National HIV Prevention Program Monitoring and Evaluation Data

OMB No. 0920-0696

REVISION

Supporting Statement A

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Contact Information

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- The goal of the National HIV Prevention Program Monitoring and Evaluation (NHM&E) Data is to monitor and evaluate HIV prevention programs funded by the Division of HIV/AIDS Prevention (DHAP) at the Centers for Disease Control and Prevention. This includes, but is not limited to, HIV testing, comprehensive prevention with HIV positive persons including Partner Services, and comprehensive prevention with high risk HIV negative persons including screening and referral to pre-exposure prophylaxis (PrEP).
- The data will be analyzed to produce multiple reports for stakeholders, including reports to Congress and the White House, State Health Departments, other recipients, and the public. These reports will be used to make funding decisions, better target resources and efforts, improve service delivery, and make HIV prevention more effective.
- Recipients will report data on all HIV prevention programs funded by DHAP. Data will be submitted through the EvaluationWeb® reporting software provided to each recipient.
- The populations to be studied are the recipients receiving HIV prevention funding from DHAP.
- All recipients report all data; no sampling is involved. Data will be analyzed in multiple ways, including comparing recipients to national goals and to average, determining trends over time, geographical distribution, etc.

Section A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention requests a revision to OMB approved data collection 0920-0696 (expiration date 02/28/2019) entitled, "National HIV Prevention Program Monitoring and Evaluation (NHM&E) Data," for a period of 3 years.

This information collection request (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 that include conducting HIV prevention programs. This ICR also covers all data collection for special program 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, HIV testing, comprehensive prevention with HIV positive persons including Partner Services, comprehensive prevention with high risk HIV negative persons including pre-exposure prophylaxis (PrEP) screening and referral, and other CDC-funded HIV prevention programs.

A review of the current OMB-approved CDC HIV data collections shows only two other approved data collections for collecting program monitoring and evaluation data on CDC-funded HIV

prevention programs currently being conducted by health department.

OMB No.	Expiration Date	Comprehensive HIV Prevention
0920-1178	04/30/2020	and Care for Men Who Have
		Sex with Men of Color
OMB No.	Expiration Date	Project PrIDE
0920-1201	10/31/2020	

NHM&E data have been an approved data collection for over 10 years for CDC-funded HIV prevention programs implemented by all health departments (currently n=66) and community-based organizations (currently n=110) funded through CDC's flagship and other funding opportunities. The two demonstration projects listed above collect information from no more than 12 health departments and for a more limited time period. Similar data elements were aligned across the OMB approved data collections.

The revision of the currently approved ICR is intended to meet the program monitoring and evaluation needs of CDC HIV prevention goals and objectives as reflected in CDC's Division of HIV/AIDS Prevention Strategic Plan 2017-2020

(<u>https://www.cdc.gov/hiv/pdf/dhap/cdc-hiv-dhap-external-strategic-</u> <u>plan.pdf</u>) and CDC's High Impact Prevention approach

(<u>https://www.cdc.gov/hiv/policies/hip/hip.html</u>). There are

adjustments to collection of budget information to account for changes in the health department flagship notice of funding opportunity PS18-1802: Integrated Human Immunodeficiency Virus (HIV) Surveillance and Prevention Programs for Health Departments that was awarded in January 2018. There are also adjustments to account for changes in HIV testing requirements. Details of these adjustments are provided in Section 12 and **Attachment 11**.

The NHM&E data are a set of standardized variables to assist health departments (HDs) and community-based organizations (CBOs) in monitoring and evaluating their programs and 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 program processes (e.g., who delivered what to whom, how many, where, and when) and clientlevel information (e.g., client demographics, behavioral risk factors, HIV test result, linkage to HIV medical care for persons testing HIV positive, screening and referrals into prevention and essential support services, and interview for partner services) for monitoring and enhancing local HIV prevention programs. Much of these data are collected by HDs and CBOs using locally developed forms as part of their usual business process.

