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2020 Supplemental Budget Decision Package

Agency:	303 - Department of Health			
Decision Package Code-Title: B7 - Eliminate Hepatitis C				
Budget Session:	2020 Supp			
Budget Level:	Policy Level			
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Agency Recommendation Summary

Hepatitis C infections continue to rise in Washington State, despite the existence of a cure. In support of Governor Inslee's Directive 18-13, the Washington State Department of Health requests an appropriation to implement public health priorities to eliminate hepatitis C. These priorities include increased screening and linkage to care activities in high-impact settings; investments in case investigation and response; dedicated viral hepatitis microbiologists for outbreak response; and investments in state data systems to manage related case report, laboratory, and vital records information.

Fiscal Summary

Dollars in Thousands

Operating Expenditures	FY 2020	FY 2021	FY 2022	FY 2023
Fund 001 - 1	\$0	\$9,761	\$11,110	\$11,302
Total Expenditures	\$0	\$9,761	\$11,110	\$11,302
Biennial Totals		\$9,761		\$22,412
Staffing	FY 2020	FY 2021	FY 2022	FY 2023
FTEs	0.0	23.8	31.3	32.8
Average Annual		11.9		32.1
Object of Expenditure	FY 2020	FY 2021	FY 2022	FY 2023
Obj. A	\$0	\$1,873	\$2,537	\$2,666
Obj. B	\$0	\$674	\$903	\$948
Obj. C	\$0	\$370	\$620	\$620
Obj. E	\$0	\$377	\$532	\$539
Obj. J	\$0	\$93	\$93	\$93
Obj. N	\$0	\$6,200	\$6,200	\$6 <i>,</i> 200
Obj. T	\$0	\$174	\$225	\$236

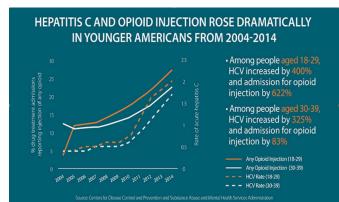
Package Description

Background and Problem Statement

The hepatitis C virus (HCV) causes more fatalities annually in Washington State than the human immunodeficiency virus (HIV) did at its epidemic peak. Between 2001 and 2017, a total of 107,954 chronic HCV cases have been reported to the Department of Health (DOH), an average of 6,747 cases per year. Chronic infection with HCV can result in cirrhosis, liver cancer, disability, reduced quality of life, and premature death. HCV is currently the leading indication for liver transplants in the United States. (https://www.hcvguidelines.org/evaluate/cost)

https://abs.ofm.wa.gov/budget/2019-21/S1/303/versions/50/decision-packages/B7-PL/review

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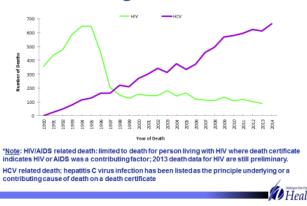
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In addition to chronic cases, the number of acute cases has risen dramatically since 2011, which is correlated to a rise in injection drug use associated with the opioid epidemic. In 2018, there were 118 reports of acute HCV infection in Washington, the most since 1995. In 2017, there were 543 deaths attributed to HCV. An estimated 60,000 Washingtonians live with HCV and an average of 582 HCV-associated deaths occur annually.

HCV is curable. Highly effective medications are available and recent studies show cure rates between 90 and 100 percent. Since the death rate from HCV is increasing despite the existence of effective treatment, an urgent public health response is critically needed. Curative medications are not easy to acquire as considerable barriers to access exist. Such barriers

include a lack of knowledge of one's HCV status, challenges with navigating complex health care systems, stigma, cost, and a lack of primary care providers treating HCV.

Deaths Related to HIV and Hepatitis C Washington 1990-2014



Governor Jay Inslee's Directive to Eliminate Hepatitis C in Washington State by the Year 2030

On September 28, 2018, Governor Jay Inslee issued Directive 18-13, unveiling a first-in nation approach to eliminate HCV by 2030 through two primary efforts:

- 1. Establishing a multisector coordinating committee to develop a comprehensive public health strategic plan ,and;
- 2. Creating an innovative medication procurement model to ensure all people with HCV whose health care costs are paid by the State of Washington (i.e. Medicaid, the Department of Corrections (DOC), the Public Employees Benefits Board program, state worker's compensation insurance, and the state hospitals) receive curative medication.

