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: 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:* Extension of a currently approved collection; *Title of Information Collection:* Fee-for-Service Recovery Audit Prepayment Review Demonstration and Prior Authorization Demonstration; *Use:* The Office of Management and Budget approved the collections required for two demonstrations of prepayment review and prior authorization. The first demonstration allows Medicare Recovery Auditors to review claims on a pre-payment basis in certain States. The second demonstration established a prior authorization program for Power Mobility Device claims in certain States. The first demonstration has ended, so we are only extending the collection of information for the second demonstration, prior authorization of power mobility devices.

For the Prior Authorization of Power Mobility Devices (PMDs) Demonstration, we are piloting prior authorization for PMDs. Prior authorization will allow the applicable documentation that supports a claim to be submitted before the item is delivered. For prior authorization, relevant documentation for review is submitted before the item is delivered or the service is rendered. CMS will conduct this demonstration in California, Florida, Illinois, Michigan, New York, North Carolina, Texas, Pennsylvania, Ohio, Louisiana, Missouri, Maryland, New Jersey, Indiana, Kentucky, Georgia, Tennessee, Washington, and Arizona based on beneficiary address as reported to the Social Security Administration and recorded in the Common Working File (CWF). For the demonstration, a prior authorization request can be completed by the (ordering) physician or treating practitioner and submitted to the appropriate Durable Medical Equipment Medicare Administrative Contractor (DME MAC) for an initial decision. The supplier may also submit the request on behalf of the physician or treating practitioner. The physician, treating practitioner or supplier who submits the request on behalf of the physician or treating practitioner, is referred to as the ''submitter.'' Under this demonstration, the submitter will submit to the DME MAC a request for prior authorization and all relevant documentation to support Medicare coverage of the PMD item. *Form Number:* CMS–10421 (OMB control number: 0938–1169); *Frequency:* Occasionally; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 50,500; *Total Annual Responses:* 50,500; *Total Annual Hours:* 25,125. (For policy questions regarding this collection contact Daniel Schwartz at 410–786–4197.)

Dated: February 2, 2018.

William N. Parham, III,

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

[FR Doc. 2018–02467 Filed 2–6–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10453 and CMS–1856]

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 April 9, 2018.

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' website 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: William 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–10453 The Medicare Advantage and Prescription Drug Program: Part C Explanation of Benefits and Supporting Regulations

CMS–1856 Request for Certification in the Medicare/Medicaid Program for Providers of Outpatient Physical Therapy and/or Speech-Language Pathology

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:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* The Medicare Advantage and Prescription Drug Program: Part C Explanation of Benefits and Supporting Regulations; *Use:* The Medicare Advantage disclosure requirements in 42 CFR 422.111(b) sets out the authority for CMS to require that Medicare Advantage Organizations (MAOs) furnish a written explanation of benefits (EOB) directly to enrollees, in a manner specified by CMS and in a form easily understandable to enrollees, when benefits are provided under part 422. In § 422.216(d)(1), all Medicare Advantage plan types that offer an M+C fee-for-service plan must provide to plan enrollees, for each claim filed by the enrollee or the provider that furnished the service, an appropriate explanation of benefits. The explanation must include a clear statement of the enrollee's liability for deductibles, coinsurance, copayment, and balance billing. Plans must disclose the information specified in § 422.111(b), as specified in § 422.111(a)(3), at the time of enrollment and at least annually thereafter, 15 days before the annual coordinated election period. *Form Number:* CMS–10453 (OMB control number: 0938–1228); *Frequency:* On occasion; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 468; *Number of Responses:* 5,616; *Total Annual Hours:* 74,880. (For policy questions regarding this collection contact Natalie Albright at 410–786–1671.)

2. *Type of Information Collection Request:* Reinstatement of a previously approved collection; *Title of Information Collection:* Request for Certification in the Medicare/Medicaid Program for Providers of Outpatient Physical Therapy and/or Speech-Language Pathology; *Use:* The form is used as an application to be completed by providers of outpatient physical therapy and/or speech-language pathology services requesting participation in the Medicare and Medicaid programs. This form initiates the process for obtaining a decision as to whether the conditions of participation are met as a provider of outpatient physical therapy, speech-language pathology services, or both. It is used by the State agencies to enter new providers into the Automated Survey Process Environment (ASPEN). *Form Number:* CMS–1856 (OMB control number: 0938–0065); *Frequency:* Annually, occasionally; *Affected Public:* Private sector—Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 350; *Total Annual Responses*: 350; *Total Annual Hours:* 88. (For policy questions regarding this collection contact Peter Ajuonuma at 410–786–3580.)

Dated: February 2, 2018.

William N. Parham, III,

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

[FR Doc. 2018–02433 Filed 2–6–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0575]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Expedited Programs for Serious Conditions—Drugs and Biologics

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 9, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0389. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry: ''**Expedited Programs for Serious Conditions—Drugs and Biologics**''

OMB Control Numbers 0910–0389 and 0910–0765—Revision

This information collection supports the previous captioned Agency guidance. The guidance provides a single resource for information on FDA's policies and procedures related to the following expedited programs for serious conditions: (1) Fast track designation, (2) breakthrough therapy designation, (3) accelerated approval, and (4) priority review designation. The guidance describes threshold criteria generally applicable to expedited programs, including what is meant by serious condition, unmet medical need, and available therapy. The guidance addresses the applicability of expedited programs to rare diseases, clarification on available therapy, and additional detail on possible flexibility in manufacturing and product quality. The guidance also clarifies the qualifying criteria for breakthrough therapy designation and provides examples of surrogate endpoints and intermediate clinical endpoints used to support accelerated approval.