The DHAP Strategic Plan goals for HIV prevention in the United States include preventing new HIV infections, improving health outcomes for persons living with HIV, and reducing HIVrelated disparities and health inequities. CDC's Division of HIV/AIDS Prevention will work closely with national, state, and local partners to ensure that 1) HIV testing is accessible; 2) persons living with HIV have their infection diagnosed, are linked to care, and have access to the support services they need to stay virally suppressed; and 3) persons at high risk for HIV infection have the prevention information and tools needed to protect themselves from infection. As plans are implemented through requirements presented in funding announcements, the NHM&E variables are modified to monitor and evaluate the requirements.

Recipients may differ in how quickly they are able to implement new NHM&E requirements associated with a funding opportunity. Challenges may include updating existing systems, developing and printing new data forms, and training of staff and contractors on the new requirements. In other cases, there is not adequate time left in the funding opportunity to implement new requirements.

Therefore, CDC has provided recipients two options for NHM&E reporting requirements, depending on the funding opportunity. Option 1 is based on 2017 requirements and available through December 31, 2018 for health departments funded under PS18-1802.

However, additional time may be granted to those health departments unable to transition to Option 2 by that date. Option 1 is required for community based organizations funded under PS15-1502 through the last year of current funding (June 30, 2020) and those funded under PS17-1704 through March 1, 2019. Option 2 is based on 2018 requirements and available to health departments beginning July 1, 2018 and required for all health departments on January 1, 2019. Option 2 will be required for any new CBO funding opportunity. New variables will become available following OMB approval.

The requested revision to the currently approved ICR is to modify the NHM&E variables to monitor and evaluate PS18-1802 budget information, to include budget allocated and budget expended data for the 11 required core HIV prevention and HIV surveillance activities. There are also adjustments to account for changes in HIV testing requirements. Data collected and reported will be used to inform progress toward the goals and objectives of the DHAP Strategic Plan.

CDC currently funds HIV prevention programs in all 50 states, District of Columbia, U.S. territories (Puerto Rico, U.S. Virgin Islands and the six Pacific Island territories), 7 city health departments (Baltimore, Chicago, Houston, Los Angeles, New York City, Philadelphia, and San Francisco), and approximately 110 CBOs through cooperative agreements. The number of CBO recipients vary over time and, as noted, may increase, and some recipients may be funded under more than one program announcement. To allow for an estimated maximum number of recipients, we have calculated the burden based on up to 150 CBOs. This is a reduction by 50 in the maximum number of CBOs from the last ICR.

HIV prevention programs, including, but not limited to, HIV testing, partner services, and referral and linkage to medical care and other prevention and essential support services are critical for reducing new HIV infections. 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. CDC depends on the NHM&E variables for standardized data from all recipients to adequately monitor program performance at both the local and national levels.

In addition, CDC routinely reports key program performance indicators as a method for demonstrating accountability as part of the budget process. The CDC HIV prevention program performance indicators include the recipient's capacity to deliver and monitor prevention services, the implementation of these processes, and outcomes associated with HIV prevention program activity. The recipients 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. 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 departments and CBOs, under CDC HIV prevention program

this may be for demonstration project ICRs. Alignment of data elements will occur whenever possible.

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.

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 recipient's activities). Moreover, given the variety in implementation of HIV prevention interventions among health departments and CBOs, when used 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

recipients in redesigning interventions that do not accomplish stated goals, such as linking HIV positives persons to medical care. 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.
- Disseminate rapid feedback reports to the recipients showing progress toward DHAP Strategic Plan goals, recipient comparison to national averages, and recipient comparison to other recipients.
- Publish peer-reviewed articles on HIV testing for priority population groups including youth, women, blacks/African Americans, Hispanics/Latinos, and men who have sex with men (MSM).
- Assess CDC HIV budget allocations with respect to prioritized 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 recipients in meeting priority goals and objectives.
- Produce other standardized and specialized reports in EvaluationWeb® to inform recipients, CDC project officers, and other stakeholders of the status and trends of a host of process, outcome, impact, and accountability measures. Topics include data quality assurance, comparison of planned activities to actual activities, and data for calculating required performance indicators. These types of reports are available on the recipient, jurisdiction, and national level.

