Medical Monitoring Project

0920-0740

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A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention requests approval for revision and 3 year extension for the previously approved Medical Monitoring Project (MMP)(0920-0740, expiration date June 2010). Interview and medical record abstraction data collection instruments were revised from the previously approved data collection instruments and a provider survey was added. Changes to the previously approved data collection instruments are outlined in the attachments and the provider survey is included as an attachment. The project activities and methods will remain the same as in the previously approved information collection request.

The following revisions were made to the OMB approved project 0920-0740:

- An application is being developed so that electronic data collection of medical record abstractions will take place in 2009. This change will not impact the burden from the previous data collection.
- The proxy interview described in the previous version has been discontinued.
- A few interview questions were added, some were removed, and others were revised from the previously approved instrument to make them easier for patients to understand and respond appropriately. Changes to the previously approved interview instruments are outlined in the attachments.
- A provider survey has been added.

<u>Background</u>

Human Immunodeficiency Virus (HIV) and Acquired Immune Deficiency Syndrome (AIDS) case reporting has been the underpinning of HIV/AIDS surveillance activities since the mid-1980s. All US states have reported AIDS cases using a standard case definition since 1985, and as of 2005, all states conduct surveillance for HIV infection without AIDS. As availability and prescription of highly active antiretroviral therapy (HAART) increased the interval between HIV infection and opportunistic infection (OI) diagnosis or development of severe immunosuppression became highly variable. Thus, case surveillance data on severe immunosuppression and AIDS-defining OI (AIDS-OI) diagnoses

were no longer sufficient for monitoring clinical outcomes of HIV infection.

At the request of Congress, an Institute of Medicine (IOM) committee in 2003 reviewed the status of HIV/AIDS surveillance data and the extent to which data currently collected by the HIV/AIDS case surveillance and supplemental surveillance systems were adequate for determining allocation of resources for treatment and care of HIV infection. The IOM committee recommended that the Health Resources and Services Administration (HRSA) and the CDC evaluate the cost and utility of redesigning studies to assess the specific needs and circumstances of people living with HIV. One of the approaches proposed by the IOM was to coordinate HRSA and CDC efforts to survey a random sample of HIV-infected persons to develop more accurate measures of need for prevention and care services. The IOM recommendations influenced the development of MMP (0920-0740).

Based on the IOM recommendations and the benefits of obtaining locally and nationally representative data on behaviors and clinical outcomes, 0920-0740 is designed to obtain a national probability sample of patients in care for HIV infection

This request is authorized by Title III – General Powers and Duties of Public Health Service, Section 301 (241.)a. Research and investigations generally (Attachment 1).

Data collection modules:
As part of the work preparing for a national probability sample of HIV-infected patients in care, 9 MMP project areas piloted the MMP methods and 26 project areas began collecting data in June 2007 following OMB approval. These project areas have identified providers of HIV care, identified providers and patients that fit the eligibility criteria for MMP, sampled and recruited providers and patients for participation, and have interviewed patients using a few questions from the Supplement to HIV/AIDS Surveillance (SHAS) project. Four project areas abstracted data from patients' medical records using an abstraction instrument developed from the Adult/Adolescent Spectrum of HIV Disease (ASD) project instrument (which had a clinical exemption from OMB review). The MMP has replaced both the clinic-based projects, SHAS and ASD, with methods that derive population based estimates.

The objectives of MMP are to collect nationally representative behavioral and clinical outcomes data on HIV-infected patients receiving medical care in the United States.

The objective of the Provider Survey is to obtain training history, areas of specialization, ongoing sources of training and continuing education about HIV care, and awareness of HIV treatment guidelines and resources from a randomly selected sample of HIV care providers (e.g., physicians, nurse practitioners and physician's assistants) in the United States. Ascertaining information about HIV care providers and the factors that influence the type of care they provide has rarely been done. Results from this survey will be used to assess who is providing HIV care, to examine the impact of provider characteristics on the quality and standard of care being provided to patients with HIV, and to identify opportunities to improve resources available to HIV care providers.

Privacy Impact Assessment

Overview of the Data Collection System

A CDC contractor will be responsible for all data management activities.

MMP project has 3 paradigms:

1. Interviews of providers and patients (approved by OMB)
2. Medical record abstraction (approved by OMB)
3. Provider survey (added in this revision)

Data from interviews will be collected through face-to-face personal interviews. Trained interviewers will collect the data using a software application loaded onto handheld or laptop computers.

MMP medical record data will be collected by trained medical record abstractors using a software application loaded onto laptop computers.

MMP Provider Survey data will be collected using a self-administered web-based application. Providers who do not wish to access the survey electronically will have the option to use paper forms which may be mailed to a postal address when completed.

The MMP Provider Survey will not collect personally identifiable information.

Items of Information to be Collected

The MMP interview will collect data on demographics, access to health care, adherence to antiretroviral therapy, HIV testing, sexual behavior, drug use, and access to HIV prevention services.

The MMP medical record abstraction will collect data on demographics, opportunistic illnesses, antiretroviral and other prescribed medications, laboratory test results, substance abuse and mental health.

Both the interview and medical record abstraction will collect date of birth; however, a combination of date of birth and other variables will not allow indirect identification of individuals.

No information in identifiable form (IIF) is being collected for the MMP Provider Survey. The MMP Provider Survey will not contain specific identifiers (e.g., name, address, social security number). Paper surveys will be destroyed three months after survey activities are completed.

