STD Surveillance Network (SSuN)

Supporting Statement
Part A

OMB# 0920-0842

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Title

Table of Contents

Attachment 2 60 day Federal Register notice
Attachment 3a Clinic-based surveillance: data elements
Attachment 3b Population based surveillance: data elements
Attachment 4 List of Collaborators
Attachment 5 IRB exemption—Determination of non-research
Attachment 6 List of Presentations and Publications

Supporting Statement

Section
A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests an OMB revision for a data collection system called the STD Surveillance Network (SSuN), OMB# 0920-0842. Current OMB approval expires on January 31st, 2013 and our SSuN cooperative agreement will end September 29, 2013. The patient interview questionnaire was revised to include 4 additional questions (revisions are outlined in Attachment 3B). Aside from these changes, the project activities and methods will remain the same as in the previously approved information collection request. The burden has not substantially changed from the burden shown in the current inventory.

The additional four questions will be added:

(1) At the time you were tested for gonorrhea, what was the main reason that you sought care from the provider who tested you?,

(2) Do you have any kind of healthcare coverage or insurance?,

(3) Is your insurance a private health insurance or publically funded health insurance, such as Medicaid?, and

(4) Did you have to pay a co-pay when you were diagnosed with gonorrhea?

These 4 questions were added 1) to allow state and local STD programs can monitor patients characteristics of gonorrhea cases

diagnosed in the county (particularly those diagnosed in public clinics) in our rapidly changing health care environment, and 2) to help strengthen arguments against closing additional public clinics both now and as the health care insurance and service delivery markets change in coming years. This revision will minimally affect the burden per respondent. The average burden per response has increased from 7 to 8 minutes; thereby increasing the total burden hours by 48 hours to 480.

SSuN has proved to be a useful adjunct to routine STD surveillance in the United States through its enhanced population-based gonorrhea and STD clinic-based surveillance activities. From a national perspective, SSuN has been a robust platform for identification of STD trends, monitoring STD epidemiology and for evaluation of the effectiveness of public health interventions. It has also provided us with the ability to evaluate integrated data for STD patients, including information on HIV testing and status, as well as provide a platform across the division of STD prevention. Benefits of SSuN participation locally include improved capacity to conduct local data analysis, enhanced comparability of data with other clinical programs, opportunities to collaborate with colleagues who have similar interests, the ratification of contributing to a program of national importance, and improved data for STD control programs.

In addition to national and local uses of SSuN, there have been a number of presentations and manuscripts that have resulted from data analyses and/or activities within SSuN (Attachment 6) including: HIV testing among patients with gonorrhea, HIV testing among men who have sex with men in STD clinics, monitoring genital warts in STD clinics, current gonorrhea treatment practices in SSuN counties and how they varied by provider type and geographic region, In vitro resistance of *Trichomonas vaginalis* among women attending STD clinics, Changes in Fluoroquinolone Use for Gonorrhea Following Publication of Revised Treatment Guidelines, and a survey of HPV Vaccine Implementation in STD Clinics.

Background

The Sexually Transmitted Disease (STD) surveillance network, SSuN, is an active network comprised of 12 surveillance sites around the United States. The purpose of SSuN is to improve the capacity of national, state, and local STD programs to detect, monitor, and respond rapidly to trends in STDs through active surveillance collection, reporting, analysis, visualization (e.g., mapping) and interpretation of disease information. A pilot project that took place from 2006 to 2008 (Reijtmeijer et al, Here Comes the SSuN: Early Experiences with the STD Surveillance Network, *Public Health Reports* 2009; 124(Suppl 2)72-77.) informed the design of the structure and functioning of the

currently submitted SSuN project. The pilot project was helpful in establishing the sample size estimations that are used in the project, the standardization of the way in which questions are asked of patients, and for demonstrating the need for greater geographic diversity. OMB clearance was not sought for this pilot project because reporting sites (public health departments) instead of people were mistakenly counted as respondents. There were only 6 sites that were reporting data to CDC for the clinic portion of the project; however, more than 10 subjects were involved with the population portion of the pilot. OMB approval was sought when this error was identified and no data was collected or transmitted for the SSuN project until the beginning of 2010, following OMB approval (OMB# 0920-0842).

