Congenital Syphilis (CS) Case Investigation and Report Form

OMB #0920-0128

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Justification

1. Circumstances Making the Collection of Information Necessary

The current CS reporting form (**Attachment 3b**) was revised and approved by OMB in 2009 to collect information based on the surveillance case definition. It is being used by all health jurisdictions reporting CS to CDC as part of the National Notifiable Diseases Surveillance.

The Centers for Disease Control and Prevention (CDC) requests a 3-year approval for the revision of the surveillance of congenital syphilis using the "Congenital Syphilis (CS) Case Investigation and Report Form". CDC requests approval for changes to the CS Investigation and Report Form **Attachment 3c.**

For the new approval period, CDC requests elimination of the field "Did the infant/child have an IgM-specific treponemal test?" This data element is no longer required because treponemal IgM technologies, for the purpose of identifying CS in an infant, are highly insensitive. The following fields have been added: "Mothers obstetric history", "Did mother have treponemal test result: If so, when was the test performed?" "What stage of syphilis did mother have?", "Date of Mother's treatment", "What was mother's treatment?" "Congenital Syphilis Case Classification – Presumptive has been replaced with probable," as there is no case definition for presumptive congenital syphilis. "What clinical and what surveillance stage of syphilis did the mother have during pregnancy" Clinical diagnosis can differ from surveillance definitions (e.g., a patient with a chancre but non-reactive RPR will not meet the surveillance definition of "primary syphilis", but will carry that clinical diagnosis and be treated as such). Also, clinical diagnosis will drive treatment choices (e.g., 1 versus 3 doses of 2.4 M units bicillin).

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

Background

Congenital syphilis (CS) is an important sentinel health event that marks potential problems in both prenatal care and syphilis prevention programs. Congenital syphilis (CS) is nearly 100% preventable by early detection and treatment of syphilis in pregnant women before or during pregnancy.

After an 18% increase in the rate of congenital syphilis during 2006-2008, the rate of congenital syphilis decreased during 2009-2010 (from 9.9 to 8.7 cases per 100,000 live births). This decrease in the rate of CS may relate to the decrease in the rate of primary and secondary syphilis occurring among women in recent years.

Past activities: Information collection via a congenital syphilis (CS) investigation report began in 1983. The last revision was 2009. In addition, reporting areas began replacing the hardcopy form with electronic line-listed records transmitted via National Electronic Telecommunications System for Surveillance (NETSS).

Current activities:

Seventeen of the sixty reporting areas (30%) provide CDC with hardcopy congenital syphilis morbidity data. These reporting areas include those that are transitioning to electronic reporting and those currently lacking the technical resources to send data electronically. The remaining 43 (70%) provide electronic data via National Electronic Telecommunications System for Surveillance (NETSS). There has been no change in the last 3 years.

The current focus of CS prevention is 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.

Reducing congenital syphilis is a national objective in the U.S. Department of Health and Human Services report entitled, “Healthy People 2020”.

The CDC continues to collect and report information on congenital syphilis morbidity as part of its ongoing Sexually Transmitted Disease (STD) surveillance efforts. A reporting form for congenital syphilis (CDC Form 73.126) was initiated in 1983 to improve detection, case management, and treatment of congenital syphilis cases. Continued data collection will assist in identifying needs for congenital syphilis prevention efforts nationwide.

Privacy Impact Assessment

Overview of the data collection system

Physicians and local providers collect demographic, risk, and clinical (including laboratory) information from persons diagnosed with notifiable STDs during a clinical encounter or counseling session. In

either electronic or hardcopy form, the providers or laboratories submit the information to health departments as notification for a potential CS case. These notifications are State-mandated disease control efforts to ensure adequate treatment of both mother and infant. Proper case management may require that health jurisdictions capture additional information from the mother's or infant's medical record, or from interviewing the mother. To fulfill the nationally notifiable disease surveillance requirements set forth in the Public Health Service Act, health jurisdictions submit surveillance data to CDC via NETSS or the CS Case Investigation and Report Form. CDC maintains these records indefinitely as part of a national data archive.

Items of Information to be collected

Attachment 3a is a comprehensive list of the congenital syphilis data elements abstracted from medical records and captured on the "Congenital Syphilis (CS) Case Investigation and Report Form". These data elements are divided into 2 tables. Table 1 is the list of the CS data elements received by CDC. These data elements have been proposed by the Council of State and Territorial Epidemiologists (CSTE) for state, local, and territorial health agencies to submit for national notifiable disease surveillance. On this form the mother's race provides an "Other" option. This option is listed as data that is abstracted from the medical record.Table 2 lists data elements on the CS form that are collected by health agencies, but that are NOT transmitted to CDC.