The NHM&E data variables have been developed with extensive input from respondents (representatives of HDs and CBOs), 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 current proposed NHM&E revisions. 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, linkage to HIV medical care, and referral to PrEP.

Collection of the NHM&E data will supply program managers with service-level information regarding program processes (e.g., who delivered what to whom, how many, where, and when) and clientlevel information (e.g., client demographics, behavioral risk factors, HIV test result, linkage to HIV medical care for persons testing HIV positive, verified referrals into prevention and essential support services, and interview for partner services) for monitoring and enhancing local HIV prevention programs. See **Attachment 5A** for the complete set of NHM&E data variables and values and **Attachment 5B** for the breakdown of the complete set by Option 1 and Option 2, the selection of which depend on the notice of funding opportunity and health department capability and timeliness to transition to Option 2. **Attachment 3A and 3B** for screenshots of the EvaluationWeb® direct data key entry screens.

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.

3. Use of Improved Information Technology and Burden Reduction

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 (e.g., HIV testing), CDC provides optional, modifiable data collection templates that recipients change and adapt for their own procedures and additional, local data needs. Many recipients use their own data system and extract data in specified formats for upload into EvaluationWeb®.

For health departments who choose to key enter data directly into the EvaluationWeb® system, recipients are allowed to customize the system within specified limits to include data for local use that is not reported to CDC. In addition, the system is set up by an administrator who specifies the type of funding received from CDC and other default information that automatically populates what appears on data entry screens in order to simplify data entry.

All directly funded CBOs key enter their data into EvaluationWeb®. Data entry from CBOs directly funded by CDC is slightly different from what is asked of CBOs who are funded by health departments using CDC funds, so the system adjusts the data entry screens for CBOs based on the type of funding.

The NHM&E data entry screen for collecting the Option 1 NHM&E requirements (**Attachment 3A**) and the other for collecting Option 2

NHM&E requirements (**Attachment 3B**). System screens may be adjusted to the needs of the specific health department or CBO.

All funded HDs and CBOs under CDC HIV prevention program funding announcements must submit required NHM&E data to CDC through an approved CDC Data System. CDC is currently using EvaluationWeb® for NHM&E data. EvaluationWeb® is a secure, browser-based software application designed to provide the necessary mechanism for collecting and reporting standardized, sensitive NHM&E data.

HDs are given the option of using their own software system to collect NHM&E data and uploading to EvaluationWeb® or keyentering data directly into the CDC-provided EvaluationWeb® software. Directly-funded CBOs are required to key-enter data directly into the CDC-provided EvaluationWeb® software. HDs 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®. HDs who choose to enter data directly into EvaluationWeb® and CBOs that are required to enter data directly 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 HDs, CBOs, and other HIV prevention partners. The EvaluationWeb® software combines agency, program, and client data into one system. This integrated system reduces the burden of entering client data separately by program 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 recipients 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 departments 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 recipients.

Within CDC, there are two demonstration projects (Comprehensive HIV Prevention and Care for Men Who Have Sex with Men of Color, OMB 0920-1178, Exp. 04/30/2020; Project PrIDE, OMB 0920-1201, Exp. 10/31/2020) that have 12 recipients in common with this ICR. Similar data elements were aligned. In addition there are shared data elements and recipients in the STD Management Information System (MIS) developed by CDC/NCHSTP/DSTDP and used by some state health departments in collaboration with HIV prevention programs to collect Partner Services (PS) data. The data collected on STD/MIS have been 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 EvaluationWeb®, 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. The STD/MIS collects additional information 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, replaced by an optional PartnerServicesWeb® software that became available in 2013 that recipients may choose to use to collect PS data. Recipients 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, two other federal systems were reviewed: 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. Although SAMHSA's Combined Rapid HIV/Hepatitis Testing Form (RHHT) includes some of the same information as CDC's NHM&E testing requirements, CDC anticipates that there will be relatively little duplication of effort.

