Hepatitis Testing and Linkage to Care Monitoring and Evaluation System (HEPTLC)

SUPPORTING STATEMENT A

NEW
0920-####

Contact Information:
Jianglan White, M.D., M.P.H.
National Center for HIV, STD, and TB Prevention
Division of Viral Hepatitis/Prevention Branch
Centers for Disease Control and Prevention
1600 Clifton Rd, NE, MS G-37
Atlanta, Georgia 30333
Voice: (404) 718-8551
Fax: (404) 718-8595
E-mail: vyg1@cdc.gov

March 21, 2012

:

Hepatitis Testing and Linkage to Care (HEPTLC) Monitoring and Evaluation System

Table of Contents

:

LIST OF ATTACHMENTS

Attachment 1 Authorizing Legislation
Attachment 2 60 Day Federal Register Notice
Attachment 3 Goals/Objectives Table
Attachment 4.1 HEPTLC Data Collection Template-HBV
Attachment 4.2 HEPTLC Data Collection Template-HCV
Attachment 4.3 Screen Shot - HEPTLC Data Collection
Attachment 5 HEPTLC Programmatic Reporting Templates
Attachment 6 Agencies and Persons Consulted
Attachment 7 Rules of Behavior - Administrators
Attachment 8 Rules of Behavior - Users
Attachment 9 AOC Letter of Approval

A. Justification

1. Circumstances Making the Collection of Information Necessary

The National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention is requesting a 1-year OMB approval for establishing a new Hepatitis Testing and Linkage to Care (HEPTLC) Monitoring and Evaluation System. Though the initial project is funded for one year under cooperative agreement (PPHF PS12-1209), there is indication that the project would be extend into three years. If additional funding is made available, we will request an ICR extension at the time.

This ICR covers the collection of standardized, non-identifying, client-level, and test-level data from all awardees funded by CDC, through Prevention Public Health Funding (PPHF), under cooperative agreements, to implement hepatitis B (HBV) and hepatitis C (HCV)testing, counseling and linkage to care initiatives. This ICR also covers aggregated programmatic data for monitoring and evaluation of the initiative in meeting goals and objectives of the initiative.

An estimated 3.5-5.3 million persons – 1-2% of the US population are living with viral hepatitis in the US and millions are at risk for infection, of those, 800,000 to 1.4 million have chronic HBV infections, and 2.7–3.9 million have chronic HCV infections, with an estimated 65-75% of infected Americans unaware of their infection and not receiving and treatment.

In accordance with the HHS Viral Hepatitis Action Plan[1] (available at http://www.hhs.gov/ash/initiatives/hepatitis), the Division of Viral Hepatitis (DVH) at the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC), is planning to implement a hepatitis testing and linkage to care initiative named “Early Identification and Linkage to Care for Persons with Chronic HBV and HCV infections”, this initiative will provide needed resources to increase early identification and linkage to care and treatment of persons with undiagnosed chronic Hepatitis C and/or B infection, with a focus on populations who are disproportionately affected by these infections in multiple settings, such as state and local health departments, community-based organization (CBOs), community health centers, persons who injecting drugs (PWID) treatment centers and other settings, including STD, HIV clinics, federally qualified health centers

(FQHCs), etc. The goals of the initiative are to increase the number and proportion of 1) persons tested for HBV and HCV, 2) persons with chronic viral hepatitis who are aware of their infection, and 3) persons linked to care, treatment, and prevention services.

DVH will directly fund as many as 40 sites to conduct hepatitis B and C testing and linkage to care (HEPTLC). Funded sites are required to collect their testing activities and results related to the implementation of HEPTLC initiative, and report to CDC DVH to satisfy the terms of the HEPTLC cooperative agreements. DVH is planning to establish a web-based data collection and reporting system to assist DVH-funded testing sites to comply with their data collection and reporting requirements. In sum, the system will be used to collect standardized, non-identifying, client-level and test-level hepatitis testing information from funded testing sites at multiple settings, in a timely and complete manner, to effectively monitor and evaluate progress made by awardees in meeting goals and objectives of the HEPTLC Initiatives for program management, improvement and accountability. This will also enable CDC DVH to report on hepatitis prevention efforts and utilize the data for policy and program planning, implementation and evaluation at the national level. The HEPTLC data enable national program evaluation, performance indicator calculation, and accountability reporting to Congress, HHS, and other stakeholders in the field of hepatitis prevention.

