Dated: May 26, 2009.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E9–12669 Filed 5–29–09; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

**[30Day–09–0743]**

### 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 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) 395–6974. Written comments should be received within 30 days of this notice.

**Proposed Project**

Assessment and Monitoring of Breastfeeding-Related Maternity Care Practices in Intra-partum Care Facilities in the United States and Territories (OMB Control No. 0920–0743, Exp. 7/31/2009)–Revision–National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

**Background and Brief Description**

Substantial evidence demonstrates the health benefits of breastfeeding. Breastfeeding mothers have lower risks of breast and ovarian cancers and type 2 diabetes, and breastfeeding better protects infants against infections, chronic diseases like diabetes and obesity, and even childhood leukemia and sudden infant death syndrome (SIDS). However, the groups that are at higher risk for diabetes, obesity, and poor health overall persistently have the lowest breastfeeding rates. Public health priorities for the U.S. include increasing the overall rate of breastfeeding, and reducing variation in breastfeeding rates across population subgroups.

The health care system is one of the most important and effective settings to improve breastfeeding. In 2007, CDC conducted the first national survey of Maternity Practices in Infant Nutrition and Care (known as the mPINC Survey) in health care facilities (hospitals and free-standing childbirth centers). The survey was designed to provide baseline information and to be repeated again in 2009. It inquired about patient education and support for breastfeeding throughout the maternity stay as well as staff training and maternity care policies. Each responding organization received a customized Benchmark Report as well as other feedback to use in self-assessment and quality improvement activities.

CDC proposes to repeat the mPINC in 2009 using previously fielded questions and methodology. In addition to all facilities that participated in 2007, the 2009 survey will include those that were invited but did not participate in 2007 and any that are new since then. All birth centers and hospitals with ≥ 1 registered maternity beds will be screened via a brief phone call to assess their eligibility, identify additional locations, and identify the appropriate point of contact.

A major goal of the 2009 survey is to be fully responsive to respondents' needs for information and technical assistance. CDC will again provide customized benchmark reports to respondents and document progress since 2007 on their quality improvement efforts. National and state reports will use de-identified data to describe incremental changes in practices and care processes over time at the facility, state, and national levels.

Participation in the survey is voluntary, and responses may be submitted by mail or through a web-based system. There are no costs to respondents other than their time. The total estimated annualized burden hours are 1,686.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondents | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) |
|---|---|---|---|---|
| Hospitals | Telephone Screening Interview for Hospitals | 3,897 | 1 | 5/60 |
| | 2009 mPINC Survey for Hospitals | 2,568 | 1 | 30/60 |
| Birth Centers | Telephone Screening Interview for Birth Centers | 192 | 1 | 5/60 |
| | 2009 mPINC Survey for Birth Centers | 122 | 1 | 30/60 |

Dated: May 26, 2009.

**Maryam I. Daneshvar,**

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

[FR Doc. E9–12631 Filed 5–29–09; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

**[60Day-0920–09BS]**

### Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 and send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov*.

*Comments are invited on:* (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the

agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

**Proposed Project**

Formative Evaluation and Message Testing to Inform the Development of Health Promotion Materials for the National Hemophilia Foundation's Hemophilia and AIDS/HIV Network for the Dissemination of Information (HANDI)—NEW—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

**Background and Brief Description**

The Division of Blood Disorders, located within the National Center on Birth Defects and Developmental Disabilities, implements health promotion and wellness programs designed to prevent secondary conditions in people with bleeding and clotting disorders. These programs are carried out in partnership with community-based organizations on the national and local level. The division's largest and longest standing cooperative agreement is held by the National Hemophilia Foundation (NHF). NHF, founded in 1948, has a long history of service through education, advocacy and research for people and families with hemophilia and other bleeding disorders.

The Hemophilia and AIDS/HIV Network for the Dissemination of Information (HANDI) is NHF's resource center which provides information, materials, and support to people with bleeding and clotting disorders. Over the past 17 years, HANDI's resource collection has grown to meet the changing needs of the community. HANDI processes thousands of requests for information from a wide variety of individuals and organizations including NHF chapters, medical professionals, consumers and their families, and teachers and students conducting research. The types of information requested reflect a diversity of needs—topics include home care, orthopedics, physical therapy, rare factor deficiencies, psychosocial issues, blood safety, women's health, and financial and insurance reimbursement issues. HANDI's current resource library collection contains nearly 13,000 items. However, the process by which materials have been selected for development has not been informed by a systematic needs assessment or other exploratory research. Therefore it is not known if the materials and messages that have been developed are meeting the information needs of the audiences they were intended to serve.

While there seems to be many HANDI materials available that focus on parents and family members of newly diagnosed children, considerably less attention has been given to developing materials for young children and adolescents, particularly materials that address transition issues. There are many types of transitions for the person with a bleeding disorder. These include acceptance of the bleeding disorder, self care, progressing through school, vocational/career planning, moving to an adult center, starting a family, middle age, and retirement. Transition occurs throughout life for all people, but for those with chronic illness, it takes on additional significance due to the nature of their condition.

