Hepatitis C Medications

Comprehensive Purchasing Strategies

Engrossed Substitute House Bill 1109; Chapter 415; Laws of 2019; Section 211(45)

October 31, 2019

Washington State Health Care Authority

Washington State Department of Health

Hepatitis C Medications

Clinical Quality and Care Transformation
P.O. Box 45502
Olympia, WA 98504
Phone: (360) 725-0473
Fax: (360) 586-9551
www.hca.wa.gov

Division of Disease Control & Health Statistics
P.O. Box 47840
Olympia, WA 98504
Phone: (800) 272-2437
www.doh.wa.gov

Table of Contents

Executive Summary

The hepatitis C virus (HCV) attacks the liver and can cause serious health problems, including cirrhosis (scarring of the liver), liver failure, cancer, and death. HCV infection is the most common disease in the United States (U.S.) spread through blood-to-blood contact. Estimates indicate that there are between 2.4 million and 3.5 million people in the U.S., and approximately 60,000 in Washington State, with HCV infection. Both nationally and in Washington, new HCV infections more than tripled between the years 2010 and 2016, primarily due to rising rates of people injecting drugs.

There is no vaccine for HCV. Newly developed direct acting antivirals (DAAs) to treat HCV infection have a cure rate over 95 percent. Most people with HCV can be cured using a DAA in eight to twelve weeks, with few side effects.

In September 2018, Washington State Governor Jay Inslee issued Directive of the Governor 18-13 that called for the "Elimination of Hepatitis C in Washington by 2030 through combined public health efforts and a new medication purchasing approach." Elimination is a state where HCV is no longer a public health threat. This means new HCV cases are identified quickly and infected individuals receive prompt treatment. Governor Inslee directed the Department of Health (DOH) and the Health Care Authority (HCA) to lead the state's elimination efforts.

The Washington State Legislature also provided direction to HCA and DOH regarding HCV elimination in the 2019-2021 operating budget. A budget proviso required HCA to work with DOH and others to establish a comprehensive DAA purchasing strategy and report on HCV elimination progress.

Both HCA and DOH have made progress toward eliminating HCV infections from Washington State. HCA entered into two contracts with drug manufacturer AbbVie to purchase the DAA Mavyret (pronounced MAV-ih-reht) for state-funded health care programs.

- The Medicaid contract is a value-based supplemental rebate agreement that provides a discount on Mavyret for HCA's Apple Health (Medicaid) fee-for-service and managed care programs. As part of the modified subscription model, HCA negotiated an annual threshold, based on the approved state budget. Additional Mavyret purchases above that annual threshold will cost HCA a nominal amount per pill for the rest of the year. This contract also leverages public health services that align with DOH's HCV elimination plan.
- The non-Medicaid contract is a pharmaceutical discount and rebate agreement that provides a discount on Mavyret to non-Medicaid state agency health plans.

State agency health care plans aim to treat about 6,000 clients with HCV annually. Under the new AbbVie contracts, the average cost of treating a client with HCV infection is about 40 percent lower than the average per-client cost before the AbbVie contracts. The total amount spent by the state however will not decrease since we are moving forward with our Hepatitis C elimination plans and intend to treat significantly more people with HCV.

DOH produced the "Hep C Free Washington Plan to Eliminate Hepatitis C in Washington State by 2030" by establishing Hep C Free Washington — a collective impact initiative composed of multi-sector partners.

- The Plan recommends 15 goals and 90 action items that contribute to HCV data and strategic information, community-based responses and interventions, and clinical strategies to eliminate HCV in Washington State.
- For the 2020 legislative session and supplemental budget, DOH requested funding to implement HCV testing and linkage to care activities and elimination implementation coordination activities to begin moving into the next phase of the HCV elimination effort.

HCA will begin working on expanding the DAA procurement after gaining sufficient experience in the contract with AbbVie. DOH will continue to lead the Hep C Free Washington Coordinating Committee and related work groups as the state transitions from planning to implementation. Through these and other collaborative efforts, Washington will continue to progress toward the goal of becoming the first state in the nation to eliminate HCV.

Background

The hepatitis C virus (HCV) is a blood-borne virus that attacks the liver and can cause serious health problems, including cirrhosis (scarring of the liver), liver failure, cancer, and death. The virus spreads through blood-to-blood contact. Currently, sharing equipment for drug injection is the most common reason for HCV transmission. Prior to improved screening methods that became available in 1992, HCV was primarily contracted through blood transfusions and organ transplants. HCV can also spread through needle stick injuries in health care settings, from a mother living with HCV to her child at birth, through unregulated tattooing or piercing, and by other methods.[1]

HCV infection is the most common blood-borne (spread by blood) disease in the United States (U.S.).[2]

- According to the Centers for Disease Control and Prevention, the estimated number of people in the U.S. living with HCV infection ranges from 2.4 million to 3.5 million people.[3,4]

[1] Hepatitis C Questions and Answers for Health Professionals, from www.cdc.gov/hepatitis/hcv/hcvfaq.htm#, accessed on August 6, 2019.
[2] Viral Hepatitis C in Washington State, page 12, from www.doh.wa.gov/Portals/1/Documents/Pubs/420-159-HCVEpiProfile.pdf, accessed on August 6, 2019.
[3] Hepatitis C Questions and Answers for Health Professionals, from www.cdc.gov/hepatitis/hcv/hcvfaq.htm#, accessed on August 6, 2019.
[4] Disease Burden from Viral Hepatitis A, B, and C in the United States, from www.cdc.gov/hepatitis/statistics/DiseaseBurden.htm, accessed on August 6, 2019.

- According to the Washington State Department of Health (DOH), the estimated number of people living with HCV in Washington State during 2018 was approximately 60,000.[5,6]

Both nationally and in Washington, reported cases of acute (new) HCV infections more than tripled between the years 2010 and 2016.[7,8] Although HCV infection has historically impacted mostly Baby Boomers (those born between 1945 and 1965), younger people are becoming infected through injection drug use, primarily due to the opioid crisis.[9]

Unlike hepatitis A and B viruses, which also infect the liver but are unrelated to HCV, there is currently no vaccine to prevent HCV infection. However, there are oral medications (pills) that can cure an infected person of HCV.[10] Current HCV treatments use combinations of drugs called direct-acting antivirals (DAAs). DAAs directly target HCV in different ways to stop it from making copies of itself. Newly developed DAAs have a cure rate over 95 percent. Most people living with HCV infection can be cured by taking DAAs for eight to twelve weeks, with few side effects.[11]

Another development for combating HCV includes a growing recognition by national experts that combining public health strategies, such as improved preventive services, education, testing, and linkage to care, with DAA treatment can lead to HCV elimination. The National Academies of Sciences, Engineering, and Medicine 2017 national strategy to eliminate viral hepatitis as a U.S. public health problem by 2030.[12] In addition, the U.S. Department of Health and Human Services developed (and is now updating) the National Viral Hepatitis Action Plan, 2017-2020.[13] Combining aspects of national strategies with the use of DAAs creates an opportunity to address HCV in Washington.

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[5] Hep C Free Washington: Plan to Eliminate Hepatitis C in Washington State by 2030, page 5, from www.doh.wa.gov/Portals/1/Documents/Pubs/150nonDOH-HepCFreeWA-PlanJuly2019.pdf, accessed on August 6, 2019.
[6] Hepatitis C Elimination in Washington State, page 2, from www.doh.wa.gov/Portals/1/Documents/Mtgs/2018/HSQAMeetingPackets/OctoberORW/Huriaux-ORW20181023.pdf, accessed on August 6, 2019.
[7] Disease Burden from Viral Hepatitis A, B, and C in the United States, from www.cdc.gov/hepatitis/statistics/DiseaseBurden.htm, accessed on August 6, 2019.
[8] Hepatitis C Elimination in Washington State, page 3, from www.doh.wa.gov/Portals/1/Documents/Mtgs/2018/HSQAMeetingPackets/OctoberORW/Huriaux-ORW20181023.pdf, accessed on August 6, 2019.
[9] Hep C Free Washington: Plan to Eliminate Hepatitis C in Washington State by 2030, pages 4-5, from www.doh.wa.gov/Portals/1/Documents/Pubs/150nonDOH-HepCFreeWA-PlanJuly2019.pdf, accessed on August 6, 2019.
[10] What is Viral Hepatitis?, from www.cdc.gov/hepatitis/abc/index.htm, accessed on August 6, 2019.
[11] Hep C Free Washington: Plan to Eliminate Hepatitis C in Washington State by 2030, page 73, from www.doh.wa.gov/Portals/1/Documents/Pubs/150nonDOH-HepCFreeWA-PlanJuly2019.pdf, accessed on August 6, 2019.
[12] A National Strategy for the Elimination of Hepatitis B and C: Phase Two Report, from nationalacademies.org/hmd/Reports/2017/national-strategy-for-the-elimination-of-hepatitis-b-and-c.aspx, accessed on August 6, 2019.
[13] National Viral Hepatitis Action Plan, from www.hhs.gov/hepatitis/viral-hepatitis-action-plan/index.html, accessed on August 14, 2019.

Even though effective treatment is now available, access to curative medications remains an issue. Considerable barriers remain, including the difficulty of navigating the health care system, stigma related to HCV and experienced by people who use drugs, and the lack of primary care providers treating HCV. Effectively linking someone to curative medication has a significant public health benefit as curing HCV prevents onward transmission of the virus. It's imperative that effective public health strategies exist to link people at highest risk for transmitting the virus to care and supportive services.

Governor's Directive to Eliminate Hepatitis C

On September 28, 2018, Washington State Governor Jay Inslee issued Directive of the Governor 18-13. The directive called for the "Elimination of Hepatitis C in Washington by 2030 through combined public health efforts and a new medication purchasing approach."[14] Elimination is not the same as eradication.

- **Elimination:** In the case of HCV, elimination is a state where HCV is no longer a public health threat and where those few who become infected with HCV learn their status quickly and access curative treatment without delay, preventing the forward spread of the virus.
- **Eradication:** Generally, eradication is the reduction of the worldwide incidence of a disease to zero as a result of deliberate efforts, obviating the necessity for further control measures. True eradication usually entails eliminating the microorganism itself or removing it completely from nature.[15]

Describing the challenge to eliminate HCV in Washington, the Governor stated:

> HCV drugs are expensive, but we can drive down costs by applying new purchasing strategies in which state agency health care purchasers collaborate with manufacturers in combination with using key public health interventions to reduce the costs of treating and ultimately curing HCV.
>
> In curing HCV, we can stem the tide of liver disease and liver cancer and save individuals the physical, emotional, and financial damage caused by HCV infection. Curing this disease will also support HCV-affected persons to engage in healthy behaviors, such as accessing treatment for opioid-use disorder, general primary care, and mental health services, which will help them live full, satisfying, and productive lives. This is an important part of the opioid response plan. [16]

[14] Directive of the Governor 18-13, Elimination of Hepatitis C in Washington by 2030 through combined public health efforts and a new medication purchasing approach, from www.governor.wa.gov/sites/default/files/18-13%20-%20Hepatitis%20C%20Elimination.pdf, accessed on August 6, 2019.
[15] Hep C Free Washington: Plan to Eliminate Hepatitis C in Washington State by 2030, page 73, from www.doh.wa.gov/Portals/1/Documents/Pubs/150nonDOH-HepCFreeWA-PlanJuly2019.pdf, accessed on August 6, 2019.
[16] Directive of the Governor 18-13, Elimination of Hepatitis C in Washington by 2030 through combined public health efforts and a new medication purchasing approach, from

Governor Inslee directed DOH and the Health Care Authority (HCA) to lead the state's elimination efforts:

- DOH shall lead the effort to develop the elimination plan as part of this comprehensive public health response; and
- HCA shall lead and coordinate with DOH and other agencies and purchasers to establish a purchasing strategy for DAAs and needed public health interventions to eliminate HCV by 2030.[17]

Appendix A of this report includes the complete text of Directive of the Governor 18-13.

Proviso in the 2019-2021 Operating Budget

The Washington State Legislature also provided direction to HCA and DOH regarding HCV elimination in the 2019-2021 operating budget. Engrossed Substitute House Bill (ESHB) 1109, Chapter 415, Laws of 2019, Section 211(45), states:

> The authority shall work with the department of health, other state agencies, and other hepatitis C virus medication purchasers to establish a comprehensive procurement strategy. As part of this work, the authority shall estimate, by program, any savings that will result from lower medication costs. It is the intent of the legislature to evaluate reinvesting any savings to expand treatment for individuals enrolled in state covered groups and to further the public health elimination effort during the 2020 legislative session. By October 31, 2019, the authority and department shall report to the governor and relevant committees of the legislature on:
>
> (a) The progress of the procurement;
> (b) The estimated savings resulting from lower medication costs;
> (c) Funding needed for public health interventions to eliminate the hepatitis C virus;
> (d) The current status of treatment; and
> (e) A plan to implement the elimination effort.

This report satisfies the requirements of the budget proviso by describing:

1. The HCV medications procurement;
2. The current status and cost-effectiveness of the treatment efforts; and
3. The HCV elimination plan, including both elimination activities and needed funding.

www.governor.wa.gov/sites/default/files/18-13%20-%20Hepatitis%20C%20Elimination.pdf, accessed on August 6, 2019.

[17] Ibid.

HCV Medications Procurement

The Governor's directive included the following detail about HCA developing a purchasing strategy for DAAs:

> HCA shall collaborate with the Department of Corrections, Office of the Insurance Commissioner (OIC), Department of Labor and Industries, Department of Social and Health Services, Department of Veterans Affairs, DOH and Tribal governments, to initiate an innovative strategy to purchase curative HCV medications and ensure timely access to curative treatment for Washingtonians with HCV. Given that several state agencies each year purchase HCV treatment medications for over 4,000 people, by January 2019, HCA shall collaborate with these agencies and issue a single request for proposals for a joint value-based purchasing agreement for curative HCV medications from one or more pharmaceutical manufacturer(s). This joint purchasing agreement shall aim to reduce the costs of the drug(s) and incorporate key known public health strategies to address the needs [in DOH's elimination strategy].[18]

This section summarizes the request for proposals (RFP) process and briefly describe the resulting purchasing agreements.

Request for Proposals (RFP) Process

Research, planning and financial analysis for purchasing DAAs and leveraging public health services for the elimination of HCV in Washington began in July 2018. To inform its financial analysis, HCA engaged the State Medicaid Alternative Reimbursement and Purchasing Test for High Cost Drugs (SMART-D) initiative. SMART-D is a program at the Center for Evidence-based Policy at Oregon Health & Science University.[19] SMART-D estimated drug manufacturers' expected future revenue for HCV drugs and calculated the portion of those future revenues created from Washington State spending. From these estimates, HCA projected future drug prices, which HCA used to create a drug cost target for the RFP.

Between August 2018 and January 2019, HCA collaborated with DOH, the Governor's Office, and the following additional partners in the development of the RFP:

- Centers for Medicare and Medicaid Services (CMS);
- Department of Corrections (DOC);
- Department of Labor and Industries (L&I);
- Department of Social and Health Services (DSHS);
- Department of Veterans Affairs (DVA);

[18] Directive of the Governor 18-13, Elimination of Hepatitis C in Washington by 2030 through combined public health efforts and a new medication purchasing approach, from www.governor.wa.gov/sites/default/files/18-13%20-%20Hepatitis%20C%20Elimination.pdf, accessed on August 6, 2019.
[19] SMART-D, from centerforevidencebasedpolicy.org/our-approach/smart-d/, accessed on August 6, 2019.

- Office of the Insurance Commissioner (OIC); and
- Oregon Health & Science University Center for Evidence-based Policy (OSHU).

HCA limited the RFP scope to benefit populations in state health care programs (phase 1), but included an option to expand that scope in the future (phase 2). State agencies with these health care programs include:

- DOC, serving individuals housed in state correctional facilities;
- DSHS, serving patients in Eastern and Western State Hospitals;
- HCA, serving clients enrolled in Washington State Apple Health (Medicaid) and in both Public and School Employees Benefits self-insured programs; and
- L&I, serving employees receiving workers' compensation insurance benefits.

The RFP sought drug manufacturers to provide:

- Discounted DAA prices to state agencies, including a modified "subscription model" for the Apple Health program and a best guaranteed net unit price (GNUP) for non-Medicaid programs; and
- Support for the DOH-led public health outreach and education efforts through public health services.

Under the modified "subscription model" for the Apple Health program, HCA would purchase DAAs for a low GNUP up to an annual threshold. Additional purchases above that threshold would cost a minimal amount. This model allows the drug manufacturer(s) to sustain revenue and enables HCA to treat as many Apple Health clients with HCV as possible. CMS approved HCA's state Medicaid plan amendment and value-based supplemental rebate agreement for the Medicaid contract on June 12, 2019.[20] The remaining, non-Medicaid, programs would purchase DAAs at the single best GNUP for all non-Medicaid programs.

Public health services that HCA suggested in the RFP to align best with DOH's public health HCV elimination efforts included support for:

- Face-to-face HCV-related health care provider education and support to significantly increase the number of primary care providers managing HCV in their practices;
- Patient self-identification and referrals through social marketing campaigns promoting HCV prevention, testing, and curative treatment;
- Syringe Service Programs to deliver HCV screening, linkage to care, and supportive services;
- Local Health Jurisdictions to deliver targeted screening and linkage to care activities;

[20] CMS Approves Washington State Plan Amendment Proposal to Allow Supplemental Rebates involving a "Subscription" Model for Prescription Drug Payment in Medicaid, from www.cms.gov/newsroom/press-releases/cms-approves-washington-state-plan-amendment-proposal-allow-supplemental-rebates-involving, accessed on August 6, 2019.

- Telehealth provider consultations to support health care providers via the University of Washington's Project ECHO (Extension for Community Health Outcomes) to diagnose, treat, and cure people with HCV infection;[21] and
- Data reporting, subject-matter expertise, and consultation for a Health Information Exchange to meet the tracking and reporting needs of DOH's HCV elimination efforts.

HCA released the RFP on January 22, 2019. Appendix B of this report includes a copy of the RFP.

Drug manufacturers' bids were due on March 4, 2019. Following proposal evaluations and oral interviews, HCA announced that AbbVie US LLC (AbbVie) was the apparently successful bidder on April 26, 2019. After successfully concluding negotiations, HCA entered into four-year, contractual agreements (from July 1, 2019, through June 30, 2023) with AbbVie. For more information about the RFP process timeline, see Table 1.

Table 1: RFP Process Timeline

RFP Process Steps	Dates
Research, planning and financial analysis began	July 1, 2018
Governor's Directive to eliminate Hep C in WA State	September 28, 2018
Work on RFP begins	August 1, 2018
Tribal notice sent	August 1, 2018
State Plan Amendment submitted to CMS with contract template	October 1, 2018
Release RFP	January 22, 2019
Manufacturer bids due	March 4, 2019
Evaluation of proposals	March 5-15, 2019
Oral interviews	April 1-2, 2019
Apparently successful bidder announced	April 26, 2019
Contract negotiations	May 28-June 21, 2019
CMS approved the State Plan Amendment	June 12, 2019
Contracts start date	July 1, 2019
Contracts end date	June 30, 2023

Source: HCA – Clinical Quality and Care Transformation Division

Contracts with AbbVie

HCA signed two contracts with AbbVie — a Medicaid contract and a non-Medicaid contract — to provide the DAA Mavyret (pronounced MAV-ih-reht) and bona fide services to help eliminate HCV in Washington.

