

National HIV Prevention Program Monitoring and Evaluation Data

0920-0696

Expiration 08/31/2013

Supporting Statement A

Contact Information

**David Davis, Ph.D.
Health Communication Specialist**

**National Center for HIV/AIDS, Viral Hepatitis, STD, and TB
Prevention
Division of HIV/AIDS Prevention
Program Evaluation Branch
Centers for Disease Control and Prevention
1600 Clifton Road NE, Mailstop E-59
Atlanta, GA 30333.**

**Voice: (404-639-0938)
Fax: (404-639-0929)
Email: dad5@cdc.gov**

12/18/2012

Title

Table of Contents

Section

A. Justification

1. Circumstances Making the Collection of Information Necessary
2. Purpose and Use of the Information Collection
3. Use of Improved Information Technology and Burden Reduction
4. Efforts to Identify Duplication and Use of Similar Information
5. Impact on Small Businesses or Other Small Entities
6. Consequences of Collecting the Information Less frequently
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency
9. Explanation of Any Payment or Gift to Respondents
10. Assurance of Confidentiality Provided to Respondents
11. Justification for Sensitive Questions
12. Estimates of Annualized Burden Hours and Costs
13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers
14. Annualized Cost to the Government
15. Explanation for Program Changes or Adjustments
16. Plans for Tabulation and Publication and Project Time Schedule
17. Reason(s) Display of OMB Expiration Date is Inappropriate
18. Exceptions to Certification for Paperwork Reduction Act Submissions

19.

20. Exhibits

21. Exhibit 12.A Estimated Annualized Burden Hours
22. Exhibit 12.B Estimated Annualized Burden Costs
23. Exhibit 14.A Estimated Cost to the Government
- 24.
- 25.

LIST OF ATTACHMENTS

- Attachment 1** Authorizing Legislation
- Attachment 2** Federal Register Notice
- Attachment 3A** EvaluationWeb PEMS Home Admin Page
- Attachment 3B** EvaluationWeb PEMS Home User Page
- Attachment 4** Agencies and Persons Consulted
- Attachment 5** NHM&E Variables
- Attachment 6A** CDC Data Systems ROB System Users
- Attachment 6B** CDC Data Systems ROB System Admin
- Attachment 7** Other CDC HIV Data Collections
- Attachment 8** EvaluationWeb Authority to Operate
- Attachment 9** Burden Estimate Calculations
- Attachment 10** Assurance of Confidentiality (308(d))

Supporting Statement

Section A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention requests a revision to approved data collection 0920-0696 (expiration date 08/31/2013) called, "National HIV Prevention Program Monitoring and Evaluation (NHME) Data," for a period of 3 years.

This ICR covers the collection of standardized program monitoring and evaluation data from all organizations funded by CDC, directly or indirectly through health department funding, under all program announcements, to conduct HIV prevention programs. This ICR also covers all data collection for special monitoring and evaluation projects that provide additional funding for expanded data collection using the approved variables. This is to include all types of HIV prevention programs, including but not limited to, Health Education/Risk Reduction (HE/RR) (and associated Health Communication/Public Information, Community-Level Interventions, and Outreach), Partner Services, HIV Testing (and associated Counseling and Referral), and other CDC-funded HIV prevention programs. This ICR does not cover HIV disease surveillance or research into biomedical interventions or the efficacy of new behavioral HIV prevention programs, which are covered under separate ICRs. A review of the current OMB-approved CDC HIV data collections (see

Attachment 7) shows that no other approved data collection collects program monitoring and evaluation data on CDC-funded HIV prevention programs currently being conducted by health departments and CBOs.

The revision of the currently approved data collection is intended to refocus the CDC HIV prevention program evaluation to match the goals of the National HIV/AIDS Strategy, reduce burden on the grantees, and account for changes in HIV prevention technology and policy.

The NHM&E data are a set of standardized variables to assist Health Departments and Community-Based Organizations (CBOs) in monitoring and evaluating their activities to help them develop, deliver, and refine successful HIV prevention interventions. These data are also used to report key program performance indicators to CDC to show whether the programs implemented or supported are efficient and effective in achieving their stated goals. NHM&E data supply program managers with service-level information regarding intervention processes (e.g., who delivered what to whom, how many, where, and when) and client-level information (e.g., client demographics, behavioral risk factors, exposure to services, verified referrals into other services, and changes in risk-behaviors for selected interventions) for monitoring and enhancing local HIV prevention programs. Much of

these data are collected by CBOs and HDs using locally developed forms as part of their usual business process.

