

increase, and sexual transmission from male travelers to their sex partners in the United States will likely continue to occur. In addition, mosquito-borne local transmission may occur in states where *Aedes* species mosquitoes are present.

In some Brazilian states where Zika virus transmission has occurred, there has been an increase in cases of infants born with microcephaly. Zika virus infections have been confirmed in several infants with microcephaly and in fetal losses in women infected during pregnancy. In addition to microcephaly, a range of other problems have been detected among fetuses and infants infected with Zika virus before birth, such as absent or poorly developed brain structures, defects of the eye, hearing deficits, and impaired growth. The Ministry of Health in Brazil, with support from the Pan American Health Organization (PAHO), the U.S. Centers for Disease Control and Prevention (CDC), and other partners, is investigating the association between Zika virus infection and microcephaly, as well as other adverse pregnancy and infant outcomes.

Zika virus disease and Zika virus congenital infection are nationally notifiable conditions for which the Council of State and Territorial Epidemiologists (CSTE) has established interim case definitions. All 50 states, the District of Columbia, and Puerto Rico, the U.S. Virgin Islands, American Samoa, Guam, and the Northern Mariana Islands currently participate in reporting of arboviral diseases through ArboNET. However, ArboNET does not capture all the information needed to provide timely situational awareness in the context of the ongoing public health response. In particular, ArboNET collects limited data on pregnancy, pregnancy and birth outcomes, and congenital infections, all of which are necessary for informing ongoing response efforts.

As part of the public health response to the Zika virus disease outbreak, CDC will conduct supplemental surveillance of antenatal diagnostic testing and clinical outcomes among pregnant women with laboratory evidence of Zika virus or unspecified flavivirus infection and their infants through the U.S. Zika

Pregnancy Registry. It is anticipated that the Registry will provide critical information to direct CDC clinical recommendations and public health guidance and messages.

The data to be collected for the Registry includes information about Zika infection-related tests and procedures conducted as part of the mother's and child's routine clinical care, and in line with existing CDC, American College of Obstetricians and Gynecologists and Society of Maternal Fetal Medicine, and American Academy of Pediatrics recommendations for evaluation, diagnosis, and follow-up of women infected with Zika virus during pregnancy and their children. No additional tests or procedures will be performed specifically for Registry purposes.

This request is submitted to extend the collection period of collection OMB number 0920-1143 for an additional three years. The total estimated annual burden hours are 23,833. There are no costs to the respondents other than their time.

ESTIMATES OF ANNUALIZED BURDEN HOURS

| Type of respondent | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden hours |
|--|------------------------------------|-----------------------|------------------------------------|--|--------------------|
| State, Territorial and Local Health Departments. | Maternal Health History Form | 1,100 | 10 | 30/60 | 5,500 |
| | Supplemental Imaging Form | 1,100 | 10 | 10/60 | 1,833 |
| | Laboratory Results Form | 1,100 | 10 | 15/60 | 2,750 |
| Clinicians and Other Providers | Assessment at Delivery Form | 1,100 | 10 | 30/60 | 5,500 |
| | Infant Health Follow-Up Form | 1,100 | 30 | 15/60 | 8,250 |
| Total | | | | | 23,833 |

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

[OMB #0985-0059]

Agency Information Collection Activities; Proposed Collection; Comment Request; Data Collection Materials for the Annual Performance Reporting of the Administration for Community Living's American Indian, Alaskan Natives and Native Hawaiian Programs

AGENCY: Administration for Community Living (ACL), HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living is announcing that the proposed collection of information listed above has been submitted to the

Office of Management and Budget (OMB) for review and clearance as required under Paperwork Reduction Act of 1995. This 30-Day notice collects comments on the information collection requirements related to the Revision of a Currently Approved Collection (ICR Rev) and solicits comments on the information collection requirements related to the annual Program Performance Report (PPR) for the American Indian, Alaskan Natives and Native Hawaiian Programs under Title VI of the Older Americans Act.

DATES: Submit written comments on the collection of information by April 3, 2019.

ADDRESSES: Submit written comments on the collection of information by:

(a) Email to: OIRA_submission@omb.eop.gov, Attn: OMB Desk Officer for ACL;

(b) fax to 202.395.5806, Attn: OMB Desk Officer for ACL; or
 (c) by mail to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW, Rm. 10235, Washington, DC 20503, Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT:
 Kristen Hudgins, Social Science Analyst, Administration for Community Living, Washington, DC 20201, 202-795-7732 or kristen.hudgins@acl.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, ACL has submitted the following proposed collection of information to OMB for review and clearance. The data collection materials for the annual performance data for the Administration for Community Living’s American Indian, Alaskan Natives and Native Hawaiian Programs (OAA Title VI) is a revision of a currently approved annual program performance data collection

(OMB# 0985–0059). These data collection materials have been updated to better align with comparable data collected for ACL’s other nutritional, supportive, and caregiving grants. Proposed changes include adding data components and updating others for more accurate reporting of persons served and activities provided through the Title VI-funded programs. The revised data collection will provide data necessary to determine the effectiveness of the program. Some examples of these changes are updating definitions in Title VI to be more in line with Title III, asking for unduplicated numbers of people served for different services and the number of hours spent providing said services. Additionally, the caregiver portion of the PPR has been updated to collect more information around types of caregivers served and unduplicated numbers of caregivers. Another element added has to do with information on expenditures. This data collection will also support ACL in tracking performance outcomes and

efficiency measures with respect to the annual and long-term performance targets established in compliance with the Government Performance Results Modernization Act (GPRAMA).