SSuN helps fill gaps that our current passive STD surveillance systems are not able to address, such as collecting information on risk behaviors with STDs or detect persons co-infected with STD and HIV.

The national passive STD surveillance system administered through the National Electronic telecommunication Surveillance System (NETSS)(0920-0819) includes a limited number of demographic data elements (e.g. age, race/ethnicity, sex, and county) collected from all states for a limited number of sexually transmitted diseases. The Gonococcal Isolate Surveillance Project (GISP) (OMB

No. 0920-0307) enhances the overall surveillance for gonorrhea susceptibility patterns and trends in the U.S. GISP is not designed to understand the clinical and behavioral characteristics of a broader population of patients with gonorrhea outside the STD clinic setting, nor does it inform CDC of any other sexually transmitted diseases. While congenital syphilis is a critical problem when it occurs, it accounts for only a small percentage of all syphilis cases in the U.S., and case information gathered through the Congenital Syphilis Case Investigation and Report Form (OMB# 0920-0128) will not inform CDC about the broader population of patients with syphilis in the U.S. The Congenital Syphilis Case Investigation and Report Form is used by several U.S. reporting areas as a mechanism for providing CDC with morbidity data on congenital infections only.

National-level data on HIV-STD co-infection in the U.S. from providers other than sexually transmitted disease (STD) clinics is largely unavailable for all sexually transmitted infections including *Chlamydia trachomatis, Trichomonas vaginalis,* primary and secondary syphilis, herpes, and others.

SSuN addresses needs of the Division of STD Prevention, (DSTDP)'s seven strategic goals outlined in the division's Strategic Plan 2008-2013: (1) Prevent STI-related cancers, (2) Prevent STI-

related HIV transmission, (3) Strengthen STD prevention capacity and infrastructure, (4) Reduce STD health disparities across and within communities and populations, (5) Strengthen STD prevention capacity and infrastructure, (6) Reduce STD health disparities across and within communities and populations, and (7) Address effects of social and economic determinants and costs of STDs and associated sequelae among specific populations.

Stakeholders for data collected from the active surveillance programs funded by SSuN include STD program managers and other public health personnel, policy makers, health care providers, and the general population.

This activity is authorized under Section 301 [241] (a) of the Public Health Service Act (**Attachment 1**) and does not respond to any specific Congressional mandates.

Privacy Impact Assessment

Overview of the data collection system

SSuN will continue to utilize two distinct surveillance strategies to collect information. The first is clinic-based STD surveillance which will abstract data from existing electronic medical records for all patient visits to participating STD clinics during the 3 year OMB time period in a standardized way

from each of the 12 SSuN sentinel surveillance sites. The second strategy is population-based STD surveillance where interviews will be conducted, using locally designed templates, on 240 persons per site who are randomly selected out of the total number of gonorrhea case reports received by each state or jurisdiction.

Items of Information to be collected

(Attachments 3a and 3b) are comprehensive lists of all items of information to be collected by the CDC for SSuN clinic-based and population-based county surveillance activities.

For clinic-based STD surveillance, the specified data elements will be abstracted on a quarterly basis from existing electronic medical records for all patient visits to participating clinics (**Attachment 3a**). Data in the electronic medical record may have been collected at time of registration, during the clinic encounter, or through laboratory testing. SSuN does not require modification of underlying electronic medical record systems for participation; each clinic's electronic medical record conforms to local data collection systems and needs.

SSuN sites will abstract data elements listed in **Attachment 3a** from the clinic's electronic medical record for transmission to CDC. These data elements that have been collaboratively defined

and agreed upon by SSuN collaborators (both CDC and site participants) will be sent to CDC. Core data elements are those items of information that should be transmitted for all patient visits every quarter. Core data elements include basic demographic, behavioral, and clinical information collaboratively identified as being necessary for routine SSuN monitoring activities (**Attachment 3a**). In addition, SSuN sites have collaboratively defined a set of standardized data elements that will only be sent to CDC when a specific analysis has been identified as being of public health importance. Both the core and standardized data elements will be transmitted to CDC in the collaboratively-defined, common SSuN format.

All SSuN sites will also be conducting population-based STD surveillance in which a random sample of patients reported with gonorrhea in the counties participating in SSuN (n=115) are contacted for interview by phone or in person. Each site is expected to obtain a common set of items of information on 240 patients reported with gonorrhea each year. Items of information to be elicited from these patients include demographic, risk behavior, and clinical information related to infection with gonorrhea. The complete list of items is listed in (**Attachment 3b)**. Although SSuN collaborators (both CDC and participating sites) have agreed upon the formats in which the information will be transmitted to CDC, each site has developed or adapted site-

specific data instruments to conform to public health program needs.

For both clinic-based and population-based STD surveillance activities, data will be collected and edit-checked on a quarterly basis by the participating SSuN state or local health department prior to transmission to CDC. Although information in identifiable form (IIF) is collected by these clinics as a routine part of providing clinical care, all potentially identifiable information (e.g., name, date of birth, medical record number, social security number) will be removed prior to transmission to CDC; thus, CDC will receive no sensitive information that can be linked back to any individual. All SSuN records will contain a non-identifiable unique identification number (for each patient) as well as a unique event identification number (for each visit).

CDC will provide edit check statistical algorithms programmed in the Statistical Analysis System (SAS), to assist with local data cleaning. All data will be transmitted to CDC as a SAS file in the collaboratively defined SSuN format, encrypted using SEAL or PGP, via the Secure Data Network (SDN). Sites may use the Secure File Transfer Protocol (FTP) established by CDC to transmit non-

data information. All data will be transmitted to CDC through a single agreed-upon point of contact from each SSuN site.

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

SSuN does not have a website and SSuN data will not be posted on the internet.

2. Purpose of Use of the Information Collection

SSuN will be an active surveillance system for dual infections of HIV and STDs. Clinical and behavioral data on persons infected with notifiable STDs are essential elements to guide local interventions to prevent STDs and their complications.

CDC envisions that the 12 sentinel sites will continue to serve with enhanced capacity for applied epidemiology and timely response. Associating STDs with clinical, demographic, and behavioral information at the local level reveals ‘hot-spots’ of health disparities and enables prevention strategies that are tailored to specific populations.

Privacy Impact Assessment Information

SSuN will collect sensitive information on sexual and drug-using behaviors associated with the case-patient identified only as a case identification number. Participating clinics collect patient

information in identifiable form (IIF) as a routine part of providing clinical care. This information will continue to exist locally and never be accessed directly by CDC. No IIF will be included in the data sets transmitted to CDC. The proposed data collection will have no effect on the respondent's privacy. Social Security numbers will never be collected.

A unique project identification number will be assigned to each case. All IIF (e.g., name, date of birth, local medical record number) will be stripped and de-linked before data are sent to CDC via CDC's Secure Data Network (SDN) as an encrypted file. The key to link data will only be available at the local level. At CDC, SSuN data will be maintained on secure servers behind the CDC firewall. Password-protected access will be required and directory-specific user access rights will be assigned by a CDC data steward. Restricted access to STD data is provided to DSTDP/CDC scientists, researchers, and program managers. CDC will work with collaborating sites to design a plan to destroy site-specific SSuN data files after data analyses have been completed.

3. Use of Improved Information Technology and Burden Reduction

Clinic-based STD Surveillance

Data will be abstracted from routine, pre-existing electronic and/or hard-copy STD clinic medical records and sent to CDC in a common SAS format. STD clinic data to be transmitted to CDC for SSuN will be periodically edited by trained personnel using a CDC-designed edit check program. Data will be uploaded on a quarterly basis by trained data managers at collaborating sites to the SDN. Data will be downloaded from the SDN, stored, and maintained at CDC by a data manager in the Statistics and Data Management Branch of the National Center for HIV, Hepatitis, STD, and TB Prevention. Completeness of reporting and the quality of data submitted will be monitored by CDC on at least a quarterly basis. Site visits, regular communication with CDC, and data quality checks will provide opportunity for evaluation and troubleshooting of these processes.