In addition, the President's Management Agenda requires all federally funded awardees to report key program performance indicators as a method for demonstrating accountability. The CDC DVH HEPTLC Initiative program performance indicators to be assessed are aligned with the goals and objectives outlined in the cooperative agreements (See **Attachment 3**: Goals/Objectives Table). The funding for this cooperative agreement was provided through a line item in the Fiscal Year 2012 budget. While Congress has not requested reports at this time, it has been made clear to the Division that we will be expected to provide a summary report of some type. It is the Division's intention to both respond directly to any queries Congress may have as well as provide an overview of grantees level of achievement on the indicators explicitly provided in the original funding opportunity announcement and a narrative summary of the project as a whole. The awardees and CDC will use performance indicators to demonstrate the implementation of the initiative in meeting program goals and objectives. CDC may place conditions or restrictions on the award of funds to respondents that fail to

meet the obligations and requirements.

Privacy Impact Assessment

In no case will client personal identifying information/data be transmitted to CDC. All identifiers will be maintained at the local level as required for public health follow-up purposes. The HEPTLC data collection and reporting system will be coherent with the CDC Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, STD and TB Programs (http://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf).

Overview of the Data Collection System

The system will provide real time access to data entry and user-generated reports, and be easily modifiable to meeting user demands and changing public health needs.

The system will consist of non-identifying, client-level, test-level data variables, including:

1) Information about test sites that provide HEPTLC services and laboratories that provide lab testing
2) Information about testing participants, including demographics, risk characteristics, vaccination history, etc.
3) Information related to diagnostic test results
4) Information about post-test follow-ups, including notification of test result, post-test-counseling, linkage to care and preventive services, and case report to surveillance authorities

The system will feature technical functionalities, including:

1) Real time data entry
2) Automation of user-generated standard reporting
3) Enabling CDC to generate dynamic query reports, queried by the minimum test data variables

Items of Information to Be Collected

Approximately 60,000 clients will be enrolled during the project period, with participants being asked to provide information on demographics, risk behaviors for chronic HCV and/or HBV infection, previous hepatitis and HIV testing and vaccination history at testing sites. Teams of trained hepatitis counseling and testing staff will provide testing and associated counseling and linkage to care and preventive services at implementation

sites. Pre- and post-test counseling will adhere to current CDC guidelines for personalized risk reduction counseling. Medical record data will be used to track linkage to care and preventive service utilization prospectively for all project participants for approximately 6 months. Items of information to be collected via the HEPTLC system listed below:

1) Monthly testing and linkage to care activity reporting via HEPTLC System based on data variables set in the system, consisting of Section A: Agency and Site Information; Section B: Client Demographic Information; Section C: Hep B and C Test Laboratory Information and Test Result; Section D: Client Vaccination History; Section E: Post Test Follow up (providing test results, post-test counseling and linkage to care, reporting to surveillance); Section F: Risk Factors (**Attachment 4.1 & 4.2: HEPTLC Data Collection Templates**);
2) Quarterly programmatic reporting via HEPTLC system automation with aggregated programmatic activities across testing, counseling and linkage to care treatment and preventive services (**Attachment 5: HEPTLC Programmatic Reporting Templates**).

Collection of these data is authorized under Section 306 of the Public Health Services Act [42 U.S.C. 242(k)]. (**Attachment 1**)

Data collected from funded sites will be submitted to CDC on a monthly. In no case will client personal identifying information will be submitted/reported to CDC.

The primary purpose of this data collection and reporting is to monitor and evaluate the implementation of hepatitis testing, linkage to care services and activities funded through Prevention Public Health Funding (PPHF) and to support reporting requirements set forth by the Congress and CDC. Moreover, the design and intent of the data collection and reporting is not to develop or contribute to generalizable research knowledge. Therefore CDC has determined that the data collection and reporting activity are not research and does not require IRB review and approval. (**Attachment 11: IRB Non-research Determination**)

Purpose and Use of Information Collection

The HEPTLC data collection and reporting system provides a comprehensive, yet, parsimonious set of program data variables essential to monitoring and evaluating the implementation of the

