**BILLING CODE: 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[60Day-17-0740]**

**[Docket No. CDC-201x-xxxx]**

**Proposed Data Collection Submitted for Public Comment and Recommendations**

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS)

**ACTION:** Notice with comment period

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the Medical Monitoring Project, which collects interview and medical record data on a probability sample of HIV-diagnosed persons in order to provide national estimates of access to and utilization of HIV-related medical care and services, the quality of HIV-related ambulatory care, and HIV-related behaviors and clinical outcomes.

**DATES:** Written comments must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-201x-xxxx by any of the following methods:

* Federal eRulemaking Portal: [Regulations.gov](http://www.regulations.gov/). Follow the instructions for submitting comments.
* Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

**Instructions:**All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to [Regulations.gov](http://www.regulations.gov/), including any personal information provided. For access to the docket to read background documents or comments received, go to [Regulations.gov](http://www.regulations.gov/).

Please note: All public comment should be submitted through the Federal eRulemaking portal ([regulations.gov](http://www.regulations.gov)) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

**SUPPLEMENTARY INFORMATION:**

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

**Proposed Project**

Medical Monitoring Project (MMP) - (OMB No. 0920-0740 Exp: 6/30/2018) – Revision -- National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

**Background and Brief Description**

 The Centers for Disease Control and Prevention (CDC), Division of HIV/AIDS Prevention (DHAP) requests a revision of the currently approved Information Collection Request: “Medical Monitoring Project” expiring June 30, 2018. This data collection addresses the need for national estimates of access to and utilization of HIV-related medical care and services, the quality of HIV-related ambulatory care, and HIV-related behaviors and clinical outcomes.

 For the proposed project, the same data collection methods will be used as for the currently approved project. Data would be collected from a probability sample of HIV-diagnosed adults in the U.S. who consent to an interview and abstraction of their medical records. As for the currently approved project, de-identified information would also be extracted from HIV case surveillance records for a dataset, referred to as the minimum dataset, which is used to assess non-response bias, for quality control, to improve the ability of MMP to monitor ongoing care and treatment of HIV-infected persons, and to make inferences from the MMP sample to HIV-diagnosed persons nationally. No other Federal agency collects such nationally representative population-based information from HIV-diagnosed adults. The data are expected to have significant implications for policy, program development, and resource allocation at the state/local and national levels.

 The changes proposed in this request update the data collection system to meet prevailing information needs and enhance the value of MMP data, while remaining within the scope of the currently approved project purpose. The result is a 11% reduction in burden, or a reduction of 786 total burden hours annually. Specifically, the removal of three unfunded project areas reduces the number of interviews conducted and the number of persons for whom healthcare facility staff will be asked for contact information, assistance with approaching for participation, and pulling medical records.

Changes were made that did not affect the burden, listed below:

* Sampled persons found to have resided in a non-funded project area on the date of sampling will be considered ineligible for the project, because non-funded project areas were deemed ineligible in the first stage of sampling.
* Tracking data reports will no longer be sent to CDC, as this information is no longer needed.
* The average token of appreciation for participants has been increased from $25 to $50.
* Changes have been made to the respondent consent form to decrease the reading comprehension level and clarify whom participants should contact for different concerns.
* Forty-two data elements were removed from the minimum data set and forty data elements were added. Because these data elements are extracted from the HIV surveillance system from which they are sampled, these changes do not affect the burden of the project.

 This proposed data collection would supplement the National HIV Surveillance System (NHSS, OMB Control No. 0920-0573, Exp. 6/30/2019) in 23 selected state and local health departments, which collect information on persons diagnosed with, living with, and dying from HIV infection and AIDS.

The participation of respondents is voluntary. There is no cost to the respondents other than their time. Through their participation, respondents will help to improve programs to prevent HIV infection as well as services for those who already have HIV.

Estimated Annualized Burden Hours

| Type of Respondent | Form Name | Number ofRespondents | Number ofResponses perRespondent | Average HoursPer Response | Total ResponseBurden(Hours) |
| --- | --- | --- | --- | --- | --- |
| Sampled, Eligible HIV-Infected Persons | Interview Questionnaire  | 7,760 | 1 | 45/60 | 5,820 |
| Facility office staff looking up contact information | N/A | 1,940 | 1 | 2/60 | 65 |
| Facility office staff approaching sampled persons for enrollment | N/A | 970 | 1 | 5/60 | 81 |
| Facility office staff pulling medical records  | N/A | 7,760 | 1 | 3/60 | 388 |
| **Total** |  |  |  |  | **6,354** |

Dated:

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Leroy A. Richardson

Chief, Information Collection Review Office

Office of Scientific Integrity

Office of the Associate Director for Science

Office of the Director

Centers for Disease Control and Prevention