Population-based STD Surveillance

Results of interviews will either be entered directly into a Microsoft Access database during the interview or will be transcribed from interview notes into the Microsoft Access database, depending on local protocols. Interview notes will remain protected to the extent permitted by law. As with clinic-based STD surveillance, data will be periodically edited by trained personnel using a CDC-designed edit check program. Data will be uploaded by trained data managers at collaborating sites

to the SDN on a quarterly basis. Data will be downloaded from the SDN, stored, and maintained at CDC by a data manager in the Statistics and Data Management Branch of the National Center for HIV, Hepatitis, STD, and TB Prevention. Completeness of reporting and the quality of data submitted will be monitored by CDC on a quarterly basis. Site visits, regular communication with CDC, and data quality checks will provide opportunity for evaluation and troubleshooting of these processes.

4. Efforts to Identify the Duplication and Use of Similar Information

CDC is the only agency that conducts national STD surveillance through the funded assistance of state and local health departments. There is no known federal Department or Agency which describes the national and regional distribution of STD morbidity by clinical exam findings, nor is this information available from other sources within our Department. CDC has also verified through the Council of State and Territorial Epidemiologists (CSTE), state and local STD prevention programs and, the National Coalition of STD Directors, that there is no other nationwide collection of STD-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 organizations. Program

reviews were conducted to identify potential areas of duplication; however, none were found.

The Program Evaluation and Monitoring System (PEMS) of the Division of HIV/AIDS Prevention collects HIV-related information at STD clinics using their standardized case report form. However, the PEMS form collects only HIV testing and counseling information and not STD information.

STD morbidity surveillance does collect demographic, clinical, and laboratory data but is a passive surveillance system and does not combine clinical findings data, drug use data, and random population-based sampling of gonorrhea patients as SSuN does.

5. Impact on Small Business or Other Small Entities

No small businesses will be involved in this data collection.

6. Consequences of Collecting the Information less Frequently

STD control is dependent upon the rapid identification of changes in disease transmission. SSuN data will be reported to the CDC on a quarterly basis which is required to allow for the early detection of potential STD outbreaks. Earlier detection should support earlier implementation of prevention and control efforts resulting in prevention of additional STD transmission. If these data are not available, CDC, state, and local health departments will not have the necessary tools to make data-based decisions

regarding national prevention program planning and resource allocation.

Information for the SSuN project will be collected on a quarterly basis in order to balance the need for timely information and the need to minimize burden on collaborating clinics and departments of health.

7. Special Circumstances relating to the Guidelines of 5 CFR1320.5

This request fully complies with the guidelines of 5CFR 1320.5.

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

A 60-day Federal Register Notice was published on 4/30/2012 in Vol.77, No 83 and Pages 25482-25483 of the Federal Register. No substantive comments have been received (See Attachment 2 for a copy of the Federal Register notice). From September 2008 to March 2009, weekly SSuN collaborative conference calls were held with participating collaborators from all SSuN sites to determine the availability of data, reasonable frequency of data collection, the clarity of instructions and record keeping, and data elements to be recorded, disclosed, and reported. Beginning in the spring of 2010, following OMB approval, SSuN collaborators began sending quarterly data transmission for both the clinic and

population component. We have had two annual PI meetings (December 2010 and December 2011) in Atlanta, GA which have included discussions on the frequency of data transmissions and the data elements to be collected, and reported given the importance of minimizing the burden on collaborating clinics and departments of health. All sites have agreed that quarterly data transmission is acceptable as well as continuing the collection of clinic and population data elements (**Attachments 3a and 3b**).

A list of collaborators can be found in (**Attachment 4**).

9. Explanation of Any Payment or Gift to Respondents

No payments or gifts are provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

Our center, the National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP) has decided that the Privacy Act does not apply to this request. To protect the privacy of persons attending STD clinics and reported with STDs, state and local surveillance program staff shall not send any IIF to CDC. The census tract of the patient’s residence will be used to identify health disparities in treatment, clinical outcomes and access to care based on distance from resident census tract. SSuN data will be accessible only to the 12 sentinel sites and CDC staff. No public use data sets are envisioned. Census tract data may be used to link SSuN data to US census data and other complementary

data sources, and any resultant datasets will also be stored on a secure server with restricted access.