The CDC's Division of Blood Disorders in conjunction with the National Hemophilia Foundation will conduct focus groups to gather information that will be used to design educational materials and health promotion programs for young children (aged 5–12 years) and adolescents (aged 16–19 years) that address transition issues. Focus groups will be used to explore the type of information, resources, and support young children and adolescents need related to transition issues. The groups will also be used to explore how young children and adolescents prefer to receive health messages and health information (e.g., brochures, videos, podcasts, U-tube, etc.). These findings will inform the development of key messages tailored to the target audiences that will then be tested during another set of focus groups to see how well the messages resonate with the intended end users.

The Contractor selected will work with CDC and NHF, through its chapter network, to identify and recruit focus group participants. Formative research participants will include parents of young children (aged 5–12 years), parents of teenagers or young adults who can reflect back upon their experience and share what information, resources, and support they wished had been available when their child was young, and adolescents (aged 16–19 years). Message testing participants will include parents of young children (aged 5–12 years) and adolescents (aged 16–19 years). Participants will be recruited to participate in one of sixteen in-person focus groups that will be conducted in the following cities:

- Detroit, Atlanta, Philadelphia, San Francisco (for the formative research task), and
- Milwaukee, Houston, Boston, and San Diego (for the message testing task)

There are no costs to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

| Respondents | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden (in hours) |
|---|---|---|---|---|
| Parents (formative groups) | 36 | 1 | 2 | 72 |
| Adolescents (formative groups) | 36 | 1 | 2 | 72 |
| Parents (message testing groups) | 36 | 1 | 2 | 72 |
| Adolescents (message testing groups) | 36 | 1 | 2 | 72 |
| Total | | | | 288 |

Dated: May 26, 2009.

**Maryam I. Daneshvar,**

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

[FR Doc. E9–12630 Filed 5–29–09; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

**[30Day–09–05CS]**

### Agency Forms Undergoing Paperwork Reduction Act Review

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**Proposed Project**

Nurse Delivered Risk Reduction Intervention for HIV-Positive Women—New—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention (CDC).

**Background and Brief Description**

During the past two decades, HIV surveillance data indicates an increase in HIV/AIDS cases among women in the non-urban Southeastern United States. In 2006, the majority of HIV/AIDS cases (80%) among women were attributed to high-risk heterosexual contact with an infected partner. Black women in particular have been disproportionately impacted by HIV/AIDS. Factors shown to be associated with HIV in the South include poverty, lack of access to medical care, poor education, lack of awareness of the disease, and exposure to other sexually transmitted diseases. Presently, there is an urgent need for enhanced HIV transmission prevention interventions for HIV positive women in the southeastern United States.

The purpose of this project is to adapt and test the efficacy of an HIV transmission prevention intervention for reducing sexual risk among 330 HIV-positive women in North Carolina and to identify factors associated with risk among women. The study will be conducted in two parts (intervention trial and individual in-depth interviews). The intervention trial will evaluate a brief, nurse delivered, single session intervention. The trial will use a randomized wait-list comparison design with a three-month follow-up assessment. To determine eligibility for participation in the study, a brief, in-person, screening will be used. Eligible participants will complete baseline and follow-up behavioral assessments. The assessments contain questions about participants' background, health and health care, sexual activity, substance use, and other psychosocial issues. The in-depth interviews will be conducted with a subgroup of 25–30 women. The purpose of the in-depth interviews is to assess experiences with the intervention, elicit recommendations for developing risk reduction intervention strategies, and to better understand the factors that place women at risk for HIV. Study participants will be recruited from health departments and clinics providing healthcare to HIV-positive women and AIDS Service Organizations. There is no cost to the participants other than their time. The total estimated annual burden hours are 635.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondents | Form name | Number of respondents | Number of responses per respondent | Avg. burden per response (in hours) |
|---|---|---|---|---|
| Potential Participants | Screener Contact Form | 550 | 1 | 10/60 |
| Intervention Participants—and Comparison Group) | Locator Form | 330 | 1 | 3/60 |
| Intervention Participants—and Comparison Group | Assessment Baseline | 330 | 1 | 45/60 |
| Intervention Participants—and Comparison Group | Assessment Follow-up | 330 | 1 | 45/60 |
| Subset of Intervention Group | In-depth Interview | 30 | 1 | 1 |

Dated: May 26, 2009.

**Maryam I. Daneshvar,**

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

[FR Doc. E9–12622 Filed 5–29–09; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2005–N–0464] (formerly Docket No. 2005N–0403)**

### Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing.'' This guidance document is designed to assist industry (e.g., manufacturers, repackers, and relabelers) with the electronic submission of drug establishment registration and drug listing information. Specifically, the document provides guidance to industry on the types of information to include for purposes of drug establishment registration and drug listing and on how to prepare and submit the information in an electronic format that FDA can process, review, and archive.

**DATES:** Submit written or electronic comments on agency guidances at any time. As of June 1, 2009, FDA will only accept electronic submissions of drug establishment registration and drug