Supporting Statement for OMB 0920-0128

Congenital Syphilis (CS) Case Investigation and Report Form

Extension

December 8, 2006

Technical Monitors

Sam Groseclose, D.V.M., M.P.H., Branch Chief
Melinda Flock, M.S.P.H., Deputy Branch Chief
Statistics and Data Management Branch
Division of STD Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention
Atlanta, Georgia
Telephone 404/639-8356
Facscimile404/639-8611

Introduction

The Centers for Disease Control and Prevention (CDC) requests a three year extension of clearance for the Congenital Syphilis (CS) Case Investigation and Report Form (OMB No. 0920-0128) that was previously approved in September 2003. No changes have been made to the data collection form since that time. This data collection activity is currently the only source of national congenital syphilis data.

To further reduce reporting burden on project areas, the hardcopy reporting forms are in the process of being replaced by electronic line-listed records transmitted via the National Electronic Telecommunications System for Surveillance (NETSS). We plan to complete the transition from paper-based reporting to electronic reporting by the end of this clearance period.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests a three year extension of clearance for the **Congenital Syphilis (CS) Case Investigation and Report Form** (OMB No. 0920-0128,) that was previously approved in September 2003. CDC first began collecting congenital syphilis data in 1941 to identify and monitor national trends. The reporting form (CDC form 73.126) for congenital syphilis (CS) was initiated in 1983 to further improve detection, case management and treatment of these cases. The form was revised in 1991 to reflect the new congenital syphilis case definition that was introduced in 1989. At the time the form was revised, it improved surveillance of CS by: (1) decreasing the reporting burden of respondents by reducing the number of variables from 143 to 44; (2) standardizing the reporting system by asking all respondents to report CS cases using a standard surveillance case definition and reporting form; and (3) improving the timeliness of reporting by eliminating long term follow-up required to report CS cases under the old case definition.

Congenital Syphilis (CS) is nearly 100% preventable by early detection and treatment of syphilis in women before or during pregnancy. However, between 1983 and 1991, the reported case rate of CS increased from 4.3 to 107.3 per 100,000 live births and has continued to decline to 8.0 in 2005. Although a substantial portion of the initial increase was due to the introduction of a new CS surveillance case definition in 1989 (see below), there was at least a 5-fold increase in reported cases since 1985 even when the old case definition was used. This increase paralleled the past national epidemic of syphilis in women.

Reducing congenital syphilis is a national objective in the U.S. Department of Health and Human Services report entitled Healthy People 2010, Volume II: Objectives for Improving Health (November 2000). Objective 25-9 of this document states the goal: "reduce congenital syphilis" to the new target of only "1 new case per 100,000 live births" by the year 2010. In order to meet this national objective, an effective surveillance system for CS must be in place to monitor current levels of disease and progress towards the year 2010 objective.

In 1989, a new CS surveillance case definition (see **Attachment 2**) was introduced to provide more useful estimates of the public health impact of CS. Congenital Syphilis is an important sentinel health event that marks potential problems in both prenatal care and syphilis prevention programs. The new case definition focuses on mothers who come to delivery with untreated syphilis rather than on infants with clinical signs and symptoms of CS. Although most infants identified as cases by the new case definition are asymptomatic, they are at extremely high risk for infection and, as such, nearly always require treatment to prevent long term sequelae of CS.

The current CS reporting form (see **Attachment 5**) was revised and cleared by OMB in 1991 to collect information based on the surveillance case definition. The current form was introduced to states in 1991 and fully implemented by all states in 1992. For this renewal, no changes have been made to the currently approved collection form since its last extension in 2003.

This data collection is authorized under Sections 301 and 318 of the Public Health Service Act (42 USC 241 and 247c). (see **Attachment 1**).

2. Purpose and Use of the Information Collection

Prevention of congenital syphilis is a high priority among CDC's sexually transmitted disease (STD) programs. The congenital syphilis surveillance system provides critical information for State and local STD programs to develop new intervention strategies and to evaluate ongoing prevention efforts to address the congenital syphilis problem. Without this congenital syphilis surveillance system, progress towards preventing congenital syphilis cannot be monitored or evaluated.

Infants with presumptive or confirmed CS, as defined by the surveillance case definition, and their mothers will be included in this study. An individual form will be completed for each case of CS, including stillbirths.

The 65 respondents in this surveillance system will be the STD project areas which are part of health departments in all 50 States, New York City, Philadelphia, Baltimore, Los Angeles, San Francisco, Chicago, the District of Columbia, the U.S. Virgin Islands, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, the Federated States of Micronesia, the Republic of Palau, the Northern Mariana Islands and

American Samoa. Information from these STD project areas will be reported on all cases of CS; no sample selection is involved. The data from each reporting area includes an individual case report form for each diagnosed case of CS, including stillbirths due to CS. All individual case reports are sent to CDC as soon as possible after the case has been reported to the health department. CDC tracks congenital case reporting and contacts project areas if there are noticeable increases or decreases in reporting.

CDC has used this data to improve case detection, case management and treatment of congenital syphilis nationwide (see **Attachment 4** for a current list of publications).

3. Use of Improved Information Technology and Burden Reduction

Information collection for the congenital syphilis investigation report began in 1983 and the current reporting form continues this process. Over time, revisions were made to decrease the reporting burden on respondents by reducing the number of variables collected.

Project sites currently have two options for transmitting data to CDC: a paper-based option and an electronic option. Approximately 25 sites are currently using the paper-based option because they do not yet have the technical capability to transmit data electronically. However, the paper hardcopy reporting option is being phased out in favor of a more efficient electronic reporting option.