The White House recently released the new National HIV/AIDS Strategy, which specified new goals and objectives for HIV prevention in the United States. In response to these new goals, the CDC Division of HIV/AIDS Prevention developed a new strategic plan that focuses more on high-impact prevention, treatment as prevention, and use of new testing and prevention technology. To accommodate this shift in focus, the NHM&E variables needed to be modified to improve evaluation effectiveness. At the same time, in response to grantee comments and analysis of the first rounds of data submissions, we have determined that some variables that focus on process evaluation are no longer high priority. Thus, many of these process evaluation variables have been deleted.

These changes in focus have been incorporated into several recent funding opportunity announcements (FOAs). For health departments, FOAs PS 12-1201 and PS11-1117 (ECHPP), and for Community-Based Organizations, FOAs PS11-1113 and PS10-1003, which fund prevention programs that reflect the goals and objectives of the National HIV/AIDS Strategy. This revision is to modify the currently approved NHM&E variables in order to monitor and evaluate these FOAs. These revisions are also needed to monitor interventions that are critical to the White House National HIV/AIDS Strategy (NHAS) and have not previously been

monitored by CDC (i.e., the variables did not exist when the previous data set was approved). Data collected and reported will be used to inform progress toward meeting goals and objectives of the NHAS.

CDC is requesting to delete 608 variables (190 of 340 required variables and 418 of 565 optional or other variables) to reduce burden on the grantees. Most of these are process evaluation variables that were intended to measure fidelity of intervention delivery. Study of data already collected, including special studies using NHM&E data, combined with the change in focus of the National HIV/AIDS Strategy, make this data a lower priority than previously, and thus we want to relieve the grantees of this burden.

In addition, 144 required variables would be added to deal with new technology and the new focus of the National HIV/AIDS Strategy. Many of these are reported in the aggregate, further reducing burden. Many of these new variables focus on the NHAS goals of finding infected persons and linking them to medical care in order to change behavior and reduce infectiousness. Other variables deal with new technologies and interventions, such a pre- or post-exposure prophylaxis and community-level interventions.

Also, some variables are modified slightly to improve data quality or adapt to the change in focus. Most of these changes are the addition of one or more values in response to analysis of previously submitted data and comments from grantees. Moreover, slight differences between variables required of health departments and community-based organizations (CBOs) have been introduced in response to the differences in the FOAs funding these agencies and the need to evaluate the FOA goals and objectives. Some variables have been modified to simplify data collection. The revised variable set is in **Attachment 5**.

In addition, to further reduce burden on grantees, we are requesting to change reporting frequency from quarterly to semiannual.

The CDC currently funds HIV prevention programs in all state and territorial health jurisdictions (including the Pacific Island territories), 9 city health departments, and approximately 153 CBOs through cooperative agreements. These numbers of grantees vary over time and, as noted, may increase, and some grantees may be funded under more than one program announcement. Because we are anticipating an increase in the number of funded CBOs, we have calculated the burden based on up to 200 CBOs.

These HIV prevention programs conduct interventions to reduce HIV-related behaviors in targeted populations. Monitoring and evaluation of these HIV prevention programs are essential for strengthening CDC's overall monitoring of HIV/AIDS prevention. Consequently, accurate and reliable program process and outcome monitoring and evaluation data must be collected. The CDC depends on the NHM&E variables for standardized data from all grantees to adequately monitor program performance at both the local and national levels.

In addition, the President's Management Agenda requires all federally funded grantees to report key program performance indicators as a method for demonstrating accountability. The CDC HIV prevention program performance indicators include the grantee's capacity to deliver and monitor prevention services, the implementation of these processes, and outcomes associated with HIV prevention program activity. The grantees and CDC will use performance indicators to show that the programs they implement or support are efficient and effective in achieving their stated HIV prevention program goals and objectives. Most HIV prevention program performance indicators are calculated using data included in this ICR for NHM&E data.

The NHM&E data make possible national program evaluation; performance indicator calculation; accountability reporting to Congress, the administration, and other HIV prevention program

stakeholders; and informed decision-making about funding and HIV prevention. These data will be used for planning and monitoring the delivery of prevention services to clients, implementing and improving HIV prevention programs, and reporting the required program performance indicators. Additionally, NHM&E data will enable CDC to provide valuable feedback to these programs and to better account for the use of HIV prevention resources. All funded health jurisdictions and CBOs, under any and all CDC HIV prevention program funding, will be required to submit the NHM&E data. Some special evaluation studies will utilize only variables included in this ICR.

Collection of these data is authorized under Section 306 of the Public Health Services Act [42 U.S.C. 242(k)] (**Attachment 1**). Respondents are required to submit NHM&E data semiannually and are accountable for conducting monitoring and evaluation of major HIV prevention program activities and services, including data collection on interventions provided and clients served. CDC may place conditions or restrictions on the award of funds to respondents that fail to meet these requirements.