The Web-based software used for provider survey supports the ability to encrypt response data and password-protect surveys so that unauthorized users will be unable to view, export, or modify collected data.

The identities of providers will not be transmitted to CDC, although they will be known to local MMP project area staff who conduct the survey at the selected providers' facilities. Identifying information will not be submitted to CDC for inclusion in the final MMP Provider Survey dataset. Please see section A.10 for detailed information regarding the de-identifying process

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

The website uniform resource locator for the provider survey will be:
http://www.cdc.gov/hiv/topics/treatment/mmp/index.htm

The MMP Provider Survey will collect information about MMP providers' education, training, characteristics of their

practice, and the care they provide to their HIV-infected patients. Only selected providers will have access to this website and selected providers must use a unique identifying code to initiate the survey. Cookies will not be used. A Secure Sockets Layer (SSL) certificate is used, which not only guarantees that all client-server transmissions are sent in an encrypted form, but also verifies that the client is actually connected to the correct server. The website contains a privacy policy and rules of conduct.

There is no website content directed at children under 13 years of age.

Collection of HIV and AIDS case surveillance data is regulated by Title III – General Powers and Duties of Public Health Service, Section 301 (241.)a. Research and investigations generally (Attachment 1).

2. Purpose and Use of Information Collection

- In anticipation of nationally representative data, CDC discontinued the ***Adult/Adolescent Spectrum of HIV Disease***, (ASD, clinically exempt from OMB) and ***Supplement to HIV/AIDS Surveillance Project***(SHAS, OMB 0920-0262, exp. 06/30/2004). Therefore, MMP data elements include those used in ASD and SHAS. If these data elements were not included in the data collection activities, CDC would not be able to publish recommendations and provide guidance to local agencies regarding HIV treatment and care and HIV prevention.
- A few data elements are shared with the National HIV Behavioral Surveillance (NHBS) (OMB 0920-0770, exp. 3/31/2011).

CDC issues recommendations for various HIV-related services several times during the year. MMP provides the evidence base for the policies and recommendations issued by CDC.

At the national level, MMP data will be useful for tracking national trends in morbidity, and service access and utilization for focusing and prioritizing national initiatives to improve the provision of treatment and prevention resources, and for benchmarking and evaluating progress towards national prevention and treatment initiatives. Annual or bi-annual national estimates of rates of opportunistic infection (OI) diagnoses will likely

be the gold standard for measuring the effectiveness of reducing the severity of HIV-related disease, and for describing the characteristics of persons who have progressive HIV disease and the reasons for progression. This information will be used to inform treatment and prevention guidelines for HIV care and guide prevention efforts. CDC, HRSA and other governmental agencies are also required to account for use of resources to Congressional funders; for example, reporting of data on prevention of OIs and provision of prevention services, and on the proportion of Comprehensive AIDS Resources Emergency (CARE) Act clients receiving CD4 counts and viral loads are required by the Government Performance and Results Act (GPRA).

The MMP Provider Survey is the first nationally representative sample that provides the base for evaluating the impact of provider characteristics on the standard of care being provided to patients with HIV, and to identify opportunities to improve resources available to HIV care providers.

National data will also be useful for documenting the need for treatment resources and the impact of treatment resources on care and treatment for people with HIV infection. Data on changing patterns of utilization of care and treatment resources will be used to determine resource requirements for future funding cycles. Data from MMP will be used to answer national questions about HIV care needs and impact of allocated resources.

Because of delays in the OMB clearance process, data collection from the 2007 cycle, the first data collection involving all 26 project areas, did not start on time. Therefore, 2007 data collection was extended into 2008, and these data have not yet been analyzed. Results from the 2005 pilot data collection are being compiled into a Surveillance Report, and following analysis of 2007 data, a 2007 National MMP Surveillance Report will also be prepared. Experience gained by the project areas from participating in the 2005 and 2007 data collection cycles, and in preparation for the 2008 cycle has improved efficiency in completing project activities at both the local and the national level.

At the local level, the MMP data will be useful for local HIV prevention program planning purposes, including the development of local epidemiologic profiles and responding to data requests from Health Resources and Services Agency

(HRSA) and other agencies which provide resources for HIV care and treatment. MMP will provide information on the characteristics of persons in care for HIV infection and the types of care they are accessing, and will identify needs for prevention and care services among a representative sample of persons in care. Information about access to and use of these services will be used in the evaluation of local care and prevention services for people living with HIV.

The estimates of unmet need for HIV care and services, and quality of HIV care provided and reported using MMP will assist state and local health departments in meeting reporting requirements of federal funders of HIV treatment and care. The implementation of electronic medical record abstraction should result in fewer errors and will allow local areas to have their data sooner as the need for data entry from paper forms will be eliminated.

Deriving state-level estimates of important behaviors and clinical outcomes using a probability sample will improve the quality of information available at the local level in two ways. First, HIV prevention community planning groups, CARE Act planning consortia and councils will for the first time have data representative of populations living with HIV in their community. Second, supplemental surveillance projects will have data with confidence intervals that reflect the range of accuracy around point estimates.

The MMP Provider Survey will collect data from a nationally representative sample of HIV care providers selected to participate in MMP. Information gained through the MMP Provider Survey will facilitate a better understanding of how and by whom HIV is being managed in the United States.