Currently, approximately 40 sites (60%) submit data electronically to CDC via the National Electronic Telecommunications System for Surveillance (NETSS). Many project areas have developed the capability to analyze and use their own data locally. To facilitate these activities, CDC also provides data management information system software (STD*MIS) to local areas to help with data entry and NETSS transmission.

CDC is in the process of working with all project areas to transmit all CS cases electronically and in a timely manner via NETSS. The electronic submission option eliminates the process of filling in paper forms and reduces the burden of reporting by 50% or more. Eventually, NETSS will be replaced with NEDSS (National Electronic Disease Surveillance System), the new CDC integrated surveillance system.

4. Efforts to Identify Duplication and Use of Similar Information

CDC has been considered the leading source of national statistics on STDs since the 1940's. No other public or private agency, university, or organization is currently collecting congenital syphilis data on a national level. CDC has developed longstanding relationship with state/local health departments which collect and tabulate the data for reporting to CDC. These constituents, and CDC experts, have

conducted an extensive review of medical research and programmatic literature on congenital syphilis which has not identified duplication of this system.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study.

6. Consequences of Collecting the Information Less Frequently

A report form is completed only once per case. All congenital syphilis case reports are completed and submitted to CDC as cases occur. This assists in timely identification of the CS problem as it occurs and allows health departments to set priorities, target interventions and evaluate programs. If national congenital syphilis data was no longer collected, or collected as each case occurs, congenital syphilis could not be monitored, evaluated and prevented. While most cases of congenital syphilis occur among infants whose mothers have had some prenatal care, late or limited prenatal care has been associated with congenital syphilis. Failure of health care providers to adhere to maternal syphilis screening recommendations also may contribute to the occurrence of congenital syphilis. Untreated early syphilis in women during pregnancy results in perinatal death in up to 40% of cases and, if acquired during the four years preceding pregnancy may lead to infection of the fetus in over 70% of cases.

There are no legal obstacles to reducing the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The collection conducted is inconsistent with the Guidelines in 5 CFR 1320.5 in only one respect: frequency of reporting. A special circumstance would be requiring respondents to report information to the agency more often than quarterly. For this reporting form, respondents are requested to report cases as they occur. This system permits CDC to maintain real-time surveillance of congenital syphilis in order to recognize clusters and potential epidemics. In all other respects, this data collection is consistent with 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

A. A 60-day notice to solicit public comments was published in the *Federal Register,* 9/13/2006, Volume 71, No. 177 (see **Attachment 3**). There were no public comments.

B. Since the form has not changed significantly since 1991, no special consultation has been conducted with persons outside the agency. However, CDC staff have ongoing communication with State and local STD program managers, including representatives on the Council of State and Territorial Epidemiologists (CSTE) on the use and distribution of congenital syphilis report forms. All State and territorial STD programs are using the current form to report cases of CS. No problems have been reported with this form.

9. Explanation of Any Payment or Gift to Respondents

No remuneration of respondents is conducted; report forms, computer software, and technical assistance are provided at no cost to the respondent.

10. Assurance of Confidentiality Provided to Respondents

The CDC Privacy Act and Confidentiality Officer has reviewed this submission and has determined that the Privacy Act is not applicable. All personal identifying information on individual patients is retained by the local STD programs, removed before data are sent to CDC, and, while appearing on the State Health Department copy, is clearly marked for "Local Use Only".

To ensure that individually identified data are not inadvertently sent to CDC, an examination of the form (**Attachment 5**) shows that while identifying information is included in the top portion of the form, the NCR copy of the form which is sent to CDC has this portion with identifying information blacked out with "Chinese writing" (Adobe Postscript type-face Galliard Bold Italic Font). The statement "Patient identifier information is <u>not</u> transmitted to CDC" is also printed on the form. State and local health departments historically have stringent safeguarding measures in place to protect individually identified data.

As discussed in A.3, project areas are converting to electronic data submission via NETSS. NETSS data are transmitted to CDC using the SDN (Secure Data Network) which meets CDC policies for data transmission via internet. It is Web based and the states have access via PC using Internet Explorer. It contains tight security controls and uses Digital certificates and dynamic data encryption for faster more secure data transmission from the states to CDC.

Since this ongoing surveillance data collection activity is not considered to be research, it does not require IRB review and approval.

11. Justification for Sensitive Questions

This data collection involves information which could be viewed as sensitive, such as diagnosis and treatment of syphilis, and Race/Ethnicity data. However, as noted in A.10, CDC receives only de-identified data.

12. Estimates of Annualized Burden Hours and Costs

A. The number of congenital syphilis cases reported annually ranges from 0 to 75 cases depending on the project area. The average for all the project areas is approximately 8 cases per year.

We are in the process of phasing-out a paper-based reporting option with an estimated average burden of 30 minutes per response, and phasing-in an electronic reporting option (NETSS) with an average estimated burden of 15 minutes per response. Approximately 40 (60%) of the 65 sites have already converted to the electronic reporting option, with full conversion expected by the end of this three-year clearance period. Table A12.1 represents an estimated annualized average of 50 sites submitting data via NETSS, and 15 sites submitting paper forms. The total estimated annualized burden for this project is 160 hours.

A12.1 Estimated Annualized Burden Hours

Respondents	Number of Respondents	Average number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Clerical and hospital staff of state and local health department STD project areas	50 (electronic data)	8	15/60	100
	15 (hardcopy data)	8	30/60	60
			Total	160

A12.2 Annualized Costs to Respondents

There are no costs to the respondents other than their time, Please note that the respondent costs itemized below are included in the cooperative agreement costs summarized in A14.

