

In the final rule for Stage 2 of meaningful use (77 FR 53967), we agreed that the burden on eligible providers, public health agencies and registries would be greatly reduced and established that we would create such a database and it would serve as the definitive information source for determining public health agency and registry readiness to receive electronic data associated with the public health meaningful use objectives. The information will be made publicly available on the CMS Web site (www.cms.gov/EHRincentiveprograms) in order to provide a centralized repository of this information to eligible providers and eliminate there multiple individual inquiries to multiple public health agencies and registries. *Form Number:* CMS-10499 (OMB control number: 0938—New); *Frequency:* Yearly; *Affected Public:* Private sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 250; *Total Annual Responses:* 250; *Total Annual Hours:* 83. (For policy questions regarding this collection contact Kathleen Connors de Laguna at 410-786-2256.)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Standards Related to Reinsurance, Risk Corridors, Risk Adjustment, and Payment Appeals; *Use:* The Affordable Care Act provides for three premium stabilization programs—a reinsurance program, a risk corridors program, and a risk adjustment program—to mitigate the negative impacts of adverse selection and market uncertainty. On March 23, 2012, we published the Premium Stabilization Rule (77 FR 17220) to implement and set standards for these premium stabilization programs. On March 11, 2013, we published the final Notice of Benefit and Payment Parameters for 2014 (“2014 Payment Notice”) (78 FR 15410), to implement requirements for various programs established by the Affordable Care Act, establish standards for the cost-sharing reduction program and the premium tax credit program, to provide for the collection of user fees from issuers to fund operations of the Federally-facilitated Exchange and the risk adjustment program in States where HHS operates risk adjustment, and to expand on standards set forth in the Premium Stabilization Rule. We published a proposed Notice of Benefit and Payment Parameters for 2015 (“2015 Payment Notice”) on December 02, 2013, to expand upon, modify, and clarify the provisions of the Premium

Stabilization Rule, the 2014 Payment Notice, and the first and second final Program Integrity Rules (78 FR 54070 and 78 FR 65046).

The transitional reinsurance program and the temporary risk corridors program are designed to provide issuers with greater payment stability as insurance market reforms begin. The reinsurance program serves to reduce the uncertainty of insurance risk in the individual market in each State by making payments for high-cost enrollees. The HHS-administered risk corridors program serves to protect against rate-setting uncertainty with respect to qualified health plans by limiting the extent of issuer losses (and gains). The permanent risk adjustment program is intended to protect health insurance issuers that attract a disproportionate number of higher risk enrollees, that is, those with chronic conditions. These programs will support the effective functioning of the American Health Benefit Exchanges (“Exchanges”), which will become operational by January 1, 2014. The Exchanges are individual and small group health insurance marketplaces designed to enhance competition in the health insurance market and to expand access to affordable health insurance for millions of Americans. Individuals who enroll in qualified health plans (QHPs) through individual market Exchanges may receive premium tax credits to make health insurance more affordable and financial assistance to reduce cost sharing for health care services. The information collection requirements contained in this information collection request will enable States, HHS or both States and HHS to implement these programs, which will mitigate the impact of adverse selection in the individual and small group markets both inside and outside the Exchange.

Form Number: CMS-10401 (OMB control number: 0938-1155); *Frequency:* Occasionally; *Affected Public:* State, Local and Tribal governments, Private sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 2,520; *Total Annual Responses:* 15,600,081,744; *Total Annual Hours:* 17,469,624. (For policy questions regarding this collection contact Jaya Ghildyal at 301-492-5149.)

Dated: May 13, 2014.

Martique Jones,

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

[FR Doc. 2014-11388 Filed 5-15-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-7032-CN]

Health Insurance Marketplace, Medicare, Medicaid, and Children’s Health Insurance Programs; Meeting of the Advisory Panel on Outreach and Education (APOE), May 22, 2014; Corrections

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Correction notice.

