DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Submission for OMB Review; Public Comment Request; of the Annual Senior Medicare Patrol/ State Health Insurance Assistance Program/Medicare Improvements for Patients and Providers Act National Training Conference Survey; OMB Control Number 0985–0068

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 Annual SMP/SHIP/MIPPA National Training Conference Survey; OMB Control Number 0985–0068.

DATES: Submit written comments on the collection of information by August 28, 2023.

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, at (202) 795–7350 or *Katherine.Glendening@acl.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 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 Office of Healthcare Information and Counseling (OHIC) hosts an annual national training conference for the federally funded programs that it administers. The audience for this training conference includes attendees from State Health Insurance Assistance Program (SHIP), Senior Medicare Patrol (SMP) programs and Medicare Improvements for Patients and Providers Act (MIPPA) programs, which are three nationally recognized programs that provide Medicare information and counseling to Medicare beneficiaries and help, fight Medicare fraud through prevention and education. Grantee leadership is required to attend this training annually to ensure they receive critical information and technical assistance needed to help them successfully meet the requirements of their grant awards. Grantees are encouraged to bring up to three (3) people from each program. Programs operate in each of the 50 states, the District of Columbia, Guam, Puerto Rico, and the U.S. Virgin Islands.

Section 4360(f) of OBRA 1990 created the State Health Insurance Assistance Program (SHIP) and requires the Secretary to support a national network of grantees to provide outreach and assistance to Medicare beneficiaries. In addition, 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 error, fraud, and abuse.

This tool provides ACL an opportunity to assess the success and impact of the training provided to the SHIP and SMP grantees by ACL along with determining the future training needs of the program grantees. Section 301 of the Public Health Service Act (42 U.S.C. 241) is the authorizing law for data collections within the Department of Health and Human Services (HHS). Specifically, agencies within HHS should ''collect and make available through publications and other appropriate means . . . research and other activities.'' The March 3, 1998, White House Memorandum, ''Conducting Conversations with America to Further Improve Customer Service,'' directs agencies ''to track customer service measurements, then take necessary actions to change or improve how the agency operates, as appropriate. Integrate what your agency learns from its customers with your agency's strategic plans, operating plans, and performance measures required by the Government Performance and Results Act of 1993, reporting on financial and program performance under the Chief Financial Officers Act of 1990, and the Government Management Reform Act of 1994.'' The information collected in this survey is necessary to ensure that ACL is meeting the technical assistance needs of the attendees and to capture valuable feedback to be used for future training meetings.

By gathering feedback on the quality of the training and content provided, we can ensure attendee satisfaction and gather information for future planning. ACL administers a contract to develop and provide the training conference evaluation tool for ACL's approval.

Comments in Response to the 60-Day Federal Register Notice

A notice published in the **Federal Register** *88 FR 30764 on Friday, May 12, 2023.* There were no comments were received during the 60-day FRN.

Estimated Program Burden: ACL estimates the burden of this collection of information as follows:

ACL will collect data once following the Annual SMP/SHIP/MIPPA National Training Conference. This evaluation will be sent to all event attendees, which is estimated to include maximum 486 participants, each survey is estimated at .25 hours to complete. This time estimate is based on research performed by ACL with the existing survey instrument and in consideration of previous survey content and length. The target number 486 is a result of 54 states/territories, each sending up to nine conference participants who may be eligible to complete a survey (54 * 9 = 486). Factoring in an additional 40 non-grantee, non-federal partner event participants (486 + 40 = 526). 526 respondents taking 15 minutes to complete for a total of 131.5 annual burden hours.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Number of respondents	Responses per respondent	Average burden hours per response (minutes)	Total burden hours
526	1	15	131.5

Dated: July 25, 2023.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2023–16015 Filed 7–27–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2757]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices—Voluntary Improvement Program

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 August 28, 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 title of this information collection is ''Voluntary Improvement Program.'' 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, *PRAStaff@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.

Voluntary Improvement Program

OMB Control Number 0910–NEW

This information collection supports FDA's implementation of its Voluntary Improvement Program (VIP). Included among the strategic priorities of our Center for Devices and Radiological Health (CDRH) is promoting a culture of quality and organizational excellence. As communicated on our website at *https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/voluntary-medical-device-manufacturing-and-product-quality-pilot-program,* we conducted a pilot project pertaining to voluntary medical device manufacturing and product quality and have incorporated some of the successes and learnings into the VIP. The VIP oversees third-party appraisers who evaluate industry participants. The VIP is facilitated by the Medical Device Innovation Consortium, a public-private partnership that evaluates the capability and performance of a medical device manufacturer's practices using third-party appraisals and is intended to guide improvement to enhance the quality of devices. As part of the VIP process, FDA receives information about participating device manufacturers' capability and performance for activities covered in third-party appraisals.

The guidance document entitled ''Fostering Medical Device Improvement: FDA Activities and Engagement with the Voluntary Improvement Program'' communicates our policy regarding participation in the VIP. Only eligible manufacturers of medical devices regulated by CDRH whose marketing applications are reviewed under the applicable provisions of the Federal Food, Drug, and Cosmetic Act (including under sections 510(k), 513, 515, and 520 (21 U.S.C. 360(k), 360c, 360e, and 360j)) may participate in the VIP. The guidance document was developed and issued consistent with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time. The guidance document includes instruction to respondents regarding eligibility, FDA engagement with participants, submission criteria, and withdrawal or removal from the program.

Information included in VIP applications is verified by FDA. This helps the third-party appraiser to determine the manufacturers' eligibility for participation in the VIP. We use aggregate data to identify broad industry trends and patterns to help inform risk-based inspection planning and improve review efficiencies. We also consider aggregate data to better allocate limited Agency resources. Also included among the goals of the program is to improve the safety, quality, and access of medical devices for patients by driving quality and continuous improvement within the device industry. The program is intended to result in increased production and access to higher quality medical devices for patients, decreases in safety issues, and lower production costs, which will increase value to industry, patients, providers, payors, and FDA.

We published a 60-day notice soliciting public comment on the proposed collection of information in the **Federal Register** of May 6, 2022 (87 FR 27165) and received several comments. Most comments included feedback on individual collection elements and the operational logistics of the program. We have considered these comments. Although we intend to revise the guidance to clarify what participants must demonstrate to benefit from the opportunities offered by VIP and add further details regarding the role of FDA in VIP in section V.B of the guidance, we are making no adjustments to our burden estimates. In addition, two comments requested FDA clarify the benefits and utility of VIP for patients and consumers. FDA intends to address these comments in the guidance document, which guides improvement to enhance the quality of devices.

Respondents: Respondents to the information collection are manufacturing sites who voluntary elect to participate in the VIP. Based on our device registration and listing data and informal feedback from stakeholders, we anticipate approximately 400 sites may participate annually.

We estimate the burden of the information collection as follows: