

Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-5806 OR Email: [OIRA\\_submission@omb.eop.gov](mailto: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' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto: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:* New collection (Request for a new control number); *Title of Information Collection:* Outpatient and Ambulatory Surgery Experience of Care Survey; *Use:* We will use the information collected through the field test to inform the development of a larger national survey effort, including development of the final survey instrument and data collection procedures. Looking toward the survey development specifically, the data collected in this survey effort will be used to conduct a rigorous psychometric analysis of the survey content. The goal of such an analysis is to assess the measurement properties of the proposed instrument and sub-domain composites created from item subsets, to assure the information reported from any future

administrations of the survey is well-defined. Such careful definition will prevent data distortion or misinformation if they are publicly reported. Data collection procedures will also be fine-tuned during this field test. The 30-day PRA package has been revised since the publication of the 60-day **Federal Register** notice on October 4, 2013 (78 FR 61848). (*Form Number:* CMS-10500 (OCN: 0938-New); *Frequency:* Once; *Affected Public:* Individuals and households; *Number of Respondents:* 2,304; *Total Annual Responses:* 2,304; *Total Annual Hours:* 384. (For policy questions regarding this collection contact Caren Ginsberg at 410-786-0713.)

2. *Type of Information Collection Request:* New collection (request for a new OMB control number); *Title of Information Collection:* Payment Collections Operations Contingency Plan; *Use:* Under sections 1401, 1411, and 1412 of the Affordable Care Act and 45 CFR part 155 subpart D, an Exchange makes an advance determination of tax credit eligibility for individuals who enroll in QHP coverage through the Exchange and seek financial assistance. Using information available at the time of enrollment, the Exchange determines whether the individual meets the income and other requirements for advance payments and the amount of the advance payments that can be used to pay premiums. Advance payments are made periodically under section 1412 of the Affordable Care Act to the issuer of the QHP in which the individual enrolls. Section 1402 of the Affordable Care Act provides for the reduction of cost sharing for certain individuals enrolled in a QHP through an Exchange, and section 1412 of the Affordable Care Act provides for the advance payment of these reductions to issuers. The statute directs issuers to reduce cost sharing for essential health benefits for individuals with household incomes between 100 and 400 percent of the Federal poverty level (FPL) who are enrolled in a silver level QHP through an individual market Exchange and are eligible for advance payments of the premium tax credit. The data collection will be used by HHS to make payments or collect charges from issuers under the following programs: advance payments of the premium tax credit, advanced cost-sharing reductions, and Marketplace user fees. The template will be used to make payments in January 2014 and for a number of months thereafter, as may be required based on HHS's operational progress. *Form Number:* CMS-10515 (OCN 0938-NEW). *Frequency:* Monthly. *Affected*

*Public:* Private sector—Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 575. *Total Annual Responses:* 7,475. *Total Annual Hours:* 51,175. (For policy questions regarding this collection contact Jaya Ghildiyal at 301-492-5149.)

Dated: December 23, 2013.

**Martique Jones,**

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

[FR Doc. 2013-31015 Filed 12-26-13; 8:45 am]

**BILLING CODE 4120-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

[Document Identifier: CMS-10510]

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

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

**ACTION:** Notice; correction.

**SUMMARY:** This document corrects a date in the December 23, 2013, **Federal Register** notice (document identifier: CMS-10510) entitled "Basic Health Program Report for Health Insurance Exchange Premium."

**FOR FURTHER INFORMATION CONTACT:** Jessica Schubel at 410-786-3032.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

On December 23, 2013 (78 FR 77469), we published an emergency Paperwork Reduction Act (PRA) notice for the information collection request entitled "Basic Health Program Report for Health Insurance Exchange Premium."

While the date requested for OMB approval (January 6, 2014) is correct in the associated PRA package, the date in the December 23, 2013, **Federal Register** notice incorrectly reads "December 23, 2013." This notice corrects that error as follows.

**II. Correction**

In the **Federal Register** of December 23, 2013, in FR Doc. 2013-30434, on page 77469, in the third column, in the third paragraph, correct the first sentence to read:

We are requesting OMB review and approval of this collection by January 6, 2014, with a 180-day approval period.

Dated: December 23, 2013.

