Background and Brief Description

Descriptive Epidemiology of Missed or Delayed Diagnoses for Conditions Detected by Newborn Screening—(OMB No. 0920–0641)—Revision—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC). 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 four and 36 different conditions including phenylketonuria (PKU) and congenital hypothroidism, 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. 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 continue to collect information about missed or delayed diagnoses in order to 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, and the potential reasons for the miss and legal outcomes. 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 135 remaining respondents will participate in our study by completing one or two short questionnaires that ask for information regarding the details of any missed or delayed 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.

Respondent burden is approximately 3 minutes for the State Form and 10 minutes for the Case Report Form. There are no costs to the respondents other than their time. The total estimated annual burden hours are 28.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Form name	Number of respondents	Number of responses per respondent	Average burden (hours) per response	Total burden (hours)
Director, State Newborn Screening Laboratory.	State Form	25	1	3/60	1.3
	Case Report Form	25	1	10/60	4.2
Follow-up State Coordinator	State Form	25	1	3/60	1.3
	Case Report Form	25	1	10/60	4.2
Metabolic Clinic Employee	State Form	60	1	3/60	3
	Case Report Form	60	1	10/60	10
Parent Advocate	Case Report Form	5	1	10/60	0.8
Parent	Case Report Form	20	1	10/60	3.3

Dated: December 8, 2006.

Joan F. Karr,

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

[FR Doc. 06–9723 Filed 12–13–06; 8:45 am]

BILLING CODE 4163–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-07–05AJ]

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

National Surveillance for Severe Adverse Events Associated with Treatment of Latent Tuberculosis Infection—New—Division of Tuberculosis Elimination (DTBE), National Center for HIV, STD, and TB Prevention (NCHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

As part of the national TB elimination strategy, the American Thoracic Society and CDC have published recommendations for targeted testing for TB and treatment for latent TB infection (LTBI). However, between October 2000 and September 2004, the CDC received reports of 50 patients with severe adverse events associated with the use of the two or three-month regimen of rifampin and pyrazinamide (RZ) for the treatment of LTBI; 12 (24%) patients

died (Morbidity and Mortality Weekly Report 2003;52[31]:735–9). A severe adverse event is defined as hospitalization or death of a person receiving treatment for LTBI. On the basis of these data, the American Thoracic Society and CDC recommended that RZ should generally not be offered for treatment of persons with LTBI, regardless of HIV status. Rifampin and pyrazinamide should continue to be administered in multidrug regimens for the treatment of persons with active TB disease.

Reports of severe adverse events related to RZ and other older LTBI regimens have prompted a need for this three year project—a national surveillance system of such events. The objective of the project is to determine the annual number and temporal trends of severe adverse events (hospitalization or death) associated with any treatment for LTBI in the United States. Surveillance of such events will provide data to support periodic evaluation of guidelines for treatment of persons with LTBI and revision, as needed.

This project will set up a passive reporting system for severe adverse events (death or hospitalization) to therapy for LTBI. The system will rely on medical chart review of already existing data by TB control staff.

Potential respondents are any of the 60 reporting areas for the national TB surveillance system (the 50 states, the District of Columbia, New York City, Puerto Rico, and 8 jurisdictions in the Pacific and Caribbean). Data will be collected using the data collection form for adverse events associated with LTBI treatment (AELT). Based on previous reporting, CDC anticipates receiving an average of 3 responses per year from the 60 reporting areas. The AELT form is completed for each reported hospitalization or death related to treatment of LTBI and contains demographic, clinical, and laboratory information. CDC will analyze and periodically publish reports summarizing national LTBI treatment adverse events statistics and also will conduct special analyses for publication in peer-reviewed scientific journals to further describe and interpret these data.

The Food and Drug Administration (FDA) collects data on adverse events related to drugs through the FDA MedWatch Program. CDC is planning to collaborate with FDA in developing the national surveillance system for adverse events associated with treatment for LTBI. Reporting will be conducted through telephone, e-mail, or during CDC site visits. The only cost to respondents is their time to gather medical records to complete the form.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Physicians	3	1	3	9
Nurses	3	1	4	12
Medical Clerk	3	1	1	3
Total				24

Dated: December 8, 2006.

Joan F. Karr,

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

[FR Doc. E6–21269 Filed 12–13–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 Day–07–0128]

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

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 10–2003). This form is currently approved under OMB No. 0920–0128, and is due to expire on 12/31/2006. 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 response for those who provide data electronically and 30 minutes per response for those who provide data via hard copy. The estimated annual number of cases expected to be reported using the current case definition is approximately 500. There are no costs to the respondents other than their time. The total estimated annual burden hours are 160.