ASSESSING THE INFRASTRUCTURE FOR PUBLIC STD PREVENTION SERVICES

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SUPPORTING STATEMENT A

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Submitted by:
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List of Attachments

1. Authorizing Legislation
2. 60-Day FRN
   2a. Public Comments
3. LHD Survey – Word Version
4. SHD Survey – Word Version
5. LHD Survey - Web Screen Shots
6. SHD Survey – Web Screen Shots
7. Definitions for Survey Terms
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Goal of the study: The primary goal of this study is to examine STD preventive and clinical services provided by local and state health departments two times over a 3 year period.

Intended use of the resulting data: Resulting data will be used to help CDC assess the delivery of timely public STD preventive and clinical services to reduce the number of newly acquired STDs and prevent STD-related sequelae.

Methods to be used to collect data: Web surveys will be sent to a sample of 668 local health departments and all 50 state health departments. Multiple reminders will be sent to non-responders in order to reach the target of 334 completed local health department and 44 completed state health department surveys. This data collection will be then be repeated in three years.

How data will be analyzed: Data will be weighted to generate estimates for all local health departments. Data will be analyzed and summarized using quantitative statistical methods that allow comparisons across time.

Justification

A.1 Circumstances Making the Collection of Information Necessary

The Division of Sexually Transmitted Diseases Prevention (DSTDP) at the Centers for Disease Control and Prevention (CDC) and the U.S. Department of Health and Human Services (USDHHS) is seeking a 3-year approval from the Office of Management and Budget (OMB) to conduct "Assessing the Infrastructure for Public STD prevention Services" (hereafter STD Infrastructure Assessment). CDC's authority to collect information for the STD Infrastructure Assessment is provided by Section 301 of the Public Health Service Act (42 U.S.C. 241) [280-1a] (**Attachment 1**). The primary goal of this study is to examine STD preventive and clinical services provided by local and state health departments two times over a 3 year period. Resulting data will be used to help CDC assess the delivery of timely public STD preventive and clinical services to reduce the number of newly acquired STDs and prevent STD-related sequelae.

Each year, 19.7 million sexually transmitted diseases (STDs) occur in the U.S.[1]-[2] The public health burden of STDs is compounded by their economic impact. In 2010, an estimated $15.6 billion in direct medical costs were attributed to STDs.[3] Undiagnosed and untreated STDs can lead to serious long-term health consequences, especially for women. For example, every year, about 24,000 women become infertile as a result of undiagnosed and untreated STDs.[4]

A significant percentage of reported cases of STDs are diagnosed in publicly funded clinics, such as STD clinics.[1] Specifically, past research has shown that a substantial proportion of HIV (10% or more), primary and secondary syphilis (14%-48%), gonorrhea (13%-41%), and chlamydia (6%-28%) are diagnosed in public STD clinics.[5] Public clinics often serve un- or under-insured populations. Because a continued role for STD clinics is likely to exist as a safety net while the US healthcare market evolves, understanding the current level of publicly funded STD services, funding, and staffing levels is important. A 2013 national survey of local health departments found gaps and reductions in public STD services, including in clinical services that are important to reduce disease transmission.[6] The study also found that STD programs in local and state health departments often provide HIV services such as HIV field testing of STD contacts and surveillance activities.[7] State and local health departments (SHD and

LHD respectively) also engage in other important STD prevention activities such as partner services and surveillance.

The mission of the DSTDP is "to provide national leadership, research, policy development, and scientific information to help people live safer, healthier lives by the prevention of STDs and their complications."[8] A major component of this objective is helping state and local health authorities delivering timely STD preventive and clinical services to reduce the number of newly acquired STDs and prevent STD-related sequelae. This assessment would allow DSTDP to periodically examine STD preventive and clinical services provided by LHDs and SHDs. This would allow us to assess the full range of publicly funded activities relevant for STD prevention. DSTDP will collect data two times over a three-year period.

A.2 Purpose and Use of the Information Collection

The purpose of this information collection is to periodically conduct a representative assessment of local and state health departments that would allow DSTDP to examine publicly funded STD prevention services over time (i.e., every 3 years). This will help inform decision makers and other stakeholders and will help to provide trends data to understand changes in STD prevention services. The information about services that are currently provided is particularly useful to characterize the role that STD clinics are currently serving in meeting their jurisdictions' health care needs. Results from the data collection will also be disseminated via reports and peer-reviewed journal articles prepared by CDC and the National Association of County and City Health Officials (NACCHO).