Medicaid Contract

The Medicaid contract is a value-based supplemental rebate agreement that provides a discount on Mavyret for HCA's Apple Health fee-for-service and managed care programs. As part of the modified subscription model, HCA negotiated an annual threshold, based on the approved state budget.

[21] UW Medicine Consultations, from www.uwmedicine.org/provider-resource/consultations, accessed on August 6, 2019.

Additional Mavyret purchases above that annual threshold will cost HCA a nominal amount per pill for the rest of the year.

Mavyret will be the only preferred HCV product on the Apple Health preferred drug list, which means most Apple Health clients will be able to access Mavyret without prior authorization. HCA will continue to exclude HCV drugs from the Apple Health managed care programs' responsibilities and cover them under the Apple Health fee-for-service program.

The state will track Mavyret utilization and evaluate its performance through outcome-based benchmarks, metrics, and evaluation methodology. AbbVie will provide quarterly reports to HCA on key metrics that demonstrate how successfully HCV patients are receiving diagnoses and HCV treatment. These key metrics include:

- HCV diagnosis rates;
- Rates of linkage to medical care;
- Prescribing rates; and
- Prescription approval rates.

Under the Medicaid contract, AbbVie will provide public health services that will compliment DOH's plan to eliminate HCV in Washington. Examples of these services include:

- Finding individuals with untreated HCV infections through community outreach;
- Educating the health care workforce about screening and providing curative HCV treatment; and
- Addressing barriers to care, such as:
    - Stigma about the disease;
    - Lack of urgency to treat HCV among patients and providers; and
    - Access to HCV specialists.

Non-Medicaid Contract

The non-Medicaid contract is a pharmaceutical discount and rebate agreement that provides a discount on Mavyret to the following state agencies:

- DOC, serving individuals housed in state correctional facilities;
- DSHS, serving patients in Eastern and Western State Hospitals;
- HCA, serving clients enrolled in self-insured health plans; and
- L&I, serving employees receiving workers' compensation insurance benefits.

Mavyret will be the only preferred HCV product on their preferred drug lists. DOC and DSHS will receive an upfront discount through their wholesale pharmaceuticals distributor. HCA and L&I will receive rebates on Mavyret prescriptions that pharmacies dispense to their members through their plans. Other treatments will be authorized for those patients not clinically indicated to receive Mavyret.

Current HCV Treatment Status

Between July 2014 and June 2018, state agency health care plans provided HCV treatment to nearly 10,400 individuals at a cost of more than $386.6 million. However, current estimates indicate that state agency health care plans might cover about 30,000 individuals who still need treatment for their HCV infections— about half of Washington's HCV population. This section describes efforts underway to treat this population for the disease and the purchasing value of Mavyret under the AbbVie contracts.

Treatment Efforts

State agency health care plans anticipate treating about 6,000 clients with HCV infection per year. This treatment rate is about 60 percent greater than the plans' average treatment rate (about 3,700 clients annually) during fiscal years 2017 and 2018. State agencies are removing barriers in an effort to maximize the number of clients that can receive treatment for HCV infection. For example, HCA recently eliminated the requirement for clients enrolled in Apple Health or self-insured health plans to receive prior authorization before accessing HCV medications.

Medication Cost-Effectiveness

Under HCA's contracts with AbbVie, it is more cost-effective to treat clients enrolled in state agency health care plans for HCV infection. The average per-client cost of treating HCV infection is about 40 percent less than before HCA finalized the purchasing agreements with AbbVie. To perform this per-client treatment cost comparison, HCA:

- Weighted the costs by the current numbers of clients in each state agency health care plan that use DAAs for HCV infections;
- Included drug rebates for all agencies;
- Considered the various drugs and regimen lengths that clients used prior to the contract;
- Assumed drug splits and length of treatment under the Hep C Free Washington initiative; and
- Accounted for an anticipated label change, which will likely occur in September 2019.

Non-disclosure requirements in HCA's contracts with AbbVie prevent us from reporting the actual costs, the numbers of clients, or the amount of HCV medication in the cost-effectiveness calculation. The total amount spent by the state however will not decrease since we are moving forward with our Hepatitis C elimination plans and intend to treat significantly more people with HCV.

HCV Elimination Plan

The Governor's directive included the following detail about DOH developing a strategy to eliminate HCV in Washington:

> DOH, in collaboration with any other relevant state agencies that it identifies, shall convene and facilitate an HCV-elimination coordinating committee comprised of stakeholders from various sectors, including individuals personally affected by HCV. The committee shall draw on existing efforts, best practices, and community knowledge to develop, by July 2019, a comprehensive strategy to eliminate the public health threat of HCV in Washington by 2030. The strategy will address needed improvements to the public health systems to help ensure that all people living in Washington who have or are at risk for contracting HCV, have access to preventive services, know their status, and connect to care and ultimately the cure. The elimination strategy shall include a major public health communications plan financed, to the extent possible, by the funds saved through the [HCA's HCV medication purchasing strategy].[22]

This section briefly summarizes the Hep C Free Washington "Plan to Eliminate Hepatitis C in Washington State by 2030", which was developed by the Coordinating Committee convened by DOH, including a sample of elimination activities and needed funding.

Hep C Free Washington Plan

Since October 2018, DOH has convened monthly meetings of multisector partners to develop the "Hep C Free Washington Plan to Eliminate Hepatitis C in Washington State by 2030."[23] Members of the Hep C Free Washington Coordinating Committee include:

- Representatives from state agencies and offices;
- Tribal health centers;
- Local health jurisdictions;
- Federally qualified health centers;
- Community-based organizations;
- Syringe service programs;
- Opioid treatment programs;
- Academic institutions (i.e., the University of Washington and Washington State University);
- Health plans;
- Professional organizations; and
- People affected by HCV.

DOH acts as the "backbone organization" for Hep C Free Washington. Within a collective impact framework, the backbone organization pursues six common activities to support and facilitate

[22] Directive of the Governor 18-13, Elimination of Hepatitis C in Washington by 2030 through combined public health efforts and a new medication purchasing approach, from www.governor.wa.gov/sites/default/files/18-13%20-%20Hepatitis%20C%20Elimination.pdf, accessed on August 6, 2019.
[23] Hep C Free Washington Plan to Eliminate Hepatitis C in Washington State by 2030, page 12, from www.doh.wa.gov/Portals/1/Documents/Pubs/150nonDOH-HepCFreeWA-PlanJuly2019.pdf, accessed on August 6, 2019.

collective impact, distinguishing this work from other types of collaborative efforts. Over the lifecycle of an initiative, the backbone organization:

1. Guides vision and strategy;
2. Supports aligned activities;
3. Establishes shared measurement practices;
4. Builds public will;
5. Advances policy; and
6. Mobilizes funding.

The Committee established three work groups, Data & Strategic Information, Community-Based Responses & Interventions, and Clinical Strategies to draft recommendations based on their specific expertise. The Committee and three work groups recommended the following 15 goals:[24]

Overarching Coordination Goal

1. Ensure implementation of the Hep C Free Washington recommendations in order to achieve HCV elimination by 2030.

Data and Strategic Information Goals

2. Identify data sources and strategies to strengthen the characterization of HCV disease burden within Washington State.
3. Obtain resources and build capacity for continuous data monitoring, evaluation, quality improvement, and reporting.
4. Identify and track data metrics using currently available data.
5. Determine metrics using data not yet available or accessible.

Community-Based Responses and Interventions Goals

6. Improve access to and use of preventive and health care services in non-clinical settings through expansion and co-location of services.
7. Improve access to and use of clinical care and supportive services by sufficiently scaling coverage and widening the scope of community-based navigation and case management programs.
8. Increase HCV awareness, resources, and education, and reduce stigma.

Clinical Strategies Goals

9. Improve access to and use of clinical care for marginalized populations at risk for or living with HCV through innovative service delivery models.
10. Build the capacity of the health care workforce to diagnose and treat HCV.
11. Improve diagnosis of HCV in primary care settings.
12. Improve HCV disease intervention services.
13. Improve access to HCV treatment and comprehensive health care.
14. Improve the ability of people taking HCV direct-acting antivirals to complete treatment.

[24] Ibid., page 1.

15. Improve follow-up clinical care for people who have completed HCV treatment.

Appendix C of this report contains the Hep C Free Washington initiative's plan.

Elimination Activities and Needed Funding

In addition to recommending 15 goals, the Hep C Free Washington initiative's plan contains 90 recommended action items or activities to eliminate HCV in our state. These activities include specific strategies to prevent new infections and link people who are living with HCV to treatment and supportive services. HCA's efforts to secure a discounted price for the DAA Mavyret is only one activity (related to goal 13) that aligns with the Hep C Free Washington initiative's plan. Additional state resources are necessary to implement the plan and successfully eliminate HCV from Washington State.

Many activities that require resources to implement the Hep C Free Washington initiative's plan are not unique to the plan. For example, disease surveillance and intervention activities (i.e., identifying and treating people who had risky contact with someone with a confirmed HCV infection) are also part of Foundational Public Health Services. Foundational Public Health Services are services that the Governmental Public Health System uniquely provides, upon which the public depends for healthy and economically vital communities. The Governmental Public Health System includes the Department of Health, State Board of Health, Local Health Jurisdictions, and Sovereign Tribal Nations.

In an effort to begin identifying additional state resources that are unique to implementing the Hep C Free Washington initiative's plan, DOH estimated the costs for 11 activities that:

- Focus on building health care workforce capacity and increasing both HCV diagnoses and linkage to treatment; and
- Align with action items in the Hep C Free Washington initiative's plan.

Table 2 below briefly describes each of the 11 HCV elimination activities DOH proposes to implement initially, and lists the additional funding amounts DOH would need, totaling:

- $3,475,000 for the first year; and
- $13,910,000 for each subsequent year.

Table 2: Initial HCV Elimination Activities and Implementation Funding Amounts

HCV Elimination Activity to Implement	First Year Funding	Subsequent Year Funding
1. Contract with the University of Washington to double the capacity of Project ECHO, meeting or exceeding current health care provider demand for HCV diagnosis, patient care, and treatment consultations. (Relates to action item 13.5.)	$70,000	$280,000

Table 2: Initial HCV Elimination Activities and Implementation Funding Amounts

HCV Elimination Activity to Implement	First Year Funding	Subsequent Year Funding
2. Increase HCV screening capacity and confirmatory testing at local health jurisdictions (LHJs) in HCV high- and medium-prevalence areas. (Relates to action item 6.12.)	$22,000	$94,000
3. Support expanding HCV screening and linkage to care activities in up to 30 county jails and link individuals in prison for short-term sentences or parole violators to care. (Relates to action item 13.7.)	$680,000	$2,719,000
4. Expand mobile HCV screening programs serving high-risk populations in up to nine rural, high-burden counties. (Relates to action item 9.2.)	$555,000	$2,222,000
5. Support expanding contracts to: • Deliver highly targeted HCV screening services and linkage to care in up to 11 high-burden jurisdictions. (Relates to action item 7.3.) • Expand an existing program to train incarcerated persons as peer health/HCV educators in all state prisons. (Relates to action item 8.6.)	$117,000	$469,000
6. Provide evidence-based, one-on-one provider education (i.e., academic or public health detailing) to educate and build provider capacity to deliver HCV screening and linkage to care in health care settings. (Relates to action item 8.3.)	$59,000	$234,000
7. Develop capacity to screen and treat clients with HCV infection in up to 25 opioid treatment (methadone) centers. (Relates to action item 9.4.)	$938,000	$3,750,000
8. Support a contract with a social marketing firm to promote a comprehensive plan to educate priority populations with HCV infection about HCV risks and the importance of screening. (Relates to action item 8.8.)	$352,000	$1,406,000
9. Support HCV screening and linkage to care in up to six emergency room settings in high-density areas. (Relates to action item 6.6.)	$225,000	$900,000
10. Support building HCV screening and linkage to care activities in up to five tribal health clinics. (Relates to action item 6.6.)	$340,000	$1,359,000

Table 2: Initial HCV Elimination Activities and Implementation Funding Amounts

HCV Elimination Activity to Implement	First Year Funding	Subsequent Year Funding
11. Support the following 4.8 DOH full-time-equivalent (FTE) positions for the Hep C Free Washington Plan implementation, beginning in April 2020. (Relates to action item 1.1.) • 1.0 FTE Health Services Consultant 3 as the Hep C Free Washington Coordinator to administer and oversee the new and expanded prevention activities in the above funding activities. • 1.0 FTE Health Services Consultant 3 as the Hep C Free Washington Linkage to Care Coordinator to coordinate statewide linkage to care activities (outlined above) and support disease intervention efforts. • 2.8 FTEs for agency administrative functions related to Hep C Free Washington Plan implementation.	$117,000	$477,000
TOTAL FUNDING	**$3,475,000**	**$13,910,000**

Source: DOH

Conclusion

Both HCA and DOH have made progress toward eliminating HCV infections from Washington State by 2030.

HCA entered into contracts with drug manufacturer AbbVie to secure a discounted price for the DAA Mavyret for state-funded health care programs— one for Medicaid and another for the non-Medicaid programs. Both contracts enable state funded health care plan beneficiaries to purchase the HCV medication at a discounted rate. AbbVie will also provide services that will compliment DOH's plan to eliminate HCV in Washington.

State agency health care plans cover approximately 30,000 individuals who still need treatment for their HCV infections— about half of Washington's HCV population. State agency health care plans aim to treat about 6,000 clients with HCV annually. Under the new AbbVie contracts, the average cost of treating a client with HCV infection is about 40 percent lower than the average per-client cost before the AbbVie contracts.

DOH worked with the Hep C Free Washington Coordinating Committee to produce the Hep C Free Washington initiative's Plan by collaborating with multi-sector partners. The plan recommends 15 goals and 90 action items that contribute to HCV data and strategic information, community-based responses and interventions, and clinical strategies to eliminate HCV in Washington State. HCA's efforts to secure a discounted price for the DAA Mavyret is only one activity (related to goal 13) that aligns with the Hep C Free Washington initiative's plan. Additional state resources are necessary to implement the plan and successfully eliminate HCV from Washington State.

Many activities that require resources to implement the Hep C Free Washington initiative's plan are not unique to the plan. For example, disease surveillance and intervention activities are also part of Foundational Public Health Services. In an effort to begin identifying additional state resources that are unique to implementing the plan, DOH estimated the costs for 11 activities that:

- Focus on building health care workforce capacity and increasing both HCV diagnoses and treatment linkage; and
- Align with action items in the Hep C Free Washington initiative's plan.

The Governor's directive included the following requirement to advance HCV elimination beyond the planning phase:

> HCA, in collaboration with other state agencies shall, as the next phase of this plan, engage a multi-state or national organization to develop a strategy to assess the interest and ability of extending our purchasing and public health strategy to not only Washington's other major purchasers of health care and commercial insurers, but also other states or purchasers. As part of this next phase, HCA shall work with Washington's Health Benefit Exchange and OIC to explore purchasing options for the health insurance markets.[25]

HCA will begin engaging in this next phase of the HCV elimination after gaining sufficient experience in purchasing DAAs and services from AbbVie to inform the procurement expansion.

DOH will continue to serve as the backbone organization for the Hep C Free Washington initiative as the state transitions from planning to implementation. The Hep C Free Washington Coordinating Committee will focus on:

- Disseminating best practices and identifying promising approaches and potential demonstration (pilot) projects;
- Shared accountability, including monitoring implementation of the recommendations, evaluating progress toward elimination, and refining the plan over time as efforts evolve;
- Reviewing progress on the recommendations, producing an annual, written progress report, and revising recommendations as necessary;
- Refining its structure, governance, and communication with state government leaders; and
- Investigating opportunities for raising funds to support activities to help Washington achieve HCV elimination.

Through these and other collaborative efforts, Washington will continue to progress toward the goal of becoming the first state in the nation to eliminate HCV.

[25] Directive of the Governor 18-13, Elimination of Hepatitis C in Washington by 2030 through combined public health efforts and a new medication purchasing approach, from www.governor.wa.gov/sites/default/files/18-13%20-%20Hepatitis%20C%20Elimination.pdf, accessed on August 6, 2019.

Appendix A: Directive of the Governor 18-13: Hepatitis C Elimination

JAY INSLEE
Governor

STATE OF WASHINGTON
OFFICE OF THE GOVERNOR
P.O. Box 40002 • Olympia, Washington 98504-0002 • (360) 902-4111 • www.governor.wa.gov

DIRECTIVE OF THE GOVERNOR
18-13

September 28, 2018

To: Washington State Executive and Small-Cabinet Agencies

From: Governor Jay Inslee

Subject: Eliminating Hepatitis C in Washington by 2030 through combined public health efforts and a new medication purchasing approach

This year, an estimated 65,000 Washingtonians are living with the chronic Hepatitis C Virus (HCV), but fortunately, we now have a cure. HCV is the leading cause of liver cancer and liver transplants. The virus also causes other health problems, including debilitating fatigue, which can significantly impact the quality of life of those affected.

HCV is the most common blood-borne disease in the United States, and in Washington, from 2012 to 2017, nearly 40,000 new cases of HCV were reported, increasing each year. And while deaths from other infectious diseases have steadily declined over the past decade, HCV-related deaths continue to rise, now exceeding all deaths from other reportable infectious conditions combined.

Newly acquired HCV-infection reports show a 126% increase in Washington between 2013 and 2017 when compared to the prior five years, an increase linked to the opioid crisis. And while the disease has historically impacted Baby Boomers (those born between 1945 and 1965), younger people are now contracting the disease with greater frequency, again related to opioid use. Ultimately, Washington's HCV-related hospitalization charges totaled $114 million between 2010 and 2014.

Confronting the HCV crisis is challenging because many Washingtonians living with HCV do not know they are infected. So, to reach affected communities, we must make enhanced public health efforts, including efforts to improve education, preventive services, and early detection of HCV to treat and cure existing infections and curb the onward transmission of the virus.

Fortunately, we see an opportunity to take action against HCV. In 2017, the National Academies of Sciences, Engineering, and Medicine released "A National Strategy" outlining how the United States can save nearly 30,000 lives from HCV-related deaths and eliminate HCV by 2030. Moreover, medications now exist to cure HCV in nearly all people appropriately linked to, and retained in, care. HCV drugs are expensive, but we can drive down costs by applying new purchasing strategies in which state agency health care purchasers collaborate with

manufacturers in combination with using key public health interventions to reduce the costs of treating and ultimately curing HCV.

