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: Delaney Roach, Administration for Community Living, *evaluation@acl.hhs.gov,* (202) 795–7316.

SUPPLEMENTARY INFORMATION: In compliance with the Paperwork Reduction Act, the Administration for Community Living (ACL) has submitted the following proposed collection of information to OMB for review and clearance. A Program Performance Report on activities under title VI of the Older Americans Act (OAA) is necessary for ACL to monitor Federal funds effectively and to be informed as to the progress of the programs. Grantees are required to submit an annual Program Performance Report to allow for efficient Federal monitoring.

The OAA states that the tribal organization (applicant) for a grant under title VI part A, Indian Program, report data for ACL to comply with requirements under the OAA. The OAA also states that an applicant under title VI part B, Native Hawaiian Program, provide that the organization will report information for the agency Assistant Secretary to reasonably require, and comply with such requirements. An applicant for a grant under title VI part C, Native American Caregiver Support Program must also prepare and submit reports on the data and records, including information on the services funded by ACL. A combined Program Performance Report form is used for reporting by grantees under Parts A, B and C. The regulations require grantees to submit annual performance reports unless ACL requires quarterly or semiannual reports.

The Program Performance Report provides a data base for ACL to: (1) monitor program achievement of performance objectives; (2) establish program policy and direction; and (3) prepare responses to Congress, the OMB, other Federal departments, and public and private agencies as required by the OAA. If ACL did not collect the program data herein requested, it would not be able to monitor and manage total program progress as expected, nor develop program policy options directed toward assuring the most effective use of limited title VI funds.

Comments in Response to the 60-Day Federal Register Notice

A 60-day FRN published in the FR on October 25, 2023, at 88 FR 73344–73345. ACL did not receive any public comments during the 60-day FRN public comment period.

Estimated Program Burden: The burden estimate is specific to the type of work done by the grantees that use this reporting format; ACL estimates it takes 3.5 hours to complete the title VI PPR. With 282 respondents taking 3.5 hours per performance report, annual burden hour totals 987 hours.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Title VI PPR	282	1	3.5	987
Total				987

Dated: December 21, 2023.

Alison Barkoff,

Principal Deputy Administrator for the Administration for Community Living, performing the delegable duties of the Administrator and the Assistant Secretary for Aging

[FR Doc. 2023–28577 Filed 12–27–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Submission for OMB Review; Public 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 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 the Paperwork Reduction Act of 1995. This 30-day notice collects comments on the information collection requirements related to 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 January 29, 2024.

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: Katherine Glendening, Administration for Community Living, *Katherine.Glendening@acl.hhs.gov,* (202) 795–7350.

SUPPLEMENTARY INFORMATION: In compliance with the Paperwork Reduction Act (44 U.S.C. 3507), the Administration for Community Living (ACL) has submitted the following proposed collection of information to OMB for review and clearance. 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) (31 U.S.C. 1115) purposes. This data collection allows ACL to communicate with Congress and the public on the SHIP, the Senior Medicare Patrol (SMP) program, and the Medicare Improvements for Patients & Providers Act (MIPPA) program, in addition to the SHIP Data Performance Reports and Information Collection under OMB 0985–0040. The SHIP, SMP, and MIPPA programs are in each of the 50 states, the District of Columbia, Puerto Rico, Guam, and the U.S. Virgin Islands. 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: The Omnibus Budget Reconciliation Act of 1990 created the State Health Insurance Assistance Program (SHIP) (U.S.C. 1395b–4) 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 with essential insight for monitoring and technical assistance purposes. In addition, MIPPA (42 U.S.C. 1935b–3 notes), provided targeted funding for the SHIPs, area agencies on aging, and Aging and Disability Resource Centers to conduct enrollment assistance to Medicare beneficiaries for the Limited Income Subsidy and Medicare Savings Program. These activities have been funded nearly annually through a series of funding or extenders bills. 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 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 ACL to work with the Department of Health and Human Services, Office of Inspector General (HHS/OIG) and the Government Accountability Office (GAO), to assess the performance of the program. 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 HHS/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 GPRA.

This information collection collects demographic data from people receiving programs and services funded by ACL. ACL will adhere to best practices for collection of all demographic information when this information is collected for the programs listed in accordance with OMB guidance.

This includes, but is not limited to, guidance specific to the collection of sexual orientation and gender identity (SOGI) items that align 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. Understanding these disparities can and should lead to improved service delivery for ACL's programs and populations served.

Comments in Response to the 60-Day Federal Register Notice

ACL published a 60-day FRN on October 25, 2023, at 88 FR 73345. ACL did not receive any public comments during the 60-day FRN.

Estimated Program Burden: ACL estimates the respondent burden hours to prepare and complete all reports associated with this collection as 329,294 annual burden hours. This estimate is based on the current data system's aggregate data and reports. Modifying several forms, ACL has reduced the overall burden hours associated with this information collection along with grantees no longer generating reports outside of the 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

Grantee respondent type	Form/report name	Number of respondents	Number of responses per respondent	Average burden per response (in minutes)	Total burden hours
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	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	STARS 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/MIPPA	Team Member Training	216	40	6	864
*SHIP/SMP/MIPPA	Summary Reports	*0	0	0	0
*SHIP/MIPPA	Part D Enrollment Outcomes Report	*0	0	0	0
Totals		37,666	571		329,294.31

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

Dated: December 21, 2023.

Alison Barkoff,

Principal Deputy Administrator for the Administration for Community Living, performing the delegable duties of the Administrator and the Assistant Secretary for Aging.

[FR Doc. 2023–28623 Filed 12–27–23; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–5408]

Reformulating Drug Products That Contain Carbomers Manufactured With Benzene; Guidance for Industry; 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 entitled ''Reformulating Drug Products That Contain Carbomers Manufactured With Benzene.'' The purpose of this guidance is to provide recommendations to applicants and manufacturers on what tests should be performed and what documentation should be submitted or available to support the reformulation of drug products that use carbomers manufactured with benzene. Certain United States Pharmacopeia (USP) carbomer monographs currently allow for unacceptable levels of benzene, which raises safety concerns. FDA has requested that the USP omit (or remove) these monographs, and applicants and manufacturers may need to reformulate their drug products to avoid use of these carbomers. This guidance provides recommendations for tests and documentation related to reformulation based on various routes of administration and dosage forms of affected drug products, and provides recommendations for application holders on the appropriate submission types to notify the Agency of reformulation changes. The intended effect of this guidance is to, as appropriate, provide a less burdensome risk-based approach to reformulation submissions relative to existing guidances on scale-up and post-approval changes (SUPAC), and address the immediate public health need to expedite the discontinuation of the use of carbomers manufactured with high levels of benzene in drug products.

DATES: The announcement of the guidance is published in the **Federal Register** on December 28, 2023.

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–2023–D–5408 for ''Reformulating Drug Products That Contain Carbomers Manufactured With Benzene; Guidance for Industry.'' 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 between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.