

for Disease Control and Prevention (CDC).

*Background and Brief Description*

Since 2012, OMB approval of a Generic Clearance of Message Testing for Tobacco Communication Activities (MTTCA, OMB Control No. 0920–0910), has been continuously maintained. CDC’s authority to collect information for public health purposes is provided by the Public Health Service Act (41 U.S.C. 241) section 301. CDC has employed the MTTCA clearance to collect information about the attitudes and perceptions of adults who smoke and adults who do not smoke, and to pretest draft messages and materials for clarity, salience, appeal, and persuasiveness. The MTTCA clearance has been used to obtain OMB approval for a variety of message testing activities, with particular emphasis on communications supporting CDC’s National Tobacco Education Campaign (NTEC) called the *Tips from Former Smokers*® campaign. This national campaign is designed to increase public awareness of the health consequences of tobacco use and exposure to secondhand smoke. The MTTCA clearance has also supported formative research relating to the development of health messages for a campaign to encourage educators to speak with middle and high school students about

the risks of e-cigarette use and empower them to avoid or quit e-cigarettes.

Information collection modes under the MTTCA clearance that are supported include in-depth interviews, in-person and online focus groups, and online surveys. Each project approved under the MTTCA framework is outlined in a project-specific Information Collection Request that describes its purpose and methodology. Messages developed from MTTCA data collection have been disseminated via multiple media channels including television, radio, print, out-of-home, and digital formats.

CDC requests OMB approval to extend the MTTCA clearance, with changes, for three years. Requested changes are to increase the number of respondents and burden hours and remove the upper age limit previously 54 years of age, to include all adults aged 18 years and older. These changes are needed to support CDC’s planned information collections and to accommodate additional needs that CDC may identify during the next three years. No modification is requested for information collection activities, methodology, or populations of interest from the existing Generic Clearance. The MTTCA Generic Clearance may be used to facilitate the development of tobacco-related health communications of interest for CDC’s collaborative efforts

with other federal partners including, but not limited to, the Food and Drug Administration’s Center for Tobacco Products. The MTTCA clearance does not replace the need for additional generic clearance mechanisms of HHS and other federal partners that may need to test tobacco messages related to their campaigns and initiatives.

CDC is requesting increases to accommodate planned message testing needs for the NTEC, the campaign to encourage educators to speak with middle and high school students about the risks of e-cigarettes use, as well as ad hoc testing activities that may involve other CDC/ATSDR programs. CDC will continue to use the MTTCA clearance to develop and test messages and materials using data collection methodologies including online surveys, in-person or online focus groups, in-depth interviews, etc. Electronic data collection methods will be employed where possible to minimize COVID–19 and/or other exposure risk. Any in-person data collection will be conducted consistent with current guidance for mitigating the risk of transmitting COVID–19 and/or other exposures. Participation is voluntary and there are no costs to respondents, other than their time. The total estimated annualized burden hours are 20,039.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
General Public and Special Populations .....	Screening .....	74,386	1	2/60
	In-Depth Interviews (In Person) .....	25	1	1
	Focus Groups (In Person) .....	628	1	90/60
	Surveys (Online, Short) .....	71,000	1	20/60
	Surveys (Online, Medium) .....	2,733	1	13/60
				25/60

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Office of Public Health Ethics and  
Regulations, Office of Science, Centers for  
Disease Control and Prevention.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**[Document Identifier: CMS–1728–20]**

**Agency Information Collection Activities: Submission for OMB Review; Comment Request**

**AGENCY:** Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing

an opportunity for the public to comment on CMS’ intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed 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 on the collection(s) of information must be received by the OMB desk officer by August 21, 2023.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](https://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

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 Parham at (410) 786-4669.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (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 (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Home Health Agency Cost Report; *Use:* The Form CMS-1728-20 cost report is used to determine a provider's reasonable cost incurred in furnishing medical

services to Medicare beneficiaries and reimbursement due to or from a provider. The Form CMS-1728-20 cost report is also used for annual rate setting and payment refinement activities, including developing a home health market basket. Additionally, the Medicare Payment Advisory Commission (MedPAC) uses the home health cost report data to calculate Medicare margins, to formulate recommendations to Congress regarding the HHA PPS, and to conduct additional analysis of the HHA PPS.

The primary function of the cost report is to implement the principles of cost reimbursement which require that HHAs maintain sufficient financial records and statistical data for proper determination of costs payable under the program. The S series of worksheets collects the provider's location, CBSA, date of certification, operations, and unduplicated census days. The A series of worksheets collects the provider's trial balance of expenses for overhead costs, direct patient care services by level of care, and non-revenue generating cost centers. The B series of worksheets allocates the overhead costs to the revenue and non-revenue generating cost centers using functional statistical bases. The C series of worksheets computes the average cost per visit for HHA services. The D series of worksheets are Medicare specific and are used to determine reimbursement due to the provider or program. The F series of worksheets collect data from a provider's balance sheet and income statement. *Form Number:* CMS-1728-20 (OMB control number: 0938-0022); *Frequency:* Yearly; *Affected Public:* Private Sector—Business or other for-profits, Not-for-profit institutions; *Number of Respondents:* 10,944; *Total Annual Responses:* 10,944; *Total Annual Hours:* 2,134,080. (For policy questions regarding this collection contact LuAnn Piccione at (410) 786-5423.)

Dated: July 17, 2023.

**William N. Parham, III,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-N-0086]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Potential Tobacco Product Violations Reporting Form

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) 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 (PRA).

**DATES:** Submit written comments (including recommendations) on the collection of information by August 21, 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 0910-0716. Also include the FDA docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, [PRASStaff@fda.hhs.gov](mailto: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.

#### Potential Tobacco Product Violations Reporting Form

*OMB Control Number 0910-0716—Extension*

This information collection supports the opportunity to accept consumer and other stakeholder feedback and notification of potential violations of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Tobacco Control Act. Tobacco products are generally governed by chapter IX of the