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 18, 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 at 45 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 at 45 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)
Hours	132.1	17	149.1	7,753

Dated: October 12, 2016.

Edwin L. Walker,

Acting Administrator and Assistant Secretary for Aging.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2406]

Emerging Issues and Cross-Cutting Scientific Advances; Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is establishing a public docket to receive input on emerging issues and cross-cutting scientific advances that may impact FDA preparedness and inter-Agency activities. Interested parties are invited to submit comments regarding emerging technologies and cross-cutting scientific advances of importance to FDA. The focus is on areas that may impact FDA in 5 or more years.

DATES: Submit either electronic or written comments by October 21, 2019.

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–2016–N–2406 for ''Emerging Issues and Cross-Cutting Scientific Advances.'' 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 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Donna Mendrick, National Center for Toxicological Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–8892, *Donna.Mendrick@fda.hhs.gov;* or Michael Morgan, Office of Regulatory Science and Innovation, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–3832, *Michael.Morgan@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our Nation's food supply, cosmetics, and products that emit radiation. FDA is tasked with advancing the public health by helping to speed innovations that protect the public health. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products, to protect the public health, and to reduce tobacco use by minors. Finally, FDA plays a significant role in the Nation's counterterrorism capability. FDA fulfills this responsibility by ensuring the security of the food supply, and by fostering development of medical products used to respond to deliberate and naturally emerging public health threats.

FDA's ability to achieve its mission relies on awareness of, and proactive preparedness for, emerging issues and scientific advances, which will impact the development of regulated products well in advance of formal FDA regulatory submissions (*e.g.,* 5–10 years). To realize this goal requires long-range horizon scanning by a cadre of scientific leaders from FDA, other government Agencies, interested stakeholders, and the public. Emerging sciences, such as synthetic biology, are expected to impact FDA regulated products in the relatively near term. The goal of this initiative is to identify issues and advances that will impact the Agency in the longer term and thus may be in their infancy.

FDA formed the Emerging Sciences Working Group to provide an FDA-wide science-based forum to identify and