REQUEST FOR OMB REVIEW AND REINSTATEMENT OF APPROVAL FOR THE

HIV PREVENTION PROGRAM EVALUATION AND MONITORING SYSTEM FOR HEALTH JURISDICTIONS AND COMMUNITY-BASED ORGANIZATIONS

(Formerly OMB 0920-0696, expired November 30, 2006)

Supporting Statement A

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Background and Overview

The National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) (proposed), Centers for Disease Control and Prevention (CDC), is requesting a 3-year OMB approval reinstatement for the HIV Prevention Program Evaluation and Monitoring System (PEMS) for Health Jurisdictions and Community-based Organizations (OMB 0920-0696).

The initial PEMS OMB request was approved October 6, 2005, “until 11/06 at which time CDC shall resubmit for OMB review including a report addressing initial results of the collection and public burden.” However, delays in the development of the data collection software and requests by grantees for additional time to modify their data collection procedures have prevented the initial data collection originally anticipated for 2006. Currently, the third release of the software occurred on November 20, 2006. There is no date for the initial data collection scheduled, which would be only a partial data collection (Counseling, Testing, and Referral data) but it could not be prior to 45 days after the end of the second quarter of 2007. Hence, there is no information on the initial results of the data collection to report. Phasing in of data collection by type of

data, starting with Counseling, Testing, and Referral data, will begin after OMB approval. Full data collection is currently anticipated to begin in 2008.

There are efforts in process to gather information on the public burden through an implementation assessment, grantee workgroups, and grantee consultations. These efforts were initiated during the summer of 2006. However, information on public burden is still in the process of being gathered, with full results not anticipated until the middle of 2007. Where preliminary information is available, these refined estimates have been incorporated into the burden calculations. This has resulted in an increase in the burden estimates over what was in the previous submission and the 60-day notice for this submission. CDC will submit a report addressing initial results of the collection and public burden within nine months of the first complete data collection.

The following application for approval is identical to the previously approved application except for the following sections.

- Section A-8 has been expanded to include external consultations that have occurred since the previously

approved submission. Some of this information has been moved to Attachment B.

- Section A-12 has been revised to take into account new information on the burden of collecting and reporting HIV Counseling, Testing, and Referral data.
- Attachment C has been updated to include the revised client-level variables in Release 3.0. Attachment C is in two parts: Attachment C1 specifies data collected from state health departments and directly funded cities, and Attachment C2 specifies data collected from directly funded community-based organizations.
- Attachment E has been updated to include the revised Counseling, Testing, and Referral form. This form is a simpler form, with a reduced number of variables from the previous form.

A. Justification

1. Circumstances Making the Collection of Information Necessary

An important goal in reducing the number of new HIV infections is to improve the quality of HIV prevention programs designed to reduce high-risk behaviors in persons most likely to acquire or transmit HIV.

The CDC currently funds HIV prevention programs in 65 state and local health jurisdictions and approximately 160 community-based organizations (CBOs) through cooperative agreements. These HIV prevention programs conduct interventions that are intended to reduce high-risk behaviors in targeted populations. Monitoring and evaluation of these HIV prevention programs are essential to helping health jurisdictions and CBOs develop, deliver, and refine successful HIV prevention interventions and for strengthening their overall monitoring of the HIV/AIDS epidemic. Consequently, accurate and reliable program process and outcome data must be collected. However, the HIV prevention program data collected and reported to CDC to date have not been standardized, are often incomplete, and are insufficient for adequately monitoring 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 to be assessed include the grantee’s capacity to deliver and monitor prevention services, the implementation of these processes, and prevention outcomes that occur. The grantees and CDC will use the performance indicators to show that the programs they implement

or support are efficient and effective in achieving their stated goals.

The PEMS is an electronic, secured, browser-based system that provides the necessary mechanism for collecting and reporting standardized HIV prevention program data. These data will be used for monitoring the delivery of prevention services to clients, implementing and improving HIV prevention programs, and reporting the required program performance indicators. Additionally, PEMS data will enable CDC to provide valuable feedback to these programs and to better account for the use of HIV prevention resources. All funded CBOs and 59 of the 65 funded health jurisdictions will be required to submit PEMS data. (The Pacific Territories will not be required to submit PEMS data.)

