collection tool may be found on the ACL Web site: *http://www.aoa.acl.gov/Program_Results/Program_survey.aspx.*

The total burden estimate for the remaining data collection is: 482.67 hours.

Dated: October 12, 2016.

Edwin L. Walker,

Acting Assistant Secretary for Aging.

[FR Doc. 2016–25416 Filed 10–19–16; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Evaluation of the Elderly Nutritional Services Program

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (formerly the Administration on Aging (AoA)) is announcing that the continuation of collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by November 21, 2016.

ADDRESSES: Submit written comments on the collection of information by fax 202.395.6974 to the OMB Desk Officer for ACL, Office of Information and Regulatory Affairs, OMB.

FOR FURTHER INFORMATION CONTACT: Susan Jenkins, 202.795.7369.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, the Administration for Community Living (Formerly the Administration for Aging) has submitted the following proposed collection of information to OMB for review and clearance. The data collection associated with the Evaluation of the Elderly Nutrition Services Program (ENSP) is necessary to meet three broad objectives of ACL: (1) To provide information to support program planning, including an analysis of program processes, (2) to develop information about program efficiency and cost issues, and (3) to assess program effectiveness, as measured by the program's effects on a variety of important outcomes, including nutrient adequacy, socialization opportunities, health outcomes, and, ultimately, helping elderly people avoid institutionalization. The renewal is to complete the data collection related to objective 3.

In response to the 60-day **Federal Register** notice related to this proposed data collection and published on July 19, 2016, no relevant comments were was received. The proposed data collection tool may be found on the ACL Web site: *http://www.aoa.acl.gov/Program_Results/Program_survey.aspx.*

The total burden estimate for the remaining data collection is: 192 hours.

Dated: October 14, 2016.

Edwin L. Walker,

Acting Assistant Secretary for Aging.

[FR Doc. 2016–25414 Filed 10–19–16; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living/Administration on Aging

Agency Information Collection Activities; Public Comment Request; State Annual Long-Term Care Ombudsman Report and Instructions

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

ACTION: Notice.

SUMMARY: The Administration on Aging (AoA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by November 21, 2016.

ADDRESSES: Submit written comments on the collection of information by fax 202.395.5806 or by email to *OIRA_submission@omb.eop.gov,* Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Louise Ryan, telephone: (206) 615–2514; email: *louise.ryan@acl.hhs.gov*

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

States provide the following data and narrative information in the report:

1. Numbers and descriptions of cases filed and complaints made on behalf of long-term care facility residents to the statewide ombudsman program;

2. Major issues identified that impact the quality of care and life of long-term care facility residents;

3. Statewide program operations; and

4. Ombudsman activities in addition to complaint investigation.

5. A new requirement to include organizational conflict of interest reporting as required by the reauthorized Older Americans Act and the LTC Ombudsman program rule CFR 1324.21.

The report form and instructions have been in continuous use, with minor modifications, since they were first approved by OMB for the FY 1995 reporting period. This current request is for a Revision of a Currently Approved Collection (ICR Rev), which will provide approval for FFY 2016–2018 with modifications to include organizational conflict of interest reporting as required by the reauthorized Older Americans Act, Section 712(f) and the LTC Ombudsman program rule CFR 1324.21.

The data collected on complaints filed with ombudsman programs and narrative on long-term care issues provide information to Centers for Medicare and Medicaid Services and others on patterns of concerns and major long-term care issues affecting residents of long-term care facilities. Both the complaint and program data collected assist the states and local ombudsman programs in planning strategies and activities, providing training and technical assistance and developing performance measures.

Comments in Response to the 60 Day Federal Register Notice

A notice was published in the **Federal Register**/Vol. 81, No. 126/Thursday, June 30, 2016 Notices, Pages 42712–42713, announcing that AoA was requesting modification of the current form and instructions to incorporate conflict of interest reporting requirements, directing readers to the AoA Web site where these documents are posted and providing an opportunity for public comment. One comment was received from the National Association of Ombudsman Programs (NASOP).

NASOP members disagreed with the burden estimate developed by AoA, stating:

Because an overwhelming majority of state long-term care ombudsman programs designate local ombudsman entities, those circumstances lead to a greater likelihood of organizational conflicts of interest. The burden is compounded by the number of local ombudsman entities within a state and will have multiple sources of reporting organizational conflicts at local or regional levels up to the states before states can report via NORS. Further, because approximately half of state

long-term care ombudsman programs are housed within an umbrella agency, this also increases the likelihood that state programs have multiple organizational conflicts that must be identified, remedied or removed, and reported via NORS.

In response to NASOP's concerns about burden estimates, we made a change in our estimated burden hours from one-half hour per state to one hour per state.

NASOP requested additions to the instructions and report form such as the ability to certify that there was no change in conflicts/remedies from the previous reporting year; and to allow for the ability to report a conflict and remedy that applies to many entities as a reporting entry. These suggestions were helpful and were incorporated into the instructions and form. They did not affect the estimated burden.

NASOP also recommended that AoA/ACL add a reporting option in a check box to indicate a state has identified a conflict, but the conflict has not been remedied. We do not intend to take this recommendation because it would be contrary to the rule and law which require states to identify, remove or remedy conflicts and to report on such remedies. ACL is providing on-going technical assistance to states on the implementation of the Ombudsman program rule, including technical assistance on conflicts of interest and steps to remedy any identified conflicts.

A reporting form and instructions may be viewed in the ombudsman section of the AoA Web site: *http://www.aoa.acl.gov/AoA_Programs/Elder_Rights/Ombudsman/index.aspx.* AoA estimates the burden of this collection and entering the additional report information as follows: Approximately 10 to 60 minutes per respondent, depending on the number of conflicts to report, with 52 state Ombudsman programs responding annually. This brings the total burden hours to approximately 7,753 hours, (149 hours on average per program) with 52 Offices of Long-Term Care Ombudsman programs responding annually.

Summary	Local Ombudsman programs	Office of state Ombudsman	Total burden hours	52 Programs
Hours	132.1	17	149.1	7,753 hours.

Dated: October 12, 2016.

Edwin L. Walker,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2016–25418 Filed 10–19–16; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0530]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Pre-Submission Program for Medical Devices

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 November 21, 2016.

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 0910–0756. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *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.

Pre-Submission Program for Medical Devices—OMB Control Number 0910–0756—Extension

The guidance entitled ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' describes the Pre-Submission program for medical devices reviewed in the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER). The guidance provides recommendations regarding the information that should be submitted in a Pre-Submission package and procedures that should be followed for meetings between CDRH and CBER staff and industry representatives or application sponsors. In addition to Pre-Submissions, the guidance addresses other feedback mechanisms including Informational Meetings, Study Risk Determinations, Formal Early Collaboration Meetings, and Submission Issue Meetings and the procedures to request feedback using these mechanisms.

A Pre-Submission is defined as a formal written request from an applicant for feedback from FDA to be provided in the form of a formal written response or, if the manufacturer chooses, a meeting or teleconference in which the feedback is documented in meeting minutes. A Pre-Submission is appropriate when FDA's feedback on specific questions is necessary to guide product development and/or application preparation. The proposed collections of information are necessary to allow the Agency to receive Pre-Submission packages in order to implement this voluntary submission program.

For clarity, we are requesting that the title of the information collection request, OMB control number 0910–0756, be changed to ''Pre-Submission Program for Medical Devices.''

In the **Federal Register** of July 28, 2016 (81 FR 49678), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows: