

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

Approved: September 6, 2006.

Robert I. Cusick,

Director, Office of Government Ethics.

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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.

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

Dated: September 7, 2006.

Joan F. Karr,

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

[60Day-06-0128]

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.

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

Congenital Syphilis (CS) Case Investigation and Report Form (CDC73.126)—OMB No. 0920-0128—Extension—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Coordinating Center for Infectious Diseases (CCID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC proposes to continue data collection for congenital syphilis case

investigations under the "Congenital Syphilis (CS) Case Investigation and Report Form" (CDC73.126, REV 11-98); this form is currently approved under OMB No. 0920-0128, and is due to expire on 9/30/2006. This request is for a 3-year extension of OMB approval.

Reducing congenital syphilis is a national objective in the DHHS Report entitled Healthy People 2010 (Vol. I and II). Objective 25-9 of this document states the goal: "Reduce congenital syphilis to 1 new case per 100,000 live births". In order to meet this national objective, an effective surveillance system for congenital syphilis must be continued to monitor current levels of disease and progress towards the year 2010 objective. This data will also be used to develop intervention strategies and to evaluate ongoing control efforts.

Respondent burden is approximately 15 minutes per reported case. The estimated annual number of cases expected to be reported using the current case definition is 500 or less. Therefore, the total number of hours for congenital syphilis reporting required will be approximately 130 hours per year. There are no costs to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Average number of responses per respondent	Average burden per response (in hours)	Total burden (hours)
Clerical and Hospital staff of state and local health department STD project areas	65	8	15/60	130
Total	130

Dated: September 6, 2006.

Joan F. Karr,

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

[FR Doc. E6-15184 Filed 9-12-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cooperative Agreement to Support the Shellfish and Seafood Safety Assistance Project; Announcement Type: Single Source Application; Agency Funding Opportunity Number: RFA-FDA-CFSAN-2006-1

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

I. Funding Opportunity Description

The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN), Office of Seafood is announcing its intent to award, noncompetitively, a cooperative agreement to the Interstate Shellfish Sanitation Conference (ISSC) in the amount of \$320,500 for fiscal year 2006, for direct and indirect costs combined. Subject to the availability of Federal funds and successful performance, 4 additional years of support will be available. FDA will support the research covered by this notice under the authority of section 301 of the Public Health Service Act (the PHS act) (42 U.S.C. 241). FDA's research program is

described in the Catalog of Federal Domestic Assistance No. 93.103. Before entering into cooperative agreements, FDA carefully considers the benefits such agreements will provide to the public. This effort will enhance FDA's molluscan shellfish sanitation program and provide the public greater assurance of the quality and safety of these products.

II. Eligibility Information

Competition is limited to ISSC because ISSC is the only organization that has the established formal structure, procedures, and expertise to direct all components (public health, environmental, resource management, and enforcement) of an effective shellfish sanitation program.