Collection of these data is authorized under Section 306 of the Public Health Services Act [42 U.S.C. 242(k)] (**Attachment A**).

2. Purpose and Use of Information Collection

The CDC *HIV Prevention Strategic Plan Through 2005* (which is the most recent published CDC HIV Prevention Strategic Plan and is expected to be in effect until a new plan is developed) provides the following overarching goals for HIV Prevention:

- Decrease by at least 50 percent the number of persons in the United States at high risk for acquiring or transmitting HIV by delivering targeted, sustained, and evidence-based HIV prevention interventions.
- Through voluntary counseling and testing, increase from the current estimated 70 to 90 percent, the proportion of HIV-infected people in the United States who know they are infected.
- Increase from the current estimated 50 to 80 percent the proportion of HIV-infected people in the United States who are linked to appropriate prevention, care, and treatment services.
- Strengthen the capacity nationwide to monitor the epidemic, develop and implement effective HIV prevention interventions, and evaluate prevention programs.

To continue to meet the goals of the *HIV Prevention Strategic Plan Through 2005,* credible HIV prevention data must be collected, analyzed, and reported. PEMS provides a comprehensive, yet parsimonious, set of program data variables essential to monitoring and evaluating HIV prevention programs.

The PEMS data variables have been developed with extensive input from respondents (representatives of health jurisdictions and

community-based organizations) and other HIV prevention partners. See **Attachment B** for a list of respondents. The data variables are based on HIV prevention business processes and sound scientific approaches to HIV prevention. Specifically, the PEMS data elements cover a range of HIV prevention activities such as agency information, program planning, community planning, HIV counseling and testing, partner counseling and referral, comprehensive risk counseling and services, and health education and risk reduction.

Collection of the PEMS 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 **Attachments C1** and **C2** for the PEMS data variables. See **Attachment D** for a sample of the PEMS Home Page.

The PEMS data enables CDC to identify best practices and to assist grantees in redesigning interventions that do not accomplish stated goals, such as the reduction of high-risk behaviors in targeted populations. CDC will use the PEMS data, in

combination with surveillance and research data, for the following purposes:

- Assess CDC HIV budget allocations with respect to prioritized risk populations
- Identify gaps in HIV prevention service provisions
- Assess the extent to which HIV prevention programs have reached their target population
- Determine if the interventions are being delivered as intended
- 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, objectives, and strategies
- Produce standardized and specialized reports that will inform grantees, CDC project officers, and stakeholders of the status and trends of a host of process, outcome, impact, and accountability measures. Reports generated by the system will include reports for quality assurance, comparison of planned activities or expenditures to actual activities or expenditures, data for calculating required performance indicators, and data on specific interventions. These types of reports are available on the grantee, jurisdiction, or national level.

3. Use of Improved Information Technology and Burden Reduction

PEMS provides an electronic mechanism for collecting and reporting standardized HIV prevention data. Consequently, agencies relying on paper-based data collection and submission systems will be able to transition to electronic reporting.

The PEMS software application was designed with input from representatives of health jurisdictions, community-based organizations, and other HIV prevention partners. The PEMS software application and supporting database were designed to combine agency, program, 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.

To facilitate data entry for counseling and testing, the PEMS software was designed to interface with a scanning technology. At this time, a scanning form and technical solution have been developed for HIV counseling, testing, and referral (CTR) (see **Attachment E.**) (Note that this CTR form includes optional fields requested by health jurisdictions; not all the data on the form

is part of PEMS or reported to CDC. Optional fields are noted on the form.) Use of this form and the scanning technology is optional; some grantees have developed their own forms.

The PEMS software also generates pre-specified reports and includes an import-export data transfer process. The import-export function enables users to extract data to analytical software packages, such as SAS and SPSS, as well as transfer data to CDC. In this way, the PEMS software accommodates submission of data to CDC from those agencies that choose or are required to use an existing electronic data collection system.

