

all comments received, which will become a matter of public record.

Approved: September 6, 2006.

**Robert I. Cusick,**

*Director, Office of Government Ethics.*

[FR Doc. E6-15129 Filed 9-12-06; 8:45 am]

BILLING CODE 6345-02-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60Day-06-0641]

**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 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**

Descriptive Epidemiology of Missed or Delayed Diagnoses for Conditions Detected by Newborn Screening—(OMB No. 0920-0641)—Extension-National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

Every State in the United States and Washington, DC, has a public health program to test newborn babies for congenital metabolic and other disorders through laboratory testing of dried blood spots. These programs screen for between 4 and 36 different conditions including phenylketonuria (PKU) and congenital hypothyroidism, with testing performed in both state laboratories and private laboratories contracted by state health departments. The screening process or system is broader than the state public health newborn screening program, which is composed only of the laboratory and follow-up personnel. It involves the collection of blood from a newborn, analysis of the sample in a screening laboratory, follow-up of abnormal results, confirmatory testing and diagnostic work-up. Parents, hospitals, medical providers including primary care providers and specialists, state laboratory and follow-up personnel, advocates, as well as other partners such as local health departments, police, child protection workers, and courts play important roles in this process. Most children born with metabolic disease are identified in a timely manner and within the parameters

defined by the newborn screening system of each State. These children are referred for diagnosis and treatment. However, some cases are not detected at all or the detection comes too late to prevent harm. These "missed cases" often result in severe morbidity such as mental retardation or death.

In this project, we will update and expand a previous epidemiological study of missed cases of two disorders published in 1986. We will assess the number of cases of each disorder missed, the reasons for the miss and legal outcomes, if any. The reasons for the miss will be tabulated according to which step or steps of the screening process it occurred. Data will be collected by asking state public health laboratory directors, newborn screening laboratory managers, follow-up coordinators, specialists at metabolic clinics and parent groups with an interest in newborn screening for information regarding missed cases. An estimated 100 subjects will be requested to complete a short questionnaire that asks for information regarding the details of any missed cases of which they are aware.

The survey will highlight procedures and actions taken by States and other participants in newborn screening systems to identify causes of missed cases and to modify policies and procedures to prevent or minimize recurrences. The information gleaned from this study may be used to help craft changes in the screening protocols that will make the process more organized and efficient and less likely to fail an affected child. Further, it is not clear that there is a systematic assessment of missed cases on a population basis; this project will seek to identify procedures for routine surveillance of missed cases. There are no costs to respondents except their time to participate in the survey.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (hours)
State laboratory directors, screening laboratory managers, follow-up coordinators, metabolic clinic specialists, and parent groups .....	100	1	10/60	17