The main focus areas of the survey will include health care provider’s professional training history, ongoing sources of training and continuing education about HIV care and treatment, perceptions of patients’ barriers to care and reasons for declining HIV care, awareness of HIV related resources, and approach to antiretroviral therapy management and HIV risk reduction counseling.

Results from this survey will be used to assess who is providing HIV care, to examine the impact of provider characteristics on the standard of care being provided to patients with HIV, and to identify opportunities to improve

resources available to HIV care providers. A copy of the data collection instrument is included in Attachment 3.

Data from MMP will provide nationally representative estimates of behaviors and clinical outcomes of HIV infected persons in care. These data will inform prevention programs and treatment services, about the unmet need in HIV care, and increase existing knowledge in the medical care of HIV disease. By increasing our understanding of conditions that were difficult to asses using only interview or medical record abstraction, the revised MMP will guide national surveillance efforts particularly in the use of both medical abstraction information and self report from an interview. As MMP is a surveillance system that represents HIV infected persons in the US it will be imperative to notify the project areas and stakeholders of the findings of this project as soon as they are available.

Each participating facility or practitioner will have authority over the release of their facility-specific data (i.e., they choose whether or not they will participate and if patients will be identified to the health department by name or coded identifier). Each participating health department will be responsible for the release of local data. CDC will have primary responsibility for the release of data aggregated from each geographic area and will provide this information to all collaborating health departments. These data will be distributed to the providers, researchers, policy makers and other interested parties through presentations at local, national and international conferences, publications in peer reviewed journals, and presentations at different forums such as continuing medical education courses and seminars. Furthermore, CDC will regularly publish surveillance reports using data collected annually.

Patients and community members will be informed of MMP findings through multiple conduits of information. National data results will be released on the CDC, MMP website and through national publications and presentations at conferences. Local data results will be reported back to the community through means such as local publications, Epidemiologic Profile reports, presentations to local AIDS Service Organizations and community planning bodies and at conferences and workshops.

Each participating health department will disseminate local

data to their constituents and stakeholders. CDC will have primary responsibility for release of data aggregated from each geographic area and will provide this information to all collaborating health departments. These data will be distributed to the providers, researchers, policy makers and other interested parties through presentations at local, national and international conferences, publications in peer reviewed journals, and presentations at different forums, such as continuing medical education courses and seminars.

Patients and community members will be informed of MMP Provider Survey findings through multiple conduits of information. National data results will be released on the CDC's MMP website and through national publications and presentations at conferences. Local data results will be reported back to the community through local publications, HIV Epidemiologic Profile reports, presentations to local AIDS Service Organizations and community planning bodies, conferences, and workshops.

Privacy Impact Assessment Information

The revised MMP will replace denominator based estimates from ASD and SHAS for population based estimates based on nationally representative data. This information is being collected in order to provide an evidence base for formulating nationwide policies and recommendations on HIV treatment modalities and service delivery at the community level. The data from the three types of studies included in the MMP will also provide national perspective on the effectiveness of the treatment protocols.

Without nationally based information from patient, provider, and quality of service delivery, CDC's recommendations could not stand the critical argument that regional differences in patient characteristics, provider profiles, and service delivery options will necessitate local variations in implementation of the recommendations in treatment and services. Without the revised MMP collections CDC will not be able to formulate service delivery requirements that can be implemented throughout the country and evaluated with a common set of criteria.

No IFF is being collected for the MMP Provider Survey.

Both the interview and medical record abstraction will collect date of birth. The date of birth is being collected in order to determine eligibility to any one of the programs included in the MMP data collection paradigms. The sensitive information collected will not be linked to any other personal identifiable information and cannot be used to

reveal the identity of any one person. The proposed data collection will have little or no effect on the respondent's privacy.

No IFF is being collected for the MMP Provider Survey.

3. Use of Improved Information Technology and Burden Reduction

Interview data will be collected electronically minimizing burden to respondents and interviewers. The standardized interview instrument (Attachment 4a) will be provided by CDC in a Handheld-Assisted Personal Interview computer format, i.e., an electronic handheld device. One hundred percent of interviews should be collected using electronic applications. The interview instrument was developed using Questionnaire Development System (QDS) software (NOVA Research Company, Bethesda, Maryland). All patient interviews will be conducted by trained state/local MMP staff.

CDC will conduct training and site visits to provide instructions and technical assistance on how to use the CDC-provided software and hardware, conduct the interviews, archive the collected data, and transfer the data. CDC will also provide a manual (Attachment 5) with detailed instructions on interview conduct to participating state and local health departments. CDC will regularly train the interviewers and convene lessons learned meetings to understand the problems that can occur with the software and hardware that is used for conducting the interviews. Automated edit checks will be built into the computer software programs as a further quality control measure.

CDC has convened monthly interviewer conference calls to share lessons learned from the project areas and to allow project areas to share comments and ask questions about the previously approved methods and instruments. These discussions have resulted in the deletion of, or changes to, data collected to provide clarity and make interviews more efficient.

Medical record abstraction will be conducted by state and local project staff trained in the abstraction of clinical

variables from medical charts for all providers of HIV care who participate. One hundred percent of abstractions should be collected using electronic applications. Standardized software on a laptop computer will be used for abstraction of medical record data.

