

and CMS document identifier, to Paperwork@cms.hhs.gov.

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

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786-1326

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:* State Children's Health Insurance Program and Supporting Regulations; *Use:* States must submit title XXI plans and amendments for approval by the Secretary. We use the plan and its subsequent amendments to determine if the state has met the requirements of title XXI. Information provided in the state plan, state plan amendments, and from the other information we are collecting will be used by advocacy groups, beneficiaries, applicants, other governmental agencies, providers groups, research organizations, health care corporations, health care consultants. States will use the information collected to assess state plan performance, health outcomes and an evaluation of the amount of substitution of private coverage that occurs as a result of the subsidies and the effect of the subsidies on access to coverage. *Form Number:* CMS-R-308 (OCN: 0938-0841); *Frequency:* Yearly, Once, and Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 400; *Total Annual Hours:* 1,473,817. (For policy questions regarding this collection contact Judith Cash at 410-786-4473).

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Evaluation of the Rural Community Hospital Demonstration (RCHD); *Use:* Section 10313 of the Affordable Care Act of 2010 (ACA) extended and expanded the Rural Community Hospital Demonstration (RCHD). Originally authorized under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), the RCHD provides enhanced reimbursement for inpatient services to small rural hospitals that do not qualify as critical access hospitals (CAHs). The RCHD is intended to increase the capability of these hospitals to meet the health care needs of rural beneficiaries in their service areas. As a demonstration, the RCHD aims to provide information that can be used to assess the feasibility and advisability of establishing a new category of rural community hospitals for reimbursement policy. As of January 2013, 23 hospitals from 11 states are participating in the RCHD. This number includes seven hospitals continuing from the original demonstration as authorized under the MMA and 15 new hospitals that joined under the expansion authorized under the ACA.

For the original demonstration, the MMA required a Report to Congress six months after the end of the demonstration, a requirement unchanged by the ACA. An initial evaluation was conducted between 2007 and 2011 toward preparing for a Report to Congress and focused on the 17 hospitals that had participated at some point between October 2004 and March 2011. Findings from this evaluation were reported to the Centers for Medicare and Medicaid Services (CMS) in the *Interim Evaluation Report of the Rural Community Hospital Demonstration* (an unpublished report).

The current five-year evaluation of the RCHD will extend and build on the prior evaluation and produce the Report to Congress required by the MMA. It will assess the impact of the RCHD in meeting its goals: to enable hospitals to achieve community benefits such as improved services for their communities (especially Medicare beneficiaries), meet their individual strategic goals, and improve the financial solvency and viability of the participating hospitals. In addition, the evaluation will determine if it is feasible and advisable to create a new payment category of rural hospitals. To achieve this objective, the evaluation will examine how RCHD hospitals responded to payment options and assess how the

costs to Medicare under RCHD compare to existing alternative payment options.

The evaluation will also summarize the characteristics of the markets served by RCHD hospitals, including beneficiaries' proximity to inpatient providers and competition among providers in the area. The information will be used to assess the implications of expanding the RCHD payment system to hospitals in various market environments. In addition, the evaluation will examine the potential costs of expanding the RCHD payment methodology, accounting for alternative approaches to targeting rural hospitals. *Form Number:* CMS-10508 (OCN: 0938-NEW); *Frequency:* Annually; *Affected Public:* State, Local or Tribal Governments, Private sector (Business or other for-profit and Not-for-profit organizations); *Number of Respondents:* 57; *Total Annual Responses:* 101; *Total Annual Hours:* 245. (For policy questions regarding this collection contact Woolton Lee at 410-786-4942.)

Dated: January 16, 2014.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2014-01208 Filed 1-22-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1064]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Application for Participation in the Medical Device Fellowship Program

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. **DATES:** Fax written comments on the collection of information by February 24, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX:

202–395–7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0551. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *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.

Application for Participation in the Medical Device Fellowship Program—(OMB Control Number 0910–0551)—(Extension)

Sections 1104, 1302, 3301, 3304, 3320, 3361, 3393, and 3394 of Title 5 of the United States Code authorize Federal Agencies to rate applicants for Federal jobs. Collecting applications for the Medical Device Fellowship Program will allow FDA’s Center for Devices and Radiological Health (CDRH) to easily and efficiently elicit and review information from students and health care professionals who are interested in becoming involved in CDRH activities. The process will reduce the time and cost of submitting written documentation to the Agency and lessen

the likelihood of applications being misrouted within the Agency mail system. It will assist the Agency in promoting and protecting the public health by encouraging outside persons to share their expertise with CDRH.

In the **Federal Register** of September 10, 2013 (78 FR 55260), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA based these estimates on the number of inquiries that have been received concerning the program and the number of requests for application forms over the past 3 years.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Application Form (Form FDA 3608)	250	1	250	1	250

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

Dated: January 16, 2014.
Leslie Kux,
Assistant Commissioner for Policy.
 [FR Doc. 2014–01221 Filed 1–22–14; 8:45 am]
BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0377]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Tobacco Health Document Submission

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Tobacco Health Document Submission” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: On August 28, 2013, the Agency submitted a proposed collection of information entitled “Tobacco Health Document

Submission” to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0654. The approval expires on December 31, 2016. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: January 16, 2014.
Leslie Kux,
Assistant Commissioner for Policy.
 [FR Doc. 2014–01222 Filed 1–22–14; 8:45 am]
BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1089]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Recommended Glossary and Educational Outreach To Support Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use

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.

DATES: Fax written comments on the collection of information by February 24, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0553. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *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.