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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-19-16JO]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Pregnancy Risk Assessment Monitoring System (PRAMS) to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on August 31, 2018 to obtain comments from the public and affected agencies. CDC received four comments related to the previous notice, two non-substantive, two in support of the data collection; no modifications were made to the PRAMS plan in response to comments. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th

Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

The Pregnancy Risk Assessment Monitoring System (PRAMS) – Existing Collection in Use without an OMB Control Number – National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Pregnancy Risk Assessment Monitoring System (PRAMS) is a surveillance project of the Centers for Disease Control and Prevention (CDC) and state health departments. Developed in 1987, PRAMS collects state-specific, population-based data on maternal attitudes and experiences before, during, and shortly after pregnancy. The Centers for Disease Control and Prevention (CDC) seeks OMB approval to collect information through the Pregnancy Risk Assessment Monitoring System (PRAMS) for three years.

PRAMS provides data not available from other sources. These data can be used to identify groups of women and infants at high risk for health problems, to monitor changes in health status, and to measure progress towards goals in improving the health of

mothers and infants. PRAMS data are used by researchers to investigate emerging issues in the field of reproductive health and by federal, state and local governments to plan and review programs and policies aimed at reducing health problems among mothers and babies.

PRAMS is a state customized survey conducted in 51 sites and covers 83% of all live births in the United States. Information is collected by 2-6 months after live birth or stillbirth by mail survey with telephone follow-up for non-responders. In addition, call back surveys may be implemented as a follow up to the initial survey to gather additional information on post-pregnancy experiences and infant and toddler health. Because PRAMS uses standardized data collection methods, it allows data to be compared among states. States can implement the survey on an ongoing basis or as a point-in-time survey. In participating states, a sample of women who have recently given birth to a live born or stillborn infant is selected from birth certificates or fetal death files. The sample is stratified based on the state's population of interest to ensure high-risk populations are adequately represented in the data.

The PRAMS survey instrument for live births is based on a core set of questions common across all states that remain the same for each three-year phase of data collection. PRAMS is currently in Phase 8, which began in 2016. In addition, CDC

provides optional standardized modules (pre-grouped questions on a select topic) that states may use to customize survey content at the beginning of each phase of data collection. For each state, the time for a respondent with a recent live birth to complete the core and selected standard module questions does not exceed 35 minutes in length. Topics for both the core and standard modules include health conditions (which includes chronic conditions such as diabetes, hypertension, mental health, oral health, cancer, as well as pregnancy-induced health conditions and family history of select conditions); health behaviors (including tobacco and alcohol use, substance use [licit and illicit], injury prevention and safety, nutrition, and physical activity); health care services (such as preconception care, prenatal care, postpartum care, contraceptive care, vaccinations, access to care and insurance coverage, receipt of recommended services and provider counseling received); infant health and development; infant care practices (such as breastfeeding, safe sleep practices); social services received (such as WIC or home visiting); the social context of child bearing (such as intimate partner violence, social support, adverse childhood experiences, stressful life experiences and racism); attitudes and feeling about the pregnancy including pregnancy intentions.

At times, states may also be funded to address emerging topics of interest with supplemental modules (pre-grouped questions on a select topic). These supplemental modules address national and state-specific priorities and are typically fielded for one year. In the recent past, they have been used to address pandemic influenza H1N1 (2009), electronic cigarettes (2014), marijuana (2016), Zika (2017), and emergency preparedness and response as they impact pregnancy (2017). Supplemental modules planned for collection for 2019 births will include family history of breast and ovarian cancer, disabilities and prescription and illicit opioid use. Additional supplemental modules (estimated respondents and burden the same each year) may be developed to address other emergent issues as they arise, such as paternal involvement, emerging infectious diseases, environmental disasters, and other public health problems affecting women of reproductive age and their pregnancies. The estimated time for a respondent to complete supplemental modules is five minutes. Because PRAMS infrastructure was developed to access a specific and vulnerable subpopulation, the PRAMS infrastructure can be rapidly adapted for targeted information collection that would not be feasible with other surveillance methods.

PRAMS can also be adapted to do call back surveys. Women who respond to the PRAMS survey may be re-contacted (opt-out

consent process used) later (approximately nine months post-birth) to collect additional information about post-pregnancy experiences and infant and toddler health. The currently planned call back survey will be targeted to areas with a high burden of opioid overdose deaths and include topics such as opioid misuse and access to medication assisted therapy, experiences with respectful care, postpartum care, rapid repeat pregnancy, infant feeding practices, infant health and social services such as well child visit attendance, home visitation, developmental delays, and social supports. The time for a respondent to complete the call back survey is 30 minutes. Additional call back surveys (estimated burden assumed the same each year) may be developed to address other emergent issues as they arise.

The stillbirth survey, administered in the state of Utah only at this current time, only includes a core survey instrument. Total time estimated for women with a recent stillbirth completing the survey, inclusive of informed consent is 25 minutes.

As part of the questionnaire development process, field testing will be conducted prior to implementation of new supplemental modules and call back surveys, as well as new or substantively revised questions for the core module prior to a new phase. Field testing will be conducted among women with infants one year or younger in health clinics to identify issues

that may affect implementation or quality of the data collected. Field testing will only be conducted for new or substantively changed questions. Total time estimated to complete the field testing process inclusive of verbal consent, survey administration and debriefing questions is approximately 20 minutes.

The burden estimate for PRAMS includes five types of information collection: (1) information collection associated with the PRAMS data collection for women with recent live births (PRAMS core questions and state-selected standard modules); (2) supplemental modules for emerging issues; (3) call back surveys; (4) PRAMS data collection for women with recent stillbirths; and (5) PRAMS field testing data collection to inform questionnaire development. Participation is voluntary and there are no costs to respondents other than their time. The total estimated annualized burden hours are 29,765.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average burden per response (in hours)
Women who recently delivered a live birth	PRAMS Phase 8 (Core Questions plus state selected standard	52,076	1	26/60

	modules)			
	Supplemental modules	61,230	1	5/60
	Call Back Surveys	3,961	1	30/60
	Field Testing	150	1	20/60
Women who recently delivered a still birth	PRAMS Stillbirth Questionnaire	160	1	25/60

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