CDC is responsible for developing, reproducing and distributing the electronic medical record abstraction application (Attachments 6a-6d) to the participating state and local health departments. CDC will conduct abstractor training, and also provide a manual (Attachment 7) with detailed instructions for data abstraction to participating state and local health departments.

CDC has convened monthly abstractor conference calls to share lessons learned from the project areas and to allow project areas to share comments and ask questions about the previously approved methods and instruments. These discussions have resulted in the deletion of, or changes to, data collected to provide clarity and make medical record abstraction more efficient.
CDC will regularly train the abstractors and convene lessons learned meetings to understand the problems that can occur with the software and hardware that are used for conducting the abstraction. Automated edit checks will be built into the computer software programs as a further quality control measure.

The MMP Provider Survey will be collected electronically through a web-based application to minimize the burden to respondents. A paper survey will also be sent to respondents and will be completed and mailed by providers who do not wish to access the survey electronically. Ninety-five percent of provider surveys are estimated to be collected electronically.

Provision of electronic data collection hardware and software, training and technical assistance will help to reduce the burden on grantees conducting MMP. Transfer of data collected electronically will eliminate the need for data entry at the state/local sites. An evaluation of supplemental surveillance data using handheld interview devices such as the ones being used for MMP has shown the following: a reduction in the duration of the interview by up to 20%; a decrease in the average number of interviewer errors per interview such as skip patterns, out of range answers and missing data from an average of 2.5 per

interview to .3 per interview; and the elimination of the need for data cleaning associated with data entry and the errors listed above, resulting in a reduction in the time between the last interview and the production of a final analysis dataset from approximately 6 months to only 1 month.

4. Efforts to Identify Duplication and Use of Similar Information

- CDC is the only federal agency that collects regional and national data on HIV clients and providers regarding treatment services. There are no locally and nationally representative data on behaviors and clinical outcomes of patients in care for HIV infection. Within CDC, MMP data collection replaces Adult/Adolescent Spectrum of HIV Disease Project (ASD) (clinically exempt from OMB) and the Supplement to HIV/AIDS Surveillance Project (SHAS) (OMB 0920-0262, exp. 06/30/2004). A few data elements are shared with the National HIV Behavioral Surveillance (NHBS) (OMB 0920-0770, exp. 3/31/2011).

CDC discontinued the ASD and SHAS projects in anticipation of MMP and to avoid duplication of data collection efforts. MMP was also formed based on information taken from the behavioral surveillance data collected by state/local health departments for CDC. NHBS is currently collecting data on specific populations at increased risk for HIV infection (men who have sex with men, drug users and high risk heterosexuals), not on a population-based sample of HIV-infected patients in care.

CDC has already established relationships with other federal stakeholders and consultants during the conception and development of MMP and the MMP Provider Survey. Beginning in September 2003, consultations have been held with state and local health departments, the RAND Corporation, National Institutes of Health (NIH), HRSA, and other agencies. To promote collection of data that will be used by multiple agencies, ongoing communications with these federal and non-governmental partners will continue for the duration of this project. Meetings with these federal stakeholders and consultants who are aware of data collection on HIV-infected persons in care ensured that duplicate or similar data collection efforts do not exist. A one-time nationally representative sample of patients in care was drawn for the

HIV Cost and Services Utilization Survey conducted by the RAND Corporation; this was done in 1996-1997 and has not been repeated.

There are currently no locally and nationally representative data on the providers of HIV care in the US.

Data elements from the following previous (non-nationally representative) provider surveys were reviewed and incorporated into the MMP Provider Survey.

- Antiretroviral Treatment Access Study I (ARTAS) Provider Survey
- HIV Cost and Services Utilization Study (HCSUS) Provider Survey

5. Impact on Small Businesses or Other Small Entities

For MMP, initially, state or local health departments may be contacting providers of HIV care, including providers that are small businesses, to get an estimate of the number of HIV-positive patients to whom they provided care during the project period. Data collection will be kept to a minimum to lessen the burden on small businesses. Because providers are sampled proportionate to size, providers that are small businesses and have small patient loads will be less likely to be included compared with hospitals, clinics and group practices with larger patient loads. State and local health department MMP staff will work with facility staff to obtain records, similar to record review and data collection activities for reporting cases to HARS.

Data collected for MMP will be the same for patients from small and large providers. It is estimated that it will take providers an average of 5 minutes to pull each medical record for data abstraction. Staff from participating providers' offices will pull medical records for MMP staff, or the MMP staff will pull the medical records themselves.

Data collected for the MMP Provider Survey will be the same from small and large providers. As described above, because providers are sampled proportionate to size, providers that are small businesses and have small patient loads will be less likely to be included compared with providers from hospitals, clinics and group practices with larger patient loads.

6. Consequences of Collecting the Information Less Frequently

MMP data collection activities will occur during each calendar year from approval date for 3 years. Each year a sample of facilities will be drawn. From each selected facility, patients will be sampled for participation in the MMP. It is possible that a patient receiving HIV care be selected for participation in MMP in more than one year, as patients in care will have some probability of being selected each project year. Patients selected during a calendar year are only eligible to participate once during that year. There are no legal obstacles to reduce the burden.

Data for prevention and resource planning need to be conducted on an annual basis to meet reporting requirements of CDC and HRSA. Collecting data less than annually would not be advantageous, nor would it meet the needs of the grantees collecting the data and planning groups that rely on the data for resource allocation.

