

CureTB connects people with TB to healthcare services as they move between the United States and other countries. The program is a collaboration between CDC’s Division of Global Migration Health (DGMH) and the County of San Diego’s Tuberculosis Control Program. CureTB collaborates with health authorities throughout the United States and around the world to link people with TB to care at their destinations. Health departments, healthcare providers, and others seeking help in linking patients to ongoing TB care in other countries can refer patients

to CureTB. CureTB has an interagency agreement with ICE (Immigration and Custom Enforcement) to refer those patients with suspected or confirmed TB when they are repatriated to their countries of origin.

CureTB collects the following types of information: (1) referring entities (referring agency and jurisdiction) information including name of referring person, telephone numbers, fax numbers, email addresses; (2) patient’s name and last name(s), demographics date of birth, gender, address (U.S. and outside of the U.S), telephone numbers,

email address, patient’s contact persons including name and telephone number; and (3) TB clinical information, including diagnostic testing (radiology reports, laboratory testing reports, other diagnostic methods used, treatment regimen and information about comorbidities).

CDC is requesting OMB approval for an additional three years. CDC requests approval for an estimated 1,125 annual burden hours. There is not cost to respondents other than their time to participate.

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
U.S. health departments .....	CureTB Transnational Notification .....	80	4	30/60	160
TB patients referred by U.S. health departments.	CureTB Transnational Notification .....	214	1	5/60	18
Tb patients referred by ICE .....	CureTB Transnational Notification .....	587	1	45/60	440
TB treating physicians in new country .....	CureTB Clinician Public Health Department Follow-up Script.	870	3	10/60	435
U.S. health departments .....	CureTB Contact/Source Investigation (CI/CS) Notification.	20	5	30/60	50
U.S. health departments .....	CureTB Program Partner Satisfaction Assessment Questionnaire 1.	100	1	10/60	17
U.S. health departments .....	CureTB Program Partner Satisfaction Assessment Questionnaire 2.	50	1	6/60	5
Total .....	.....	.....	.....	.....	1,125

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**

[CMS–1800–N2]

**Inflation Reduction Act (IRA) Revised Program Guidance**

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

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing the availability of CMS’ revised guidance for the Medicare Part B and Part D Prescription Drug Inflation Rebate Program for the implementation of the Inflation Reduction Act. CMS will be releasing additional Inflation

Reduction Act-related guidance; all can be viewed on the dedicated Inflation Reduction Act section of the CMS website.

**FOR FURTHER INFORMATION CONTACT:** Inquiries related to the revised guidance should be sent to [IRAREbateandNegotiation@cms.hhs.gov](mailto:IRAREbateandNegotiation@cms.hhs.gov) with the relevant subject line, “Medicare Inflation Rebate Program Guidance.”

**SUPPLEMENTARY INFORMATION:** The Inflation Reduction Act was signed into law on August 16, 2022. Section 11101 of the Inflation Reduction Act added a new section 1847A(i) to the Social Security Act (the Act), which establishes a requirement for manufacturers to pay Medicare Part B rebates for single source drugs and biological products with prices that increase faster than the rate of inflation for a calendar quarter to the Federal Supplementary Medical Insurance Trust Fund, and provides for lower Part B beneficiary cost sharing on these drugs and biologicals. Section 11102 of the Inflation Reduction Act added a new section 1860D–14B to the Act, which establishes a requirement for manufacturers to pay rebates to the Federal Supplementary Medical

Insurance Trust Fund for certain Part D drugs when prices increase faster than the rate of inflation for each 12-month applicable period. Collectively, this program to implement these rebates is referred to as the Medicare Prescription Drug Inflation Rebate Program, or the Inflation Rebate Program.

To obtain copies of the revised guidance and the responses to comments from the initial guidance, as well as other Inflation Reduction Act-related documents, please access the CMS Inflation Reduction Act website by copying and pasting the following web address into your web browser: <https://www.cms.gov/inflation-reduction-act-and-medicare>. If interested in receiving CMS Inflation Reduction Act updates by email, individuals may sign up for CMS Inflation Reduction Act’s email updates at <https://www.cms.gov/About-CMS/Agency-Information/Aboutwebsite/EmailUpdates>.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Vanessa Garcia, who is the Federal Register Liaison, to electronically sign this document for

purposes of publication in the **Federal Register**.

Dated: December 12, 2023.

**Vanessa Garcia,**

*Federal Register Liaison, Centers for Medicare & Medicaid Services.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-304/-304a, CMS-368/-R-144, and CMS-10249]

### 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 February 13, 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-304/-304a** Reconciliation of State Invoice (ROSI) (CMS-304) and Prior Quarter Adjustment Statement (PQAS) (CMS-304a)

**CMS-368/-R-144** State Agency Contact Form (CMS-368) and Quarterly State Invoice (CMS-R-144)

**CMS-10249** Administrative Requirements for Section 6071 of the Deficit Reduction Act

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 Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Reconciliation of State Invoice (ROSI) and Prior Quarter Adjustment Statement (PQAS); *Use:* Form CMS-304 (ROSI) is used by manufacturers to respond to the state's rebate invoice for current quarter utilization. Form CMS-304a (PQAS) is required only in those instances where a change to the original rebate data submittal is necessary. *Form Number:* CMS-304 and -304a (OMB control number: 0938-0676); *Frequency:* Quarterly; *Affected Public:* Private sector (business or other for-profits); *Number of Respondents:* 749; *Total Annual Responses:* 5,841; *Total Annual Hours:* 248,584. (For policy questions regarding this collection contact Robert Giles at 667-290-8626.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Drug Rebate Program State Reporting Forms; *Use:* Form CMS 368 is a report of contact for the State to name the individuals involved in the Medicaid Drug Rebate Program (MDRP) and is required only in those instances where a change to the originally submitted data is necessary. The ability to require the reporting of any changes to these data is necessary to the efficient operation of these programs. Form CMS-R-144 is required from States quarterly to report utilization for any drugs paid for during that quarter. *Form Number:* CMS-368 and -R-144 (OMB control number: 0938-0582); *Frequency:* Quarterly and on occasion; *Affected Public:* State, local, or Tribal governments; *Number of Respondents:* 56; *Total Annual Responses:* 290; *Total Annual Hours:* 13,669. (For policy questions regarding this collection contact Robert Giles at 667-290-8626.)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Administrative Requirements for Section 6071 of the Deficit Reduction Act; *Use:* State Operational Protocols should provide enough information such that: the CMS Project Officer and other Federal officials may use it to understand the operation of the demonstration, prepare for potential site visits without needing additional information, or both; the State Project Director can use it as the manual for program implementation; and external stakeholders may use it to understand the operation of the demonstration. The financial