

Dated: October 20, 2023.

Alison Barkoff,

Senior official performing the duties of the Administrator and the 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; State Health Insurance Assistance Program (SHIP) Client Contact Forms OMB Control Number 0985–0040

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 notice solicits comments on the proposed Revision for the information collection requirements related to the State Health Insurance Assistance Program (SHIP) Client Contact Forms OMB Control Number 0985–0040.

DATES: Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by December 26, 2023.

ADDRESSES: Submit electronic comments on the collection of information to: Katherine.Glendenning@acl.hhs.gov. Submit written comments on the collection of information to Administration for Community Living, 330 C Street SW, Washington, DC 20201, Attention: Katherine Glendenning.

FOR FURTHER INFORMATION CONTACT: Katherine Glendenning at Katherine.Glendenning@acl.hhs.gov, or (202) 795–7350.

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 as and includes agency requests or

requirements that members of the public submit reports, keep records, or provide information to a third party. The PRA requires Federal agencies to provide a 60-day 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) Ways to enhance the quality, utility, and clarity of the information to be collected;

(3) 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; 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.

The purpose of this data collection is to collect performance data from grantees, grantee team members and partners. Congress requires this data collection for program monitoring and Government Performance Results Act (GPRA) purposes. This data collection allows ACL to communicate with Congress and the public on the SHIP, the SMP program, and the Medicare Improvements for Patients & Providers Act (MIPPA) program. The SHIP, SMP, and MIPPA programs are located in each of the 50 states, the District of Columbia, Puerto Rico, Guam and the U.S. Virgin Islands. In order to ensure that grantees report activity accurately and consistently, it is imperative that these data collection tools remain active. The respondents for this data collection are grantees, grantee team members, and partners who meet with Medicare beneficiaries and older adults’ in-group settings and in one-on-one sessions to educate them on Medicare enrollment, Medicare benefits and subsidy programs, the importance of being aware of Medicare fraud, error and abuse, and having the knowledge to protect the Medicare system.

Authorizing Legislation

Section 4360(f) of OBRA 1990 created the State Health Insurance Assistance Program (SHIP) and requires the Secretary to provide a series of reports to the U.S. Congress on the performance of the SHIP program annually. The law also requires ACL to report on the program’s impact on beneficiaries and to obtain important feedback from beneficiaries. This tool captures the information and data necessary for ACL to meet these Congressional requirements, as well as, capturing performance data on individual grantees providing ACL essential insight for monitoring and technical assistance purposes. In addition, the Medicare Improvements for Patients and Providers Act (MIPPA), initially passed in 2008, provided targeted funding for the SHIPs, area agencies on aging (AAAs), and Aging and Disability Resource Centers (ADRC) to conduct re enrollment assistance to Medicare beneficiaries for the Limited Income Subsidy (LIS) and Medicare Savings Program (MSP). These activities, collectively known as the MIPPA Program, have been funded nearly annually through a series of funding or extenders bills (Pub. L. 110–275 as amended by Pub. L. 111–148; Pub. L. 113–67; Pub. L. 113–93; Pub. L. 114–10; Pub. L. 115–123; and Pub. L. 116–59). Public Law 116–136, div. A, title III, section 3803(a), Mar. 27, 2020, 134 Stat. 428, extended funding for MIPPA through November 30, 2020. This tool also collects performance and outcome data on the MIPPA Program providing ACL necessary information for monitoring and oversight.

Under Public Law 104–208, the Omnibus Consolidated Appropriations Act of 1997, Congress established the Senior Medicare Patrol Projects in order to further curb losses to the Medicare program.

The Senate Committee noted that retired professionals, with appropriate training, could serve as educators and resources to assist Medicare beneficiaries and others to detect and report errors, fraud and abuse.

Among other requirements, it directed the ACL to work with the Office of Inspector General (OIG) and the Government Accountability Office (GAO) to assess the performance of the program. The ACL employs this tool to collect performance and outcome data on the SMP Program necessary information for monitoring and oversight. ACL has shared this data and worked with HHS/OIG to develop SMP performance measures.

The HHS/OIG has collected SMP performance data and issued SMP performance reports since 1997. The information from the current collection is reported by the OIG to Congress and the public. This information is also used by ACL as the primary method for monitoring the SMP Projects.

This data collection will also support ACL in tracking performance outcomes and efficiency measures with respect to annual and long-term performance targets established in the Government Performance Results Modernization Act of 2010 (GPRMA). The Performance Data for the SHIP, SMP, and MIPPA, data collection will continue to provide data necessary to determine the effectiveness of the programs.

To support alignment with Executive Order 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, Executive Order 14075 on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals, and Executive Order 13988 on Preventing and Combating Discrimination on the Basis of Gender Identity and Sexual Orientation, ACL is adding three sexual orientation and gender identity (SOGI) items to this information collection. Understanding these disparities can and should lead to improved service delivery for ACL's programs and populations served.

The proposed data collection tools may be found on the ACL website for review at: <https://www.acl.gov/about-acl/public-input>.

Estimated Program Burden

ACL estimates the respondent burden hours to prepare and complete all reports associated with this collection will be hours. This estimate is based on the current data systems ability to aggregate data and generate reports. By modifying several forms ACL has reduced the overall burden and grantees will no longer have to generate reports outside of the newly created data system.

