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Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10316, CMS-10260, CMS-367a – e, and CMS-10243]

Agency Information Collection Activities: Submission for OMB Review; 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 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 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 . 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, 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 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:* Revision of a currently approved collection; *Title of Information Collection:* Implementation of the Medicare Prescription Drug Plan (PDP) and Medicare Advantage (MA) Plan Disenrollment Reasons Survey; *Use*: The Balanced Budget Act of 1997 required that the CMS publicly report two years of disenrollment rates on all Medicare + Choice (M+C) organizations. Disenrollment rates are a useful measure of beneficiary dissatisfaction with a plan; this information is even more useful when reasons for disenrollment are provided to consumers, insurers, and other stakeholders. Advocacy organizations agree that CMS needs to report disenrollment reasons so that disenrollment rates can be interpreted correctly.

Specifically, the MMA under Sec. 1860D-4 (Information to Facilitate Enrollment)

requires CMS to conduct consumer satisfaction surveys regarding the PDP and MA contracts pursuant to section 1860D-4(d). Plan disenrollment is generally believed to be a broad indicator of beneficiary dissatisfaction with some aspect of plan services, such as access to care, customer service, cost of the plan, services, benefits provided, or quality of care.

The information generated from the disenrollment survey supports CMS' ongoing efforts to assess plan performance and provide oversight to the functioning of Medicare Advantage (Part C) and PDP (Part D) plans, which provide health care services to millions of Medicare beneficiaries (i.e., 28 million for Part C coverage and 49 million for Part D coverage).

Beneficiary experiences of care (as measured in the MCAHPS survey) and dissatisfaction (as measured in the disenrollment survey) with plan performance are both important sources of information for plan monitoring and oversight. The disenrollment survey assesses different aspects of dissatisfaction (i.e., reasons why beneficiaries voluntarily left a plan), which can identify problems with plan operations; performance areas evaluated include access to care, customer service, cost, coverage, benefits provided, and quality of care. Understanding how well plans perform on these dimensions of care and service helps CMS understand whether beneficiaries are satisfied with the care they are receiving from contracted plans. When and if plans are found to be performing poorly against an array of performance measures, including beneficiary disenrollment, CMS may take corrective action. *Form Number*: CMS-10316 (OMB control number: 0938-1113); *Frequency*: Yearly; *Affected Public:* Individuals and Households; *Number of Respondents:* 32,750; *Total Annual_Responses:* 32,750; *Total Annual Hours:* 7,055. (For policy questions regarding this collection contact Beth Simons at 415-744-3780).

2. *Type of Information Collection Request*: Revision of a currently approved collection; *Title of Information Collection*: Medicare Advantage and Prescription Drug Program: Final Marketing Provisions in 42 CFR 422.111(a)(3) and 423.128(a)(3); *Use*: CMS requires MA

organizations and Part D sponsors to use the standardized documents being submitted for OMB approval to satisfy disclosure requirements mandated by section 1851 (d)(3)(A) of the Act and §422.111 for MA organizations and section 1860D-1(c) of the Act and §423.128(a)(3) for Part D sponsors. The regulatory provisions at §§ 422.111(b) and 423.128(b) require MA organizations and Part D sponsors to disclose plan information, including: service area, benefits, access, grievance and appeals procedures, and quality improvement/assurance requirements. MA organizations and sponsors may send the ANOC separately from the EOC, but must send the ANOC for enrollee receipt by September 30. The required due date for the EOC is 15 days prior to the start of the AEP.

CMS requires MA organization and Part D sponsors to submit marketing materials to CMS for review prior to the MA organization or sponsor distributing those materials to the public. In section 1851(h), paragraphs (1), (2), and (3) establish this requirement for MA organizations. Section 1860D-1(b)(1)(B)(vi) directs Part D sponsors to follow the same requirements in section 1851(h) that MA organizations must follow for this purpose. *Form number*: CMS-10260 (OMB control number: 0938-1051); *Frequency*: Annually; *Affected Public*: State, Local, or Tribal Governments; *Number of Respondents*: 800; *Number of Responses*: 48,439; *Total Burden Hours:* 13,568. (For questions regarding this collection contact Elizabeth Jacob at 410-786-8658).