Respondents	Number of Respondents	Average number of responses per respondent	Average burden per response (in hours)	Average hourly wage	Total cost
Clerical and hospital staff of state and local health department STD project areas	50 (electronic)	8	15/60	$20.00	$2,000
	15 (hardcopy)	8	30/60	$20.00	$1,200
				Total	$3,200

13. Estimates of Other Total Annual Cost Burden to Respondents and Recordkeepers

There are no capital or maintenance costs to the respondent.

14. Annualized Cost to the Federal Government

For these reports, the estimated annualized cost to the Federal Government is $3,750. This figure includes the cost of printing the form, management review of forms, data entry or electronic transmission, cost of office time in preparing reports for publication and mailing reports.

The personnel costs of federal employees involved in oversight and/or analysis involve a GS-11 IT Specialist (1/4 time), GS-13 IT Specialist (1/4 time), and a Medical Epidemiologist (1/4 time). The current combined yearly salaries for part-time is approximately $68,750.

Federal Personnel and Expenses		Annualized Costs
Medical Epidemiologist IT Specialist (11) IT Specialist (13) Report Preparation and Forms Management	$115,000/yr x .25 $70,000/yr x .25 $90,000/yr x .25 $3,750	$28,750 $17,500 $22,500 $3,750
	Subtotal, Federal	$72,500
Cooperative agreements	Subtotal, Cooperative Agreements	$190,000
	Total	$262,500

15. Explanation for Program Changes or Adjustments

Incidence of primary and secondary syphilis (P&S, or infectious syphilis) among women has been declining during the past several years, and consequently cases of congenital syphilis have shown decreases as well. In 2000 there were 580 congenital syphilis cases with a rate of 14.3 per 100,000 live births, which has decreased over the last five years to 329 cases (rate 8.0 per 100,000 live births) in 2005. No specific program change has been made.

A further 50% reduction in hour burden is expected since the CDC is requiring project areas to move toward the electronic reporting of line-listed STD morbidity data via the National Electronic Telecommunications System for Surveillance (NETSS).

16. Plans for Tabulation and Publication and Project Time Schedule

Data provided to CDC will be used for multiple publications which inform the public, health professionals, health departments, STD control programs, health administrators, and others about the trends and status of congenital syphilis in the U.S. Examples of past publications are available on request from medical libraries or CDC (see **Attachment 4** for a current list). The national *Sexually Transmitted Disease Surveillance Report* and *Syphilis Supplement* are published annually using analyses from this data collection. For examples of these and other related reports, see http://www.cdc.gov/std/stats. In addition, information based on these data is frequently quoted by newspapers, television, magazines, etc.

The Project Time Schedule is provided below:

Congenital Syphilis Surveillance - Project Time Schedule	
Activity	**Time Schedule**
Notice of renewed form sent to respondents	1 - 2 months after OMB approval
Renewed data collection form printed and distributed to the field	2 - 4 months after OMB approval
Initiate use of renewed form	2007 (6 months after OMB approval)
Validation	Ongoing
Analyses and Publication	Ongoing

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Previous requests for OMB approval of this data collection had included a request for exemption of display of the expiration date. In the past, State health departments collected these data and CDC printed forms and sent them to the States in large quantities. However, CDC is in the process of phasing out this form and replacing it with the NETSS electronic data record. More than half of the states have already made this transition, and we expect the other states to follow in the next three years. Therefore, CDC is **not** requesting an exemption from display of the expiration date at this time.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

Item (f) -- indicates for each record keeping requirement the length of time persons are required to maintain the records specified. These data belong to the respective health departments that collected and reported them. CDC does not specify to State or local health departments the length of time that data must be retained, but due to the need for ongoing analysis, most areas retain such data indefinitely. Hardcopy report forms may be destroyed after five years.

B. Statistical Methods

1. Respondent Universe and Sampling Methods

This data collection does not employ statistical methods since no statistical sampling is performed. Reported cases are assumed to represent all cases of CS in the United States. Rates are calculated using standard live birth and population denominators available from the U.S. Census Bureau. Ongoing evaluations of completeness of reporting are performed at the State/local level and by CDC.

2. Procedures for Collection of Information

Forms will be completed by respondents in duplicate (via chemically treated copy paper). Originals, including personal identifying information, are maintained in files and databases at the State or local health department. Copies, with personal identifiers removed, are sent to CDC. In some instances, project areas choose to send the data to CDC electronically via NETSS. Again, all personal identifiers are removed before data are sent via these mechanisms to CDC.

CDC will log, edit, and enter all data it receives into the CDC databases for computer processing and analysis.

3. Methods to Maximize Response Rates and Deal with Nonresponse

CDC is required to routinely monitor the timeliness and quality of reported data and provides feedback to reporting areas in order to maintain consistency of the data.

4. Tests of Procedures or Methods to be undertaken

Does not apply. The data collection methods used are routine and have been in place for many years. Minor modifications include clarification of existing fields.

5. Individuals Consulted on Statistical Aspects and Individuals and/or Analyzing Data

Data are analyzed by CDC epidemiologists and statisticians. For further information on epidemiological and statistical procedures, contact Dr. Hillard Weinstock or Dr. John Beltrami, Epidemiology and Surveillance Branch, Division of STD Prevention, National

Center for HIV, STD, and TB Prevention, CDC at (404)639-2059.

LIST OF ATTACHMENTS

1. **Public Health Service Acts**
2. **Surveillance Case Definition**
3. **Copy of 60-day Federal Register Notice**
4. **Examples of Publications on Congenital Syphilis**
5. **Data Collection Form CDC73.126**

ATTACHMENT 1

Contents:

1a. PUBLIC HEALTH SERVICE ACT, SEC. 301:

TITLE 42 - THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A - PUBLIC HEALTH SERVICE
SUBCHAPTER II - GENERAL POWERS AND DUTIES
Part A - Research and Investigations

U.S. Code as of: 01/26/1998

Sec. 241. Research and investigations generally

(a) Authority of Secretary

The Secretary shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams. In carrying out the foregoing the Secretary is authorized to -

(1) collect and make available through publications and other appropriate means, information as to, and the practical application of, such research and other activities;

(2) make available research facilities of the Service to appropriate public authorities, and to health officials and scientists engaged in special study;

(3) make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research projects as are recommended by the advisory council to the entity of the Department supporting such projects and make, upon recommendation of the advisory council to the appropriate entity of the Department, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research;

(4) secure from time to time and for such periods as he deems advisable, the assistance and advice of experts, scholars, and consultants from the United States or abroad;

(5) for purposes of study, admit and treat at institutions, hospitals, and stations of the Service, persons not otherwise eligible for such treatment;

(6) make available, to health officials, scientists, and appropriate public and other nonprofit institutions and organizations, technical advice and assistance on the application of statistical methods to experiments, studies, and surveys in health and medical fields;

(7) enter into contracts, including contracts for research in accordance with and subject to the provisions of law applicable to contracts entered into by the military departments under sections 2353 and 2354 of title 10, except that determination, approval, and certification required thereby shall be by the Secretary of Health and Human Services; and

(8) adopt, upon recommendations of the advisory councils to the appropriate entities of the Department or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers necessary or appropriate to carry out the purposes of this section.

The Secretary may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary

determines appropriate.

(b) Testing for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects; consultation

(1) The Secretary shall conduct and may support through grants and contracts studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects. In carrying out this paragraph, the Secretary shall consult with entities of the Federal Government, outside of the Department of Health and Human Services, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct for such entity studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects.

(2)(A) The Secretary shall establish a comprehensive program of research into the biological effects of low-level ionizing radiation under which program the Secretary shall conduct such research and may support such research by others through grants and contracts.

(B) The Secretary shall conduct a comprehensive review of Federal programs of research on the biological effects of ionizing radiation.

(3) The Secretary shall conduct and may support through grants and contracts research and studies on human nutrition, with particular emphasis on the role of nutrition in the prevention and treatment of disease and on the maintenance and promotion of health, and programs for the dissemination of information respecting human nutrition to health professionals and the public. In carrying out activities under this paragraph, the Secretary shall provide for the coordination of such of these activities as are performed by the different divisions within the Department of Health and Human Services and shall consult with entities of the Federal Government, outside of the Department of Health and Human Services, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct and support such activities for such entity.

(4) The Secretary shall publish a biennial report which contains -

(A) a list of all substances (i) which either are known to be carcinogens or may reasonably be anticipated to be carcinogens and (ii) to which a significant number of persons residing in the United States are exposed;

(B) information concerning the nature of such exposure and the estimated number of persons exposed to such substances;

(C) a statement identifying (i) each substance contained in the list under subparagraph (A) for which no effluent, ambient, or exposure standard has been established by a Federal agency, and

(ii) for each effluent, ambient, or exposure standard established by a Federal agency with respect to a substance contained in the list under subparagraph (A), the extent to which, on the basis of available medical, scientific, or other data, such standard, and the implementation of such standard by the agency, decreases the risk to public health from exposure to the substance; and

(D) a description of (i) each request received during the year involved -

(I) from a Federal agency outside the Department of Health and Human Services for the Secretary, or

(II) from an entity within the Department of Health and Human Services to any other entity within the Department, to conduct research into, or testing for, the carcinogenicity of substances or to provide information described in clause (ii) of subparagraph (C), and (ii) how the Secretary and each such other entity, respectively, have responded to each such request.

(5) The authority of the Secretary to enter into any contract for the conduct of any study, testing, program, research, or review, or assessment under this subsection shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance in appropriation Acts.

(c) Diseases not significantly occurring in United States

The Secretary may conduct biomedical research, directly or through grants or contracts, for the identification, control, treatment, and prevention of diseases (including tropical diseases) which do not occur to a significant extent in the United States.

(d) Protection of privacy of individuals who are research subjects The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.

1b. PUBLIC HEALTH SERVICE ACT, SEC. 318:

TITLE 42 - THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A - PUBLIC HEALTH SERVICE
SUBCHAPTER II - GENERAL POWERS AND DUTIES
Part B - Federal-State Cooperation

U.S. Code as of: 01/26/1998

Sec. 247c. Sexually transmitted diseases; prevention and control projects and programs

(a) Technical assistance to public and nonprofit private entities and scientific institutions

The Secretary may provide technical assistance to appropriate public and nonprofit private entities and to scientific institutions for their research in, and training and public health programs for, the prevention and control of sexually transmitted diseases.

(b) Research, demonstration, and public information and education projects

The Secretary may make grants to States, political subdivisions of States, and any other public and nonprofit private entity for -

(1) research into the prevention and control of sexually transmitted diseases;

(2) demonstration projects for the prevention and control of sexually transmitted diseases;

(3) public information and education programs for the prevention and control of such diseases; and

(4) education, training, and clinical skills improvement activities in the prevention and control of such diseases for health professionals (including allied health personnel).