DOH and the Washington State Health Care Authority (HCA) are the state agencies assigned to lead each effort. In October 2018, DOH convened a coordinating committee comprised of diverse representatives, including tribal health centers, local health jurisdictions (LHJ), federally qualified health centers, health plans, professional organizations, community-based organizations, people affected by HCV, drug treatment providers, syringe service programs (SSP), academic institutions, and others interested in HCV elimination. The coordinating committee named the initiative "Hep C Free Washington" and developed goals and action items within a comprehensive elimination plan for Washington State (<u>www.doh.wa.gov/HepCFreeWA</u>), which was submitted to the Governor in July 2019. The plan addresses needed improvements to the public health system to ensure all people with or at risk to contract HCV have access to preventive services, know their status, and connect to care and ultimately a cure.

In May 2019, the legislature passed a 2019-2021 biennium budget proviso related to HCV, directing HCA to develop a savings estimate that will result from lower medication costs and a plan to reinvest expected savings to further the public health elimination effort. While the budget proviso is a step to implement the Hep C Free Washington plan, it is important to note the implementation of this proviso is designed to be budget neutral; there may be no cost savings to dedicate to a public health elimination plan.

While public health tools certainly exist to achieve HCV elimination in Washington State by 2030, without the appropriation and staff requested in this proposal, DOH will lack the necessary resources to deploy them at the level needed. Resources at the federal level are inadequate to assist the state, as the Division of Viral Hepatitis at the Centers for Disease Control and Prevention (CDC) only receives \$32 million for the entire country's hepatitis A, hepatitis B, and HCV response. DOH receives a small percentage of this federal funding, as well as some state funds. To scale the state's effort to a level sufficient to reach the elimination goal.

The Hep C Free Washington Plan

The development of the plan has been a coordinated effort among state, LHJs and other public and private partners. It identifies key strategies and activities to eliminate HCV. Resources are required to implement these strategies and to coordinate and convene the Hep C Free Washington coordinating committee and other work groups to ensure monitoring, evaluation, and quality improvement over time.

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Proposed Solution:

DOH requests expenditure authority to implement the following strategies, most of which are outlined within the Hep C Free Washington plan:

- Increase screening and link those infected to treatment;
- Invest in HCV case investigation and response;
- Dedicate viral hepatitis microbiologists for hepatitis outbreak response; and
- Invest in the state HCV data systems to manage related case report, laboratory, and vital records information.

Increase screening and link those infected to treatment

Research shows expanding testing and access to treatment are essential elements to HCV elimination efforts. Both the Washington State Hepatitis C Strategic Plan and the U.S. Department of Health & Human Services National Viral Hepatitis Action Plan recommend expanding access to, and delivery of, hepatitis prevention, care, and treatment services in high-impact settings. The Hep C Free Washington plan highlights the importance of reaching key populations with HCV testing and linkage to care and treatment services. These populations include people who inject drugs, the homeless, incarcertated individuals, and people who are Native American.

SSPs are also highlighted as an effective strategy to ensure people who inject drugs have access to HCV prevention services in by U.S. Department of Health & Human Services National Viral Hepatitis Action Plan[1] and the World Health Organization's viral hepatitis elimination plan[2]. Mobile or outreach screening units increase access and screening programs for marginalized and stigmatized priority populations.

HCV screening and providing treatment within venues providing medication for opioid use disorder (e.g., opioid treatment programs) provides an opportunity to deliver services to this key population[3].

Invest in HCV case investigation and response (Foundational)

HCV is spreading throughout the state; it is not just focused on the large counties in the I-5 corridor. DOH needs clearer data to understand the burden HCV places on the state and must use this information to implement consistent surveillance work in accordance with the law. Clear data from improved HCV case investigations and response will also drive other future initiatives that prevent and control disease.