In curing HCV, we can stem the tide of liver disease and liver cancer and save individuals the physical, emotional, and financial damage caused by HCV infection. Curing this disease will also support HCV-affected persons to engage in healthy behaviors, such as accessing treatment for opioid-use disorder, general primary care, and mental health services, which will help them live full, satisfying, and productive lives. This is an important part of the opioid response plan.

Accordingly, I direct my health sub-cabinet and the health and human service state agencies under my authority to begin immediately to work with Tribal governments, local public health officials, and other partners across the state, to develop and implement a statewide HCV elimination plan. The Department of Health (DOH) shall lead the effort to develop the elimination plan as part of this comprehensive public health response. The Health Care Authority (HCA) shall lead and coordinate with DOH and other agencies and purchasers, in a corresponding effort to establish a comprehensive procurement strategy for the purchase of HCV medications that also includes financing the needed public health interventions to affordably eliminate HCV by 2030. Furthermore, I direct the following:

1. DOH, in collaboration with any other relevant state agencies that it identifies, shall convene and facilitate an HCV-elimination coordinating committee comprised of stakeholders from various sectors, including individuals personally affected by HCV. The committee shall draw on existing efforts, best practices, and community knowledge to develop, by July 2019, a comprehensive strategy to eliminate the public health threat of HCV in Washington by 2030. The strategy will address needed improvements to the public health systems to help ensure that all people living in Washington who have or are at risk for contracting HCV, have access to preventive services, know their status, and connect to care and ultimately the cure. The elimination strategy shall include a major public health communications plan financed, to the extent possible, by the funds saved through the purchasing strategy described below.

2. HCA shall collaborate with the Department of Corrections, Office of the Insurance Commissioner (OIC), Department of Labor and Industries, Department of Social and Health Services, Department of Veterans Affairs, DOH and Tribal governments, to initiate an innovative strategy to purchase curative HCV medications and ensure timely access to curative treatment for Washingtonians with HCV. Given that several state agencies each year purchase HCV treatment medications for over 4,000 people, by January 2019, HCA shall collaborate with these agencies and issue a single request for proposals for a joint value-based purchasing agreement for curative HCV medications from one or more pharmaceutical manufacturer(s). This joint purchasing agreement shall aim to reduce the costs of the drug(s) and incorporate key known public health strategies to address the needs described above.

3. HCA, in collaboration with DOH, shall request that the Centers for Medicaid and Medicare Services (CMS) enter into a shared-savings agreement for Medicare-program-cost avoidance resulting from the implementation of the state's HCV prevention and

treatment strategy. Our state program will save Medicare significant costs by not only treating people sooner, alleviating Medicare from needing to pay for HCV medications, but also the dire costs of liver disease and cancer and other health effects that would occur later in one's life while they are covered under Medicare.

4. HCA and DOH shall work with CMS, the Centers for Disease Control and Prevention, the Surgeon General, Veterans Affairs, other federal agencies, and Tribal governments to consider additional health care purchasing and disease elimination strategies, especially for rural and underserved populations—including Vietnam veterans living in rural areas—to address HCV in a cost-effective manner.

5. HCA, in collaboration with other state agencies shall, as the next phase of this plan, engage a multi-state or national organization to develop a strategy to assess the interest and ability of extending our purchasing and public health strategy to not only Washington's other major purchasers of health care and commercial insurers, but also other states or purchasers. As part of this next phase, HCA shall work with Washington's Health Benefit Exchange and OIC to explore purchasing options for the health insurance markets.

6. DOH and HCA shall also use data and information to detect cases of HCV, monitor HCV-related morbidity and mortality, monitor HCV-curative treatment access, and evaluate the impact of interventions and activities designated by this directive.

7. DOH and HCA shall develop a communications plan for this project. This communications plan shall include filing quarterly reports to my office and the health committees of the legislature to ensure the status and outcomes herein.

Appendix B: Health Care Authority Request for Proposals (RFP), RFP No. 3233, Eliminating Hepatitis C in Washington State

STATE OF WASHINGTON
HEALTH CARE AUTHORITY

REQUEST FOR PROPOSALS (RFP)

RFP NO. 3233

NOTE: *If you download this RFP from the Health Care Authority (HCA) website, you are responsible for sending your name, address, email address, and telephone number to the RFP Coordinator in order for your organization to receive any RFP amendments or bidder questions/agency answers. HCA is not responsible for any failure of your organization to send the information or for any repercussions that may result to your organization because of any such failure.*

PROJECT TITLE: Eliminating Hepatitis C in Washington State

PROPOSAL DUE DATE: March 4, 2019 by 5:00 p.m. *Pacific Time*.

E-mailed bids will be accepted. Faxed bids will not.

ESTIMATED INITIAL TIME PERIOD FOR CONTRACT: July 1, 2019 to June 30, 2023

HCA reserves the right to extend the contract for additional two year periods up to June 30, 2031, although no such extension is guaranteed.

BIDDER ELIGIBILITY: This procurement is open to those Bidders that satisfy the minimum qualifications stated herein and that are available for work in Washington State.

1. INTRODUCTION

1.1. PURPOSE AND BACKGROUND

The Washington State Health Care Authority (HCA) is initiating this Request for Proposals (RFP) to solicit proposals from drug manufacturers interested in participating on a project to eliminate hepatitis C virus (HCV) in Washington through public health outreach, education, preventive services, testing, linkage to care, and the provision of direct acting antiviral drugs (DAAs).

National HCV Trends

According to the Centers for Disease Control and Prevention (CDC), HCV infection is the most common blood-borne condition in the U.S. HCV is unrelated to other types of viral hepatitis, such as hepatitis A and hepatitis B virus infections, and unlike those diseases, has no vaccine available to prevent infection.

HCV is usually spread when blood from an infected person enters the body of someone who is not infected. Today, most people become infected with HCV by sharing needles or other equipment to prepare or inject drugs. Before 1992, HCV was also commonly spread through blood transfusions and organ transplants. After that, widespread screening of the blood supply in the U.S. virtually eliminated this source of infection.

Persons born between the years 1945 and 1965 ("baby boomers") are at higher risk for HCV. Baby boomers make up roughly one-quarter of the U.S. population but around three-quarters of chronic HCV cases. They account for at least two-thirds of HCV-associated outpatient, emergency department, and hospital visits. As young adults, baby boomers had higher risks of blood-borne exposures due to unscreened blood products, medical or dental exposures without modern infection control measures, and injection drug use when compared to previous or subsequent generations. HCV testing only became available for clotting factor products in 1987, and for blood and organs in 1992. One-time screening for HCV infection is recommended for baby boomers, who have around a 3% prevalence of HCV infection.

The CDC estimates 1% of the U.S. population is infected with chronic HCV, or roughly 3.5 million individuals. Nationally, between 2010 and 2015, there was a 2.9 fold increase in new HCV cases. Only about half of those with chronic HCV are diagnosed and aware of their infections. After diagnosis of HCV, linkage to ongoing healthcare is critical so that the infected person can be evaluated by a clinician and referred as appropriate. Nationally, only about one-third of those diagnosed with HCV (32–38%) are referred to care, around one-tenth (7–11%) receive treatment, and about half of those treated (5–6%) are cured. The burden of HCV infection is much higher in the U.S. correctional population compared to the general community. Typical HCV prevalence among inmates nationally has been reported as 17% to 29%.

In the past few years, new medications have become available to treat HCV, and numerous national organizations have noted that, with these treatments, HCV could be eliminated in the U.S. "Elimination" is a state where HCV is no longer a public health threat and is achieved by identifying newly infected patients, providing preventive services, and providing treatment as early as possible, which improves individual health and prevents ongoing transmission of the virus. Yet, the high cost for these drugs has stifled aggressive outreach efforts and limited the ability to eliminate this disease.

HCV in Washington State

Washington has experienced a 3.3 fold increase in reported HCV cases in recent years, with nearly 40,000 cases reported from 2012 through 2017. This is primarily due to the opioid epidemic and the increase in the number of individuals who inject drugs. Overall, about 65,000 Washingtonians live with chronic HCV.

In Washington, there are four state agencies that have some responsibility for paying for and/or providing health care services to the people they serve: HCA, the Department of Corrections (DOC), the Department of Social and Health Service (DSHS), and the Department of Labor and Industries (L&I).

Since June 2014, these agencies have treated 10,377 individuals at a total cost of $386,637,704. This leaves about 30,000 individuals chronically infected with HCV to be treated by state programs. (Please note that this figure is an epidemiological estimate, and that while HCA anticipates treating a roughly equal number of HCV infected persons on an annual basis over the life of the contract resulting from this RFP, treatment numbers may vary on an annual basis.) Table 1 through Table 3 summarize the total expenditures and number of individuals treated by program.

Table 1. Annual HCV DAA expenditures

Fiscal Year	Medicaid	DOC	DSHS	UMP	L&I
FY2015	$28,121,077	$6,069,599	$89,596	$12,140,363	$336,420
FY2016	$92,861,663	$6,143,223	$269,192	$9,244,209	$927,842
FY2017	$127,534,556	$9,767,666	$1,003,850	$11,560,336	$374,220
FY2018	$68,016,405	$7,313,679	$633,384	$4,318,151	$173,340

Table 2. Average Cost per individual treated

Fiscal Year	Medicaid	DOC	DSHS	UMP	L&I
FY2015	$43,599	$94,837	$89,596	$110,367	$84,105
FY2016	$47,991	$71,433	$89,596	$96,294	$115,980
FY2017	$34,394	$54,265	$91,259	$66,823	$124,740
FY2018	$22,433	$36,206	$30,244	$44,063	$57,780

Table 3. Number of individuals treated

Fiscal Year	Medicaid	DOC	DSHS	UMP	L&I
FY2015	645	64	<10	110	<10
FY2016	1,935	86	<10	96	<10
FY2017	3,708	180	11	173	<10
FY2018	3,032	202	23	98	<10

On September 30, 2018, Governor Jay Inslee issued Governor's Directive #18-13, attached as Exhibit D (the Directive), The Directive requires DOH and HCA to immediately begin working with state agencies, tribal governments, local public health officials, and other partners across the state, to develop and implement a statewide plan to eliminate HCV in Washington State by 2030.

DOH was directed to lead the effort to develop an elimination plan as part of this comprehensive public health response, and to develop and implement the State HCV elimination program, called "Hep C Free WA." In order to achieve this, DOH has convened stakeholders to develop a public health strategy to eliminate HCV (the WA Hepatitis C Elimination Coordinating Committee). It is expected that the Apparent Successful Bidder(s) will be invited to the stakeholder meetings. Stakeholders include individuals affected by HCV, local health jurisdictions, tribal governments, medical providers, and others with an interest in HCV elimination.

HCA was directed to lead, coordinate with DOH and other agencies and purchasers, and implement a comprehensive procurement strategy for the purchase of DAAs that includes provision of needed public health interventions to affordably eliminate HCV. Specifically, HCA was directed to collaborate with agencies and issue a single request for proposals for a joint, value-based purchasing agreement for DAAs from one or more pharmaceutical manufacturer(s) in January 2019. This joint purchasing agreement will aim to reduce the costs of the drugs, increase the numbers of Washingtonians treated, and incorporate key known public health strategies to address the needs described above.

Furthermore, HCA was directed to collaborate with other state agencies, and possibly to engage multi-state or national organizations, to develop a strategy to assess the interest and ability of extending our purchasing and public health strategy to not only Washington's other major purchasers of health care and commercial insurers, but also other states or purchasers (Phase II). This work may include either working to partner with a multi-state collaborative or other states individually. As part of Phase II, HCA shall work with Washington's Health Benefit Exchange and the Office of the Insurance Commissioner to explore purchasing options for the health insurance markets.

1.2. **RFP OBJECTIVES AND SCOPE**

Pursuant to the Directive, this RFP is designed for the provision and receipt of:

a. Discounted pricing for the purchase of DAAs by state agencies, including a modified "subscription model" for the Washington State Apple Health program and guaranteed net unit best price for non-Medicaid programs,
b. The option to extend the discounted prices beyond the initial state agency-purchased DAAs, and
c. Drug manufacturer support of the DOH-led public health outreach and education efforts through bona fide services.

A key objective of this RFP is to work with a drug manufacturer to bring down the cost of medications to enable the state, and ultimately other purchasers, to eliminate Hepatitis C without exceeding current expenditures. HCA hopes that the pricing, rebate and terms associated with this procurement will create the stability that is required to ensure long-term and predictable expenditures on treating HCV, and obtain necessary resources that are critical to a successful statewide public health HCV elimination strategy.

HCA intends to select a single Apparent Successful Bidder (ASB), but reserves the right to select more than one ASB. In addition, if resistance patterns emerge, or there are changes in the standard of care, HCA reserves the right to re-procure for new drugs consistent with those changes. In addition, as there are DAAs that treat specific genotypes only, and DAAs that are pangenoptypic, nothing in this RFP or any resulting contract shall prohibit HCA from purchasing other DAAs that may assist treatment for patients when medically necessary. Separate contract provisions or sub-agreements will be entered with the ASB(s) (i) for the Medicaid population and (ii) for the non-Medicaid population.

The first phase of this initiative targets the estimated 30,000 individuals with a HCV infection who are covered by a state agency health plan: HCA (Medicaid, and Public Employees Benefits and School Employees Benefits programs (collectively, "ERB Programs"), DSHS (Eastern and Western State Hospitals), L&I, and DOC.

Medicaid Program

Through this procurement, HCA seeks a modified "subscription model" supplemental rebate specific to the Medicaid program. An unmodified "subscription model" is one where a drug manufacturer provides an unlimited supply of its DAA to treat infected residents of a state in exchange for a flat recurring fee. (*See,* Trusheim MR, Cassidy WM, Bach PB. Alternative State-Level Financing for

Hepatitis C Treatment—The "Netflix Model". JAMA. 2018;320(19):1977–1978. doi:10.1001/jama.2018.15782.) In this RFP, HCA seeks a low guaranteed net unit price (GNUP) for DAAs with an annual maximum dollar threshold, at which point any additional purchase of DAAs will be at a minimal to no additional cost to HCA. This will allow the ASB to sustain its revenue and also ensures that HCA is able to treat as many Medicaid enrollees with HCV as possible. For example, and for illustration purposes only, a GNUP for a particular DAA might be $1 per day with a $1 million threshold. After HCA pays the total threshold, the GNUP might fall to $0.01 per day.

GNUP up to and including $1 million	GNUP above $1 million
$1.00 per day	$0.01

For the Medicaid population, HCA will give preferred status to the selected DAA(s) of the ASB(s). Consistent with the current Preferred Drug List (PDL) and existing programs, this preferred status will allow providers to prescribe the selected regimen with minimal prior authorization criteria. Also consistent with the current PDL and other HCA programs and processes, other DAAs will still be considered as non-preferred regimens, but will require prior authorization, and such authorization will only be made when (i) such alternative DAA is clinically appropriate and (ii) the preferred DAA is not clinically appropriate.

Non-Medicaid Programs

The non-Medicaid programs are managed by agencies that purchase DAAs directly and indirectly for individuals not enrolled in the Medicaid program. These agencies are DOC, DSHS, HCA (self-insured options offered through the ERB Programs), and L&I. DOC and DSHS have facilities that directly purchase DAAs and distribute them to HCV-infected individuals within those facilities. The self-funded health plans administered under the ERB Programs and L&I use group programs and reimburse pharmacies for DAAs dispensed to individuals covered by their respective programs.

Through this RFP, HCA seeks a single best GNUP for all non-Medicaid programs. For group programs, HCA expects that the selected ASB will make all rebates and any other price concessions that are included in a Proposal to be recovered using a state-selected administrator, who will be responsible for billing, collecting, and disbursing rebates and concessions on behalf of the state (the Rebate Administrator). Any administrative fees required by the Rebate Administrator will be clearly identified and paid for by the ASB. Bidders may also propose an alternative method for the group programs to get the GNUP at the point of service (*see*, Section 3.3).

For facilities, HCA expects that the selected ASB will also provide for a distribution channel to deliver drugs to facilities that purchase DAAs directly. It is possible that DOC could purchase drugs on behalf of DSHS through an intragovernmental agreement and distribute to DSHS.

As with the Medicaid population, non-Medicaid programs will give preferred status in a manner consistent with the existing PDL and current processes to the selected DAA(s) of the ASB(s). This preferred status will allow providers to prescribe the regimen with minimal prior authorization criteria. Non-preferred regimens will still be covered, but will require prior authorization, and such authorization will only be made when (i) such alternative DAA is clinically appropriate and (ii) the preferred DAA is not clinically appropriate.

As noted above, Phase II may expand this procurement to other private or public purchasers, including other states that may wish to participate. These purchasers may include state and local government purchasers of DAAs not identified above, fully insured plans offered to government employees or retirees, and private self- or fully-insured plans. The ASB(s) will have the right of first refusal for Phase II by extending certain contract terms to cover such populations.

Bona Fide Service Plan

In addition to discounted costs of DAAs, the state is requesting Bidders propose bona fide services as described in Section 3.2 of this RFP to provide in support of Hep C Free WA. These services may include the ASB(s) hiring additional staff, engaging with contractors, and/or dedicating their current staff and resources to these efforts. The programs and resources defined as bona fide services are intended to support provider education and link patients to testing and treatment. Examples of such services include support for:

- Project ECHO (*see*, Section 3.2.5)
- Provider education to build the healthcare workforce capacity to test and cure HCV
- Increased HCV screening and linking those infected to treatment
- Social marketing to develop a HCV health promotion and education campaign
- Reporting, consultation, and support of Health Information Exchange (HIE) to track patients throughout treatment as well as providing population level outcome reporting.

These bona fide services to be provided by the ASB(s) will be documented as part of the contracts between HCA and such ASB.

Additional Information

Bidders should note that HCA has submitted or will soon submit a portion of a contract for the Medicaid population to the Centers for Medicare and Medicaid Services ("CMS") for its review and approval. At the time of the release of this RFP, HCA has not yet received any comment or approval from CMS. Depending on the timing of receipt of any CMS approval or comments, HCA will notify Bidders of any changes either through an amendment to this RFP; or, if received after the date Proposals are due and before a contract resulting from this RFP is fully executed, through direct communication with each Bidder.

1.3. MINIMUM QUALIFICATIONS

The following are the minimum qualifications for Bidders:

1.3.1. Licensed to do business in the state of Washington, or provide a commitment that it will become licensed in Washington within 30 calendar days of being selected as the Apparent Successful Bidder.

1.3.2. Manufactures or labels and sells an FDA-approved DAA indicated for the treatment of HCV genotype 1.

1.4. FUNDING

Cost of services provided under any contracts that result from this RFP will be made based on the agreed upon amounts, if any. Therefore, a maximum level of available funding is not being identified at this time. Nonetheless, any contract awarded as a result of this RFP is, and will remain throughout its term, contingent upon the availability of funding.

1.5. PERIOD OF PERFORMANCE

The initial period of performance of any contract resulting from this RFP is tentatively scheduled to begin on or about July 1, 2019 and terminate on June 30, 2023. HCA reserves the right to extend the contract for periods of two years through June 30, 2031, although no extensions are guaranteed.

