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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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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