This project proposes to continue collecting information on individuals with ALS which can be combined with information obtained from existing sources of information and add additional optional risk factor surveys. This combined data will become the National ALS Registry and will be used to provide more accurate estimates of the incidence and prevalence of disease as well as the demographic characteristics of the cases. Information obtained from the surveys will be used to better characterize potential risk factors for ALS which will lead to further in-depth studies.

The existence of the Web site has been advertised by ATSDR and advocacy groups such as the Amyotrophic Lateral Sclerosis Association (ALSA) and the Muscular Dystrophy Association (MDA).

There are between 15,000 and 30,000 individuals living with ALS at any given time. In addition, approximately 6,000 people are diagnosed with ALS each year and we expect about one-quarter of them will participate in the registry. Because an advantage to registration is participating in the surveys, we expect the one time surveys, and the twice yearly survey participation rate will be 50%.

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

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Person with ALS	Validation questions (Screener) for suspected ALS cases.	1670	1	2/60	56
	Registration Form of ALS cases	1500	1	7/60	175
	Cases of ALS completing 1-time surveys	750	16	5/60	1000
	Cases of ALS completing twice yearly surveys*.	750	2.7	5/60	169
Total					1400

*The disease progression survey is taken initial and then 3 times the first year (3, 6, 12 months after the initial survey). Because some people's disease progresses more rapidly, clinicians recommended adding the survey at 3 months to make sure everyone had the opportunity to take the survey a second time. In years 2 and 3, the survey would be taken at 6 and 12 months.

Kimberly S. Lane,

Deputy Director, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-13–13GX]

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 404–639–7570 or send comments to Ron Otten, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email 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

Assessment of a Comprehensive Human immunodeficiency virus (HIV) Clinic-Based Intervention to Promote Patients' Health and Reduce Transmission Risk—New—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is requesting Office of Management and Budget (OMB) approval to collect data that will be used to evaluate an HIV clinic-based intervention to increase the number of HIV patients who (1) have undetectable levels of HIV in their blood, (2) adhere optimally to antiretroviral therapy (ART), (3) attend clinic regularly for primary care, and (4) practice safer sex. These are objectives of the National HIV/AIDS Strategy and goals of the strategic plan of the Division of HIV/AIDS Prevention, Centers for Disease Control and Prevention.

The project will be conducted at six HIV clinics in the United States. This proposed data collection will occur over 3 years.

The intervention that is part of this project focuses primarily on HIV patients who have a detectable viral load, i.e., their viral load is not as low as it can be and is not fully controlled. The intervention components include: (1) Brief counseling from medical providers during primary care visits informed by a behavioral screener completed by patients; (2) a computer-based intervention (CBI) in which patients see short videos of HIV medical providers (not their own providers) talking about the importance of regular clinic attendance, adherence to ART, and safer sex; and (3) one-on-one counseling from a prevention specialist if needed.

The following data will be collected in this project:

- A data manager at each clinic will electronically transmit patient clinical data to CDC using a unique study identification code as the only means of identifying a patient's data. The data files sent to CDC will not contain any medical record numbers, names, or social security numbers. The information will be encrypted and stored in a secure CDC server. The data

collected from patients include (1) a behavioral screener self-administered by patients each time they have a primary care visit. Patients complete the screener in the waiting room before seeing their primary care provider. (2) CBI assessment items on demographic factors, clinic attendance, ART status, ART adherence, and sexual risk behavior that are completed before patients see the CBI videos. Patients with detectable viral loads will be asked to do the CBI three times, spaced approximately three months apart. Patients' CBI responses are not shared with their clinic providers. (3) On a quarterly basis, 50 patients at each clinic will be asked to complete a brief exit survey after their medical exam, asking about topics that the provider may have discussed with them at their medical visit (e.g., adherence, clinic attendance).

• Data collected from primary care medical providers includes a quarterly survey asking them to indicate the types of topics/issues they discussed with their HIV patients.

There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (hours)	Total burden hours
Data manager at clinic ..	Electronic transmittal of clinical variables archived in clinic databases (no form).	6	4	24	576
Patient	Behavioral screener (patients with detectable or undetectable VL; paper form).	6,315	4	5/60	2,105
Patient	CBI assessment items for patients with detectable VL (electronic form).	2,069	3	10/60	1,035
Patient	Patient exit survey (electronic form)	1,200	1	5/60	100
Primary care provider	Provider survey (electronic form)	120	4	10/60	80
Total	.....	.....	.....	.....	3,896

Kimberly S. Lane,

Deputy Director, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day–13–0743]

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 404–639–7570 or send comments to Kimberly Lane, 1600 Clifton Road, MS D–74, Atlanta, GA 30333 or send an email 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

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. 12/31/2011)—Reinstatement—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 social, economic, and health benefits of breastfeeding for both the mother and infant as well as for society in general. 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.

Health professionals recommend at least 12 months of breastfeeding, and Healthy People 2020 establishes specific national breastfeeding goals. In addition to increasing overall rates, a significant public health priority in the United States (U.S.) is to reduce variation in breastfeeding rates across population subgroups. Although CDC surveillance data indicate that breastfeeding initiation rates in the U.S. are climbing, rates for duration and exclusivity continue to lag, and significant disparities in breastfeeding rates persist between African-American and white women.

The health care system is one of the most important and effective settings to improve breastfeeding initiation rates because hospital practices strongly influence infant feeding outcomes. In 2003, CDC convened a panel of experts in surveillance and monitoring of hospital practices related to breastfeeding to identify the most effective way for CDC to address the urgent public health need for nationally representative data on these practices. The Expert Panel's consensus recommendation was to establish an ongoing, national system to monitor and evaluate hospital practices related to breastfeeding among all facilities that routinely provide intrapartum care in the United States. In response to this input, CDC created 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 birth centers). The mPINC survey was first