Finally, data variable business rules have been built into the PEMS software application to enhance the reliability and integrity of the PEMS data. These business rules establish the interrelationships among variables and serve as system performance checks for accurate data entry. CDC grantees gain access to the PEMS application through a secure internet connection, which requires electronic authentication of the users and maintains data confidentiality and security.

4. Efforts to Identify Duplication and Use of Similar Information

Efforts to identify duplication of HIV prevention program data reported in PEMS include the assessment of existing or previously used HIV prevention data collection systems used by CDC, other federal agencies, as well as health jurisdictions and community-based organizations.

Within CDC, data elements from several current or 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 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 state health jurisdictions in collaboration with HIV prevention programs to collect Partner Counseling and Referral Service (PCRS) data (STD/MIS data are not reported to CDC, except for morbidity data, which is reported through the NETSS system). PCRS data are submitted at the aggregate level to CDC (refer to OMB No. 0920-0497, Evaluating CDC Funded Health Department HIV Prevention Programs, Partner Counseling and Referral Services).

To reduce duplication, the PEMS software and supporting database combine these four systems into one. With the exception of the STD MIS system, the other systems (ERAS, CBOS, and CTS) will be replaced by PEMS. The STD MIS collects additional information, not reported to CDC, outside the purview of HIV prevention.

In addition to 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.

Finally, an appraisal was conducted to obtain a comprehensive understanding of existing health jurisdiction and CBO systems and their HIV prevention processes. Beginning in October 2002, reviews were conducted via consultations, workshops, and site visits. Several large health jurisdictions have developed data collection systems that have electronic and/or paper submission processes to meet jurisdiction-specific needs. Examination of these systems revealed that the information collected varies widely from state to state and program to program, providing only a limited and fragmented view of HIV prevention services. Several of the existing systems were not designed to collect client-level data. With these systems, clients could not be linked across programs and their referrals could not be tracked. Furthermore, the data collected for these systems was not of sufficient detail to cover the range of data needed for a national perspective.

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 PEMS will significantly advance the monitoring and

evaluation of HIV prevention programs by providing a comprehensive system for collecting, storing, and reporting prevention data. 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 PEMS 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 Businesses or Other Small Entities

State health jurisdictions and community-based organizations that receive CDC funding for HIV prevention vary greatly in size and their capacity to collect the data required in PEMS. The PEMS variables represent a parsimonious 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 PEMS data variables have been kept to a minimum, and all respondents will be expected to complete the required data. 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 or expand 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 quarterly basis. Less frequent data submission would result in a lag time between the occurrence of program problems and their identification. This delay would permit 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 Guidelines 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. A 60-day notice to solicit public comments was published in the *Federal Register*, November 21, 2006, Volume 71, Number 224, page 67354. See **Attachment F** for a copy of the *Federal Register* notice. No public comments were received.

B. CDC is developing PEMS with feedback from state, territorial, and local health jurisdictions and CBOs. Developing PEMS has been a long process. A detailed description of consultations, site visits, workshops, etc. is found in **Attachment B**. Also in **Attachment B** is a list of persons who were consulted on this project. Representatives from funded agencies continue to be informed through phone calls and e-mail correspondence.

Additional consultations, workshops, and site visits are also scheduled.

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

The CDC Privacy Office staff have reviewed this OMB application and have determined that the Privacy Act is not applicable. As previously discussed, much of the information to be collected through PEMS relates to program activities and characteristics of respondent organizations. However, the health jurisdictions will also collect identifiers (name, address, etc.) on clients who received HIV prevention services, including HIV counseling, testing, and referral services. The Privacy Act is not applicable to the client-level data because the information will become a part of the health jurisdictions' already established record systems; moreover, its use will be limited to the provision of services at the local level.

