

comparability review or a validation review inspection is not acceptable, as described under § 493.573 and § 493.575, or if the State of Washington fails to pay the required fee every 2 years as required under § 493.646.

#### *Laboratory Data*

In accordance with our regulations at § 493.557(b)(8), the approval of this exemption for laboratories located in and licensed by the State of Washington is conditioned on the State of Washington's continued compliance with the assertions made in its application, especially the provision of information to us about changes to a laboratory's specialties or subspecialties based on the state's survey, and changes to a laboratory's certification status, such as a change from a CLIA certificate of compliance to a CLIA certificate of waiver.

#### *Required Administrative Actions*

CLIA is a user-fee funded program. The registration fee paid by laboratories is intended to cover the cost of the development and administration of the program. However, when a state's application for exemption is approved, we do not charge a fee to laboratories in the state. The state's share of the costs associated with CLIA must be collected from the state, as specified in § 493.645.

The State of Washington must pay for the following:

- Costs of federal inspections of laboratories in the state to verify that Washington State's laboratory licensure program requirements are equivalent to or more stringent than those in the CLIA program, and that they are enforced in an appropriate manner. The average federal hourly rate is multiplied by the total hours required to perform federal validation surveys within the state.

- Costs incurred for federal surveys, including investigations of complaints that are substantiated. We will bill the State of Washington on a semiannual basis.

- The State of Washington's proportionate share of the costs associated with establishing, maintaining, and improving the CLIA computer system, based on the portion of those services from which the State of Washington received direct benefit or which contributed to the CLIA program in the state. Thus, the State of Washington is being charged for a portion of our direct and indirect costs of administering the CLIA program. Such costs will be incurred by CMS, the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA) and contractors

working on behalf of these respective agencies.

To estimate the State of Washington's proportionate share of the general overhead costs to develop and implement CLIA, we determined the ratio of laboratories in the state to the total number of laboratories nationally. Approximately 1.5 percent of the registered laboratories are in the State of Washington. We determined that a corresponding percentage of the applicable CMS, CDC, FDA, and their respective contractor costs should be borne by the State of Washington.

The State of Washington has agreed to pay the state's pro rata share of the anticipated overhead costs and costs of actual validation (including complaint investigation surveys). A final reconciliation for all laboratories and all expenses will be made. We will reimburse the state for any overpayment or bill it for any balance.

## **II. Approval**

In light of the foregoing, we grant approval of the State of Washington's laboratory licensure program under subpart E. All laboratories located in and licensed by the State of Washington under the Medical Test Site law, Chapter 70.42 of the Revised Code of Washington, are CLIA-exempt for all specialties and subspecialties until September 27, 2019.

**Authority:** Section 353(p) of the Public Health Service Act (42 U.S.C. 263a).

Dated: August 8, 2013.

**Marilyn Tavenner,**  
*Administrator, Centers for Medicare & Medicaid Services.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. FDA-2008-N-0656]**

#### **Secure Supply Chain Pilot Program; Correction**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a document that appeared in the **Federal Register** of August 20, 2013 (78 FR 51192). The document announced the start of the Secure Supply Chain Pilot Program (SSCPP). The document was published with an incorrect email address for the SSCPP mailbox. This document corrects that error.

#### **FOR FURTHER INFORMATION CONTACT:**

Katharine Neckers, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Building 51, Rm. 4259, 301-796-3339, email: [Katharine.Neckers@fda.hhs.gov](mailto:Katharine.Neckers@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In FR Doc. 2013-20215, appearing on page 51192 in the **Federal Register** of August 20, 2013, the following correction is made:

On page 51194, in the second column, under "IV. Process for Applying to Participate in the Pilot," in the third full paragraph, the sentence that reads "For communications other than the submission of the SSCPP application (Form FDA 3676), please contact the CDER SSCPP mailbox at [SSCPPMailbox@fda.hhs.gov](mailto:SSCPPMailbox@fda.hhs.gov)" is corrected to read "For communications other than the submission of the SSCPP application (Form FDA 3676), please contact the CDER SSCPP mailbox at [CDERSSCPP@fda.hhs.gov](mailto:CDERSSCPP@fda.hhs.gov)."

Dated: September 24, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **Proposed Collection; 30-Day Comment Request; Evaluation of a Kidney Disease Education and Awareness Program in the Hispanic Community**

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on July 19, 2013, Volume 78, pages 43214-43215, and allowed 60-days for public comment. One public comment was received. The purpose of this notice is to allow an additional 30 days for public comment. The National Kidney Disease Education Program, the National Institute of Diabetes and Digestive and Kidney Diseases, the National Institutes of Health (NIH), may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.