1.6. CONTRACTING WITH CURRENT OR FORMER STATE EMPLOYEES

Specific restrictions apply to contracting with current or former state employees pursuant to chapter 42.52 of the Revised Code of Washington (RCW). Bidders should familiarize themselves with the requirements prior to submitting a proposal that includes current or former state employees.

1.7. DEFINITIONS

Definitions for the purposes of this RFP include:

Apparent Successful Bidder (ASB) – The Bidder selected as the entity to perform the anticipated services under this RFP, subject to completion of contract negotiations and execution of a written contract.

Bidder – Individual or company interested in the RFP that submits a proposal in order to attain a contract with the Health Care Authority.

Bona Fide Service Fee (BFSF) – A fee paid by a manufacturer to a third-party purchaser of covered outpatient drugs that represents fair market value for a bona fide, itemized service and that otherwise meets the definition of "bona fide service fee" codified at 42 C.F.R. Section 447.502. Examples include fees associated with administrative service agreements and patient care programs, such as medication compliance and patient education programs. 42 C.F.R. Section 447.502 describes the bona fides service fee as "a fee paid by a manufacturer to an entity that represents fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that is not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug. The fee includes, but is not limited to, distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative service agreements and patient care programs (such as medication compliance programs and patient education programs)."

Bona Fide Service Plan – A plan agreed upon by the parties for a manufacturer to pay Bona Fide Service Fees, or provide bona fide services, to third-party purchasers. The value of the Bona Fide Service Fees paid under the Bona Fide Service Plan will be part of the drug manufacturer proposal and will be documented in the final contract between the parties.

Business Days – Monday through Friday, 8:00 a.m. to 5:00 p.m., Pacific Time, except for holidays observed by the State of Washington, unless otherwise specified in this RFP.

Calendar Days – All days, including weekends and holidays. If the time when something must be performed falls on a weekend, a day observed as a holiday by the State of Washington as an employer, or a day when HCA is officially closed for other reasons, then that action is due on the next Business Day.

Direct-Acting Antivirals (DAAs) – A class of medication that acts to target specific steps in the HCV viral life cycle.

Elimination - A state where Hepatitis C is no longer a public health threat which improves individual health and prevents ongoing transmission of the virus.

Group Program – A program that reimburses pharmacies for the cost of drugs dispensed to its members.

Local Health Jurisdiction – Washington has 31 county health departments, three multi-county health districts and two city-county health departments referred to as Local Health Jurisdictions. They

are local government agencies that carry out a wide variety of programs to promote health, help prevent disease and build healthy communities.

Mandatory (M) – A response to these items must be included in the Proposal in order for the Proposal to be deemed responsive to this RFP. Proposals that fail to include a response to Mandatory Scored items will be found non-responsive and will be disqualified.

Mandatory Scored (MS) – A response to these items must be included in the Proposal in order for the Proposal to be deemed responsive to this RFP, and such response will be evaluated and scored by the RFP evaluation team. Proposals that fail to include a response to Mandatory Scored items will be found non-responsive and will be disqualified.

Proposal – A formal offer submitted in response to this RFP.

Request for Proposals (RFP) – Formal procurement document in which a service or need is identified but no specific method to achieve it has been chosen. The purpose of an RFP is to permit the bidder community to suggest various approaches to meet the need at a given price.

1.8. **ADA**

HCA complies with the Americans with Disabilities Act (ADA). Bidders may contact the RFP Coordinator to receive this RFP in Braille or on tape.

2. GENERAL INFORMATION FOR BIDDERS

2.1. RFP COORDINATOR

The RFP Coordinator is the sole point of contact in HCA for this procurement. All communication between the Bidder and HCA upon release of this RFP must be with the RFP Coordinator, as follows:

Name	Vicki Sprague
E-Mail Address	contracts@hca.wa.gov
Mailing Address	PO Box 42702 Olympia, WA 98504-2702
Phone Number	360-725-9794

Any other communication will be considered unofficial and non-binding on HCA. Bidders are to rely only on written statements issued by the RFP Coordinator. **Communication directed to parties other than the RFP Coordinator may result in disqualification of the Bidder.**

2.2. ESTIMATED SCHEDULE

Issue Request for Proposals	January 22, 2019
Bidders Conference	January 28, 2019
Questions from Bidders Due	January 31, 2019
Answers Posted	February 8, 2019
Proposals Due	March 4, 2019
Evaluate Proposals	March 5 – March 15, 2019
Conduct Oral Interviews with Finalists, if required	Week of April 1, 2019
Announce “Apparently Successful Bidder”	April 12, 2019
Hold Debriefing Conferences (if requested)	Week of April 15, 2019
Begin Contract Negotiations	April 29, 2019
Begin Contract Work	July 1, 2019

HCA reserves the right in its sole discretion to revise the above schedule.

2.3. PRE-PROPOSAL CONFERENCE

A pre-proposal conference is scheduled to be held on January 28, 2019 at 11:30 a.m., Pacific Time via a web conference. The internet address to register for the web conference is: https://attendee.gotowebinar.com/register/4623494338631774 75. All prospective Bidders should attend; however, attendance is not mandatory.

HCA will be bound only by its written answers to questions. Questions arising at the pre-proposal conference or in subsequent communication with the RFP Coordinator will be documented and answered in written form. A copy of the questions and answers will be sent to each prospective Bidder that has made the RFP Coordinator aware of its interest, and will also be posted on the Washington Electronic Business Solution (WEBS), found at https://fortress.wa.gov/ga/webs/.

Potential Bidders not registered as a vendor on WEBS should do so in order to download this RFP and any amendments.

2.4. SUBMISSION OF PROPOSALS

The proposal must be received by the RFP Coordinator no later than the Proposal Due deadline in Section 2.2, *Estimated Schedule*. Proposals must be submitted electronically as an attachment to an email to the RFP Coordinator at the email address listed in Section 2.1. Attachments to email should be in Microsoft Word or Excel formats, or PDF. Zipped files cannot be received by HCA and should not be used for submission of Proposals. The Letter of Submittal and the Certifications and Assurances form must have a scanned signature of an individual within the organization authorized to bind the Bidder to the offer. HCA does not assume responsibility for problems with Bidder's email. If HCA email is not working, appropriate allowances will be made.

Proposals may not be transmitted using facsimile transmission. Bidders should allow sufficient time to ensure timely receipt of the proposal by the RFP Coordinator. Late proposals may not be accepted and may be disqualified from further consideration. All proposals and any accompanying documentation become the property of HCA and will not be returned.

2.5. PROPRIETARY INFORMATION / PUBLIC DISCLOSURE

Proposals submitted in response to this RFP will become the property of HCA. All proposals received will be considered public records under chapter 42.56 of the RCW. However, proposals will remain confidential until the Apparent Successful Bidder(s) are announced; thereafter, the proposals will be subject to disclosure under chapter 42.56 RCW.

Any information in the proposal that the Bidder desires to claim as proprietary and exempt from disclosure under chapter 42.56 RCW, or other state or federal law that provides for the nondisclosure of a document, must be clearly designated. The information must be clearly identified and the particular exemption from disclosure upon which the Bidder is making the claim must be cited as part of Bidder's Letter of Submittal (*see,* Section 3.1). Each page containing the information claimed to be exempt from disclosure must be clearly identified by the words "Proprietary Information" or similar printed on the lower right hand corner of the page. Marking the entire proposal exempt from disclosure or as proprietary or confidential information will not be honored.

If a public records request is made for the information that the Bidder has marked as proprietary or confidential, HCA will notify the Bidder of the request and of the date that the records will be released to the requester unless the Bidder obtains a court order enjoining that disclosure. If the Bidder fails to obtain the court order enjoining disclosure, HCA will release the requested information on the date it specifies. If a Bidder obtains a court order from a court of competent jurisdiction enjoining disclosure pursuant to chapter 42.56 RCW, or other state or federal law that provides for nondisclosure, HCA will maintain the confidentiality of the Bidder's information per the court order.

A charge will be made for copying and shipping, as outlined in chapter 42.56 RCW. No fee will be charged for inspection of contract files, but 24 hours' notice to the RFP Coordinator is required. All requests for information should be directed to the RFP Coordinator.

The submission of any public records request to HCA pertaining in any way to this RFP will not affect the procurement schedule, as outlined in Section 2.2, unless HCA, in its sole discretion, determines that altering the schedule would be in HCA's best interests.

2.6. REVISIONS TO THE RFP

If HCA determines in its sole discretion that it is necessary to revise any part of this RFP, then HCA will provide amendments via email to all individuals who have made the RFP Coordinator aware of their interest. Amendments will also be published on WEBS.

HCA also reserves the right to cancel or to reissue the RFP in whole or in part, prior to execution of a contract, for any reason.

2.7. DIVERSE BUSINESS INCLUSION PLAN (M)

Bidders are required to submit a Diverse Business Inclusion Plan with their Proposal. In accordance with legislative findings and policies set forth in chapter 39.19 RCW, the state of Washington encourages participation in all contracts by firms certified by the Office of Minority and Women's Business Enterprises (OMWBE), set forth in RCW 43.60A.200 for firms certified by the Washington State Department of Veterans Affairs, and set forth in RCW 39.26.005 for firms that are Washington Small Businesses. Participation may be either on a direct basis or on a subcontractor basis. However, no preference on the basis of participation is included in the evaluation of Diverse Business Inclusion Plans submitted, and no minimum level of minority- and women-owned business enterprise, Washington Small Business, or Washington State certified Veteran Business participation is required as a condition for receiving an award. Any affirmative action requirements set forth in any federal governmental regulations included or referenced in the contract documents will apply.

2.8. ACCEPTANCE PERIOD

Proposals must provide that the offers made in such Proposal remain open for acceptance by HCA for one hundred twenty (120) Calendar Days from the Proposal due date as set forth in Section 2.2 of this RFP.

2.9. COMPLAINT PROCESS

2.9.1. Potential Bidders may only submit a complaint to HCA based on any of the following:

a. The RFP unnecessarily restricts competition;

b. The RFP evaluation or scoring process is unfair or unclear; or

c. The RFP requirements are inadequate or insufficient to prepare a response.

2.9.2. A complaint must be submitted to HCA prior to five (5) Business Days before the Proposal due date. The complaint must:

a. Be in writing;

b. Be sent to the RFP Coordinator in a timely manner;

c. Clearly articulate the basis for the complaint; and

d. Include a proposed remedy.

The RFP Coordinator will respond to the complaint in writing. The response to the complaint and any changes to the RFP will be posted on WEBS. The Director of HCA will be notified of all complaints and will be provided a copy of HCA's response. **A Bidder cannot raise during a bid protest (*see*,**

Section 4.7 for additional information regarding protests) any issue that the Bidder or potential Bidder raised in a complaint, or that could have been raised in a complaint. HCA's action or inaction in response to a complaint will be final. There will be no appeal process.

2.10. RESPONSIVENESS

The RFP Coordinator will review all Proposals to determine compliance with administrative requirements and instructions specified in this RFP. A Bidder's failure to comply with any part of the RFP may result in rejection of the Proposal as non-responsive. HCA reserves the right to contact a Bidder for clarification of its Proposal.

HCA also reserves the right at its sole discretion to waive minor administrative irregularities.

2.11. MOST FAVORABLE TERMS & BAFO

HCA reserves the right to make an award without further discussion of the Proposal submitted. Therefore, the proposal should be submitted initially on the most favorable terms which the Bidder can propose.

Following the evaluation of written Proposals and oral presentations (if any), HCA reserves the right to invite one or more Bidders to participate in a "Best and Final Offer" (BAFO) process in order to determine the Proposal providing the best value to HCA. The BAFO process may include the contract terms and conditions, pricing, or any other appropriate subject in Bidder's final Proposal, as solely determined by HCA. Bidders will be responsible for their own costs and expenses related to the BAFO process. There is no guarantee that HCA will decide to use the BAFO process.

The objective of the BAFO is to allow selected Bidders to refine and document changes to their Proposals for submission to HCA for final review and evaluation. However, this process may not be used to turn a non-responsive Proposal into a responsive one. Each Bidder will be provided a document identifying areas, topics, or issues HCA would like to see refined by the Bidder (each a BAFO Request). HCA reserves the right for each BAFO Request to be different for each Bidder invited to participate as each Proposal will be unique, with its own strengths and weaknesses. The BAFO Request will include additional details and instructions on the form, format, and timing for the Bidder to provide a response (BAFO Response).

At the conclusion of the BAFO process, HCA will evaluate the BAFO Responses and select an ASB. This evaluation approach described is intended to identify the Proposal that offers the greatest benefit to HCA based on consideration of the total best value, which may not necessarily be the Proposal with the highest score during the written or oral evaluation, or the lowest cost.

The ASB should be prepared to accept this RFP for incorporation into a contract resulting from this RFP. Such contract will incorporate some, or all, of the Bidder's Proposal, including materials provided during any BAFO process. The Proposal will become a part of the official procurement file on this matter without obligation to HCA.

2.12. PROPOSED CONTRACT

HCA expects that a contract resulting from this RFP will consist of multiple parts. In addition to general terms and conditions, it is anticipated there will be multiple exhibits, attachments, or sub-agreements detailing rebate amounts and services for each of the populations described in this RFP. The contract will also include terms ensuring that it is "performance based" in compliance with Washington State law and executive order, including metrics or performance standards tied to agreed upon Bona Fide Services. HCA will not accept any draft contracts prepared by any Bidder.

If, after the announcement of the ASB, and after a reasonable period of time, the ASB and HCA cannot reach agreement on acceptable terms for the contract, HCA may (1) cancel the selection and award the contract to the next most qualified Bidder, or (2) not enter into any contract at all.

2.13. COSTS TO PROPOSE

HCA will not be liable for any costs incurred by the Bidder in preparation of a Proposal submitted in response to this RFP, in conduct of a presentation, as part of a BAFO process, or any other activities related in any way to this RFP.

2.14. RECEIPT OF INSUFFICIENT NUMBER OF PROPOSALS

If HCA receives only one responsive Proposal as a result of this RFP, HCA reserves the right to (1) directly negotiate and contract with the Bidder; or (2) not award any contract at all. HCA may continue to have such Bidder complete the entire RFP process. HCA is under no obligation to tell the Bidder if it is the only Bidder.

2.15. NO OBLIGATION TO CONTRACT

This RFP does not obligate HCA to enter into any contract for services specified herein.

2.16. REJECTION OF PROPOSALS

HCA reserves the right, at its sole discretion, to reject any and all proposals received without penalty and not to issue any contract as a result of this RFP.

2.17. COMMITMENT OF FUNDS

The Director of HCA or his/her delegate is the only individual who may legally commit HCA to the expenditures of funds for a contract resulting from this RFP. No cost chargeable to the proposed contract may be incurred before receipt of a fully executed contract.

2.18. ELECTRONIC PAYMENT

The State of Washington prefers to utilize electronic payment in its transactions. The ASB will be provided a form to complete with the contract to authorize such payment method.

2.19. INSURANCE COVERAGE

As a requirement of the resultant contract, the ASB may be required to furnish HCA with a certificate(s) of insurance executed by a duly authorized representative of each insurer, showing compliance with the insurance requirements set forth below.

The ASB must, at its own expense, obtain insurance coverage which will be maintained in full force and effect during the term of the contract. The ASB must furnish evidence in the form of a Certificate of Insurance that insurance will be provided, and a copy must be forwarded to HCA within fifteen (15) Calendar Days of the contract effective date.

2.19.1. Liability Insurance

a. Commercial General Liability Insurance

The ASB shall maintain commercial general liability (CGL) insurance and, if necessary, commercial umbrella insurance, with a limit of not less than $1,000,000 per each occurrence. If CGL insurance contains aggregate limits, the General Aggregate limit must be at least twice the “each occurrence” limit. CGL insurance must have products-completed operations aggregate limit of at least two times the “each occurrence” limit. CGL insurance must be written on ISO occurrence from CG 00 01 (or a substitute form providing equivalent coverage). All insurance must cover liability assumed under an insured contract (including the tort liability of another assumed in a business contract), and contain separation of insureds (cross liability) condition.

Additionally, the ASB is responsible for ensuring that any subcontractors provide adequate insurance coverage for the activities arising out of subcontracts.

b. Business Auto Policy

As applicable, the ASB shall maintain business auto liability and, if necessary, commercial umbrella liability insurance with a limit not less than $1,000,000 per accident. Such insurance must cover liability arising out of “Any Auto.” Business auto coverage must be written on ISO form CA 00 01, 1990 or later edition, or substitute liability form providing equivalent coverage.

c. Employers Liability (“Stop Gap”) Insurance

In addition, the ASB shall buy employers liability insurance and, if necessary, commercial umbrella liability insurance with limits not less than $1,000,000 each accident for bodily injury by accident or $1,000,000 each employee for bodily injury by disease.

2.19.2. Additional Provisions

Above insurance policy must include the following provisions:

a. Additional Insured

The State of Washington, HCA, its elected and appointed officials, and its agents and employees must be named as an additional insured on all general liability, auto liability, cyber liability, excess, umbrella and property insurance policies. All insurance provided in compliance with this contract must be primary as to any other insurance or self-insurance programs afforded to or maintained by the state.

b. Cancellation

The State of Washington, HCA, must be provided written notice before cancellation or non-renewal of any insurance referred to therein, in accord with the following specifications. Insurers subject to Chapter 48.18 RCW (Admitted and Regulation by the Insurance Commissioner): The insurer must give the state 45 Calendar Days advance notice of cancellation or non-renewal. If cancellation is due to non-payment of premium, the state must be given ten days advance notice of cancellation. Insurers subject to Chapter 48.15 RCW (Surplus lines): The state must be given 20 Business Days advance notice of cancellation. If cancellation is due to non-payment of

premium, the state must be given ten (10) Business Says advance notice of cancellation.

c. Identification

The policy must reference the state's contract number and HCA.

d. Insurance Carrier Rating

All insurance and bonds should be issued by companies admitted to do business within the state of Washington and have a rating of A-, Class VII or better in the most recently published edition of Best's Reports. Any exception must be reviewed and approved by the Health Care Authority Risk Manager, or the Risk Manager for the state of Washington, before the contract is accepted or work may begin. If an insurer is not admitted, all insurance policies and procedures for issuing the insurance policies must comply with Chapters 48.15 RCW and 284-15 WAC.

e. Excess Coverage

By requiring insurance herein, the state does not represent that coverage and limits will be adequate to protect the ASB, and such coverage and limits will not limit the ASB's liability under the indemnities and reimbursements granted to the state in the contract resulting from this RFP.

2.19.3. Workers' Compensation Coverage

The ASB will at all times comply with all applicable workers' compensation, occupational disease, and occupational health and safety statutes and regulations to the full extent applicable. The state will not be held responsible in any way for claims filed by the ASB or its employees for services performed under the terms of the contract resulting from this RFP.