Better surveillance allows for accurate and timely disease intervention, treatment, notification, screening, and linkage to care. When individuals with HCV, and their social networks, are quickly identified, treated, and cured, the chance to transmit the infection is reduced.

Dedicated viral hepatitis microbiologists for outbreak response (Foundational)

DOH's State Public Health Laboratory (PHL) provides critical laboratory services that positively impact the public's health by supporting communicable and infectious disease investigation programs. As the state addresses HCV elimination through increased disease surveillance and case management (as proposed above), it will need to increase diagnostic laboratory capability for serological, molecular, and subtyping testing.

This proposal will expand current procedures to perform a comprehensive suite of tests to support Viral Hepatitis control efforts in Washington State. Testing will include serological tests for hepatitis A, B and C and molecular diagnostic testing for hepatitis B and C. This includes advanced molecular subtyping methods to aid in cluster detection and genotyping. In simpler terms, the funding in the proposal allows DOH to increase its capacity to perform testing and analyses to more clearly pinpoint the sources of HCV infections so it may focus its intervention in those areas. This testing will be phased in over the first year to 18 months. Some equipment will be needed but will be procured through a reagent lease.

Invest in the state HCV data systems to manage related case report, laboratory, and vital records information (Foundational)

Washington Disease Reporting System (WDRS)

The WDRS data system is the the singular disease reporting system used by both local and state communicable disease investigators to monitor ongoing disease investigations, follow up on community transmission of disease, understand surveillance trends in disease burden from the local perspective, and meet both local, state, and federal reporting requirements for notifiable conditions. To maintain this critical infrastructure, this proposal supports ongoing maintenance and operational needs.

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Current, newly emerging, and novel communicable diseases continue to impact communities throughout Washington State. While disease reporting and surveillance is not new, the use of "Big Data", data driven decision making, and data system interoperability are an integral part of public health practice in recent years. Very few, if any, LHJs are staffed to use these varying and increasingly rich data sources. Within the area of communicable disease epidemiology, there is a need to reconcile, consolidate, design, and implement new practices for conducting disease reporting and surveillance. Adoption of these practices is driven by federal requirements for standardization and data system interoperability. These resources will aid in supporting the state's efforts to integrate and standardize data streams for surveillance and reporting.

Laboratory Information Management System (LIMS)

Delivering rapid and accurate HCV lab results to local, state, tribal and federal stakeholders is currently limited by an infrastructure deficiency – the lack of a modern LIMS. Updating this infrastructure will enable PHL to receive and test specimens in a safe and expeditious manner and deliver critical results into the hands of disease investigators and physicians faster. This will greatly improve disease surveillance efforts, not only for HCV, but also for foodborne diseases, influenza, and vaccine preventable diseases.

The LIMS system will track all samples submitted to the PHL, house applicable demographic data used by LHJs and state epidemiologists, and report results to the specimen submitter and all appropriate local, state, and federal stakeholders. The current, antiquated LIMS used at the PHL was purchased in 2004 and is nearing the end of its useful life. This proposal will allow the PHL to purchase and implement a new LIMS through a competitive bid process. The new LIMS system will be compatible with all data transfer standards currently in use and integrated into ongoing Health Information Exchange (HIE) work within DOH.

National public health stakeholders including the CDC and the Association of Public Health Laboratories, have expressed concerns regarding the age, functionality and interoperability of current PHL LIMS, as it is unable to meet the basic expectations of a modern LIMS, such as transmitting necessary and timely public health information to all relevant stakeholders.

Streamlined Analytic Functionality

Updating and expanding self-service menu driven analytic functionality for key population health data will improve the timeliness, quality, and comprehensiveness of core DOH data systems. It will allow the entire public health system – state, local and tribal – to more readily share datasets, analytic tools, and analytic expertise which will result in more timely and informed decision-making.

One option to gain this functionality is to upgrade the existing Community Health Assessment Tool (CHAT). This system is a menu driven analytic tool allowing LHJ assessment staff to quickly identify data trends and stratified analyses without the need to engage in statistical programming. The current tool is outdated and does not include some newer DOH datasets, nor does it have mapping or data visualization capability. This enhanced functionality is needed by state, local and tribal health staff to quickly respond to program, media and other requests, and to quickly compile information for Community Health Assessments, grant applications, and decision-making. This request includes sufficient, one-time funding for project planning and system requirement development to upgrade the existing CHAT system.

