (HAI/AR) outbreaks at the individual trainee and program level.

DATES: CDC must receive written comments on or before March 18, 2025.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2025–0004 by either of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *www.regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (*www.regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected;

4. 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 submissions of responses; and

5. Assess information collection costs.

Proposed Project

Healthcare-Associated Infections and Antimicrobial Resistance (HAI/R) Programs Response and Prevention Workforce Development Activities—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC funds Healthcare-Associated Infection and Antibiotic Resistance (HAI/AR) Programs in 65 state, local, and territorial health departments. Funding is awarded through the Epidemiology and Laboratory Capacity cooperative agreements (ELC). Funds are intended to provide critical resources to recipients in support of a broad range of healthcare infection prevention and control and epidemiologic surveillance activities to detect, monitor, mitigate, and prevent the spread of HAI/AR in healthcare settings.

CDC has developed various workforce development activities including high-priority trainings requested by the health department programs and CDC site visits. The goal of these activities is to strengthen public health workforce capacity to prevent and respond to HAI/AR outbreaks in healthcare settings and prepare for other emerging healthcare threats. Additionally, the evaluation data collected will be used to improve future CDC-developed resources.

CDC requests OMB approval for an estimated 455 annual burden hours. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	No. of respondents	No. of responses per respondent	Average burden per response	Total burden hours
Public Health Participants—Standard Trainings ..	Registration	600	2	5/60	100
Public Health Participants—Standard Trainings ..	Pre-test	600	2	5/60	100
Public Health Participants—Standard Trainings ..	Post-test	600	2	5/60	100
Public Health Participants—Training Programs ...	Application	30	1	120/60	60
HAI/AR Program Leads—Training Programs	Nomination Letter	30	1	60/60	30

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	No. of respondents	No. of responses per respondent	Average burden per response	Total burden hours
Public Health Participants—Training Programs ...	Activity Reports	13	4	45/60	39
Public Health Participants—Training Programs ...	Program Evaluation	13	1	30/60	7
HAI/AR Program Leads—Site Visits	Program Evaluation	12	1	15/60	3
HAI/AR Program Leads	Program Impact of Workforce Development Activities.	65	1	15/60	16
Total	.....	.....	.....	.....	455

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[FR Doc. 2025–01153 Filed 1–16–25; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10697]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by March 18, 2025.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number:, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10697 Medicare Coverage of Items and Services for Coverage with Evidence Development

Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires Federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collections

1. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Medicare Coverage of Items and Services for Coverage with Evidence Development;

Use: This Paperwork Reduction Act (PRA) package is for Coverage with Evidence Development (CED). As noted above, CMS has utilized the CED pathway since 2006 under 1862(a)(1)(E) of the Act. Early on, there were only 2 CED National Coverage Determinations (NCDs) that required data collection in registries, all of which had publicly available data collection forms. Currently, there are over 120 approved CED studies involving complex data collections, most of which are proprietary to the study sponsor.

There is no specific submission form required for a CED clinical study submission. We note that CMS may publish guidance, including templates, to provide information to manufacturers or other study sponsors to assist them in creating study protocols to satisfy CED requirements (for example, guidance on developing RWD study protocols). Any approved CED study submission should satisfy each of the criteria ''1–17'' provided in the CMS Coverage with Evidence Development guidance document. CMS uses the 17 criteria listed in the 2024 CED guidance