The CS form is a carbonless three-copy form. The three copies are labeled "Copy 1: State Health Department", "Copy 2: CDC", and "Copy 3: Local Health Department". **Attachment 3a** includes all three copies (pages three through five). CDC receives only copy 2. Copy 2 does not include the patient identifier information located in the header of Copy 1 and Copy 3.

"Did the infant/child have an IgM-specific treponemal test?" will be removed because CDC no longer uses this field because treponemal IgM technologies, for the purpose of identifying CS in an infant, are highly insensitive. Gender of the infant will be removed because CDC no longer uses this field and the information is not needed to determine staging of disease. The following fields will be collected: "Mothers obstetric history", "Did mother have treponemal test result: If so, when was the test performed?" "What stage of syphilis did mother have?", "Date of Mother's treatment", "What was mother's treatment?" "What was Mother's HIV Status?" "Congenital Syphilis Case Classification – Presumptive has been replaced with probable," as there is no case definition for presumptive congenital syphilis, "What

clinical and what surveillance stage of syphilis did the mother have during pregnancy". (see **Attachment 3c)** the CS form.

Date of birth and medical information on the diagnosis and treatment of syphilis in the mother are transmitted to CDC on the "Congenital Syphilis (CS) Case Investigation and Report Form". These data elements, considered Information in Identifiable Form (IIF), are associated with a unique case identification number assigned by the state or local health department. CDC does not receive the case identification number or have access to the provider's case report received by the state or local health jurisdictions. No personally identifiable information is associated with date of birth and mother's medical information in the case reports transmitted to CDC. As a result, it is not possible for any individual to be identified based on the information in the case reports received by CDC. The date of birth is necessary to assist in resolving any duplicate records in which the same case identification number is used for two different case reports or a single case is assigned two different identification numbers.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age.

CDC does not have a website for congenital syphilis (CS) information nor website content for children under 13 years of age.

2. Purpose of Use of the Information Collection

CDC uses the congenital syphilis morbidity information to plan and implement interventions, and to evaluate ongoing congenital syphilis prevention efforts. Without the CS morbidity data, information on the distribution of CS by risk behavior group across the United States will be unavailable. As a result, CDC will not be able to make data-driven decisions for national prevention program planning and resource allocation using CS incidence data.

CDC's morbidity reporting for CS assists local and state health departments in improving CS prevention and control efforts. The reporting of selected demographic and risk behavior data on persons infected with notifiable STDs, including syphilis, from state and local STD prevention programs allows CDC to identify cross-jurisdictional, regional, and national STD trends and emerging epidemiological patterns and to guide public health response.
The use and release of the CS morbidity data by CDC are guided by the June 1996 policy, "Data Release Guidelines of the Council of State and

Territorial Epidemiologists (CSTE) for the National Public Health Surveillance System" (NPHSS). These guidelines define the subgroups of the CS morbidity data that can be released **(Attachment 4)**. The CDC policy for data release facilitates the use of national notifiable CS and other STD morbidity data while preserving the confidentiality of the data.

Annually, CDC disseminates a comprehensive summary of the trends in CS and other STD morbidity, by etiology, in the STD surveillance report and syphilis surveillance supplement: http://www.cdc.gov/std/stats10/toc.htm, http://www.cdc.gov/std/Syphilis2010/default.htm.

Privacy Impact Assessment Information

The congenital syphilis (CS) morbidity information collection includes potentially sensitive information. The original report to the local health jurisdictions from the provider includes case-patient identifiers as well as information on diagnosis and treatment of syphilis. In the case report submitted to CDC, the case-patient identifiers are replaced with a case identification number. In NETSS, date of birth is requested as a core data element for all nationally notifiable diseases, including CS. The date of birth from the case report is submitted to CDC to assign age of the patient. This information is needed to assess case management for both maternal prenatal care and care/assessment of the infant. Date of birth also helps in data cleaning activities to distinguish duplicate records and births of multiples. No other personal information that can be used to identify an individual in the CS morbidity surveillance at CDC is linked to date of birth. The proposed collection will have little or no effect on privacy of case-patients.

