



Centers for Medicare & Medicaid Services

[Document Identifier: CMS-304 and 304a, CMS-10383]

Agency Information Collection Activities: Submission for OMB Review; 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 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 DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

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.

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 web site 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 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. 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 (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:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Review and Approval Process for Waivers for State Innovation; *Use:* The information required under this collection is necessary to ensure that states comply with statutory and regulatory requirements related to the development and implementation of section 1332 waivers. States seeking waiver authority under section 1332 of the ACA are required to meet certain requirements for applications, public notice, and reporting. The authority for these requirements is found in section 1332 of the ACA. This information collection reflects the requirements provided in the final rules published in February 2012 (77 FR 11700) and September 2021 (86 FR 3412).

On October 24, 2018, the Departments published guidance (86 FR 53575) that provided supplementary information about the requirements that must be met for the approval of a section 1332 waiver, the Secretaries' application review procedures, the calculation of pass-through funding, certain analytical requirements, and operational considerations. However, the September 2021 final rule superseded and rescinded policies and interpretations outlined in the 2018 guidance and repealed the previous codification of the interpretations of the statutory guardrails in part 1 of the 2022 Payment Notice final rule (86 FR 6138). The September 2021 final rule (86 FR 53412) finalized modifications to section 1332 waiver implementing regulations, including changes to many of the policies and interpretations of the statutory guardrails codified in regulation. In addition, the September 2021 final rule modified regulations to provide flexibilities in the public notice requirements and post-award public participation requirements for section 1332 waivers under certain future emergent situations. The final rule also provided new information regarding the processes and procedures for amendments and extensions for approved waiver plans. *Form Number:* CMS-10383 (OMB Control Number 0938-1389; *Frequency:* Occasionally; *Affected Public:* State Governments; *Number of Respondents:* 19; *Total Annual Responses:* 399; *Total Annual Hours:* 5,549. (For policy questions regarding this collection contact Lina Rashid at 301-492-4193.)

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Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

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