

about Agents and Brokers that have registered with, successfully completed CMS training, and are certified by an FFE or FF-SHOP to provide outreach and education resources to consumers about obtaining health care coverage in their states..

12. To provide information regarding complaints to other Federal agencies and agencies of a state government for the purpose of resolving complaints and identifying insurer non-compliance with Federal, state, and other applicable law.

13. To assist a CMS contractor that is engaged to perform a function or provide administrative, technical or physical support to the FFEs (including FF-SHOPs) or to a grantee of a CMS-administered grant program, when the disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste or abuse in such program.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM**

**STORAGE:**

Electronic records will be stored on both tape cartridges (magnetic storage media) and in a relational database management environment (DASD data storage media). Any hard copies of program related records containing PII at CMS and contractor locations will be kept in secure hard-copy file folders locked in secure file cabinets during non-duty hours.

**RETRIEVABILITY:**

The records will be retrieved electronically by a variety of fields, including but not limited to first name, last name, middle initial, date of birth, or Social Security Number (SSN).

**SAFEGUARDS:**

Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access. Access to records in the HIX Program system will be limited to authorized CMS personnel and contractors through

password security, encryption, firewalls, and secured operating system. Any electronic or hard copies of records containing PII at CMS, Exchanges and contractor locations will be kept in secure electronic files or in hard-copy file folders locked in secure file cabinets during non-duty hours.

**RETENTION AND DISPOSAL:**

These records will be maintained until they become inactive, at which time they will be retired or destroyed in accordance with published records schedules of the Centers for Medicare & Medicaid Services as approved by the National Archives and Records Administration.

**SYSTEM MANAGER AND ADDRESS:**

Director of Operations, Center for Consumer Information and Insurance Oversight, 7501 Wisconsin Avenue, Bethesda, Maryland 20814.

**NOTIFICATION PROCEDURE:**

An individual record subject who wishes to know if this system contains records about him or her should write to the system manager who will require the system name, and for verification purposes, the subject individual's name (individual's former name(s) name, if applicable), and SSN (furnishing the SSN is voluntary, but it may make searching for a record easier and prevent delay).

**RECORD ACCESS PROCEDURE:**

An individual seeking access to records about him or her in this system should use the same procedures outlined in Notification Procedures above. The requestor should also reasonably specify the record contents being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5(a)(2).)

**CONTESTING RECORD PROCEDURES:**

To contest a record, the subject individual should contact the system manager named above, and reasonably identify the record and specify the information being contested. The individual should state the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7.)

**RECORD SOURCE CATEGORIES:**

Personally identifiable information in this database is obtained from the application submitted by or on behalf of

applicants, enrollees, and appellants seeking eligibility determinations, from qualified employers and other employers who provide employer-sponsored coverage, from CMS and other Federal and state agencies as part of verifications and information retrievals to make eligibility determinations, from Marketplace assisters facilitating the eligibility and enrollment processes, from QHPs, from State-based Exchanges that provide information to perform the statutory functions, from states participating in State Partnership Exchanges pursuant to Conditional Approval Decision letters, and from third party data sources to determine eligibility as described in this notice.

**EXEMPTIONS CLAIMED FOR THIS SYSTEM:**

None.

Dated: October 18, 2013.

**Michelle Snyder,**

*Chief Operating Officer, Centers for Medicare & Medicaid Services.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

[CFDA Number: 93.508]

**Announcing the Award of Four Single-Source Expansion Supplement Grants Under the Tribal Maternal, Infant, and Early Childhood Home Visiting (MIECHV), Tribal Early Learning Initiative Program**

**AGENCY:** Office of Child Care, ACF, HHS.

**ACTION:** Notice of the award of four single-source program expansion supplement grants to Tribal Maternal, Infant, and Early Childhood Home Visiting (MIECHV) grantee participants in the Tribal Early Learning Initiative.

**SUMMARY:** This announces the award of single-source program expansion supplement grants to the following Tribal Maternal, Infant, and Early Childhood Home Visiting (MIECHV) grantees to support their ongoing participation in the Tribal Early Learning Initiative, by the Office of Child Care, a program of the Administration for Children and Families.

