

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-23-1353; Docket No. CDC-2023-0059]

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 effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled, Integrated Viral Hepatitis Surveillance and Prevention Funding for Health Departments (CDC-RFA-PS21-2103). This data collection is for viral hepatitis (VH) case reporting data collected from the National Notifiable Diseases Surveillance System (NNDSS) which provides the primary population-based data used to describe the epidemiology of VH in the United States and for annual reporting of surveillance, prevention, and epidemiology performance measures via an Annual Performance Report.

DATES: CDC must receive written comments on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2023-0059 by either of the following methods:

- Federal eRulemaking Portal: www.regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number.

CDC will post, without change, all relevant comments to www.regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal

(www.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 Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329; Telephone: 404-639-7118; E-mail: 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 the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;

4. 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 submissions of responses; and
5. Assess information collection costs.

Proposed Project

Integrated Viral Hepatitis Surveillance and Prevention Funding for Health Departments (CDC-RFA-PS21-2103) (OMB Control No. 0920-1353, Exp. 11/30/2024) - Revision - National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) requests three-year OMB approval for the Revision of an information collection package (OMB Control No. 0920-1353, Exp. Date 11/30/2024). CDC is authorized under Sections 304 and 306 of the Public Health Service Act (42 USC 242b and 242k) to collect information on cases of viral hepatitis (VH). Data collected by NNDSS (OMB Control No. 0920-0728) are the primary data used to monitor the extent and characteristics of the VH burden in the United States. VH surveillance data are used to describe trends in VH incidence, prevalence, and characteristics of infected persons and are used widely at the federal, state, and local levels for planning and evaluating prevention programs and health-care services and to allocate funding for prevention and care.

In 2021, CDC implemented activities under a new cooperative agreement Integrated Viral Hepatitis Surveillance and Prevention Funding for Health Departments (CDC-RFA-PS21-2103). Tools exist to prevent new cases of hepatitis A, B, and C, to treat people living with hepatitis B, and to cure people living with hepatitis C. Yet, new cases of VH continue to rise, many people infected with VH remain undiagnosed, and far too many VH-related deaths occur

in the US each year. The purpose of these activities is to enable state and local health departments to collect data to evaluate disease burden and trends and to analyze and disseminate that data to develop or refine recommendations, policies, and practices that will ultimately reduce the burden of VH in their jurisdictions. The goals of the activities are to reduce new VH infections, VH-related morbidity and mortality, and VH-related disparities and to establish comprehensive national VH surveillance, which are in accordance with the Division of Viral Hepatitis 2025 Strategic Plan. In addition, the cooperative agreement supports VH elimination planning in these jurisdictions and maximize access to testing, treatment, and prevention services for populations at high risk for viral hepatitis (including service provision in high-impact settings).

The activities of this cooperative agreement include two components (Component 1: Surveillance, and Component 2: Prevention), containing six strategies: 1.1 - develop, implement, and maintain a plan to rapidly detect and respond to outbreaks for hepatitis A, B, and C; 1.2 - collect, analyze, interpret, and disseminate data to characterize trends, and implement public health interventions for hepatitis A, acute hepatitis B and acute and chronic hepatitis C; 1.3 - (contingent on available funding), collect, analyze, interpret, and disseminate data to characterize trends and implement public health interventions for chronic hepatitis B and perinatal hepatitis C; 2.1 - support VH elimination planning and surveillance, and maximize access to testing, treatment, and prevention; 2.2 - (contingent on available funding), increase access to HCV and HBV testing and referral to care in high-impact settings; and 2.3 - (contingent on available funding), improve access to services preventing VH among persons who inject drugs. Contingent on funding, an optional component (Component 3: Special Projects) will support improved access to prevention, diagnosis, and treatment of viral, bacterial and fungal infections related to drug use in settings disproportionately affected by drug use.

In 2023, CDC will fund health department recipients to implement additional activities through supplemental funding. These activities relate to increasing access to viral hepatitis testing and linkage to care in high-impact settings. Specific activities include increasing routine

VH testing in high-impact settings; providing counseling, linkage to treatment, and referral to prevention services in high-impact settings; and building public health laboratory capacity. These activities are the same activities described in the cooperative agreement (Component 2) but provide additional funding to health department recipients to expand/increase these services in their jurisdictions.

Performance measures are monitored to assess recipient performance, including quality of data, effective program implementation, and accountability of funds. Data collection via the Annual Performance Report is used for program accountability and to inform performance improvement. Outbreak reporting are submitted throughout the year. These data, which complement case data as another key component of national viral hepatitis surveillance, are critical to determining both the level of viral hepatitis activity within a jurisdiction as well as the effectiveness of each jurisdiction's approach to cluster and outbreak response. A standardized Case Report Form is used for surveillance data collection submitted to the National Notifiable Diseases Surveillance System (NNDSS). De-identified data including national VH surveillance data are submitted to CDC electronically per each jurisdiction's usual mechanism. Recipients submit other required quantitative and qualitative performance measure data annually via an Annual Performance Report and as needed for outbreak reporting.

In the first two years of this cooperative agreement, health department recipients worked toward establishing a jurisdictional framework to respond to VH-related outbreaks; assessed public health reporting of chronic and perinatal HCV and chronic HBV infection, and undetectable HCV RNA and HBV DNA laboratory results; increased engagement with community partners in elimination planning across their jurisdiction; and increased the level of hepatitis testing services in a variety of setting types (including linkage to care and treatment for individuals diagnosed with VH).

With the data submitted through the Annual Performance Report data collection forms in Year 1 and Year 2, CDC assessed the progress of jurisdictions in meeting the deliverables of CDC-RFA-PS21-2103. Additionally, CDC developed and provided feedback reports to

recipients to summarize progress made toward meeting the overarching objectives of the funding award which include: establishment of comprehensive national VH surveillance, reduced new VH infections, increased access to care for persons with VH, improved health outcomes for people with VH, reduced deaths among people with VH, reduced VH-related health disparities and decreased overdose deaths. Specifically, jurisdictions reported developing VH outbreak response plans and elimination plans and serving persons who inject drugs, including number of clients tested for HBV and HCV and number of clients vaccinated against HAV and HBV.

CDC requests OMB approval for an estimated 6,657 annual burden hours. There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hours)	Total Annual Burden (in hours)
Health Departments	Viral Hepatitis Case Report Form	51	381	20/60	6,412
Health Departments	APR: Component 1	59	1	70/60	69
Health Departments	APR: Component 2	59	1	70/60	69
Health Departments	APR: Component 3	20	1	70/60	23
Health Departments	Supplemental APR	8	1	45/60	6
Health Departments	Initial Outbreak Report Form	59	2	20/60	39
Health Departments	Outbreak Summary Report Form	59	2	20/60	39
Total					6,657

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