(c) Project grants to States

The Secretary is also authorized to make project grants to States and, in consultation with the State health authority, to political subdivisions of States, for -

(1) sexually transmitted diseases surveillance activities, including the reporting, screening, and followup of diagnostic tests for, and diagnosed cases of, sexually transmitted diseases;

(2) casefinding and case followup activities respecting sexually transmitted diseases, including contact tracing of infectious cases of sexually transmitted diseases and routine testing, including laboratory tests and followup systems;

(3) interstate epidemiologic referral and followup activities respecting sexually transmitted diseases; and

(4) such special studies or demonstrations to evaluate or test sexually transmitted diseases prevention and control strategies and activities as may be prescribed by the Secretary.

(d) Grants for innovative, interdisciplinary approaches

The Secretary may make grants to States and political subdivisions of States for the development, implementation, and evaluation of innovative, interdisciplinary approaches to the prevention and control of sexually transmitted diseases.

(e) Authorization of appropriations; terms and conditions; payments; recordkeeping; audit; grant reduction; information disclosure

(1) For the purpose of making grants under subsections (b) through (d) of this section, there are authorized to be appropriated $85,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 1998.

(2) Each recipient of a grant under this section shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of

the proceeds of such grant, the total cost of the project or undertaking in connection with which such grant was given or used, and the amount of that portion of the cost of the project or undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(3) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipients of grants under this section that are pertinent to such grants.

(4) The Secretary, at the request of a recipient of a grant under this section, may reduce such grant by the fair market value of any supplies or equipment furnished to such recipient and by the amount of pay, allowances, travel expenses, and any other costs in connection with the detail of an officer or employee of the United States to the recipient when the furnishing of such supplies or equipment or the detail of such an officer or employee is for the convenience of and at the request of such recipient and for the purpose of carrying out the program with respect to which the grant under this section is made. The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies, equipment, or personal services on which the reduction of such grant is based.

(5) All information obtained in connection with the examination, care, or treatment of any individual under any program which is being carried out with a grant made under this section shall not, without such individual's consent, be disclosed except as may be necessary to provide service to him or as may be required by a law of a state or political subdivision of a State. Information derived from any such program may be disclosed -

(A) in summary, statistical, or other form; or

(B) for clinical or research purposes; but only if the identity of the individuals diagnosed or provided care or treatment under such program is not disclosed.

(e) (FOOTNOTE 1) Consent of individuals

(FOOTNOTE 1) So in original. Probably should be "(f)".

Nothing in this section shall be construed to require any State or any political subdivision of a State to have a sexually transmitted diseases program which would require any person, who objects to any treatment provided under such a program, to be treated under such a program.

ATTACHMENT 2

Contents:

1. SURVEILLANCE CASE DEFINITION FOR CONGENITAL SYPHILIS

A **confirmed case** of congenital syphilis is an infant or child in whom **Treponema pallidum** is identified by darkfield microscopy, direct fluorescent antibody, or other specific stains in specimens from lesions, placenta, umbilical cord, or autopsy material.

A **presumptive case** of congenital syphilis is either of the following:

RRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRR

any infant whose mother had untreated or inadequately treated[1] syphilis at the time of delivery,

regardless of the findings in the infant or child;

B. any infant or child who has a reactive treponemal test for syphilis and any one of the following:

1. evidence of congenital syphilis on physical examination[2];
2. evidence of congenital syphilis on long bone X-ray;
3. reactive cerebrospinal fluid CSF-VDRL;
4. elevated CSF cell count or protein (without other cause)[3];
5. reactive test for IgM antibody[4].

A **svphilitic stillbirth** is defined as a fetal death in which the mother had untreated or inadequately treated syphilis at the time of delivery of a fetus after a 20-week gestation or of a fetus weighing >500g.

---

[1]Inadequate treatment consists of any non-penicillin therapy or penicillin given less than 30 days before delivery.

[2]Signs of CS in an infant or a child younger than 2 years of age may include condyloma lata, snuffles, syphilitic skin rash, hepatosplenomegaly, jaundice due to syphilitic hepatitis, pseudoparalysis, or edema from nephrotic syndrome or malnutrition. Stigmata in an older child may include interstitial keratitis, nerve deafness, anterior bowing of shins, frontal bossing, mulberry molars, Hutchinson's teeth, saddle nose, rhagades or Clutton's joints.

[3]In the immediate newborn period, interpretation of these tests may be difficult; normal values differ with gestational age and are higher in preterm infants. CSF cell count and protein in a neonate should be interpreted by a clinician. Beyond the neonatal period, a CSF count >5 wbc/mm3 or CSF protein >40 mg/dl is abnormal.

[4]A treponemal test that detects a specific subunit of antitreponemal IgM. This test is not yet widely available and should not be confused with FTA-ABS.

ATTACHMENT 3

Contents:

1. Copy of published 60-day Federal Register Notice

Dated: September 7, 2006.
Joan F. Karr,
Acting Reports Clearance Officer, Centers for Disease Control and Prevention.
[FR Doc. E6–15151 Filed 9–12–06; 8:45 am]
BILLING CODE 4163–18–P

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] BILLING CODE 4163–18–P

ATTACHMENT 4

Contents:

1. Examples of Publications on Congenital Syphilis

1. EXAMPLES OF PAST PUBLICATIONS ON CONGENITAL SYPHILIS

Mascola L, et al. Inadequate treatment of syphilis in pregnancy. Am J Obstet Gynecol 150:945-47, 1984.

CDC. Guidelines for prevention and control of congenital syphilis. MMWR 37: (Suppl. No. S-1), 1988.

Ehling LR. Control and prevention of congenital syphilis. Border Health 5(2):11-13, 1989.