Choctaw Nation of Oklahoma .....	Durant, OK .....	\$25,000
Pueblo of San Felipe .....	San Felipe, NM .....	25,000

Confederated Salish and Kootenai Tribes .....	Pablo, MT .....	25,000
White Earth Band of Chippewa Indians .....	White Earth, MN .....	25,000

The program expansion supplement awards will support expanded services to identify and analyze systems to improve effectiveness and efficiencies across early childhood programs, share action plans to improve outcomes, continue the implementation of and expand the development of concrete community plans, and develop peer learning relationships.

**DATES:** September 30, 2013–September 29, 2014.

**FOR FURTHER INFORMATION CONTACT:** Shannon Rudisill, Director, Office of Child Care, 901 D Street SW., Washington, DC 20447. Telephone: (202) 401-6984; Email: [shannon.rudisill@acf.hhs.gov](mailto:shannon.rudisill@acf.hhs.gov).

**SUPPLEMENTARY INFORMATION:** One of the stated goals of the Tribal MIECHV program is to support and strengthen cooperation and coordination, and promote linkages among various programs that serve pregnant women, expectant fathers, young children, and families, resulting in the establishment of coordinated and comprehensive early childhood systems in grantee communities.

The activities of the four grantees are expected to result in models for tribal early learning systems that can be replicated in other tribal communities as well as to expand the reach and impact of technical assistance activities for the four participating tribal grantees.

In addition, the supplements will expand the reach and impact of technical assistance efforts by supporting and strengthening existing coordination and collaboration activities and expanding the scope of additional such activities in tribal communities.

**Statutory Authority:** Awards are supported by section 511(h)(2)(A) of Title V of the Social Security Act, as added by Section 2951 of the Patient Protection and Affordable Care Act, Public Law 111-148, also known as the Affordable Care Act (ACA).

**Shannon L. Rudisill,**

*Director, Office of Child Care.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0730]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Threshold of Regulation for Substances Used in Food-Contact Articles

**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 November 22, 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](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0298. 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.

#### Threshold of Regulation for Substances Used in Food-Contact Articles—21 CFR 170.39 (OMB Control Number 0910-0298)—Extension

Under section 409(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(a)), the use of a food additive is deemed unsafe unless one of the following is applicable: (1) It conforms to an exemption for investigational use under section 409(j) of the FD&C Act; (2) it conforms to the terms of a regulation prescribing its use;

or (3) in the case of a food additive which meets the definition of a food-contact substance in section 409(h)(6), there is either a regulation authorizing its use in accordance with section 409(a)(3)(A) or an effective notification in accordance with section 409(a)(3)(B).

The regulations in § 170.39 (21 CFR 170.39) established a process that provides the manufacturer with an opportunity to demonstrate that the likelihood or extent of migration to food of a substance used in a food-contact article is so trivial that the use need not be the subject of a food additive listing regulation or an effective notification. The Agency has established two thresholds for the regulation of substances used in food-contact articles. The first exempts those substances used in food-contact articles where the resulting dietary concentration would be at or below 0.5 part per billion (ppb). The second exempts regulated direct food additives for use in food-contact articles where the resulting dietary exposure is 1 percent or less of the acceptable daily intake for these substances.

In order to determine whether the intended use of a substance in a food-contact article meets the threshold criteria, certain information specified in § 170.39(c) must be submitted to FDA. This information includes the following components: (1) The chemical composition of the substance for which the request is made; (2) detailed information on the conditions of use of the substance; (3) a clear statement of the basis for the request for exemption from regulation as a food additive; (4) data that will enable FDA to estimate the daily dietary concentration resulting from the proposed use of the substance; (5) results of a literature search for toxicological data on the substance and its impurities; and (6) information on the environmental impact that would result from the proposed use.

FDA uses this information to determine whether the food-contact article meets the threshold criteria. Respondents to this information collection are individual manufacturers and suppliers of substances used in food-contact articles (i.e., food packaging and food processing equipment) or of the articles themselves.

In the **Federal Register** of June 26, 2013 (78 FR 38349), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.