In order to gain the maximum benefit for existing congenital syphilis prevention and control efforts, CDC will continue to disseminate aggregated CS morbidity data to local and state STD prevention programs, policy makers, academia, and the general public, in the form of MMWR series of publications, including the weekly MMWR, the MMWR Surveillance Summaries, and the annual Summary of Notifiable Diseases, United States. In addition, DSTDP annually publishes a Sexually Transmitted Disease Surveillance report in hardcopy, and on the Internet [http://www.cdc.gov/std/Stats.htm]

3. Use of Improved Information Technology and Burden Reduction

Local data collection methods are not directed or mandated by CDC. However, the majority of state STD prevention and control programs use either STD*MIS (CDC-provided freeware) or a commercial or locally developed information system to collect and manage a wide range of surveillance and programmatic information, including that for CS. Only a subset of the collected data is reported to CDC as part of an STD case report.

Some locally developed information systems do not support electronic reporting of CS data. In addition, the outlying project areas (Guam, Puerto Rico, and Virgin Islands) do not report any notifiable diseases electronically. CDC supports project areas that seek to transition from hardcopy to electronic data transmission by confirming the data quality of electronic submissions prior to cessation of hardcopy reporting. Once the transition occurs, the overall paperwork burden is further reduced.

An estimated ten project areas are expected to continue hardcopy reporting. The current barriers to electronic reporting of CS data include locally-developed systems not designed to capture the additional data required for CS surveillance and local resource constraints. Although procedures vary by state, health departments typically either destroy the forms or maintain the confidentiality of information on paper forms by storing the completed forms in a locked filing cabinet in an access-controlled location.

4. Efforts to Identify Duplication and Use of Similar Information

CDC is the only agency that conducts national surveillance for congenital syphilis through the funded assistance of state and local health departments. CDC has verified through CSTE, state and local STD prevention programs, and the National Coalition of STD Directors, that there is no other nationwide collection of CS-specific morbidity information.

CDC has also confirmed the absence of duplicate information systems in the U.S. through literature searches and communication with other health professionals and other organizations.

5. Impact on Small Business or Other Small Entities

Several states mandate the reporting of STDs by private physicians to report STDs to their local and state health authorities. There is no additional impact on small businesses or other small entities imposed by continuing the CS reporting.

6. Consequences of Collecting the Information Less Frequently

The control of congenital syphilis (and other STDs) depends on timely reporting of CS morbidity data as well as the analysis of these data to detect any unusual patterns that may indicate a CS outbreak.

There are no legal obstacles to reduce the burden.

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

The CS morbidity information collection revision request is consistent with 5 CFR 1320.5(d)(2) except for the frequency of reporting.

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

A 60-day notice to solicit public comments was published in the Federal Register on Tuesday, August 7, 2012, Vol. 77, No. 152, pp. 47072-47073 **(Attachment 2).** No substantive comments were received.

Since the form has not changed materially since 2009, no special consultation has been conducted with persons outside of the CDC. However, CDC staff members maintain ongoing communication with State and local STD program managers, including representatives on the Council of State and Territorial Epidemiologists (CSTE) regarding the use and distribution of congenital syphilis report forms. All State and territorial STD programs that report CS cases via a hardcopy form use the current version of the form.

9. Explanation of Any Payment or Gift to Respondents

No payment or gifts are provided to the 17 State and local health departments that report CS cases to CDC using the Congenital Syphilis (CS) Case Investigation and Report form. The report forms and any technical assistance are provided at no cost to the respondents.

10. Assurance of Confidentiality Provided to Respondents

The CDC Privacy Act Officer reviewed this submission and determined that the Privacy Act does not apply. CDC will receive “date of birth” delinked from other personal identifiers on the Congenital Syphilis (CS) Case Investigation and Report form. All other IIF data are retained by the health departments and are not transmitted to CDC. CDC also does not receive copies of reporting documents submitted to the

health departments by providers or laboratories. The Congenital Syphilis (CS) Case Investigation and Report forms transmitted to CDC include a state-assigned case number and do not include a patient ID.

The reporting of congenital syphilis morbidity is not considered research involving human subjects and is exempted from Regulations for the Protection of Human Subjects (45 CFR 46).

At CDC, paper copies of congenital syphilis morbidity reports arrive without personal identifiers and are secured in locked cabinets with access limited to the CS surveillance officer. The data are entered and maintained on secure servers on the CDC mainframe behind the CDC firewall. Directory-specific user access rights are assigned by a CDC data steward following review of and sign-off on a data use policy that references the CSTE data release guidelines **(Attachment 4)**. Users are given passwords by the data stewards and access is restricted to STD data.

