Enhancing Substance Abuse Treatment Services to Address Hepatitis Infection Among Intravenous Drug Users Hepatitis Test and Vaccine Tracking Form

SUPPORTING STATEMENT

A. Justification

1. Circumstances of Information Collection

Reducing viral hepatitis is an important public health strategy. Highly efficacious vaccines are available to prevent new hepatitis A virus (HAV) and hepatitis B virus (HBV) infections, but unfortunately, a vaccine for hepatitis C virus (HCV) is not available. Further, a HCV vaccine is difficult to produce because mutations occur during viral replication. Even with effective vaccines, HAV and HBV continue to be among the most commonly reported vaccine-preventable diseases in the United States (U.S.), and HCV infection is the most common chronic blood-borne infection in the U.S. In order to reduce viral hepatitis it is necessary to identify people at risk of infection, educate them about hepatitis, test them for hepatitis exposure, vaccinate those who qualify for it, and treat those with acute infections.

In order to continue efforts in addressing the above, Substance Abuse and Mental Health Services Administration (SAMHSA) has recently awarded ***Enhancing Substance Abuse Treatment to Promote Healthy Lifestyles through Addressing Hepatitis Infection among Injection drug Users*** contact no.283-07-5302.

As a part of SAMHSA's Strategic Initiative on Health Reform -- one of eight strategic initiatives (http://www.samhsa.gov); efforts of this project facilitates the development and expansion of culturally competent and effective integrated behavioral health and primary care networks, which include HIV services and medical treatment, within racial and ethnic minority communities most impacted by HIV/AIDS. The expected outcomes for the program include reducing the impact of behavioral health problems, HIV risk and incidence, and HIV-related health disparities in these areas.

This project also supports the National HIV/AIDS Strategy and the Health and Human Services (HHS) Minority AIDS Initiative (MAI) 12 Cities Project. The HHS-wide project supports and accelerates comprehensive HIV/AIDS planning and cross-agency response in 12 U.S. jurisdictions that bear the highest AIDS burden in the country.

In order to access the overall effectiveness of the program, SAMHSA uses a data collection form which captures pertinent data in accessing overall program performance and quality issues. However, the current data collection form approved under OMB No. 0930-0300, expires on May 31, 2012. Thus, SAMHSA's Center Substance Abuse Treatment (CSAT), is requesting a reinstatement from OMB for the Minority AIDS Initiative (MAI) for the Enhancing Substance Abuse Treatment Services to Address Hepatitis Infection among Intravenous Drug Users, Hepatitis Test and Vaccine Tracking Form (see Attachment A).

SAMHSA is authorized under section 505 of the Public Health Service Act (42 USC §290aa-4)

to collect data annually on the national incidence and prevalence of mental illness and substance abuse. The current form seeks information relevant to such data collections.

The data collected aids SAMHSA in providing a comprehensive approach for preventing and treating viral hepatitis and to reduce the incidence of liver disease among Opioid Treatment programs (OTPs) high risk minority patients. Collection of this data gives SAMHSA the ability to assess each OTP effectiveness in providing cost-effective delivery of the health services to their at risk racial/ethnic minority population. The attached data collection form reflects the following:

1. Racial/minority demographics; age and ethnicity (Section. B)
2. Hepatitis-related service provided; i.e, vaccination (Divalent), counseling, education (Section. C)
3. Viral Hepatitis C screening (history/rapid test kits) among patients in OTPs (Section. D)
4. Type of referral services involving primary care or specialty hepatitis (gastroenterology, infectious disease, psychiatry, reproductive/prenatal) care for individuals who test positive for HBV or HCV infection (Section. E)
5. Confirmatory Testing for Hepatitis C positive results (Section. F)
6. Brief explanation of vaccine refusal (if applicable) (Section. F)

The form collects limited patient information from those who participate in the MAI program. The information that we require, also serve to justify the use of Federal funds to benefit these communities.

The contractor is responsible for collecting completed forms from each OTPs monthly. The data is then submitted to SAMHSA quarterly and annually in aggregated form. The data is designed to inform and assist SAMHSA in accessing the programs for quality assurance, quality performance, product monitoring in participating OTPs, as well as to assure that the hepatitis tests/vaccines are reaching their intended audience.

Information System Security Plan is compliant with National Institute of Standards and technology (NIST) Special Publication (SP) 800-18, rev1. (see attachment)

2. Purpose and Use of Information

The data collected on the SAMHSA/CSAT Hepatitis Test and Vaccine Tracking Form will be used for quality assurance, quality performance, and product monitoring. The SAMHSA/CSAT Hepatitis Test and Vaccine Tracking Form is one-page, and it takes approximately 3 minutes to complete.

