Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2016–28899 Filed 12–1–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–26]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

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 any of the following subjects: 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 January 31, 2017.

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 *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email 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: Reports Clearance Office at (410) 786–1326.

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–26 Clinical Laboratory Improvement Amendments (CLIA) 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:* Clinical Laboratory Improvement Amendments (CLIA) Regulations; *Use:* The information is necessary to determine an entity's compliance with the Congressionally-mandated program with respect to the regulation of laboratory testing (CLIA). In addition, laboratories participating in the Medicare program must comply with CLIA requirements as required by section 6141 of OBRA 89. Medicaid, under the authority of section 1902(a)(9)(C) of the Social Security Act, pays for services furnished only by laboratories that meet Medicare (CLIA) requirements. *Form Number:* CMS–R–26 (OMB Control Number: 0938–0612); *Frequency:* Monthly, occasionally; *Affected Public:* Private sector—Business or other for-profits and Not-for-profit institutions, State, Local or Tribal Governments, and the Federal government; *Number of Respondents:* 70,861; *Total Annual Responses:* 1,979,300; *Total Annual Hours:* 14,975,785. (For policy questions regarding this collection contact Raelene Perfetto at 410–786–6876).

Dated: November 29, 2016.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2016–29011 Filed 12–1–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10340, CMS–10476, CMS–10525, and CMS–10630]

Agency Information Collection Activities: Submission for OMB Review; 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 (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 any of the following subjects: 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 January 3, 2017.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 *OR*, Email: *OIRA_submission@omb.eop.gov*.

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 *http://www.cms.hhs.gov/PaperworkReductionActof1995*.

2. Email 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: Reports Clearance Office at (410) 786–1326.

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:* Collection of Encounter Data From: Medicare Advantage Organizations, Section 1876 Cost HMOS/CMPS, Section 1833 Health Care Prepayment Plans (HCPPS), and PACE Organizations; *Use:* We collect encounter data or data on each item or service delivered to enrollees of Medicare Advantage (MA) plans offered by MA organizations. The MA organizations currently obtain this data from providers. We collect this information using standard transaction forms and code sets. We will use the data for determining risk adjustment factors for payment, updating the risk adjustment model, calculating Medicare DSH percentages, Medicare coverage purposes, and quality review and improvement activities. The data is also used to verify the accuracy and validity of the costs claimed on cost reports. For PACE organizations, encounter data would serve the same purpose it does related to the MA program and would be submitted in a similar manner. *Form Number:* CMS–10340 (OMB control number: 0938–1152); *Frequency:* Weekly, bi-weekly, and monthly; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 691; *Total Annual Responses:* 18,854,605; *Total Annual Hours:* 54,054. (For policy questions regarding this collection contact Michael Massimini at 410–786–1566.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medical Loss Ratio (MLR) Report for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP); *Use:* We will use the data collection of annual reports provided by plan sponsors for each contract to ensure that beneficiaries are receiving value for their premium dollar by calculating each contract's medical loss ratio (MLR) and any remittances due for the respective MLR reporting year. The recordkeeping requirements will be used to determine plan sponsors' compliance with the MLR requirements, including compliance with how plan sponsors' experience is to be reported, and how their MLR and any remittances are calculated. *Form Number:* CMS–10476 (OMB control number: 0938–1232); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 616; *Total Annual Responses:* 616; *Total Annual Hours:* 130,004. (For policy questions regarding this collection contact Diane Spitalnic at 410–786–5745.)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Program of all-Inclusive Care for the Elderly (PACE) Quality Data Entry in CMS Health Plan Monitoring System; *Use:* PACE organizations coordinate the care of each participant enrolled in the program based on his or her individual needs with the goal of enabling older individuals to remain in their community. To be eligible to enroll in PACE, an individual must: be 55 or older, live in the service area of a PACE organization (PO), need a nursing home-level of care (as certified by the state in which he or she lives), and be able to live safely in the community with assistance from PACE (42 CFR 460.150(b)).

