Medical Monitoring Project Facility Survey

OMB Control Number: 0920-New

Supporting Statement A

February 1, 2021

R. Luke Shouse, MD, MPH
Physician,
Division of HIV/AIDS Prevention
Centers for Disease Control and Prevention

phone: 404.639.4678 fax: 404.639.8640 email: zxz3@cdc.gov

Table of Contents

A. Justification

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

List of Attachments

Attachment 1	Legislative Authority: Section 301 (a)-Public Health Service Act [42 U.S.C. 241 (a)]
Attachment 2	60-day Federal Register Notice
Attachment 2a	60 Day FRN Public Comment
Attachment 2b	60 Day FRN Public Comment response memo
Attachment 3	MMP Facility Survey Web-based Application Screen Shots
Attachment 4	MMP Facility Survey Questionnaire
Attachment 5a	MMP Facility Survey Initial Cover Letter
Attachment 5b	MMP Facility Survey Outgoing Envelope
Attachment 5c	MMP Facility Survey Postcard Reminder
Attachment 5d	MMP Facility Survey Reminder Cover Letter
Attachment 5e	MMP Facility Survey Thank You Letter
Attachment 6	Short MMP Facility Survey Questionnaire
Attachment 7	Short MMP Facility Survey Web-based Application Screen Shots
Attachment 8	NCHHSTP Project Determination Form
Attachment 9	MMP Facility Survey Minimal Data Set
Attachment 10	References

- Goal: To conduct a survey of HIV care facilities in order to collect information on the nation's existing HIV care infrastructure and the capacity of facilities to implement the strategies of the U.S. Ending the HIV Epidemic federal initiative
- Intended use: To guide national and local HIV prevention and care efforts and identify gaps
- Methods: Survey of HIV care facilities where participants of the Medical Monitoring Project (MMP; OMB # 0920-0740) received health care, MMP is a surveillance system that collects behavioral and clinical data on a population-based sample of U.S. adults with diagnosed HIV
- Subpopulation: U.S. HIV care facilities where MMP participants received health care
- Analysis: Data will be analyzed using descriptive and multivariable methods, including linking

A. Justification

1. Circumstances Making the Collection of Information Necessary

Background

The Centers for Disease Control and Prevention requests a 1-year approval for a new information collection, "*Medical Monitoring Project Facility Survey*,". This data collection is authorized under Section 301 of the Public Health Service Act 42 U.S.C. 241, (**Attachment 1**).

The Ending the HIV Epidemic (EHE) federal initiative focuses on four key strategies to end the HIV epidemic in the U.S.: 1) diagnose all people with HIV as early as possible after infection, 2) treat the infection rapidly and effectively to achieve sustained viral suppression, 3) protect people at risk for HIV using potent and proven prevention interventions including PrEP, and 4) respond rapidly to detect and disrupt HIV clusters and prevent new infections (Fauci A, Redfield RR, Sigounas G et al, 2019). The Centers for Disease Control and Prevention (CDC) and its public health and community partners need information on the nation's existing HIV care infrastructure and the ability of HIV care facilities to implement these strategies. However, there is no other data source that comprehensively collects this information. There are challenges to identifying the universe of HIV care facilities, so the Clinical Outcomes Team proposes to leverage an existing surveillance system that describes behavioral and clinical characteristics of adults with diagnosed HIV, the Medical Monitoring Project (MMP; OMB # 0920-0740), to survey HIV care facilities where participants of the MMP received medical care to inform the EHE initiative. Although the resulting data will not be representative of all HIV care facilities in the United States, it will reflect the characteristics of facilities that provided HIV care to a probability-based national sample of adults with diagnosed HIV.