Data must be collected more often than quarterly because patients will be approached at their health care appointments and ideally interviewed at that time. Data collection from the patient's medical record will be done the same day or later in the project year. Quarterly data collection would not be logistically possible with approximately 400 patients to be interviewed and their medical records abstracted, because these 400 patients may have been selected for participation from 25-50 different facilities. Although data collection will occur on a more frequent basis than quarterly, each patient will only be approached, interviewed and have their medical records reviewed once during the project year. Each patient approached will be asked if they have been interviewed for the project during the project year. Patients who indicate that they have been interviewed previously will not be interviewed again.

MMP data collection activities will occur during each calendar year from the approval date for 3 years. Each year a sample of facilities will be drawn. From each selected facility, a sample of providers will be selected to participate in the MMP Provider Survey. It is possible that an HIV care provider be selected to participate in the MMP Provider Survey in more than one year, as providers will

have some probability of being selected each project year. Providers selected during a calendar year are only eligible to participate once during that year. Each provider sampled will only be surveyed once during the project year. Providers will be assigned a unique provider MMP identification number; therefore, only one MMP Provider Survey will be completed per provider.

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

This request fully complies with the regulation 5 CFR 1320.5.

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

8A. A 60-day notice to solicit public comments was published in the *Federal Register*, June 6, 2008, Volume 73, Number 110, page 32334. See Attachment 2 for a copy of the *Federal Register* notice. There was one public comment (Attachment 2a). The following comment was received on June 6, 2008: "this collection is outdated. this information has been collected for decades now. we do not need to collect the same information over and over. the word is out there on this disease. it is old. enough data has been collected to shut this boondoggle down,." CDC has received this exact same comment from the same person for all of its HIV-related information collections. No response or revision was made.

8B. Several consultations outside of the agency were conducted with the following people:

Consultations to discuss sampling methods and lessons learned from previous projects; to commence planning, identify sampling approaches and design for clinical outcomes surveillance; to discuss Medical Monitoring Project domains; to discuss second and third stage sampling, review project progress and discuss sampling issues, stratification parameters, and review scientific quality issues; and to discuss patient sampling methods and tasks were held with the RAND Corporation. They have also participated in bi-weekly conference calls from 2004 to the present.

Consultations to discuss how to use MMP data to meet HRSA data needs, how to avoid redundancy in data collections by CDC and HRSA grantees, and discuss research questions of

interest to HRSA, and future collaborations between CDC and HRSA on MMP were held with HRSA and NIH.

The MMP Provider Survey was discussed with the MMP Provider Advisory Board, Community Advisory Board, Principal Investigators and Project Coordinators.

The contact information for all consultants, dates of consultations and a summary of any major problems that were resolved during the consultation are in Attachment 8.

9. Explanation of any Payment or Gift to Respondents

Because the MMP interview will take approximately 45 minutes to complete, it is anticipated that incentives will increase participation. The majority of project areas offer patients who participate an incentive of $25 in cash or kind, however, a few project areas have supplemented this amount using health department funds and offer participants $30. Patients will be given approximately $25 in cash for participation in the interview. If local regulations prohibit cash incentives, equivalent incentives may be offered in the form of personal gifts, gift certificates, or bus or subway tokens.

Providers will also receive an incentive in the form of a gift card in the amount of $25 for their participation in the Provider Survey because providers frequently receive surveys in the mail and a nominal token of appreciation could increase participation rates.

10. Assurance of Confidentiality Provided to Respondents

A. This section has been reviewed by ICRO, who determined that the Privacy Act does not apply.

The Health Insurance Portability and Accountability Act (HIPAA) regulates how covered entities (including most health care delivery organizations) use and disclose certain individually identifiable information called protected health information (PHI). Surveillance data are specifically exempted from HIPAA because these data are required to be reported to the health department by state and local laws, and HIPAA permits health care providers to disclose PHI to public health authorities for the purposes of preventing or controlling disease. As a result, health department personnel can work with

health care providers to identify potential respondents for the MMP. The project areas have a letter to providers from CDC's Acting Privacy Rule Coordinator to give to providers who would like further guidance regarding their participation in MMP and the impact of HIPAA on the disclosure of personally identifiable health information to a public health authority.

B. MMP participants and data will be covered by the appropriate CDC Assurance of Confidentiality ("Surveillance of Acquired Immunodeficiency Syndrome (AIDS) and Infection with Human Immunodeficiency virus (HIV) and Surveillance-Related Data," RK-2001-036, Attachment 9). The Assurance provides the highest level of legal confidentiality protections to the individual persons who are the subject of this data collection, and to the individuals and organizations responsible for data collection. The terms of the Assurance of Confidentiality reflect the collective experience of CDC, health departments, and the Council of State and Territorial Epidemiologists with respect to the collection, electronic transmission, and dissemination of HIV/AIDS surveillance data. The Assurance includes established policies and procedures governing all aspects of data collection and de-identification, physical security for paper forms and records, electronic data storage and transmission, and the release of aggregate data in forms that cannot be linked back to individual respondents. The protections afforded by the Assurance of Confidentiality last forever, and endure even after the respondent's death.