If the number of new HIV infections is to be reduced, the quality of HIV prevention programs designed to conduct HIV testing, link persons to HIV medical care and other essential support services, and refer high risk HIV negative persons to PrEP and other support services must be improved. The NHM&E data significantly advance 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

HDs and CBOs that receive CDC funding for HIV prevention vary greatly in size and in their capacity to collect and report the NHM&E data. Some CBOs 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 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 recipients. 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, 04/23/2018, Volume 83, Number 78 pages

17662-17663. See **Attachment 2** for a copy of the *Federal Register* notice. No public comments were received.

CDC developed the NHM&E data variables with feedback from state, territorial, and local health departments and CBOs. Developing the NHM&E data variables has been a long and collaborative process with these stakeholders. There was extensive consultation by email on revisions to the variables and allrecipient webinars held. A detailed listing of agencies and persons consulted is found in **Attachment 4**. Representatives from funded agencies continue to be informed through quarterly 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. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The CDC Privacy Review Officer and the NCHHSTP IT Security Information System Security Officer (ISSO), have assessed this package for applicability of 5 U.S.C. § 552a, and determined that the Privacy Act does not apply to the overall information collection. A privacy impact assessment was completed (see Attachment 10).

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.

Health departments may collect identifiers (name, address, etc.) on clients who receive HIV prevention services, including HIV testing as a normal process in providing patient care. The Privacy Act is not applicable to the client-level data because the information will become a part of the health departments' already established record systems; moreover, its availability and use will be limited to the provision of services at the local level.

All funded HDs and CBOs under CDC HIV prevention program funding announcements must submit required NHM&E data to CDC through an approved CDC Data System. CDC is currently using EvaluationWeb® for NHM&E data. EvaluationWeb® is a secure, browser-based software application designed to provide the necessary mechanism for collecting and reporting standardized, sensitive NHM&E data.

EvaluationWeb® resides outside the CDC network and is hosted by Luther Consulting, LLC. Twice per year, each of the participating HDs and CBOs send their data, either by key entry or uploading a file, directly to EvaluationWeb® which processes the data and makes specific elements available to authorized agencies or individuals.

Prior to gaining access to EvaluationWeb®, individuals must successfully authenticate their credentials through a process overseen by the CDC and Luther Consulting, LLC. Luther Consulting, LLC enforces required access controls. Users from contracted entities (CDC) must complete Electronic Authentication Assurance Level 2 identity proofing requirements established by CDC and the completed authorization is transmitted to Luther Consulting via the Secure Access Management System (SAMS). Luther Consulting, LLC will only authorize accounts for individuals who have successfully completed the identity proofing process, who have been recommended by their appropriate jurisdiction, and have been authorized by the CDC program official. Users are assigned access level based on organizational role in the recipient jurisdiction. Once users have been granted access they are issued a unique user name and password. Users are not permitted to share their login information with anyone. Each user must have his or her own unique user name and password. Users must also read and sign the rules of behavior for the EvaluationWeb® on an annual basis to ensure they adhere to the requirements for use of the system.

Luther Consulting, LLC maintains configuration management of the EvaluationWeb® system by adhering to the System Baseline Configuration (SBC) established by CDC for all system servers. Changes to the system are managed by using the CDC Office of the Chief Information Security Officer (OCISO) Information System

Change Management (ISCM) Standard Operating Procedures (SOP), which requires that all changes must be approved by OCISO prior to implementation into the production environment.