2. Purpose and Use of Information Collection

The primary objective of the MMP Facility Survey will be to conduct a one-time survey of the characteristics of HIV care facilities in order to collect information on the nation's existing HIV care infrastructure and the capacity of facilities to implement the strategies of the U.S. Ending the HIV Epidemic federal initiative (Fauci A, Redfield RR, Sigounas G et al, 2019). CDC will also use the findings to guide national and local HIV prevention and care efforts and identify gaps as part of the Division of HIV/AIDS Prevention's Strategic Plan.

Specifically, information is needed about the capacity of care facilities to deliver care and prevention services, provide HIV prevention messaging, partner with public health programs, offer services for HIV negative partners of HIV positive persons, engage and retain patients, offer PrEP, medication-assisted therapy (MAT), and substance use treatment/referrals, etc. Information on facility location, key populations served, and workforce capacity is also needed to identify areas in need of expanded support to deliver these services. Facility data will also be linked to MMP person-level data to enhance the understanding of facility-level facilitators and barriers to improving health outcomes among people with HIV.

With these aims in mind, the MMP Facility survey domains are mapped to the four pillars of the U.S. Ending the HIV Epidemic federal initiative—Diagnose, Treat, Prevent, and Respond—as illustrated in the following table.

Survey Domains	Diagnos	Treat	Prevent	Respond
General characteristics				

Survey Domains	Diagnos	Treat	Prevent	Respond
FIPS code	X	X	X	
Facility type	X	X	X	
Ryan White funding		X		
Coverage accepted	X	X	X	
Provider types and numbers	X	X	X	
HIV caseload		X		
PrEP/PEP			X	
Stigma/discrimination training	X	X	X	
Clinical and supportive services				
 Onsite clinical and support services or linkage agreements for off- site services 		X		
HIV testing for partners of HIV patients and others	X			
o Clinic-based	X			
o Free home self-testing				
Syringe services			X	
Enrollment and initiation of antiretroviral therapy				
Rapid linkage to care and barriers		X		
Rapid ART initiation and barriers		X		
HIV telehealth/telemedicine				
Receipt of and delivery of remote consultation		X		
Direct HIV care by videoconference		X		
Supporting retention in care				
Types of data used		X		
Collaboration with public health		X		X
Methods/technology to increase retention in care		X		
Prevention of patient exposure to COVID-19				
Measures taken				

3. Use of Improved Information Technology and Burden Reduction

The MMP Facility Survey will be collected electronically through a web-based application (**Attachment 2**) to minimize the burden to respondents and improve the quality of the data. A paper questionnaire (**Attachment 4**) will be sent to respondents and will be completed only by facility staff who do not wish to access the survey electronically. At least fifty percent of facility surveys are expected to be collected electronically.

Facilities with email addresses will receive an email invitation to participate in the MMP Facility Survey containing a clickable link to the web-based application in addition to the mailed survey recruitment packet (**Attachments 5a-5e**). Clicking the link will eliminate the need to type the URL for the web-based application in web browser.

The web-based application will be programmed to reduce the burden to the survey respondent by

incorporating features such as the use of checkboxes and drop-down lists. Any skip logic will be programmed into the survey so that it occurs automatically, and the user will be able to continue to the desired question or section. The survey will also be programmed to save respondent's answers automatically, so that users can stop the survey at any point and return to the question that they last completed. Burden is minimized since respondents may participate in the study at their convenience and proceed at their own pace.

CDC will require the contractor to monitor data collection daily to ensure that any problems with the website or survey software are immediately identified and remedied. CDC and the contractor will maintain regular meetings to discuss problems and lessons learned as well as to help reduce the burden to respondents participating in the proposed information collection.

Facilities that do not respond to the survey after multiple recruitment attempts will be offered a short version of the survey that will consist of selected key questions from the full questionnaire (**Attachment 6**). This survey will take no longer than 5 minutes to complete and will be collected electronically through a web-based application (**Attachment 7**) that will have the same features as the full survey application. At least ninety percent of short facility surveys are expected to be collected electronically.

Electronic data collection results in a reduction in the time to prepare the final analysis dataset because automated edit checks and skip patterns are built into the survey program for real-time quality control and the need for entry of survey response data has been eliminated.