Privacy Impact Assessment

Overview of the data collection system

Each respondent will determine how data are to be collected. There are no required forms or other data collection instruments. For some types of data, CDC provides optional, modifiable data collection templates that grantees change and adapt for their own procedures and additional, local data needs.

CDC provides EvaluationWeb®, an HIV prevention program data collection and reporting software system operated by Luther Consulting, LLC. EvaluationWeb® is an electronic, secure, browser-based software application designed to provide the necessary mechanism for collecting and reporting standardized, sensitive HIV prevention data. About half the health department jurisdictions maintain their own electronic data collection systems and upload data from their systems into EvaluationWeb®. The other health departments and almost all community-based organization (CBO) grantees key-enter data directly into EvaluationWeb®. CDC grantees gain access to EvaluationWeb® through a secure internet connection, which requires electronic authentication of the users and maintains data confidentiality and security. All data, from all systems, are submitted electronically, using approved encryption.

Program data accessible by CDC will not contain client names, but will include "sensitive" information such as client demographics (age, gender, race, pregnancy status, HIV status, risk behaviors, etc.) and exposure characteristics. Information

in Identifiable Form (IIF), such as name, address, birthday, etc., may be collected by the health department or CBO working with the individual for purposes of local program activity such as case management, but no individually identifiable information will be submitted to CDC. All NHM&E data is covered by a CDC Assurance of Confidentiality specific to NHM&E data under the Public Health Services Act 308(d), as well as state confidentiality laws. Data will be transmitted to CDC from Luther Consulting over the Internet using Secure Socket Layer/Transport Layer Security (SSL/TLS software to encrypt data between EvaluationWeb and CDC).

Since the design and intent of the data collection is not to develop or contribute to generalizable knowledge (i.e., it is not possible to induce or derive a general conclusion or principle about all HIV prevention from the particulars of the evaluation of a particular grantee's activities), but to improve individual HIV prevention programs and services provided by CDC-funded health departments and CBOs, CDC has determined that NHM&E is not research and IRB review is not required.

Items of Information to be collected

See **Attachment 5** for a complete list of all data elements (variables and values, with definitions). The information to be collected includes data about the agency, the CDC funding

received, the clients served and their associated HIV risk factors, and the interventions conducted (including, but not limited to, HIV testing; health education and risk reduction and associated health communication, public information, and outreach; and partner services). This information is reported by the grantees from their usual and customary data collection, using the standardized NHM&E variables.

No Information in Identifiable Form (IIF) is reported to CDC.

Identification of Websites and Website Content Directed at Children Under 13 Years of Age.

There is no content directed at children under 13 years of age. Data are entered into an electronic, secure, browser-based software application designed to provide the necessary mechanism for collecting and reporting standardized, sensitive HIV prevention data. Access to this website is tightly controlled using the CDC Secure Access Management System e-authentication process as well as separate access rights to the EvaluationWeb software. Access is limited to appropriate grantee and CDC staff. Cookies are not used. Rules of behavior are enforced as part of memoranda of understanding with all grantees (see **Attachment 6 A & B**).

2. Purpose of Use of the Information Collection

The NHM&E data variables provide a comprehensive, yet parsimonious, standardized set of program data variables essential to monitoring and evaluating HIV prevention programs. As program evaluation, the results of analyses of NHM&E data are not generalizable (i.e., it is not possible to induce or derive a general conclusion or principle about all HIV prevention from the particulars of the evaluation of a particular grantee's activities). Moreover, given the variety in implementation of HIV prevention interventions among health departments and CBOs, when utilized for assessing outcomes associated with CDC-funded HIV prevention program activities, the results of analyses of NHM&E data will not be generalizable. However, the NHM&E data enable CDC to track program activity, identify best practices, and assist grantees in redesigning interventions that do not accomplish stated goals, such as the reduction of high-risk behaviors in targeted populations. CDC has used the NHM&E data received to date, in combination with surveillance and research data, for the following purposes:

- Publish annual reports on HIV testing at the national and jurisdiction levels, including HIV positivity rates
- Publish Program Evaluation Branch updates on data quality, Partner Services provided, and budget allocations compared to HIV case distribution

- Assess CDC HIV budget allocations with respect to prioritized risk populations at the jurisdiction level
- Publish peer-reviewed articles on the fidelity of delivery and effectiveness in the field of Evidence-Based Interventions disseminated by CDC
- Identify gaps in HIV prevention service provisions
- Respond to data requests from Congress, the administration, HIV researchers, and other interested parties
- Assess the extent to which HIV prevention programs have reached their target population
- Highlight opportunities to strengthen collaboration among CDC, its prevention partners, and other federal agencies
- Assess the annual performance of CDC and its grantees in meeting priority goals and objectives
- Produce other standardized and specialized reports in EvaluationWeb to inform grantees, CDC project officers, and other stakeholders of the status and trends of a host of process, outcome, impact, and accountability measures. Reports include reports for quality assurance, comparison of planned activities to actual activities, data for calculating required performance indicators, and data on specific interventions. These types of reports are available on the grantee, jurisdiction, and national level.