**Martique Jones,**

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

[FR Doc. 2013-30989 Filed 12-26-13; 8:45 am]

BILLING CODE 4120-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2011-N-0179]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002**

**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 January 27, 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 [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0520. 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](mailto: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. Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002—21 CFR 1.278 to 1.285 (OMB Control Number 0910-0520)—Revision.

The Public Health Security and Bioterrorism Preparedness and

Response Act of 2002 (the Bioterrorism Act) added section 801(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(m)), which requires that we receive prior notice for food, including food for animals, that is imported or offered for import into the United States. Sections 1.278 to 1.282 of our regulations (21 CFR 1.278 to 1.282) set forth the requirements for submitting prior notice; §§ 1.283(d) and 1.285(j) (21 CFR 1.283(d) and 1.285(j)) set forth the procedure for requesting our review after we have refused admission of an article of food under section 801(m)(1) of the FD&C Act or placed an article of food under hold under section 801(l) of the FD&C Act; and § 1.285(i) (21 CFR 1.285(i)) sets forth the procedure for post-hold submissions.

Section 304 of the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353) amended section 801(m) of the FD&C Act to require a person submitting prior notice of imported food, including food for animals, to report, in addition to other information already required, “any country to which the article has been refused entry.” In the **Federal Register** of May 5, 2011 (76 FR 25542), we issued an interim final rule (IFR) entitled “Information Required in Prior Notice of Imported Food” (2011 IFR) that implemented section 304 of FSMA and requested public comments. OMB approved the collection of information requirements of the 2011 IFR under OMB control number 0910-0683. On May 30, 2013 (78 FR 32359), we published a final rule that adopts, without change, the regulatory requirements established in the 2011 IFR, specifically that a person submitting prior notice of imported food, including food for animals, must report the name of any country that has refused entry of that product. In this request for extension of OMB approval under the PRA, we are combining the burden hours associated with OMB control number 0910-0683 (collection entitled “Information Required in Prior Notice of Imported Food”) with the burden hours approved under OMB control number 0910-0520 (collection entitled “Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002”).

Advance notice of imported food allows us, with the support of the U.S. Customs and Border Protection (CBP), to target import inspections more effectively and help protect the nation’s food supply against terrorist acts and other public health emergencies. By requiring that a prior notice contain additional information that indicates prior refusals by any country and also

identifies the country or countries, we may better identify imported food shipments that may pose safety and security risks to U.S. consumers. This additional knowledge can further help us to make better informed decisions in managing the potential risks of imported food shipments into the United States.

Any person with knowledge of the required information may submit prior notice for an article of food. Thus, the respondents to this information collection may include importers, owners, ultimate consignees, shippers, and carriers.

Our regulations require that prior notice of imported food be submitted electronically using CBP’s Automated Broker Interface of the Automated Commercial System (ABI/ACS) (§ 1.280(a)(1)) or the FDA Prior Notice System Interface (PNSI) (Form FDA 3540) (§ 1.280(a)(2)). PNSI is an electronic submission system available on the FDA Industry Systems page at <http://www.access.fda.gov/>. Information we collect in the prior notice submission includes: The submitter and transmitter (if different from the submitter); entry type and CBP identifier; the article of food, including complete FDA product code; the manufacturer, for an article of food no longer in its natural state; the grower, if known, for an article of food that is in its natural state; the FDA Country of Production; the name of any country that has refused entry of the article of food; the shipper, except for food imported by international mail; the country from which the article of food is shipped or, if the food is imported by international mail, the anticipated date of mailing and country from which the food is mailed; the anticipated arrival information or, if the food is imported by international mail, the U.S. recipient; the importer, owner, and ultimate consignee, except for food imported by international mail or transshipped through the United States; the carrier and mode of transportation, except for food imported by international mail; and planned shipment information, except for food imported by international mail (§ 1.281).

Much of the information collected for prior notice is identical to the information collected for our importer’s entry notice, which has been approved under OMB control number 0910-0046. The information in an importer’s entry notice is collected electronically via CBP’s ABI/ACS at the same time the respondent files an entry for import with CBP. To avoid double-counting the burden hours already counted in the importer’s entry notice information collection, the burden hour analysis in