Given the varying roles and functions that LHDs and SHDs play in STD prevention and public health, this information collection will include two surveys: one for LHDs (**Attachment 3**) and one for SHDs (**Attachment 4**). The surveys overlap when appropriate and contain sections on STD program structure, public STD clinical services (LHD only), STD partner services, other STD prevention services such as surveillance and health promotion (SHD only), and STD program workforce and impact of budget cuts on STD services.

A.3 Use of Improved Information Technology and Burden Reduction

Data will be collected by NACCHO via web-based surveys using the Qualtrics online data collection platform. This online platform will allow respondents to complete and submit their responses electronically using web surveys (**Attachments 5 and 6**). This method was chosen to reduce the overall burden on respondents. The survey data collection was designed to collect the minimum information necessary for the purposes of this project. Although STD programs may perform countless activities, data collection is limited to 36 items for LHDs and 33 for SHDs and is formatted in a manner to enable respondents to rapidly click on buttons (where possible) to advance through the data collection. Skip patterns, presented at the beginning and throughout the survey as appropriate, are enabled to minimize the likelihood of respondents being presented with irrelevant questions. Additionally, Qualtrics provides the ability to create "hover boxes" that show definitions for any terms that may not be readily understandable to the respondent (**Attachment 7**).

Qualtrics online data collection platform uses encryption for data transmission. Once the data collection closes, the data will be accessed by staff at NACCHO, encrypted, and transmitted electronically to CDC.

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

CDC/DSTDP conducts ongoing searches of all major health-related electronic databases, reviews related literature, consults with key external partners and other experts, and maintains continuing communications with Federal agencies with related missions. NACCHO does collect data from

members periodically, but does not include questions on its data collection that provide the level of detail included in this information collection effort. Questions are limited to whether STD screening or treatment are provided (yes/no), with no further details.[9] The only data collection of a similar scope and population was our baseline data collection in 2013.[6,7] It was successful in helping DSTDP to understand the range and scope of STD activities in LHDs and SHDs.

A.5 Impact on Small Businesses or Other Small Entities

No small businesses will be involved in data collection; therefore, there will be no impact on small businesses or other small entities.

A.6 Consequences of Collecting the Information Less frequently

The activities involve two collections of data with the second data collection occurring three years after the first. Each collection of data will span approximately 2 months. Estimated annual burden hours for each response should not significantly change given that the survey and sampling methodology will remain the same for each collection of data.

Not collecting this information would hinder DSTDP's the ability to: (1) assess and understand public STD preventive and clinical services in a changing healthcare environment and (2) help CDC prioritize STD prevention activities.

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

No special circumstances require the collection to be conducted in a manner inconsistent with the guidelines in 5 CFR 1320.6.

A.8 Comments in Response to the FRN and Efforts to Consult Outside the Agency

A 60-Day Federal Register Notice was published in the *Federal Register* on March 2, 2017, volume 82, number 40, pp. 12357 (see Attachment 2 - 60-Day FRN). 5 public comments were received (see **Attachment 2a** – Public Comments). No CDC responses were sent because commenters did not provide contact information.

CDC is partnering with the National Association of County and City Health Officials (NACCHO) for this information collection. Both organizations including DSTDP subject matter experts (SMEs) had significant input into the initial and/or revised data collection instruments. Subject matter experts included: Thomas Gift, PhD, DSTDP who has over two decades of experience in health services and economic research (Branch Chief, DSTDP, CDC, 404-639-1831, tgift@cdc.gov) and Elizabeth Torrone, PhD, DSTDP who has significant experience with surveillance and related activities (Team Lead, DSTDP, CDC, 404-639-8948, igf0@cdc.gov). Additionally, no groups are currently collecting, or have plans to collect, information included in this collection.

A.9 Explanation of Any Payment or Gift to Respondents

CDC will not provide any payments or gifts to respondents.

A.10 Protection of the Privacy and Confidentiality of Information Provided by Respondents

The CDC NCHHSTP Privacy and Confidentiality Review Officer has assessed this package for applicability of 5 U.S.C. § 552a, and has determined that the Privacy Act does not apply to the information collection. Employees of state and local public health agencies will provide information about service provision, routine activities, and answer questions about the structure of the health agency. The project will collect no personally identifiable information (PII) from respondents and no names or PII will be received by CDC nor stored in a system of records at CDC.

Data will be collected by the National Association of County and City Health Officials (NACCHO) using the Qualtrics web-based online survey data collection platform. The Qualtrics platform uses encryption for data transmission (https://www.qualtrics.com/security-statement/). When the information collection is complete, NACCHO staff will download the data, encrypt the data, and transmit the data electronically to CDC. Data collected through Qualtrics will be stored in on a specific Qualtrics server, and will not be transmitted from one data center to another. All of Qualtrics' data centers have been independently audited using the industry standard SSAE-16 method and as met and/or exceed the minimum requires for data storage.

