



Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10636, CMS-10874, and CMS-319]

Agency Information Collection Activities: Proposed Collection; 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 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 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, 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 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-10636	Triennial Network Adequacy Review for Medicare Advantage Organizations and 1876 Cost Plans
CMS-10874	Part D Drug Management Program
CMS-319	State Medicaid Eligibility Quality Control Sample Selection Lists and Supporting Regulations

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:* Triennial Network Adequacy Review for Medicare Advantage Organizations and 1876 Cost Plans; *Use:* CMS regulations at 42 CFR 417.414, 417.416, 422.112(a)(1)(i), and 422.114(a)(3)(ii) require that all Medicare Advantage organizations (MAOs) offering coordinated care plans, network-based private fee-for-service (PFFS) plans, and as well as section 1876 cost organizations, maintain a network of appropriate providers that is sufficient to provide adequate access to covered services to meet the needs of the population served. To enforce this requirement, CMS regulations at § 422.116 outline network adequacy criteria which set forth the minimum number of providers and maximum travel time and distance from enrollees to providers, for required provider specialty types in each county in the United States and its territories. Organizations must be in compliance with the current CMS network adequacy criteria guidance, which is updated and published annually on CMS's website. This collection of information is essential to appropriate and timely compliance monitoring by CMS, in order to ensure that all active contracts offering network-based plans maintain an adequate network; *Form Number:* CMS-10636 (OMB control number: 0938-1346); *Frequency:* Yearly; *Affected Public:* Private sector; *Number of Respondents:* 502; *Number of Responses:* 2,753; *Total Annual Hours:* 27,470. (For policy questions regarding this collection contact Jackie Ford at 410-786-7767.)

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Part D Drug Management Program (DMP);

Use: Section 1860D-4(c)(5)(A) of the Social Security Act requires that Part D sponsors have a DMP for beneficiaries at risk of abuse or misuse of frequently abused drugs (FADs). The information in this collection of information request is necessary for sponsor conformance with DMP requirements at § 423.153(f), including communicating with prescribers and pharmacies, informing beneficiaries that they have been identified as a PARB or ARB, and informing beneficiaries and CMS whether a beneficiary's access to FADs will be restricted to a selected prescriber and/or network pharmacy(ies) and/or through a beneficiary-specific point-of-sale claim edit. Part D sponsors will use the standardized and model documents to communicate with providers, enrollees, and other sponsors. Specifically, Part D sponsors may use the Model Part D Drug Management Program Prescriber Inquiry Letter to inform providers that their patient's pattern of use or history of use of FADs is potentially unsafe and has prompted a case management review under the plan's DMP. Part D sponsors must use the standardized Initial Notice and Second Notice, or Alternate Second Notice, to inform enrollees, following identification by CMS's OMS and subsequent case management, whether the beneficiaries have been identified as being potentially at risk or at risk for abuse or misuse of FADs. Part D sponsors may use the Model Part D Drug Management Program Sponsor Information Transfer Memorandum to communicate to a gaining sponsor the enrollee's history of misuse or abuse of FADs; *Form Number:* CMS-10874 (OMB control number: 0938-1465); *Frequency:* Yearly and once; *Affected Public:* Private sector; *Number of Respondents:* 319; *Number of Responses:* 62,248; *Total Annual Hours:* 152,585. (For policy questions regarding this collection contact Valerie Yingling at 667-290-8657.)

3. *Type of Information Collection Request:* Reinstatement with change to the previously approved information collection: *Title of Information Collection:* State Medicaid Eligibility Quality Control Sample Selection Lists and Supporting Regulations; *Use:* Title XIX and Title XXI State agencies are required to submit the MEQC pilot planning document in accordance with § 431.814(b), and the MEQC case level and CAP reports based on pilot findings in

accordance with §§ 431.816 and 431.820, respectively. The primary users of this information are State Medicaid (and where applicable CHIP) agencies and CMS. State agencies are expected to use the information collected for continuous quality improvement purposes. They will identify patterns of error in their eligibility processing operations and systems and take corrective actions to address issues and improve the eligibility determination process. CMS will use the data collected to identify and help those States that are most in need of technical assistance. CMS will also use the data set to identify potential weaknesses in Federal regulations. It will propose regulatory modifications designed to ensure that there are more effective quality controls in the eligibility determination process.; *Form Number:* CMS-319 (OMB control number: 0938-0147); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 35; *Number of Responses:* 647; *Total Annual Hours:* 9,840. (For policy questions regarding this collection contact Camiel Rowe at 410-786-0069.)

William N. Parham, III,

Director,

Division of Information Collections and Regulatory Impacts,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

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