



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10191]

Agency Information Collection Activities: Proposed Collection; 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 (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 <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](mailto: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:

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-10191 Medicare Parts C and D Program Audit and Timeliness Monitoring 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: Medicare Parts C and D Program Audit and Timeliness Monitoring Data Requests; Use: Medicare Part D plan sponsors and Medicare Advantage organizations (collectively referred to as sponsoring organizations) are required to comply with all Medicare Parts C and D program requirements. In 2010, the explosive growth of these sponsoring organizations precipitated the need for CMS to develop an annual audit strategy to ensure that we evaluate sponsoring organizations compliance with the program requirements. In addition to describing how sponsoring organizations are selected for audit and which program areas will be audited, CMS' annual audit strategy reflected a move to a more targeted, data-driven, and risk-based audit approach. Since 2010, CMS has continued to focus on assisting the industry with improving their operations to ensure beneficiaries receive appropriate access to care. CMS has developed audit protocols that focus on high-risk areas that have the greatest potential for beneficiary harm.

CMS' program audit protocols are posted to the CMS website each year for use by sponsoring

organizations to prepare for their audit. Currently CMS utilizes the following 5 protocols to audit sponsoring organizations' performance: Compliance Program Effectiveness (CPE), Formulary Administration (FA); Coverage Determinations, Appeals, and Grievances (CDAG); Organization Determinations, Appeals, and Grievances (ODAG), Special Needs Program Model of Care (SNP-MOC) (only administered on organizations who operate SNPs). Beginning in audit year 2019, the SNP-MOC program area has been more accurately renamed Special Needs Program Care Coordination Quality Improvement Performance Evaluation (SNP-CCQIPE). In addition, the Medication Therapy Management (MTM) pilot protocol has been suspended until further notice. For that reason, it is no longer posted to the CMS website.

Beginning in audit year 2019, the data collected via program-specific record layouts, and collected via impact analyses on an as-needed basis, will be consolidated into each program area data request document. The pre-audit issue summary was updated for technical terminology changes. Three of the questionnaires and the power point template that previously have been distributed as part of our CPE audits will remain. However, the CPE self-assessment questionnaire and the CDAG and ODAG questionnaires have been removed. We have added new questionnaires for FA and SNP-CCQIPE. A revised template for collecting root cause analyses from organizations on an as-needed basis during the program audit has been included in this package.

We have also included a new independent validation audit work plan template that will be collected from sponsors that are required to undergo an independent validation audit. The validation audit is part of our robust audit process where CMS requires sponsoring organizations that 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. This validation audit work plan template will be populated by the sponsoring organization's independent auditing firm to describe how it plans to test for correction of the deficiencies identified during the program audit.

To assist in improving the audit process, we have also included an audit feedback questionnaire that is representative of the survey link we send to sponsoring organizations at the end of each program audit. Completion of this questionnaire is optional for sponsoring organizations to provide feedback on the audit process.

The proposed changes to each data collection instrument, along with the new FA and SNP-CCQIPE questionnaires, root cause template, validation audit work plan template and audit feedback questionnaire are included in the posted PRA package.

Finally, separate from the audit process and in order to address sponsoring organizations' concerns regarding undue harm in Star Ratings during audit years. The number of sponsoring organizations that are required to submit universes annually for their coverage/organization determinations and appeals increased. In 2016, CMS expanded this annual collection to all MA and Part D sponsoring organizations. The universes are submitted in the same format as required for audits under the Part D CDAG protocol and the Part C ODAG protocol. The universes are then analyzed for timeliness on an annual basis, across all sponsoring organizations, to allow a more comprehensive review of the accuracy of Part C and D appeals data to calculate Star Ratings. 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: 166; Total Annual Responses: 211; Total Annual Hours: 51,548. (For policy questions regarding this collection contact Brenda Hudson at 443-743-9299.)

Dated: March 28, 2018.

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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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