

safety and quality of care and other patient protections. The emphasis is on major regulations issued within the last ten (10) years.

ASPE requests that commenters, in the selection of which reform ideas to submit, consider the extent to which (1) Benefits (quantitative and/or qualitative) are likely to exceed costs for the reform, (2) benefits (quantitative and/or qualitative) can be increased without exceeding costs, (3) the suggested change would improve patients' health and quality of care, (4) the agency or multiple agencies have statutory authority to make the suggested change, and (5) the rule or program is a major contributor to the regulatory burden imposed on the health care sector. While both legislative and administrative reforms are welcome, administrative reforms such as those that require discretionary rulemaking are more likely to be initiated in a timely manner. The reforms may include modifying, extending, or rescinding regulatory programs, guidance documents or paperwork requirements.

Once we receive the nominations from the public, HHS, in cooperation with OMB, will assemble and evaluate the reform nominations and discuss each of them with the relevant HHS Operating Divisions, taking into account statutory, economic, public health, and budgetary considerations.

**ADDRESSES:** ASPE requests that nominations (including explanations of the suggested reforms) be submitted in writing electronically to ASPE at [ReducingRegulatoryBurden@hhs.gov](mailto:ReducingRegulatoryBurden@hhs.gov) within 30 calendar days from the date of publication of this notice in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Marty McGeein, Office of the Assistant Secretary for Planning and Evaluation, 200 Independence Avenue, SW., Washington, DC 20201. Telephone: (202) 690-6443.

Dated: September 20, 2005.

**Michael J. O'Grady,**

*Assistant Secretary for Planning and Evaluation (ASPE), HHS.*

**John D. Graham,**

*Administrator, Office of Information and Regulatory Affairs (OIRA), OMB.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[60Day-05-05CZ]

#### 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 404-371-5983 and send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an e-mail to [omb@cdc.gov](mailto: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

Assessing Diabetes Detection Initiative for Policy Decisions—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

#### Background and Brief Description

Type 2 diabetes is a chronic disease that affects more than 18 million Americans, approximately 5 million of whom do not know that they have the disease. As the disease progresses, it often causes severe complications, including heart disease, blindness, lower extremity arterial disease, and kidney failure. Native Americans, African Americans, Latino Americans, and some Asian Americans and Pacific Islanders are disproportionately affected by diabetes. Identifying persons who

have undiagnosed diabetes and treating them could prevent or delay diabetes complications.

In November 2003 the Diabetes Detection Initiative (DDI) was launched in 10 pilot sites around the U.S. to identify a portion of the estimated 5 million people with undiagnosed Type 2 diabetes, targeting specific areas in each of 10 locales in which residents are likely to be at higher risk for Type 2 diabetes. Implementation of the DDI involved distributing a paper-and-pencil risk test. Individuals whose score indicated that they were at an increased risk for diabetes were advised to see their regular doctor (or to schedule an appointment at one of several clinics that had agreed to participate in the DDI) to receive a finger-stick or other tests to confirm whether or not they have diabetes. Whether or not the DDI should be expanded to other communities depends on the health benefits and costs of the program. The CDC is planning to conduct a study to provide this critical information.

The planned study will assess the resources used, the cost per case detected, and the perceived benefit of the DDI to participants. Data for the economic assessment will be obtained by conducting surveys of local DDI implementation teams, leadership at participating health clinics, and patients at participating health clinics. The results of the study will also provide information needed for conducting a more complete cost-effectiveness analysis of screening for undiagnosed diabetes.

The point-of-contact (Implementation team member) in each of the 10 regions will be sent a mail survey to collect information regarding the staff time and other resources used to implement the DDI program (including the staff time and resources used by community-based organizations that participated in the DDI implementation). These planning and implementation activities include participating in meetings and conference calls, recruiting clinics and community-based organizations to participate in the DDI, distributing risk tests, organizing health fairs and other community events, and designing media campaigns to promote the DDI.