NACCHO will restrict access to the data to select staff. Once the data collection closes, a designated NACCHO staff member will download the data and send an encrypted copy to CDC while keeping a copy of the raw data on an encrypted NACCHO server

There is no justification for a Privacy Impact Assessment (PIA) to be completed for this information collection request. The objective of the PIA is to systematically identify the risks and potential effects of collecting, maintaining, and disseminating personally identifiable information (PII) and to examine and evaluate alternative processes for handling that information to mitigate potential privacy risks and risks to confidentiality. CDC will not receive or maintain names or other individually identifiable data stored in a system of records for this project so there are no privacy issues to address.

A.11 Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB

This data collection is not research involving human subjects. NCHHSTP determined on March 29, 2017, that this information collection constitutes routine Public Health Program activity.(**Attachment 8**).

Justifications for Sensitive Questions

No information will be collected that is of a personal or sensitive nature. All questions focus on health department structure and activities only.

A.12 Provide an Estimate in Hours of the Burden of the Collection of Information

This estimate for burden hours is annualize for the two information collections over 3 years. The estimate for burden hours is based on a March 2017 pilot test of the survey information collection instrument by 8 public health professionals (5 from LHDs and 3 from SHDs). In the pilot test, the average time to complete the survey including time for reviewing the instructions and instrument (available from the landing page for the online version), gathering needed information and completing the survey data collection, was approximately 15 minutes for LHDs and 85 minutes for SHDs. Based on pilot feedback, we believe that the SHDs did not follow survey instructions that asked for state-level information only. Instead, it appears as though states tried to obtain some local level data as well as state data. Thus, we significantly revised all instructions throughout the survey (i.e., each section and some items) to remind SHDs that they are reporting state-level data only. Although we used the 85 minute estimate for burden calculations, we do not think the survey will take that long to complete.

We used statistical sampling techniques to estimate the number of respondents for each information collection, separately. For LHDs, given the population size of 2,533 (LHDs who responded to the most recent NACCHO Forces of Change Survey), a 50% response rate (this was what was obtained for the 2013 survey), and using a 95% confidence interval, we will need to sample 668 LHDs to get to our target of 334 LHDs. For SHDs, given a population size of 50 and using a 95% confidence interval our target is 44 SHDs. This will require a response rate > 80%. Table A-12.a provides the estimated annual

burden hours for the two information collections, reflecting 0.667 collections per year (rounded up to 1 response annually in the table). For the second data collection, a different sample of respondents will be drawn.

Table A.12.a. Estimated Annual Burden Hours for 2017 data collection

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
STD program director, LHDs	LHD survey Att. 3	334	1	15/60	84
STD program director, SHDs	SHD survey Att. 4	44	1	85/60	62
				Total Annual Burden Hours	146

For this information collection, there are no direct costs to the respondents themselves. However, the cost to respondents can be calculated in terms of the time it will take to respond to the survey. Table A.12.b illustrates the total calculation of annual costs to respondents for both data collections over a three year period.

Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) Bureau of Labor Statistics for occupational employment for medical and health services managers http://www.bls.gov/oes/current/oes_nat.htm. Based on DOL data, an average hourly wage of $57.11 is estimated for all 378 respondents (334 for LHD and 44 for SHD). Table A-12b shows estimated burden and cost information.

Table A.12.b. Estimated Annual Burden Cost for 2017 data collection

Type of Respondent	Form Name	Total Burden Hours	Average Hourly Wage Rate (in dollars)	Total Respondent Costs
STD program director, LHDs	LHD survey	84	$57.11	$4797
STD program director, SHDs	SHD survey	62	$57.11	$3541
			Total Annual Burden Cost	$8338

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

No capital or maintenance costs are expected.

A.14 Annualized Cost to the Government

There are no equipment or overhead costs. The only cost to the federal government would be the salary of CDC staff supporting the data collection activities and associated tasks, and the funding awarded to NACCHO. For each data collection, it is estimated that two CDC employees will be involved for approximately 5% of their time each (for federal personnel 100% time = 2,080 hours annually). The two salaries are $37.95 and $65.00 per hour. The direct annual costs in CDC staff time will be approximately $7,639 annually. The annualized cost to the government for the two data collections would be $151,026.

