



Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10241 and CMS-10717]

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:* Revision of a currently approved collection; *Title of Information Collection:* Survey of Retail Prices; *Use:* This information collection request provides for a survey of the average acquisition costs of all covered outpatient drugs purchased by retail community pharmacies. CMS may contract with a vendor to conduct monthly surveys of retail prices for covered outpatient drugs. Such prices represent a nationwide average of consumer purchase prices, net of discounts and rebates. The contractor shall provide notification when a drug product becomes generally available and that the contract includes such terms and conditions as the Secretary shall specify, including a requirement that the vendor monitor the marketplace. CMS has developed a National Average Drug Acquisition Cost (NADAC) for states to consider when developing reimbursement methodology. The NADAC is

a pricing benchmark that is based on the national average costs that pharmacies pay to acquire Medicaid covered outpatient drugs. This pricing benchmark is based on drug acquisition costs collected directly from pharmacies through a nationwide survey process. This survey is conducted on a monthly basis to ensure that the NADAC reference file remains current and up-to-date. *Form Number:* CMS-10241 (OMB control number 0938-1041); *Frequency:* Monthly; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 72,000; *Total Annual Responses:* 72,000; *Total Annual Hours:* 36,000. (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:* Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols; *Use:* Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and implementing regulations at 42 CFR parts 422 and 423, Medicare Part D plan sponsors and Medicare Advantage organizations are required to comply with all Medicare Parts C and D program requirements. CMS' annual audit plan ensures that we evaluate sponsoring organizations' compliance with these requirements by conducting program audits that focus on high-risk areas that have the greatest potential for beneficiary harm. As such, CMS has developed the following audit protocols for use by sponsoring organizations to prepare for their audit:

- Compliance Program Effectiveness (CPE)
- Part D Formulary and Benefit Administration (FA)
- Part D Coverage Determinations, Appeals, and Grievances (CDAG)
- Part C Organization Determinations, Appeals, and Grievances (ODAG)
- Special Needs Plans Care Coordination (SNPCC)

CMS generally conducts program audits at the parent organization level in an effort to

reduce burden and, for routine audits, subjects each sponsoring organization to all applicable program area protocols. For example, if a sponsoring organization does not offer a special needs plan, or an accrediting organization has deemed a special needs plan compliant with CMS regulations and standards, CMS would not apply the SNPCC protocol. Likewise, CMS would not apply the ODAG audit protocol to an organization that offers only a standalone prescription drug plan since that organization does not offer the MA benefit. Conversely, ad hoc audits resulting from referral may be limited in scope and, therefore, all program area protocols may not be applied.

The information gathered during this program audit will be used by the Medicare Parts C and D Oversight and Enforcement Group (MOEG) within the Center for Medicare (CM) and CMS Regional Offices to assess sponsoring organizations' compliance with Medicare program requirements. If outliers or other data anomalies are detected, Regional Offices will work in collaboration with MOEG and other divisions within CMS for follow-up and resolution. Additionally, MA and Part D organizations will receive the audit results and will be required to implement corrective action to correct any identified deficiencies. *Form Number:* CMS-10717 (OMB control number: 0938-1395); *Frequency:* Yearly; *Affected Public:* Private Sector, State, Local, or Tribal Governments, Federal Government, Business or other for-profits, Not-for-Profit Institutions; *Number of Respondents:* 182; *Total Annual Responses:* 182; *Total Annual Hours:* 36,444. (For policy questions regarding this collection contact Matthew Guerand, at 303-844-7120.)

Dated: October 11, 2023.

William N. Parham, III,

Director,

Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

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