

specific topical areas as well as invitation to provide information on any matter relevant to ACF's work with and on behalf of AI/AN populations.

HHS received feedback that the original comment period of 60 days was insufficient to provide for comprehensive and responsive input, particularly from AI/AN elected representatives and leadership. Therefore, HHS is extending the comment period for an additional 60 days to maximize the opportunity for all interested parties to collect relevant data and submit information and feedback in response to the RFI, including the nine specific topical areas for which input is sought.

Dated: February 6, 2017.

**Naomi Goldstein,**

*Acting Assistant Secretary for Children and Families.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Tribal Consultation Meetings

**AGENCY:** Office of Head Start (OHS), Administration for Children and Families, HHS.

**ACTION:** Notice of meetings.

**SUMMARY:** Pursuant to the Improving Head Start for School Readiness Act of 2007, Public Law 110-134, notice is hereby given of two 1-day Tribal Consultation Sessions to be held between the Department of Health and Human Services (HHS), Administration for Children and Families, OHS leadership and the leadership of Tribal Governments operating Head Start (including Early Head Start) programs. The purpose of these Consultation Sessions is to discuss ways to better meet the needs of American Indian and Alaska Native children and their families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations [42 U.S.C. 9835, Section 640(l)(4)].

**DATES:**

March 14, 2017, from 1:30 p.m. to 5:00 p.m.

August 7, 2017, from 1:30 p.m. to 5:00 p.m.

**Locations:**

- March 7, 2017—Hotel Albuquerque at Old Town, 800 Rio Grande Blvd. NW., Albuquerque, New Mexico 87104

- August 8, 2017—Northern Quest Resort & Casino, 100 North Hayford Road, Airway Heights, WA 99001

**FOR FURTHER INFORMATION CONTACT:**

Angie Godfrey, Regional Program Manager, Region XI/AIAN, Office of Head Start, email [Angie.Godfrey@acf.hhs.gov](mailto:Angie.Godfrey@acf.hhs.gov), or phone (202) 205-5811. Additional information and online meeting registration is available at: <https://eclkc.ohs.acf.hhs.gov/hslc/hs/calendar/tc2017>.

**SUPPLEMENTARY INFORMATION:** HHS announces OHS Tribal Consultations for leaders of Tribal Governments operating Head Start and Early Head Start programs. The agenda for the scheduled OHS Tribal Consultations in Albuquerque, New Mexico, and Spokane, Washington, will be organized around the statutory purposes of Head Start Tribal Consultations related to meeting the needs of American Indian and Alaska Native children and families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations. In addition, OHS will share actions taken and in progress to address the issues and concerns raised in the 2016 OHS Tribal Consultations.

The Consultation Sessions will be conducted with elected or appointed leaders of Tribal Governments and their designated representatives [42 U.S.C. 9835, Section 640(l)(4)(A)]. Designees must have a letter from the Tribal Government authorizing them to represent the tribe. Tribal Governments must submit the designee letter at least 3 days in advance of the Consultation Session to Angie Godfrey at [Angie.Godfrey@acf.hhs.gov](mailto:Angie.Godfrey@acf.hhs.gov). Other representatives of tribal organizations and Native nonprofit organizations are welcome to attend as observers.

A detailed report of each Consultation Session will be prepared and made available within 45 days of the Consultation Sessions to all Tribal Governments receiving funds for Head Start and Early Head Start programs. Tribes wishing to submit written testimony for the report should send testimony to Angie Godfrey at [Angie.Godfrey@acf.hhs.gov](mailto:Angie.Godfrey@acf.hhs.gov) either prior to each Consultation Session or within 30 days after each meeting. OHS will summarize oral testimony and comments from the Consultation Session in each report without attribution, along with topics of concern and recommendations.

Dated: February 6, 2017.

**Ann Linehan,**

*Acting Director, Office of Head Start.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

[Document Identifier: HHS-OS-0990-0452-60D]

#### Agency Information Collection Activities; Proposed Collection; Public Comment Request

**AGENCY:** Office of the Assistant Secretary for Health, Office of Adolescent Health, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting that ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on the ICR must be received on or before April 11, 2017.

**ADDRESSES:** Submit your comments to [Information.CollectionClearance@hhs.gov](mailto:Information.CollectionClearance@hhs.gov) or by calling (202) 690-6162.

**FOR FURTHER INFORMATION CONTACT:** Information Collection Clearance staff, [Information.CollectionClearance@hhs.gov](mailto:Information.CollectionClearance@hhs.gov) or (202) 690-6162.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the document identifier HHS-OS-0990-0452-60D for reference.

