Leroy A. Richardson,

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Public Comment Request; Redesign of Existing Data Collection; National Survey of Older Americans Act Participants

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing an opportunity for the public to 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 a 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 a proposed revision to an existing data collection related to the National Survey of Older Americans Act Participants (NSOAAP)(ICR Rev).

DATES: Submit written or electronic comments on the collection of information by November 27, 2017.

ADDRESSES: Submit electronic comments on the collection of information to: *heather.menne@acl.hhs.gov*.

Submit written comments on the collection of information to: U.S. Department of Health and Human Services, Administration for Community Living, Washington, DC 20201, Attention: Heather Menne.

FOR FURTHER INFORMATION CONTACT: Heather Menne by telephone: (202) 795–7733 or by email: *heather.menne@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 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 provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or update of an existing collection of information, before submitting the collection to OMB for approval.

To comply with the above requirement, ACL is publishing a notice of the proposed revision of a currently approved collection of information set forth in this document. With respect to the following collection of information, ACL invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility; (2) the accuracy of ACL'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.

Purpose

The purpose of this data collection is to fulfill requirements of the Older Americans Act and the Government Performance and Results Modernization Act of 2010 (GPRAMA) and related program performance activities. Section 202(a)(16) of the OAA requires the collection of statistical data regarding the programs and activities carried out with funds provided under the OAA and Section 207(a) directs the Assistant Secretary for Aging to prepare and submit a report to the President and Congress based on those data. Section 202(f) directs the Assistant Secretary to develop a set of performance measures for planning, managing, and evaluating activities performed and services provided under the OAA. Requirements pertaining to the measurement and evaluation of the impact of all programs authorized by the OAA are described in section 206(a). The National Survey of Older Americans Act Participants (NSOAAP) is one source of data used to develop and report performance outcome measures and measure program effectiveness in achieving the stated goals of the OAA.

The National Survey of Older Americans Act Participants (NSOAAP) information collection will include consumer assessment surveys for the Congregate and Home-delivered meal nutrition programs; Case Management, Homemaker, and Transportation Services; and the National Family Caregiver Support Program. This survey builds on earlier national pilot studies and surveys, as well as performance measurement tools developed by ACL grantees in the Performance Outcomes Measures Project (POMP). This information will be used by ACL to track performance outcome measures; support budget requests; comply with the GPRA Modernization Act of 2010 (GPRAMA) reporting requirements; provide national benchmark information; and inform program development and management initiatives.

Revisions

With the exception of changes to selected questions (*e.g.,* addition of questions about oral health in 2014), the NSOAAP has been collected in its current form since 2008. This proposed collection is a revision that will replace the currently approved version (OMB Control Number: 0985–0023) by transitioning from a cross-sectional survey to a longitudinal survey. The current National Survey of Older Americans Act Participants (NSOAAP), an exclusively cross-sectional survey, can transition to a longitudinal information collection component by establishing a baseline cohort and conducting follow-up interviews with that cohort at specified time intervals. A baseline cohort can be selected in the same manner as in prior cycles of the cross-sectional NSOAAP. Area Agencies on Aging (AAAs) would be selected with a probability proportional to their size, with some large AAAs sampled with certainty. Random samples of clients within each selected AAA will be sampled from the agencies' client lists. However, in a change from current procedures, the target sample size would be increased from current standards (n=6000) to account for attrition of individuals over time. For the duration of the longitudinal cohort analysis, the same sample of AAAs and clients should be maintained to preserve the longitudinal nature of the study. Three strategies are key for transforming the current survey into a longitudinal study, while preserving the ability to produce nationally representative cross-sectional estimates of client characteristics at each wave. The three strategies include: (1) A higher initial sample size (n=6600), (2) an intensive

operational campaign to keep track of respondents over time, and (3) limiting the number of waves for each cohort study (*e.g.,* three waves are proposed).

The factors that influenced the proposed revision of the NSOAAP, include:

(1) The need to minimize reporting burden on the AAAs by only having AAAs provide client lists for the initial data collection (as there would be no need to re-contact the AAAs until such time as a new longitudinal cohort would be established);

(2) the opportunity to incorporate selected new questions and topics of interest based on public comment and the input from an expert workgroup comprised of gerontologists, survey methodologists, and OAA program experts;

(3) the ability to provide more precise estimates of changes over time in measured quantities than repeated cross-sectional studies with the same sample size;

(4) the ability to track certain types of attrition as outcomes (*e.g.,* client transitions from independent living to group quarters; a client dies, a client no longer uses a service because of moving in with a family member);

(5) the ability to examine changes in the natural history of physical functioning and health and how these outcomes relate to patterns of service utilization over the three annual data collections (*e.g.,* to what extent do clients increase or decrease the use of services over time and what indicators are associated with the change in services?); and

(6) the opportunity to add a rotating topical module in waves 2 and 3 to collect information on emerging issues (*e.g.,* nutrition; health care access; or client experiences with discrimination based on age, sexual orientation, race, or other characteristics) and provide a broader picture of the types of individuals receiving OAA services.