Table A.14.a. Annualized Cost to the Government

Type of Cost	Annualized Cost
Grantee Costs: NACCHO	$143,333
Federal Employee Time Costs	$7693
Total Annual Estimated Costs	**$151,026**

A.15 Explanation for Program Changes or Adjustments

The 2013 STD Infrastructure Assessment consisted of one web survey sent to both LHD and SHD and was approved under OSTLTS OMB Clearance Center (O2C2) – OMB No. 0920-0879. Subsequent to the initial survey in 2013 (which serves as our baseline data), we have made several adjustments to the sampling frame and surveys. First, our LHD sample size in 2013 was not large enough to detect differences using a 95% confidence interval for some key survey items. Therefore, we used statistical techniques to estimate the appropriate sample size for this information collection (334 respondents from a sample of 668). Second, given that portions of the 2013 survey were not relevant for each type of health department (LHD and SHD), we decided to develop two surveys for this information collection (**Attachments 3 –** Local Health Department Survey and **4 –** State Health Department Survey). Third, in an effort to reduce the burden on participants we reduced the survey from 44 items in 2013 to 33-36 in 2017 (for SHD, LHD, respectively). Revisions were based on 2013 items that did not yield the desired information and a renewed focus on key items only. However, the key items that have been retained will allow for trend analysis. Finally, in 2013, all follow-up was handled via email reminders. For the current survey, we will also include a phone reminder if necessary to obtain the needed sample sizes.

A.16 Plans for Tabulation and Publication and Project Time Schedule

Item non-response will be analyzed to identify any potentially problematic questions or survey sections that may lead to partial survey completion by respondents. The dataset will be carefully reviewed for unusual or inconsistent responses that might also signal problems of comprehension, recall, or reporting in either the questions or the response categories.

As part of analysis, weighting adjustments will be developed to increase the respondent representativeness relative to the sample for LHDs. Weights will be developed by examining U.S. Census region, jurisdiction population size and non-response. Weights will be appended to each survey record (“case” weights) in the final data file for use in analyses.

Data will be tabulated and published in either reports or peer-reviewed journal articles. Selected results will also be provided to NACCHO and NCSD for dissemination through regular communications. All

publications will be submitted to CDC's clearance process for scientific documents to insure that any results that are released will maintain the privacy of the LHD and SHDs (i.e., no data that could be used to identify a given health department will be publicly released).

For the first data collection, the timeline to collect data is August through September 2017 (pending OMB approval). The second data collection would occur in year 3.

Exhibit 1. Project time schedule for each collection period

Activity	Time Period
Implement Survey	Within 1 month of OMB approval
Develop Secure Data Repository Develop Data Sharing Plan	Within 1 month of OMB approval
Develop Data Dictionary Provide Quality Checks of all Data Deliverables	1-2 months after OMB approval 2-3 months after OMB approval
Develop Data Analysis Plan and Analysis	1-2 months after OMB approval
Survey Implementation Status Reporting	1 –4 months after OMB approval (throughout 60 day data collection period)
Data Submission	4 months after OMB approval
Anticipated publications	9-12 months after OMB approval

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate
CDC will display the expiration date for OMB approval.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions
No exceptions to the certification are made.

Reference List

1. Centers for Disease Control and Prevention. Sexually Transmitted Disease Surveillance 2015. Atlanta: U.S. Department of Health and Human Services; 2016. http://www.cdc.gov/std/stats15/std-surveillance-2015-print.pdf
2. Satterwhite CL, Torrone E, Meites E, et al. Sexually transmitted infections among US women and men: prevalence and incidence estimates, 2008. Sex Transm Dis. 2013;40(3):187-193.
3. Owusu-Edusei K, Jr., Chesson HW, Gift TL, et al. The estimated direct medical cost of selected sexually transmitted infections in the United States, 2008. Sex Transm Dis. 2013;40(3):197-201.
4. Division of STD Prevention website http://www.cdc.gov/std/stats08/trends.htm#f3.
5. Golden MR, Kerndt PR. Improving clinical operations: can we and should we save our STD clinics? Sex Transm Dis 2010; 37(4):264-265.
6. Leichliter JS, Heyer K, Peterman TA, et al. U.S. public STD clinical services in an era of declining public health funding: 2013-14. Sex Transm Dis. (under review)
7. Cuffe KM, Esie P, Leichliter JS, Gift TL. HIV services provided by STD programs in state and local health departments. MMWR Morb Mortal Wkly Rep 2017;66:355–358.
8. Division of STD Prevention website http://www.cdc.gov/std/stats08/trends.htm#f3.
9. Ellison J, Gold S, Morgan L, et al. 2010 national profile of local health departments. 1-94. 2011. Washington, National Association of County & City Health Officials.

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