Persons who have access to the CS databases are staff in the Division of STD Prevention (DSTDP)/CDC scientists, researchers, and program managers via a web-based database application called STDNet. DSTDP epidemiologists and program consultants create analytic data files from the electronic CS data in order to monitor trends in CS by demographic and geographic characteristics.

Privacy Impact Assessment Information

A. Data collection and processing procedures described:

Date of birth, delinked from other personal identifiers, will be part of the dataset. Date of birth will be used to determine whether duplicate case identification numbers belong to the same or two different case reports. Each case report represents a single case in congenital syphilis case reporting and is assigned as a unique case identification number by the local, state, or territorial agencies. The case report submitted to CDC does not include personal identifiable elements. Local health jurisdictions maintain the information needed for case follow-up and other disease control interventions.

B. Security of the information addressing relevant technical, physical, and administrative safeguards.

CS Data will be accessible to the project staff and will not be disclosed, unless otherwise compelled by law. The data elements

collected for CS Morbidity Surveillance will follow the data security protocols established by CDC.

As with all STD morbidity data, access to congenital syphilis data is limited even within CDC, by means of technical controls (user identification, passwords, and firewalls), physical controls (guards, identification badges, key cards), and administrative controls (daily file backups, data release guidelines, and data user agreements).

No sensitive identifiable information is maintained at CDC, and CDC does not have access to any personal information maintained by health jurisdictions. CDC does not maintain nor have access to identifiable information that will be filed and retrieved based on the name of an individual.

C. Obtaining respondent consent

Physician or laboratory reporting of notifiable STD conditions to local and state public health systems is mandated by local or state law or regulation. Consent of the patient is not required.

D. Informing respondents about the voluntary or mandatory nature of their responses

State and territorial health departments report notifiable diseases including congenital syphilis to CDC on a voluntary basis according to state and territorial requirements for notifiable disease reporting.

11. Justification for Sensitive Questions

This information collection involves information that might be viewed as sensitive because it includes information on diagnosis and treatment of syphilis and race/ethnicity data. This information is delinked from personal identifiers and is used to help CDC formulate efficient intervention strategies, and evaluate the impact of ongoing control efforts.
CS surveillance data are collected by health jurisdictions to fulfill State-mandated disease control functions. These jurisdictions submit CS surveillance data to CDC in support of nationally notifiable disease surveillance requirements. Consent of the case-patient is not relevant.

12. Estimates of Annualized Burden Hours and Costs

Physicians and other providers submit congenital syphilis case information to local health departments in paper form. For reporting to CDC via hardcopy forms, the congenital syphilis case reports are completed by public health professionals in the local health departments. The total annualized burden estimate for the STD Morbidity Surveillance request is 62 hours. CDC estimates that 17 respondents will spend 20 minutes to process a single congenital syphilis reporting form. Each health jurisdiction will provide an estimated 11 reports a year.

Table 12-A: Estimate of Annualized Burden Hours

Types of Respondent	Form name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Annual Burden (in hours)
State Health Departments	Congenital Syphilis (CS) Case Investigation and Report	10	11	20/60	36
Territorial Health Agencies	Congenital Syphilis (CS) Case Investigation and Report	3	11	20/60	11
City and county health departments	Congenital Syphilis (CS) Case Investigation and Report	4	11	20/60	15
Total		**17**			**62**

B. The cost for state and local health departments to prepare or review and then submit the forms is estimated at $31 per hour and that amount has been used to estimate the annualized cost to the respondents for the “Congenital Syphilis (CS) Case Investigation and Report Form”. These funds are included in the funds provided to the state, local, and territorial health departments to support their participation in STD surveillance activities.

Table 12-B: Estimate of Annualized Cost to Respondents

Types of respondents	Total Burden Hours	Hourly Wage Rate*	Total Respondent Costs**
State Health Departments	36	$31	$1116
Territorial Health	11	$31	

Agencies			$341
City and county health departments	15	$31	$465
Totals	**62**	**$31**	**$1922****

* Hourly wage estimate based on median Epidemiologist (19-1041) hourly wage available at: http://www.bls.gov/oes/2011/may/oes191041.htm.
** Respondents receive federal funds for comprehensive STD prevention services through CDC cooperative agreements.

