

Request for Comment

Comments are invited on: (a) Whether the collections of information are necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collections, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collections of information on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on February 29, 2024.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2024-04580 Filed 3-4-24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

[Document Identifier: CMS-304 and 304a, CMS-10383]

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 April 4, 2024.

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:* Extension of a currently approved collection; *Title of Information Collection:* Reconciliation of State Invoice (ROSI) and Prior Quarter Adjustment Statement (PQAS); *Use:* Form CMS-304 (ROSI) is used by manufacturers to respond to the state's rebate invoice for current quarter utilization. Form CMS-304a (PQAS) is required only in those instances where

a change to the original rebate data submittal is necessary. *Form Number:* CMS-304 and -304a (OMB control number: 0938-0676); *Frequency:* Quarterly; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 749; *Total Annual Responses:* 5,841; *Total Annual Hours:* 248,584. (For policy questions regarding this collection contact Robert Giles at 667-290-8626.)

2. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Review and Approval Process for Waivers for State Innovation; *Use:* The information required under this collection is necessary to ensure that states comply with statutory and regulatory requirements related to the development and implementation of section 1332 waivers. States seeking waiver authority under section 1332 of the ACA are required to meet certain requirements for applications, public notice, and reporting. The authority for these requirements is found in section 1332 of the ACA. This information collection reflects the requirements provided in the final rules published in February 2012 (77 FR 11700) and September 2021 (86 FR 3412).

On October 24, 2018, the Departments published guidance (86 FR 53575) that provided supplementary information about the requirements that must be met for the approval of a section 1332 waiver, the Secretaries' application review procedures, the calculation of pass-through funding, certain analytical requirements, and operational considerations. However, the September 2021 final rule superseded and rescinded policies and interpretations outlined in the 2018 guidance and repealed the previous codification of the interpretations of the statutory guardrails in part 1 of the 2022 Payment Notice final rule (86 FR 6138). The September 2021 final rule (86 FR 53412) finalized modifications to section 1332 waiver implementing regulations, including changes to many of the policies and interpretations of the statutory guardrails codified in regulation. In addition, the September 2021 final rule modified regulations to provide flexibilities in the public notice requirements and post-award public participation requirements for section 1332 waivers under certain future emergent situations. The final rule also provided new information regarding the processes and procedures for amendments and extensions for approved waiver plans. *Form Number:* CMS-10383 (OMB Control Number 0938-1389; *Frequency:* Occasionally;

Affected Public: State Governments;
Number of Respondents: 19; *Total Annual Responses:* 399; *Total Annual Hours:* 5,549. (For policy questions regarding this collection contact Lina Rashid at 301-492-4193.)

William N. Parham, III

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-0894]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; The Real Cost Monthly Implementation Assessment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA 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 April 4, 2024.

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 “The Real Cost Monthly Implementation Assessment.” Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, 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.

The Real Cost Monthly Implementation Assessment

OMB Control Number 0910-NEW

This information collection supports the development and implementation of FDA public education campaigns related to tobacco use. To reduce the public health burden of tobacco use in the United States and educate the public—especially young people—about the dangers of tobacco use, the FDA Center for Tobacco Products (CTP) is developing and implementing multiple public education campaigns.

FDA launched “The Real Cost” in February 2014, seeking to reduce tobacco use among at-risk teens ages 12–17 in the United States who are open to smoking cigarettes and/or using electronic nicotine delivery systems (ENDS) products, or who have already experimented with cigarettes and/or ENDS products. Complementary evaluation studies, including the “Evaluation of FDA’s Public Education Campaign on Teen Tobacco,” were implemented to measure awareness of “The Real Cost” paid media campaign among teens ages 12–17 in the United States, and to understand how awareness is related to change in key outcomes.

Although outcome evaluation studies of “The Real Cost” have and continue to assess the impact of awareness on outcomes, no studies have sought to assess the implementation of “The Real Cost.” As FDA continues to increase the presence of “The Real Cost” on digital channels (e.g., Hulu, YouTube, Instagram), the need for an implementation evaluation has become clear as these messages are received by the target audience on digital channels differently compared to how the messages are received on broadcast channels. Before the migration of campaign ads to digital channels, ads from “The Real Cost” were primarily aired on broadcast TV. In the broadcast space, for people to avoid receiving the message, they needed to be proactive (e.g., finding the remote to change the channel or leaving the room). In the digital space, however, people need to be proactive to watch the full message, like stopping scrolling on social media or watching the full ad on YouTube. Assessment of this information is integral to understanding self-reported ad awareness levels, as well as how our audience experiences and processes the ads as they are airing in a digital setting.

Therefore, we propose a study to help us understand, in a digital setting, how teens experience the messages, how they engage with messages, the extent to which teens report being exposed to

messages, and how teens process the messages. Data gathered from this assessment will also provide the necessary and timely information to optimize campaign messages, the digital media buy (i.e., where, how, and when ads are shown), and creative rotations (i.e., which ads are shown).

“The Real Cost” Monthly Implementation Assessment (MIA) is a repeated cross-sectional survey that will be conducted using web-based surveys that are self-administered on personal computers or web enabled mobile devices to collect rapid data on “The Real Cost” stimuli. Data from up to 2,000 teens in the United States will be collected each month for up to 24 months. To be eligible, participants must be between the ages of 12–20 and have not taken the MIA survey within the past 3 months. We will use an Ipsos Knowledge Panel to collect data on “The Real Cost” stimuli. This design offers flexibility to assess new stimuli messages, as they air across various digital platforms, examine their performance over time, as well as the ability to pivot and add new survey measures as necessary. Monthly data will also allow us to obtain timely information on stimuli awareness, perceived effectiveness, as well as on teen attention and processing of the stimuli.

The purpose of FDA’s “The Real Cost” is to evaluate the following key components about “The Real Cost” stimuli:

- Awareness of “The Real Cost” stimuli.
- Attention behaviors when seeing “The Real Cost” stimuli.
- Processing of “The Real Cost” stimuli, including:
 - Engagement with the stimuli.
 - Main message comprehension.
 - Acceptance and/or rejection of the stimuli.
- Perceived effectiveness of “The Real Cost” stimuli.
- Potential unintended consequences of viewing “The Real Cost” stimuli.

In addition to the above components, the survey will ask participants to report on tobacco use and other psychographic and demographic items. The time frame that the survey items will ask about for stimuli awareness (i.e., past 30 days or past week) will depend on several factors, including how long the stimuli was on air. The survey will take an average of approximately 25 minutes to complete per participant. As the survey items are tested, any irrelevant items will be cut as necessary. Stimuli creative for both vaping and cigarette products will be assessed; therefore, two similar surveys (one on ENDS-focused