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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-13-13GX]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 or send comments to Ron Otten, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

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; and (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. Written comments should be received within 60 days of this notice.

Proposed Project

Assessment of a Comprehensive Human immunodeficiency virus (HIV) Clinic-Based Intervention to Promote Patients' Health and Reduce Transmission Risk – New - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is requesting Office of Management and Budget (OMB) approval to collect data that will be used to evaluate an HIV clinic-based intervention to increase the number of HIV patients who (1) have undetectable levels of HIV in their blood, (2) adhere optimally to antiretroviral therapy (ART), (3) attend clinic regularly for primary care, and (4) practice safer sex. These are objectives of the National HIV/AIDS Strategy and goals of the strategic plan of the Division of HIV/AIDS Prevention, Centers for Disease Control and Prevention.

The project will be conducted at six HIV clinics in the United States. This proposed data collection will occur over 3 years.

The intervention that is part of this project focuses primarily on HIV patients who have a detectable viral load, i.e., their viral load is not as low as it can be and is not fully controlled. The intervention components include: (1) brief counseling from medical providers during primary care visits informed by a behavioral screener completed by patients; (2) a computer-based intervention (CBI) in which patients see short videos of HIV medical providers (not their own providers) talking about the importance of regular clinic attendance, adherence to ART, and safer sex; and (3) one-on-one counseling from a prevention specialist if needed.

The following data will be collected in this project:

- A data manager at each clinic will electronically transmit patient clinical data to CDC using a unique study identification code as the only means of identifying a patient’s data. The data files sent to CDC will not contain any medical record numbers, names, or social security numbers. The information will be encrypted and stored in a secure CDC server. The data collected from patients include (1) a behavioral screener self-administered by patients each time they have a primary care visit. Patients complete the screener in the waiting room before seeing their primary care provider. (2) CBI assessment items on demographic factors, clinic attendance, ART status, ART adherence, and sexual risk behavior that are completed before patients see the CBI videos. Patients with detectable viral loads will be asked to do the CBI three times, spaced approximately three months apart. Patients’ CBI responses are not shared with their clinic providers. (3) On a quarterly basis, 50 patients at each clinic will be asked to complete a brief exit survey after their medical exam, asking about topics that the provider may have discussed with them at their medical visit (e.g., adherence, clinic attendance).

- Data collected from primary care medical providers includes a quarterly survey asking them to indicate the types of topics/issues they discussed with their HIV patients.

There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (Hours)	Total Burden Hours
Data manager at clinic	Electronic transmittal of clinical variables archived in clinic databases (no form)	6	4	24	576
Patient	Behavioral screener (patients with detectable or undetectable VL; paper form)	6,315	4	5/60	2,105
Patient	CBI assessment items for patients with detectable VL (electronic form)	2,069	3	10/60	1,035
Patient	Patient exit survey (electronic form)	1,200	1	5/60	100

Primary care provider	Provider survey (electronic form)	120	4	10/60	80
Total					3,896

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