

Dated: March 26, 2021.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

[OMB # 0985-0023]

Agency Information Collection Activities; Submission for OMB Review; Public Comment Request; National Survey of Older Americans Act Participants

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living is announcing that the proposed collection of information listed above has been submitted to the Office of Management and Budget (OMB) for review and clearance as required under section 506(c)(2)(A) of the Paperwork Reduction Act of 1995. This 30-Day notice collects comments on the information collection requirements related to the information collection requirements for consumer assessment surveys used by ACL to measure program performance for programs funded under Title III of the Older Americans Act. This notice solicits comments on a proposed revision of a currently approved collection with the addition of a new rotating module to the National Survey of Older Americans Act Participants.

DATES: Submit written comments on the collection of information by May 3, 2021.

ADDRESSES: Submit written comments and recommendations for the proposed information collection within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find the information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. By mail to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW, Rm. 10235, Washington, DC 20503, Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Susan Jenkins, Administration for Community Living, Washington, DC

20201, by email at Susan.Jenkins@acl.hhs.gov or by telephone at 202-795-7369.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, ACL has submitted the following proposed collection of information to OMB for review and clearance. The Administration for Community Living (ACL) is requesting approval to collect data for the National Survey of Older Americans Act (OAA) Participants information collection to 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). Changes identified as a result of these initiatives were incorporated into the last data collection package that was approved by OMB and are included in this proposed extension of a currently approved collection. This information will be used by ACL to track performance outcome measures; support budget requests; comply with the GPRMA Modernization Act of 2010 (GPRMA) reporting requirements; provide national benchmark information; and inform program development and management initiatives.

In addition to the proposed extension of the existing collection of information, ACL is requesting approval for a module on COVID-19 to be added to the currently approved NSOAAP data collection effort. This module supplants the module on Emergency Preparedness that was included in the 60-day FRN due to the ongoing health crisis older adults are experiencing as a result of COVID-19. The Emergency Preparedness module will be added to the 2022 collection instrument.

As part of a nationwide effort to slow transmission of COVID-19, communities have closed locations such as senior centers, adult day care centers, and congregate meal facilities where many older adults received vital home- and community-based services. In addition, many of the in-home services that help older adults to remain in their homes, such as home-delivered meals, homemaker services, and respite care have been curtailed due to fear of spreading COVID-19. This, combined

with families and friends unable to assist loved ones due to the fear of spreading the virus, have left many older adults isolated and without the programs and services they need to remain living safely in the community. The purpose of adding questions on COVID-19 to the NSOAAP is to measure the effect COVID-19 has had on older adults' access to and use of Older Americans Act programs and services during the past year.

The results of this information collection will be used by ACL/AoA to:

- Provide refined national benchmarks for use by states and AAAs.
- Provide secondary data for analysis of various Title III program evaluations.
- Provide performance information for key demographic subgroups, geographical sub regions, and different types of AAAs which will enable ACL/AoA to identify variations in performance and examine the need for additional targeted technical assistance.
- Provide secondary data for analysis of the effect of COVID-19 on access to and use of OAA programs and services among older adults that will be shared with states and AAAs to help structure their programs and services in response to COVID-related changes.

The data will be used by the Administrator of the Administration for Community Living/Assistant Secretary for Aging in testimony and presentations; it will be incorporated into the agency's Annual Report; and it will be used by program staff to identify areas that may need attention at the national level.

Descriptions of previous National Surveys of OAA Participants can be found under the section on OAA Performance Information on ACL's website at: <https://acl.gov/programs/performance-older-americans-act-programs>. Copies of the survey instruments and data from previous National Surveys of OAA Participants can be found and queried using the Aging, Independence, and Disability (AGID) Program Data Portal at <http://www.agid.acl.gov/>.

Comments in Response to the 60-Day Federal Register Notice

A notice published in the **Federal Register** on Tuesday, November 17, 2020 in 85 FR No. 222 page 73273. There were thirteen public comments received during the 60-day FRN, please see ACLs response to comment listed below.

Topic/issue	Comment	ACL response
Food insecurity in older adults.	<p>“We support the inclusion of the USDA module to provide national estimates of the rate of food insecurity among OAA program participants. We recommend this module be continuously included in future administration of this survey.”</p>	<p>ACL concurs and plans to maintain the USDA module and associated questions for the foreseeable future.</p>
Risk of malnutrition	<p>“We suggest that ACL consider adding malnutrition screening questions in addition to the USDA module’s food insecurity questions, such as:</p> <ul style="list-style-type: none"> • Do you ever eat only one meal daily?” • Do limits on chewing, swallowing or physical mobility ever prevent you from eating your home-delivered meals, even though you may be hungry?” • Do limits on chewing, swallowing or physical mobility ever prevent you from getting to your local congregate meal site and eating your meal, even though you may be hungry?” 	<p>ACL recognizes the importance of reducing and assessing risk for malnutrition. However, further deliberation is needed to ensure that we select the most appropriate and universally accepted language. ACL will call upon the expertise of a nutrition workgroup to make recommendations to ACL on selecting the best language to use. The workgroup’s recommendation will inform a redesign of future NSOAAP survey collection efforts.</p>
Medically-tailored meals for participants requiring special diets.	<p>“We suggest that ACL consider adding a question about the need for therapeutic diets or texture-modified meals to better understand the needs of participants as it relates to medically tailored meals.”</p>	<p>ACL recognizes the importance of capturing data on the capability of OAA nutrition programs to accommodate special diets. ACL will call upon nutrition experts to make recommendations and inform a redesign of future NSOAAP collection efforts.</p>
Ethnic and cultural barriers to communication and nutritional preferences.	<p>“We suggest that ACL consider including a question about communication barriers to both the congregate and home-delivered meals modules, such as:</p> <ul style="list-style-type: none"> • Do you have language or cultural barriers to talking with staff at your congregate meal site/your home delivery staff? <p>We also suggest that ACL consider adding a question to both the congregate and home-delivered meals modules about meals meeting cultural preferences.</p>	<p>ACL recognizes that ethnic and cultural barriers may affect participants in the nutrition programs. ACL will call upon nutrition experts to make recommendations and inform a redesign of future NSOAAP collection efforts.</p> <p>ACL is considering a special topical module related to equity and underserved populations.</p>
Nutrition counselor: Rephrase question to improve clarity.	<p>“SVC1(k) asks whether the respondent has access to a “nutrition counselor” who is providing dietary advice based on the respondent’s condition, medications, and related factors. We question why the survey would not specify “a qualified nutrition professional such as a registered dietitian” (or registered dietitian nutritionist), since these professionals are the most qualified to answer such questions. Moreover, in 28 states, only licensed professionals are legally eligible to provide such advice. The term “nutrition counselor” allows for substantial subjective interpretations, and could theoretically include food service staff or other program participants who may be providing such advice against state law.”</p>	<p>ACL recognizes “nutrition counselor” may offer subjective responses. However, respondents may not know if the qualifications of the person providing dietary advice. ACL will call upon nutrition experts to make recommendations and inform a redesign of future NSOAAP collection efforts. The use of terminology for this item will be tested.</p>
Modify item response in nutrition modules to include positive as well as negative changes.	<p>“We note that the survey asks about changes in meals, but almost all coding options for the interviewer are about reductions or negative changes with few opportunities for interviewers to code any positive changes reported by participants. In addition to coding for both reductions and improvements in quality of the food, we recommend adding the corresponding “positive” option for all other codes.”</p>	<p>ACL concurs with this suggested change. The requested change has been made to the survey instrument.</p>
Consistent language in meals program.	<p>“Ensure that consistent language is used to describe the program, particularly for congregate or senior dining meals. Some questions use the term “meals program” while others use the term “lunch program” or, generically, “this service”, including CNR20–23 where three different terms are used across four consecutive questions. This also applies to SVC1 question in Additional Services module. We recommend using the term “meals program” unless exclusively referring to lunch, as some programs serve breakfast or dinner meals rather than lunch meals.”</p>	<p>ACL recognizes that the language used to describe the meals programs may need to be revised to be more consistent. ACL will call upon nutrition experts to make recommendations and inform a redesign of future NSOAAP collection efforts.</p> <p>The term “meals program” will be used at this time due to the variety of food services during the COVID–19 pandemic.</p>
Living independently	<p>“SVC3 asks about continuing to “live independently” vs. “living at home” (as they do in CS15, CNR23, HNR28, HC9 and TR20). The terminology “living independently” is preferred. Simply continuing to live “at home” does not mean that the person is living independently, is living in their own home (vs that of a relative), or has autonomy over where he or she lives.”</p>	<p>ACL concurs with this suggested change. The requested change has been made to the survey instrument.</p>

Topic/issue	Comment	ACL response
Context of “secure”	“SVC3(b) should be more specific with regard to the context of “secure.” We are unsure whether the context is financial, food-based, or related to physical safety.”	The question refers to how participants feel about additional services that they or their care recipient receive. ACL recognizes that the use of the word “secure” may be ambiguous. ACL will call upon experts in the aging network to make recommendations to inform a redesign of future NSOAAP collection efforts.
Multiple meals	“HNR5 should be re-phrased to reflect the fact that many HDM clients receive more than one meal and may consume multiple HDMs in a day.”	ACL recognizes that the question may need to be modified. ACL will call upon nutrition experts to make recommendations and inform a redesign of future NSOAAP collection efforts.
Care recipients under age 60 with dementia.	The 2020 reauthorization of OAA allows “individuals living with dementia under the age of 60 to access certain OAA supports like nutritional services and respite care through the National Family Caregiver Support program. We respectfully request that ACL analyze the data collected on these younger individuals and the services they receive so that those services can be tailored and improved.”	While ACL recognizes the value of collecting data on care recipients of the NFCSP who are under 60, that is not the focus of the NSOAAP. The focus of the NSOAAP is the service recipients, that is, the caregivers.
Emergency preparedness	The advocacy organizations “support ACL’s request to add an emergency preparedness module to the survey. . .”	ACL is not going to add this module for the 2021 administration but still plans to use it in the future.
Question on participant sex (gender identity).	“I encourage the modification of the questions about participant sex to include response options (which are recorded but not verbally offered as options) to include “transgender” and or “other” with a write-in option. The questions this relates to are: DE1 (DEGENDR); CGC (CGPMF); CG83 (CGPMF)—both of the last have the same variable labels and this should be corrected in the survey construction.”	In order to improve demographic data collection related to the LGBT community, ACL is supporting the Measuring Sex, Gender Identity, and Sexual Orientation for the National Institutes of Health an ad hoc panel of the National Academies of Sciences, Engineering, and Medicine which will review current measures and the methodological issues related to measuring sex as a non-binary construct, gender identity, and sexual orientation. The panel will produce a consensus report which is expected in December 2021. ACL will use the report as a foundation for testing new survey questions and administrative data elements. The variable label in the survey instrument for CGPMF was corrected to RGENDER.

Estimated Program Burden

ACL estimates the burden associated with this collection of information as follows:

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours	Cost per hour	Annual burden (cost)
Area Agency on Aging: Respondent selection process.	350	1	4.0	1,400	\$44	\$61,600
Service Recipients (<i>i.e.</i> , Congregate and Home-delivered meal nutrition programs; Case Management, Homemaker, and Transportation Services) + Rotating Module.	4,400	1	.75	3,300	\$25	82,500
National Family Caregiver Support Program Clients + Rotating Module.	2,200	1	.75	1,650	\$25	41,250
Total	6,950	1	.914 (weighted mean).	6,350	Varies	185,350

Dated: March 26, 2021.

Alison Barkoff,

Acting 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-0520]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substances Prohibited From Use in Animal Food or Feed

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: Submit written comments (including recommendations) on the collection of information by May 3, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0627. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRASStaff@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.

Substances Prohibited From Use in Animal Food or Feed—21 CFR Part 589

OMB Control Number 0910-0627—
Extension

This information collection supports Agency regulations regarding substances prohibited from use in animal food or feed. Bovine spongiform encephalopathy (BSE) is a progressive and fatal neurological disorder of cattle that results from an unconventional transmissible agent. BSE belongs to the family of diseases known as transmissible spongiform encephalopathies (TSEs). All TSEs affect the central nervous system of infected animals. Our regulation at § 589.2001 (21 CFR 589.2001), entitled “Cattle materials prohibited in animal food or feed to prevent the transmission of bovine spongiform encephalopathy,” is designed to further strengthen existing safeguards against the establishment and amplification of BSE in the United States through animal feed. The regulation prohibits the use of certain cattle origin materials in the food or feed of all animals. These materials are referred to as “cattle materials prohibited in animal feed” or CMPAF.

Under § 589.2001, no animal feed or feed ingredient can contain CMPAF. As a result, we impose requirements on renderers of specifically defined cattle materials, including reporting and recordkeeping requirements. For purposes of the regulation, we define a renderer as any firm or individual that processes slaughter byproducts; animals unfit for human consumption, including carcasses of dead cattle; or meat scraps. Reporting and recordkeeping requirements are necessary because once materials are separated from an animal it may not be possible, without records, to know whether the cattle material meets the requirements of our regulation.

Reporting: Under our regulations, we may designate a country from which cattle materials are not considered CMPAF. Section 589.2001(f) provides that a country seeking to be so designated must send a written request to the Director of the Center for Veterinary Medicine. The country is required to submit information about its BSE case history, risk factors, measures to prevent the introduction and transmission of BSE, and any other information relevant to determining whether the cattle materials from the requesting country do or do not meet the definitions set forth in § 589.2001(b)(1). We use the information to determine whether to grant a request for designation and to

impose conditions if a request is granted. Section 589.2001(f) further states that countries designated under that section will be subject to our future review to determine whether their designations remain appropriate. As part of this process, we may ask designated countries from time to time to confirm that their BSE situation and the information submitted by them in support of their original application remains unchanged. We may revoke a country’s designation if we determine that it is no longer appropriate. Therefore, designated countries may respond to our periodic requests by submitting information to confirm their designations remain appropriate. We use the information to ensure their designations remain appropriate.

Recordkeeping: Renderers that receive, manufacture, process, blend, or distribute CMPAF, or products that contain or may contain CMPAF, must take measures to ensure that the materials are not introduced into animal feed, including maintaining adequate written procedures specifying how such processes are to be carried out (§ 589.2001(c)(2)(ii)). Renderers that receive, manufacture, process, blend, or distribute CMPAF are required to establish and maintain records sufficient to track the CMPAF to ensure that they are not introduced into animal feed (§ 589.2001(c)(2)(vi)).

Renderers that receive, manufacture, process, blend, or distribute *any* cattle materials must establish and maintain records sufficient to demonstrate that material rendered for use in animal feed was not manufactured from, processed with, or does not otherwise contain, CMPAF (§ 589.2001(c)(3)(i)).

Renderers that receive, manufacture, process, blend, or distribute *any* cattle materials must, if these materials were obtained from an establishment that segregates CMPAF from other materials, establish and maintain records to demonstrate that the supplier has adequate procedures in place to effectively exclude CMPAF from any materials supplied (§ 589.2001(c)(3)(i)). Records will meet this requirement if they include either: (1) Certification or other documentation from the supplier that materials supplied do not include CMPAF (§ 589.2001(c)(3)(i)(A)), or (2) documentation of another method acceptable to FDA, such as third-party certification (§ 589.2001(c)(3)(i)(B)).

Description of Respondents: Respondents to this information collection include rendering facilities, feed manufacturers, livestock feeders, and foreign governments seeking designation under § 589.2001(f).