The NHM&E data variables have been developed with extensive input from respondents (representatives of health jurisdictions and community-based organizations), other HIV prevention partners, and the leadership of the Division of HIV/AIDS Prevention (NCHHSTP/CDC). See **Attachment 4** for a list of external organizations and persons who provided input to the development or modification of the NHM&E variables during the past three years. Based on this input, this revision would significantly reduce the number of variables and frequency of reporting in order to reduce reporting burden on the grantees. The data variables are based on HIV prevention business processes and sound scientific approaches to HIV prevention. Specifically, the NHM&E data variables cover a range of HIV prevention activities such as agency information, HIV testing, partner services, and a range of health education and risk reduction interventions including Comprehensive Risk Counseling and Services, health communication/public information activities, and community-level interventions.

Collection of the NHM&E data will supply program managers with service-level information regarding intervention processes (e.g., who delivered what to whom, how many, where, and when) and client-level information (e.g., client demographics, behavioral risk factors, exposure to services, verified referrals into other services, and changes in risk-behaviors for selected

interventions) for monitoring and enhancing local HIV prevention programs. See **Attachment 5** for the NHM&E data variables and values. See **Attachment 3A&B** for a sample of the EvaluationWeb Home Page.

Without these data, CDC would be unable to determine what is being done with the funding it provides, what populations are being served, what services are being provided, or which programs are having the most effect in preventing HIV. It would be unable to account to the administration, Congress, or other stakeholders for the proper use of public money or provide transparency for the programs it funds.

2.1 Privacy Impact Assessment

No individually identifiable information will be collected.

3. Use of Improved Information Technology and Burden Reduction

All NHM&E data are to be submitted to CDC electronically. While grantees may collect the data by whatever means they choose, data must be submitted to CDC electronically from EvaluationWeb® using the Secure Socket Layer/Transport Layer Security. Grantees are given the option of using their own software system to collect NHM&E data and uploading to EvaluationWeb or key-entering data directly into the CDC-provided EvaluationWeb software. Grantees who use their own software must

collect the standardized NHM&E data and then convert those data into one of several CDC-specified formats for upload to EvaluationWeb®. Grantees who choose to enter data directly into EvaluationWeb® are provided a free, browser-based, secure electronic mechanism for collecting and reporting the standardized NHM&E HIV prevention program data. The data from both sources is checked for quality and conformity to NHM&E requirements by the contractor before being compiled into analyzable databases and submitted to CDC.

The optional EvaluationWeb® software application was designed with input from representatives of health jurisdictions, community-based organizations, and other HIV prevention partners. The EvaluationWeb® software was designed to combine agency, intervention, and client data into one system. This integrated system reduces the burden of entering client data separately by intervention and allows for enhanced flexibility in monitoring and analyzing data across a range of HIV prevention activities.

Data variable business rules have been built into the EvaluationWeb software application to enhance the reliability and integrity of the data. These business rules establish the interrelationships among variables and serve as system performance checks for accurate data entry. CDC grantees gain access to EvaluationWeb® after authentication of user identities.

4. Efforts to Identify Duplication and Use of Similar Information

Efforts to identify duplication of NHM&E data include the assessment of existing or previously used HIV prevention data collection systems used by CDC, other federal agencies, as well as health department jurisdictions and community-based organizations. It should be noted that because the NHM&E data reporting requirements are specific to CDC-funded HIV prevention activities, the only possible duplication is if other federal or state organizations or entities are also funding the same HIV prevention activities to be performed by the same grantees.

Within CDC, data elements from several previously used HIV prevention data collection systems were identified and assessed. These include the following systems:

- The Evaluation Reporting and Analysis System (ERAS), an electronic system used by health jurisdictions to submit health education and risk reduction data at the aggregate level. Evaluating CDC Funded Health Department HIV Prevention Programs (OMB No. 0920-0497, expired March 2006)
- Community-based Organizations System (CBOS), an electronic system used by selected CBOs to submit health education and risk reduction intervention data at both the client and aggregate levels. Assessing the Effectiveness of CBOs for the Delivery of HIV Prevention Programs (OMB No. 0920-0525, discontinued February 2005)

- HIV Counseling and Testing System (CTS), implemented in 1989 and used to collect client-level HIV counseling and testing (CT) data from health jurisdictions. As the volume of CT data increased, scan forms were created by CDC to facilitate data entry. HIV/AIDS Prevention and Surveillance Project Reports (OMB No. 0920-0208 expired October 2005)
- STD Management Information System (MIS) developed by CDC/NCHSTP/DSTDP and used by some state health jurisdictions in collaboration with HIV prevention programs to collect Partner Services (PS) data. The data collected on STD/MIS have been recently modified to match NHM&E data for those items related to HIV PS so that funded state or city health departments have the option of using PEMS, STD/MIS, or their own system to collect PS data. Other STD/MIS data are not reported to CDC, except for morbidity data, which are reported through the NETSS system). (Refer to OMB No. 0920-0497, Evaluating CDC Funded Health Department HIV Prevention Programs, Partner Counseling and Referral Services).