Zenker P, Berman S. Congenital syphilis: reporting and reality. Am J Public Health 80:271-72, 1990.

Cohen DA, et al. The effects of case definition, maternal screening, and reporting criteria on rates of congenital syphilis. Am J Public Health 80:316-17, 1990.

Dunn RA, Webster LA, Nakashima AK, Sylvester GC. Surveillance for Geographic and Secular Trends in Congenital Syphilis - United States, 1983-1991, MMWR Vol 42, No.55-56.

CDC. Guidelines for prevention and control of congenital syphilis. MMWR 1988; 37(No. S-1).

Thompson, Betsy, et al. Congenital Syphilis in Maryland: 1986-1991: The Effect of Changing the Case Definition and Opportunities for Prevention. Sexually Transmitted Disease 22(6):364-369, 1995.

Coles, BF, Hipp SS, Silberstein GS, Chen JH. Congenital syphilis surveillance in upstate New York, 1989-1992: implications for prevention and clinical management. J Infect Dis. 1995;171:732-5.

Finelli L, Crayne EM, Spitalny KC. Treatment of infants with reactive syphilis serology, New Jersey: 1992-1996. Pediatrics 1998; 102:1-6.

Risser WL, Hwang LY. Problems in the current case definitions of congenital syphilis. J Pediatr 1996; 129:499-505.

Gust DA, Levine WC, St Louis ME, Braxton J, Berman SM. Mortality associated with congenital syphilis in the United States, 1992-1998. Pediatrics 2002;109:E79-9.

Martin D, Bertrand J, McKegney C, Thompson L, Belongia E, Mills W. Congenital syphilis surveillance and newborn evaluation in a low-incidence state. Arch Pediatr Adolesc Med 2001;155:140-4.

CDC. Congenital syphilis – United States, 2002. MMWR 2004;53:716-9.

CDC. Sexually transmitted disease surveillance, 2004. Atlanta, Georgia: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, September 2005.

CDC. Syphilis Surveillance Supplement, 2004. Atlanta, Georgia: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, December 2005.

CDC. Sexually transmitted diseases treatment guidelines, 2006. MMWR 2006 (55): No.RR-11.

ATTACHMENT 5

Contents:

1. **Electronic NETSS Record Layout for Form CDC73.126**
2. **Hardcopy Data Collection Form CDC73.126**

National Electronic Telecommunications System for Surveillance (NETSS)
RECORD LAYOUT FOR TRANSMISSION OF STD MORBIDITY DATA
***CONGENITAL SYPHILIS* CASE RECORD (LINE-LISTED DATA)**

OMB NOTE: Burden estimates for this electronic form is approximately 15 minutes per response. The first 60 columns of this record layout are consistent with the standard NETSS record layout for all national notifiable diseases reported to CDC. Also, note that the burden estimate for the hardcopy form immediately following this electronic record layout is approximately 30 minutes per response.

Field Name	Columns	Notes
RECTYPE	1	Record type will determine how the record is handled when it arrives at CDC. Value for case data: *M=MMWR report*
UPDATE	2	**Currently not implemented.** (Pad with a 9)
STATE	3-4	Reporting State **FIPS** code - Q2 on 126 form.(e.g., "06", "13").
YEAR	5-6	MMWR Year (2-digits) for which case information reported to CDC.
CASEID	7-12	Unique Case ID **(numeric only)** assigned by the state.
SITE	13-15	Location code used by the state to indicate where report originated and who has responsibility for maintaining the record. (NOTE: STD*MIS software substitutes a '#' for the leading 'S' in codes listed below). Values include: *S01=State epidemiologist* *S02=State STD Program* *S03=State Chronic Disease Program* *S04-S99=Other state offices* *R01-R99=Regional or district offices* *001-999=County health depts (FIPS codes)* *L01-L99=Laboratories within state* *CD1=Historical records (prior to new format)* *CD2=Entered at CDC (based on phone reports)*
WEEK	16-17	MMWR Week on Surveillance Calendar, i.e., week for which case information reported to CDC.
EVENT	18-22	Event (disease) code for the disease being reported: *10316=Syphilis (congenital)*
COUNT	23-27	*For case records this field will always contain "00001".*
COUNTY	28-30	FIPS code for reporting county (Unknown=999) - Q3 on 126 form.
BIRTHDATE	31-38	Date of birth of infant in YYYYMMDD format (Unknown=99999999) - Q27 on 126 form.
AGE	39-41	Estimated Gestational Age in weeks - Q32 on 126 form(e.g., "038", "042") (Unknown=999)
AGETYPE	42	Indicates the units (weeks) for the AGE field. Values:

		2=0-52 Weeks *9=Gestational Age Unknown (AGE field should be 999)*
SEX	43	Gender - Q30 on 126 form. Values: *1=Male, 2=Female, 9=Unknown*
RACE	44	Race of Mother - Recoded Q13 on 126 form. Values: *1=American Indian/Alaska Native* *2=Asian or Pacific Islander* *3=Black* *5=White* *8=Other* *9=Unknown* ***NOTE: Please use only one of the codes above if a single race was selected. If multiple races were selected, enter code 8=Other for Race and also select the appropriate race categories that apply in columns 238-244.***
HISPANIC	45	Indicator for Mother's Hispanic ethnicity - Q12 on 126 form. Values: *1=Hispanic or Latino, 2=Not-Hispanic or Latino,9=Unknown*
EVENTDATE	46-51	Date of Report to Health Department in YYMMDD format - Q1 on 126 form.
DATETYPE	52	A code describing the type of date provided in EVENTDATE. Value: *4=Date of first report to community health system*
CASE STATUS	53	Recode of Case Classification *1=Confirmed, Presumptive, or Syphilitic stillbirth (Default for STD*MIS)* *2=Not a case* *9=Unknown*
IMPORTED	54	Indicates if the case was imported into the state or the U.S. Values: *1=Acquired in USA in reporting state* *2=Acquired outside USA* *3=Acquired in USA, but outside the reporting State* *9=Unknown*
OUTBREAK	55	Indicates whether the case was associated with an outbreak. Values: *1=Yes, 2=No, 9=Unknown*
FUTURE	56-60	Reserved for future use (Pad with 99999).