Additionally, the EvaluationWeb® system uses Transport Layer Security (TLS) 1.1 and 1.2 as required by CDC to encrypt the browser to browser connection between EvaluationWeb® and the HDs and CBOs when they upload data to the system. Additional encryption used by the EvaluationWeb® system includes AES-256 (for cell level SQL encryption), ColdFusion which installs the RSA BSafe Crypto-J library, ASA 5515x firewalls, and RSA (2048bit PGP or GNUPGP method encryption). All encryption used by the EvaluationWeb® system meets Federal Information Processing Standards (FIPS) 140-2 requirements and are certified by NIST.

The EvaluationWeb[®] system has passed the full Security Assessment and Authorization Process and has an authority to operate (ATO) until May 17, 2019 (**Attachment 7**.) This means that our security measures meet the requirements of the NIST 800-53, HHS, and CDC.

About half the HDs maintain their own electronic data collection systems and upload data from their systems into EvaluationWeb®. The other HDs and all directly funded CBO recipients key-enter data directly into EvaluationWeb®.

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. 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, such as name, address, birthday, etc., may be collected by the HD 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.

Whether data is uploaded to EvaluationWeb® using CDCspecified formats or directly entered into EvaluationWeb®, no individually identifiable information is submitted to CDC. For NHM&E data management purposes, each individual record will be identified by a 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.

11. Institutional Review Board (IRB) and Justification for

IRB Approval

This data collection has been determined not research involving

human subjects. Therefore, IRB approval is not required.

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 behavior 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 behavior and needs 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

The estimates for the number of annualized burden hours are provided in the table below. The calculations on which these estimates are based are provided in **Attachment 8**. There are two types of organizations that are required to provide data. The

first is the 66 state, territorial, District of Columbia, and directly funded city HDs. The second type of organization providing information are CBOs. The data required by respondents for this ICR include variables for the following NHM&E data sets:

- Agency Data
- HIV Testing Data
- Partner Services (PS) Data (HDs only)
- Budget Data (HDs only)

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 and CBOs will also receive training on NHM&E. This burden is included.

CBOs generally do not conduct Partner Services beyond identifying index cases, so that burden will be reported only for health departments. Budget data are also only required for HDs.

The calculations for annualized burden are derived from the HD 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. The total estimated annualized hourly burden anticipated for all data collections would be approximately 204,498 hours. A total 206,226 burden hours per year were approved

under the existing ICR covering February 9, 2016 – February 28, 2019.

The revised variable set with changes indicated is in Attachment 5A and 5B. We are continuing to work with the recipients to keep the burden to a minimum while still obtaining the data necessary for national reporting and program management.

Number of Average Responses Burden per Total Type of Form Name Number of response Burden per Respondents Respondents Respondent (in hours) Hours Health Health Department departments 66 2 1,426.5 188,298 Reporting (att 5b) Community-Community-Based Based Organization 150 2 54 16,200 Organizations Reporting (att 5b) Total 204,498

Table A.12-A. Estimated Annualized Burden Hours

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 departments representing a range of sizes and HIV prevalence in their funding applications, it is estimated that health department staff who collect NHM&E information will be paid about \$57,000 annually. Based on the OMB Pay Tables for the Atlanta area, comparable annual salary for Federal General Schedule (GS) employees is that of a GS-9 step 3 (\$56,680 annually or \$27.16/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 \$40,000 annually. Comparable annual salary for Federal General Schedule (GS) employees is that of a GS-6, step 2 (\$40,394 annually or \$19.36/hour).

Table A.12-B.	Annualized	Cost	to	Respondents
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Type of	Numbe r of Respo n-	Form Name	Number of Respon ses per respon	Average Burden per Response (in	Hourly Wage	Total Respondent
Respondents	dents		dent	hours)	Rate	Cost
Health jurisdic- tions	66	Health Department Reporting (Att 5b)	2	1,426.5	\$27.16	\$5,114,174
Community- Based Organizatio ns	150	Community- Based Organizati on Reporting (Att 5b)	2	54	\$19.36	\$313,632
TOTAL				\$5,427,806		

Source:

https://www.opm.gov/policy-data-oversight/pay-leave/salarieswages/2018/general-schedule/

See Attachment 8 for calculation of Average Burden per Response.

