DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10191 and CMS-10305]

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 any of the following subjects: 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 http://www.cms.hhs.gov/PaperworkReductionActof1995.
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: Reports Clearance Office at (410) 786-1326.

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: 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. In 2010, the explosive growth of these sponsoring organizations forced CMS to develop an audit strategy to ensure we continue to obtain meaningful audit results. As a result, CMS' audit strategy reflected a move to a more targeted, data-driven and risk-based audit approach. We focused on high-risk areas that have the greatest potential for beneficiary harm.

To maximize resources, CMS will focus on assisting the industry to improve their operations to ensure beneficiaries receive access to care. One way to accomplish this is CMS will develop an annual audit strategy which describes how sponsors will be selected for audit and the areas that will be audited. CMS has developed several audit protocols and these are posted to the CMS website each year for use by sponsors to prepare for their audit. Currently CMS utilizes the following 7 protocols to audit sponsor performance: Formulary Administration (FA), Coverage Determinations, Appeals & Grievances (CDAG), Organization Determination, Appeals and Grievances (ODAG), Special Needs Model of Care (SNPMOC) (only administered on organizations who operate SNPs), Compliance

Program Effectiveness (CPE), Medication Therapy Management (MTM) and Provider Network Accuracy (PNA). 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, questionnaires are distributed as part of our CDAG, ODAG and CPE audits. These questionnaires are also included in this package.

As part of a robust audit process, CMS also requires sponsors 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. Finally, to assist in improving the audit process, CMS sends sponsors a link to a survey (Appendix D) at the end of each audit to complete in order to obtain the sponsors' feedback. The sponsor is not required to complete the survey. Form Number: CMS-10191 (OMB control number: 0938-1000); Frequency: Yearly; Affected Public: Private Sector (business or other for-profit and not-for-profit institutions); Number of Respondents: 40; Total Annual Responses: 40; Total Annual Hours: 13,640. (For policy questions regarding this collection contact Dawn Johnson at 410-786-3159.)

2. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Medicare Part C and Part D Data Validation (42 CFR 422.516(g) and 423.514(g)); Use: Organizations contracted to offer Medicare Part C and Part D benefits are required to report data to us on a variety of measures. For the data to be useful for monitoring and performance measurement, the data must be reliable, valid, complete, and comparable among sponsoring organizations. To meet this goal, we have developed reporting standards and data validation specifications with respect to the Part C and Part D reporting requirements. These standards provide a review process for Medicare Advantage Organizations,

Cost Plans, and Part D sponsors to use to conduct data validation checks on their reported Part C and Part D data.

The FDCF is revised for the 2017 and 2018 DV collection periods by changing the scoring of six standards from a binary scale to a five-point Likert-type scale. This change is expected to improve the precision of the data validation scores by increasing overall variation in total scores among the MAOs and PDPs. The revision is not expected to alter resource requirements, since the assessment by DV contractors in scoring standards will continue to be based on the percentage of records that meet the standards. Form Number: CMS-10305 (OMB control number: 0938-1115); Frequency: Yearly; Affected Public: Private sector - Business or other for-profits; Number of Respondents: 639; Total Annual Responses: 639; Total Annual Hours: 209,271. (For policy questions regarding this collection contact Terry Lied at 410-786-8973.)

Dated: November 1, 2016

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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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