For PEMS data management purposes, 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 PEMS, but only at the local level can the client key be re-linked to identifiers. The client-level data accessible by CDC will not contain client names, but will include client demographics (age, gender, race, pregnancy status, HIV status, risk behaviors, etc.) and exposure characteristics (see Attachment C, Table G1, 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 other CDC HIV/AIDS surveillance systems, the program has determined that an Assurance of Confidentiality for prevention program clients (and the establishments furnishing the information) under section 308(d) of the Public Health Service (PHS) Act is necessary. This application is in the process of being reviewed by the CDC Confidentiality Office. 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, will be imposed.

CDC grantees gain access to the PEMS application through a secure internet connection, which requires electronic authentication of the users and maintains data confidentiality and security. All system users are trained in privacy, confidentiality, and security policies; and a memorandum of understanding between CDC

and each PEMS 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 Administrators (**Attachment G1**) and Users (**Attachment G2**) to clarify rules, roles, and responsibilities associated with the system.

While sensitive data will be submitted to CDC through PEMS, personally identifiable data will not be submitted to CDC. In cases where health jurisdictions and CBOs utilize the CDC-developed centralized PEMS, the data will then be sent to an intermediate database (DB1) at CDC. A subset of that data will then be submitted quarterly to the PEMS database (DB2) from DB1. The data on the PEMS database (DB2) will not contain any personal identifying information. In cases where health jurisdictions choose not to use the CDC-developed centralized PEMS software, but enter data into their own software, only the de-identified data will be submitted to CDC. Public used 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 PEMS system has passed the full Certification and Accreditation Process and has an authority to operate (ATO) until 10/27/08. This means that our security measures meet the requirements of the NIST 800-53, HHS and CDC.

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

PEMS R3.0 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.

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.

11. Justification for Sensitive Questions

Some of the client-level data to be collected is 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. While there have been some minor changes to the variables previously submitted for approval, they are basically unchanged from what was previously approved. Because collection of these data will be used to target high-risk populations and 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) and to support compliance with the HHS Policy Statement on Inclusion of Race and Ethnicity in DHHS Data Collection Activities of October 24, 1997.

12. Estimates of Annualized Burden Hours and Costs

A. Annualized Burden Hours

The estimates for the number of burden hours are summarized in the table below. There are two types of organizations that are required to provide data. The first is State and directly funded local health departments whose burdens are described in the first 4 lines of the burden table. There are 59 health jurisdictions and the data required by respondents for this project includes variables for the following PEMS data sets:

- Agency and Program Plan Data
- Health Education and Risk Reduction (HE/RR) Data
- HIV Counseling, Testing, and Referral (CTR) Data
- Partner Counseling Referral Services (PCRS) Data

Some jurisdictions will provide scanned CTR data (30) and others will provide non-scanned CTR data (29). All will also receive training.

The second type of organizations providing information are community-based organizations (CBO). They will be providing the same data sets as shown in the bullets above and their burdens are summarized on lines 5-7 of the table. There are 160 CBOs, of which 70 will be providing counseling, testing and referral data. All will be receiving training.

The calculations for annualized burden are derived from the time needed to search the PEMS 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 PEMS data reporting burden is summarized in the following table. However, the burden is substantial so the explanation for the estimate in each cell is in **Attachment H**. These estimates are higher than the estimates provided in the 60-day Notice; during the time between submission of the 60-day Notice and the submission of this package, the burden estimate has been re-evaluated, based on additional information about the PEMS as it was developed and actual experience with system prototypes, and determined to be larger than the original estimates.

Table A.12-A. Estimated Annualized Burden

Type of Respondents	Number of Respondents	Form Name	Number of Responses per Respondent	Average Burden per response (in hours)	Total Burden (in hours)
Health jurisdictions	59	PEMS Data Variables and Values (HD)	4	137	32,332
Health jurisdictions (CTR-scan)	30	Counseling, Testing and Referral Form	4	509	61,080
Health jurisdictions (CTR non-scan)	29	PEMS Data Variables and Values (HD)	4	165	19,140
Health jurisdictions (Training)	59	PEMS Data Variables and Values (HD)	4	10	2,360
Community-Based Organizations	160	PEMS Data Variables and Values (CBO)	4	84	53,760
Community-	70	Counseling,	4	23	6,440

Table A.12-A. Estimated Annualized Burden

Type of Respondents	Number of Respondents	Form Name	Number of Responses per Respondent	Average Burden per response (in hours)	Total Burden (in hours)
Based Organizations (CTR)		Testing and Referral Form			
Community-Based Organizations (Training)	160	PEMS Data Variables and Values (CBO)	4	10	6,400
Total					**181,512**

B. Annualized Cost to Respondent

It is estimated that health jurisdiction staff who collect PEMS information will be paid $40,000 annually. Comparable annual salary for Federal General Schedule (GS) employees is that of a GS-9 step 5 ($41,342 annually or $19.81/hour).

