DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
Proposed Data Collections Submitted for
Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 or send comments to Kimberly S. Lane, at 1600 Clifton Road, MS D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

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; and (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. Written comments should be received within 60 days of this notice.
Proposed Project


Background and Brief Description

The National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention is requesting a three-year OMB approval for establishing a Hepatitis Testing and Linkage to Care (HEPTLC) Monitoring and Evaluation System to collect standardized, non-identifying, client-level and test-level hepatitis testing information from funded testing sites at multiple settings. Grantees will be required to use this web-based HEPTLC software application to collect and report testing and linkage to care activities.

The HEPTLC data collection and reporting system will enable CDC to receive standardized, non-identifying information from funded grantees, 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. CDC will use HEPTLC data for
the following purposes: (1) Monitor the implementation activities of the HEPTLC initiative, as well as evaluate the progress and performance made by the grantees. Findings will further inform strategic planning and program improvement; (2) Inform recommendations and strategies of increasing early identification of infected persons and linkage to care, based on participant characteristics and linkage to care among those persons who are infected; (3) Identify best practices and gaps in implementing HEPTLC in various testing settings, and guide CDC in providing technical assistance to the grantees; (4) Produce standardized and specialized reports that will inform grantees, CDC Project Officers, HHS, and other stakeholders of the process, outcome and accountability measures; (5) Assess public health prevention funds and resources allocations with respect to prioritized risk populations; (6) Advocate the needs for priority setting and budget allocation for hepatitis prevention.

Funded sites will use HEPTLC data for the following purposes: (1) Understand targeted populations (demographics, risk behaviors, vaccination histories, etc.) and assess the extent to which the targeted populations have been reached; (2) 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; (3) Highlight opportunities for local program collaboration and service integration (PCSI) to prevent hepatitis; (4) Fulfill data collection and reporting requirements outlined in the cooperative agreements.
The total estimated annualized hourly burden anticipated for all data collections and training would be approximately 6,080 hours. Respondents will be testing sites at multiple settings, including health departments, community based organizations (CBOs), community health centers (CHCs), person who inject drugs (PWID) treatment centers, and other settings, e.g. human immunodeficiency virus (HIV) or sexually transmitted disease (STD) clinics, Federally Qualified Health Centers (FQHCs). They will routinely collect, enter, and report information about the test site, client demographics and behaviors, testing results and linkage to care follow up information within the web-based HEPTLC system.

CDC anticipates that routine information collection will begin immediately after OMB approval. CDC intends for grantees to bear minimum burdens with minimal standardized data variables, while fulfilling mandatory reporting requirements. There are no costs to respondents other than their time.

### Estimated Annualized Burden Hours

<table>
<thead>
<tr>
<th>Type of Respondents</th>
<th>Form Name</th>
<th>Number of Respondents</th>
<th>Number of Responses per Respondent</th>
<th>Average Burden per response (in hours)</th>
<th>Total Burden (in hours)</th>
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</thead>
<tbody>
<tr>
<td>HBV – CBOs/Health Jurisdictions</td>
<td>HEPTLC Data Variables &amp; Values (test-level monthly reporting)</td>
<td>40</td>
<td>12</td>
<td>12</td>
<td>5,760</td>
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<tr>
<td>Type of Respondents</td>
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<tr>
<td>HBV - CBOs/Health Jurisdictions</td>
<td>HEPTLC Template (program-level reporting/quarterly)</td>
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<td>4</td>
<td>1.5</td>
<td>240</td>
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<td>HCV - multiple sites (IDU, CHCs, Others, ECHO)</td>
<td>HEPTLC System</td>
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<td>2</td>
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<tr>
<td>Total</td>
<td></td>
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Kimberly S. Lane,
Deputy Director
Office of Science Integrity
Office of the Associate Director for Science
Office of the Director
Centers for Disease Control and Prevention