Burden Estimate

The proposed NSOAAP revision reduces the estimated average hour burden per respondent by 11% compared to the current NSOAAP due to the proposed change of a longitudinal data collection in which Area Agencies on Aging need only provide client lists in the first of three years of data collection (compared to annually in the current cross-sectional data collection). Limited expansions in data elements are found in the Family Caregiver Survey. The proposal includes the addition of new questions about caregiving and the well-being of the caregiver. Across the OAA services, greater detail regarding falls, life changes, and social integration are proposed; for clients of Case Management Services, Congregate Nutrition, Home-delivered Nutrition, Homemaker Services, and Transportation Services, greater detail about food security is proposed. The ACL also seeks the opportunity to: (1) Introduce unique topical modules in waves 2 and 3 to collect information on emerging issues such as nutrition, health care access, or client experiences with discrimination based on age, sexual orientation, race, or other characteristics, and (2) conduct brief informant follow-up interviews in waves 2 and 3 when baseline respondents are unreachable.

Taken as a whole, the proposed reductions exceed the proposed increases in data burden. The proposed information collection instruments may be found on the ACL Web site under Proposed Revisions for National Survey of Older Americans Act Participants (NSOAAP), available at: *https://www.acl.gov/about-acl/public-input.*

The estimated average hour burden per respondent for the Redesigned NSOAAP will change from the 0.80 hour estimate in 2017 to 0.71 hours, a decrease due to the proposed change of a longitudinal data collection in which Area Agencies on Aging need only provide client lists in the first of three years of data collection (compared to annually in the current cross-sectional data collection). ACL estimates the burden of this revised collection of information as follows:

TABLE—ESTIMATED ANNUALIZED BURDEN HOURS

Respondent/data collection activity	Number of respondents	Responses per respondent	Average hours per response	Annual burden hours
Baseline				
Area Agency on Aging: Respondent selection process	250	1	4.0	1,000
Service Recipients (*i.e.,* Case Management; Congregate Nutrition; Home-delivered Nutrition; Homemaker; Transportation).	4,400	1	.6667	2,933
National Family Caregiver Support Program Clients	2,200	1	.6667	1,467
Year 2				
Area Agency on Aging: Respondent selection process	0	0	0	0
Service Recipients (*i.e.,* Case Management; Congregate Nutrition; Home-delivered Nutrition; Homemaker; Transportation).	4,200	1	.6667	2,800
National Family Caregiver Support Program Clients	2,100	1	.6667	1,400
Year 3				
Area Agency on Aging: Respondent selection process	0	0	0	0
Service Recipients (*i.e.,* Case Management; Congregate Nutrition; Home-delivered Nutrition; Homemaker; Transportation).	4,000	1	.6667	2,667
National Family Caregiver Support Program Clients	2,000	1	.6667	1,333
Total	19,150	Varies	.710 (weighted mean)	13,600

Dated: September 19, 2017.

Lance Robertson,

Administrator and Assistant Secretary for Aging.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0429]

Classification of Products as Drugs and Devices and Additional Product Classification Issues; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry and FDA staff entitled ''Classification of Products as Drugs and Devices & Additional Product Classification Issues.'' This guidance provides the Agency's current thinking on approaches for classifying products as drugs and devices, and on certain additional product classification issues.

DATES: The announcement of the guidance is published in the **Federal Register** on September 26, 2017.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2011–D–0429 for ''Classification of Products as Drugs and Devices & Additional Product Classification Issues.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff office 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance document entitled ''Classification of Products as Drugs and Devices & Additional Product Classification Issues'' to the Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: John Barlow Weiner, Associate Director for Policy, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993–0002, 301–796–8930.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and FDA staff entitled ''Classification of Products as Drugs and Devices & Additional Product Classification Issues.'' This guidance finalizes two related draft guidance documents issued in June 2011, entitled ''Classification of Products as Drugs and Devices & Additional Product Classification Issues'' and ''Interpretation of the Term 'Chemical Action' in the Definition of Device under Section 201(h) of the Federal Food, Drug, and Cosmetic Act.''

This guidance is intended to provide the Agency's current thinking on approaches for classifying products as drugs and devices, and on certain additional product classification issues. FDA determines whether to classify a product as a drug or device based on the statutory definitions for these terms set forth in section 201(g) and (h) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321(g) and (h)), respectively, as applied to the scientific data concerning the products