

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:* Annual Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Participation Report; *Use:* The collected baseline data is used to assess the effectiveness of state early and periodic screening, diagnostic and treatment (EPSDT) programs in reaching eligible children (by age group and basis of Medicaid eligibility) who are provided initial and periodic child health screening services, referred for corrective treatment, and receiving dental, hearing, and vision services. This assessment is coupled with the state's results in attaining the participation goals set for the state. The information gathered from this report, permits federal and state managers to evaluate the effectiveness of the EPSDT law on the basic aspects of the program. *Form Number:* CMS-416 (OMB control number 0938-0354); *Frequency:* Yearly and on occasion; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 1,512. (For policy questions regarding this collection contact Karen Matsuoka at 410-786-9726.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* PACE State Plan Amendment Preprint; *Use:* If a state elects to offer PACE as an optional Medicaid benefit, it must complete a state plan amendment preprint packet described as "Enclosures 3, 4, 5, 6, and 7." CMS will review the information provided in order to determine if the state has properly elected to cover PACE services as a state plan option. In the event that the state changes something in the state plan, only the affected page must be updated. *Form Number:* CMS-10227 (OMB control number: 0938-1027); *Frequency:* Once and occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 7; *Total Annual Responses:* 2; *Total Annual Hours:* 140. (For policy questions regarding this collection contact Angela Cimino at 410-786-2638.)

Dated: January 22, 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

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10725]

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 March 30, 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-10725 Pharmacy Benefit Manager Transparency

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:* New information collection (Request for a new OMB control number); *Title of Information Collection:* Pharmacy Benefit Manager Transparency; *Use:* The Patient Protection and Affordable Care Act

(Pub. L. 111–148) and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively, the Patient Protection and Affordable Care Act (PPACA)) were signed into law in 2010. The PPACA established competitive private health insurance markets, called Marketplaces or Exchanges, which give millions of Americans and small businesses access to qualified health plans (QHPs), including stand-alone dental plans (SADPs)—private health and dental insurance plans that are certified as meeting certain standards. The PPACA added section 1150A of the Social Security Act, which requires pharmacy benefit managers (PBMs) to report prescription benefit information to the Department of Health and Human Services (HHS). PBMs are third-party administrators of prescription programs for a variety of types of health plans, including QHPs. The Centers for Medicare and Medicaid Services (CMS) files this information collection request (ICR) in connection with the prescription benefit information that PBMs must provide to HHS under section 1150A. The burden estimate for this ICR reflects the time and effort for PBMs to submit the information regarding PBMs and prescription drugs. *Form Number:* CMS–10725 (OMB control number: 0938–NEW); *Frequency:* Annually; *Affected Public:* Private Sector (business or other for-profits), *Number of Respondents:* 40; *Number of Responses:* 275. *Total Annual Hours:* 1,400. For questions regarding this collection contact Ken Buerger at 410–786–1190.

Dated: January 23, 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–2019–N–5900]

Agency Information Collection Activities; Proposed Collection; Comment Request; Endorser Status and Explicitness of Payment in Direct-to-Consumer Promotion

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is

announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on a proposed study entitled “Endorser Status and Explicitness of Payment in Direct-to-Consumer Promotion.”

DATES: Submit either electronic or written comments on the collection of information by March 30, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 30, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 30, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, 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 No. FDA–2019–N–5900 for “Endorser Status and Explicitness of Payment in Direct-to-Consumer Promotion.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff 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 made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the