



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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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
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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 document to ensure that the submitted CED study has a high degree of likelihood to generate the data and evidence needed to support Medicare coverage. *Form Number:* CMS-10697 (OMB control number 0938-1387); *Frequency:* Annually; *Affected Public:* Private sector - Not-for-profit institutions and Businesses or other for-profits; *Number of Respondents:* 13; *Total Annual Responses:* 13; *Total Annual Hours:* 1,300. (For policy questions regarding this collection,

contact Andrew Ward at 4107-786-1794.)

William N. Parham, III,

Director,

Division of Information Collections and Regulatory Impacts,

Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2025-01242 Filed: 1/16/2025 8:45 am; Publication Date: 1/17/2025]