



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-304/CMS-304a, CMS-368/CMS-R-144, and CMS-R-308]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

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 a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate 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 on the collection(s) of information must be received by the OMB desk officer by **[Insert date 30 days after the date of publication in the Federal Register]**.

ADDRESSES: When commenting on the proposed information collections, please reference the

document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

OMB, Office of Information and Regulatory Affairs

Attention: CMS Desk Officer

Fax Number: (202) 395-5806 OR

E-mail: OIRA_submission@omb.eop.gov

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at Web Site address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>
2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

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. 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 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-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.

Comments submitted in response to the 60-day FR Notice have been addressed in Appendix A of the ICR. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Reconciliation of State Invoice and Prior Quarter Adjustment Statement; Use: Form CMS-304 (Reconciliation of State Invoice) is used by manufacturers to respond to the state's rebate invoice for current quarter utilization. Form CMS-304a (Prior Quarter Adjustment Statement) 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: Business or other for-profits; Number of Respondents: 1,037; Total Annual Responses: 4,148; Total Annual Hours: 187,880. (For policy questions regarding this collection contact Andrea Wellington at 410-786-3490.)

2. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Medicaid Drug Rebate Program Forms; Use: We develop the rebate amount per drug unit from information supplied by the drug manufacturers and distributes these data to the states. States then must report quarterly to the drug manufacturers and report to us the total number of units of each dosage form/strength of their covered outpatient drugs

reimbursed during a quarter and the rebate amount to be refunded. This report is due within 60 days of the end of each calendar quarter. The information in the report is based on claims paid by the state Medicaid agency during a calendar quarter. Form CMS-R-144 (Quarterly Report Data) is required from states quarterly to report utilization for any drugs paid for during that quarter. Form CMS-368 (Administrative Data) is required only in those instances where a change to the original data submittal is necessary. Form Number: CMS-368 and -R-144 (OMB control number: 0938-0582); Frequency: Quarterly; Affected Public: State, Local, or Tribal Governments; Number of Respondents: 56; Total Annual Responses: 224; Total Annual Hours: 12,101. (For policy questions regarding this collection contact Andrea Wellington at 410-786-3490.)

3. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: State Children's Health Insurance Program and Supporting Regulations; Use: States must submit title XXI plans and amendments for approval by the Secretary. We use the plan and its subsequent amendments to determine if the state has met the requirements of title XXI. Information provided in the state plan, state plan amendments, and from the other information we are collecting will be used by advocacy groups, beneficiaries, applicants, other governmental agencies, providers groups, research organizations, health care corporations, health care consultants. States will use the information collected to assess state plan performance, health outcomes and an evaluation of the amount of substitution of private coverage that occurs as a result of the subsidies and the effect of the subsidies on access to coverage. Form Number: CMS-R-308 (OMB control number: 0938-0841); Frequency: Yearly,

Once, and Occasionally; Affected Public: State, Local, or Tribal Governments; Number of Respondents: 56; Total Annual Responses: 28,294,596; Total Annual Hours: 1,473,885. (For policy questions regarding this collection contact Amy Lutzky at 410-786-0721).

Dated: April 25, 2017

William N. Parham, III

Director, Paperwork Reduction Staff

Office of Strategic Operations and Regulatory Affairs

Billing Code: 4120-01-U-P

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