information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by January 2, 2024.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10558 Machine Readable Data for Provider Network and Prescription Formulary Content for FFM QHPs

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. The term ''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 requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension of currently approved collection; *Title of Information Collection:* Machine Readable Data for Provider Network and Prescription Formulary Content for FFM QHPs; *Use:* Under 45 CFR 156.122(d)(1)(2), 156.230(b), and 156.230(c), as finalized in the rule, the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2018 (CMS–9934–F), established standards for qualified health plan (QHP) issuers for the submission of provider and formulary data in a machine-readable format to the Department of Health and Human Services. (HHS) and for posting the data on issuer websites. These standards provide greater transparency for consumers, including by allowing software developers to access formulary and provider data to create innovative and informative tools. On September 30, 2015, the Office of Management and Budget (OMB) granted approval to the data collection Information Collection for Machine Readable Data for Provider Network and Prescription Formulary Content for FFE QHPs under OMB control number 0938–1284. OMB approval was granted again on November 3, 2017 and March 22, 2021. The Centers for Medicare and Medicaid Services (CMS) is continuing that information collection request (ICR) in connection with these machine-readable standards. This ICR serves as a formal request for the renewal of the data collection clearance. The burden estimate for the ICR included in this package reflects the time and effort for QHP and SADP issuers to update and publish the appropriate data and submit it to CMS. *Form Number:* CMS–10558 (OMB control number: 0938–1284); *Frequency:* Annually; *Affected Public:* Private Sector, State, Business, and Not-for Profits; *Number of Respondents:* 434; *Number of Responses:* 434; *Total Annual Hours:* 39,126. (For questions regarding this collection, contact Ana Alza at (667) 290–8569, ext. 70008569).

Dated: October 31, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–24371 Filed 11–2–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Submission for OMB Review; Public Comment Request; Assessment and Evaluation of ACL's American Indian, Alaska Natives, and Native Hawaiian Programs Older Americans Act Title VI (OMB Control Number 0985–0059)

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 Assessment and Evaluation of ACL's American Indian, Alaska Natives, and Native Hawaiian Programs Older Americans Act Title VI (OMB Control Number 0985–0059).

DATES: Submit written comments on the collection of information by December 4, 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: Amanda Cash at *Amanda.Cash@acl.hhs.gov* or (202) 795–7369.

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 Administration for Community Living (ACL) is requesting approval for data collection associated with the Assessment and Evaluation of ACL's American Indian, Alaska Natives, and Native Hawaiian Programs Older Americans Act Title VI (OMB Control Number 0985–0059). OAA Title VI establishes grants to Native Americans for nutrition services, supportive services, and family caregiver support services.

The purpose of Title VI is ''to promote the delivery of supportive services, including nutrition services, to American Indians, Alaskan Natives, and Native Hawaiians that are comparable to services provided under Title III'' (42 U.S.C. 3057), which provides nutrition, caregiver and supportive services to the broader U.S. population. Title VI is comprised of three parts; Part A provides nutrition and supportive services to American Indians and Alaska Natives, Part B provides nutrition and supportive services to Native Hawaiians, and Part C provides caregiver services to any programs that have Part A/B.

The previous data collection for this project entailed a series of interviews and focus groups with Title VI program staff, elders, and caregivers. American Indian, Alaska Native, and Native Hawaiian (AI/AN/NH) populations experience significant health and socioeconomic disparities compared to the rest of the U.S. population. The AI/AN population has the highest rate of disabilities and the lowest life expectancy compared to the averages for the overall population (Centers for Disease Control and Prevention [CDC], 2008; Goins, Moss, Buchwald, & Guralnik, 2007). While 18% of the non-Hispanic white population is 65 years or older, just 8% of Native Hawaiians and 10% of the AI/AN population is 65 years or older (AoA, 2015). However, as overall life expectancy increases, the proportion of older AI/AN adults is expected to increase. By 2050, the percentage of non-Hispanic white adults is expected to decrease by 20%, while the population of older minority population adults, including AI/AN/NH, is expected to increase by 110% (AoA, 2015; CDC, 2013). For AI/AN populations, this translates to a 93% increase in the number of older adults. In addition, the population aged 75 and older needing long-term care is expected to double by the year 2030 (AoA, 2015; CDC 2013; Goins et al., 2007).

