

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
State/Local Health department staff	Form 1 Medical Tourism Case Intake Form (Part B-Medical Chart Abstraction).	50	15	5/60	63
Ill persons who have experienced an adverse health outcome related to medical tourism.	Form 1 Medical Tourism Case Intake Form (Part A-Interviews).	750	1	10/60	125
Ill persons who have experienced an adverse health outcome related to medical tourism.	Form 2 Medical Tourism Enhanced Surveillance Form.	500	1	30/60	250
Total	438

Jeffrey M. Zirger,

Lead, Information Collection Review Office,
Office of Public Health Ethics and
Regulations, Office of Science, Centers for
Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10147 and
CMS-10905]

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 October 8, 2024.

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-10147 Medicare Drug Coverage and Your Rights

CMS-10905 Service Level Data Collection for Initial Determinations and Appeals

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:* Revision of a currently approved information collection; *Title of Information Collection:* Medicare Drug Coverage and Your Rights; *Use:* Section 423.562(a)(3) and an associated regulatory provision at § 423.128(b)(7)(iii) require that Part D plan sponsors' network pharmacies provide Part D enrollees with a printed copy of our standardized pharmacy notice "Medicare Drug Coverage and Your Rights" (hereafter, "notice") if an enrollee's prescription cannot be filled.

The purpose of this notice is to provide enrollees with information about how to contact their Part D plans to request a coverage determination, including a request for an exception to the Part D plan's formulary. The notice reminds enrollees about certain rights

and protections related to their Medicare prescription drug benefits, including the right to receive a written explanation from the drug plan about why a prescription drug is not covered. Through delivery of this standardized notice, a Part D plan sponsor's network pharmacies are in the best position to inform enrollees at point of sale about how to contact their Part D plan if the prescription cannot be filled. *Form Number*: CMS-10147 (OMB control number: 0938-0975); *Frequency*: Yearly; *Affected Public*: Private Sector, Business or other for-profits, Not for-profits; *Number of Respondents*: 72,900; *Number of Responses*: 55,215,940; *Total Annual Hours*: 919,898. (For policy questions regarding this collection contact Sabrina Edmonston at 410-786-3209 or Sabrina.Edmonston@cms.hhs.gov).

2. Type of Information Collection Request: New collection (Request for a new OMB control number); *Title of Information Collection*: Service Level Data Collection for Initial Determinations and Appeals; *Use*: The Part C and D Reporting Requirements, as set forth in §§ 422.516(a) and 423.514(a), provide CMS with the ability to collect more granular data related to all plan activities regarding adjudicating requests for coverage and plan procedures related to making service utilization decisions. This includes collecting more timely data with greater frequency or closer in real-time. The proposed data elements listed in the Technical Specifications document in this proposed PRA would provide key data to CMS on the utilization of benefits, enhance audit activities to ensure plans are operating in accordance with CMS guidelines, and ensure appropriate access to covered services and benefits.

CMS staff will use this information to monitor health plans and to hold them accountable for their performance. CMS users include group managers, division managers, branch managers, account managers, and researchers. Health plans can use this information to measure and benchmark their performance. CMS receives inquiries from the industry and other interested stakeholders about beneficiary access to the items, services, and drugs, including service level data for initial determinations and appeals, and other factors pertaining to use of government funds, as well the performance of MA plans. *Form Number*: CMS-10905 (OMB control number: 0938-New); *Frequency*: Quarterly; *Affected Public*: Private Sector, Business or other for-profits, Not for-profits and Federal Government State, Local; *Number of Respondents*:

728; *Number of Responses*: 2,912; *Total Annual Hours*: 728. (For policy questions regarding this collection contact Sabrina Edmonston at 410-786-3209 or sabrina.edmonston@cms.hhs.gov).

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Child Abuse and Neglect Background Checks for Child Care and Early Education Project (New Collection)

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Planning, Research, and Evaluation (OPRE), Administration for Children and Families (ACF) is proposing an information collection activity for the Child Abuse and Neglect Background Checks for Child Care and Early Education (CAN Checks for CCEE) Project. The goal of the project is to better understand how states and territories use findings from CAN registry background checks, as required by the Child Care and Development Block Grant Act of 2014 (CCDBG), to make child care employment eligibility determinations. The study will also be used to understand state and territory variation, facilitators, and challenges in implementing CAN registry background checks; and explore any resulting within- or across-state/territory equity implications.

DATES: *Comments due within 30 days of publication.* The Office of Management and Budget (OMB) must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written 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. You can also obtain copies of the proposed collection of information by emailing OPREinfocollection@acf.hhs.gov. All emailed requests should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The proposed information collections for the CAN Checks for CCEE Project is designed to explore how states and territories implement CAN registry background checks for child care employment eligibility decisions. While the CCDBG Act of 2014 clearly describes procedures and exclusionary criteria pertaining to the use of criminal and sexual offender registry background checks to inform child care employment eligibility decisions, requirements for the use of CAN registry background checks are less clear. The findings will be of interest to ACF, and, in particular, to OPRE and the Office of Child Care, who are interested in the effective and equitable implementation of CAN registry background checks for prospective and current child care staff. Findings will also be of interest to Child Care and Development Fund (CCDF) state/territory lead agencies that oversee the CCDF program in their states/territories and the state/territory offices that oversee early care and education. The results of this study also have implications for child care programs and staff. Further, given the U.S. Congress' interest in prior exploratory work on this topic, it may also be informative to federal lawmakers.

CCDF lead agency staff that participate in this information collection will be asked to complete a voluntary, one-time web-based survey. The survey will focus on the practices and policies related both to in-state/territory and interstate CAN registry checks, including what data they request and receive, as well as how they use it in making child care employment eligibility decisions.

Respondents: Each state, territory, and the District of Columbia will be invited to complete one web-based survey. Given that each agency may have multiple staff members with relevant knowledge of different survey topics and no one staff member may possess all of the knowledge to complete the survey, CCDF Lead Agencies may have multiple staff members work together to complete the survey. For burden estimates, we are assuming up to 3 respondents may work on the survey