The Assurance of Confidentiality (Attachment 9) is enforced with appropriate training and contractual agreements which clarify the responsibilities of all participants in HIV/AIDS surveillance activities who have access to directly identifiable data or to data that are potentially identifiable through indirect means. State and local health department personnel who conduct HIV/AIDS surveillance are subject to the confidentiality obligations described in the CDC guidelines for the security and confidentiality of HIV/AIDS Reporting System (HARS) data (http://www.cdc.gov/hiv/topics/surveillance/index.htm) and are required to undergo security and confidentiality training. MMP interviewers, abstractors, and data managers will undergo the same security and

confidentiality training as required for health department staff. CDC's Procurement and Grants Office will require the inclusion of 308(d) clauses in any HIV/AIDS support services work done by contractors (e.g., data analysis, computer programming, LAN support). All CDC permanent employees and their contractors will be required to attend annual confidentiality training, to sign a Nondisclosure Agreement and to update their confidentiality agreements on an annual basis. Contractors must sign a "Contractor's Pledge of Confidentiality." Access to HIV/AIDS surveillance data maintained at CDC is restricted to authorized personnel who have signed the "Agreement to Abide by Restrictions on Release of Data." CDC-funded cooperative agreements to state and local health departments reference that successful awardees must comply with the requirements of the Assurance of Confidentiality as a condition of award. The authority for this data collection is provided by Section 306 of the Public Health Service Act (Attachment 9).

NCHHSTP has determined that the MMP data collections are not research and do not require review by the CDC IRB. Local data collection sites may require review and approval by a local IRB (Attachment 14).

In order to conduct the proposed MMP activities, local health departments and other MMP staff have access to respondent identifiers. This information will not be transmitted to CDC. The personal information is used to contact potential respondents, obtain informed consent, conduct respondent interviews, and facilitate medical record review and abstraction. Paper records that support these functions will be filed by the unique respondent ID code and the date of visit (not the respondent's name), and stored under lock and key.

After MMP data are collected, health department personnel and other MMP personnel are responsible for deleting patient and physician names and other identifiers from the records transmitted to CDC (see Attachments 4a-4c and Attachments 6a-6d for paper copies of the electronic data collection forms, and note that they do not contain specific identifiers). The records maintained by CDC are identified only by a computer-generated code, the respondent's date of birth, sex, and a state/city assigned patient

identification number. CDC does not have access to information that would allow CDC personnel to re-link the data to respondent identifiers.

State/local health departments may link patients in MMP with those in the HARS database, but the data collection applications used for MMP will not collect the HARS number. There is no linkage of MMP and HARS at CDC.

Encryption security for all MMP data must meet the current National Institute of Standards and Technology (NIST) Federal Information Processing Standards (FIPS), which meet or exceed Advanced Encryption Standards (AES). See the document "Technical Guidance for HIV/AIDS surveillance Programs, Volume III: Security and Confidentiality Guidelines" for further information (www.cdc.gov/hiv/surveillance.htm).

Licenses for encryption software were provided to project areas by CDC prior to the start of data collection for the 2007 MMP cycle. The MMP data files must be transferred, or uploaded, from the electronic devices to the project area's secure storage drive on a frequent basis. All MMP data files must be transmitted to CDC using the Secure Data Network (SDN).

The MMP Provider Survey will not contain specific identifiers (e.g., name, address, social security number). Paper surveys will be destroyed three months after survey activities are completed.

The Web-based software supports the ability to encrypt response data and password-protect surveys so that unauthorized users will be unable to view, export, or modify collected data.

The identities of providers will be known to MMP project area staff as a result of conducting MMP at the selected providers' facilities. The records maintained by CDC are identified only by a computer-generated code, the respondent's date of birth, sex, and a unique identification number. The MMP Provider Survey is covered by the same Assurance of Confidentiality (Attachment 9) described above.

A CDC contractor will be responsible for all data

management activities. If the survey data is in paper format, then the CDC contractor will be responsible for shipping these paper survey forms to CDC for locked storage. The CDC contractor will not be permitted to make copies of these completed paper surveys. The CDC contractor will also be responsible for data entry of the paper surveys into the electronic application. The CDC contractor will then transfer all electronic survey information to CDC using CDC's Secure Data Network. The secure transmission encrypts all data transferred from the client machine and the Secure Data Network server. Each record in the MMP Provider Survey database will be identified by the pre-assigned unique provider ID and will not contain any directly or indirectly personally identifying information. CDC will provide project area specific combined weighted data sets back to each project area at the end of the survey period.

C. Informed consent will be obtained from all respondents prior to the interview. The informed consent process for respondents may be fulfilled by obtaining a consent document signed by the respondent, or by having the interviewer sign a consent document attesting to the respondent's verbal consent. CDC does not require this surveillance project to be reviewed by the CDC IRB (Attachment 14), however, local data collection sites may require review and approval by a local IRB. A model consent document is included (Attachment 10); local IRBs may require minor modifications. All project areas must obtain consent from respondents and store the forms in a secure location. Even project areas that do not require local IRB approval for this project have agreed to obtain consent to insure that participants understand the purpose and the content of the interview prior to participating.

The MMP Provider Survey will have a recruitment letter included in the recruitment package. This letter will reiterate the voluntary nature of the participation in this survey. No formal informed consent will be obtained.

D. Respondents are informed of the voluntary nature of participating in MMP, and may choose to participate or not.

Providers are informed of the voluntary nature of participating in the MMP Provider Survey and may choose not to participate by not accessing the electronic survey or not completing the paper survey and mailing it to the CDC contractor.