The following data (columns 61-255) is EXTENDED or STD-Program data.

INFOSRCE	61-62	Information Source/Provider Codes (from Interview Record if available). Values: *01=HIV Counseling and Testing Site* *02=STD* *03=Drug Treatment* *04=Family Planning* *05=Prenatal/Obstetrics* *06=Tuberculosis* *07=Other Clinic* *08=Private Physician/HMO* *09=Hospital (Inpatient)* *10=Emergency Room* *11=Correctional Facility* *12=Laboratory* *13=Blood Bank* *14=Delivery* *15=Prenatal* *16=Job Corps* *17=School-based Clinic* *18=Mental Health Provider* *66=Indian Health Service* *77=Military* *88=Other* *99=Unknown* (if data not available)
DETECTED	63-64	Method of Case Detection (from Interview Record if available). Values: *01=Provider Referral* *02=Cluster* *03=Patient Referral* *04=Prenatal* *05=Delivery* *06=Institutional Screening* *07=Community Screening* *08=Reactor* *09=Provider Report* *10=Volunteer* *88=Other* *99=Unknown* (if data not available)
MZIP	65-69	Zip Code for Mother's Residence - Q10 on 126 form. *99999=Unknown* (if data not available)
FUTURE	70-79	Blank
CITY	80-83	Reporting City FIPS Code - Q4 on 126 form.
SENTINEL	84	Sentinel Reporting Site - This question is not on the version 10-2003 126 form and will be left blank. It was Q6 prior to this revised 126 form. Values: *1=Yes, 2=No*
MSTATE	85-86	FIPS Code for Mother's State of Residence - Q7 on 126. Code 98 for Mexico and 97 for any other non-USA residence.
MCOUNTY	87-89	FIPS Code for Mother's County of Residence - Q8 on 126. Code 998 for Mexico and 997 for any other non-USA

		residence.
MCITY	90-93	FIPS Code for Mother's City of Residence - Q9 on 126. Code 9998 for Mexico and 9997 for any other non-USA residence.
MBIRTH	94-101	Mother's Date of Birth in YYYYMMDD format - Q11 on 126.
MARITAL	102	Mother's Marital Status - Q14 on 126. Values: *1=Single, never married* *2=Married* *3=Separated/Divorced* *4=Widow* *8=Other* *9=Unknown*
LMP	103-110	Date of Mother's Last Menstrual Period before delivery in YYYYMMDD format - Q15 on 126 form.
PRENATAL	111	Did mother have prenatal care? - Q16 on 126 form. Values: *1=Yes, 2=No, 9=Unknown*
PNCDATE1	112-119	Date of mother's first prenatal visit in YYYYMMDD format - Q17 on 126 form.
PNCNUM	120-121	Number of prenatal visits - Q18 on 126 form.
NONTREP	122	Did mother have nontreponemal test (e.g., RPR or VDRL) in pregnancy, at delivery, or soon after delivery? - Q19 on 126 form. Values: *1=Yes, 2=No, 9=Unknown*
DATEA	123-130	Date of nontreponemal test in YYYYMMDD format - Q20.a. on 126 form.
RESULTA	131	Result of nontreponemal test - Q20.a. on 126 form. Values: *1=Reactive, 2=Nonreactive, 9=Unknown*
DATEB	132-139	Date of nontreponemal test in YYYYMMDD format - Q20.b. on 126 form.
RESULTB	140	Result of nontreponemal test - Q20.b. on 126 form. Values: *1=Reactive, 2=Nonreactive, 9=Unknown*
DATEC	141-148	Date of nontreponemal test in YYYYMMDD format - Q20.c. on 126 form.
RESULTC	149	Result of nontreponemal test - Q20.c. on 126 form. Values: *1=Reactive, 2=Nonreactive, 9=Unknown*
DATED	150-157	Date of nontreponemal test in YYYYMMDD format - Q20.d. on 126 form.
RESULTD	158	Result of nontreponemal test - Q20.d. on 126 form. Values: *1=Reactive, 2=Nonreactive, 9=Unknown*

