



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R-267 and CMS-10396]

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-R-267 Medicare Plus Choice Program Requirements Referenced in 42 CFR 422.000 - 422.700

CMS-10396 Medication Therapy Management Program Improvements - Standardized Format

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 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.)

2. *Type of Information Collection Request:* Revision with change of a currently approved collection; *Title of Information Collection:* Medication Therapy Management Program Improvements - Standardized Format; *Use:*The Medicare Modernization Act of 2003 (MMA) under title 42 CFR Part 423, Subpart D, establishes the requirements that Part D sponsors, an organization which has one or more contract(s) with CMS to provide Part D benefits to Medicare beneficiaries, must meet with regard to cost control and quality improvement including requirements for medication therapy management (MTM) programs. MTM is a patient-centric and comprehensive approach to improve medication use, reduce the risk of adverse events, and improve medication adherence. At minimum, a Part D sponsors' MTM program must offer to its enrollees an annual comprehensive medication review with written summaries, quarterly targeted medication reviews, and follow-up interventions for both beneficiaries and prescribers when necessary.

Information collected by Part D MTM programs as required by the Standardized Format for the CMR summary, which is used by beneficiaries or their authorized representatives, caregivers, and their healthcare providers to improve medication use and achieve better healthcare outcomes. The Standardized Format must comply with applicable industry standards for medication therapy management and electronic data interchange, and should enable CMR data elements to be captured for clinical, reporting or measurement purposes.

After a CMR is performed, the sponsor creates and sends a summary of the CMR to the beneficiary that includes a medication action plan and personal medication list using the Standardized Format. The information users are beneficiaries or their authorized representatives,

caregivers, and their healthcare providers as stated in this section.. *Form Number:* CMS-10396
(OMB control number: 0938-1154); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal
Governments; *Number of Respondents:* 735; *Total Annual Responses:* 2,173,254; *Total Annual
Hours:* 1,448,908. (For policy questions regarding this collection contact Victoria Dang at 410-786-
3991.)

Dated: February 18, 2020.

William N. Parham, III,

Director,

Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

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