To reduce duplication, the NHM&E dataset combines these four datasets into one. With the exception of the STD/MIS system, the other systems (ERAS, CBOS, and CTS) have been replaced by the standardized, routinely reported NHM&E data. The STD/MIS collects additional information, not reported to CDC, outside the

purview of HIV prevention. Only NHM&E PS data collected in STD/MIS are reported to CDC as part of the NHM&E data collection. In addition, the STD/MIS system is being phased out, to be replaced by an optional PartnerServicesWeb software sometime in 2013 that grantees may choose to use to collect Partner Services data. Grantees may also choose to use their own data collection system. In either case, only the required NHM&E data will be uploaded to EvaluationWeb for submission to CDC.

In addition to systems at CDC, other federal systems were reviewed. Specifically, consultations were held with the Health Resources and Services Administration (HRSA) and the Substance Abuse and Mental Health Services Administration (SAMHSA) to identify and match similar data elements to avoid duplication. Given that HRSA and SAMHSA do not collect detailed HIV prevention program data, very few similarities were identified. The only overlap detected was in the collection of HIV testing data, and SAMHSA determined that they would use the NHM&E HIV testing data variables collect data from their grantees. SAMHSA submitted a separate ICR for this data collection. The burden for the SAMHSA data collection is not included in the burden calculations for this ICR.

If the number of new HIV infections is to be reduced, the quality of HIV prevention programs designed to reduce high-risk behaviors in persons most likely to acquire or transmit HIV must

be improved. The NHM&E data significantly advances the monitoring and evaluation of HIV prevention programs by providing national, standardized information. Using standardized data will allow CDC to evaluate programs on national and regional scales and to compare programs providing similar services or targeting similar populations. On the local level, use of the standardized NHM&E variables will enhance the capacity of HIV prevention programs to thoroughly assess and refine their HIV prevention interventions and to identify unmet needs and redundancies while providing accountability to their stakeholders.

5. Impact on Small Business or Other Small Entities

State health department jurisdictions and community-based organizations that receive CDC funding for HIV prevention vary greatly in size and in their capacity to collect and report the NHM&E data. Some of them would qualify as small businesses or other small entities. The NHM&E variables represent a set of data with sufficient detail to monitor and improve client outcomes, service delivery, and program design and implementation. In addition, collection of the data will enable agencies to meet their program indicator reporting mandates. Required NHM&E data variables have been kept to a minimum (and reduced from the previous ICR), and thus all respondents will be expected to complete the required data. Moreover, the cost of collecting and

reporting this data are included in the CDC funding to all grantees. For small organizations, collection and use of these data are essential to maintaining and improving their HIV prevention activities. When faced with limited resources, these agencies will have the data needed to defend and make the case for expanding existing programs, thereby ensuring continued service delivery to populations in need.

6. Consequences of Collecting the Information Less Frequently

Respondents are required to submit data to the CDC on a semiannual basis. Less frequent data submission would result in a lag time between the occurrence of program problems and their identification. This lag time could result in costly program inefficiencies, defects, and failures to continue or worsen without a timely opportunity for CDC to provide valuable assistance and corrective measures to agencies funded to prevent the spread of HIV. There are no legal obstacles to reducing the burden.

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

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

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*, 08/22/2012, Volume 77, Number 163 pages 50697-50698. See **Attachment 2** for a copy of the *Federal Register* notice. CDC received one non-substantive comment.

CDC developed the NHM&E data variables with feedback from state, territorial, and local health jurisdictions and CBOs. Developing the NHM&E data variables has been a long and collaborative process. There was extensive consultation on revisions to the variables during a series of advisory panel and all-grantee webinars held during 2012. A detailed listing of agencies and persons consulted during consultations, web-conference, workshops, etc. is found in **Attachment 4**. Representatives from funded agencies continue to be informed through monthly phone calls and e-mail correspondence. Additional consultations, workshops, and web-conferences will occur as needed.