There are no additional costs to the respondents.

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

There are no costs to respondents.

14. Annualized Cost to the Federal Government

The estimated annualized cost to the Federal Government is **$97,057**. This amount includes the cost of printing the form and the cost of personnel time to review the forms, manually enter data from the form into a database, manage the process to merge entered data with electronically transmitted data, prepare reports for publication, and mail reports.

These data are collected and entered at the state and local level. This data collection activity is funded through broadly defined cooperative agreements between CDC and each state. CDC does not separately fund or contract for data collection activities. The personnel costs associated with the federal employees involved in oversight and/or data analysis include costs for a GS-12, step 5 IT Specialist (0.25 time), GS-13, step 5 IT Specialist (0.25 time), and a GS-14, step 5 Health Scientist (0.25 time). The CDC personnel provide technical support and data management, analysis, and dissemination support for this information collection activity.

The current combined cost for this part-time effort is estimated at $97,057. The annual cost is summarized in Exhibit A.14.

Table 14-A: Estimate of Annualized Cost to Federal Government

Expense type	Explanation of expense	Annual Costs ($)
Direct Costs	GS-2210-12, IT Specialist, 0.25 FTE	$19,589

Expense type	Explanation of expense	Annual Costs ($)
	GS-2210-13, IT Specialist, 0.25 FTE	$23,294
	GS-601-14, Health Scientist, 0.25 FTE	$27,526
	Office supplies and equipment	$200
	Printing of surveillance reports	$3,000
Cooperative Agreements	Health Jurisdictions using the hardcopy reporting form	1,789
Employee Benefits	33% of FTE and cooperative agreement wages	$21,659
	Total estimated annualized cost to the government	**$97,057**

* Included as cost to respondent in Table 12.B.
Salary estimates were obtained from OPM salary scale (http://www.opm.gov/ica/11tables/html/gs.asp).

15. Explanation for Program Changes or Adjustments

CDC requests elimination of the field "Did the infant/child have an IgM-specific treponemal test?" This data element is no longer required because treponemal IgM technologies, for the purpose of identifying CS in an infant, are highly insensitive. The following fields have been added to provide clarification and analysis of case classification: "Mothers obstetric history", "Did mother have treponemal test result: If so, when was the test performed?" "What stage of syphilis did mother have?", "Date of Mother's treatment", "What was mother's treatment?" "Congenital Syphilis Case Classification – Presumptive has been replaced with probable," as there is no case definition for presumptive congenital syphilis.

16. Plans for Tabulation and Publication and Project Time Schedule

Data provided to CDC will be used for multiple publications that inform the public, health professionals, health departments, STD control programs, health administrators and others about the status and trends of CS in the U.S. On an annual basis, CDC publishes the national *Sexually Transmitted Disease Surveillance Report* using analyses from this data collection (http://www.cdc.gov/std/stats).

Exhibit A.16: Project Time Schedule

Activity	Time Schedule
Notice of form renewal sent to respondents	1-2 months after OMB approval
Print and distribute the renewed data collection form to state and local health departments	2-4 months after OMB approval
Initiate use of renewed form	2013 (6 months after OMB approval)
Validation	Ongoing
Data analyses and Publication	Ongoing
Dissemination of results	Ongoing 6-36 months after OMB approval

The dissemination of nationally surveillance information of congenital syphilis and other STDs, is accomplished through the *MMWR* series of publications, including the weekly *MMWR*, the *MMWR* Surveillance Summaries, the Recommendations and Reports, and the annual Summary of Notifiable Diseases, United States. Since STD Morbidity data are disseminated each week, data validation and analysis occurs each week throughout the year.

Additionally, CDC publishes an annual syphilis-specific surveillance summary and supplements in hard copy on CD-ROM and on the Internet (http://www.cdc.gov/ std/Stats.htm). The annual STD surveillance summary is usually published in paper-copy and disseminated and posted to the internet within 11 months following the end of the calendar year (i.e., the 2010 annual STD surveillance summary was distributed in November 2011).

Annual summaries will be distributed to persons and agencies included in the CDC mailing list and list provided by the Superintendent of Documents. These summaries are for use by local, state, and federal health agencies, schools of medicine and public health, communications media, and other agencies or persons interested in notifiable disease surveillance and epidemiology in the United States.

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

CDC is not requesting an exemption to the display of the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act (PRA) Submissions 5CFR 1320.3(h)(1)-(10)

There are no exceptions.