Comments in Response to the 60-Day Federal Register Notice

A notice was published in the **Federal Register** on August 15, 2018, Vol. 83, No. 158, pp. 40519–40520. ACL received comments from ten (10) organizations and two (2) individuals about the Program Performance Report (PPR) redesign. ACL reviewed all of the comments. However, some of the comments were deemed to not be relevant because they were: (a) About the data submission process itself; (b) did not request a change; (c) only related to format; or (d) indicated topics for technical assistance and training for the final data collection. For ease of review, the remaining comments and their responses have been grouped by topic or issue. The ACL responses for each topic/issue are detailed below:

| Topic/issue | Comment | ACL response |
|---|---|--|
| Additional comment boxes for story telling. | One of the comments was to include a comment box to the PPR to allow for programs to better share their stories. | ACL has added a comment box at the end of the PPR for program staff to share contextual information about how their program is addressing the needs of Elders in their community. |
| Additional data reporting | There were some concerns expressed around having to keep track of and report additional data. | Although ACL understands that reporting can be a burdensome process, having better and richer data is a priority for the Title VI program, particularly where it allows us to align with the data collection for Title III. |
| “Tribal Organization” | There was a suggestion posited by two organizations to change the term “Tribal Organization” to something more encompassing. | ACL has decided to use the term “Grantee Name” to be more inclusive of tribal consortia, Native Hawaiian organizations, and other entities that did not feel covered under the previous term of “Tribal Organization”. |
| Staffing/Volunteers | Five organizations commented that they found the prospect of collecting data on volunteers and their hours to be an unnecessary reporting burden. | Upon consideration of the issues brought up through the FRN comments, ACL has decided to remove the question on volunteers and volunteer hours. |
| Nutrition Questions | There was one comment noting that there were too many questions around nutrition education and counseling. | ACL understands that reporting can be a burdensome process and so have updated the questions under “Other Nutrition Services” to only ask one additional question regarding number of persons receiving nutrition counseling. In keeping with Title III’s SPR we have updated Nutrition Education hours to “sessions”. |
| Meal Mileage | There were many comments (both positive and asking for clarification) related to a proposed question around home-delivered meal mileage. | ACL has decided to remove this question from the PPR and will consider posing it to grantees through a different data collection source at a later date. |
| Ombudsman | Removal of the ombudsman question | ACL will not add an ombudsman question back into the Title VI PPR as official ombudsman services should be reported through the State Ombudsman and collected in the NORS tool. However, ACL has decided to add in a question related to visiting nursing homes and other assisted living facilities as we agree that these activities are important to capture. |
| Other Supportive Services ... | Suggestions to add space for grantees to report on the types of supportive services they provide. | ACL has decided to add an optional text box for programs to share other supportive services they may offer that are not currently listed. |
| Transportation | Suggestions to split transportation into assisted and un-assisted as they are in Title III’s SPR. | ACL appreciates the suggestion to collect more data but has decided in the interest of balancing data collection and burden to not make the distinction between the different “types” of transportation provided by a program. |

| Topic/issue | Comment | ACL response |
|---|---|--|
| Social Events | Question about the purpose of "social events held" and whether it would be better to change to "social/recreation events held" to allow cost sharing with Title III. | Title III does not ask for this information. A social event, as it is being defined in Title VI, can be recorded as "Other" in SPR. |
| Finance Section for Part A/B | The comments on the newly added finance section for Part A/B were varied and ran from asking that the question be removed and others asking for more options to share data. | ACL is sensitive to the burden that may be caused by asking for new kinds of information from our grantees, we find that requiring this information will allow us to better advocate for our programs and their financial needs. Based on the comments ACL has added an optional text box for grantees to explain more about their financial situations, and has also added additional options under the section asking for types of funding used. |
| Caregiver (language) | Suggestions to change some of the language in the caregiver section to make it clearer. | ACL has updated the language in this section to be less wordy and using the term "caregiver" rather than "persons" to make it clearer that the intended recipients of services are caregivers and not those they care for. |
| Caregiver (Information and Assistance). | There were a couple of suggestions that Information and Assistance should be separated from one another. | ACL has chosen to maintain consistency in this area with Title III's SPR and will ensure that training and technical materials make it clear how we are defining Information and Assistance and how to best collect it. |
| Finance Section for Part C .. | Suggestion to not add the finance section and asking for the cost of respite care to be pulled out. | ACL is sensitive to the burden that may be caused by asking for new kinds of information from our grantees, we find that requiring this information will allow us to better advocate for our programs and their financial needs. ACL chose respite care from the five required services based on the thinking that the cost of this service would be easier to track. |

The proposed form(s) may be found on the ACL website at <https://www.acl.gov/about-acl/public-input>.

Estimated Program Burden

Title VI funding is broken into three categories. Parts A and B are for nutritional and supportive

programming, and ask for the same information. Part A is for American Indian and Alaska Native grantees, and Part B is for Native Hawaiian grantees. Part C is for caregiver programming. All Part C grantees must have Part A/B funding; but not all Part A/B grantees will have Part C programs. Therefore,

there are 270 unique respondents, but only 237 will have to complete all portions of the PPR. ACL believes that the increase in burden hours is justified by the improved quality of the data and will ultimately improve the services provided to Native Elders.

| Respondent/data collection activity | Number of respondents | Responses per respondent | Hours per response | Annual burden hours |
|-------------------------------------|-----------------------|--------------------------|--------------------|---------------------|
| PPR Part A/B | 270 | 1 | 1.83 | 494.1 |
| PPR Part C | 237 | 1 | 1.66 | 393.4 |
| Total | | | | 887.5 |

Dated: February 22, 2019.
Mary Lazare,
Principal Deputy Administrator.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
 [Docket No. FDA-2018-N-3490]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Exempt Infant Formula Production: Current Good Manufacturing Practices, Quality Control Procedures, Conduct of Audits, and Records

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 April 3, 2019.

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 0910-0811. Also include the FDA docket number found