Form name	Estimated time in minutes	Fraction of an hour
SMP Media Outreach & Education	4	0.0667
SMP Group Outreach & Education	4	0.0667
SMP Individual Interaction	5	0.0833
SMP Team Member Activity	5	0.0833
SMP Interaction	5	0.0833
SMP Team Member	7	0.1166
SHIP Media Outreach & Education	4	0.0667
SHIP Group Outreach & Education	4	0.0667
SHIP Team Member	7	0.1166
SHIP Beneficiary Contact	5	0.0833
SHIP Training Form	6	0.10
SHIP Team Member Activity	7	0.1166
SHIP Training	4	0.0667

ESTIMATED ANNUALIZED BURDEN HOURS

Grantee respondent type	Form/report name	Number of respondents	Number of responses per respondent	Average burden per response (in minutes)	Total burden hours
SMP	Media Outreach & Education	216	46	4	662.4
SMP	Group Outreach & Education	6,935	4	4	1,849.33
SMP	Individual Interaction	6,935	41	5	23,694.58
SMP	Team Member	216	31	5	558
SMP	SIRS Team Member Activity	216	31	5	558
SMP	SMP Interaction	6,935	2	5	1,155.83
* SMP	OIG Report	* 0	0	0	0
* SMP	Time Spent Report	* 0	0	0	0
SHIP/MIPPA	Media Outreach & Education	3,750	15	4	3,750
SHIP/MIPPA	Group Outreach & Education	3,750	15	4	3,750
SHIP/MIPPA	SHIP Team Member	216	75	5	1,350
SHIP/MIPPA	Beneficiary Contact	15,000	233	5	291,250
* SHIP/MIPPA	SHIP Performance Report	* 0	0	0	0
* SHIP/MIPPA	Resource Report	* 0	0	0	0
* SHIP/MIPPA	MIPPA Performance Report	* 0	0	0	0
SHIP/MIPPA	SHIP Team Member Activity	216	40	7	1,008
* SHIP/SMP/MIPPA	Summary Reports	* 0	0	0	0
* SHIP/MIPPA	Part D Enrollment Outcomes Report	* 0	0	0	0
Totals	49,769	4,042,681	345,646.47

* This data collection activity is an automated task in the system and does not compute to an estimate of time for burden.

Dated: October 19, 2023.

Alison Barkoff,

Senior official performing the duties of the Administrator and the Assistant Secretary for Aging.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0584]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Standardized Reporting Forms for Food and Drug Administration Federally Funded Public Health Projects and Agreements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 November 24, 2023.

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 0910–0909. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, PRASaff@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.

Standardized Reporting Forms for FDA Federally Funded Public Health Projects

OMB Control Number 0910–0909—Revision

This information collection supports federally funded public health projects administered by FDA. As part of FDA’s efforts to protect the public health, we work collaboratively with State partners to enhance oversight of FDA-regulated products. Consistent with applicable regulations, we collect information related to an awardee’s progress in completing agreed-upon performance metrics.

To increase our efficiency in evaluating program effectiveness and return-on-investment (ROI)/return-on-value (ROV) for the federally funded projects that we administer, we developed and established the use of digital forms under a pilot project information collection that contain tailored, standardized questions to capture data elements necessary to measure/track ROI/ROV, best practices, and program effectiveness. Forms are submitted by email and aggregated into dynamic reports by program for FDA evaluators allowing for quick comparison of program data between report periods and comparable metrics to evaluate program success or lack of performance in a timely manner. The pilot project confirmed that the use of standardized forms will reduce the time required by awardees in completing and submitting data collection reports. Additional findings include: a drastic increase in data quality, a significant reduction in the number of follow-ups needed to request additional information or clarify responses, and the ability to aggregate data quickly into a useable format for programmatic review and respond effectively to requests for program performance data. Coupled with positive feedback from FDA data users and external partners received during the pilot project, we considered the pilot phase a success and plans to continue use of tailored forms for program performance metrics including ROI/ROV data for its current and new funded public health projects moving forward.

Respondents complete an initial report and progress/performance reports which include data fields to identify the award project and contact person and directs specific questions to respondents regarding project and progress updates. As the public, partnering awardees, and FDA data users provide feedback through various opportunities, we will revise the reports tailoring for project specificity and purpose, to include, but

not limited to, improvements in metrics analysis, question clarity, and formatting and design, such as drop-down menu selections and potential common response indicators. This method will ensure a continuation of the reduced time for respondents and allow us to more quickly process information and determine impacts at the Agency level as observed during the pilot. As information will be requested of actively funded projects, it still may become necessary to request additional information for a particular project to complete the performance evaluation(s) in a timely manner. To ensure data is sufficient, on a case-by-case basis, FDA anticipates a need for follow-up questionnaire(s) to supplement the progress reports and as instruments of collection are developed and fine-tuned through this effort. We do not have any specific adjustments or revisions to the approved forms at this time, other than the inclusion of PRA statements. Due to the evolving nature of public health issues, non-substantive modifications may be made to the forms during the 3-year approval period of this information collection. Prior to implementation, such modifications will be submitted to OMB for approval, and they will be made available for public review and comment during the standard information collection extension/revision approval process.

In the **Federal Register** of July 29, 2021 (86 FR 40853), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received. Subsequent to the close of the 60-day notice public comment period, additional comments were received from internal and external stakeholders through our solicitation of feedback external to the PRA public comment opportunity. Upon our review, these comments were generally supportive of the piloted forms, and many contained suggestions for additional technical improvements. At the same time, none of the comments suggested any change to our estimated burden and we have therefore retained those currently submitted. While we are not making changes to the forms with this submission, we plan to implement changes based on the feedback received as part of the continuous improvement process for the information collection over the next few years.

Description of Respondents: Respondents to the information collection are State, local, Tribal and Territorial governments who are recipients of FDA-funded projects who submit required information to FDA.