9. Explanation of Any Payment or Gift to Respondents

No payments or gifts will be provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

Much of the information to be collected as part of the NHM&E data relates to program activities and characteristics of respondent organizations. However, the health jurisdictions may

also collect identifiers (name, address, etc.) on clients who receive HIV prevention services, including HIV testing. An Authorization to Extend 308(d) Assurance of Confidentiality Protection has been approved can be found in Attachment 10. The Privacy Act is not applicable to the client-level data because the information will become a part of the health department jurisdictions' already established record systems; moreover, its availability and use will be limited to the provision of services at the local level.

Privacy Impact Assessment Information

Whether data is uploaded to EvaluationWeb using CDC-specified formats or directly entered into EvaluationWeb, no IIF is submitted to CDC, and, as explained in more detail below, the data that is submitted is submitted in encrypted form. Each individual client record will be identified by a randomly generated unique key that is linked to a particular agency and state. This key is maintained in EvaluationWeb, but only at the local level can the client key be re-linked to identifiers. The client-level data submitted to CDC will not contain IIF such as client names, but will include client demographics (age, gender, race, pregnancy status, HIV status, risk behaviors, etc.) and exposure characteristics (see **Attachment 5** for more information on the client key and demographic variables). Because of the

highly sensitive information and the potential for indirect identification of individuals, as is true with CDC HIV/AIDS surveillance systems, the program has determined that an Assurance of Confidentiality for prevention program clients (and the organizations furnishing the information) under section 308(d) of the Public Health Service (PHS) Act is necessary. This Assurance of Confidentiality for the NHM&E data has been granted by the CDC Associate Director for Science. Safeguards for client data during data analysis, such as deleting small cell sizes, requiring confidentiality agreements, and other safeguards similar to those used for HIV/AIDS surveillance data have been imposed.

CDC grantees gain access to the EvaluationWeb® application through a secure internet connection, which requires electronic authentication of the users and maintains data confidentiality and security. All system users are provided information on privacy, confidentiality, and security policies; and a memorandum of understanding between CDC and each grantee agency is established. All system users will be required to sign appropriate 308d pledges. Written rules of behavior have been developed for PEMS Agency System Users (**Attachment 6A**) and Administrators (**Attachment 6B**) to clarify rules, roles, and responsibilities associated with the system.

While sensitive data will be submitted to CDC, IIF will not be submitted to CDC. Public use data sets derived from the de-identified data will be further protected by eliminating cells with small numbers and other steps to prevent the identification of individuals. The EvaluationWeb® system has passed the full Certification and Accreditation Process and has an authority to operate (ATO) until March 23, 2014 (**Attachment 8.**) This means that our security measures meet the requirements of the NIST 800-53, HHS, and CDC.

The EvaluationWeb® application uses Secure Sockets Layer (SSL) between web-browser clients and the web server that accepts data from users. Each of these SSL sessions employs the same type of encryption used by all major financial services and electronic commerce sites today. Thus, from a user's perspective, sensitive information is encrypted from the time it leaves the PC to the time it is stored in the database.

EvaluationWeb® also supports persistent encryption of specific data variables (identified as sensitive by the CDC) using the 3DES algorithm. This algorithm is also known as Triple DES, employs a 168-bit encryption key, and is FIPS 140-2 compliant. Thus, in addition to being encrypted with SSL during transit, some information remains encrypted within the database, visible only to the agency that entered it. The process for

handling security incidents is defined in the system's Security Plan. Event monitoring and incident response is a shared responsibility between the system's team and the Office of the Chief Information Security Officer (OCISO). Reports of suspicious security or adverse privacy-related events should be directed to the component's Information Systems Security Officer, CDC helpdesk, or to the CDC Incident Response Team. The CDC OCISO reports to the HHS Secure One Communications Center, which reports incidents to US-CERT as appropriate.

Because the primary purpose of this data collection is to improve HIV prevention programs and services, CDC has determined that the data collection activity does not require IRB review and approval.

10.1 Privacy Impact Assessment Information

Information about agencies and programs is required as part of the Program Announcement. Information about clients is collected by the agencies as part of their routine data collection, and clients are informed of any consent required by the agency or state regulations. As described above, no individually identifiable information is being reported to CDC.

11. Justification for Sensitive Questions

Some of the client-level data to be collected are highly sensitive. HIV can be transmitted from person to person through sexual contact and the sharing of HIV contaminated needles and syringes. These modes of transmission necessitate the collection of sensitive data regarding sexual practices as well as alcohol and drug use. Because collection of these data will be used to provide improved HIV prevention services to high-risk populations, to enhance HIV prevention programs at the local level, and to reduce high-risk behaviors in persons most likely to acquire or transmit HIV, specific information about client demographics and client risk profiles is essential to designing appropriate interventions and programs and to monitoring and evaluating these programs.

This data collection also includes race and ethnicity questions, which may also be viewed as sensitive by some respondents, for use in data analysis (e.g., designing and evaluating programs, as discussed above).