11. Justification for Sensitive Questions

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 HIV/AIDS status and medical history, sexual orientation, and sexual practices as well as alcohol and drug use. The MMP data collection will also request sensitive information relating to race/ethnicity, alcohol and drug use, mental health conditions such as depression and psychosis, history of suicide attempt, and history of arrest. Although the information requested is highly sensitive, the purposes of MMP cannot be accomplished without their collection. Collection of these data will be used to understand barriers to HIV care and treatment and the impact of behaviors on the clinical course of HIV disease. These data will also be used to enhance HIV prevention programs designed to reduce high risk behaviors in persons most likely to acquire or transmit HIV.

Patients will be informed during the consent process that sensitive questions will be asked, the importance of obtaining this information for the survey, and the assurance of confidentiality for the information.

All patient interviews will be conducted by trained MMP staff in a private location either as part of a routine visit to a medical facility, or by an interview at home, in a hospital or clinic, or other mutually agreed upon location.

The MMP Provider Survey will not ask providers any sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

Revisions were made to the previously approved data

collection instruments. Revisions to the standard interview did not result in any change in burden hours. The proxy interview was discontinued, decreasing the burden hours associated with that instrument, and the number of people expected to participate in the short interview is expected to increase, resulting in an increase in burden hours. Revisions to the abstraction form and the implementation of the electronic abstraction application will not impact the number of burden hours. There was no change in burden hours for staff pulling medical records, providing estimated patient loads or patient lists, or approaching patients for enrollment compared with the previously approved information collection request. The provider survey and its associated burden hours are new.

Health department staff in most project areas will recruit sampled patients to participate in MMP. In some facilities, providers may inform the patient that they have been selected to participate in the MMP and refer them to the health department MMP staff. Model patient recruitment scripts are included (Attachment 11).

The goal for MMP is to interview 10,400 patients. If the response rate is 80%, 8,320 patients will complete the interview. Each Standard interview, which will be used on approximately 96% or 7,988 patients will take approximately 45 minutes. Interviews of patients who engage in few risk behaviors or have no risk behaviors (sexual behavior, drug and alcohol use) or who take few HIV-related medications or no medications will take slightly less time. Interviews of patients who engage in many risk behaviors or are taking many HIV-related medications may take slightly longer. The short interview, which will be used on approximately 4% or 332 patients, will take approximately 20 minutes. The amount of time for patient interviews is the same as in the previous data collection cycle.

MMP medical record abstractors and project coordinators at state and local health departments provided estimates of time to: pull patient medical records, estimate patient loads, provide patient lists and approach patients for enrollment. Medical records are only pulled once for each abstraction, the estimate to abstract 7,488 medical records is 3 minutes per record; the same patient chart is used for all 4 medical record abstraction forms. The burden for this activity remains the same as in the previous data collection cycle. It is estimated that approximately 936 patient loads

will be completed with an average burden of 3 minutes each. Providing 1,030 patient lists is estimated to take 30 minutes. It is estimated that 3,120 patients will be approached by facility staff to participate in the project, this process is estimated to take 5 minutes per patient.

Health department staff in most project areas will send recruitment packages to sampled providers to invite them to participate in the MMP Provider Survey. In some project areas, MMP staff will work with the CDC contractor to invite selected providers to take the MMP Provider Survey, providers may inform the patient that they have been selected and refer them to the health department MMP staff. The Provider Survey instrument is new to this information request.

The goal for the MMP Provider Survey is to survey 1,920 HIV care providers. If the response rate is 80%, 1,440 providers will complete the survey. Each survey will take approximately 20 minutes.

Exhibit 12.A Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (In Hours)	Total Burden (Hours)
Patients	Standard Interview	7,988	1	45/60	5,991
Patients	Short Interview	332	1	20/60	111
Facility office staff	Medical Record Abstraction (pulling records)	7,488	1	3/60	374
Facility office staff	None (providing estimated patient loads)	936	1	2	1,872
Facility office staff	None (providing patient lists)	1,030	1	30/60	515

Facility office staff	None (approaching patients for enrollment)	3,120	1	5/60	260
Physicians, nurse practitioners, physician's assistants	Provider Survey	1,440	1	20/60	480
Total					9,602

B. Estimated Annualized Cost to Respondents

Note: The hourly rate was determined by using information obtained from the US Department of Labor, Bureau of Labor Statistics.

Exhibit 12.B Estimated Annualized Cost to Respondents

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Patients Interviewed with standard form	5,991	$16.34	$97,893
Patients Interviewed with short form	110	$16.34	$1798
Facility staff pulling medical records	374	$13.82	$5,169
Facility staff providing estimated patient loads	1,872	$13.82	$25,871
Facility staff providing patient lists	515	$13.82	$7,117
Patients approached by facility staff for enrollment	259	$13.82	$3,579
Providers surveyed	475	$72.04	$34,219
Total	6,101		$175,646

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

There are no other costs to respondents associated with this proposed collection of information.

14. Annualized Cost to the Federal Government

The cost of this project for the three years is estimated to be $41,143,275. The annual cost is summarized in Exhibit 14.A.

