

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 on the collection(s) of information must be received by the OMB desk officer by *August 1, 2016*.

**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](mailto: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:* Implementation

of the Medicare Prescription Drug Plan (PDP) and Medicare Advantage (MA) Plan Disenrollment Reasons Survey; *Use:* This data collection complements the satisfaction data collected through the Medicare Consumer Assessment of Healthcare Providers and Systems survey by providing dissatisfaction data in the form of reasons for disenrollment from a Prescription Drug Plan. The data collected in this survey can be used to improve the operation of Medicare Advantage (MA) (both MA and MA-PD) contracts and standalone prescription drug plans (PDPs) through the identification of beneficiary disenrollment reasons. Plans can use the information to guide quality improvement efforts. The data can also be used by beneficiaries who need to choose among the different MA and PDP options. To the extent that these data identify areas for improvement at the contract level they can be used for contract oversight. *Form Number:* CMS-10316 (OMB control number: 0938-1113); *Frequency:* Yearly; *Affected Public:* Individuals or households; *Number of Respondents:* 56,972; *Total Annual Responses:* 56,972; *Total Annual Hours:* 15,032. (For policy questions regarding this collection contact Beth Simon at 415-744-3780.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Outcome and Assessment Information Set (OASIS) OASIS-C2/ICD-10; *Use:* Home health agencies (HHAs) are required to collect the outcome and assessment information data set (OASIS) to participate in the Medicare program. The OASIS item set has been revised and is now referred to as OASIS-C2. It is scheduled for implementation on January 1, 2017. The OASIS C2 is being modified to include changes pursuant to the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act), and formatting changes throughout the document. *Form Number:* CMS-10545 (OMB control number: 0938-1279); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 12,198; *Total Annual Responses:* 17,900,000; *Total Annual Hours:* 15,812,511. (For policy questions regarding this collection contact Michelle Brazil at 410-786-1648).

Dated: June 27, 2016.

**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

### Administration for Community Living

#### Administration on Aging

#### Agency Information Collection Activities; Proposed Collection; Comment Request; State Annual Long-Term Care Ombudsman Report Amended Data Collection

**AGENCY:** Administration for Community Living, Administration on Aging, HHS.

**ACTION:** Notice.

**SUMMARY:** The Administration on Community Living, Administration on Aging (ACL/AoA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. 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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to conflict of interest reporting per the Code of Federal Regulations and Older Americans Act Title VII.

**DATES:** Submit written or electronic comments on the collection of information by August 29, 2016.

**ADDRESSES:** Submit electronic comments on the collection of information to: [louise.ryan@acl.hhs.gov](mailto:louise.ryan@acl.hhs.gov).

Submit written comments on the collection of information to: U.S. Department of Health and Human Services: Administration for Community Living 701 Fifth Avenue, Suite 1600 M/S RX-33, Seattle, WA 98104, Attention: Louise Ryan.

**FOR FURTHER INFORMATION CONTACT:** Louise Ryan by telephone: (206) 615-2514 or by email: [louise.ryan@acl.hhs.gov](mailto:louise.ryan@acl.hhs.gov)

**SUPPLEMENTARY INFORMATION:** 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. "Collection of information" is defined

in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency request 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 provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL/AoA is publishing notice of the proposed collection of information set forth in this document. With respect to the following collection of information, AoA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of AoA's functions, including whether the information will have practical utility; (2) the accuracy of AoA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

Section 1327.21 (conflicts of interest) of the Long-Term Care Ombudsman Program rule requires the State agency and the Ombudsman to identify and take steps to remove or remedy organizational conflicts of interest between the Office and the State agency or other agency carrying out the Ombudsman program. Additionally the rule requires the Ombudsman to identify organizational conflicts of interest in the Ombudsman program and describe steps taken to remove or remedy conflicts within the annual report submitted to the Assistant Secretary through the National Ombudsman Reporting System. The proposed form and instructions are posted on the ACL/AoA Web site at: [http://www.aoa.acl.gov/AoA\\_Programs/Elder\\_Rights/Ombudsman/index.aspx](http://www.aoa.acl.gov/AoA_Programs/Elder_Rights/Ombudsman/index.aspx).

AoA estimates the burden of this additional collection of information as follows: Approximately 10 to 30 minutes per respondent, depending on the number of conflicts to report, with 52 state Ombudsman programs responding annually for a range of 8.6 to 26 hours.

Dated: June 23, 2016.

**Kathy Greenlee,**

*Administrator and Assistant Secretary for Aging.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0065]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Extension of Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA or we) is extending the comment period for the notice that appeared in the **Federal Register** of May 5, 2016. In the notice, FDA announced an opportunity for public comment on the proposed collection of certain information by the Agency. We are taking this action due to maintenance on the Federal eRulemaking portal from July 1 through July 5, 2016.

**DATES:** FDA is extending the comment period on the notice published May 5, 2016 (81 FR 27140). Submit either electronic or written comments by July 12, 2016.

**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-2013-N-0065 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002." 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 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 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 <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. 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