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Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-16-15ARG]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or

send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Prevent Hepatitis Transmission among Persons Who Inject Drugs—New—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Hepatitis C virus (HCV) infection is the most common chronic blood borne infection in the United States; approximately three million persons are chronically infected. Identifying and reaching persons at risk for HCV infection is critical to prevent transmission and treat and cure if infected. CDC monitors the national incidence of acute hepatitis C through passive surveillance of acute, symptomatic cases of laboratory confirmed hepatitis C cases. Since 2006, surveillance data have shown a trend toward reemergence of HCV infection mainly among young persons who inject drugs (PWID) in nonurban counties. Of the cases reported in 2013 with information on risk factors 62% indicated injection drug use as the primary risk for acute hepatitis C. The prevention of HCV infection among PWIDs requires an integrated approach including harm reduction interventions, substance abuse treatment, and prevention of other blood borne infections, and care and treatment of HCV infection.

The purpose of the proposed study is to address the high prevalence of HCV infection by developing and implementing an integrated approach for detection, prevention, care and treatment of infection among persons aged 18–30 years who reside in non-urban counties. Awardees will develop and implement a comprehensive strategy to enroll young non-urban PWID, collect epidemiological information, test for viral hepatitis and HIV infection and provide linkage to primary care services, prevention

interventions, and treatment for substance abuse and HCV infection. In addition to providing HCV testing, participants will be offered testing for the presence of co-infections with hepatitis B virus (HBV) and HIV. Adherence to prevention services and retention in care will be assessed through follow up interviews. Furthermore, re-infection with HCV will be evaluated through follow-up blood tests.

The project will recruit an estimated total of 995 young PWIDs to enroll 895 PWIDs. The participants will be recruited from settings where young PWIDs obtain access to care and treatment services. Recruitment will be direct and in-person by partnering with local harm reduction sites. Recruiters will enroll subjects across recruitment sites primarily through drug treatment programs and syringe exchange programs, as well as persons referred to these sites as a result of referral from other programs and respondent driven sampling. Those who consent to participate will be administered an eligibility interview questionnaire by trained field staff. If found eligible, the participant will take an interviewer-administered survey that includes information on initiation of drug use, injection practices, HCV, HBV and HIV infection status, access to prevention and medical care, desire to receive and barriers to receiving HCV treatment, and missed opportunities for hepatitis prevention. Participants will receive counselling regarding adherence to medical and/or drug treatment services and prevention services. Participants will be interviewed for a maximum of 5 times within any 12-month interval during the course of the study: consent and interview at enrollment/baseline for an estimated 60 minutes, and 30-minute follow-up interviews every 3 months thereafter. Participants will be interviewed throughout the study during the 3-year project. However, most of the recruitment will be spread over first two years to allow for one year follow up period of the later recruits.

Participation in interviews and responses to all study questions are totally voluntary and there is no cost to respondents other than their time. The annualized burden to participants is 974 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Young PWIDs	Screener	332	1	10/60
Eligible young PWIDs	Initial Survey	298	1	60/60
Eligible young PWIDs	Follow-up survey	298	4	30/60

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-16-16JD; Docket No. CDC-2016-0004]

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 the proposed information collection entitled “Young Men who have Sex with Men (YMSM) Study Thailand”. CDC is requesting a three-year approval for this new project.

DATES: Written comments must be received on or before March 14, 2016.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2016-0004 by any of the following methods:

- *Federal eRulemaking Portal: Regulation.gov.* Follow the instructions for submitting comments.

- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., 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 the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: *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

Cohort Study of HIV, STIs and Preventive Interventions among Young MSM in Thailand—New—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This is a new information collection request for 3 years of data collection. In Thailand, there is a very high HIV incidence in men who have sex with men (MSM) and transgender women (TGW). It is estimated that over 50% of all new HIV infections are occurring in MSM and TGW. At Silom Community Clinic @Tropical Medicine (SCC @TropMed), there is a reported average HIV prevalence of 28% and HIV incidence of 8 per 100 person-years in young men.

An area with gaps of understanding regarding the HIV epidemic in Thailand, as well as globally, is the epidemiology, risk factors, and HIV beliefs and knowledge of gay identified and transgender youth. In 2013, UNAIDS reported that 95% of new HIV infections were in low- and middle-income countries, where more than one third were in young people (<18 years) who were unaware of their HIV status. Adolescents living with HIV are more