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 HDs and CBOs varied widely from state to state and program to program, it is the usual and customary business practice of the recipients 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, recipients that collect NHM&E data should incur little or no net additional costs to respond to this data collection.

Overall, HDs 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 HD
- 2) Revise their existing HIV prevention information technology system and upload the required NHM&E data in one of the allowed formats into EvaluationWeb®

CBOs are required to directly key-enter data into the EvaluationWeb® software provided by CDC at no cost to the CBO.

Services offered to the recipients by CDC to support NHM&E data collection include training, technical assistance, and continued support to recipients 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 recipients for these updates.

14. Annualized Cost to the Federal Government

The annualized cost to the government is \$844,958.40. 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 threeyear 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. The cooperative agreements for which NHM&E data are collected are CDC-RFA-PS18-1802, Integrated HIV Surveillance and Prevention Programs for Health Departments; CDC-RFA-PS17-1704, Comprehensive High-Impact HIV Prevention Projects for Young Men of Color Who Have Sex with Men and Young Transgender Persons of Color; CDC-RFA-PS15-1502, Comprehensive High-Impact HIV Prevention Projects for Community-Based Organizations. Additional expenses will be incurred by CDC for training recipients, 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 \$844,958 annually (see table below).

Training for recipients 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 \$55.61/hour will each expend approximately twenty-five percent (25%) of their time or a total of 1040 hours/FTE annually to oversee these trainings.

Technical assistance will be provided through an e-mail and telephone service center overseen by a CDC FTE. It is expected that the equivalent of two GS-13 step 9 (\$55.61/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 (\$49.76/hour) and the data analysts would be at the pay scale of GS-12 step 5 (\$41.85/hour).

Table 14.A Annualized Cost to the Government

Employee Function	Annual Burden (in hours)	Hourly Wage Rate	Annual Cost		
Training	1,040	\$55.61	\$ 57,834.40		
Technical Assistance	1,040	\$55.61	\$ 57,834.40		
Data Manager	4,160	\$49.76	\$207,001.60		
Data Monitoring,					
Analysis, and Reporting	12,480	\$41.85	\$522,288.00		
TOTAL ANNUAL FEDERAL GOVERNMENT COSTS: \$844,958.40					
Source: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-					

wages/2018/general-schedule/

15. Explanation for Program Changes or Adjustments

This is a program change of a currently approved data collection. There is a burden decrease from the 2016 approved 206,226 hours, to the currently requested approval for 204,498 burden hours (1,728 hours or 0.8%).

CDC is requesting the following revisions to adjust the variables from the most recently approved change request (May 25, 2018) in the following ways:

- Removed 48 health department budget allocation variables associated with the previous health department funding (PS12-1201).
- Added 83 health department budget reporting variables.
 Health departments will be required to annually estimate the percentage of their overall funding allocated and

expended for 11 required core strategies and activities associated with the new integrated health department funding awarded in January 2018 (PS18-1802). Although this represents an increase of 35 budget related variables, we anticipate no additional data collection burden since it is likely these data are already being collected by health departments and we are requesting estimated percentages rather than dollar figures annually.

- Removed 13 of the 15 system-level variables associated with the schema for those health departments that upload data into EvaluationWeb.
- Added one additional variable to further ascertain priority populations (sex with a transgender person).

The revised variable set is in **Attachment 5A and Attachment 5B**. The variables no longer required are listed in **Attachment 5C**.

The costs above the normal cost of doing business are covered by the CDC funding rather than imposing a financial cost on the recipient. 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 2009-2010 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 are 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 recipient, 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 <u>5CFR 1320.3(h)(1)-(10)</u>

There are no exceptions to the certification.