*Information Collection Request Title:* Federal Evaluation of Making Proud Choices! (MPC!)

*Abstract:* The Office of Adolescent Health (OAH), U.S. Department of Health and Human Services (HHS) is requesting approval by OMB on a revised data collection. The Federal Evaluation of Making Proud Choices! (MPC) will provide information about program design, implementation, and impacts through a rigorous assessment of a highly popular teen pregnancy prevention curriculum—MPC. This revision to this information collection request includes the follow-up survey instrument, administered approximately 9 and 15 months post baseline, and related to the impact study. The

evaluation will be conducted in 39 schools nationwide. The data collected from this instrument will provide a detailed understanding of program impacts. Clearance is requested for three years.

*Need and Proposed Use of the Information:* The follow-up survey data will be used to determine program effectiveness by comparing sexual behavior outcomes, such as postponing

sexual activity, and reducing or preventing sexual risk behaviors and STDs and intermediate outcomes, such as improving exposure, knowledge and attitudes between treatment (program) and control youth.

The findings from these analyses of program impacts will be of interest to the general public, to policymakers, and to schools and other organizations interested in supporting a

comprehensive approach to teen pregnancy prevention.

*Likely Respondents:* The follow-up surveys will be administered to study participants, who will primarily be in 10th–12th grade at the time of the follow-up surveys.

*Burden Statement:* The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Follow up survey (9 months post baseline) .....	819	1	30/60	409.5
Follow up survey (15 months post baseline) .....	774	1	30/60	387
Total .....	1593	.....	.....	796.5

OS specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency’s functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**Terry S. Clark,**  
Asst Information Collection Clearance Officer.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of the Secretary**

**Declaration Under the Public Readiness and Emergency Preparedness Act for Zika Virus Vaccines**

**ACTION:** Notice.

**SUMMARY:** The Acting Secretary is issuing a Declaration pursuant to the Public Health Service Act to provide liability immunity protection for activities related to Zika Virus vaccines consistent with the terms of the Declaration.

**DATES:** The Declaration is effective as of August 1, 2016.

**FOR FURTHER INFORMATION CONTACT:** George Korch, Ph.D., Acting Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human

Services, 200 Independence Avenue SW., Washington, DC 20201; Telephone: 202–205–2882.

**SUPPLEMENTARY INFORMATION:** The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the administration or use of medical countermeasures (Covered Countermeasures), except for claims that meet the PREP Act’s definition of willful misconduct. The Secretary may, through publication in the **Federal Register**, amend any portion of a Declaration. Using this authority, the Acting Secretary is issuing a Declaration to provide liability immunity to Covered Persons for activities related to the Covered Countermeasures, Zika Virus vaccines as listed in Section VI of the Declaration, consistent with the terms of this Declaration.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, Section 2. It amended the Public Health Service (PHS) Act, adding Section 319F–3, which addresses liability immunity, and Section 319F–4, which creates a compensation program. These sections are codified in the U.S. Code as 42 U.S.C. 247d–6d and 42 U.S.C. 247d–6e, respectively.

The Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, was enacted on March 13, 2013. Among other things, PAHPRA added sections 564A and 564B to the Federal Food,

Drug & Cosmetic (FD&C) Act to provide new authorities for the emergency use of approved products in emergencies and products held for emergency use. PAHPRA accordingly amended the definitions of “Covered Countermeasures” and “qualified pandemic and epidemic products” in Section 319F–3 of the Public Health Service Act (PREP Act provisions), so that products made available under these new FD&C Act authorities could be covered under PREP Act Declarations. PAHPRA also extended the definition of qualified pandemic and epidemic products that may be covered under a PREP Act Declaration to include products or technologies intended to enhance the use or effect of a drug, biological product, or device used against the pandemic or epidemic or against adverse events from these products.

Zika virus is a mosquito-borne flavivirus that usually causes mild symptoms, but has been determined to cause microcephaly and other severe brain abnormalities in fetuses and infants born to women infected with Zika virus before birth. Zika virus has also been associated with other adverse pregnancy outcomes, including miscarriage, stillbirth, and congenital Zika syndrome, and with Guillain-Barre Syndrome. Beginning in 2015, Brazil has experienced the largest outbreak of disease caused by Zika infection since its discovery in Uganda in 1947. On February 1, 2016, the World Health Organization (WHO) determined that microcephaly cases and other neurologic disorders reported in Brazil constituted a Public Health Emergency of International Concern (PHEIC) in accordance with the International