The form does collect limited patient information. It does contain space for lot number identification in the event that the FDA determines that problems exist with a specific lot; such problems have already occurred in several areas of the United States, making this information of critical importance to providers and to patients.

3. Use of Information Technology

The design of the SAMHSA/CSAT Hepatitis Test and Vaccine Tracking Form encourages the use of automation to reduce burden on participating opioid treatment programs. The form can be completed within Microsoft Word and then e-mailed; it can be completed by hand and faxed or mailed in pre-paid envelopes. Additionally, if the program previously collects the information needed on the form, they can send the information in the format they use. The use of information technology and the methods for transmitting the form will be determined by program based on the least burden for the opioid treatment program staff.

It is estimated that 80 percent of the responses will be submitted electronically. For the programs where electronic submission increases burden, paper forms will be preprinted and provided at no cost to the opioid treatment programs as needed.

4. Efforts to Identify Duplication

The information is collected only for the purposes of this program and is not available elsewhere. It is possible that the information requested by the SAMHSA/CSAT Hepatitis Test and Vaccine Tracking Form is already being collected by the participating opioid treatment programs. In the cases where the opioid treatment program has a hepatitis protocols in place, the information can be sent without reliance on the form.

5. Involvement of Small Entities

The participating opioid treatment programs are usually small not-for-profit organizations, not dominant in the field. They are considered “small entities” but they do not have a significant impact on these organizations.

6. Consequences if Information is Collected Less Frequently

Each respondent is asked to respond annually. The first part the respondent is asked to provide demographic information, vaccination history, and hepatitis testing information. The second and third parts the respondent is asked to provide the date and lot number for subsequent vaccinations and/or HCV test. The forth part is one month after intake, the programs are asked to send the Hepatitis Test and Vaccine Tracking Form.

If the information is not collected, the program will be contacted by phone in order to determine the problem. For those cases, when the third dose information is not received, the program will be contacted to verify that the patient did not return for the service.

7. Consistency with the Guidelines in 5 CFR 1320.5 (d) (2)

This information collection fully complies with 5 CFR 1320.5 (d) (2).

8. Consultation Outside the Agency

The notice required in 5 CPR 1320.8 (d) was published on April 23, 2012 (Vol. 77, p. 24211). No comments were received.

CSAT e-mailed the following potential respondents draft copies of the form on August 19, 2008 to solicit views on whether the information requested was reasonable and whether the form was written in plain, unambiguous language.

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9. Payment to Respondents

Respondents will not be paid.

10. Assurance of Confidentiality

The information the forms are stored and compiled by a contractor which has experience in securing the information collected during the collection processing (electronically via unique secured password). The contractor recognizes the importance of restricting access to data of this nature. The information will be compiled in aggregated form only.

11. Questions of a Sensitive Nature

The information collection includes questions concerning sensitive information such as the patient's risk factors, and no patient identifying information is collected. The information collected relates the normal use of hepatitis vaccination and testing in the community. The opioid treatment program retains all patient identifying information and the code by which a specific patient can be identified. The Federal Government receives only a randomly assigned patient identifier which can only be used to determine that a specific unknown patient received the test kit and that certain demographic and referral information.

12. Estimates of Project Hour Burden

Form	Number of Screened Respondents	Responses/ Respondents	Hours/Response	Total Hour Burden	Hourly Wage Cost	Total Hour Cost
Hepatitis Test and Vaccine Tracking Form	50,000	1	0.05	2,500	$38.15	$250,500

13. Estimates of Annualized Cost Burden to Respondents

This information is routinely collected and stored. There are no system, technology acquisition, capital, or start-up costs associated with its collection.

14. Estimates of the Annualized Cost to the Government

The annualized cost to the government is approximately $93,000 which will be expended to cover distribution and collection of the tracking form. This cost includes a 5 percent time commitment of Federal FTE at GS- 14 level at an estimated cost of $5,500 annually.

15. Changes in Burden

There is no burden change.

16. Time Schedule, Publication, and Analysis Plans

The interpretation or publication of this information may be used at SAMHSA sponsored conferences, reports to the Secretary of Health or Congress.

Activity and time schedule

The information is collected on a continuous basis by the grantee. The information will be complied by the contractor and sent to SAMHSA quarterly.

17. Display of Expiration Date

The expiration date for OMB approval will be displayed.

18. Exceptions to Certification Statement

This collection of information involves no exceptions to the Certification for Paperwork Reduction Act Submissions. The certifications are included in this submission.