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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	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)
Young PWIDs	Screeners	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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 Office of Scientific Integrity
 Office of the Associate Director for Science

Office of the Director
Centers for Disease Control and Prevention
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