The health clinic leadership survey will be mailed to one person at each of the 43 clinics that participated in the DDI implementation. The survey will collect information regarding the costs associated with the clinic's participation in the DDI. These will include the medical costs of providing care to patients who visited the clinic as a result of the DDI, staff time associated with DDI planning and implementation,

and any staff time that was devoted to performing finger stick tests at locations other than the health clinic (e.g., health fairs, shopping malls, work sites, housing complexes). Of the 43 clinics to be surveyed, we expect that 30 (70%) will complete the survey.

A computer-assisted in-person interview will be administered to 600 clinic patients—60 in each of the 10 regions in which the pilot DDI was implemented. The survey will collect background information, out-of-pocket medical and non-medical direct health

care costs (e.g., co-payments, transportation costs, value of patients' time associated with the clinic visit), and preferred features of a diabetes screening program. There are no costs to respondents other than their time.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Implementation team members .....	10	1	2	20
Clinic staff .....	30	1	1	30
Patients at DDI clinics .....	600	1	20/60	200
Total .....	640	.....	.....	250

Dated: September 27, 2005.

**Betsy Dunaway,**

*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-05-0439x]

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

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) 371-5983 or send an e-mail to [omb@cdc.gov](mailto:omb@cdc.gov). Send written comments to CDC Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 or by fax to (202) 395-6974. Written comments should be received within 30 days of this notice.

**Proposed Project**

Assessment of State Early Hearing Detection and Intervention Programs (EHDI): A Program Operations Evaluation Protocol—New—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description:*

Every year, an estimated 12,000 newborns are diagnosed with

permanent hearing loss, a condition that if not identified and treated early can lead to impaired functioning and development. CDC's role in the detection, diagnosis, and treatment of early hearing loss through the "Early Hearing Detection and Intervention Program" (EHDI) is of vital importance for families of newborns and infants affected by hearing loss. Nonetheless, recent data indicate that only 60 percent of the newborns that fail hearing screening are evaluated by the recommended 3 months of age.

The evaluation will involve an integrative evaluation approach that encompasses the following activities, conducted in Arkansas, Massachusetts, Michigan, Utah, and Virginia: (1) A 10-minute survey of 3,000 mothers whose newborns have been screened (the "Maternal Exit Survey"); and (2) a 20-minute computer-assisted telephone interviewing (CATI) survey of 1,000 mothers of newborns who have been referred for additional hearing evaluation (the "Maternal CATI Interview.") To complete these interviews, it is expected that 5,000 will be contacted. The overall burden on all contacted women is expected to be approximately 940 hours. The Maternal Exit Survey and the Maternal CATI Interview will address the following research questions: (1) What are the factors that impede or enable families to follow-up for early hearing evaluation and intervention; (2) What EHDI strategies implemented by hospitals appear to be most successful in reducing loss to follow-up; and (3) Is loss to follow-up associated with maternal characteristics such as parity, age or ethnicity? Both surveys will be available in English and Spanish.

Hearing loss is the most common disorder that can be detected through newborn screening programs. Prior to

the implementation of newborn hearing screening, children with hearing loss typically were not identified until 2 to 3 years of age. This is well beyond the period of early language development. Now, with comprehensive EHDI programs, the average age of identification of children with hearing loss has been reduced so that it is now possible to provide interventions for children younger than one year of age. With early identification, children with hearing loss can begin receiving appropriate intervention services that provide the best opportunity for these children to reach their maximum potential in such areas as language, communication, social and emotional development, and school achievement.

Newborn hearing screening is only the first step in the identification of children with hearing loss. Children who do not pass their screening need to be further evaluated to determine if they have hearing loss. The value of newborn hearing screening cannot be realized unless children complete the screening, evaluation, and intervention process. Since recent data indicate that nearly 40 percent of children do not complete the evaluation-intervention process, this project is designed to understand what barriers exist in following through with evaluation and intervention. This evaluation also plans to provide data necessary to develop innovative solutions that can be applied by states, hospitals, and local programs. Results from this collection have the potential to strengthen the EHDI process and minimize social and economic disability among persons born with hearing loss.

By evaluating the policy, structural, personal, and financial factors and barriers associated with loss to follow-up in the EHDI program, this study seeks to identify "best practices" for improving detection, referral to