

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 May 5, 2020.

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 website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

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 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-10275 CAHPS Home Health Care Survey

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 without change of a currently approved collection; *Title of Information Collection:* CAHPS Home Health Care Survey; *Use:* The national implementation of the Home Health Care CAHPS Survey is designed to collect ongoing data from samples of home health care patients who receive skilled services from Medicare-certified home health agencies.

The survey is necessary because it fulfills the goal of transparency with the public about home health patient experiences. The survey is used by Medicare-certified home health agencies to improve their internal quality assurance in the care that they provide in home health. The HHCAPHS survey is also used in a Medicare payment program. Medicare-certified home health agencies (HHAs) must contract with CMS-approved survey vendors that conduct the HHCAPHS on behalf of the HHAs to meet their requirements in the Home Health Quality Reporting Program. *Form Number:* CMS-10257 (OMB control number: 0938-1066); *Frequency:* Yearly; *Affected Public:* Individuals and Households; *Number of Respondents:* 1,195,930; *Total Annual Responses:* 1,294,820; *Total Annual Hours:* 453,239. (For policy questions

regarding this collection contact Lori Teichman at 410-786-6684.)

Dated: *March 3, 2020.*

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2020-04612 Filed 3-5-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10718, CMS-304-304a and CMS-368/R-144]

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 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 April 6, 2020.

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' website address at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

1. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

2. 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:* New collection; *Title of Information Collection:* Model Medicare Advantage and Medicare Prescription Drug Plan Individual Enrollment Request Form; *Use:* This information collection is necessary for the Medicare beneficiary (or their legal representative), to enroll in an MA or PDP plan, even if switching plans within the same MA or PDP organization. To consider an election complete, the individual must:

- Complete an enrollment request;
- Provide required information to the MA or PDP organization within the required time frames;
- Submit the completed request to the MA or PDP organization during a valid enrollment period.
- MA and PDP organizations, applicants to MA and PDP

organizations, and the CMS will use the information collected to comply with the eligibility and enrollment requirements for Medicare Part C and Part D plans.

Section 4001 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33) enacted August 5, 1997, established Part C of the Medicare program, known as the Medicare + Choice program, (now referred to as Medicare Advantage (MA)). As required by 42 CFR 422.50(a)(5), an MA-eligible individual who meets the eligibility requirements for enrollment into an MA or MAPD plan may enroll during the enrollment periods specified in § 422.62, by completing an enrollment form with the MA organization or enrolling through other mechanisms that CMS determines are appropriate.

Section 101 of Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) enacted December 8, 2003, established Part D of the Medicare program, known as the Voluntary Prescription Drug Benefit Program. As required by 42 CFR 423.32(a) and (b), a Part D-eligible individual who wishes to enroll in a Medicare prescription drug plan (PDP) may enroll during the enrollment periods specified in § 423.38, by completing an enrollment form with the PDP, or enrolling through other mechanisms CMS determines are appropriate. *Form Number:* CMS-10718 (OMB control number: 0938-New); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 14,749,256; *Total Annual Responses:* 14,749,256; *Total Annual Hours:* 7,861,354. (For policy questions regarding this collection contact Deme Umo at (410) 786-8854.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Reconciliation of State Invoice (ROSI) and Prior Quarter Adjustment Statement (PQAS); *Use:* Form CMS-304 (ROSI) is used by manufacturers to respond to the state's rebate invoice for current quarter utilization. Form CMS-304a (PQAS) is required only in those instances where a change to the original rebate data submittal is necessary. *Form Number:* CMS-304 and -304a (OMB control number: 0938-0676); *Frequency:* Quarterly; *Affected Public:* Business or other for-profits; *Number of Respondents:* 1,255; *Total Annual Responses:* 5,020; *Total Annual Hours:* 227,416. (For policy questions regarding this collection contact Andrea Wellington at 410-786-3490.)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicaid Drug Rebate State Reporting Program Forms; *Use:* We develop the rebate amount per drug unit from information supplied by the drug manufacturers and distributes these data to the states. States then must report quarterly to the drug manufacturers and report to us the total number of units of each dosage form/strength of their covered outpatient drugs reimbursed during a quarter and the rebate amount to be refunded. This report is due within 60 days of the end of each calendar quarter. The information in the report is based on claims paid by the state Medicaid agency during a calendar quarter. Form CMS-R-144 (Quarterly Report Data) is required from states quarterly to report utilization for any drugs paid for during that quarter. Form CMS-368 (Administrative Data) is required only in those instances where a change to the original data submittal is necessary. *Form Number:* CMS-368 and -R-144 (OMB control number: 0938-0582); *Frequency:* Quarterly and on occasion; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 234; *Total Annual Hours:* 12,101. (For policy questions regarding this collection contact Shannon Evans at 410-786-3083.)

Dated: March 3, 2020.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0179]

Training Program for Regulatory Project Managers; Information Available to Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) Center for Drug Evaluation and Research (CDER) is announcing the continuation of the Regulatory Project Management Site Tours and Regulatory Interaction Program (the Site Tours Program). The purpose of this document is to invite pharmaceutical companies interested in