Exhibit 14.A. MMP Annualized Cost to the Federal Government

Expense Type	Expense Explanation				Annual Costs (dollars)
Direct Costs to the Federal Government	MMP – Personnel				$1,173,486
	Epidemiologist-13	1	50%	$41,587	
	Behavioral Scientist-13	1	75%	$62,786	
	Epidemiolgist-14 equiv.	1	100%	$98,924	
	Epidemiolgist-14	1	100%	$98,924	
	Epidemiolgist-14	1	75%	$74,193	
	Epidemiolgist-14	1	75%	$74,193	
	Statistician-14	1	50%	$49,462	
	Public Health Advisor-12	1	75%	$52,800	
	Support Staff				
	Proj. Coordinators(GS-10 equiv)	3	100%	$203,079	
	Admin. Assistant(GS-7 equiv.)	1	75%	$37,956	
	Data Managers (GS-13 equiv.)	1	75%	$62,786	
	Data Managers (GS-12 equiv.)	4	100%	$281,596	
	Data Managers (GS-12 equiv.)	1	50%	$35,200	
	MMP Provider Survey - Personnel				$174,679
	Epidemiologist-13	1	50%	$41,857	
	Epidemiolgist-14	1	100%	$98,924	
	Public Health Advisor-12	1	10%	$7,040	
	Statistician-14	1	10%	$9,892	
	Support Staff				
	Proj. Coordinators(GS-10 equiv)	1	10%	$5,060	
	Admin. Assistant(GS-7 equiv.)	1	10%	$3,535	
	Data Managers (GS-13 equiv.)	1	10%	$8,371	
	Cooperative agreement funds to project areas				$11,642,400
Contractor and Other Expenses	Incentives to patients ($25 x 10,400)				$260,000
	CDC Contractor for interview application development				$45,000
	CDC Contractor for medical record abstraction				$200,000

	application development	
	CDC Contractor for provider survey Web Programmer@ 141 hrs = 29,307 Web Implementation Leader @ 28 hrs = $42,786 Survey Methodologist @ 84 hrs = $25,292 Survey Methodologist @ 96 hrs = 37,735	$119,360
	Travel	$30,000
	Meetings	$67,500
	Printing	$2,000
	TOTAL COST TO THE GOVERNMENT	$13,714,425

Salary estimates were obtained from the US Office of Personnel Management salary scale at http://www.opm.gov/oca/08TABLES/.

The personnel related to the MMP data collection include project officers at the GS 14 and 13 levels, a GS 13 level public health analyst, a GS 14 level statistician, a project coordinator, a data manager, and a programmer. Approximately fifteen to twenty percent of related personnel's time will be allocated to data collection. Incentives of $25 will be offered to each respondent. Travel is related to providing technical assistance and conducting site visits. Examples of meetings that will be held include interviewer and abstractor training, the community and the provider advisory board, and the local principal investigators' meeting.

The personnel related to the Provider Survey data collection include project officers at the GS 14 and 13 levels, a GS 12 level public health analyst, a GS 14 level statistician, a data analyst and the CDC contract staff. Approximately fifteen percent of related personnel's time will be allocated to. Incentives of $25 that will be offered to each respondent are included in the contract costs.

The contract staff costs to develop the interview were $45,000 and the costs to develop the medical record abstraction application were $200,000. The cost to develop the provider survey application was $36,478; this cost is included in the CDC contractor for provider survey expenses.

15. Explanation for Program Changes or Adjustments

The interview and medical record abstraction instruments have been updated since the last submission to OMB based on feedback from project areas participating in the 2007 data collection cycle. Data collection instruments were changed

to ensure that interview questions will be easy for respondents to understand, and that data are collected on the medical record abstraction is consistent across all 26 project areas. Interview questions and medical record abstraction fields previously collected were deleted from the instruments. None of the changes to the data collection instruments altered the burdens estimated for the respondents. The Provider Survey is a new data collection and is incorporated as one of the paradigms in the Medical Monitoring Project.

16. Plans for Tabulation and Publication and Project Time Schedule

A projected timeline of the MMP activities including a detailed description of data collection and submission information was provided to the 26 grantees in December 2004 and November 2005. The following is a brief overview of the MMP and Provider Survey Timeline.

Activities	**Time Schedule**
Facility recruitment	1 month after OMB approval
Provider Survey recruitment packets to sampled providers	1 month after OMB approval
Patient lists obtained	2-3 months after OMB approval
Survey providers	2-3 months after OMB approval
Interview patients	3-6 months after OMB approval
Abstract medical records of interviewed patients	3-6 months after OMB approval
Data management	3-6 months after OMB approval
Evaluation	7-8 months after OMB approval
Analysis	9-12 months after OMB approval
Publication	12 months after OMB approval
Facility recruitment (year 2)	13 months after OMB approval
Patient lists obtained	14-15 months after OMB approval
Interview patients	15-18 months after OMB approval
Abstract medical records of interviewed patients	15-18 months after OMB approval
Evaluation	19-20 months after OMB approval
Analysis	21-24 months after OMB approval
Publication	24 months after OMB approval

Facility recruitment (year 3)	25 months after OMB approval
Patient lists obtained	26-27 months after OMB approval
Interview patients	27-30 months after OMB approval
Abstract medical records of interviewed patients	27-30 months after OMB approval
Evaluation	31-32 months after OMB approval
Analysis	33-36 months after OMB approval
Publication	36 months after OMB approval

National surveillance reports will be published annually for MMP and for the Provider Survey. A 12-month period is required for data collection, and data collection will occur annually. Therefore, a 3-year clearance is requested. Data collection must begin following the Population Definition Period – the first four months of the calendar year.

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

The OMB expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.