CDC will receive a SSuN site-assigned case number that does not include any IIF. Respondents will be STD clinic patients, and the unique Case ID assigned by the State is not a number that in and of itself can lead to the identification of an individual.

Clinic-based STD surveillance

All SSuN participating sites are public health departments, covered entities under HIPAA regulation: (HIPAA Privacy Rule, Disclosures for Public Health Activities, 45 CFR 164.512 (b)). Data sent to CDC will contain no personal identifiers such as name, social security number, date of birth, street address, or medical record number.

Population-based STD surveillance

State and/or local health departments will contact individuals for interviews. CDC will not have access to IIF or conduct any interviews with patients. Verbal consent will be obtained prior to the administration of the telephone survey. Individuals being contacted for interviews will offer verbal consent over the phone or in person prior to the administration of the survey.

The NCHHSTP Associate Director of Science has determined that this project is not research and does not involve human subjects.

Privacy Impact Assessment Information

This project is not subject to the Privacy Act. The state or local health department will encrypt data prior to transmission using either Software Encryption Algorithm (SEAL) or Pretty Good Privacy (PGP, data encryption software). Sites will send encrypted SSuN data to CDC through the SDN. CDC agrees to accept and securely store these data at headquarters in Atlanta. SSuN data will not be integrated into NETSS datasets by CDC, but will be stored separately on a secure server with restricted access.

The Division of STD Prevention, Statistics and Data Management Branch, is charged with the responsibility of maintaining the privacy, security, and scientific integrity of all SSuN databases. The Project Data Managers will be designated as custodians of the SSuN data files, and will be responsible for observance of all conditions of use, and for establishment and maintenance of security arrangements to prevent unauthorized use. Access to the data shall be limited to key members of the Division of STD Prevention who are integral officers and collaborators of the study in the performance of their assigned duties. The SSuN Project Officers will be responsible for granting access to SSuN data by other CDC staff in the Division

of STD Prevention as needed. The SSuN Principal Collaborators will be promptly notified of any CDC personnel changes that affect access to the data for this project. All CDC staff with data access have completed, and will remain current with, the annual Health and Human Services Information Security Awareness Training. A record of the completion of security training for all CDC staff is maintained by the CDC Information Technology Services Office (ITSO).

CDC may retain SSuN data as long as the data are protected as described herein. CDC will annually review the need for the data with SSuN Principal Collaborators and shall destroy all copies of the data if it is determined that no further analysis will be conducted.

11. Justification for Sensitive Questions

Sensitive information elements reported to CDC as part of the SSuN study are limited to sexual and drug-using behaviors associated with the STD case report (**Attachment 3b**). Sexual and drug-use behaviors impact STD distribution and epidemiology. These sensitive elements are essential to better understand the sexual practices that increase the risk of transmission or acquisition of the STDs. This information will help CDC formulate more efficient intervention strategies and evaluate the impact of

ongoing control efforts. For clinic-based STD surveillance, these questions will be asked as part of routine health care interviews for patients seeking health care. For population-based STD surveillance, these questions will be asked as part of the follow-up interview with patients identified as having gonorrhea.

In the U.S., racial and ethnic minorities are disproportionately affected by STDs and HIV, and one of CDC's Division of STD Prevention's major goals is to reduce STD health disparities across and within populations and communities. It is essential to collect the race and ethnicity of each respondent in order to provide useful information to guide interventions to reduce health disparities from STDs and their complications.

12. Estimates of Annualized Burden Hours and Costs.

The respondents for the clinic-based portion of the SSuN project are the 12 SSuN collaborating state or local health departments (=sites (Exhibit B.1.A)) There are a total of 42 STD clinics that report to the 12 health jurisdictions. Each health department will abstract line-listed clinic data on all patient visits entered into their STD clinic database. On a quarterly basis, the 12 collaborating sites will consolidate the data for the previous quarter, encrypt and transmit the dataset to CDC via the SDN.

The respondents for the population-based portion of the SSuN project are members of the general public identified by state or municipal health departments as having a gonorrhea case report. In 2011 there were 62,711 such case reports (Exhibit B.1.B). Each of the 12 collaborating SSuN sites will interview 240 people who have a gonorrhea case report per year for a total of 2880 persons with STD case reports interviewed by all 12 sites.

