

Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents OMB Control Number 0910-0312—Extension

This is a request for an extension of OMB approval for the information collection requirements contained in FDA's regulations for cigarettes and smokeless tobacco containing nicotine. The regulations that are codified at 21

CFR part 1140 are authorized by section 102 of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111-31). Section 102 of the Tobacco Control Act required FDA to publish a final rule regarding cigarettes and smokeless tobacco identical in its provisions to the regulation issued by FDA in 1996 (61 FR 44396, August 28, 1996), with certain specified exceptions including that subpart C (which included 21 CFR

897.24) and 897.32(c) be removed from the reissued rule (section 102(a)(2)(B)). The reissued final rule was published in the **Federal Register** of March 19, 2010 (75 FR 13225).

This collection includes reporting information requirements for § 1140.30 which directs persons to notify FDA if they intend to use a form of advertising that is not addressed in the regulations. The requirements are as follows:

§ 1140.30	Reporting	Directs persons to notify FDA if they intend to use a form of advertising that is not originally described in the March 19, 2010, final rule.
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In the **Federal Register** of January 12, 2016 (81 FR 1428), FDA published a 60-day notice requesting public comment

on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1140.30—Scope of Permissible Forms of Labeling and Advertising	300	1	300	1	300

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 industry-prepared data and information regarding cigarette and smokeless tobacco product advertising expenditures.

Section 1140.30 requires manufacturers, distributors, and retailers: (1) To observe certain format and content requirements for labeling and advertising and (2) to notify FDA if they intend to use an advertising medium that is not listed in the regulations. The concept of permitted advertising in § 1140.30 is sufficiently broad to encompass most forms of advertising. FDA estimates that approximately 300 respondents will submit an annual notice of alternative advertising, and the Agency has estimated it should take 1 hour to provide such notice. Therefore, FDA estimates that the total time required for this collection of information is 300 hours.

Dated: June 16, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-14628 Filed 6-20-16; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR must be received no later than August 22, 2016.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14N-39, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call the HRSA Information Collection Clearance Officer at (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Children's Hospitals Graduate Medical Education Payment Program Application and Full-Time Equivalent Resident Assessment Forms OMB No. 0915-0247 Revision.

Abstract: The Children's Hospitals Graduate Medical Education (CHGME) Payment Program was enacted by Public Law 106-129, and reauthorized by the CHGME Support Reauthorization Act of 2013 (Pub. L. 113-98) to provide Federal support for graduate medical education (GME) to freestanding children's hospitals. The legislation indicates that eligible children's hospitals will receive payments for both direct and indirect medical education. The CHGME Payment Program application and full-time equivalent (FTE) resident assessment forms received OMB clearance on June 30, 2014.

The CHGME Support Reauthorization Act of 2013 included a provision to

allow certain newly qualified children's hospitals to apply for CHGME Payment Program funding. The CHGME Payment Program application forms have been revised to accommodate the new statute. In addition, a payment question included in the CHGME Payment Program application forms has been removed, since the participating children's hospitals are now required to electronically communicate their financial information to the Payment Management System through the Electronic Handbook.

The form changes are only applicable to the HRSA 99-1 (also known as Exhibit O (2)) and the HRSA 99-5. All other hospital and auditor forms are the same as currently approved. The changes to the HRSA 99-1 and HRSA 99-5 forms require OMB approval and are as follows:

1. HRSA 99-1: Add additional description to Line 4.06 (both Page 2 and Page 2 Supplemental), 5.06 and 6.06. The current description is, "FTE adjusted cap." The new description will be, "FTE adjusted cap or 2013 CHGME Reauthorization cap due to Public Law 113-98."

2. HRSA 99-5: Remove Payment Information question and check boxes (Applicable only to: (1) Hospitals which have not previously participated in the CHGME Payment Program, and (2)

hospitals in which financial institution information has changed since submission of its last application).

Need and Proposed Use of the Information: Data on the number of FTE residents trained are collected from children's hospitals applying for CHGME Payment Program funding. These data are used to determine the amount of direct and indirect medical education payments to be distributed to participating children's hospitals. Indirect medical education payments will also be derived from a formula that requires the reporting of discharges, beds, and case mix index information from participating children's hospitals. As required by legislation, the FTE resident assessment shall determine any changes to the FTE resident counts initially reported to the CHGME Payment Program.