SUMMARY: This notice corrects an error in the notice of meeting that published in the May 2, 2014 **Federal Register** titled “Health Insurance Marketplace, Medicare, Medicaid, and Children’s Health Insurance Programs; Meeting of the Advisory Panel on Outreach and Education (APOE), May 22, 2014.”

FOR FURTHER INFORMATION CONTACT: Kirsten Knutson, (410) 786-5886.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2014- 09989, which published in the May 2, 2014 **Federal Register** (79 FR 25133) titled “Health Insurance Marketplace, Medicare, Medicaid, and Children’s Health Insurance Programs; Meeting of the Advisory Panel on Outreach and Education (APOE), May 22, 2014”, there was an error that is identified and corrected in the Correction of Errors section of this correction notice.

II. Summary of Errors

On page 25134, we made an error in providing information regarding the public’s offsite participation in the May 22, 2014 APOE meeting.

III. Correction of Errors

In FR Doc. 2014-09989 of May 2, 2014 (79 FR 25133), make the following correction:

1. On page 25134, first column, second paragraph (**ADDRESSES** section), line 21, the phrase “engage virtually in the open meetings, this APOE meeting will be available to view via live Web streaming by visiting the link www.cms.gov/live during the designated time of the meeting.” is corrected to read “engage in the open meeting, this APOE meeting will be available for listening only via a conference call. To listen to the meeting, the public may dial 1-877-267-1577, then follow the instructions on the phone and enter the following meeting ID number, 996 925 940, followed by the pound sign.”

Authority: (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance, Program No. 93.774, Medicare—Supplementary Medical Insurance Program, and Program No. 93.714, Medical Assistance Program)

Dated: May 13, 2014.

Kathleen Cantwell,

Director, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2014–11380 Filed 5–15–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–N–0037]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Animal Drug User Fee Act Waivers and Reductions

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 June 16, 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 0910–0540. 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.

Animal Drug User Fees and Fee Waivers and Reductions (OMB Control Number 0910–0540)—Extension

Enacted on November 18, 2003, the Animal Drug User Fee Act (ADUFA) (Pub. L. 108–130) amended the Federal Food, Drug, and Cosmetic Act and requires FDA to assess and collect user fees for certain applications, products,

establishments, and sponsors. It also requires the Agency to grant a waiver from, or a reduction of those fees in certain circumstances. Thus, to implement this statutory provision of ADUFA, FDA developed a guidance entitled “Guidance for Industry: Animal Drug User Fees and Fee Waivers and Reductions.” This document provides guidance on the types of fees FDA is authorized to collect under ADUFA, and how to request waivers and reductions from FDA’s animal drug user fees. Further, this guidance also describes the types of fees and fee waivers and reductions; what information FDA recommends be submitted in support of a request for a fee waiver or reduction; how to submit such a request; and FDA’s process for reviewing requests.

Respondents to this collection of information are new animal drug sponsors. Requests for waivers or reductions may be submitted by a person paying any of the animal drug user fees assessed including application fees, product fees, establishment fees, or sponsor fees.

In the **Federal Register** of February 25, 2014 (79 FR 10532) FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
740(d)(1)(A); significant barrier to innovation.	45	1 time for each application	45	2	90
740(d)(1)(B); fees exceed cost	8	3.75	30	² 0.5	15
740(d)(1)(C); free choice feeds	5	1 time for each application	5	2	10
740(d)(1)(D); minor use or minor species.	76	1 time for each application	76	2	152
740(d)(1)(E); small business	3	1 time for each application	3	2	6
Request for reconsideration of a decision.	2	1 time for each application	2	2	4
Request for review—(user fee appeal officer).	0	1 time for each application	0	0	0
Total					277

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

² 30 minutes.

Based on FDA’s database system, from fiscal years 2010 to 2012 there were an estimated 173 sponsors subject to ADUFA. However, not all sponsors will

have any submissions in a given year and some may have multiple submissions. The total number of waiver requests is based on the average

number of submission types received by FDA in fiscal years 2010 to 2012.