HEPTLC initiative. The HEPTLC data variables have been developed with extensive input from funded sites/respondents from multiple sites. The data variables are based on evidence-based strategies and practices in hepatitis prevention and control, aligned with the Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C, Institute of Medicine (http://www.cdc.gov/hepatitis/pdfs/iom-hepatitisandlivercancerreport.pdf), and HHS Viral Hepatitis Action Plan (http://www.hhs.gov/ash/initiatives/hepatitis). Specifically, the HEPTLC data system variables cover a limited range of testing, counseling and linkage to care activities in implementing HEPTLC initiative to achieve program goals to increase the number and proportion of 1) persons tested for HBV and HCV, 2) persons with chronic viral hepatitis who are aware of their infection, and 3) persons linked to care, treatment, and prevention services.

CDC will use HEPTLC data for the following purposes:

- Monitor the implementation activities of HEPTLC initiative, as well as evaluate the progress and performance made by the awardees in meeting with goals and measurable objectives out lined in the cooperative agreements (**Attachment 3**: Goals/Objectives Table). Findings will further inform strategic planning and program improvement;
- Inform recommendations and strategies to increase early identification of infected persons and linkage to care, based on the information of client characteristics and linkage to care. Data collected via the HEPTLC system will inform whether the target populations have been reached under the hepatitis control and prevention recommendations and strategies, which calling for prevision of testing and linkage to care services to control and prevention of chronic hepatitis B among foreign born populations, and of chronic hepatitis C among baby boomers and injection drug users, based on demographic information, risk factors, vaccination history…etc. (**Attachment 4 & 5**);
- Based on data collected via HEPTLC (**Attachment 4 & 5**), CDC will be able to determine the progress of awardees in achieving the goals and measurable objectives outlined in the cooperative agreement (**Attachment 3**), identify best practices (effective targeting strategies, implementation models, collaborative partnerships)and gaps in implementation of hepatitis testing & linkage to care , and guide CDC in the provision of technical assistance to grantees;
- Produce standardized and specialized reports with process and outcome measures that will inform awardees, CDC Project

Officers, HHS, Congress and other stakeholders of project accountability and transparency. The HEPTLC data are also used to inform stakeholders, including federal and state executive offices and legislative bodies, based on specific information regarding how public health resources are used programmatically, for what purpose, to whom and to what effect;

- Assess Prevention Public Health Funds (PPHF) budget allocation with respect to prioritized risk populations;
- Advocate the needs for priority setting and budget allocation for hepatitis prevention.

Funded sites will use HEPTLC data for the following purposes:

- Understand targeted populations (demographics, risk behaviors, vaccination histories, etc.) and assess the extent to which the targeted populations have been reached;
- Document how well the project is progressing in meeting goals/objectives set forth by CDC (e.g. who delivered what to whom, how many, where, when, and how well);
- as well as performance indicators related to testing, counseling and linkage to care;
- Highlight opportunities for local program collaboration and service integration (PCSI) to prevent viral hepatitis and other infectious diseases, including HIV, STD and TB;
- Fulfill data collection and reporting requirements outlined in the cooperative agreements.
-

In sum, without these data, CDC would be unable to determine what is being done with the funding it provides, what populations are being served, what services are being provided, or which setting or sites are having most effective strategies and practices in implementing HEPTLC. It would be unable to account to the administration, Congress, or other stakeholders for the proper use of public money or provide transparency for the program it funds.

2. Use of Improved Information Technology and Burden Reduction

The system will provide real time access to data entry and user-generated reports, and be easily modifiable to meet user demands and changing public health needs.

The system will consist of non-identifying, client-level, test-level data variables, including:

:

1) Information about test sites that provide HEPTLC services and laboratories that provide lab testing
2) Information about testing participants, including demographics, risk characteristics, vaccination history, etc.
3) Information related to diagnostic test results
4) Information about post-test follow-ups, including notification of test result, post-test-counseling, linkage to care and preventive services, and case report to surveillance authorities

The system will feature technical functionalities, including:

1) Real time data entry
2) Automation of user-generated standard reporting
3) Enabling CDC to generate dynamic query repots, queried by the minimum test data variables

In sum, the system provides a free browser-based, secure electronic mechanism for entering and reporting standardized HEPTLC data that is intuitive to navigate and operate and require little training for entering data and/or generating and submitting standard reports. The testing sites will enter data information directly into the system (**Attachment 4.1 & 4.2: HEPTLC Data Collection Templates, Attachment4.3 & 4.5 Screen Shots - HEPTLC Data Collection Templates**). The system will also provide the ability to pre-populate data (i.e. Agency and Site Information) where needed and appropriate to reduce grantee data entry time and increase data quality; for example, test site contact information. Consequently, it will reduce the burden of entering and reporting data on paper-based forms, and minimize data entry errors associated with writing on paper-based forms. And there is no cost to funded sites utilizing this secured system.