Exhibit A.12.A

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
SSuN site	None	12	4	2	96
Gonorrhea Case	None	2880	1	8/60	384
Total					480

B. Annualized cost to respondents for the burden hours is provided in Exhibit A.12.B for both the STD Clinic and the population-based surveillance. The hourly wage rate for Clinic portion is based on the average rate reported by the US Office of Personnel Management, 2011 General Schedule (GS) Locality Pay Tables (http://www.opm.gov/oca/11tables/indexGS.asp). We estimated the hourly wage for cases of gonorrhea to be minimum wage ($7.25/hour) as outlined by the US Department of Labor http://www.dol.gov/dol/topic/wages).

Exhibit A.12.B: Estimated Annualized Burden Costs

Type of Respondent	Total Burden hours	Hourly Wage Rate	Total Respondent Cost
SSuN site	96	$18.00	$1,728.00
Gonorrhea Case	384	$7.25	$2,784.00
Total	**480**		**$4,512.00**

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

There are no costs to respondents other than their time.

14. Annualized Cost to the Federal Government

The cost of the project for the 5 years is estimated to be $10,222,920 or $2,044,584 annually. The annual cost is summarized in Exhibit A.14.

Exhibit A.14: Estimates of Annualized Costs to the Federal Government.

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC Project Officer (GS-13, 1.0 FTE)	$ 86,000
	CDC Co-Project Officer (GS-14, 1.0 FTE)	$ 101,000
	CDC Medical Epidemiologist (GS-13, .25 FTE)	$21,500
	CDC Medical Epidemiologist (GS-13, .25 FTE)	$21,500
	CDC Computer Programmer (GS-13, 0.25)	$27,000
	CDC Data Management (GS-12, .6 FTE)	$49,000
Operational	Travel (site visits)	$10,000

	Meeting expenses	$5,000
	Subtotal, Direct Costs to the Government	$321,000
Contractor and Other Expenses	Public Health Analyst I (contractor, .5 FTE)	$35,000
	Alabama Site Cost	$150,000
	Baltimore Site Cost	$150,000
	Chicago Site Cost	$122,287
	Colorado Site Cost	$149,000
	Connecticut Site Cost	$150,000
	Los Angeles Site Cost	$150,000
	Louisiana Site Cost	$121,000
	New York City Site Cost	$150,000
	Philadelphia Site Cost	$148,990
	San Francisco Site Cost	$150,000
	Virginia Site Cost	$120,000
	Washington Site Cost	$127,307
	Subtotal, Contracted Services	$1,723,584
	TOTAL COST TO THE GOVERNMENT	$2,044,584

Salary estimates were obtained from *http://www.opm.gov/oca/12tables/pdf/ATL.pdf*

15. Explanation for Program Changes or Adjustments

The burden in this revision has increased slightly. The following revisions were made to the OMB approved project 0920-0842.

- Four additional questions were added to the standard interview questionnaire. These questions are outlined on page 4 and are included in Attachment 3B.

- The average burden per response has increased to 8 minutes compared to the previously approved information collection time of 7 minutes; thereby increasing the total burden hours by 48 hours to 480.

16. Plans for Tabulation and Publication and Project Time Schedule

Exhibit 16A: Project Time Schedule

Data will be collected in 3-month cycles; clearance is requested for 3 years. The following is a brief overview of the SSuN timeline.

Activity	Time Schedule
Clinic data transmission	4 months after OMB approval
Data management	5 months after OMB approval
Analysis	5-6 months after OMB approval
Publication of quarterly report	6 months after OMB approval
Interview patients (population-based)	1-3 months after OMB approval
Population data transmission	4 months after OMB approval
Analysis	5-6 months after OMB approval
Publication of quarterly report	6 months after OMB approval

The processes of collection and analysis will continue for the duration of the project, and the development and distribution of data reports will be repeated on a quarterly basis throughout the duration of the project.

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

No paper-based data collection form supports the collection of the STD morbidity case report variables. Collaborating partners abstract relevant data from their own information systems into the record format for reporting to CDC. Therefore, there is no physical form on which to display an OMB expiration date and no such exception is requested.

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

There are no exceptions to the certification.