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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-24-24HD; Docket No. CDC-2024-
0054]

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 Adverse Health
Outcomes Associated with Medical
Tourism Surveillance System. This
information collection project will help
CDC detect outbreaks and trends in
cases to identify prevention measures
and improve awareness of risks
associated with medical tourism.

DATES: CDC must receive written
comments on or before October 8, 2024.

ADDRESSES: You may submit comments,
identified by Docket No. CDC-2024-
0054 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

Adverse Health Outcomes Associated
with Medical Tourism Surveillance
System—New—National Center for
Emerging Zoonotic and Infectious
Diseases (NCEZID), Centers for Disease
Control and Prevention (CDC).

Background and Brief Description

Millions of Americans travel abroad
each year to get medical care. This
practice of medical tourism is
increasing, with even some U.S.-based
health insurance companies sending
patients abroad for medical care.
Medical tourism has been associated
with a variety of adverse health
outcomes including serious infection,
importation of antibiotic-resistant
pathogens to the United States, and
death. Outbreaks among medical
tourists can be difficult to identify for
many reasons. Complications from
treatment(s) and procedure(s) obtained
abroad are underreported by U.S.
healthcare facilities. Jurisdictions
throughout the United States have
varying policies on reporting medical
tourism-related adverse health events to
CDC that can lead to underreporting
from some jurisdictions. Infections
acquired from health care abroad may
not be locally or nationally reportable.
Currently, there is no national
surveillance system or mechanism for
states to link cases between jurisdictions
for medical tourism-related adverse
health outcomes. This makes it difficult
to identify patients with exposures
linked to the same clinic or provider
abroad since they will be returning to
different parts of the United States.

Collaboration with state and local
health departments is essential to detect
outbreaks, and as a federal entity, CDC
can fulfill this role. The information
collected through this surveillance
system will help CDC detect outbreaks
and trends in cases to identify
prevention measures and improve
awareness of risks associated with
medical tourism. State and local health
departments will conduct surveys and
send them electronically to CDC. Data
collected will be stored in an electronic
database and will be extracted for
further analysis.

CDC requests OMB approval for an
estimated 438 annual burden hours.
There are no costs to respondents other
than their time.

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
III 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
III 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

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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