Likely Respondents: The likely respondents include both the estimated 60 children's hospitals that apply and receive CHGME Payment Program funding, as well as the 30 auditors contracted by HRSA to perform the FTE resident assessments of all the children's hospitals participating in the CHGME Payment Program. Children's hospitals applying for CHGME Payment Program funding are required by the CHGME Payment Program statute to submit data on the number of FTE

residents trained in an annual application. Once funded by the CHGME Payment Program, these same children's hospitals are required to submit audited data on the number of FTE residents trained during the Federal fiscal year to participate in the reconciliation payment process. Contracted auditors are requested by HRSA to submit assessed data on the number of FTE residents trained by the children's hospitals participating in the CHGME Payment Program in an FTE resident assessment summary.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Application Cover Letter (Initial and Reconciliation)	60	2	120	0.33	39.6
HRSA 99 (Initial and Reconciliation)	60	2	120	0.33	39.6
HRSA 99-1 (Initial)	60	1	60	26.5	1,590
HRSA 99-1 (Reconciliation)	60	1	60	6.5	390
HRSA 99-1 (Supplemental) (FTE Resident Assessment) ..	30	2	60	3.67	220.2
HRSA 99-2 (Initial)	60	1	60	11.33	679.8
HRSA 99-2 (Reconciliation)	60	1	60	3.67	220.2
HRSA 99-4 (Reconciliation)	60	1	60	12.5	750
HRSA 99-5 (Initial and Reconciliation)	60	2	120	0.33	39.6
CFO Form Letter (Initial and Reconciliation)	60	2	120	0.33	39.6
Exhibit 2 (Initial and Reconciliation)	60	2	120	0.33	39.6
Exhibit 3 (Initial and Reconciliation)	60	2	120	0.33	39.6
Exhibit 4 (Initial and Reconciliation)	60	2	120	0.33	39.6
FTE Resident Assessment Cover Letter (FTE Resident Assessment)	30	2	60	0.33	19.8
Conversation Record (FTE Resident Assessment)	30	2	60	3.67	220.2
Exhibit C (FTE Resident Assessment)	30	2	60	3.67	220.2
Exhibit F (FTE Resident Assessment)	30	2	60	3.67	220.2
Exhibit N (FTE Resident Assessment)	30	2	60	3.67	220.2
Exhibit O(1) (FTE Resident Assessment)	30	2	60	3.67	220.2
Exhibit O(2) (FTE Resident Assessment)	30	2	60	26.5	1590
Exhibit P (FTE Resident Assessment)	30	2	60	3.67	220.2
Exhibit P(2) (FTE Resident Assessment)	30	2	60	3.67	220.2
Exhibit S (FTE Resident Assessment)	30	2	60	3.67	220.2
Exhibit T (FTE Resident Assessment)	30	2	60	3.67	220.2
Exhibit T(1) (FTE Resident Assessment)	30	2	60	3.67	220.2
Exhibit 1 (FTE Resident Assessment)	30	2	60	0.33	19.8
Exhibit 2 (FTE Resident Assessment)	30	2	60	0.33	19.8
Exhibit 3 (FTE Resident Assessment)	30	2	60	0.33	19.8

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Exhibit 4 (FTE Resident Assessment)	30	2	60	0.33	19.8
Total	* 90	* 90	8018.4

* The total is 90 because the same hospitals and auditors are completing the forms.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Jason E. Bennett,
Director, Division of Executive Secretariat.
[FR Doc. 2016-14656 Filed 6-20-16; 8:45 am]
BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: 4040-0005 30-day notice]

Agency Information Collection Request; 30-Day Public Comment Request, Grants.gov

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, *Grants.gov* (EGOV), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, email your request, including your address, phone number,

OMB number, to *Ed.Calimag@hhs.gov*, or call the Reports Clearance Office on (202) 690-6162. Send written comments and recommendations for the proposed information collections within 30 days of this notice directly to the *Grants.gov* OMB Desk Officer; faxed to OMB at 202-395-6974.

Proposed Project

Application for Federal Assistance SF-424 Individual
3 Year Extension

Office: Grants.gov

Abstract: 4040-0005 is an OMB-approved collection. This information collection is used by more than 2 Federal grant-making entities, but not by HHS. Therefore, burden hours are not reported for HHS. Since this IC is used by more than 2 Federal grant-making entities, *Grants.gov* seeks to assign this as a common form. This IC expires on July 31, 2016. We are requesting a three-year clearance for 4040-0005 and that the form be designated as a common forms.

ESTIMATED ANNUALIZED BURDEN TABLE

Forms (If necessary)	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Application for Federal Assistance SF-424 Individual.	Grant Applicant	0	1	1	0
Total	0	0

Terry S. Clark,
Asst. Information Collection Clearance Officer.
[FR Doc. 2016-14476 Filed 6-20-16; 8:45 am]
BILLING CODE 4151-AE-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), notice is hereby given of a meeting of the Board of Scientific Counselors, National Center for Biotechnology Information.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for review, discussion, and evaluation of