DEPARTM

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10621, CMS-10141 and CMS-10630]

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 (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 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.

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-10621 Quality Payment Program/Merit-Based Incentive Payment System (MIPS)

CMS-10141 Medicare Prescription Drug Benefit Program

CMS-10630 The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460

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*: Extension of a currently approved collection; *Title of Information Collection*: Quality Payment Program/Merit-Based Incentive Payment System (MIPS); *Use*: The Merit-based Incentive Payment System (MIPS) is a program for certain eligible clinicians that makes Medicare payment adjustments based on performance on quality, cost and other measures and activities. MIPS and Advanced Alternative Payment Models (AAPMs) are the two paths for clinicians available through the Quality Payment Program authorized by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). As prescribed by MACRA, MIPS focuses on the following performance areas: quality – a set of evidence-based, specialty-specific standards; improvement activities that focus on practice-based improvements; cost; and use of Certified Electronic Health Record Technology (CEHRT) to support interoperability and advanced quality objectives in a single, cohesive program that avoids redundancies.

Under the AAPM path, eligible clinicians may become Qualifying APM Participants (QPs) and are excluded from MIPS. Partial Qualifying APM Participants (Partial QPs) may opt to report and be scored under MIPS. APM Entities and eligible clinicians must also submit all of the required information about the Other Payer Advanced APMs in which they participate, including those for which there is a pending request for an Other Payer Advanced APM determination, as well as the payment amount and patient count information sufficient for us to make QP determinations by December 1 of the calendar year that is 2 years to prior to the payment year, which we refer to as the QP Determination Submission Deadline (82 FR 53886).

The implementation of MIPS requires the collection of quality, Promoting Interoperability, and improvement activities performance category data. For the quality performance category, MIPS eligible clinicians and groups will have the option to submit data using various submission types, including Medicare claims, direct, log in and upload, CMS Web Interface and CMS-approved survey vendors. For the improvement activities and Promoting Interoperability, clinicians and groups can submit data through direct, log in and upload, or log in and attest submission types. As finalized in the CY 2021 PFS final rule (85 FR 84860), for clinicians in APM Entities, the APM Performance Pathway will be available for both ACOs and non ACOs to submit quality data. Due to data limitations and our inability to determine who would use the APM Performance Pathway versus the traditional MIPS submission mechanism for the CY 2022 performance period/2024 MIPS payment year, we assume ACO APM Entities will submit data through the APM Performance Pathway, using the CMS Web Interface option, and non-ACO APM Entities would participate through traditional MIPS, thereby submitting as an individual or group rather than as an entity. We are finalizing in the CY 2022 PFS final rule the policy to extend the CMS Web Interface measures as a quality performance category collection type/submission type for the CY 2022 performance period/2024 MIPS payment year. We note that we are finalizing to extend the CMS Web Interface as a collection type/submission type for clinicians in Shared Savings Program reporting the APM Performance Pathway through the CY 2024 performance period/2026 MIPS payment year. We are also finalized the sunsetting of the CMS Web interface measures as a quality performance category collection type/submission type starting with the CY 2023 performance period/2025 MIPS payment year.

In the CY 2022 PFS final rule, we finalized to implement voluntary MIPS Value Pathways (MVP) reporting for eligible clinicians beginning with January 1 of the CY 2023 performance period/2025 MIPS payment year. Beginning with the CY 2023 performance period/2025 MIPS payment year, we also finalized voluntary subgroup reporting within MIPS limited to eligible clinicians reporting through the MVPs or the APP.

For the Promoting Interoperability performance category, in the CY 2022 PFS final rule, we finalized that, beginning with the CY 2022 performance period/2024 MIPS payment year, eligible clinicians must attest to conducting an annual assessment of the High Priority Guides of the SAFER Guides beginning January 1 of CY 2022. We finalized to automatically reweight the Promoting Interoperability for small practices who previously had to apply for reweighting of this performance category.

For the improvement activities performance category, beginning with the CY 2022 Annual Call for MIPS improvement activities, we finalized two new criteria for nomination of improvement activities. We are also requesting to add three new ICRs that are currently with OMB for approval: MVP registration, MVP quality submissions, and Subgroup registration. The MVP registration reflects the burden associated with the finalized registration process for clinicians reporting MVPs beginning with the CY 2023 performance period/2025 MIPS payment year. Subgroup registration reflects the burden associated with the finalized registration process for subgroups reporting the MVPs. The MVP quality submission reflects the decrease in burden associated with the finalized MVP Inventory available for MIPS eligible clinicians. *Form Number*: CMS-10621 (OMB control number: 0938-1314); *Frequency*: Annually; *Affected Public*: Individuals or Households and Business or other for-profit institutions; *Number of Respondents*: 239,813; *Total Annual Responses*: 633,021; *Total Annual Hours*: 2,825,380. (For policy questions regarding this collection contact Michelle Peterman at 410-786-2591)

2. *Type of Information Collection Request*: Revision of a currently approved collection; *Title of Information Collection*: Medicare Prescription Drug Benefit Program; *Use*: Plan sponsor and State information is used by CMS to approve contract applications, monitor compliance with contract requirements, make proper payment to plans, and ensure that correct information is disclosed to potential and current enrollees. *Form Number*: CMS-10141 (OMB control number: 0938-0964); *Frequency*: Annually; *Affected Public*: Private Sector and Business or other for-profit institutions; *Number of Respondents*: 11,771,497; *Total Annual Responses*:

675,231,213; *Total Annual Hours*: 9,261,354. (For policy questions regarding this collection contact Chad D. Buskirk at 410-786-1630)

3. *Type of Information Collection Request*: Revision of a currently approved collection; *Title of Information Collection*: The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460; *Use*: Sections 1894(e)(4) and 1934(e)(4) of the Act and the implementing regulations at 42 CFR 460.190 and 460.192 state that CMS, in conjunction with the State Administering Agency (SAA), must oversee a PACE organization's continued compliance with the requirements for a PACE organization.

The data collected with the data request tools included in this package allow CMS to conduct a comprehensive review of PACE organizations' compliance in accordance with specific federal regulatory requirements. The information gathered during this audit will be used by the Medicare Parts C and D Oversight and Enforcement Group (MOEG) within the Center for Medicare (CM), as well as the SAA, to assess POs' compliance with PACE program requirements. If outliers or other data anomalies are detected, other offices within CMS will work in collaboration with MOEG for follow-up and resolution. Additionally, POs will receive the audit results, and will be required to implement corrective action to correct any identified deficiencies. *Form Number*: CMS-10630 (OMB control number: 0938-1327); *Frequency*: Annually; *Affected Public*: Private Sector, State, Local, or Tribal Governments and Business or other for-profit institutions; *Number of Respondents*: 40; *Total Annual Responses*: 40; *Total Annual Hours*: 31,200. (For policy questions regarding this collection contact Kathleen Flannery at 410-786-6722)

Dated: December 16, 2021.

William N. Parham, III,

Director,

Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

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