DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10137 and CMS-10191

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid 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 (the 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 **[INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

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, 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 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-10137 Title Solicitation for Applications for Medicare Prescription Drug Plan 2021 Contracts

CMS-10191 Medicare Parts C and D Program Audit Protocols and Data Requests

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:* Revision of a currently approved collection; *Title of Information Collection:* Solicitation for Applications for Medicare Prescription Drug Plan 2021 Contracts; *Use:* Coverage for the prescription drug benefit is provided through contracted prescription drug plans (PDPs) or through Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA-PD plans). Cost Plans that are regulated under Section 1876 of the Social Security Act, and Employer Group Waiver Plans (EGWP) may also provide a Part D benefit. Organizations wishing to provide services under the Prescription Drug Benefit Program must complete an application, negotiate rates, and receive final approval from CMS. Existing Part D Sponsors may also expand their contracted service area by completing the

Service Area Expansion (SAE) application.

Collection of this information is mandated in Part D of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) in Subpart 3. The application requirements are codified in Subpart K of 42 CFR 423 entitled "*Application Procedures and Contracts with PDP Sponsors."*

The information will be collected under the solicitation of proposals from PDP, MA-PD, Cost Plan, Program of All Inclusive Care for the Elderly (PACE), and EGWP applicants. The collected information will be used by CMS to: (1) ensure that applicants meet CMS requirements for offering Part D plans (including network adequacy, contracting requirements, and compliance program requirements, as described in the application), (2) support the determination of contract awards. *Form Number*: CMS-10137 (OMB control number: 0938-0936); *Frequency*: Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 243; *Total Annual Responses:* 290; *Total Annual Hours:* 1,384.79. (For policy questions regarding this collection contact Arianne Spaccarelli at 410-786-5715.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Parts C and D Program Audit Protocols and Data Requests; *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. CMS program audits focus on high-risk areas that have the greatest potential for beneficiary harm. As such, CMS has developed several audit protocols that are included within the program area data request documents and that are posted to the CMS website

each year for use by sponsoring organizations to prepare for their audit. As part of a robust audit process, CMS also requires sponsoring organizations who have been audited and found to have deficiencies to undergo a validation audit to ensure correction. The validation audit utilizes the same audit protocols, but only tests the elements where deficiencies were found, as opposed to re-administering the entire audit.

Currently CMS utilizes the following 5 protocols to audit sponsoring organization performance: Part D Formulary and Benefit Administration (FA); Coverage Determinations, Appeals, and Grievances (CDAG); Organization Determinations, Appeals, and Grievances (ODAG); Special Needs Model of Care (SNP-MOC) (only administered on organizations who operate SNPs); and, Compliance Program Effectiveness (CPE). The data collected is detailed in each of these protocols and the exact fields are located in the record layouts, at the end of each protocol. In addition, this collection request includes a pre-audit issue summary, three CPE questionnaires, one CPE organizational structure presentation template, one FA impact analysis template, two CDAG impact analysis templates, four OAG impact analysis templates, and three SNP-MOC impact analysis templates.

The information gathered during this 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-10191 (OMB control number: 0938-1000); *Frequency*: Yearly; *Affected Public:* State, Local, or

Tribal Governments; *Number of Respondents:* 201; *Total Annual Responses:* 207; *Total Annual Hours:* 17,525. (For policy questions regarding this collection contact Brenda Hudson at 303-844-7056.)

Dated: August 13, 2019.

William N. Parham, III,

Director,

Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

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