12. Estimates of Annualized Burden Hours and Costs

Annualized Burden Hours

The estimates for the number of annualized burden hours are provided in the table below. There are two types of organizations that are required to provide data. The first is State, Territorial, and directly funded local health departments, whose

burdens are described in the first line of the burden table. There are 69 health jurisdictions and the data required by respondents for this ICR include variables for the following NHM&E data sets:

- Agency Data
- Health Education and Risk Reduction (HE/RR) Data
- HIV Testing Data
- Partner Services (PS) Data

The numbers on the burden table (Table A.12-A) are estimates since new program announcements may alter the number and types of services provided at any time. All health departments will also receive training on NHM&E, as noted in the burden table.

The second type of organization providing information is community-based organizations (CBOs). CBOs conducting HIV testing report their data through their jurisdiction health department, so CBO testing burden will be calculated as part of health department burden. Also, CBOs generally do not conduct Partner Services beyond identifying index cases, so that burden will also be incorporated into the burden for health departments. CBO burdens for agency data and HE/RR are shown on lines 3 of the table.

The calculations for annualized burden are derived from the health department and CBO time needed to search the EvaluationWeb® database for existing records, gather and maintain

the data, complete the collection of records, and review the information prior to submission to CDC.

The annual NHNM&E data reporting burden is summarized in the following table. For simplicity, the burdens for Agency Data and for HE/RR data (and for PS data for health departments) have been combined since all agencies report these data.

Table A.12-A. Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per response (in hours)	Total Burden Hours
Health jurisdictions	Health Department Reporting Form	69	2	1377	190,026
Community-Based Organizations	Agency Data	200	2	30/60	200
Community-Based Organizations	HE/RR Data	200	2	20	8,000
Community-Based Organizations	NH&E Data Training	200	2	20	8,000
Total					206,226

The total estimated annualized hourly burden anticipated for all data collections would be approximately 206,226 hours. A total 298,660 burden hours per year were approved under the existing ICR covering August 18, 2010 – August 31, 2013. As requested by OMB in the last approval, there have been numerous efforts in collaboration with grantees to reduce the burden on grantees. This is shown by the reduction in the burden by almost a third. Note that there has been an increase in the number of directly

funded city health departments so that the total number of funded health departments is now 69. We anticipate additional funding in the future to support more grantees, especially CBOs to conduct even more prevention activities. We have offset some of this potential increase in burden by reducing the number of required variables and are continuing to work with the grantees to keep the burden to a minimum while still obtaining the data necessary for national reporting and program management. We have also reduced the reporting frequency from quarterly to semiannual and transitioned to a more efficient data reporting software.

B. Annualized Cost to Respondent

The collection and reporting of NHM&E data are part of the activities specified in the HIV prevention program announcements as part of the funded activities. Any expense incurred collecting and submitting the NHM&E data, above the routine collection of data required to conduct business, is supported by CDC funding. There is no actual cost to the respondent.

The estimated cost to be supported by CDC funding is as follows. Based on a review of salaries reported by eight health department jurisdictions representing a range of sizes and HIV prevalence in their funding applications, it is estimated that health jurisdiction staff who collect PEMS information will be paid about \$54,000 annually. Comparable annual salary for Federal

General Schedule (GS) employees is that of a GS-9 step 10 (\$54,028 annually or \$25.89/hour).

Based on a review of salaries of HIV prevention staff at eight CBOs of various sizes reported in funding applications, the average salary is about \$38,500 annually. Comparable annual salary for Federal General Schedule (GS) employees is that of a GS-7, step 5 (\$38,511 annually or \$18.45/hour).

Table A.12-B. Annualized Cost to Respondents

Type of Respondents	Number of Respondents	Form Name	Number of Responses per respondent	Average Burden per Response (in hours)	Hourly Wage Rate	Total Respondent Cost
Health jurisdiction Staff	69	NHM&E Data	2	1,377	\$25.89	\$4,919,773
CBO Staff	200	NHM&E Data	2	41	\$18.45	\$298,890
TOTAL						\$5,218,669

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

There are no costs to respondents that are not supported by CDC funding under the program announcement beyond usual and customary business practices that would be carried out even if NHM&E data collection were not required. The conditions of the cooperative agreements that CDC awards for HIV prevention programs require recipients to conduct evaluation of major

program activities, interventions, and services, including data collection on interventions and clients served. Program announcements specify that a portion of the funding is to be used for evaluation activities, including data collection. Although the data previously collected by health jurisdictions and CBOs varied widely from state to state and program to program, it is the usual and customary business practice of the grantees to gather and maintain HIV prevention program data, complete the collection of records, and review the information prior to submission to CDC. Since the collection of data is a routine and customary practice, grantees that collect NHM&E data should incur little or no net additional costs to respond to this data collection.