The HEPTLC software also generates pre-specified reports and includes an export dataset transfer process. The export function will enable both CDC and funded sites to extract data to analytical software packages, such as SAS and SPSS.

Finally, data variable business rules have been built into the HEPTLC software application to enhance the reliability and integrity of the HEPTLC data. These business rules establish the interrelationships among variables and serve as system performance checks for assurance of quality data entry. CDC awardees gain access to the HEPTLC system through a secure internet application, which requires electronic authentication of the users and maintains data confidentiality and security.

:

3. Efforts to Identify Duplication and Use of Similar Information

Efforts to identify duplication of HEPTLC data include the assessment of existing hepatitis prevention data collection systems used by CDC, other federal agencies, as well as health department jurisdictions and community-based organizations. It should be noted that because the HEPTLC data reporting requirements are specific to CDC-funded hepatitis testing and linkage to care activities, the only possible duplication is if other federal or state organizations or entities are also funding the same activities to be performed by the same awardees.

Within CDC, data elements from several currently used data collection systems including hepatitis prevention data were identified and assessed. These include the following systems:

- Viral Hepatitis Surveillance Case Report (Request for a new OMB Control Number), managed by and used by Surveillance and Epidemiology Branch at CDC/NCHHSTP/DVH, collects demographics, risk factors and testing-results by using viral hepatitis case report forms. Information collected through EIP surveillance case report only reflect persons who tested positive within 10 funded EIP sites.
- National HIV Behavior Surveillance System, developed by CDC/NCHHSTP/DHAP, its study questionnaires (OMB 0920—0770 exp. 5/31/2014), collecting risk behaviors, testing history and vaccination history related to hepatitis from probability sample participants, who are at highest risks for HIV infection – Men have sex with Men (MSM), Injection Drug User (IDU) and Heterosexual at risk (HET) within funded metropolitan statistical areas. It is entirely anonymous self-reported information, not actual testing information, and does not address targeted populations for hepatitis testing.
- Medical Monitoring Project, administrated by CDC/NCHHSTP/DHAP, collect hepatitis status and vaccination history (OMB 0920-0740 exp. 5/31/2015). It is information abstracted from probability sampled HIV infected patients who are in the care at outpatient settings.

In addition to systems at CDC, other federal systems were reviewed. Specifically, consultations were held with the Health Resources and Services Administration (HRSA) and the Substance Abuse and Mental Health Services Administration (SAMHSA) to identify and match similar data elements to avoid duplication. Given that HRSA and SAMHSA only collect some level of hepatitis testing or hepatitis status data within specific targeted population, i.e. under HRSA Ryan White program, data collected

through CAREWare is for persons who are infected with HIV and are under care and treatment funded by Ryan White. In addition, National Health and Nutrition Examination Survey (NHANES) has been reviewed. NHANES collects hepatitis testing history, vaccination history, as well as performing hepatitis testing and Hepatitis C Follow-Up Questionnaires, but there is the limitation and the representation of NHANES, due to its sample size, which is very small.

Overall, the HEPTLC will significantly advance the monitoring and evaluation of hepatitis testing and linkage to care programs by providing a comprehensive system for collecting standardized client-level and test level data. Using these standardized data will enable CDC to evaluate programs on a national and regional scale and to compare programs providing similar services or targeting similar populations. On the local level, use of the standardized data will enhance the capacity of hepatitis prevention programs to thoroughly assess and refine their efforts in HEPTLC and to identify best strategies and opportunities for program collaboration and services integration, while providing accountability to their stakeholders.