To derive an estimated pay for CBO staff, the salaries of four (4) mid-level staff were obtained from a CBO in Texas and a CBO in New York City. The average salary is $29,899 annually. Comparable annual salary for Federal General Schedule (GS) employees is that of a GS-6, step 5 ($30,416 annually or $14.57/hour). The average annual salary of four mid-level staff working in CBOs located in New York City and Texas: $33,798 + $26,000 = $59,798 divided by 2 locations = $29,899.

Table A.12-B. Annualized Cost to Respondents

Type of Respondents	Number of Respon-dents	Form Name	Number of Responses per respondent	Average Burden per Response (in hours)	Hourly Wage Rate	Respondent Cost
Health jurisdic-tion Staff	59	PEMS Data Variables and Values (HD)	4	147	$19.81	$687,249
Health jurisdic-tion Staff (CTR)-Scan	30	Counseling, Testing and Referral Form	4	509	$19.81	$1,209,995
Health jurisdic-tion Staff (CTR)- non-scan	29	PEMS Data Variables and Values (HD)	4	165	$19.81	$379,163
CBO Staff	160	PEMS Data Variables and Values (CBO)	4	94	$14.57	$876,531
CBO Staff (CTR)	70	Counseling, Testing and Referral Form	4	23	$14.57	$93,831
					TOTAL	**$3,246,769**

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

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 customary and usual 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 choose to use the CDC-provided software should incur no net additional costs to respond to this data collection.

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

1) Use the PEMS software provided and installed by CDC at no cost to the respondent (Centralized PEMS, “CPEMS”)
2) Revise their existing HIV prevention information technology system and use the import-export data transfer process in the PEMS (External PEMS, “XPEMS”)
3) Deploy PEMS locally, within the respondent facility using equipment purchased by the respondent (Decentralized PEMS, “DPEMS”)

In addition, respondents may choose to enter the required PEMS CTR data variables using the CDC developed scan form and the associated scanning technology, or use one of the three methods mentioned above.

Services offered to the grantees by CDC to support PEMS will include training, technical assistance during installation of the software, and continued support to grantees through a help desk, website, and various forms of correspondence. Implementing the PEMS software will require no start-up costs for the respondents electing to use the CPEMS option.

For those health jurisdictions and directly funded CBOs who will use the CTR scan form, the capital costs associated with this technology option are estimated to be approximately $1,000.00 per scanner. This would affect the 30 health jurisdictions directly funded to do CTR if they need to purchase scanners. This cost can be annualized over the useful lifespan of the scanner, estimated to be 7 years (based on the timeframe that health jurisdictions presently replace their scanner). This would result in an annualized cost of $143/year over 7 years for each organization that purchases a scanner.

There will also be the additional cost of the scanning software for the 30 health jurisdictions that will scan the new CT form. The cost of this software is estimated to range from $16,000 - $30,000, with an average of $20,000. The lifespan of this software is estimated to be 13 years; based on the life of the present CTS software. The annualized estimated average cost for the software is $1,538/year over 13 years for each of the 30 health jurisdictions that decide to purchase this software ($20,000/13 years = $1,538/year).

Release of various PEMS software versions will be necessary over time, but it is anticipated that PEMS and its data variables will be essential tools for monitoring and evaluating HIV prevention programs for many years.

14. Annualized Cost to the Federal Government

The Program Evaluation and Monitoring System 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 PEMS data, and generating assorted reports. Total costs for these activities are estimated at $307,227 annually (see table below).