3. PROPOSAL CONTENTS

Proposals must be written in English and submitted electronically to the RFP Coordinator in the order noted below:

A. Letter of Submittal, including signed Certifications and Assurances (Exhibit A to this RFP)

B. Bona Fide Services

C. Distribution Channels

D. Cost Proposal

E. Diverse Business Inclusion Plan (Exhibit B to this RFP; *see*, Section 2.7)

Proposals must provide information in the same order as presented in this RFP with the same headings.

Items marked "(M)" must be included as part of the Proposal for the Proposal to be considered responsive; however, these items are not scored. Items marked "(MS)" must be included as part of the Proposal for the Proposal to be considered responsive and are awarded points as part of the evaluation conducted by the evaluation team. This Section 3 contains information on what must be included in Proposals. Information about the evaluation of the Proposals and how the ASB will be selected is covered in Section 4.

3.1. LETTER OF SUBMITTAL (M)

The Letter of Submittal and the attached Certifications and Assurances form (Exhibit A to this RFP) must be signed and dated by a person authorized to legally bind the Bidder to a contractual relationship. Along with introductory remarks, the Letter of Submittal is to include the following information about the Bidder and any proposed subcontractors:

3.1.1. Name, address, principal place of business, telephone number, and email address of legal entity or individual with whom any contract would be written.

3.1.2. Name, address, and telephone number of each of Bidder's principal officers (President, Vice President, Treasurer, Chairperson of the Board of Directors, etc.).

3.1.3. Legal status of the Bidder (sole proprietorship, partnership, corporation, etc.) and the year the entity was organized to do business as the entity now substantially exists.

3.1.4. Federal Employer Tax Identification number or Social Security number and the Washington Uniform Business Identification (UBI) number issued by the state of Washington Department of Revenue. If the Bidder does not have a UBI number, the Bidder must state that it will become licensed in Washington within thirty (30) Calendar Days of being selected as the Apparent Successful Bidder.

3.1.5. The current U.S. Food & Drug Administration approved package insert of each DAA that Bidder is including within its Proposal.

3.1.6. Identify any state employees or former state employees employed or on the Bidder's governing board as of the date of the Proposal. Include their position and responsibilities within the Bidder's organization. If, following a review of this information, it is determined by HCA that a conflict of interest exists, the Bidder may be disqualified from further consideration for the award of a contract.

3.1.7. In addition to indicating what the Bidders construes as the confidential or proprietary nature of information included in a Proposal, the Letter of Submittal must separately identify any information in the Proposal that the Bidder desires to claim as proprietary and exempt from disclosure under the provisions of Chapter 42.56 RCW. The page must be and the particular exemption from disclosure upon which the Bidder is making the claim must be listed.

3.2. **BONA FIDE SERVICES (MS)**

A successful elimination strategy requires those with HCV be identified, screened, and treated. DOH will lead development and implementation of these public health efforts. Currently, DOH supports and coordinates a limited number of targeted HCV screening, linkage to care, and supportive service programs, as well as strategies that strengthen health care workforce capacity. These efforts primarily focus on people who inject drugs (PWID) and other communities disproportionately impacted by HCV incidence in order to stem the tide of new infections. It is HCA's intention to partner with one or more ASBs that will fund public health efforts related to identification and screening of those with HCV.

DOH has identified several additional public health strategies, and is leading a multisector coordinating committee to advance this work. The intention is to expand upon or complement the already successful outreach strategies in place, and to leverage the unique expertise, perspective, and capabilities of a DAA manufacturer to augment those with additional services and resources in order to achieve elimination. These bona fide services will supplement the work being performed by the state.

Further, DOH and HCA expect that these bona fide services may change over time. While the services proposed by Bidders will serve as the basis for HCA's evaluation of Proposals, and the contract resulting from this RFP will incorporate those services, some services may prove more effective than others, new strategies may be identified, or the state's needs may change over time.

DOH will make recommendations regarding what is needed to implement a comprehensive public health response. DOH will develop, oversee and support implementation of Hep C Free WA as described above. DOH, in collaboration with the Hepatitis C Elimination Coordinating Committee, will be responsible to:

- Finalize the public health program designs and implementation plans
- Provide data collection, assessment and dissemination
- Engage in evidence gathering and analysis to prioritize regions, communities, and populations for services and to assess success
- Determine the best practices and standards for community based organizations delivering highly targeted education and screening services
- Disseminate best practices for replication throughout the State of Washington
- Develop and oversee related contracts, including quality assurance

Washington views the ASB(s) as a critical partner(s) in the effort to reach HCV patients and get them into treatment. The ASB(s) will present to and be actively engaged with the WA Hepatitis C Elimination Coordination Committee as Hep C Free WA is implemented. It is expected that the supports provided by the ASB(s) will be documented as part of a Bona Fide Service Plan and included in any contracts resulting from this RFP.

Bona Fide Services Description

HCA is seeking Bidders to propose a Bona Fide Service Plan that will identify and screen potential patients, support the education of the provider community and help track and monitor incidence and cures. Identified in subsections 3.2.1 through 3.2.6 below are several strategies currently being considered by DOH as part of Hep C Free WA and the ideal approach to fulfill that strategy. While the

strategies listed below are ones suggested by DOH, Bidders may propose alternative or additional public health elimination strategies. Bidder may also choose to support the strategy below and propose a different approach to address it.

In a **maximum of 30 pages**, please provide a Bona Fide Service Plan that (i) describes strategies, (ii) an approach to fulfill that strategy, and (iii) the expected outcome, for bona fide services the Bidder is proposing in support of Hep C Free WA, including, as applicable, the number and type of staff, the number and types of supplies, details on communication and outreach methods and collaterals, the project management or implementation support, and operationalization support. Also include a single, aggregate estimated fair market value for all such services. **Please note that pages in excess of the 30-page limit set forth above will not be reviewed or scored, including any supplemental materials referenced or linked to in the Proposal**. Accordingly, all information Bidders want to be considered should be included entirely within the 30-page response.

HCA anticipates that the resource requests will be brought in through a phased approach, which will be developed collaboratively with DOH and in alignment with Hep C Free WA. Bidders should recommend the ideal phasing of the services described in their proposed Bona Fide Service Plan.

Bona fide services that HCA believes best align with the goals and expected outcomes of Hep C Free WA are as follows.

3.2.1. Strategy 1: Health Care Workforce Preparation

DOH and HCA seek to improve academic detailing and health care workforce preparation to educate and build provider capacity to deliver HCV screening, and linkage to care activities within health care settings.

Ideally this would include support from at least one (1) full-time clinically trained practice detailer to provide face-to-face HCV-related provider education and support to increase the number of primary care providers managing HCV in their practices.

The expected outcome of this strategy is face to face HCV-related provider education and support to significantly increase the number of primary care providers managing HCV in their practices.

3.2.2. Strategy 2: Health Promotion & Education

DOH and HCA seek to launch a social marketing campaign. This work would engage a social marketing firm to promote a comprehensive plan aimed at priority populations to deliver education through various media formats, with a focus on educating those at risk about the importance of screening to identify infection, and educating those with infection about the importance of obtaining treatment.

Ideally this would include use of a social marketing firm to develop and place 4-5 HCV culturally appropriate campaigns promoting HCV prevention, testing, and curative treatment for PWID, and testing and curative treatment for Baby Boomers (particularly Boomers from disproportionately impacted communities, such as Native Americans and African Americans).

The expected outcome is the self-identification and referral of patients through media campaigns promoting HCV prevention, testing, and curative treatment.

3.2.3. Strategy 3: Syringe Service Programs

DOH and HCA seek to modernize Syringe Service Programs (SSPs) to deliver enhanced HCV screening, linkage to care and supportive services. DOH intends to expand the total amount of SSPs with the goal of ensuring each county has a minimum of one (1) SSP site and modern clinical linkages to care activities.

Ideally, this would include support for six (6) full-time HCV Medical Case Managers ("MCMs") providing care management, including, but not limited to HCV Ab screening, performing phlebotomy for confirmatory testing, conducting risk/need assessments, signing up clients for insurance, healthcare system navigation, linkage to care, and adherence counseling.

MCMs would be stationed in DOH supported SSP sites throughout WA State. MCMs to be provided by Bidder(s) would be assigned by DOH to an SSP that meets the following criteria:

a. Currently operating a DOH approved onsite HCV rapid screening program,
b. Delivering services within a moderate/high burden jurisdiction,
c. Past history of identifying cases (>15% zero-positivity rate), and
d. The ability to scale screening services to meet population needs.

Expected outcomes, based on ideal staffing and supplies is, on an annual basis, the ASB will (i) engage in 10,000 case management encounters (i.e., any documented contact with an individual client throughout their time being managed by a case manager) for people living with HCV, and (ii) provide approximately 1,500 RNA laboratory tests per year for clients that screen Ab+ through SSP settings. The number of encounters is based on Hepatitis Education Project's HCV case management program. DOH supports the HEP's case management program and they are able to reach ~5,000 encounters per calendar year. It's common that clients need multiple encounters with their case manager throughout the course of receiving services.

3.2.4. Strategy 4: Local Health Jurisdiction Enhancement

DOH and HCA seek to enhance the ability of Local Health Jurisdictions (LHJs) to deliver highly targeted screening and linkage to care activities. Expansion will target LHJs located in medium and high prevalence jurisdictions. LHJs selected for MCM support represent the ten (10) most highly impacted counties within the state (selected jurisdictions represent 90% of HCV case reports from 2013 – 2017). LHJ screening sessions should include, but not limited to, risk assessment, pre-test counseling, risk reduction counseling, post-test counseling, and referral to medical care and supportive services.

Ideally, this would include:

a. Support for fifteen (15) full-time HCV MCMs who would be stationed in ten (10) LHJs throughout the state. MCMs will provide care management, including, but not limited to:

   - HCV Ab screening, performing phlebotomy for confirmatory testing,
   - Conducting risk/need assessment,
   - Signing up clients for insurance,
   - Healthcare system navigation,
   - Linkage to care, and
   - Adherence counseling.

   In addition, MCMs shall provide services to hard-to-reach populations, including, but not limited to, HCV screening services, education, medication adherence services, linkage to clinical care and supportive services, and provide/exchange harm reduction supplies.

b. Support for five (5) pharmacists (PharmD). Pharmacists will provide regional coverage for the selected (10) jurisdictions for the State and will cover the following counties:

   - Region 1: Mason, Thurston, Cowlitz and Clark (1 pharmacist)
   - Region 2: Whatcom and Snohomish (1 pharmacist)
   - Region 3: King County and Pierce County (2 pharmacists)
   - Region 4: Yakima, Walla Walla, and Spokane (1 pharmacist)

Pharmacists will provide direct care, including but not limited to: HCV Ab screening, perform phlebotomy for confirmatory testing, prescribe DAA treatment under collaborative practice agreements approved by the Pharmacy Quality Commission, and adherence counseling.

Expected outcomes based on ideal staffing and supplies is, on an annual basis, (i) engage in 35,000 case management encounters for people living with HCV, and (ii) provide approximately 5,000 RNA laboratory tests per year for clients that screen Ab+ through SSP settings.

3.2.5. Strategy 5: Project ECHO

DOH and HCA seek to build workforce capacity via Project ECHO to support a health care workforce prepared to diagnose, care for, treat and cure persons infected with hepatitis C. (For more information, please see: https://www.uwmedicine.org/referrals/telehealth-services/provider)

Ideally, this would include support of Project ECHO's capacity for primary care provider enrollment. HCA recommends contracting with the University of Washington. Capacity should be two weekly 90-minute sessions.

The expected outcome is participation by 150 providers and 40 participating sites.

3.2.6. Strategy 6: Health Information Exchange Reporting and Analytics

HCA and DOC intend to build, or utilize an existing Health Information Exchange (HIE) to meet the tracking and reporting needs of Hep C Free WA. Additionally, pricing and rebate information may be tracked in the HIE for Hep C Free WA.

As that system is developed, and potentially on an ongoing basis, HCA and DOH seek regular, timely reporting on the DDA treatments provided; and on non-PHI statistics on patients by patient treatment categories listed in Exhibit C, patient outcomes, and patient referral source. Also being requested is HCV Washington State population surveillance, consultation, and support as Hep C Free WA develops its data strategy.

Ideally, the bona fide services would include reporting and subject matter expertise and consultation on establishing and maintaining an HIE platform that allows all entities to input data specific to their requirements.

3.3. DISTRIBUTION TO NON-MEDICAID PROGRAMS (M)

In addition to the bona fide services described in Section 3.2, Bidders need to describe how they intend to meet the distribution needs of Hep C Free WA. Accordingly, Bidders must submit confirmation of its capability to support the distribution processes described below. Bidders may also submit suggested revisions or alternatives to the distribution methods described. Attached as Exhibit E to this RFP are diagrams of both the current and anticipated future distribution models for three (3) populations that will be served by Hep C Free WA.

3.3.1. Non-Medicaid Programs – Facilities

This distribution model ensures the delivery of drugs to facilities managed by DOC and DSHS. For DOC, Moda Health contracts with PeaceHealth for access to GPO prices through Premier. PeaceHealth contracts with Cardinal, a distributor, who sells the drugs directly to DOC using Premier's GPO rates. DOC pays Cardinal the GPO prices directly. PeaceHealth negotiated additional GPO price concessions from Cardinal in exchange for agreeing to an exclusive wholesale distribution

relationship. This concession is extended to Premier affiliates, including DOC, in the form of a lower cost.

DSHS currently contracts directly with PeaceHealth. Like DOC, Cardinal sells the drugs to DSHS and DSHS pays Cardinal.

In its Proposal, Bidders must include a description of the following:

a. Confirmation that Bidder will use existing distribution process, or
b. An alternative distribution process.

3.3.2. Non-Medicaid Programs – Group Programs (ERB Programs and L&I)

Both the ERB Programs and L&I currently contract with Moda Health to access drug manufacturer rebates negotiated through MedImpact. The entirety of the rebates are passed through Moda to the programs.

For the ERB Programs, MedImpact sends 100% of the rebates to Moda, who passes 100% of the rebates on to UMP.

L&I sends quarterly claims to Moda. Moda passes the claims information on to Medimpact. MedImpact invoices the manufacturer for rebates. MedImpact sends 100% of the L&I rebate to Moda, Moda subtracts the administrative fee and passes the remaining rebate amount to L&I.

The selected ASB(s) will make all rebates and any other price concession that are included in a Proposal to be recovered using either (i) a state-selected administrator who will be responsible for billing, collecting, and disbursing rebates and concessions on behalf of the state, or (ii) Bidders may propose an alternative method for the group programs to get the GNUP at the point of service. Any administrative fees required by the HCA administrator or Bidder's alternative will be paid for by the drug manufacturer. HCA estimates that such administrative fee for its administrator would be approximately $25,000 per non-Medicaid program per quarter. However, the actual administrative fees will be determined at a later date and will be incorporated into the contract resulting from this RFP.

3.4. MEDICAID DISTRIBUTION MODEL (M)

Medicaid: Apple Health

Coverage for all DAAs within the Apple Health program is through the fee-for-service plan. Apple Health currently participates in the TOP$ program through Magellan for negotiated supplemental rebates. The contracted retail pharmacies buy the drugs from a wholesaler. The Apple Health members receive their drugs from the contracted retail pharmacies. Apple Health reimburses the contracted retail pharmacies for drugs dispensed to Apple Health members. Apple Health then invoices the manufacturers, who pay the federal and supplemental rebates directly to Apple Health.

HCA expects that the selected ASB(s) will make all rebates and any other price concession that are included in a Proposal for Medicaid programs to be recovered using HCA staff and systems, who will be responsible for billing, collecting and disbursing rebates and concessions on behalf of the state.

After selecting an ASB(s), HCA will contract directly with that HCV drug manufacturer for supplemental and value-based rebates. The drug distribution process will remain the same.

3.5. **COST PROPOSAL (MS)**

The evaluation process is designed to award this procurement not necessarily to the Bidder of least cost, but rather to the Bidder whose proposal best meets the requirements of this RFP. However, Bidders are encouraged to submit proposals which are consistent with state government efforts to conserve state resources.

Bidders are asked to provide a detailed cost proposal using the form provided as Exhibit C, *Cost Proposal*. In the Cost Proposal, populations historically treated by HCA and DOC are divided into four (4) categories for each HCV genotype. Those categories are based on (1) whether the patient was treatment naïve or treatment experienced, and (2) whether or not the patient was or was not diagnosed with cirrhosis.

The Cost Proposal Form has two (2) primary parts: one tab for treatment of the Medicaid population, and one for the treatment of the non-Medicaid population. Instructions for completion of the form are included on the first tab of the worksheet. Included in each cost table is an estimated number of patients categorized in one of four (4) ways for each HCV genotype. Again, these categories are based on (1) whether the patient was treatment naïve or treatment experienced, and (2) whether or not the patient was or was not diagnosed with cirrhosis. These "Patient Counts" are based on estimates of the remaining undiagnosed HCV patients expected to be treated over the initial 4-year period. For the purposes of determining a total cost for each Bidder, HCA will calculate an aggregate cost for the 4-year period using the following formula:

Patient Count x % Patient Type Treated x Average Cost/Day x Treatment Duration = Type Cost

After the Type Cost for each category of patient for each genotype is determined, HCA will then sum all of the Type Costs to determine Bidder's total costs for each of the Medicaid and non-Medicaid populations. Each of these totals are scored independently as described in Section 4.2.2, below.

Also included in the Cost Proposal Form for the Medicaid population is the annual maximum amount HCA would have to pay for the treatment of that population. Under this modified "subscription model," HCA will agree to pay the GNUP for all DAAs purchased to treat Medicaid patients up to the agreed upon Subscription Max. For any purchase of DAAs in excess of that amount, the GNUP would be reduced to $0.01.

4. EVALUATION AND CONTRACT AWARD

4.1. **EVALUATION PROCEDURE**

Responsive Proposals will be evaluated strictly in accordance with the requirements stated in this RFP and any amendments issued. The evaluation of proposals will be accomplished by an evaluation team, to be designated by HCA, which will determine the ranking of the proposals. Evaluations will only be based upon information provided in the Bidder's Proposal.

All proposals received by the stated deadline, Section 2.2, *Estimated Schedule of Procurement Activities*, will be reviewed by the RFP Coordinator to ensure that the Proposals contain all of the required information requested in the RFP. Only responsive Proposals that meet the requirements will be evaluated by the evaluation team. Any Bidder who does not meet the stated qualifications or any Proposal that does not contain all of the required information will be rejected as non-responsive.

The RFP Coordinator may, at his or her sole discretion, contact the Bidder for clarification of any portion of the Bidder's Proposal. Bidders should take every precaution to ensure that all answers are clear, complete, and directly address the specific requirement.

Responsive Proposals will be reviewed and scored by an evaluation team using a weighted scoring system, Section 4.2, *Evaluation Weighting and Scoring*. Proposals will be evaluated strictly in accordance with the requirements set forth in this RFP and any amendments issued.

HCA, at its sole discretion, may elect to select the top-scoring firms as finalists for an oral presentation.

