

collection contact William Long at 410-786-7927.)

Dated: March 13, 2018.

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

Centers for Medicare & Medicaid Services

[Document Identifier CMS-29 and CMS-209]

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

AGENCY: Centers for Medicare & Medicaid 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 16, 2018.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax

Number: (202) 395-5806 OR, Email: *OIRA_submission@omb.eop.gov.*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*.

3. Call the Reports Clearance Office at (410) 786-1326.

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:* Verification of Clinic Data—Rural Health Clinic Form and Supporting Regulations; *Use:* The form is utilized as an application to be completed by suppliers of Rural Health Clinic (RHC) services requesting participation in the Medicare program. This form initiates the process of obtaining a decision as to whether the conditions for certification are met as a supplier of RHC services. It also promotes data reduction or introduction to and retrieval from the Automated Survey Process Environment (ASPEN) and related survey and certification databases by the CMS Regional Offices. Should any question arise regarding the structure of the organization, this information is readily available. *Form*

Number: CMS-29 (OMB control number 0938-0074); *Frequency:* Occasionally (initially and then every six years); *Affected Public:* Private Sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 820; *Total Annual Responses:* 820; *Total Annual Hours:* 137. (For policy questions regarding this collection contact Caroline Gallaher at 410-786-8705.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Laboratory Personnel Report (CLIA) and Supporting Regulations; *Use:* The information collected on this survey form is used in the administrative pursuit of the Congressionally-mandated program with regard to regulation of laboratories participating in CLIA. The surveyor will provide the laboratory with the CMS-209 form. While the surveyor performs other aspects of the survey, the laboratory will complete the CMS-209 by recording the personnel data needed to support their compliance with the personnel requirements of CLIA. The surveyor will then use this information in choosing a sample of personnel to verify compliance with the personnel requirements. Information on personnel qualifications of all technical personnel is needed to ensure the sample is representative of the entire laboratory. *Form Number:* CMS-209 (OMB control number 0938-0151); *Frequency:* Biennially; *Affected Public:* Private Sector—State, Local, or Tribal Governments; and Federal Government; *Number of Respondents:* 19,051; *Total Annual Responses:* 9,592; *Total Annual Hours:* 4,796. (For policy questions regarding this collection contact Kathleen Todd at 410-786-3385.)

Dated: March 13, 2018.

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

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Community Services Block Grant (CSBG) State Plan Application. *OMB No.:* 0970-0382.

Description: Section 676 of the Community Services Block Grant

(CSBG) Act requires states, including the District of Columbia and the Commonwealth of Puerto Rico, and U.S. territories applying for CSBG funds to submit an application and plan (CSBG State Plan). The CSBG State Plan must meet statutory requirements prior to states and territories being funded with CSBG funds. Applicants have the option to submit a detailed plan annually or biannually. Entities that submit a biannual plan must provide an abbreviated plan the following year if substantial changes to the initial plan will occur.

This request is to revise the automated CSBG State Plan format for

states and territories by revising questions for clarity and system compatibility. It is not anticipated that these revisions will cause any additional burden to states as they have been completing the automated plan for three years. It is anticipated that the burden will continue to diminish in subsequent years due to improved pre-population and automation.

In addition to the CSBG State Plan, states will be requested to complete a CSBG Eligible Entity Master List in year one, and then make updates as necessary in subsequent years. As the states have the information about their eligible entities (or sub-grantees), the

burden will be minimal to the states to complete this the first year.

Lastly, the request includes a survey for the CSBG eligible entities (or sub-grantees). The survey focuses on the customer service that the eligible entities receive from the CSBG states. The survey is optional, and this will be the third time that the eligible entities that chose to submit will complete it.

Respondents: State Governments, including the District of Columbia and the Commonwealth of Puerto Rico, and U.S. territories, and local level sub-grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
CSBG State Plan Application for States	56	1	31	1736
CSBG State Plan Eligible Entity List	56	1	1	56
CSBG ACSI Survey of Eligible Entities	1019	1	.15	152.85

Estimated Total Annual Burden Hours: 1,792 hours for states and territories; 152.85 for eligible entities.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: infocollection@acf.hhs.gov.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2018-05395 Filed 3-15-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0529]

Draft Concept Paper: Illicit Trade in Tobacco Products After Implementation of a Food and Drug Administration Product Standard; Availability; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft concept paper entitled “Illicit Trade in Tobacco Products after Implementation of an FDA Product Standard.” FDA seeks public comment on the draft concept paper regarding the potential for illicit trade markets to develop in response to a tobacco product standard. This draft concept paper is offered to stimulate dialogue around the subject of possible illicit trade in connection with tobacco product standards.

DATES: Although you can comment at any time, to ensure that the Agency considers your comment on this draft concept paper, submit either electronic or written comments by June 14, 2018.

ADDRESSES: You may submit comments 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.