TITER	159-162	Titer of nontreponemal test a. – Q20.a. on 126 form. It was Q21 on version 09-1991 126 form. The titers for dates b, c and d are in columns 214-225. *0=weakly reactive*
TREPONEM	163	Did mother have confirmatory treponemal test result (e.g., FTA-ABS or MHATP)? - Q21 on 126 form. Values: *1=Yes, reactive* *2=Yes, nonreactive* *3=No test* *9=Unknown*
LESIONS	164	Did mother have darkfield or direct fluorescent antibody (DFA) exam of lesions at delivery? - Q22 on 126 form. Values: *1=Yes, positive* *2=Yes, negative* *3=No test of lesions* *4=No lesions present* *9=Unknown*
LASTREAT	165	When was mother last treated for syphilis? - Q23 on 126 form. The treatment date is located in columns 226-233. Values: *1=Before pregnancy* *2=During pregnancy* *3=No Treatment* *9=Unknown*
TXADQBEF	166	Before pregnancy, was mother's treatment adequate? - Q24 on 126 form. Values: *1=Yes, adequate* *2=No, inadequate* *9=Unknown*
TXADQDUR	167	During pregnancy, was mother's treatment adequate? - Q25 on 126 form. Values: *1=Yes, adequate* *2=No, inadequate; non-penicillin therapy* *3=No, inadequate; penicillin therapy begun < 30 days before delivery* *4=Unknown*
RESPAPPR	168	Appropriate serologic response? - Q26 on 126 form. Values: *1=Yes, appropriate response with adequate serologic follow-up during pregnancy* *2=Yes, appropriate response but no follow-up serologic titers during pregnancy* *3=No, inappropriate response: evidence of treatment failure or reinfection* *4=No, response was equivocal or could not be determined from available nontreponemal titer information*
VITAL	169	Vital status of child - Q28 on 126 form. Values: *1=Alive* *2=Born alive, then died*

		3=Stillborn *9=Unknown*
DEATHDAT	170-177	Date of death of child in YYYYMMDD format - Q29 on 126 form (Leave blank, if alive).
BIRTHWT	178-181	Birthweight in grams - Q31 on 126 form.
REACSTS	182	Did infant have reactive non-treponemal test for syphilis? - Q33.a. on 126 form. Values: *1=Yes, 2=No, 9=Unknown*
REACDATE	183-190	Date of child's first reactive non-treponemal test for syphilis in YYYYMMDD format – Q33.b. on 126 form.
SIGNSCS	191	Did child have any classic signs of CS? - Q35 on 126 form. Values: *1=Yes, 2=No, asymptomatic child, 9=Unknown*
DARKFLD	192	Did child have a darkfield exam? - Q36 on 126 form. Values: *1=Yes, positive* *2=Yes, negative* *3=No test* *9=Unknown*
DFA	193	Did child have a direct fluorescent antibody test? - This question is no longer on the 126 form and should be left blank. It was Q38 prior to the 06-2000 126 form. Values: *1=Yes, positive* *2=Yes, negative* *3=No test* *9=Unknown*
IGM	194	Did child have an IgM-specific treponemal test? - Q37 on 126 form. Values: *1=Yes, reactive* *2=Yes, nonreactive* *3=No test* *9=Unknown*
XRAYS	195	Did child have long bone x-rays? - Q38 on 126 form. Values: *1=Yes, changes consistent with CS* *2=Yes, no signs of CS* *3=No xrays* *9=Unknown*
CSFVDRL	196	Did child have a CSF-VDRL? – Q39 on 126 form. Values: *1=Yes, reactive* *2=Yes, nonreactive* *3=No test* *9=Unknown*
CSFCOUNT	197	Did child have a CSF cell count or CSF protein test? - Q40 on 126 form. Values: *1=Yes, one or both elevated* *2=Yes, both not elevated*

		3=No test *9=Unknown*
TREATED	198	Was child treated? - Q41 on 126 form. Values: *1=Yes, with Aqueous or Procaine Penicillin for >=10 days* *2=Yes, with Ampicillin followed by Aqueous or Procaine Penicillin for a total of >=10 days* *3=Yes, with Benzathine penicillin x 1* *4=Yes, with other treatment* *5=No treatment* *9=Unknown*
CLASS	199	Case Classification - Q42 on 126 form. Values: *1=Not a case* *2=Confirmed Case (laboratory confirmed identification of T.pallidum, e.g., darkfield or direct fluorescent antibody positive lesions)* *3=Syphilitic stillbirth* *4=Presumptive case (a case identified by the above algorithm, which is not a confirmed case or syphilitic stillbirth)*
ID126	200-206	CDC 73.126 form Case ID number
VERSION	207-213	This information is automatically entered for areas using STD*MIS. Values: *09-1991* *06-2000* *10-2003*
TITERB	214-217	Titer of nontreponemal test b. - Q20.b. *0=weakly reactive*
TITERC	218-221	Titer of nontreponemal test c. - Q20.c. *0=weakly reactive*
TITERD	222-225	Titer of nontreponemal test d. - Q20.d. *0=weakly reactive*
TREATDAT	226-233	Date mother was treated in YYYYMMDD format - Q23 on 126 form.
INFTITER	234-237	Titer of infant's first reactive non-treponemal test for syphilis - Q33c on 126 form.
		NOTE: If multiple races were selected and you entered code 8=Other for Race (column 44), please also select the appropriate race categories that apply in columns 238-244.
AMIND	238	If mother multi-racial, 1 = Yes, 2 = No, otherwise blank.
ASIAN	239	If mother multi-racial, 1 = Yes, 2 = No, otherwise blank.
BLACK	240	If mother multi-racial, 1 = Yes, 2 = No, otherwise blank.

WHITE	241	If mother multi-racial, 1 = Yes, 2 = No, otherwise blank.
NAHAW	242	If mother multi-racial, 1 = Yes, 2 = No, otherwise blank.
RACEOTH	243	If mother multi-racial, 1 = Yes, 2 = No, otherwise blank.
RACEUNK	244	If mother multi-racial, 1 = Yes, 2 = No, otherwise blank.
MCOUNTRY	245-246	Mother's country of residence. Q.6 on 126 form.
REACTREP	247	Did infant have reactive treponemal test? Q.34.a. on 126 form. Values: *1 = Yes* *2 = No* *9 = Unknown*
RTDATE	248-255	Date of infant reactive treponemal test in YYYYMMDD format. Q.34.b. on 126 form.