Consequences of not taking action:

The peak of HCV complications (e.g., cirrhosis complications, liver cancer, liver transplants, and deaths) is estimated to occur around 2030. In addition, acute HCV is increasing due to the opioid crisis and increased injection drug use among people 40 years of age and younger. It is imperative to identify, link, and cure all Washingtonians with HCV as quickly as possible

Failure to scale public health efforts to prevent new infections and link people to curative medication will allow the HCV epidemic to indefinite continue and hinder Governor Inslee's directive to eliminate HCV.

Economically, several recent studies demonstrate the economic value of HCV treatment and make it clear HCV therapy is cost-effective (Chahal, 2016); (Chatwal, 2015); (Chidi, 2016); (Linas, 2015); (Martin, 2016a); (Najafzadeh, 2015); (Rein, 2015); (Tice, 2015); (Younossi, 2015a). Preventing new infections and linking people with HCV to cost-effective treatment will reduce Washington State's expenditures in the long term by reducing health care costs.

[1]US Department of Health & Human Services. 2017. National viral hepatitis action plan. https://www.hhs.gov/sites/default/files/National%20Viral%20Hepatitis%20Action%20Plan%202017-2020.pdf

[2]World Health Organizations. Combating hepatitis B & C to reach elimination by 2030. http://apps.who.int/iris/bitstream/handle/10665/206453/WHO_HIV_2016.04_eng.pdf;jsessionid=57F5DA4E1B1735749D0238CB1257AD98? sequence=1

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[3]Key populations: Identification and Management of HCV in People Who Inject Drugs. American Association for the Study of Liver Disease. https://www.hcvguidelines.org/unique-populations/pwid

Assumptions and Calculations

Expansion or alteration of a current program or service:

During the 2015-2017 biennium, total DOH expenditures to address HCV was \$8,090,155. Total budget during this period was \$8,239,929.

Through fiscal month 12 of the 2017-2019 biennium, total DOH expenditures to address HCV was \$4,543,408. Total budget during this period was \$4,940,715.

Detailed assumptions and calculations:

The total amount proposed to carry out this this proposal:

- Increase screening and link those infected to treatment: \$3,375,000 for fiscal year 2021 and ongoing;
 - Elimination implementation requested DOH FTE: 1.0 Hep C Free Washington Associate Annual cost: \$129,000;
 - Community Investments to local health jurisdictions, DOC, local jails, tribal entities, community based organizations, and Medication Assistant Treatment programs – Annual cost: \$3,246,000;
- Invest in HCV case investigation and response: \$3,000,000 for fiscal year 2021 and ongoing;
 - Provide capacity to LHJs to conduct acute and select chronic HCV disease investigations, testing social networks, linkage to care and supportive services, and follow-up;
- Dedicate viral hepatitis microbiologists for outbreak response: \$499,000 for fiscal year 2021, \$498,000 for fiscal year 2022 and beyond;
 - Expand laboratory testing to perform a comprehensive suite of tests to support Viral Hepatitis control efforts in Washington State;
- Investments in the state HCV data systems to manage related case report, laboratory, and vital records
 - information: \$2,887,000 for fiscal year 2021, \$4,237,000 for fiscal year 2022, and \$4,428,000 for fiscal year 2023;
 - Washington Disease Reporting System (WDRS): \$348,000 for fiscal year 2021, \$347,000 in fiscal year 2022 and beyond;
 - Funds 2 DOH FTEs and vendor costs for system operation and maintenance;
- Laboratory Information Management System (LIMS): \$1,539,000 for fiscal year 2021, \$2,890,000 for fiscal year 2022, and \$3,080,000 for fiscal year 2023;
 - Support replacement of outdated LIMS through a competitive bid process;
- Community Health Assessment Tool (CHAT): \$1,000,000 for fiscal year 2020 and beyond;
 - $\circ~$ Supports project planning and requirement development to upgrade the outdated CHAT system.

