DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10630, CMS-R-263, CMS-437A and CMS-437B]

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-10630 Programs of All-Inclusive Care for the Elderly (PACE) 2020 Audit Protocol

CMS-R-263 Site Investigation for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)

CMS-437A and CMS-437B State Agency Sheets for Verifying Exclusions from the Inpatient Prospective Payment System and Supporting Regulations Rehabilitation Unit/ Rehabilitation Hospital Criteria Worksheets

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 changes of a currently approved collection; *Title of Information Collection:* Programs of All-Inclusive Care for the Elderly (PACE) 2020 Audit Protocol; *Use:* Sections 1894(e)(4) and 1934(e)(4) of the Act and the implementing regulations at 42 CFR §§ 460.190 and 460.192 mandate that CMS, in conjunction with the SAA, audit PACE organizations (POs) annually for the first 3 years (during the trial period), and then at least every 2 years following the trial period. 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) and CMS Regional Offices, as well as the SAA, to assess PO's compliance with PACE program requirements. If outliers or other data anomalies are detected, CMS' Regional Offices will work in collaboration with MOEG and other divisions within CMS 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.

CMS currently uses 18 data collection instruments for conducting PACE audits. These instruments are categorized as a PACE audit process and data request, a questionnaire, a pre- audit issue summary, a Root Cause Analysis template and 14 impact analyses templates. Beginning in audit year 2020, the number of data collection tools will increase from 18 to the following 31 documents. 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.

CMS developed and implemented a revised PACE audit protocol. The audit protocol was designed to account for the continued growth of the PACE program and CMS' commitment to a more targeted, data-driven and outcomes-based audit approach, focused on high-risk areas that have the greatest potential for participant harm. *Form Number*: CMS-10630 (OMB control number: 0938-1327); *Frequency*: Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 70; *Total Annual Responses:* 70; *Total Annual Hours:* 42,000. (For policy questions regarding this collection contact Caroline Zeman at 410 786-0116.)

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Site Investigation for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS); *Use:* The primary function of the site investigation form is to provide a standardized, uniform tool to gather information from a

DMEPOS supplier that tells us whether it meets certain qualifications to be a DMEPOS supplier (as found in 42 CFR § 424.57(c)) and where it practices or renders its services. This site investigation form also aides the Medicare contractor (the National Supplier Clearinghouse Medicare Administrative Contractor (NSC MAC)) in verifying compliance with the required supplier standards found in 42 CFR § 424.57(c). *Form Number*: CMS-R-263 (OMB control number: 0938-0749); *Frequency*: Yearly; *Affected Public:* Private Sector – Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 4,811; *Total Annual Responses:* 1,603; *Total Annual Hours:* 1,603. (For policy questions regarding this collection contact Thomas Pryor at 410-786-1132.)

3. *Type of Information Collection Request:* Revision of a currently approved collection.

Title of Information Collection: State Agency Sheets for Verifying Exclusions from the Inpatient Prospective Payment System and Supporting Regulations -Rehabilitation Unit/ Rehabilitation Hospital Criteria Worksheets; *Use:* The purpose of this information collection is to renew forms CMS-437A and 437B. Inpatient Rehabilitation Facility (IRF) hospitals and units must initially attest that they meet the Inpatient Prospective Payment System (IPPS) exclusion criteria set forth at 42 CFR §412.20 to §412.29 prior to being placed into IPPS exempt status. Form CMS-437A must be completed by IRF units and form CMS-437B must be completed by IRF hospitals.

For first time verification requests for exclusion from the IPPS, an IRF unit or hospital must notify the Regional Office (RO) servicing the State in which it is located that it believes it meets the criteria for exclusion from the IPPS. Currently, all new IRF units or hospitals must provide written certification that the inpatient population it intends to serve will meet the requirements of the IPPS exclusion criteria for IRFs. The completed CMS-437A and 437B forms are submitted to the State Agency (SA) no later than 5 months before the date the IRF unit or hospital would become subject to

Inpatient Rehabilitation Facility Prospective Payment System (IRF-PPS). For IRF units and hospitals already excluded from the IPPS, annual onsite re-verification surveys by the SA are no longer required. IRF units and hospitals must now re-attest to meeting the exclusion criteria every 3 years thereafter.

IRF units and hospitals that have already been excluded need not reapply for exclusion. These facilities will automatically be reevaluated yearly to determine whether they continue to meet the exclusion criteria. For the tri-annual re-verification, IRF units and hospitals will be provided with a copy of the appropriate CMS-437 worksheet at least 5-months prior to the beginning of its cost reporting period, so that the IRF unit or hospital official may complete and sign an attestation statement and complete and return the appropriate form CMS-437A or CMS-437B at least 5-months prior to the beginning of the cost reporting period. However, Fiscal Intermediaries (FIs) will continue to verify, on an annual basis, compliance with the 60 percent rule (42 CFR 412.29(b)(2)) for IRF units and hospitals through a sample of medical records and the SA will verify the medical director requirement.

The SA will notify the RO at least 60 days prior to the end of the IRF unit's or hospital's cost reporting period of the status of compliance or non-compliance with the payment requirements. The information collected on the 437A and 437B forms, along with other information submitted by the IRF is necessary for determining the IRF's IPPS exclusion status. *Form Number:* CMS-437A and CMS-437B (OMB control number: 0938-0986); *Frequency*: tri-annually; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 1,126; *Total Annual Responses*: 1,126; *Total Annual Hours*: 1,126. (For policy questions regarding this collection contact Caroline Gallaher at 410-786-8705).

Dated: March 12, 2019

William N. Parham, III,

Director,

Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

[FR Doc. 2019-04895 Filed: 3/14/2019 8:45 am; Publication Date: 3/15/2019]