4. Efforts to Identify Duplication and Use of Similar Information

There is no other source of comprehensive information on the characteristics of HIV care facilities that includes information needed to inform the EHE initiative. While other federal data collections focus on HIV, they do not collect information on the nation's existing HIV care infrastructure and the capacity of facilities to implement EHE strategies. For example, the National HIV Surveillance System (OMB# 0920-0573, exp. 11/30/2022) collects a limited number of individual-level characteristics among a census of persons with diagnosed HIV but does not collect information on the characteristics and service capacity of HIV care providers. MMP (OMB# 0920-0740, exp. 6/30/2021) collects information on clinical and behavioral characteristics among a probability sample of adults with diagnosed HIV but does not collect information about the HIV care facilities those persons attend. The National HIV Behavioral Surveillance System (OMB# 0920-0770, exp. 1/31/2023) collects data on specific populations at increased risk for HIV infection (men who have sex with men, drug users and high-risk heterosexuals) but does not collect information on medical facilities attended by these persons.

5. Impact on Small Businesses or Other Small Entities

Data collection will be kept to a minimum to lessen the burden on small businesses, i.e., privately owned medical practices. Participation in the provider survey is voluntary and can be completed in 30 minutes or less. Although the survey has a question that will identify small practices, there are no facility selection criteria that aim to target small practices. The survey is designed as a one-time collection and does not impose ongoing burden to any participating facilities.

6. Consequences of Collecting the Information Less Frequently

The proposed project involves a one-time data collection. There are no legal obstacles to reducing the burden to the respondents.

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

This request fully complies with the guidelines in 5 CFR 1320.5, and no special circumstances require the information to be collected in any other manner.

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

A 60-day Federal Register Notice was published in the *Federal Register* on June 2, 2020, Volume 85, Number 106, Pages 33681-33682 (**see Attachment 2**). There was 1 public comment (**see Attachment 2a**). In response to the public comment, we made the following modifications to the survey questionnaire (**see Attachment 4**): added "Indian Health Service Health Center, Tribal Health Center, or Urban Indian Health Center" as a response to the question about facility type, added a link to an example for the cultural competency question, and replaced the term "nutrition counseling" with "medical nutrition therapy" (**see Attachment 2b**).

The following persons outside of CDC provided consultation on the Facility Survey methods and questionnaire:

Antigone Dempsey, Director, Division of Policy and Data at the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau, ADempsey@hrsa.gov

Sharon Mannheimer, Associate Professor of Epidemiology and Clinical Medicine at Columbia College of Physicians and Surgeons, sbm20@columbia.edu

Jonathan Colasanti. Assistant Professor of Global Health and Medicine, Emory University, jonathan.colasanti@emory.edu

Joseph Yozviak, Infectious disease physician, Lehigh Valley Health Network,

Joseph.Yozviak@lvhn.org

Nallely Trejo, Project coordinator, Texas Department of State Health Services,

Nallely.Trejo@dshs.texas.gov

Kathleen Brady, Infectious disease physician, Philadelphia Department of Health,

Kathleen.A.Brady@phila.gov

Ank Nijhawan, Infectious disease physician, Texas Department of State Health Services,

Ank.Nijhawan@UTSouthwestern.edu

Susan Buskin, Epidemiologist, Seattle King County Department of Health,

Susan.Buskin@kingcounty.gov

Bridget Anderson, Director, Bureau of HIV/AIDS Epidemiology, New York State Department of Health, bridget.anderson@health.ny.gov

Gregory Felzein, Medical Advisor, Division of Health Protection/IDI-HIV, Georgia Department of Public Health, Gregory.Felzien@dph.ga.gov

Jeffrey Beal, Medical Director of the Bureau of HIV/AIDS for the Florida Department of Health, Jeff.Beal@flhealth.gov

Susa Coffey, Professor of Medicine, University of California San Francisco, Susa.Coffey@ucsf.edu

9. Explanation of Any Payment or Gift to Respondents

The respondents will not receive payments or gifts.