In fiscal year 2023, ACL awarded 290 Title VI three-year grants to tribes/tribal organizations elders for the provision of nutrition and supportive services, and a portion of awardees also received funds for the Native American Caregiver Support Program. The Assessment and Evaluation of the Title VI Programs will examine the effects of the program on:

1. Older Indians, their families and caregivers
2. Tribal communities
3. Intergenerational connections in tribal communities
4. Management of the Title VI program

Additionally, the assessment will examine how using COVID supplemental funds impacted Title VI services provided to older adults. This work will help ACL better understand and document the impact of these funds, how service provision changed over time, and what gaps existed despite the additional funding.

The Need for Assessment and Evaluation

The Assessment and Evaluation of the Title VI Programs is authorized under Section 206(a, c) of Title II of the OAA, which directs ACL to ''. . . measure and evaluate the impact of all programs authorized by this Act, their effectiveness in achieving stated goals in general, and in relation to their cost, their impact on related programs, their effectiveness in targeting for services under this Act unserved older individuals with greatest economic need (including low-income minority individuals and older individuals residing in rural areas) and unserved older individuals with greatest social need (including low-income minority individuals and older individuals residing in rural areas), and their structure and mechanisms for delivery of services, including, where appropriate, comparisons with appropriate control groups composed of persons who have not participated in such programs.''

Consistent with requirements of the Government Performance Results Modernization Act (GPRMA), ACL's Administration on Aging (AoA) integrates its strategic priorities and plans with performance measurement criteria. The AoA has three major performance measures: improve program efficiency, improve client outcomes, and improve effective targeting of vulnerable elders. Through program assessments, ACL seeks a better understanding of key programs, such as the programs under Title VI of the OAA for AI/AN/NH. Having completed most of the data collection, the Assessment and Evaluation of the Title VI Programs has an interest in adding a data collection activity to do a follow-up interview with grantees after they have completed the current evaluation cycle to understand which components of the technical assistance, they have received have been the most useful for them.

Table 1 provides an overview of the Assessment and Evaluation of the Title VI Program data collection activity.

Data Collection Activities

TABLE 1

Activity	Purpose, respondents, method, and relevant study
Title VI Program Staff Follow-up Interviews.	The Program Staff Follow-up Interviews will assess how the Title VI Programs have been utilizing and implementing the Technical Assistance they have received from the contractor around the practice of evaluation. Data will include how evaluation practice is being implemented and on what occurring basis, as well as perceptions of met and unmet needs around evaluation; and barriers to using evaluation. Up to 2 local staff (*e.g.,* program director and evaluation staff person) will participate in each interview. The interviews will be conducted via telephone in Year 4 with up to 12 evaluation grantees, for a maximum of 24 participants, and will take 60 minutes to complete. *See Attachment A (Title VI Program Staff Consent Form and Interview Guide).*

Use of Information Collected

ACL's strategic priorities are to empower older people and their families to (1) make informed decisions about, and easily access, health and long-term care options and (2) enable seniors to remain in their own homes through the provision of home and community-based services.

Central to these priorities is the pursuit of consistent and effective approaches to support older adults in their own homes and communities, and to coordinate the provision of

supportive services to seniors and their caregivers in an integrated system of long-term care. Information gathered through the Assessment and Evaluation of the Title VI Programs will inform ACL and its partners, other Federal agencies and administrators, current grantees, policymakers, and the field about ways to improve service delivery for elders and their caregivers and helping them to remain in their homes for as long as possible. For example, information gathered through the evaluation will be used to identify gaps and challenges in service delivery, as well as areas of further need.

Without this assessment and evaluation, Federal and local officials will not be able to determine whether the Title VI Programs are having the intended impact on AI/AN/NH elders and whether the grantees are meeting the individual goals of the programs. The new proposed data collection with further allow ACL to understand how successful the training and technical assistance provided to Title VI evaluation grantees was for their practice of data collection and use.

Comments in Response to the 60-Day Federal Register Notice

A notice published in the **Federal Register 88 FR 56633** on August 18, 2023. There were no public comments received during the 60-day FRN.

Estimated Program Burden:

ESTIMATED PROGRAM BURDEN

Respondent type	Form name	Number of annual respondents	Number of responses per respondent	Average burden (in hours) per response	Annual burden hours
Program director	Program staff follow-up interview guide	12	1	1	12

Dated: October 30, 2023.

Alison Barkoff,

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

[FR Doc. 2023–24255 Filed 11–2–23; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4372]

Enforcement Policy for Clinical Electronic Thermometers; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance entitled ''Enforcement Policy for Clinical Electronic Thermometers.'' This guidance applies to clinical electronic thermometers, which are regulated as class II devices. This guidance has been implemented without prior comment, but it remains subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidance is published in the **Federal Register** on November 3, 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–N–4372 for ''Enforcement Policy for Clinical Electronic Thermometers.'' 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.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80