4.2. EVALUATION WEIGHTING AND SCORING

4.2.1. Evaluation of Proposals

Proposals that have passed the initial screening described above will be evaluated and scored by the evaluation team, and may include evaluators from outside HCA. Evaluators are under no obligation to create written notes or explanation of their scores during Proposal evaluation. Any award will be made to the lowest responsive and responsible Bidder whose Proposal, in the sole opinion of HCA, offers the greatest benefit to HCA. The decision will be based on consideration of the total best value, including, but not limited to, the responsiveness of the Proposal to the requirements as set forth in this RFP, the competence and responsibility of the Bidder, quality of service, breadth and depth of offering, the strength and form of contractual commitments made by the Bidder to HCA, and total cost. HCA reserves the right to make the award to the Bidder(s) whose Proposal is deemed to be in the best interest of HCA and the State of Washington. Hence, HCA may choose to not award to the highest scoring or lowest-cost Proposal.

4.2.2. Written Proposals

Evaluation teams will be formed to evaluate the written Proposals. Evaluation team members will individually review each Proposal before meeting with the rest of their evaluation team to discuss the Proposals. HCA may bring in subject matter experts with specific, relevant backgrounds to assist in evaluating portions of the written Proposals, in determining how well each Proposal responds to the RFP requirements, and how the Proposal and Bidder meet the needs of HCA. Evaluation team members will take into account their own expertise and any input from experts to individually evaluate and score the Proposals. It is important that each Proposal be concise, clear, and complete. HCA may elect to award a contract at the end of the evaluation process for the written Proposals. However, the HCA reserves the right to advance Bidders to the oral presentation phase.

The scores assigned by individual team members will be used in calculating the total number of points awarded to each Bidder. For bona fide services, the points awarded to a Bidder will be calculated by averaging the scores assigned by individual evaluation team members, and multiplying that average by the weight listed below. Scores used by individual team members (0 – 10) and a brief statement about the general characteristics of a Proposal earning each of those individual scores is provided in the table below.

Score	Description	Discussion
9 – 10	Far Exceeds Requirements	Bidder has provided an innovative, detailed, efficient approach or established, by presentation of material, far superior capability in this area.
6 – 8	Exceeds Requirements	Bidder has demonstrated an above-average capability, approach, or solution and has provided a complete description of the capability, approach, or solution.
5	Meets Requirements	Bidder has an acceptable capability of solution to meet this criterion and has described its approach in sufficient detail to

		be considered "as substantially meeting the requirements".
3 – 4	Below Requirements	Bidder has established some capability to perform the requirement but descriptions regarding their approach are not sufficient to demonstrate the Proposer will be fully able to meet the requirements.
1 – 2	Substantially Below Requirements	Bidder has not established the capability to perform the requirement, has marginally described its approach, or has simply restated the requirement.
0	No value	Bidder has omitted any discussion of this requirement or the information provided is of no value.

As indicated in the table below, Bidder's Proposal with regard to bona fide services and each of the strategies listed in Section 3.2 will be evaluated and **scored as a whole**. Points will be awarded based on the Bidder's demonstrated understanding of patient outreach, the quality and comprehensiveness of services to identify and engage those with HCV, the quality and comprehensiveness of any provider training proposed by Bidder, the quality and comprehensiveness of proposed use of media proposed by the vendor, and the alignment of Bidder's proposed services to those outlined in Section 3.2 as part of Hep C Free WA.

BONA FIDE SERVICES		
Section	**Weight**	**Maximum Points**
Modernizing Syringe Service Programs (SSPs)	140	1,400
Enhance Local Health Jurisdictions		
Academic Detailing and Health Care Workforce Preparation		
Project ECHO		
Health Promotion and Education		
Health Information Exchange Platform		
Other Bona Fide Services		

The Cost Proposal will be scored by summing all of the total costs calculated as described in Section 3.5. The lowest total cost will receive all of the points listed in the table below for each year and cost category. Point totals for the remaining Bidders will be calculated by dividing the lowest total cost by the Bidder's total cost, and then multiplying the result by the number of points listed for each year and cost category.

Year	**DAA – Non-Medicaid**	**DAA – Medicaid**	**Subscription Max**
1 (2019 – 2020)	350	70	700
2 (2020 – 2021)	350	70	700
3 (2021 – 2022)	350	70	700
4 (2022 – 2023)	350	70	700

For example, if there are two bidders and they have proposed the total costs for each population and the Subscription Max listed in the following table:

	Bidder 1			Bidder 2		
Year	DAA – Non-Medicaid	DAA – Medicaid	Subscription Max	DAA – Non-Medicaid	DAA – Medicaid	Subscription Max
1	$50	$45	$10,000	$55	$50	$12,000
2	$48	$42	$10,000	$52	$45	$11,000
3	$46	$40	$10,000	$46	$40	$10,000
4	$45	$38	$10,000	$42	$36	$9,000

The following scores would be assigned:

	Bidder 1			Bidder 2		
Year	DAA – Non-Medicaid	DAA – Medicaid	Subscription Max	DAA – Non-Medicaid	DAA – Medicaid	Subscription Max
1	350	70	700	318.2	63	583.3
2	350	70	700	323.1	65.3	636.4
3	350	70	700	350	70	700
4	326.7	66.3	630	350	70	700
TOTAL	1,376.7	276.3	2,730	1,341.3	268.3	2,619.7
COST TOTAL	**4,383**			**4,229.3**		

The following table shows the total points available for both the non-cost and cost elements of Proposals:

RFP Element	**Total Available Points**
Bona Fide Services	1,400
DAA – Non-Medicaid (Years 1 – 4)	1,400
DAA – Medicaid (Years 1 – 4)	280
Subscription Max (Years 1 – 4)	2,800
TOTAL	**5,880**
Oral Presentation (if any)	1,000
TOTAL	**6,880**

HCA reserves the right to award the contract to the Bidder whose proposal is deemed to be in the best interest of HCA and the State of Washington.

4.3. ORAL PRESENTATIONS MAY BE REQUIRED

HCA may, after evaluating the written proposals, elect to schedule oral presentations for one (1) or more Bidders. Should oral presentations be scheduled, HCA will contact the top-scoring firm(s) from the written evaluation to schedule a date, time, and location. Commitments made by the Bidder at the oral interview, if any, will be considered binding.

The scores from the written evaluation and the oral presentation combined together will determine the Bidders with the highest scores.

4.4. SUBSTANTIALLY EQUIVALENT SCORES

Substantially equivalent scores are scores separated by two percent or less in total points. If multiple Proposals receive a Substantially Equivalent Score, HCA may leave the matter as scored, or select

as the ASB the one Proposal that is deemed by HCA, in its sole discretion, to be in HCA's best interest relative to the overall purpose and objective as stated in Sections 1.1 and 1.2 of this RFP.

If applicable, HCA's best interest will be determined by HCA managers and executive officers, who have sole discretion over this determination. The basis for such determination will be communicated in writing to all Bidders with equivalent scores.

4.5. NOTIFICATION TO BIDDERS

HCA will notify the ASB(s) of their selection in writing upon completion of the evaluation process. Bidders whose proposals were not selected for further negotiation or award will be notified separately by email.

4.6. DEBRIEFING OF UNSUCCESSFUL BIDDERS

Any Bidder who has submitted a Proposal and been notified it was not selected as an ASB may request a debriefing. The request for a debriefing conference must be received in writing (email is acceptable) by the RFP Coordinator no later than 5:00 p.m., Pacific Time, within three (3) Business Days after the Unsuccessful Bidder Notification is emailed to the Bidder. The debriefing will be held within three (3) Business Days of the request, or as schedules allow.

Discussion at the debriefing conference will be limited to the following:

- Evaluation and scoring of the Bidder's Proposal;
- Critique of the Proposal based on the evaluation; and
- Review of the Bidder's final score in comparison with other final scores without identifying the other Bidders.

Topics a Bidder could have raised as part of the complaint process (Section 2.9) cannot be discussed as part of the debriefing conference, even if the Bidder did not submit a complaint.

Comparisons between proposals, or evaluations of the other proposals, will not be allowed. Debriefing conferences may be conducted in person or on the telephone and will be scheduled for a maximum of thirty (30) minutes.

4.7. PROTEST PROCEDURE

A bid protest may be made only by Bidders who submitted a response to this RFP and who have participated in a debriefing conference. Upon completing the debriefing conference, the Bidder is allowed five (5) Business Days to file a protest with the RFP Coordinator. Protests must be received by the RFP Coordinator no later than 4:30 p.m., Pacific Time, in Olympia, Washington on the fifth Business Day following the debriefing. Protests may be submitted by email or by mail. The Bidder is solely responsible for ensuring the RFP Coordinator receives the protest, and the Bidder must maintain proof of delivery of the protest.

Bidders protesting this RFP must follow the procedures described below. Protests that do not follow these procedures will not be considered. This protest procedure constitutes the sole administrative remedy available to Bidders under this RFP.

All protests must be in writing, addressed to the RFP Coordinator, and signed by the protesting party or an authorized agent. The protest must state (1) the RFP number, (2) the grounds for the protest

with specific facts, (3) complete statements of the action(s) being protested, and (4) the relief or corrective action being requested.

4.7.1. Only protests alleging an issue of fact concerning the following subjects will be considered:

a. A matter of bias, discrimination, or conflict of interest on the part of an evaluator;

b. Errors in computing the score; or

c. Non-compliance with procedures described in the RFP or HCA requirements.

Protests based on anything other than those items listed above will not be considered. Protests will be rejected as without merit to the extent they address issues such as: 1) an evaluator's professional judgment on the quality of a Proposal; or 2) HCA's assessment of its own needs or requirements.

Upon receipt of a protest, HCA will undertake a protest review. The HCA Director, or an HCA employee delegated by the HCA Director who was not involved in the RFP, will consider the record and all available facts. If the HCA Director delegates the protest review to an HCA employee, the Director nonetheless reserves the right to make the final agency decision on the protest. The HCA Director or his or her designee will have the right to seek additional information from sources he or she deems appropriate in order to fully consider the protest.

If HCA determines in its sole discretion that a protest from one Bidder may affect the interests of another Bidder, then HCA may invite such Bidder to submit its views and any relevant information on the protest to the RFP Coordinator. In such a situation, the protest materials submitted by each Bidder will be made available to all other Bidders upon request.

4.7.2. The final determination of the protest will:

a. Find the protest lacking in merit and uphold HCA's action; or

b. Find only technical or harmless errors in HCA's acquisition process and determine HCA to be in substantial compliance and reject the protest; or

c. Find merit in the protest and provide options to the HCA Director, which may include:

(i) Correct the errors and re-evaluate all Proposals; or

(ii) Issue a new solicitation document and begin a new process; or

(iii) Make other findings and determine other courses of action as appropriate.

If the protest is not successful, HCA will enter into a contract with the ASB(s), assuming the parties reach agreement on the contract's terms.

5. RFP EXHIBITS

Exhibit A	Certifications and Assurances
Exhibit B	Diverse Business Inclusion Plan
Exhibit C	Cost Proposal
Exhibit D	Governor's Directive 18-13
Exhibit E	Distribution Models

EXHIBIT A

CERTIFICATIONS AND ASSURANCES

I/we make the following certifications and assurances as a required element of the proposal to which it is attached, understanding that the truthfulness of the facts affirmed here and the continuing compliance with these requirements are conditions precedent to the award or continuation of the related contract:

1. I/we declare that all answers and statements made in the proposal are true and correct.

2. The prices and/or cost data have been determined independently, without consultation, communication, or agreement with others for the purpose of restricting competition. However, I/we may freely join with other persons or organizations for the purpose of presenting a single proposal.

3. The attached proposal is a firm offer for a period of 120 days from the due date for receipt of proposals, and it may be accepted by HCA without further negotiation (except where obviously required by lack of certainty in key terms) at any time within such period.

4. In preparing this proposal, I/we have not been assisted by any current or former employee of the State of Washington whose duties relate (or did relate) to this proposal or prospective contract, and who was assisting in other than his or her official, public capacity. If there are exceptions to these assurances, I/we have described them in full detail on a separate page attached to this document.

5. I/we understand that HCA will not reimburse me/us for any costs incurred in the preparation of this proposal. All proposals become the property of HCA, and I/we claim no proprietary right to the ideas, writings, items, or samples, unless so stated in this proposal.

6. Unless otherwise required by law, the prices and/or cost data which have been submitted have not been knowingly disclosed by the Bidder and will not knowingly be disclosed by him/her prior to opening, directly or indirectly, to any other Bidder or to any competitor.

7. I/we agree that submission of the attached proposal constitutes acceptance of the solicitation contents. If there are any exceptions to these terms, I/we have described those exceptions in detail on a page attached to this document.

8. No attempt has been made or will be made by the Bidder to induce any other person or firm to submit or not to submit a proposal for the purpose of restricting competition.

9. I/we grant HCA the right to contact references and other, who may have pertinent information regarding the ability of the Bidder and the lead staff person to perform the services contemplated by this RFP.

10. If any staff member(s) who will perform work on this contract has retired from the State of Washington under the provisions of the 2008 Early Retirement Factors legislation, his/her name(s) is noted on a separately attached page.

On behalf of the Bidder submitting this proposal, my name below attests to the accuracy of the above statement. *If electronic, also include*: We are submitting a scanned signature of this form with our proposal.

_____
Signature of Bidder

_____
Printed Name

_____
Title Date

Exhibit B

DIVERSE BUSINESS INCLUSION PLAN

Do you anticipate using, or is your firm, a State Certified Minority Business?	Y/N
Do you anticipate using, or is your firm, a State Certified Women's Business?	Y/N
Do you anticipate using, or is your firm, a State Certified Veteran Business?	Y/N
Do you anticipate using, or is your firm, a Washington State Small Business?	Y/N

If you answered No to all of the questions above, please explain:

_____

Please list the approximate percentage of work to be accomplished by each group:

Minority	__%
Women	__%
Veteran	__%
Small Business	__%

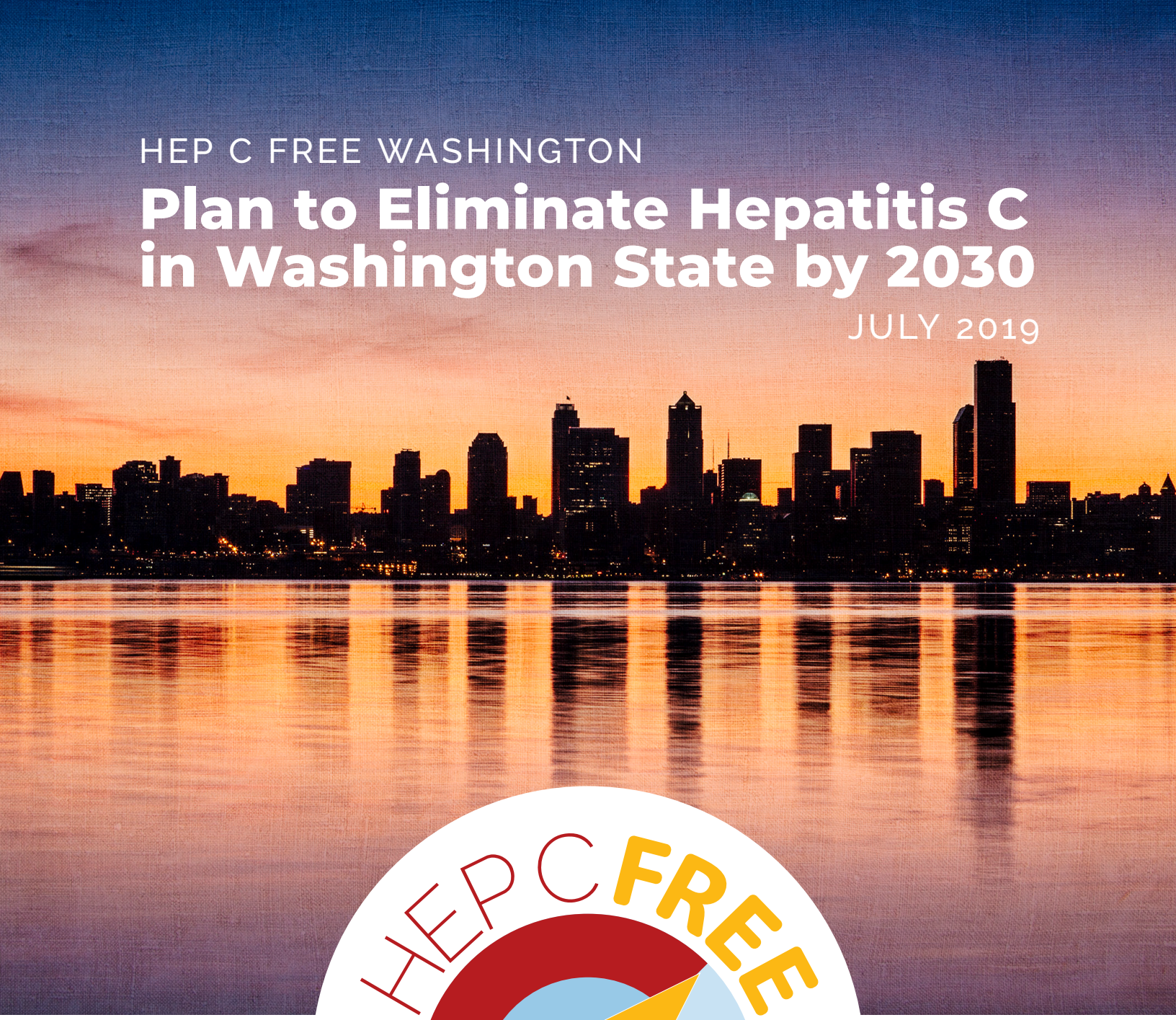
Please identify the person in your organization to manage your Diverse Inclusion Plan responsibility.

Name: _____

Phone: _____

E-Mail: _____

Appendix C: Hep C Free Washington Plan to Eliminate Hepatitis C in Washington State by 2030



HEP C FREE WASHINGTON

Plan to Eliminate Hepatitis C in Washington State by 2030

JULY 2019

HEP C FREE

WASHINGTON 2030

WORLD HEPATITIS DAY | JULY 28

For more information

Hep C Free Washington
c/o Washington State Department of Health
Division of Disease Control & Health Statistics
Office of Infectious Disease
P.O. Box 47840 Olympia, WA 98504-7840
800-272-2437
HepCFreeWA@doh.wa.gov
www.doh.wa.gov/HepCFreeWA

150-NonDOH

Contents

Hepatitis C Free Washington (Hep C Free WA)

Who we are: A collective impact initiative seeking a multisector response to the public health threat of hepatitis C.

Our vision: A world free from hepatitis C.

Our mission: Working together to eliminate hepatitis C in Washington State by the year 2030.

Our values:

- **Easy access for all.** Hep C Free WA believes all people at risk for and living with hepatitis C should have easy access to testing, care, and a cure for hepatitis C.
- **Uphold the dignity of each person.** Hep C Free WA believes we must reduce hepatitis C related stigma, recognize the worth of affected communities, and ensure whole-person care to eliminate hepatitis C and promote wellness.
- **Clear communication.** Hep C Free WA strives to educate all Washingtonians about hepatitis C, including how to prevent hepatitis C, where to get tested, and how to get cured.
- **Health equity.** Hep C Free WA works so that all communities impacted by hepatitis C receive what they need, including services that are culturally relevant and in language they understand, to prevent, diagnose, and cure hepatitis C and achieve the highest level of health and wellbeing.
- **Innovative solutions.** Hep C Free WA seeks new and creative ideas to address hepatitis C by centering the voices of those disproportionately impacted and pairing community wisdom and strengths with the best available data.

Executive Summary

The hepatitis C virus (HCV) is a public health crisis in Washington State. At the beginning of 2018, an estimated 59,100 Washingtonians were living with HCV. In September 2018, Governor Inslee issued **Directive of the Governor 18–13** (the Directive), "Eliminating Hepatitis C in Washington by 2030 through combined public health efforts and a new medication purchasing approach." In response to the Directive, the Washington State Department of Health brought together a broad range of partners to develop the Hep C Free Washington initiative. With a shared mission of eliminating HCV in Washington State by the year 2030, the partners developed a set of recommended goals and actions to achieve the mission.

Hep C Free WA Goals

Overarching Coordination Goal

1. Ensure implementation of the Hep C Free WA recommendations in order to achieve HCV elimination by 2030.

Data and Strategic Information Goals

2. Identify data sources and strategies to strengthen the characterization of HCV disease burden within Washington State.
3. Obtain resources and build capacity for continuous data monitoring, evaluation, quality improvement, and reporting.
4. Identify and track data metrics using currently available data.
5. Determine metrics using data not yet available or accessible.

Community-Based Responses and Interventions Goals

6. Improve access to and use of preventive and health care services in non-clinical settings through expansion and co-location of services.
7. Improve access to and use of clinical care and supportive services by sufficiently scaling coverage and widening the scope of community-based navigation and case management programs.
8. Increase HCV awareness, resources, and education, and reduce stigma.

Clinical Strategies Goals

9. Improve access to and use of clinical care for marginalized populations at risk for or living with HCV through innovative service delivery models.
10. Build the capacity of the health care workforce to diagnose and treat HCV.
11. Improve diagnosis of HCV in primary care settings.
12. Improve HCV disease intervention services.
13. Improve access to HCV treatment and comprehensive health care.
14. Improve the ability of people taking HCV direct-acting antivirals to complete treatment.
15. Improve follow-up clinical care for people who have completed HCV treatment.

Hep C Free Washington Coordinating Committee and Work Group Members

Julie Akers, PharmD, BCACP (Washington State University)

Hilary Armstrong, MPH (Public Health – Seattle & King County)

Amanda Avalos, MPA (Washington State Health Care Authority); *Co-chair, Data & Strategic Information Work Group*

Scott D. Bertani, MNM (Lifelong AIDS Alliance)

Lauren A. Beste, MD, MSc (University of Washington & VA Puget Sound Health Care System)

Jessica Blose, CDP, LMHC (Washington State Health Care Authority)

Tarrah Calender, MN, RN (VA Puget Sound Health Care System)

Stella Chang (Washington State Health Care Authority)

Jim Coffee (Cowlitz Family Health Center)

Emily Colgate, MD (CHAS Health)

Carri Comer (Washington State Department of Health)

Sarah Deutsch, MPH (Washington State Department of Health)

Warren Dinges, MD, PhD (Seattle Infectious Disease Clinic)

Jeff Duchin, MD (Public Health – Seattle & King County)

Leta Evaskus (Washington State Health Care Authority)

Tessa Fairfortune, MPH (Washington State Department of Health)

Mary Fliss, MHA (Washington State Health Care Authority)

Mary P. Goelz, RN/PHN (Pacific County Public Health and Human Services)

Monica Graybeal, PharmD (Yakima Valley Farm Workers Clinic); *Co-Chair, Clinical Strategies Work Group*

William Hayes, PharmD (Washington State Department of Corrections)

Edgar Hernandez-Garcia, MSW, LICSW (VA Puget Sound Health Care System)

Leah Hole-Marshall, JD (Washington Health Benefit Exchange)

Emalie Huriaux, MPH (Washington State Department of Health)

George Ioannou, MD, MS (University of Washington & VA Puget Sound Health Care System); *Co-chair, Data & Strategic Information Work Group*

Meg Jones, JD (Association of Washington Healthcare Plans)

Patrick Judkins (Thurston County Public Health & Social Services)

Danielle Kenneweg, MPA (Washington State Department of Health)

Asif Khan, MD (Northwest Integrated Health)

Jennifer Lam, MPH (Washington State Department of Health)

Malika Lamont, MPA (Public Defender Association)

Jessica Leston, DrPH, MPH (Northwest Portland Area Indian Health Board)

Scott Lindquist, MD, MPH (Washington State Department of Health)

Kathy Lofy, MD (Washington State Department of Health)

Bob Lutz, MD, MPH (Spokane Regional Health District)

Krista Lynch Concannon (Washington State Health Care Authority)

Jaymie Mai, PharmD (Washington State Department of Labor & Industries)

Aleks Martin, MSW, CDP (Hepatitis Education Project)

Jasmine Matheson, MPH (Washington State Department of Health)

Vanessa McMahan, PhD, MS (People's Harm Reduction Alliance)

Brittany Millard-Hasting, MD (Northwest Integrated Health)

Bethany Mizushima (Grays Harbor Public Health & Social Services)

Thea Mounts (Washington State Office of Financial Management)

Meaghan Munn, MPH (Public Health – Seattle & King County)

Erik Ness, MD, M.Phil.

Kara Nester, MPH (Washington Health Benefit Exchange)

Michael Ninburg (Hepatitis Education Project)

Shana Paulsen, MPH (Washington State Department of Health)

Ryan Pistoresi, PharmD, MS (Washington State Health Care Authority)

Willie Rhodes, Jr., BBA, M.Div. (Washington State Department of Health)

Jessica Rienstra, RN (Lummi Tribal Health Center)

John Scott, MD, MSc (University of Washington)

Erick Seelbach, MAT (Pierce County AIDS Foundation)

Alisa Solberg, MPA (Tacoma-Pierce County Health Department)

Mark Springer (Spokane Regional Health District)

Kim Steele-Peter, MPH (Tacoma-Pierce County Health Department)

Jason Sterne (Hepatitis Education Project); *Chair, Community-Based Responses & Interventions Work Group*

Jon Stockton, MHA, BS (Washington State Department of Health)

Lara Strick, MD, MSc (Washington State Department of Corrections & University of Washington)

Donna Sullivan, PharmD, MS (Washington State Health Care Authority); *Co-Chair, Clinical Strategies Work Group*

Kathryn Szymanowski (Tacoma Needle Exchange, Dave Purchase Project)

Judith Tsui, MD, MPH (University of Washington)

Thomas Weiser, MD, MPH (Portland Area Indian Health Service)

Sydney Wilson (community member)

Wendy T. Wong, RPh (Providence Centralia Hospital Pharmaceutical Care Clinic)

Judy Zerzan, MD, MPH (Washington State Health Care Authority)

Introduction

"Hepatitis" means inflammation of the liver. There are many causes of liver inflammation, including heavy alcohol use, toxins, some medications, and certain medical conditions. Hepatitis is often caused by a virus (known as "viral hepatitis"). A virus that primarily attacks the liver, causing inflammation, is called "hepatitis," followed by a letter (e.g., A, B, C, D).

The three most common forms of viral hepatitis in the United States are hepatitis A virus (HAV), hepatitis B virus (HBV), and hepatitis C virus (HCV). Although each can cause similar symptoms, they are spread in different ways and can affect the liver differently.

- **Hepatitis A** is usually a short-term (acute) infection that goes away on its own. It spreads through oral-fecal contact, such as through contaminated food or water. This can happen when a person with HAV does not adequately wash their hands and prepares or serves food. It can also spread during oral-anal sex contact ("rimming") with someone with HAV). There are vaccines to prevent HAV. There is no specific medical treatment for HAV.
- **Hepatitis B** can also begin as a short-term infection, but in some people the virus remains in the body and causes lifelong (chronic) infection. More than 90% of infants that are infected develop chronic HBV infection. In otherwise healthy adults, only 5-10% of those infected develop chronic HBV infection. For the other 90% of adults, the infection will go away on its own. Hepatitis B spreads through blood-to-blood contact (e.g., sharing of needles and syringes, sharing of medical equipment such as glucose monitoring devices) or when sexual fluid from someone living with HBV enters the body of someone without the virus (e.g., through condomless sex). A pregnant person living with HBV can transmit the virus to their child at birth. Many

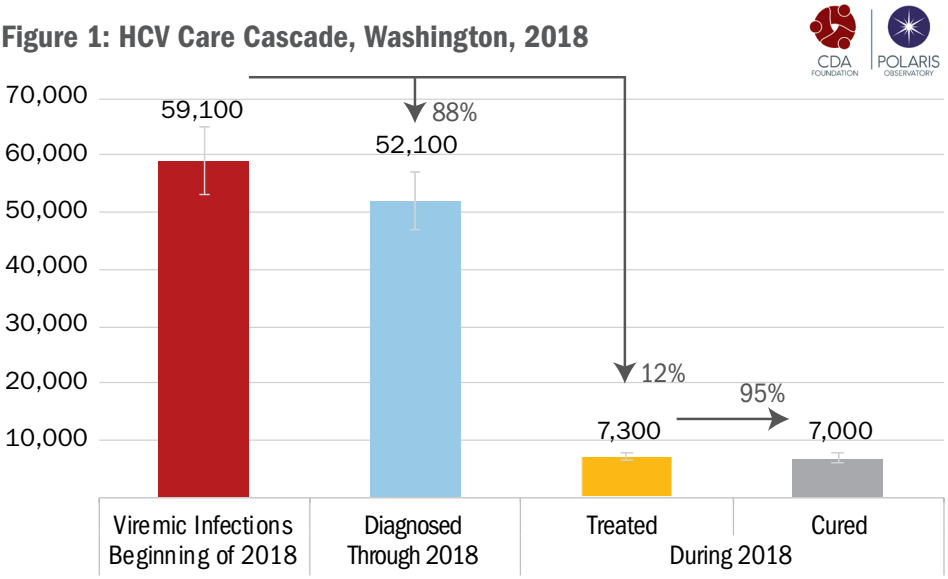
people will not have any noticeable symptoms for many years, but during this time the virus damages the liver. Like HAV, there are vaccines to prevent HBV. Most people diagnosed with chronic HBV infection need medical treatment for the rest of their lives. While not a cure, the medication helps reduce the risk of liver disease and prevents the spread of HBV to others.

- **Hepatitis C** can also begin as a short-term infection (occurring within the first six months after someone is exposed to the hepatitis C virus). It spreads through blood-to-blood contact. For about 75% of people, the virus stays in the body and becomes a chronic (lifelong) infection if left untreated. Many people will not have any noticeable symptoms for many years, but during this time the virus damages the liver. Unfortunately, there is no vaccine to prevent HCV. However, new all-oral medications called "direct acting antivirals" (DAAs) can cure the infection in almost all patients in as little as eight weeks with minimal or no side effects.

Every year HCV kills more people than over 60 other CDC-reportable infectious diseases combined, including HIV, HBV, and tuberculosis.

Hepatitis C is the most common bloodborne (spread by blood) infection in the United States. The United States Centers for Disease Control and Prevention (CDC) estimate that about 2.4 million people are living with HCV in this country, but the actual number could be much higher. In the United States, reported cases of acute (new) HCV infection increased 350% from 2010 through 2016 (from 850 to 2,967 reported cases), rising each year during this period. This increase reflects new infections associated with rising rates of injection-drug use, and, to a lesser extent, improved testing and case detection. Several investigations of newly acquired HCV infections found that most occurred among young persons (20-39 years old) who inject drugs. Most new cases of acute HCV are not identified or reported to public health because most adults and adolescents with HCV do not have symptoms. The CDC estimates 41,200 new HCV infections happened in 2016.[1] In the United States, HCV is a leading cause of liver cancer and one of the leading causes of liver damage resulting in the need for liver transplant. In addition, HCV has extrahepatic manifestations — in other words, HCV can cause conditions outside of the liver. For example, HCV is associated with hematologic, endocrine, neurologic, cardiovascular, and renal disease.[2] Every year HCV kills more people than over 60 other CDC-reportable infectious diseases combined, including HIV, HBV, and tuberculosis.

Figure 1: HCV Care Cascade, Washington, 2018



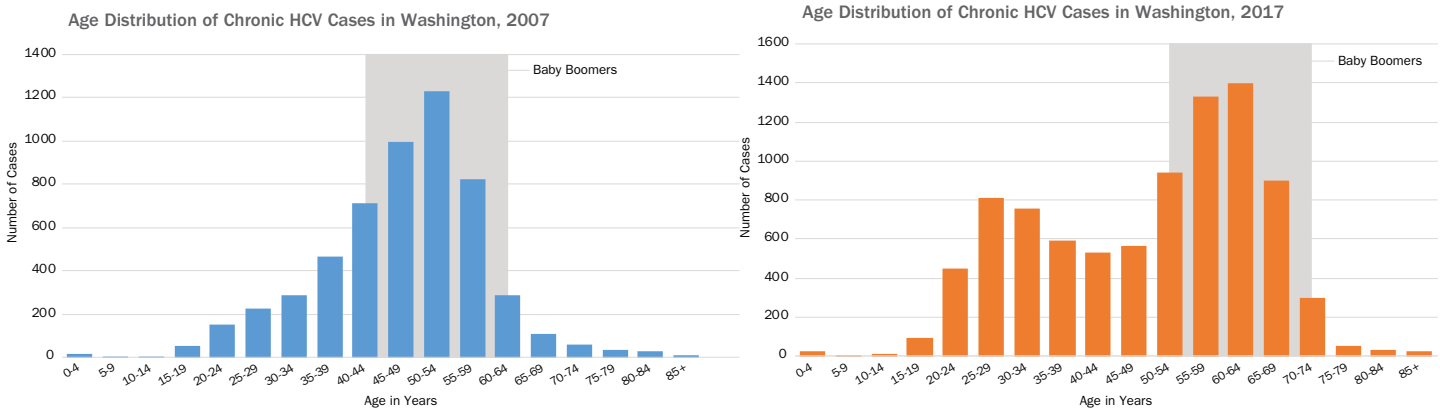
Source: Center for Disease Analysis Foundation report, 2019 (Appendix A)

In 2018, there were 188 reports of acute HCV infection in Washington, the most since 1995.

The HCV "treatment cascade," sometimes called the "care cascade," outlines the sequence of steps or continuum of services critical for addressing the testing, linkage to care, and treatment needs of people living with HCV.[3] **Figure 1** uses projections developed by the Center for Disease Analysis Foundation based on the best available data in Washington (**Appendix A**). It shows that while a high proportion of people living with HCV (labeled as "viremic infections) know their HCV status (labeled as "diagnosed"), few of them were actually connected to care and received HCV treatment in 2018. In Washington State, at the beginning of 2018, 79%, or 46,500, of the estimated 59,100 people (using a 95% uncertainty interval, 32,500-71,500 people is the possible range) living with chronic HCV were diagnosed. Of the total number of people living with HCV, 12% (7,300) were treated. Of the 7,300 treated, 95% (7,000) were cured. In 2018, it was estimated that about 2,950 Washingtonians were newly infected with HCV (39.9 per 100,000).

In Washington State, HCV poses a significant public health threat. On average, at least 582 people die from HCV-associated causes each year. From 2001 to 2010, an average of 24 cases of acute HCV infection were reported each year. Similar to national trends, since 2011, the number of acute cases in the state has risen dramatically. This reflects a rise in injection drug use associated with increased opioid and methamphetamine use, as well as improved detection of acute infection by health care providers. In 2018, there were 118 reports of acute HCV infection in Washington, the most since 1995. The number of chronic HCV cases reported to public health agencies has also increased. From 2001 to 2010, there were an average of 5,322 newly reported chronic HCV cases yearly. In 2016, there were 8,118 and, in 2017, there were 8,839 new reports. At this time, the data for 2018 are not finalized, but the number of chronic case reports is expected to be higher than previous years. Increases of chronic case reports are due to the rise in people injecting drugs, and improved testing — including universal one-time testing of Baby Boomers (people born from 1945 through 1965) and risk-based HCV testing — as recommended by the CDC.[4]

Figure 2: Age Shift among Chronic HCV Cases in Washington State, 2007 and 2017



Source: Washington State Department of Health, Hepatitis Surveillance Records

From 2007 to 2017 the state had a noticeable shift in the age distribution of newly reported chronic cases. This indicates two epidemics of chronic HCV — one among Baby Boomers and one among younger persons who were likely infected by sharing drug injection equipment.

From 2007 to 2017 the state had a noticeable shift in the age distribution of newly reported chronic cases. This indicates two epidemics of chronic HCV — one among Baby Boomers (indicated by the gray shaded areas in **Figure 2**), and one among younger persons (people under the age of 40 in 2017) who were likely infected by sharing drug injection equipment. In 2007, 68.6% of chronic cases were among Baby Boomers and 21.9% were among people under 40. In 2017, 52.2% of chronic cases were among Baby Boomers and 31.0% were among people under 40 (see **Figure 2**). People who were infected with HCV decades ago are at high risk of cirrhosis and liver cancer. People who inject drugs, including those who are living with HCV, are also at high risk of other health problems including overdose, skin and soft-tissue infections, HIV infection, and fulminant (severe and sudden) hepatitis caused by HAV or HBV co-infection.

Priority Populations for Hepatitis C in Washington State

Identifying priority populations who are impacted by HCV more than others helps focus public health and treatment efforts toward those most affected and address health disparities. In addition to Baby Boomers and people who inject drugs, other priority populations include people who have experienced incarceration, people living with HIV, African Americans, and Native Americans.

People in jails or prisons

While about 1% of the population of the United States is living with HCV, the rates among people in correctional institutions (i.e., jails and prisons) are much higher. Recent estimates of the rate of chronic HCV infections in U.S. prisons is 17.4%[5] to 23.1%.[6] Correctional populations represent about one third of total HCV cases in the United States.[7] Populations most affected by incarceration, such as people who inject drugs, are more likely to be at risk for or living with HCV. About 11–15% of people incarcerated at any one time in Washington State Department of Corrections facilities are living with chronic HCV.[8]

People living with HIV

In the United States, about 1 in 5 people living with HIV have evidence of past or present HCV infection. As both HIV and HCV can be transmitted through direct blood-to-blood contact (e.g., sharing equipment for drug injection), having both HCV and HIV infection (co-infection) is common among people who inject drugs. An estimated 62-80% of people who inject drugs who are living with HIV are also living with HCV.[9 10 11] Sexual transmission of HCV is generally rare, but possible. An increasing number of studies show that sexual transmission of HCV is an important mode of HCV acquisition among men who have sex with men who are living with HIV.[12 13 14 15] Activities that may increase vulnerability to HCV include condomless anal sex, sharing of unsterilized sex toys, and non-injection drug use (e.g., smoking or snorting stimulants like methamphetamine, or inhaling "poppers").[16] Hepatitis C can accelerate liver disease in people living with HIV.[17 18 19 20 21] Of people newly diagnosed with HIV in Washington in the year 2018, 10% had acute or chronic HCV infection. Of all people living with HIV in Washington at the end of 2018, 9% had chronic HCV infection.[22] Recent studies have shown that acute HCV may be impacting men who have sex with men who are not living with HIV. Vigilance may be needed to address the prevention needs of this population.[23 24]

Nationally, American Indian/Alaska Natives have the highest rates of acute HCV and a rate of death related to HCV that is 2.7 times higher than non-Hispanic whites.