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicaid Drug Rebate Program Labeler Reporting Format; *Use*: Labelers transmit drug product and pricing data to CMS within 30 days after the end of each calendar month and quarter. CMS calculates the unit rebate amount (URA) and the unit rebate offset amount (UROA) for each new drug application (NDC) and distributes to all State Medicaid agencies. States use the URA to invoice the labeler for rebates and the UROA to report onto CMS-64. The monthly data is used to calculate Federal Upper Limit (FUL) prices for applicable drugs and for states that opt to use this data to establish their pharmacy

reimbursement methodology. In this 2023 iteration, we adding a new use of the reported data. The new use would allow us to calculate inflationary rebates under the Inflation Reduction Act of 2022. The change has no impact on our burden estimates. We are not revising any of our reporting forms. *Form Number*: CMS-367a, b, c, d, and e (OMB control number: 0938-0578); *Frequency*: Monthly, quarterly, and on occasion; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 818; *Total Annual Responses*: 15,742; *Total Annual Hours:* 591,042. (For policy questions regarding this collection contact Andrea Wellington at 410-786-3490.)

4. *Type of Information Collection Request*: Extension of a currently approved collection; *Title of Information Collection*: Testing Experience and Functional Tools (TEFT): Functional Assessment Standardized Items (FASI) Based on the CARE Tool; *Use:* As part of the National Testing Experience and Functional Assessment Tools (TEFT) demonstration, CMS tested the use of functional assessment standardized items (FASI) among community-based long term services and supports (CB-LTSS) populations. The TEFT initiative built on the national efforts to create electronically exchangeable data across providers and the caregiving team to develop more person-centered services under the Medicare and Medicaid programs. After conclusion of the field test, states have begun implementing the related FASI performance measures and the FASI team continues to recruit additional states. While the team has not conducted data collection since the FASI field test in 2017, and that there are no concrete immediate plans to collect new data, new data collection to support measure re-endorsement activities due in 2025 will be needed. The data collection may also need to be conducted sooner if significant changes are made to the measures' technical specifications, in the interim. Due to the uncertainty on when data collection may need to be done, an extension of the existing package and a subsequent revision would facilitate expedient resumption of the data collection and testing efforts, especially given the quick turnaround time for activities (such as National Quality Forum measure endorsement) which depend on the data collection.

FASI is based on a subset of the July 27, 2007 (72 FR 144) Continuity Assessment Record and Evaluation (CARE) items which are now included in post-acute setting Federal assessment forms for nursing facilities - Resident Assessment Instrument (RAI) Minimum Data Set (MDS), Inpatient Rehabilitation Facilities Patient Assessment Instrument (IRF-PAI), and Long Term Care Hospitals Continuity Assessment Record & Evaluation (CARE) Data Set (LCDS) to measure function in a standardized way. The FASI items include the standardized mobility and self-care items included in the MDS, IRF-PAI, and, LCDS as well as some additional mobility items appropriate to measuring independence in the community and personal preferences or goals items related to function. Also included are certain instrumental activities of daily living and some modified caregiver assistance items from the Home Health Outcome and Assessment Information Set (OASIS) tool. A few additional items to describe the populations' age, gender, and geographic area of residence are also included. Use of the same items to measure functional status in nursing facilities and community-based programs will help states report on their rebalancing efforts. Also, because these items will have electronic specifications developed by CMS, they can assist state efforts to develop exchangeable electronic data to follow the person across services and estimate total costs as well as measure functional status across time. The complete FASI set is included in this information collection request. *Form Number*: CMS-10243 (OMB control number: 0938-1037); *Frequency*: On occasion; *Affected Public*: Individuals and Households; *Number of Respondents:* 1,570; *Total Annual Responses:* 1,570; *Total Annual Hours:* 785. (For policy questions regarding this collection contact Kerry Lida at 410-786-4826.)

Dated: April 25, 2023.

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William N. Parham, III,

Director,

Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

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