5. Impact on Small Businesses or Other Small Entities

There will be as many as 40 test sites to conduct hepatitis B and C testing and linkage to care (HEPTLC) initiative in multiple settings, such as state and local health departments, community health centers, PWID treatment centers and other settings, including STD, HIV clinics, FQHCs, etc. The HEPTLC variables represent a parsimonious set of data with sufficient details to monitor and improve client outcomes, testing and linkage to care service delivery, and to extend project planning and implementation. In addition, collection of the data will enable funded awardees to meet their program performance indicators and reporting mandates. Moreover, there is no cost to awardees in using HEPTLC data collection and reporting system. The HEPTLC data variables have been kept to a minimum, in order to fulfill mandate requirements from the Congress for accountability, and all respondents will be expected to meet the requirements. For small organizations, collection and use of these data and data reports are essential to maintaining and enhancing their testing activities. When faced with limited resources or potential funding, these agencies will have the data needed to defend or expand existing programs, thereby ensuring continued service delivery to populations in need.

6. Consequences of Collecting the Information Less Frequently

Since the PPHF HEPTLC project period is initially funded for one year with a potential for an extension for three years, respondents are required to submit test-level data to the CDC on a monthly basis during the initial year, and programmatic aggregated data quarterly. Less frequent data submission would result in a lag time between the occurrence of program problems and their identification. This delay could result in costly program inefficiencies, defects, and failures to continue or worsen without a timely opportunity for CDC to provide valuable assistance and corrective measures to agencies funded to increase early identification and linkage to care of infected person. There are no legal obstacles to reducing the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the guidelines of 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A 60-day notice to solicit public comments was published on June 12, 2012, Vol.77 No.133, page numbers 34952-34953. A copy is attached (**Attachment 2**).

CDC is developing HEPTLC with feedback from representatives from state, territorial, and local health jurisdictions and community health centers, PWID treatment centers and other settings, including STD, HIV clinics, FQHCs. A detailed listing of agencies and persons consulted during consultations, workshops, etc. is located in **Attachment 6**

9. Explanation of any Payment or Gift to Respondents

No payments or gifts will be provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

Much of the information to be collected through HEPTLC monitoring and evaluation system are non-identifying, test-level data variables related to program participants, as well as general information related to test sites and laboratories. All personal identifying information will be removed prior to submitting/transferring to the CDC. Since records are not going to be retained by the Federal agency in a system of records, the privacy act does not apply. The data will not be able to be retrieved by name by CDC. However, the test sites may collect

identifiers (name, address, etc.) from clients who receive hepatitis testing and linkage to care services. In order to reduce disclosure risks, participating sites will not retain, in routine files either direct personal identifying information or the randomly generated patient id used in the HEPTLC. The participating sites will have only one crosswalk file containing both the patient id and the patient PII and this crosswalk file will contain no other information about the participants. The crosswalk file will be securely stored and have highly restricted access at the reporting site. The collected data are covered under Section 308(d) of the Public Health Service Act, which allows CDC programs to assure individuals and institutions involved in research or non-research projects that those conducting the project will protect the confidentiality of the data collected. It is used for projects conducted by CDC staff or contractors that involve the collection or maintenance of sensitive identifiable or potentially identifiable information. The data will be transmitted to CDC in an approved secure and confidential manner. Electronic data transmitted by CDC staff and contractors are done so via a SSL or via the SDN. All data transmissions are automatically encrypted by the software that generates the transfer files. In addition, a select number of HEPTLC variables collected by test sites that relate to personally identifying information (e.g., age, agency client codes, last name, and first name) are encrypted within the HEPTLC database and visible only to the agency that entered the information.

Privacy Impact Assessment Information

For awardees that use the HEPTLC system, each individual client record will be identified by a randomly generated unique key that is linked to a particular testing site and agency. This key is maintained in the HEPTLC system, but only at the local level can the client key be re-linked to identifiers. The client-level data accessible by CDC will not contain PII such as client name, address or phone number, but will include client demographics, i.e. age, gender, race, pregnancy status, risk behaviors, vaccination history and self-reported HIV status, hepatitis test results, etc. (See **Attachment 4**: Minimum Test-level Data variables). Although all personal identifying information will be removed prior to submission to CDC, because of the highly sensitive information and the potential for indirect identification of individuals, the program has determined that an Assurance of Confidentiality for prevention program clients (and the organizations furnishing the information) under section 308(d) of the Public Health Service (PHS) Act is

necessary. Safeguards for client data during data analysis, such as suppressing small cell sizes, requiring confidentiality agreements, and other safeguards similar to those used for hepatitis surveillance data have been imposed. The system will be coherent with the CDC Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, STD and TB Programs (http://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf).