10. Protection of the Privacy and Confidentiality of Information Provided By Respondents

The CDC National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP) Information System Security Officer reviewed this submission and determined that the Privacy Act does

not apply to this activity because activities do not involve the collection of individually identifiable information (IIF). The Privacy Act is not applicable. Respondents are HIV care facilities and the information collected is limited to the characteristics of the facility and not specific individuals.

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

IRB Approval

This submission was reviewed by the National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention and determined not to involve human subjects (**Attachment 8**). This activity does not require IRB review and approval.

Sensitive Questions

Questions of a sensitive nature will not be asked; the information collected is limited to facility characteristics, practices, and services provided. The survey will not collect data on organizational policies or performance data, so it is unlikely that the information collected could result in liability or competitive disadvantage to the facility. The survey will not collect information about the person completing the survey or any individuals working at the facility.

12. Estimates of Annualized Burden Hours and Costs

Staff in 23 health departments funded to conduct MMP will collect and transfer contact information for HIV care facilities to the CDC contractor who will conduct the survey. The goal for the MMP Facility Survey is to survey 1,500 facilities. If the response rate is 80%, 1,200 facilities will complete the survey. Each survey will take approximately 30 minutes to complete. Facilities that do not respond to the full survey will be offered a short version that will take approximately 5 minutes to complete. We expect 15% of facilities will complete the short survey. We expect all facility surveys to be completed by facility administrative staff.

Table A.12.1: MMP Facility Survey Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondent s	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Facility administrative staff	MMP Facility Survey	1,200	1	.5	600
Facility administrative staff	Short MMP Facility Survey	225	1	5/60	18
Total					618

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: http://www.bls.gov/cps/cpsaat39.htm.

Table B.12.1: MMP Facility Survey Estimated Annualized Burden Costs

Type of Respondents	Form Name	Total Burden Hours	Hourly Wage Rate*	Total Respondent Costs
Facility administrative staff (e.g., facility administrator, nurse manager, clinical director)	MMP Facility Survey	600	\$35.20	\$21,120
Facility administrative staff (e.g., facility administrator, nurse manager, clinical director)	Short MMP Facility Survey	18	\$35.20	\$634
Total				\$21,754

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 Government

The annualized cost to the government is \$565,000.

Table B.14: MMP Facility Survey Estimated Annualized

Expense Type	Expense Explanation		
		Annual Costs (dollars)	
Direct Costs to the Federal Government	MMP Facility Survey– Personnel		
Government	Epidemiologist-14 1 20%	\$38,500	
	Epidemiologist-14 1 20%	\$29,500	
	Nurse Consultant-13 1 20%	\$22,000	
	Epidemiologist-13 1 10%	\$11,000	
	Data Manager 1 10%	\$11,000	
	Total MMP Provider Survey Personnel	\$112,000	

Contractor and other Expenses		\$453,000
	TOTAL COST TO THE GOVERNMENT	\$565,000

15. Explanation for Program Changes or Adjustments

This is a new data/information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

All data collection will be completed during the 7 month period after OMB approval. Data will be disseminated in the form of reports, presentations, and publications. Because the MMP Facility Survey will solicit participation from a census of facilities, no complex analytical techniques will be used.

Table A.16.1: Project Time Schedule

Activity	Time Schedule
Survey distribution begins	Immediately after OMB approval
Follow-up communication to non-	within 1 month of OMB approval
respondents	
Data collection completed	2 months after OMB approval
Verify completeness of data	4 months after OMB approval
Clean data entry errors	5 months after OMB approval
Analyze data files for quality assurance	6 months after OMB approval
Transfer final dataset to CDC	7 months after OMB approval
Final report completed	12 months after OMB approval

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

No exemption is sought. The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification included in this request.