become a PO must submit an application to CMS that describes how the entity meets all the requirements in the PACE program. An entity's application must be accompanied by an assurance from the State Administering Agency (SAA) of the State in which the PO is going to be located.

Beginning in 2016, initial PACE applications will be submitted via a new automated, electronic submission process. An application also must be submitted for a PO that seeks to expand its service area and/or add a new PACE center site.

The purpose of this PRA package is to enable the submission of both initial PACE applications, as well as service area expansion applications. We have successfully transitioned the Medicare Advantage application and Prescription Drug Plan (PDP) application to a fully electronic submission process, enabling a more organized and streamlined review, and would like to bring those same efficiencies to all PACE application processes. OMB approval would help ensure applicant compliance with CMS' requirements and ability to gather data used to support approval or denial of either an initial PACE application or a service area expansion application submitted by an existing PO. *Form Number:* CMS–R–244 (OMB control number: 0938–0790); *Frequency:* Once and occasionally; *Affected Public:* Private sector (Not-for-profit institutions); *Number of Respondents:* 730; *Total Annual Responses:* 55,060; *Total Annual Hours:* 5,748. (For policy questions regarding this collection contact Debbie Vanhoven at 410–786–6625.)

Dated: April 27, 2016.

William N. Parham, III,

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

[FR Doc. 2016–10231 Filed 4–29–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–367 and CMS–10243]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Department of Health and Human 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 require; 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: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by July 1, 2016

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–367 Medicaid Drug Program—Monthly and Quarterly Drug Reporting Format

CMS–10243 Testing Experience and Functional Tools: Functional Assessment Standardized Items (FASI) Based on the CARE Tool

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.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicaid Drug Program—Monthly and Quarterly Drug Reporting Format; *Use:* Labelers transmit drug product and pricing data to CMS within 30 days after the end of each calendar month and quarter. CMS calculates the unit rebate amount (URA) and the unit rebate offset amount (UROA) for each new drug application (NDC) and distributes to all State Medicaid agencies. States use the URA to invoice the labeler for rebates and the UROA to report onto the CMS–64. The monthly data is used to calculate Federal Upper Limit (FUL) prices for applicable drugs and for states that opt to use this data to establish their pharmacy reimbursement methodology. *Form Number:* CMS–367 (OMB control number: 0938–0578); *Frequency:* Monthly and Quarterly; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 610;

Total Annual Responses: 12,810; *Total Annual Hours:* 3,618,703. (For policy questions regarding this collection contact Samone Angel at 410–786–1123.)

2. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Testing Experience and Functional Tools: Functional Assessment Standardized Items (FASI) Based on the CARE Tool; *Use:* In 2012, CMS funded a project entitled, Technical Assistance to States for Testing Experience and Functional Tools (TEFT) Grants. One component of this demonstration is to amend and test the reliability of a setting-agnostic, interoperable set of data elements, called ''items,'' that can support standardized assessment of individuals across the continuum of care. Items that were created for use in post-acute care settings using the Continuity Assessment Record and Evaluation (CARE) tool have been adopted, modified, or supplemented for use in community-based long-term services and supports (CB–LTSS) programs. This project will test the reliability and validity of the function-related assessment items, now referred to as Functional Assessment Standardized Items (FASI), when applied in community settings, and in various populations: Elders (65 years and older); younger adults (18–64) with physical disabilities; and adults of any age with intellectual or developmental disabilities, with severe mental illness, or with traumatic brain injury.

Individual-level data will be collected two times using the TEFT FASI Item Set. The first data collection effort will collect data that can be analyzed to evaluate the reliability and validity of the FASI items when used with the five waiver populations. Assessors will conduct functional assessments in client homes using the TEFT FASI Item Set. Changes may be recommended to individual TEFT FASI items, to be made prior to releasing the TEFT FASI items for use by the states. The FASI Field Test Report will be released to the public.

The second data collection will be conducted by the states to demonstrate their use of the FASI data elements. The assessment data could be used by the states for multiple purposes. They may use the standardized items to determine individual eligibility for state programs, or to help determine levels of care within which people can receive services, or other purposes. In the second round of data collection, states will demonstrate their proposed uses, manage their FASI data collection and conduct their own analysis, to the extent they propose to do such tasks. The states have been funded under the demonstration grant to conduct the round 2 data collection and analysis. These states will submit reports to CMS describing their experience in the Round 2 data collection, including the items they collected, how they planned to use the data, and the types of challenges and successes they encountered in doing so. The reports may be used by CMS in their evaluation of the TEFT grants. *Form Number:* CMS–10243 (OMB control number: 0938–1037); *Frequency:* On occasion; *Affected Public:* Individuals and households; *Number of Respondents:* 5,650; *Total Annual Responses:* 5,650; *Total Annual Hours:* 2,825. (For policy questions regarding this collection contact Allison Weaver at 410–786–4924.)

Dated: April 27, 2016.

William N. Parham, III,

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

[FR Doc. 2016–10232 Filed 4–29–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0755]

Compliance Policy Guide Sec. 690.150 Labeling and Marketing of Dog and Cat Food Diets Intended To Diagnose, Cure, Mitigate, Treat, or Prevent Diseases; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a compliance policy guide (CPG) entitled ''Compliance Policy Guide Sec. 690.150 Labeling and Marketing of Dog and Cat Food Diets Intended to Diagnose, Cure, Mitigate, Treat, or Prevent Diseases.'' This CPG provides guidance to FDA staff on issues related to dog and cat diets that are labeled and/or marketed as intending to diagnose, cure, mitigate, treat, or prevent diseases and to provide all or most nutrients in support of meeting the animal's total daily nutrient requirements. This CPG finalizes the draft CPG entitled ''Compliance Policy Guide Sec. 690.150 Labeling and Marketing of Nutritional Products Intended for Use to Diagnose, Cure, Mitigate, Treat, or Prevent Disease in Dogs and Cats,'' dated September 10, 2012.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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 No. FDA–2012–D–0755 for ''Compliance Policy Guide Sec. 690.150 Labeling and Marketing of Dog and Cat Food Diets Intended to Diagnose, Cure, Mitigate, Treat, or Prevent Diseases.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets