

Dated: November 25, 2020.

Lance Robertson,

Administrator and Assistant Secretary for Aging.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Proposed Collection; Comment Request; Inventory of Adult Protective Services Practices and Service Innovations

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 information listed above. 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 survey previously ran a 60-day FRN in 83 FR 66276 on 12/26/2018. As required under the PRA we are providing the public an opportunity to comment on any changes or updates applied to this IC since the 2018 publication. We are requesting an abbreviated public comment period for additional 30-days prior to publication of a 30-day FRN and submittal to OMB.

Any changes to the survey from the initial 60-day FRN publication are incorporated into the revised version of the survey. This notice solicits comments on any revisions since the initial publication in 2018. This is a new information collection 0985-New Inventory of Adult Protective Services Practices and Service Innovations.

DATES: Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by December 31, 2020.

ADDRESSES: Submit electronic comments on the collection of information to Stephanie Whittier Eliason Stephanie.WhittierEliason@acl.hhs.gov. Submit written comments on the collection of information to Administration for Community Living, Washington, DC 20201, Attention: Stephanie Whittier Eliason

FOR FURTHER INFORMATION CONTACT:

Stephanie Whittier Eliason, Administration for Community Living, Washington, DC 20201, Phone: (202) 795-7467, Email:

Stephanie.WhittierEliason@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 notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, ACL invites comments on our burden estimates or any other aspect of this collection of information, including:

- (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 to determine burden estimates;
- (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.

Authority

The Elder Justice Act of 2009 requires the Secretary of the U.S. Department of Health and Human Services to carry out a number of activities related to adult protective services (APS) (42 U.S.C. 1397m-1), including developing and disseminating information on APS best practices and conducting research related to the provision of APS.

Furthermore, the Elder Justice Coordinating Council included as its third recommendation for increasing federal involvement in addressing elder

abuse, neglect, and exploitation: "develop a national APS system based upon standardized data collection and a core set of service provision standards and best practices."

Background

The Administration for Community Living (ACL) in the U.S. Department of Health and Human Services (HHS) plans to initiate an Inventory of Adult Protective Services Practices and Service Innovations (APS Practice Survey) in early 2021. Under a contract with ACL, the National Adult Protective Services Technical Assistance Resource Center (APS TARC) is conducting a national program evaluation of APS programs. As part of this evaluation, the APS Practice Survey will identify barriers to meeting policy mandates, and practice innovations and model programs that address such barriers and community-identified needs. It also seeks to identify practice variations in the way APS programs serve older adults and adults with disabilities.

The results of the survey will serve to advance the field of APS and will be useful to many audiences. It will provide baseline information regarding the status of APS programs and services, and the resulting information will help states and territories compare their program characteristics with those of other states and territories. The survey will provide a context for other researchers examining APS programs. It will inform ACL's efforts to support improvement of APS programs through activities such as innovation grants. Finally, it will inform the APS TARC team's efforts to develop resources to enhance APS programs around the country.

This survey has been developed to gather information on APS practices that is not available from other sources. As part of the National Adult Maltreatment Reporting System (NAMRS), ACL collects descriptive data on state and territory agency policies through the Agency Component of that data collection.

Therefore, the proposed survey will not collect any background policy or data items. As part of the APS Program Evaluation, the APS TARC also conducted a detailed examination of state APS policies through development of individual state policy profiles. The profiles were based exclusively on extant information sources obtained without additional data requests from the states. Information on practices gathered in this survey will complement, but will not duplicate, these policy profiles.

Finally, the National Adult Protective Services Association (NAPSA) conducted a survey of State APS programs in 2012, and the National Association of State Units on Aging and Disability (NASUAD) fielded a survey to its members, which are not APS programs, in January 2018 intended to update findings from the NAPSA 2012 survey. Since the survey replicates the original NAPSA survey, the questions in it are not focused on APS practice and are not directed at the same respondents as the proposed survey. As noted, a few topics in the original survey overlap with the proposed instrument, but the wording and focus of the few questions on similar topics are different. From this analysis, we conclude the proposed APS Practice Survey will yield vital information on APS practice not available from other sources.

Proposed Collection Efforts

The APS Practice Survey will collect state- and territory-specific practices for

all aspects of APS casework practice, including staffing, intake, investigation, service planning and delivery, and quality assurance. Across these areas, the survey will collect information on practices such as community partnerships and use of assessment tools.

The APS Practice Survey will be administered online using SurveyMonkey or a similar commercial survey-programming tool. The online survey will include data validation routines to minimize errors or unintentional omissions and will include appropriate skip patterns to reduce burden. Respondents will be state and territory APS agencies, including APS agencies in the District of Columbia, Puerto Rico, Guam, Northern Marianas Islands, Virgin Islands, and American Samoa. No personally identifiable information will be collected.

A pilot version of The APS Practice Survey was tested in nine (9) diverse

states between July and September 2017. Following their pretest of the survey instrument, pilot respondents participated in focus groups in which they provided recommendations on data collection procedures, views on the availability of data being requested, and estimates of the burden to each state and territory for completion of the survey. It is assumed that nearly every state and territory will participate and that time to develop a response will be similar to the experience of states during the pilot test. ACL has calculated the following burden estimates based on the results of the survey pilot test.

To review and comment on the proposed data collection, please visit the ACL public input site at <https://www.acl.gov/about-acl/public-input>.

Estimated Program Burden

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

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
APS Practice Survey	56	1	3.50	196

Estimated Total Annual Burden Hours: 196.

Dated: November 25, 2020.

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-2020-N-1671]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Good Laboratory Practice for Nonclinical Laboratory Studies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 December 31, 2020.

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 0910-0119. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, 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.

Good Laboratory Practice for Nonclinical Laboratory Studies—21 CFR Part 58

OMB Control Number 0910-0119—Extension

Sections 409, 505, 512, and 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348, 355, 360b, and 360e) and related statutes require manufacturers of food additives, human drugs and biological products, animal drugs, and medical devices to demonstrate the safety and utility of their product by submitting applications to FDA for research or marketing permits. Such applications contain, among other important items, full reports of all studies done to demonstrate product safety in man and/or other animals. In order to ensure adequate quality control for these studies and to provide an adequate degree of consumer protection, the Agency issued good laboratory practice (GLP) regulations for nonclinical laboratory studies in part 58 (21 CFR part 58). The regulations specify minimum standards for the proper conduct of safety testing and contain sections on facilities, personnel, equipment, standard operating procedures (SOPs), test and control articles, quality assurance, protocol and conduct of a safety study, records and reports, and laboratory disqualification,