B. CDC awardees gain access to the HEPTLC application through a secure internet connection, which requires electronic authentication of the users and maintains data confidentiality and security. All system users are provided trainings on privacy, confidentiality, and security policies; and a memorandum of understanding between CDC and each funded agency will be established. All system users will be required to sign appropriate 308d pledges. Written rules of behavior have been developed for HEPTLC M & E Agency System Administrators (**Attachment 7**) and Users (**Attachment 8**) to clarify rules, roles, and responsibilities associated with the system.

While test-level data will be submitted to CDC, PII will not be submitted to CDC. The HEP TLC system will request to pass the full Certification and Accreditation Process and an authority to operate (ATO, in order for our security measures meet the requirements of the NIST 800-53, HHS, and CDC).

The HEP TLC system application uses Secure Sockets Layer (SSL) between web-browser clients and the web server that accepts data from users. Additional SSL sessions secure data between the web server and the application server and between the application server and the database server. Each of these SSL sessions employs the same type of encryption used by all major financial services and electronic commerce sites today. Thus, from a user’s perspective, sensitive information is encrypted from the time it leaves the PC to the time it is stored in the central database.

The process for handling security incidents is defined in the system's Security Plan. Event monitoring and incident response is a shared responsibility between the system's team and the Office of the Chief Information Security Officer (OCISO). Reports of suspicious security or adverse privacy-related events should be directed to the component's Information Systems Security Officer, CDC helpdesk, or to the CDC Incident Response Team. The CDC OCISO reports to the HHS Secure One Communications Center, which reports incidents to US-CERT as appropriate.

The primary purpose of this data collection and reporting is to monitor and evaluate the implementation of hepatitis testing and linkage to care services and activities funded through Prevention Public Health Funding (PPHF),as well as support mandated reporting requirements set forth by Congress and CDC. Moreover, the design and intent of the data collection and reporting is not to develop or contribute to generalizable research knowledge, and data collected from funded sites will not be generalized to other populations.

C. Information about agencies and programs is required as part of the Program Announcement. Information about clients is collected by the agencies as part of their routine data collection, and clients are informed of any consent required by the agency or state regulations.

D. As described above, no PII will be reported to CDC, the system and data information will be accessible only by the agency that entered the data, and has been granted an Assurance of Confidentiality (Section 308[d]).

11. Justification for Sensitive Questions

Some client-level data to be collected are sensitive, such as risk behaviors, including sexual practices, and injection drug use histories. These data will be used to target high-risk populations and thereby provide insight into the need for hepatitis testing and services in such settings, enhance viral hepatitis prevention program at multiple settings, and to reduce high-risk behavior in persons most likely to acquire or transmit viral hepatitis. Specific information about client demographics and risk profiles is essential to designing appropriate interventions and programs and to monitoring and evaluating these programs.

This data collection also includes race and ethnicity questions, which may also be viewed as sensitive by some respondents, for use in data analysis (e.g., designing and evaluating programs, as discussed above) and to support compliance with the HHS Policy Statement on Inclusion of Race and Ethnicity in DHHS Data Collection Activities of October 24, 1997.

12. Estimates of Annualized Burden Hours and Costs

The goal of HEPTLC is to increase the number and proportion of 1)

persons tested for HBV and HCV, 2) persons with chronic viral hepatitis who are aware of their infection, and 3) persons linked to care, treatment, and prevention services. The initiative will span for one year and may be funded for additional years. DVH will directly fund as many as 40 sites to conduct hepatitis B and C testing and linkage to care (HEPTLC). Funded sites are required to collect their testing activities and results related to the implementation of HEPTLC initiative, and report to CDC DVH to satisfy the terms of the HEPTLC cooperative agreements. Respondents are required to submit test-level data to the CDC on a monthly basis, and programmatic aggregated data quarterly.

