

## ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total Burden hours
Intergovernmental Reference Guide: State Profile Guidance—(States and Territories) .....	54	18	0.3	291.6
Intergovernmental Reference Guide: Tribal Profile Guidance .....	62	18	0.3	334.8
Total .....	.....	.....	.....	626.4

*Estimated Total Annual Burden Hours:* 626.4 hours.

*Additional Information:* Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

*OMB Comment:* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: [OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV), Attn: Desk Officer for the Administration for Children and Families.

**Robert Sargis,**

*Reports Clearance Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Submission for OMB Review; Comment Request

*Title:* Tribal Maternal, Infant, and Early Childhood Home Visiting Program: Guidance for Submitting an Annual or Final Report to the Secretary.

*OMB No.:* Renewal of Collection OMB Control No. 0970-0409, Expiration Date 10/31/18.

*Description:* Section 511(e)(8)(A) of Title V of the Social Security Act requires that grantees under the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) program for states and jurisdictions submit an annual report to the Secretary of Health and Human Services regarding the program and activities carried out under the program, including such data and information as the Secretary shall require. Section 511(h)(2)(A) further states that the requirements for the MIECHV grants to tribes, tribal organizations, and urban Indian organizations are to be consistent, to the greatest extent practicable, with the requirements for grantees under the MIECHV program for states and jurisdictions.

The Administration for Children and Families, Office of Child Care, in collaboration with the Health Resources and Services Administration, Maternal and Child Health Bureau, has awarded grants for the Tribal Maternal, Infant, and Early Childhood Home Visiting Program (Tribal Home Visiting). The Tribal Home Visiting discretionary grants support cooperative agreements to conduct community needs assessments; plan for and implement high-quality, culturally-relevant, evidence-based home visiting programs in at-risk tribal communities; establish, measure, and report on progress toward meeting performance measures in six legislatively-mandated benchmark areas; and conduct rigorous evaluation activities to build the knowledge base on home visiting among Native populations.

Tribal Home Visiting grantees have been notified that in every year of their grant, after the first year, they must

comply with the requirement for submitting an Annual Report to the Secretary that should feature activities carried out under the program during the past reporting period and a final report to the Secretary during the final year of their grant. In order to assist grantees with meeting the requirements of the Annual and Final Report to the Secretary, ACF created guidance for grantees to use when writing their reports. The existing guidance (OMB Control No. 0970-0409, Expiration Date 10/31/18) provides sections where grantees must address the following:

- Update on Home Visiting Program Goals and Objectives
- Update on the Implementation of Home Visiting Program in Targeted Community(ies)
- Progress toward Meeting Legislatively Mandated Benchmark Requirements
- Update on Rigorous Evaluation Activities
- Home Visiting Program Continuous Quality Improvement (CQI) Efforts
- Administration of Home Visiting Program
- Technical Assistance Needs

The proposed data collection form is as follows: ACF is requesting approval to renew and update the existing Tribal Home Visiting Guidance for Submitting an Annual or Final Report to the Secretary (OMB Control No. 0970-0409) that will include instructions for grantees to submit either an annual or final report on the progress of their program to the Secretary, depending on the reporting period.

*Respondents:* Tribal Maternal, Infant, and Early Childhood Home Visiting Program Managers (The information collection does not include direct interaction with individuals or families that receive the services).

## ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Total responses	Average burden hours per response	Total annual burden hours
Annual/Final Report to the Secretary (depending on reporting period) .....	25	1	1	50	1,250

*Estimated Total Annual Burden Hours: 1,250.*

**Additional Information:** Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW, Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

**OMB Comment:** OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202-395-7285, Email: [OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV), Attn: Desk Officer for the Administration for Children and Families.

**Robert Sargis,**

*Reports Clearance Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-N-0001]

### Annual Public Meeting; Reagan-Udall Foundation for the Food and Drug Administration

**AGENCY:** Reagan-Udall Foundation for the Food and Drug Administration.

**ACTION:** Notice of annual meeting.

**SUMMARY:** The Reagan-Udall Foundation (the Foundation) for the Food and Drug Administration (FDA), which was created by Title VI of the Food and Drug Administration Amendments Act of 2007, is announcing its annual public meeting. The Foundation will discuss its activities and how it supports FDA.

**DATES:** The public meeting will be held on May 4, 2018, from 10 a.m. until 12 noon. Registration to attend the meeting must be received by May 3, 2018, at 5 p.m. Eastern Time. Requests for oral presentations must be received before May 2, 2018, at 5 p.m. Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information. The public is also invited to submit written comments by sending them via email to Elisabeth Shaefer (see **FOR FURTHER INFORMATION CONTACT**) before May 3, 2018, at 5 p.m. Eastern Time.

**ADDRESSES:** The public meeting will be held at Alston & Bird, 950 F St. NW, Washington, DC 20006.

**FOR FURTHER INFORMATION CONTACT:** Elisabeth Shaefer, Executive Assistant to the Executive Director, Reagan-Udall Foundation for the FDA, 202-849-2255, [eshaefer@reaganudall.org](mailto:eshaefer@reaganudall.org).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

The Reagan-Udall Foundation for the FDA is an independent 501(c)(3) not-for-profit, organization created by Congress to advance the mission of FDA to modernize medical, veterinary, food, food ingredient, and cosmetic product development; accelerate innovation, and enhance product safety. With the ultimate goal of improving public health, the Foundation provides a unique opportunity for different sectors (FDA, patient groups, academia, other government entities, and industry) to work together in a transparent way to create exciting new research and engagement projects to advance regulatory science.

The Foundation acts as a neutral third party to establish novel, scientific collaborations. Much like any other independently developed information, FDA evaluates the scientific information from these collaborations to determine how the Foundation projects can help the Agency to fulfill its mission.

Foundation projects currently include: Innovation in Medical Evidence Development and Surveillance, a public-private partnership that allows researchers to study drug safety concerns of interest to public health; an Expanded Access Navigator that offers instructional

material and resources for physicians, patients, and their caregivers on how to access investigational drugs outside of clinical trials; and a new joint Foundation and FDA regulatory science fellowship program.

##### **II. Topics for Discussion at the Public Meeting**

FDA Commissioner, Dr. Scott Gottlieb, will deliver a keynote address, followed by a panel discussion on the "Evolution of FDA Science and Engagement" and the role of the Foundation. Panelists will include the current FDA Commissioner, Dr. Scott Gottlieb, and former FDA Commissioners Drs. Robert Califf and Andrew C. von Eschenbach. The panel moderator will be Susan Dentzer, President and Chief Executive Officer of the Network for Excellence in Health Innovation. Find the meeting agenda at <https://reaganudall.org/public-meeting>.

##### **III. Participating in the Public Meeting**

**Registration:** To register for the public meeting, please visit the following website to register: <https://reaganudall.org/public-meeting>. Persons interested in attending this public meeting must register online by May 3, 2018, at 5 p.m. Eastern Time.

If you need special accommodations due to a disability, please contact Elisabeth Shaefer (see **FOR FURTHER INFORMATION CONTACT**) no later than May 1, 2018.

**Requests for Oral Presentations:** Interested persons may present comments at the public meeting. Comments will be scheduled to begin approximately at 11:30 a.m. Time allotted for comments may be limited to 3 minutes, dependent on the number of requests received. Those desiring to make oral comments should notify Elisabeth Shaefer (see **FOR FURTHER INFORMATION CONTACT**) by May 2, 2018. Please include a brief statement of the general nature of the comments you wish to present along with your name, address, telephone number, and email address. The contact person will notify individuals regarding their request to speak by May 3, 2018.