grants and cooperative agreements. In addition to allowing for uniformity of information collection, this format will support systematic electronic collection and submission of information. The form contains non-personal identifying data elements and a section for a performance narrative.

There are no costs to respondents other than their time. The total estimated annual burden hours are 11,676. This estimate reflects an increase from the 60 day notice as a result of an increase in respondents and adjustments to average burden hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Number of respondents (estimated)	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
States: Section 317 Immunization Program—Reaching More Children & Adults	64	4	6	1,536
States: Section 317 Immunization Program—Innovative Initiatives	15	4	6	360
States: Section 317 Immunization Program—Communication & Provider Education	10	4	6	240
States: Section 317 Immunization Program—Strengthening the Evidence Base	64	4	6	1,536
States: Healthcare Associated Infections—Emerging Infections Program	10	4	6	240
States: Healthcare Associated Infections—Epidemiology & Laboratory Capacity	52	4	6	1,248
States: Health Information Technology and Public Health	64	4	6	1,536
Universities: Health Information Technology Professionals in Health Care	30	4	6	720
States: Communities Putting Prevention to Work—Quitline Support	50	4	2	400
States: Communities Putting Prevention to Work—Policy Activities	50	4	2	400
States: Communities Putting Prevention to Work—Policy Implementation	50	2	1	100
States: Communities Putting Prevention to Work—Community Policy Activities	40	4	16	2,560
Communities: Communities Putting Prevention to Work—Policy Implementation	40	2	8	640
State Cancer Registries: Comparative Effectiveness Research to Enhance Cancer Registry Data Systems	15	4	2	120
Universities: Comparative Effectiveness Research to Improve Prevention and Wellness	5	4	2	40

Dated: September 21, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 Day–09–07AA]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call Maryam I. Daneshvar, the CDC Reports Clearance Officer, at (404) 639–5960 or send an e-mail to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Evaluating the Quality of Interview Data Collected by Teratology Information Services About Pregnancy Outcomes, Maternal and Infant Health, Following Medication Use During Pregnancy and Lactation—New—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This data collection is based on the following components of the Public Health Service Act: (1) Act 42 USC 241, Section 301, which authorizes ''research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man.'' (2) 42 USC 247b–4, Section 317 C, which authorizes the activities of the National Center on Birth Defects and Developmental Disabilities. This section was created by Public Law 106–310, also known as ''the Children's Health Act of 2000.'' This portion of the code has also been amended by Public Law 108–154, which is also known as the ''Birth Defects and Developmental Disabilities Prevention Act of 2003''.

The use of a number of medications during pregnancy is known to be associated with serious adverse effects in children. However, because pregnant and lactating women are traditionally excluded from clinical trials, and because premarketing animal studies do not necessarily predict the experience of humans, little information is available about the safety of most prescription medications during pregnancy and lactation at the time they are marketed. Nevertheless, many women inadvertently use medications early in gestation before realizing they are pregnant, and many maternal conditions require treatment during pregnancy and breastfeeding to safeguard the health of both mother and infant. Currently, the United States does not does not conduct comprehensive monitoring for pregnancy or infant outcomes related to medication exposures. To try to address these concerns, a number of pharmaceutical manufacturers have established pregnancy drug registries to monitor the effects of use of selected medications during pregnancy on pregnancy outcomes and fetal and infant health. In some instances, the U.S. Food and Drug Administration has required postmarketing monitoring of pregnancy outcomes after medication

exposure as a condition of new drug approval. However, registries such as these monitor only a small number of medications, and many suffer from methodologic limitations including high loss to follow-up rates and incomplete or nonspecific outcome information.