Overall, respondents may choose one of the following options in which to enter and submit the required NHM&E data variables:

- 1) Directly key-enter data into the EvaluationWeb software provided by CDC at no cost to the respondent
- 2) Revise their existing HIV prevention information technology system and upload the required NHM&E data in one of the allowed formats into EvaluationWeb

Services offered to the grantees by CDC to support NHM&E data collection include training, technical assistance, and continued support to grantees through a help desk, website, and

various forms of correspondence. Implementing the EvaluationWeb software will require no start-up costs for the respondents.

Release of various EvaluationWeb software versions will be necessary over time, but it is anticipated that EvaluationWeb® and the NHM&E data variables will be essential tools for monitoring and evaluating HIV prevention programs for many years and there will be no cost to the grantees for these updates.

14. Annualized Cost to the Federal Government

The NHM&E data collection is a multi-year project expected to be in use for many years. For the purposes of this submission, a three year life expectancy has been used to estimate the annualized cost to the government.

CDC supports costs for HIV prevention program cooperative agreements using funds budgeted for these purposes. Additional expenses will be incurred by CDC for training grantees, providing technical assistance, monitoring and analyzing the submitted NHM&E data, and generating assorted reports. Total costs for these activities, using the Atlanta locality salary schedule, are estimated at \$788,344 annually (see table below).

Training for grantees is currently available online and is being revised to reflect these revised data requirements. Instruction will include topics such as confidentiality and computer security, evaluation principles, and use of data for

program improvement. The base Federal General Schedule (GS) salary for full-time employees (FTEs) with experience in these areas is estimated to be a GS-13 step 9. It is expected that the equivalent of two FTEs paid \$51.89/hour will each expend approximately twenty-five percent (25%) of their time or 1040 hours/FTE annually to oversee these trainings.

Technical assistance will be provided through an e-mail service center overseen by a CDC FTE. It is expected that the equivalent of two GS-13 step 9 (\$51.89/hour) FTEs will expend approximately twenty-five percent (25%) of working hours (1040 hours) to oversee this service center.

Monitoring, analyzing, and reporting the NHM&E data are projected to require the expertise of the equivalent of two data managers and six data analysts. The data managers would be at the pay scale of GS-13 step 5 (\$46.43/hour) and the data analysts would be at the pay scale of GS-12 step 5 (\$39.05/hour).

Employee Function	Annual Burden (in hours)	Hourly Wage Rate	Annual Cost
Training	1,040	\$51.89	\$ 53,965.60
Technical Assistance	1,040	\$51.89	\$ 53,965.60
Monitoring, Analyzing and	4,160 1,2480	\$46.43 \$39.05	\$193,148.80 \$487,344.00

Reporting			
TOTAL ANNUAL FEDERAL GOVERNMENT COSTS:		\$788,424.00	

15. Explanation for Program Changes or Adjustments

This is a program change of a currently approved data collection. The burden approved in 2010 was 298,660 hours. We currently request approval for 206,226 burden hours.

This significant decrease in burden is caused by a significant reduction in the number of required and optional but reported variables. The change from quarterly to semiannual reporting also reduced the burden. In addition, the switch to more efficient reporting software has provided a reduction in the actual data entry burden.

Moreover, the costs above the normal cost of doing business are covered by the CDC funding rather than imposing a financial cost on the grantee. All of these data collections will be part of HIV prevention programs funded by CDC so that even the hours spent collecting the data are part of the CDC funded activities, so, in effect, there is no burden. These activities should be made visible to OMB through the normal program announcement approval process, so that OMB is aware of the programs that are covered under this ICR.

16. Plans for Tabulation and Publication and Project Time Schedule

Data are being collected under the existing approved ICR, and is anticipated to continue semiannually for the 3 year requested approval period without interruption if this ICR is approved.

Analysis is focused on improving program monitoring, conducting national analysis of HIV prevention programs, identifying needs for prevention research and evaluation studies, and responding to data requests from Congress and the Executive Branch. All of these activities are currently in process. Annual reports on the data, starting with reports on the 2009-1010 data, have been produced or are in production for more recent years. NHM&E data will also be analyzed in conjunction with data from other Division of HIV/AIDS Prevention (DHAP) collection systems for enhanced monitoring of the HIV epidemic.

In addition, NHM&E data is being used to improve knowledge of local prevention practices, implementation of effective HIV prevention interventions, adherence to program reporting requirements, and compliance with the National HIV/AIDS Strategy. Reports generated by the system include reports for quality assurance, comparison of planned activities or expenditures to actual activities or expenditures, data for calculating required

performance indicators, data on specific interventions, data for contract monitoring, and data for assessing needs. These types of reports are available on the grantee, jurisdiction, or national level.

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

Not applicable.

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

There are no exceptions to the certification.