

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.
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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 CBEB 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:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

FDA center	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
CDRH	2,465	1	2,465	137	337,705
CBER	79	1	79	137	10,823
Total					348,528

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents are medical device manufacturers subject to FDA's laws and regulations. FDA's annual estimate of 2,544 submissions is based on experienced trends over the past several years. FDA's administrative and technical staffs, who are familiar with the requirements for current Pre-Submissions, estimate that an average of 137 hours is required to prepare a Pre-Submission.

Dated: October 13, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Comments on the Proposed Measures and 2020 Targets for the National Action Plan for Adverse Drug Event Prevention: Inpatient and Outpatient Measures for Reduction of Adverse Drug Events From Anticoagulants, Diabetes Agents, and Opioid Analgesics

AGENCY: Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Office of Disease Prevention and Health Promotion (ODPHP), on behalf of the U.S. Department of Health and Human Services (HHS) Federal Interagency Steering Committee for Adverse Drug Events, proposes new measures and targets for adverse drug events (ADEs) from anticoagulants, diabetes agents, and opioid analgesics for the *National Action Plan for Adverse Drug Event Prevention (ADE Action Plan)*. Based on input from the Federal Interagency Workgroups for Adverse Drug Events, six national measures and targets for the reduction of ADEs are being proposed. Each drug class highlighted in the *ADE Action Plan* (anticoagulants, diabetes agents, and opioid analgesics) includes

a proposed inpatient and outpatient measure to track national progress in reduction of ADEs from these drug classes. The proposed targets will reflect improvement efforts over a four to six year period since the release of the *ADE Action Plan* in August 2014. As such, HHS is proposing a baseline year of 2014 for five of the measures and 2016 for one measure. All targets are to be achieved by 2020. HHS invites interested public and private professionals, organizations, and consumer representatives to submit written comments on the proposed 2020 ADE targets, found at <https://health.gov/hcq/ade-measures.asp>.

DATES: Comments on the proposed ADE 2020 measures and targets must be received no later than 5 p.m. on November 21, 2016.

ADDRESSES: Interested persons or organizations are invited to submit written comments by any of the following methods:

- *Email:* OHQ@hhs.gov (please indicate in the subject line: Proposed ADE Measures and Targets)
- *Mail/Courier:* Office of Disease Prevention and Health Promotion, Attn: Division of Health Care Quality, Department of Health and Human Services, 1101 Wootton Parkway, Suite LL100, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Anna Gribble, Health Policy Fellow, Office of Disease Prevention and Health Promotion, via email at anna.gribble@hhs.gov.

SUPPLEMENTARY INFORMATION: In September 2012, in response to heightened awareness of the contribution of ADEs to the burden of health care-related harm and costs, the Office of the Assistant Secretary for Health (OASH) marshaled the wide-ranging and diverse resources of federal partners to form an extensive interagency partnership, the Federal Interagency Steering Committee and Workgroups for Adverse Drug Events, whose goals would be to develop the *ADE Action Plan*, as well as identify measures to track national progress in

reducing ADEs and targets to meet based on those measures.

ODPHP, in conjunction with the Federal Interagency Steering Committee and three Federal Interagency Workgroups, developed and released the final *ADE Action Plan* in 2014. The *ADE Action Plan* seeks to engage all stakeholders in a coordinated, aligned, and multi-sector effort to reduce ADEs that are clinically significant, account for the greatest number of measurable harms as identified by existing surveillance systems, and are largely preventable; these were identified as ADEs resulting from inpatient and outpatient use of anticoagulants, diabetes agents, and opioid analgesics (with specific focus on ADEs from therapeutic use of opioids). The *ADE Action Plan* identifies the federal government's highest priority strategies and opportunities for advancement, which will have the greatest impact on reducing ADEs. Implementation of these strategies is expected to result in safer and higher quality health care services, reduced health care costs, informed and engaged consumers and ultimately, improved health outcomes. The reduction of ADEs subsequent to implementation of these strategies will be tracked by the proposed measures and will aim to meet the targeted reduction rate by 2020.

The six proposed measures use data from the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA). The inpatient and outpatient measures for anticoagulants and diabetes agents and the outpatient measure for opioids will set baseline rates using data from 2014 and establish targets to be achieved by 2020. The inpatient opioids measure will have a 2016 baseline and a 2020 target year. The inpatient opioids measure will use data from AHRQ's Quality Safety Review System (QSRS) which will begin collecting data in 2016. The inpatient measures for anticoagulants and diabetes agents will use AHRQ's Medicare Patient Monitoring System (MPSMS) for 2015