



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Medicare & Medicaid Services**

**[Document Identifier CMS-10717, CMS-10468 and CMS-R-267]**

#### **Agency Information Collection Activities: Submission for OMB Review; 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 (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 THE 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](http://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, 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-](https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html)

[Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html](https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html)

1. 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).

2. Call the Reports Clearance Office at (410) 786-1326.

**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:* New 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.

In addition, as part of the robust program audit process, CMS also requires sponsoring organizations that have undergone a program audit and found to have deficiencies to undergo a validation audit to ensure correction. The validation audit uses the same audit protocols, but only tests the elements where deficiencies were found as opposed to re-administering the entire audit. Finally, CMS conducts annual industry-wide timeliness monitoring of all Part C organizations by using a subset of the ODAG protocol. However, Sponsoring organizations that successfully submitted all of their Part C data in response to a program audit in the prior year are excluded from submitting new data for the timeliness monitoring effort in the year following their program audit.

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, MOEG requires audited organizations to provide impact analyses to better understand and report the scope of the noncompliance. These MA and Part D organizations then receive their audit results, are required to implement corrective actions, and to demonstrate correction of all conditions cited in the final

audit report by undergoing a validation audit. If the validation audit demonstrates substantial correction of the conditions, MOEG will communicate its decision to close the audit in a letter to the MA and Part D organization. Any new or isolated issues of non-compliance that remain will be referred to the CMS Account Manager for follow-up. Regional Offices will work in collaboration with MOEG and other divisions within CMS for resolution. *Form Number:* CMS-10717 (OMB control number: 0938-New); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for-profits, Not-for-profits institutions; *Number of Respondents:* 190; *Total Annual Responses:* 179; *Total Annual Hours:* 36,082. (For policy questions regarding this collection contact Kellie Simons at 410-786-0886.)

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment; *Use:* The Exchanges, which became operational on January 1, 2014, enhanced competition in the health insurance market, expanded access to affordable health insurance for millions of Americans, and provided consumers with a place to easily compare and shop for health insurance coverage. The reporting requirements and data collection in Medicaid, Children's Health Insurance Programs, and Exchanges: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment (CMS-2334-F) address: (1) standards related to notices, (2) procedures for the verification of enrollment in an eligible employer-sponsored plan and eligibility for qualifying coverage in an eligible employer-

sponsored plan; and (3) other eligibility and enrollment provisions to provide detail necessary for state implementation. The submission seeks OMB approval of the information collection requirements associated with selected provisions in 45 CFR parts 155, 156 and 157. *Form Number:* CMS-10468 (OMB control number: 0938-1207); *Frequency:* Annually; *Affected Public:* Individuals, Households and Private Sector; *Number of Respondents:* 1,522; *Total Annual Responses:* 9,533; *Total Annual Hours:* 103,710. (For policy questions regarding this collection contact Anne Pesto at 410-786-3492.)

3. *Type of Information Collection Request:* Revision with change of a currently approved collection; *Title of Information Collection:* Medicare Plus Choice Program Requirements Referenced in 42 CFR 422.000 - 422.700; *Use:* The information collection requirements are mandated by 42 CFR part 422. Section 4001 of the Balanced Budget Act of 1997 (BBA) added sections 1851 through 1859 to the Social Security Act to establish the Managed Care program. The Medicare, Medicaid, and SCHIP Benefits Improvement Act and Protection Act of 2000, P. L. 106-554 added requirements to the Managed Care program. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P. L. 108-173) created the Medicare Advantage program.

A major goal of the Medicare Advantage program is to provide ease of access for Original Medicare beneficiaries who wish to enroll in a Medicare Advantage program. Certain populations of beneficiaries such as the dually eligible population (those beneficiaries enrolled in both Medicaid and Medicare) have grown since the program was created and these populations require more flexibilities.

MA organizations (formerly M+C organizations) and potential MA organizations (applicants) use the information collected based on the regulations at 42 CFR part 422 to comply with the application requirements and the MA contract requirements. CMS uses the information collected based on the regulations at 42 CFR part 422 to approve contract applications, monitor compliance with contract requirements, make proper payment to MA organizations, determine compliance with the new prescription drug benefit requirements established by the MMA, and to ensure that correct information is disclosed to Medicare beneficiaries, both potential enrollees and enrollees.

Information supplied by organizations is used to determine eligibility for contracting with CMS, for determining compliance with contract requirements, and for calculating proper payment to the organizations. Information supplied by Medicare beneficiaries is used to determine eligibility to enroll in the M+C organization and to determine proper payment to the organization that enrolled the beneficiary. Separate OMB approval was sought for each form as required.

The information collection request also incorporates the new minimum criteria for dual eligible special needs plans (D-SNPs) to integrate Medicare and Medicaid benefits detailed in Section 50311(b) of the Bipartisan Budget Act of 2018 and set forth in in Final rule (CMS-4185-F, RIN 0938-AT59) for CY2020 and 2021. The integration requirements improve care coordination, quality of care, and beneficiary satisfaction while reducing administrative burden.

*Form Number:* CMS-R-267 (OMB control number: 0938-0753); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 6,727,508; *Total Annual*

*Responses: 6,750,814; Total Annual Hours: 1,848,180.* (For policy questions regarding this collection contact Marna Metcalf Akbar at 410-786-8251.)

Dated: May 29, 2020.

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Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

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