or other forms of information technology to minimize the information collection burden.

Darius Taylor,

Deputy Information Collection Clearance Officer.

[FR Doc. 2013–22450 Filed 9–13–13; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–10371]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Center for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections 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.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. This is necessary to ensure compliance with an initiative of the Administration. We are requesting an emergency review under 5 CFR Part 1320(a)(2)(i) because public harm is reasonably likely to result if the normal clearance procedures are followed. The approval of the data collection tools for outcomes and operational metrics is essential to ensuring that State-based Marketplaces provide substantive operational and monitoring data to CMS in a uniform format from the beginning of the enrollment period, October 1, 2013. Without an emergency clearance process, systematic data collection would not begin until well into the open enrollment period, and states would have to delay critical steps to integrating this reporting into their information systems. Without consistent data, we will be limited in our ability to effectively track states' progress and identify problems during this crucial early implementation period.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Cooperative Agreement to Support Establishment of State-Operated Health Insurance Exchanges; *Use:* All States (including the 50 States, consortia of States, Territories, and the District of Columbia herein referred to as States) that received a State Planning and Establishment Grant for Affordable Care Act's (ACA) Exchanges are eligible for the Cooperative Agreement to Support Establishment of State Operated Insurance Exchanges. Section 1311 of the Affordable Care Act offers the opportunity for each State to establish an Exchange [now referred to as Marketplace], and provides for grants to States for the planning and establishment of these Exchanges. Given the innovative nature of Exchanges and the statutorily-prescribed relationship between the Secretary and States in their development and operation, it is critical that the Secretary work closely with States to provide necessary guidance and technical assistance to ensure that States can meet the prescribed timelines, Federal requirements, and goals of the statute.

In order to provide appropriate and timely guidance and technical assistance, the Secretary must have access to timely, periodic information regarding State progress. Consequently, the information collection associated with these grants is essential to facilitating reasonable and appropriate federal monitoring of funds, providing statutorily-mandated assistance to States to implement Exchanges in accordance with Federal requirements, and to ensure that States have all necessary information required to proceed, such that retrospective corrective action can be minimized.

The submitted revision adds lists and suggested data reporting formats for Outcomes and Operational Metrics to states' data collection requirements; we will use the resulting data to evaluate Marketplace performance and overall effectiveness of the ACA. Key areas of measurement are the effectiveness of eligibility determination and enrollment processes, impact on affordability for consumers, and the effect of Marketplace participation on health insurances markets. Furthermore, these metrics facilitate actionable feedback and technical assistance to States for quality improvement efforts during the critical early period of operations. This funding opportunity was first released on January 20, 2011. *Form Number:* CMS–10371(OCN: 0938–1121); *Frequency:* Occasionally; *Affected Public:* State, Local or Tribal governments; *Number of Respondents:* 40; *Total Annual Responses:* 1,475; *Total Annual Hours:* 64,695. (For policy questions regarding this collection contact Christina Daw at 301–492–4181.)

We are requesting OMB review and approval of this collection by September 23, 2013, with a 180-day approval period. Written comments and recommendation will be considered from the public if received by the individuals designated below by the noted deadline below.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995* or Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by September 23, 2013:

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier (CMS–10371), Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850 and,

OMB Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, New Executive Office Building, Room 10235, Washington,

DC 20503, Fax Number: (202) 395–6974.

Dated: September 12, 2013.

Martique Jones,

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

[FR Doc. 2013–22517 Filed 9–13–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0514]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Requests for Clinical Laboratory Improvement Amendments Categorization

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 October 16, 2013.

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 0910–0607. 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. Requests for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Categorization—42 CFR 493.17 (OMB Control Number 0910–0607)—Extension.

A guidance document entitled ''Guidance for Administrative Procedures for CLIA Categorization'' was released on May 7, 2008. The document describes procedures FDA uses to assign the complexity category to a device. Typically, FDA assigns complexity categorizations to devices at the time of clearance or approval of the device. In this way, no additional burden is incurred by the manufacturer because the labeling (including operating instructions) is included in the premarket notification (510(k)) or premarket approval application (PMA). In some cases, however, a manufacturer may request CLIA categorization even if FDA is not simultaneously reviewing a 510(k) or PMA. One example is when a manufacturer requests that FDA assign CLIA categorization to a previously cleared device that has changed names since the original CLIA categorization. Another example is when a device is exempt from premarket review. In such cases, the guidance recommends that manufacturers provide FDA with a copy of the package insert for the device and a cover letter indicating why the manufacturer is requesting a categorization (e.g. name change, exempt from 510(k) review). The guidance recommends that in the correspondence to FDA the manufacturer should identify the product code and classification as well as reference to the original 510(k) when this is available. In the **Federal Register** of May 22, 2013 (78 FR 30312), 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 BURDEN ACTIVITY [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Operating and maintenance costs
Request for CLIA categorization	60	15	900	1	900	$46,800

[1] There are no capital costs associated with this collection of information.

The number of respondents is approximately 60. On average, each respondent will request categorizations (independent of a 510(k) or PMA) 15 times per year. The cost, not including personnel, is estimated at $52 per hour ($52 \times 900$), totaling $46,800. This includes the cost of copying and mailing copies of package inserts and a cover letter, which includes a statement of the reason for the request and reference to the original 510(k) numbers, including regulation numbers and product codes. The burden hours are based on FDA familiarity with the types of documentation typically included in a sponsor's categorization requests, and costs for basic office supplies (e.g. paper).

Dated: September 10, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–22443 Filed 9–13–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Blood Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 1, 2013, from 8 a.m. to 4:30 p.m.

Location: FDA Fishers Lane Building, 5630 Fishers Lane, rm. 1066, Rockville, MD 20857. For those unable to attend in person, the meeting will also be Web cast. The Web cast will be available at the following link: *http://fda.yorkcast.com/webcast/Viewer/?peid=18390c01dfff405681afa644b1837e5a1d.*

Contact Person: Bryan Emery or Pearline Muckelvene, Center for Biologics Evaluation