**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[60Day-17-1080; Docket No. CDC 2017-0078]**

**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 efforts 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 *HIV Outpatient Study (HOPS)*.

**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-2017-0078 by any of the following methods:

- Federal eRulemaking Portal: 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, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Leroy A. Richardson, 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

HIV Outpatient Study (HOPS) (OMB Control Number 0920-1080, Expiration, 8/31/2018) - 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 CDC requests a three-year approval and a revision to the *HIV Outpatient Study* data collection activity. The *HIV Outpatient Study (HOPS)* is a prospective longitudinal cohort of HIV-infected outpatients at eight well-established private HIV care practices and university-based U.S. clinics, in Tampa, Florida; Washington, DC; Stony Brook, New York; Chicago, Illinois; Denver, Colorado; and Philadelphia, Pennsylvania. Researchers abstract clinical data on an ongoing basis from the medical records of adult HIV-infected HOPS study participants, who also complete an optional telephone/Web-based behavioral assessment as part of their annual clinic visit, which on

average takes about seven minutes. Before enrolling in this study, all potential study participants will undergo an informed consent process (including signing of a written informed consent), which is estimated to take 15 minutes.

The revisions consist of adding 12 additional survey questions to assess additional risk behaviors that may affect the long-term care and treatment of HIV positive patients participating in the HIV Outpatient Study. Based on review of the current survey response items and the average completion time, these new questions will not pose additional burden on participants.

The core areas of HOPS research extending through the present HIV treatment era include: (i) Monitoring death rates and causes of death; (ii) characterizing the optimal patient management strategies to reduce HIV related morbidity and mortality (*e.g.,* effectiveness of antiretroviral therapies and other clinical interventions); (iii) monitoring of sexual and drug use behaviors to inform Prevention with Positives; and (iv) investigating disparities in the HIV care continuum by various demographic factors.

In recent years, the HOPS has been instrumental in bringing attention to emerging issues in chronic HIV infection with actionable opportunities for prevention, including cardiovascular disease, fragility fractures, renal and

hepatic disease, and cancers. The HOPS remains an important source for multi-year trend data concerning conditions and behaviors for which data are not readily available elsewhere, to include: Rates of opportunistic illnesses, rates of comorbid conditions (*e.g.,* hypertension, obesity, diabetes) and antiretroviral drug resistance.

Researchers will collect data through medical record abstraction by trained abstractors and by telephone or internet based, computer-assisted interviews at eight funded study sites in six U.S. cities. Collection of data abstracted from patient medical records provides data in five general categories: Demographics and risk behaviors for HIV infection; symptoms; diagnosed conditions (definitive and presumptive); medications prescribed (including dose, duration, and reasons for stopping); all laboratory values, including CD4+ Tlymphocyte (CD4+) cell counts, plasma HIV-RNA determinations, and genotype, phenotype, and trophile results. Researchers will acquire data on visit frequency, AIDS, and death from the clinic chart. Data collected using a brief Telephone Audio-Computer Assisted Self- Interview (T-ACASI) survey or an identical Web-based Audio-Computer Assisted Self-Interview (ACASI) include: Age, sex at birth, use of alcohol and drugs, cigarette smoking, adherence to antiretroviral medications, types of sexual intercourse, condom use, and disclosure of HIV status to partners.

We anticipate the annual recruitment of 450 new HOPS study participants into the HOPS from a pool of HIV-infected individuals currently in HIV-care at nine clinics (50 patients per site). Researchers will approach patients during one of the patients' routine clinic visits to participate in the HOPS. Researchers will give patients interested in participating in the HOPS detailed information about the nature of the study and provide them with a written informed consent form that the patient must complete prior to enrollment. Annually, the researchers will add the 450 newly enrolled participants to the database of existing participants. Researchers will conduct medical record abstractions and will not impose direct burden on HOPS study participants.

Participation of respondents is voluntary. There is no cost to the respondents other than their time.

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 |
|---|---|---|---|---|---|
| HOPS study Patients | Behavioral survey | 2,500 | 1 | 7/60 | 292 |
| HOPS Study Patients | Consent form | 450 | 1 | 15/60 | 113 |
| Total | | | | | 405 |

**Leroy A. Richardson,**

*Chief,*

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*Office of Scientific Integrity,*

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[FR Doc. 2017-20511 Filed: 9/25/2017 8:45 am; Publication Date: 9/26/2017]