For more details on how these investments will be strategically employed, please refer to a support document titled, :"Eliminate Hepatitis C-Strategic Approach".

Workforce Assumptions:

See attached financial calculator (FNCAL)

Strategic and Performance Outcomes

Strategic framework:

This request directly contributes to the Governor's Executive Order 16-09 "Addressing the Opioid Use Public Health Crisis" and Directive 18-13 "Eliminating Hepatitis C in Washington by 2030 through combined public health efforts and a new medication purchasing approach."

As noted by Jonathan Mermin, M.D., M.P.H., former director of CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, "Hepatitis C is a deadly, common, and often invisible result of America's opioid crisis... By testing people who inject drugs for hepatitis C infection, treating those who test positive, and preventing new transmissions, we can mitigate some of the effects of the nation's devastating opioid crisis and save lives." https://www.cdc.gov/nchhstp/newsroom/2017/hepatitis-c-and-opioid-injection-press-release.html

The request relates to the agency's public safety objectives and strategies:

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"Improve statewide disease prevention, surveillance, and response systems," and "Ensure persons who inject drugs have access to hepatitis C, HIV, and STD screening services".

Performance outcomes:

Strategies and activities proposed within this request work towards the WHO's goals of eliminating HCV as a public health threat. Elimination performance indicators described by the WHO include a target timeline of 2030. Service coverage *targets* that will eliminate HCV by 2030 include:

- Diagnosis of HCV (coverage %): 90 percent;
- Treatment of HCV (coverage %): 80 percent eligible treated;
- Incidence of chronic HCV infections: reduce by 90 percent; and
- Mortality from chronic HCV infections: reduce by 65 percent .

Service coverage benchmarks that will work towards eliminate HCV by 2030 adjusted for two-year proposed biennium (2020):

- Diagnosis of HCV (coverage %): 30 percent;
- Treatment of HCV (coverage %): n/a;
- Incidence of chronic HCV infections: reduced by 30 percent; and
- Mortality from chronic HCV infections: reduce by 10 percent.

Other Collateral Connections

Intergovernmental:

HCA is concurrently working on an HCV medication procurement strategy in the hopes of increasing access to curative treatment and reducing long-term state investment in treating HCV. This proposal complements HCA's effort by addressing workforce readiness, prevention, diagnosis, and access to care and treatment. Ultimately, it will reduce the costs incurred by other state agencies and state taxpayers.

In addition, this proposal will fund specific projects for Tribal Nations as HCV infections and the opioid crisis disproportionately impact these communities. DOH included representatives from Tribal Nations and the Northwest Portland Area Indian Health Board in the Hep C Free Washington planning process. DOH anticipates support from the Tribal Nations.

This proposal also funds HCV screening and linkage to care efforts within local health jurisdictions to support efforts in highly burdened communities.

Stakeholder response:

In October 2018, DOH convened a coordinating committee comprised of diverse representatives, including tribal health centers, LHJs, federally qualified health centers, health plans, professional organizations, community-based organizations, people affected by HCV, health plans, drug treatment providers, SSPs, academic institutions, health care agencies serving veterans, multiple state agencies, and others with an interest in HCV elimination. The coordinating committee developed the recommendations and strategies outlined above. DOH expects strong stakeholder support for this request.

Legal or administrative mandates:

This request is not driven by legal or administrative mandates.

Changes from current law:

This request does not require any changes to statutes or rules.

State workforce impacts:

This request does not impact existing collective bargaining agreements.

State facilities impacts:

This request enhances the functioning of the state's sole public health laboratory.

Puget Sound recovery:

This request is not related to Puget Sound recovery efforts.

Reference Documents

- Eliminate Hepatitis C-IT Addendum.docx
- Eliminate Hepatitis C-Other Sources and References.docx
- Eliminate Hepatitis C-Strategic Approach.docx
- PL B7 Eliminate Hepatitis C-FNCAL.xlsm

IT Addendum

Does this Decision Package include funding for any IT-related costs, including hardware, software, (including cloud-based services), contracts or IT staff?

Yes

Eliminate Hepatitis C-IT Addendum.docx