The PACE program provides comprehensive care whereby an interdisciplinary team of health professionals provides individuals with coordinated care. The overall quality of care is analyzed by information collected and reported to CMS related to specific quality indicators that may cause potential or actual harm. CMS analyzes the quality data to identify opportunities to improve the quality of care, safety and PACE sustainability and growth.

Previously, quality reporting was identified as Level I or Level II reporting. Level I reporting requirements refer to those data elements that POs regularly report to CMS via the CMS Health Plan Management System (HPMS) PACE monitoring module. (Please see Appendix A for the list of data elements.) POs have been collecting, submitting and reporting data to CMS and State administering agencies (SAA) since 1999.

When analyzing the Level I data, findings may or may not trigger a Quality Improvement (QI) process of analysis (*e.g.,* Plan, Do, Study, Act known as PDSA). Findings may indicate the need for a change in policies, procedures, systems, clinical practice or training. Level II reporting requirements apply specifically to unusual incidents that result in serious adverse participant outcomes, or negative national or regional notoriety related to PACE.

In this PRA package, we are making title changes from Level I and Level II to PACE Quality Data. We are requesting to update and implement previously collected PACE data elements known as

Level I and Level II into PACE quality data. Additionally, we are establishing three PACE Quality measures adopted from the National Quality Forum (NQF) and modified for PACE use. These modified PACE quarterly measures are Falls, Falls with Injury, and Pressure Injury Prevalence/Prevention. Currently, the existing Level I and Level II elements have not been tested for reliability or feasibility. By adopting NQF defined reliable data collection process for these elements, certain existing Level I and Level II elements will then officially meet quality measures collection standards. These measures will be used to improve quality of care for participants in PACE. PACE Quality measures will be implemented via the existing HPMS. POs will be educated on data criteria, entry and will report quarterly. *Form Number:* CMS–10525 (OMB control number: 0938–1264); *Frequency:* Quarterly and occasionally; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 100; *Total Annual Responses:* 29,500; *Total Annual Hours:* 211,500. (For policy questions regarding this collection contact Tamika Gladney at 410–786–0648.)

4. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* The PACE Organization (PO) Monitoring and Audit Process in 42 CFR part 460; *Use:* Historically, the Programs of All-Inclusive Care for the Elderly (PACE) audit protocols have been included in the Medicare Advantage (MA) and Medicare Part D audit protocol's information collection request (CMS–10191, OMB 0938–1000). However, in examining previous submissions, we do not believe that including it with the MA and Part D audit protocols allowed for an accurate representation of the PACE burden. Due to PACE audits being substantially different from our MA and Part D audits, we have separated the PACE audit protocols from the MA and Part D protocols and created this information collection request which seeks OMB approval under a new control number.

POs are required to comply with all PACE program requirements. The growth of these PACE organizations forced CMS to develop an audit strategy to ensure we continue to obtain meaningful audit results. As a result, CMS' audit strategy reflected a move to a more targeted, data-driven and outcomes-based audit approach. We focused on high-risk areas that have the greatest potential for participant harm.

CMS has developed an audit protocol and will post it to the CMS Web site each year for use by POs to prepare for their audit. The data collected for audit is detailed in this protocol and the exact fields are located in the record layouts, at the end of the protocol. In addition, a questionnaire will be distributed as part of our audit. This questionnaire is also included in this package. *Form Number:* CMS–10630 (OMB control number: 0938—New); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other for-profits and Not-for-profits institutions); *Number of Respondents:* 72; *Total Annual Responses:* 72; *Total Annual Hours:* 12,960. (For policy questions regarding this collection contact Caroline Zeman at 410–786–0116.)

Dated: November 29, 2016.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2016–29007 Filed 12–1–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2015–E–3158; FDA–2015–E–3159]

Determination of Regulatory Review Period for Purposes of Patent Extension; TRUMENBA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for TRUMENBA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by January 31, 2017. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by May 31, 2017. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket Nos. FDA–2015–E–3158 and FDA–2015–E–3159 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; TRUMENBA.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be