Teratology Information Services (TIS) utilize trained specialists to provide free phone consultation, risk assessment, and counseling about exposures during pregnancy and breastfeeding—including medications—to women and healthcare providers. Altogether, they respond to approximately 70,000–100,000 inquiries each year in the United States and Canada. Because they have direct contact with pregnant and breastfeeding women, TIS are in a unique position to monitor the effects of medication exposures during pregnancy and lactation. The objective of this project is to assess the quality of information on (1) pregnancy outcomes (*e.g.*, live birth, stillbirth, premature birth, low birth weight, *etc.*) and (2) maternal and infant health following medication use during pregnancy and lactation that can be obtained from maternal interviews conducted by TIS in the U.S. The project will assess the willingness of pregnant and breastfeeding women who contact a TIS about medication exposure to participate in and complete a follow-up study; whether these women are similar in demographic characteristics to the U.S. population of child-bearing age women; the specificity and completeness of the information obtained from such a study about pregnancy outcomes, and maternal and infant health; and the amount of time required to conduct the follow-up.

Within a continuous six-month period, three individual TIS will recruit all women who contact their service (up to a maximum of 250 enrollees per TIS) who have used any prescription or over-the-counter medication, vitamin, herbal, or other dietary supplement during pregnancy or while breastfeeding to participate in a follow-up study. Informed consent to participate will be obtained from each woman by telephone. For each pregnant woman who agrees to participate, the TIS will then conduct 4 telephone interviews: (1) At enrollment; (2) during the third trimester of pregnancy; (3) approximately one month after delivery; and (4) when the infant is about 3 months old. For each breastfeeding woman who agrees to participate, the TIS will then conduct 3 telephone interviews: (1) At enrollment; (2) approximately one month after enrollment; and (3) 3 months after enrollment, if the woman is still taking medication and still breastfeeding. The interviews will assess maternal and fetal health throughout pregnancy, and maternal and infant health at delivery, during the newborn and early infancy period, and while breastfeeding, and correlate these outcomes with medication exposure during pregnancy and while breastfeeding. There is no cost to respondents other than their time. The total estimated annualized burden is 516 hours.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Responses per respondent	Avg. burden per response (in hours)
All Respondents	Telephone script	294	1	3/60
Screened Eligible Respondents-	Tracking	250	1	5/60
Pregnancy Exposure (Group 1)/Lactation Exposure (Group 2)/Pregnancy and Lactation Exposure (Group 3).	Consent	250	1	20/60
Groups 1, 2 and 3	Enrollment	250	1	10/60
Group 1 and 3	Initial Pregnancy	200	1	30/60
	Follow-up Pregnancy	200	1	20/60
	Initial Infant	200	1	20/60
	Follow-up Infant	200	1	15/60
Groups 2 and 3	Initial breastfeeding	100	1	20/60
	Follow-up breastfeeding	100	1.5	15/60

Dated: September 18, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Proposed Projects:

Title: Project LAUNCH Cross-Site Evaluation.

OMB No.: New Collection.

Description: The Administration for Children and Families (ACF), U.S. Department of Health and Human Services, is planning to collect data as part of a cross-site evaluation of a new initiative called Project LAUNCH (Linking Actions for Unmet Needs in Children's Health): Project LAUNCH is intended to promote the healthy development and wellness of children ages birth to eight years. A total of 18 Project LAUNCH grantees will be funded to improve coordination among child-serving systems, build infrastructure, and improve methods for providing services. Grantees will also implement a range of public health strategies to support young child wellness in a designated locality.

Data for the cross-site evaluation of Project LAUNCH will be collected through: (1) Interviews conducted during annual site visits to Project LAUNCH grantees, and (2) semi-annual reports that will be submitted electronically on a Web-based data-entry system. Information will be collected from all Project LAUNCH grantees.

During annual site visits, researchers will conduct interviews with Project LAUNCH service providers and collaborators in States/Tribes and local communities of focus. Site visitors will ask program administrators questions about all Project LAUNCH activities, including: infrastructure development; collaboration and coordination among partner agencies, organizations, and service providers; and development, implementation, and refinement of service strategies.

As part of the proposed data collection, Project LAUNCH staff will be asked to submit semi-annual electronic reports on State/Tribal and local