Annualized Burden Hours

Approximately 40 directly funded hepatitis test sites will collect and report the required Hepatitis Testing and Linkage to Care monitoring and evaluation (HEPTLC) data. An estimated maximum has been used to calculate burden. Efforts made to keep the number of required variables indicated in this ICR to a minimum to limit burden while still obtaining the data necessary for reporting, program monitoring and evaluation.

Each test site will be required to submit the required HEPTLC data, including: 1) Information about test sites that provide HEPTLC services and laboratories that provide lab testing; 2) Information about testing participants, including demographics, risk characteristics, vaccination history, etc.3) Information related to diagnostic test results; and 4)Information about post-test follow-ups, including notification of test result, post-test-counseling, linkage to care and preventive services, and case report to surveillance authorities.

The estimates for the number of annualized burden hours are based on two categories of data that are required:

- Test-level data – reporting monthly for both HBV and/or HCV
- Programmatic-level data – reporting quarterly for both HBV and/or HCV

In addition, all funded agencies will receive training on HEPTLC M&E system.

The burden calculations that follow are presented in the order listed in above categories based on the time required to enter data into the Hepatitis Testing and Linkage to Care Monitoring and Evaluation System (HEPTLC) and the time for training.

:

The HEPTLC software will be developed and provided by CDC for use by hepatitis grantees. The HEPTLC variables and values are standardized and non-identifiable within system and submitted to CDC based on specified timelines (Two categories above).

Some CDC-funded sites may subcontract with smaller test sites that provide various direct services to clients in need of providing hepatitis testing and linkage to care services. The cost of contracting out for information collection is not included in the annualized burden for respondents; however, it is expected that majority of the CDC-funded test sites will enter data into HEPTLC system for their subcontracted agencies.

TEST-LEVEL DATA – MONTHLY SUBMISSION

The test-level data variables will be entered once a month and 12 times, annually, during the one-year project period, then must be reviewed and updated by the test sites as needed.

Based on the minimum test-level data variables and associated data fields within the HEPTLC system, we calculated that it will take 3 minutes to complete data entry for each individual testing participant, and will take an average of 12 hours based on required tests needed to be completed by each test site. The test-level date will be reported monthly by all funded test sites. Total burden for each test site is estimated to be [12 hours/monthly x 12 months = 144 hours annually]. Total burden for all 40 test sites is estimated to be [12 hours/monthly x 12 month x 40 sites = 5760 hours annually].

PROGRAMMATIC-LEVEL DATA – QUARTERLY SUBMISSION

Based on the programmatic-level data variables and associated data fields within the HEPTLC system, we calculated that it will take 30 seconds to generate an automatic aggregated quarterly report, and will take average 1.5 hours based on required tests which need to be completed by each test site. The test-level data will be reported quarterly by all funded test sites. Total burden for each test site is estimated to be [1.5 hours x 4 quarters = 6 hours annually]. Total burden for all 40 test sites is estimated to be [1.5 hours/quarterly x 4 quarters x 40 sites = 240 hours annually].

Total estimated for each test site:

Monthly Test-level Data Reporting:	144 hours
Quarterly Programmatic-level Data Reporting:	6 hours

:

TOTAL ANNUAL HOURS 150 hours

Table A.12-A. Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per response (in hours)	Total Burden (in hours)
HBV – CBOs/Health Jurisdictions **HCV** – multiple sites (IDU, CHCs, Others, ECHO)	HEPTLC Data Variables & Values (test-level monthly reporting)	40	12	12	5,760
HBV – CBOs/Health Jurisdictions **HCV** – multiple sites (IDU, CHCs, Others, ECHO)	HEPTLC Template (program-level reporting/ quarterly)	40	4	1.5	240
Total					**6,000**

The total estimated annualized hourly burden anticipated for all data collections is approximately 6,000 hours.

B. Annualized Cost to Respondent

The collection and reporting of HEPTLC M&E data are part of the activities specified in the HEPTLC program announcements as part of the funded activities. Any expense incurred collecting and submitting the HEPTLC M&E data, above the routine collection of data required to conduct business, is supported by CDC funding. There is no actual cost to the respondent.

The estimated cost to be supported by CDC funding is as follows. It is estimated that a part-time staff who enters HEPTLC M&E data

information will be paid approximately $20,000 annually. Comparable annual salary for Federal General Schedule (GS) employees is that of a GS-7 step 1 ($40,534 annually or $19.42/hour).

