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.* 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.

[FR Doc. 2023–15461 Filed 7–20–23; 8:45 am]

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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, *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.

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

FD&C Act (sections 900 through 920) (21 U.S.C. 387 through 21 U.S.C. 387t). The FD&C Act provides FDA authority to monitor compliance with Federal tobacco laws and regulations and take corrective action when violations occur.

As part of its enforcement strategy, FDA accepts information from the public regarding potential tobacco product violations of the FD&C Act. Potential tobacco product violations include (but are not limited to): (1) sales to underage purchasers (persons under 21); (2) flavored cigarette sales; (3) illegal marketing and advertising; (4) distribution of free samples of tobacco products except in limited circumstances; (5) placement of cigarette or smokeless tobacco product vending machines in prohibited areas (or providing access to self-service or direct access of tobacco products in prohibited areas); and (6) sale of cigarettes in packages of less than 20.

FDA currently provides a form that may be used to collect this information from the public (Form FDA 3779, Potential Tobacco Product Violations Report). The Potential Tobacco Product Violations Report, Form FDA 3779, asks for the following information: (1) date potential violation occurred; (2) product type (*e.g.,* cigarette, smokeless, roll-your-own, cigar, e-cigarette, hookah, pipe tobacco); (3) tobacco brand; (4) potential violation type; (5) type of potentially violative promotional materials; (6) who potentially violated; (7) name, address, phone number, and email address of the potential violator (if known); (8) potential violator's website or internet address URL (if available); (9) description of the potential violation; and (10) any additional files or information pertinent to the potential violation.

The public and interested stakeholders can report possible tobacco product violations of the FD&C Act by submitting information on Form FDA 3779 online, via email or postal mail, or by calling FDA's Tobacco Call Center. Information on how to submit possible tobacco product violations using the options above can be found at *https://www.accessdata.fda.gov/scripts/ptvr/index.cfm.* Further details about reporting possible tobacco product violations of the FD&C Act can also be found at *https://www.fda.gov/tobacco-products/compliance-enforcement-training/report-potential-tobacco-product-violation.*

In the **Federal Register** of February 2, 2023 (88 FR 7091), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received that was PRA related.

(Comment) The form does not have a specific option under ''Potential violation type'' for reporting products that have not gone through any of the new pathways to market required by the Tobacco Control Act, including the Premarket Tobacco Product Application (PMTA). The lack of this option may be confusing and make it difficult for members of the public who want to report such violations to determine what sort of violation they are reporting. Thus, we recommend FDA add ''Product without a marketing authorization'' or a similar category title, as an option under ''Potential violation type''.

(Response) FDA has reviewed the comment requesting revisions to the Potential Tobacco Product Violations Report, Form FDA 3779 (Potential Tobacco Violation Report Form). The comment correctly points out that the Potential Tobacco Violation Report Form provides the public with a mechanism to report potential violations of the tobacco laws and regulations enforced by the FDA. FDA agrees that a revision to the Potential Tobacco Violation Report Form is warranted and would assist the public in reporting potential violations related to the premarket review and authorization requirements under the law.

The Potential Tobacco Violation Report Form includes some specific options related to potential violation types that are often reported, including, but not limited to, those related to the retail sale of tobacco products to underage purchasers, flavored cigarette sales, the distribution of free samples of tobacco products, and other marketing and advertising requirements. The form has been updated to include an additional potential violation type: ''Unauthorized Tobacco Product.''

The Potential Tobacco Violation Report Form is one of many ways the public can report potential tobacco product violations directly to FDA. The public and interested stakeholders can also provide detailed descriptions of potential violations by phone, email, and through the mail.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity and Form FDA 3779	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Reporting potential tobacco product violations of the FD&C Act.	3,000	2	6,000	0.25 (15 minutes)	1,500

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden hour estimates for this collection of information were based on the type and rate of reporting submitted through the Potential Tobacco Violation Report Form and based on a review of the information collection since our last request for OMB approval. FDA estimates that submitting the information (online, telephone, email, or mail) will take 0.25 hours (i.e., 15 minutes) per response.

FDA estimates the number of annual respondents to this collection of information will be 3,000, who will each submit 2 reports. Each report is expected to take 0.25 hours to complete and submit; therefore, total burden hours for this collection of information is estimated to be 1,500 hours (6,000 responses × 0.25 hours per response).

Our estimated burden for the information collection reflects an overall increase of 157 hours and a corresponding increase of 630 responses. FDA attributes this adjustment to an increase in the number of submissions received over the last few years.

Dated: July 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–15459 Filed 7–20–23; 8:45 am]

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