Training for grantees is currently being planned. It is probable PEMS training for grantees will be conducted annually. Instruction will include topics such as confidentiality and computer security, use of PEMS, 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-12 step 5. It is expected that the equivalent of two FTEs paid $29.44/hour will each expend approximately twenty-five percent (25%) of their time or 1080 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 a GS-13 step 5 ($35.01/hour) will expend approximately twenty-five percent (25%) of working hours (540 hours) to oversee this service center.

Monitoring, analyzing, and reporting the PEMS data are projected to require the expertise of the equivalent of one data manager and three data analysts. The data manager would be at the pay scale of GS-13 step 5 ($35.01/hour) and the data analysts would

be at the pay scale of GS-12 step 5 ($29.44/hour). Prior to PEMS, a data manager and two analysts reviewed, analyzed, and interpreted HIV prevention program data submitted by 65 health jurisdictions and 90 CBOs. It is estimated that one additional analyst is needed for PEMS data due to the increase in data variables required for PEMS and the submission of data from 70 additional CBOs, even though the number of health jurisdictions reporting PEMS data will be only 59, as the Pacific Territories will not be required to report the full PEMS data set.

Employee Function	**Annual Burden (in hours)**	**Hourly Wage Rate**	**Annual Cost**
Training	1080	$29.44	$31,795
Technical Assistance	540	$35.01	$18,905
Monitoring, Analyzing and Reporting	2080 6240	$35.01 $29.44	$72,821 $183,706
TOTAL ANNUAL FEDERAL GOVERNMENT COSTS:			**$307,227**

15. Explanation for Program Changes and Adjustments

The previously approved burden was 122,172 hours. We are currently requesting 181,512 hours, an increase of 59,340 hours. The Program Evaluation and Monitoring System is a new data collection system that has not yet been fully implemented. Since

the previously approved data collection there have been some reductions and modifications to the required data variables to simplify data collection; a simplification of the Counseling, Testing, and Referral (CTR) form; and a recalculation of the annual burden. The reductions in the required variables were done at the request of the grantees, as was the simplification of the CTR form (detailed in Attachment E). The recalculation of the burden hours was based on actual testing of the software as additional functionality became active and on reports of selected grantees who provided estimates of actual time to input certain types of data. These reports indicated that the initial estimates of time to input CTR data, especially using the scanning system, were low. For various technical reasons, the scanning system is not as efficient as anticipated. The previous submission also did not fully account for the time required to input CTR data without using the scanning system. This additional information, much of which was not available at the time of the previous submission, has resulted in an increase in the estimated annual burden. However, as previously noted, there is still not data on the actual burden because a full data collection has not been done.

16. Plans for Tabulation and Publication and Project Time Schedule

The following is a brief overview of the current PEMS timeline.

16. Project Time Schedule	
Activity:	**Time Schedule**
PEMS CTR Data Collection	After OMB approval
PEMS Agency/Program Data Collection	Fall 2007
PEMS HERR Data Collection	Winter 2007
Full PEMS Data collection	Spring/Summer 2008

Once data from PEMS are received, analysis will be 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. Data from PEMS 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, PEMS data will be used to improve knowledge of local prevention practices, implementation of effective HIV prevention interventions, implementation of the Advancing HIV Prevention Initiative (AHP) interventions, and adherence to program reporting requirements. Reports generated by the system will 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 will be 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 Submissions

No exception is requested.

List of Attachments

Attachment A - Section 306 of the Public Heath Service Act

Attachment B - Description of consultations, site visits, workshops, and list of persons contacted outside the agency

Attachment C1 – PEMS Data Variables and Values for Health Jurisdictions

Attachment C2 – PEMS Data Variables and Values for Community-Based Organizations

Attachment D – PEMS Home Page

Attachment E – Counseling, Testing and Referral Form

Attachment F - Federal Register 60-day notice

Attachment G1 – Rules of Behavior for PEMS Agency System Administrators

Attachment G2 – Rules of Behavior for PEMS Agency Users

Attachment H – Burden Estimate Calculations