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no other costs to respondents. The conditions of the cooperative agreements that CDC awards for hepatitis testing and linkage to care initiatives require recipients to implement testing and linkage to care activities, and to collect standardized, non-identifying, client-level and test-level hepatitis testing information from funded testing sites at multiple settings via Hepatitis Testing and Linkage to Care (HEPTLC) monitoring and evaluation system.

HEPTLC system will fully support data collecting and reporting activities, while providing training, technical assistance, and continued support to awardees through a help desk, website, and various forms of correspondence. Implementing the HEPTLC software will require no start-up costs for the awardees. The system may be updated overtime when necessary, and there will be no cost to the awardees for any updates.

14. Annualized Cost to the Government

The HEPTLC data collection software are multi-year projects expected to be in use for many years. For the purposes of this submission, a three year life expectancy has been used to estimate the annualized cost to the government.

CDC supports costs for hepatitis testing and linkage to care program cooperative agreements using funds budgeted for these purposes. Additional expenses will be incurred by CDC for training awardees, providing technical assistance, monitoring and analyzing the submitted HEPTLC data, and generating assorted reports. Total costs for these activities are estimated at $63,278.80 annually. The costs of the cooperative agreement are $500,000. (see table below).

Training on HEPTLC for awardees will be developed. Instruction will include topics such as confidentiality and computer security, use of HEPTLC, evaluation principles, and use of data for program improvement. The base Federal General Schedule (GS) salary for full-time employees (FTEs) with experience in these areas is estimated to be a GS-12 step 1. It is expected that the

equivalent of one FTE at $34.45/hour, will expend approximately 80 hours/FTE annually to assist these trainings.

Technical assistance will be provided through an e-mail service center overseen by CDC. It is expected that the equivalent of one GS-13 step 1 ($40.97/hour) FTE will expend approximately twenty-five percent (25%) of working hours (520 hours) to oversee this service center.

Monitoring, analyzing, and reporting the HEPTLC data are projected to require the expertise of the equivalent of one data manager and three data analysts. The data manager would be at the pay scale of GS-13 step 1 ($40.97/hour) and the data analysts would be at the pay scale of GS-12 step ($34.45/hour), will each expend approximately twenty-five percent(25%)of their time or 1040 hours/FTE annually.

Employee Function	**Annual Burden (in hours)**	**Hourly Wage Rate**	**Annual Cost**
Training	80	$34.45	$ 2,756.00
Technical Assistance	520	$40.97	$ 21,304.40
Monitoring, Analyzing and Reporting	520 520	$40.97 $34.45	$ 21,304.40 $ 17,914.00
Cost of Cooperative Agreement			$ 500,000.00
TOTAL ANNUAL FEDERAL GOVERNMENT COSTS:			**$563,278.80**

15. Explanation for Program Changes or Adjustments

The HEPTLC is a new data collecting and reporting system.

16. Plans for Tabulation and Publication and Project Time Schedule

Data collection will begin immediately after the program receives the OMB approval. As previously mentioned, we expect to received monthly and quarterly reports from the funded sites.

Analysis is focused on supporting program monitoring and evaluation, conducting analysis of hepatitis testing and linkage

to care programs, identifying needs for prevention research and evaluation studies, and responding to data requests from Congress and the Executive Branch. Annual reports on the data, starting with reports covering the entire project period (Sept. 30, 2012 – Sept.30, 2013), will be scheduled to be produced at the end of 2013. However there is an indication that the project would be extended to three year period. In addition, HEPTLC data will be used to improve knowledge of local hepatitis testing and linkage to care practices, implementation of effective viral hepatitis prevention interventions, and adherence to program reporting requirements. Reports generated by the system include reports for quality assurance, comparison of planned activities or expenditures to actual activities or expenditures, data for calculating required performance indicators, data on specific interventions, data for contract monitoring, and data for assessing needs.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB Expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act (PRA) Submissions 5CFR 1320.3(h)(1)-(10)

No exception is requested.

References

[1] Combating the Silent Epidemic of Viral Hepatitis: Action Plan for the Prevention, Care and Treatment of Viral Hepatitis (http://www.hhs.gov/ash/initiatives/hepatitis)