African Americans are about 11% of the U.S. population, but they represent 25% of people living with chronic HCV.

African Americans and Native Americans

Although nearly 75% of race/ethnicity data is not provided on HCV case reports submitted to the Washington State Department of Health, other sources of national and state data show there are significant HCV-related disparities among African Americans and Native Americans.

African Americans are about 11% of the U.S. population, but they represent 25% of people living with chronic HCV.[25] This disparity is particularly evident among African Americans ages sixty and older, where the rate of HCV is 10 times higher than among older individuals of other races in the United States. In addition, HCV-related illness and death are higher among African Americans than among people who identify with other races.

Nationally, American Indian/Alaska Natives have the highest rates of acute HCV[26] and a rate of death related to HCV that is 2.7 times higher than non-Hispanic whites.[27] A recent analysis by the Northwest Portland Area Indian Health Board found that, during 2006-2012 in Washington State, American Indian/Alaska Native residents had a higher rate of HCV-associated death when compared to non-Hispanic whites.[28]

Stigma Experienced by People Living with Hepatitis C

Because of the relationship between HCV transmission and drug injection, people living with and those cured of HCV report social challenges telling people about their status. They report concern that they may be perceived as having injected drugs, whether they have or not, and therefore treated poorly in their communities, including by health and social service providers. Stigma may lead to isolation and withdrawal from medical care.[29]

During two community events held in May 2019, one in Seattle and one in Spokane, participants spoke powerfully about their experiences living with HCV. The selected quotes provided below underscore the importance of addressing HCV-related stigma and offering opportunities for people affected by HCV to discuss their experiences and learn from each other.

There is a stigma that only certain people get HCV — anyone can get it.

- *"You kept [HCV] quiet, you didn't say anything."*
- *"I'm co-infected [with HIV and HCV] and I got treated [and cured for HCV] and got re-infected… It was a lot harder to talk to my provider a second time… I felt their disappointment."*
- *"[When I first found out I was living with HCV] I told my husband… it was scary."*
- *"There is a stigma that only certain people get HCV — anyone can get it."*
- *"I didn't tell anyone — I was ashamed big time. I told my mom because she had it. I went to [a substance use treatment program] and talked to a counselor and that helped."*
- *"You can feel really lousy after addiction and some providers treat you crappy."*
- *"I had co-infection with HIV and hep C. It really sucked. I would talk to someone [living] with HIV online, but when I told him I also had hep C I got turned down [for a hook up] and rejected so I stopped disclosing the hep C… I stopped telling anyone about hep C."*
- *"People are really uneducated about hep C. My sister didn't want to share my soda or my soap in the shower. It hurt."*
- *"Everyone wanted to know how I got [HCV] and I didn't know. I just told everyone I was a child of the 70s — sex, drugs, and rock n roll."*
- *"I had neck surgery and got hooked on Dilaudid and eventually started injecting [heroin]. It was devastating to find out I had hep C… I got a massage… and told the massage therapist I had headaches related to my hep C treatment and that's why I was there. She walked out and came back and said, 'My supervisor says it's okay to touch you… Do you have any open sores?' I felt like I had the plague. I'm so ashamed because of my addiction. I haven't really told anyone except one of my daughters… My self-esteem is in the toilet."*
- *"It was embarrassing and I'm ashamed of what I did to my life and I'm really grateful for being treated [for HCV]. I don't feel like I'm worth it."*

Hep C Free Washington — The State Hepatitis C Elimination Initiative

Hepatitis C elimination is defined as a state where HCV is no longer a public health threat and where those few people who become infected with HCV learn their status quickly and access curative treatment without delay, preventing the spread of the virus. There is a global conversation about HCV elimination occurring, both at the World Health Organization[30] and in a number of countries (e.g., Georgia[31], Australia[32], Scotland[33]). While the United States does not have a federally supported national HCV elimination strategy, the National Academies of Sciences, Engineering & Medicine released **A National Strategy for the Elimination of Hepatitis B and C** (2017),[34] and the U.S. Department of Health & Human Services developed the **National Viral Hepatitis Action Plan, 2017–2020**.[35] In addition, a number of Tribal Nations (e.g., Lummi Nation[36], Cherokee Nation[37]) and state and local jurisdictions (e.g., San Francisco[38], New Mexico[39], New York State[40]) are working on HCV elimination strategies.

The tools exist to eliminate the public health threat of HCV in Washington, but currently resources are not available at the level needed to achieve this goal.

The clock is ticking as HCV-related illness and death rise. Almost all people living with HCV can be cured with a short-course, well-tolerated, all-oral treatment. Scaled up HCV treatment paired with prevention of infection and re-infection (e.g., access to sterile injection equipment and medication treatment, such as buprenorphine and methadone, for opioid use disorder) can lead to HCV elimination. The tools exist to eliminate the public health threat of HCV in Washington, but currently resources are not available at the level needed to achieve this goal.

The federal response to HCV has been very different from the response to similar public health threats like HIV and sexually transmitted infections. These conditions receive much more robust federal funding through agencies like CDC and the Health Resources Services Administration.

In Washington State, given the lack of resources for HCV, most local health jurisdictions do not have staff dedicated to working on HCV. The Washington State Department of Health leverages limited federal and state funds to support some local community efforts including: rapid HCV antibody screening in community settings, an HCV health education program, Project ECHO (a virtual clinical consultation program to train primary care providers to treat HCV), and a few screening programs in local county jails and federally qualified health centers. In addition, the Department of Health supports a number of syringe service programs throughout the state. These programs play a critical role in supporting people who inject drugs to prevent infection and re-infection, and helping connect them to healthcare and social services. The resources available through the Department of Health are not sufficient to meet the need for these services throughout the state. In most cases, these community efforts must also look for support from other partners (e.g., local governments, private donors).

Because medications can cure almost everyone living with HCV, it is imperative to identify, link, and cure everyone living with HCV as quickly as possible. For Baby Boomers, the peak of HCV-related complications (e.g., cirrhosis complications, liver cancer, liver transplants, and deaths) is estimated to be around the year 2030. Among younger people, acute HCV is increasing due to the opioid crisis and increased injection drug use.

Failure to increase testing and treatment means the HCV epidemic will continue and there will be more preventable illnesses and deaths. In addition to the human value of providing treatment, recent studies show that HCV treatment is cost effective and creates a clear economic benefit. Preventing new infections and linking people living with HCV to treatment will reduce Washington State's expenditures in the long term by reducing health care costs.[41]

Preventing new infections and linking people living with HCV to treatment will reduce Washington State's expenditures in the long term by reducing health care costs.

In September 2018, Governor Inslee issued **Directive of the Governor 18–13** (the Directive), "Eliminating Hepatitis C in Washington by 2030 through combined public health efforts and a new medication purchasing approach" (**Appendix B**).

One part of the Directive calls for the Washington State Health Care Authority[42] to secure innovative methods to purchase HCV direct acting antiviral medication and ensure timely access for Washingtonians living with HCV. According to the Health Care Authority, about 30,000 people living with HCV in Washington are covered by state-purchased health care insurance and programs, including Washington Apple Health (Medicaid), the Public Employees Benefits Board Program, the Department of Corrections, the Department of Labor & Industries, and the Department of Social & Health Services (state hospitals).[43]

Through participation in the State Medicaid Alternative Reimbursement and Purchasing Test for High Cost Drugs (SMART-D) collaborative, the Health Care Authority released a request for proposals for drug manufacturers to bid on January 22, 2019, and on April 25, 2019 announced AbbVie US LLC (AbbVie) as the apparently successful bidder (the bidder advanced to the next step in the process to engage in contract negotiations). AbbVie was chosen because they provided the best overall portfolio to assist Washington with eliminating HCV. They offer a product that is clinically appropriate for about 97% of all people living with HCV and they have demonstrated a commitment to partner with the Health Care Authority to eliminate HCV through its investment in the Hep C Free WA initiative. The Health Care Authority finalized the contract with AbbVie on July 1, 2019.

Another of the Directive's major components is the establishment of a committee comprised of a broad array of stakeholders, including people personally affected by HCV. The committee's charge was to draw on existing efforts, best practices, and community knowledge to develop a comprehensive strategy to eliminate the public health threat of HCV in Washington by 2030.

Hep C Free Washington

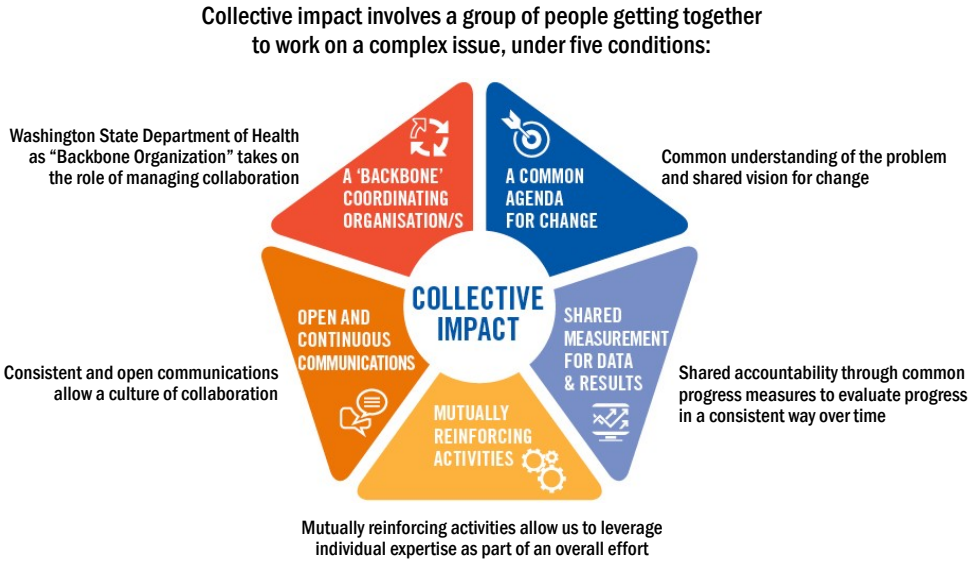
Our vision: A world free from hepatitis C.

Our mission: Working together to eliminate hepatitis C in Washington State by the year 2030.

Our values:

- **Easy access for all**. Hep C Free WA believes all people at risk for and living with hepatitis C should have easy access to testing, care, and a cure for hepatitis C.
- **Uphold the dignity of each person**. Hep C Free WA believes we must reduce hepatitis C related stigma, recognize the worth of affected communities, and ensure whole-person care to eliminate hepatitis C and promote wellness.
- **Clear communication**. Hep C Free WA strives to educate all Washingtonians about hepatitis C, including how to prevent hepatitis C, where to get tested, and how to get cured.
- **Health equity**. Hep C Free WA works so that all communities impacted by hepatitis C receive what they need, including services that are culturally relevant and in language that they understand, to prevent, diagnose, and cure hepatitis C and achieve the highest level of health and wellbeing.
- **Innovative solutions**. Hep C Free WA seeks new and creative ideas to address hepatitis C by centering the voices of those disproportionately impacted and pairing community wisdom and strengths with the best available data.

Figure 3: Collective Impact Model



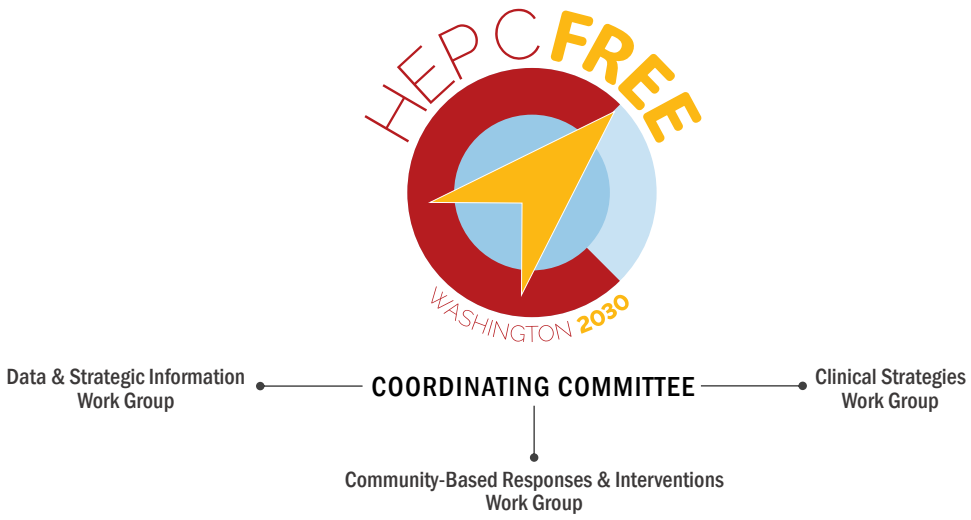
Using the principles of collective impact,[44] in October 2018, the Washington State Department of Health brought together multisector partners for the first meeting of what became the Hep C Free Washington (WA) Coordinating Committee. The committee has met monthly since. Members include representatives from state agencies and offices (e.g., the Health Care Authority, Department of Corrections, Department of Labor and Industries, Office of Financial Management, Office of the Insurance Commissioner, and the Department of Health), Tribal health centers, local health jurisdictions, federally qualified health centers, community-based organizations, syringe service programs, opioid treatment programs, academic institutions (University of Washington, Washington State University), health plans, professional organizations, and people affected by HCV.

The Department of Health acts as the "backbone organization" for Hep C Free WA. In the collective impact framework, the backbone organization pursues six common activities to support and facilitate collective impact, distinguishing this work from other types of collaborative efforts. Over the lifecycle of an initiative, the backbone organization:

1) Guides vision and strategy;
2) Supports aligned activities;
3) Establishes shared measurement practices;
4) Builds public will;
5) Advances policy; and
6) Mobilizes funding.

The Committee established three work groups, Data & Strategic Information, Clinical Strategies, and Community-Based Responses & Interventions, to draft recommendations based on their specific expertise.

Figure 4: Hep C Free WA Coordinating Committee Workgroups



The Data & Strategic Information Work Group reviewed existing data sources for the Hep C Free WA initiative to set baselines for measuring progress and to evaluate data strengths and limitations. The Work Group was charged with developing recommendations related to data, outcomes, and monitoring, including developing indicators for the initiative, and recommending improvements to data systems to capture needed baseline information.

The Community-Based Responses & Interventions Work Group was charged with developing recommendations to address HCV community health education and awareness, preventive services, testing, linkage to care, case management, and access to curative treatment in non-clinical (community-based settings that do not traditionally provide clinical services), high-impact settings (settings that serve a high proportion of clientele who inject drugs, such as outreach sites, syringe service programs, substance use disorder treatment facilities, opioid treatment programs, organizations serving people experiencing homelessness) to reach populations disproportionately impacted by HCV.

The Clinical Strategies Work Group was charged with developing recommendations related to clinically based HCV services, including: Health care provider education; testing and treatment in primary care; linkage from primary care to specialty care when needed; treatment and cure of HCV; treatment adherence and medical support services; and follow up care (e.g., liver cancer surveillance in people who are cured, but have advanced fibrosis).

The recommendations developed by the Hep C Free WA Coordinating Committee and Work Groups follow, along with a description of next steps as we enter the implementation and evaluation phase.

Recommendations

Below are the Hep C Free WA recommendations approved by the Hep C Free WA Coordinating Committee. Each recommended goal includes several action items.

Overarching Coordination Goal

The Hep C Free WA Coordinating Committee identified an overarching goal and funding and activities needed to ensure coordination and implementation of the recommendations contained herein.

Goal 1. Ensure implementation of the Hep C Free WA recommendations in order to achieve HCV elimination by 2030.

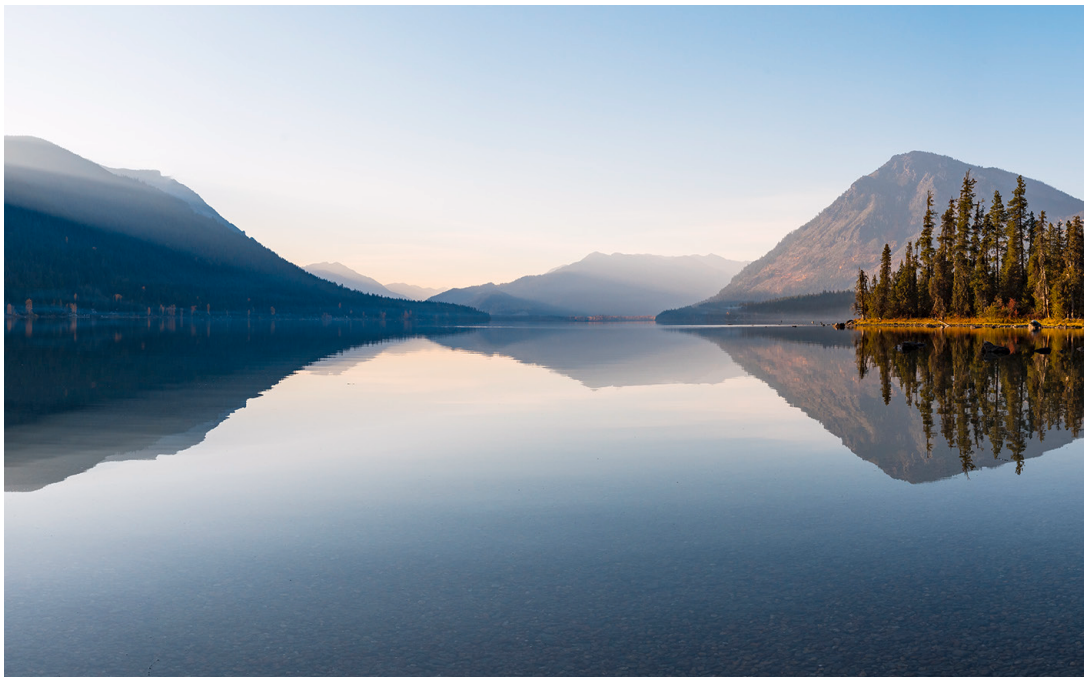
1.1 **Allocate funding to the Department of Health, the backbone organization for Hep C Free WA, to facilitate coordination of the Hep C Free WA initiative and coordinate implementation of the Hep C Free WA recommendations with other state agencies (e.g., Health Care Authority, Department of Corrections) and other public and private partners (e.g., Tribal nations, local health jurisdictions, community-based organizations, health care organizations).**

1.2 **Define governance and provide resources (e.g., to employ staff to support the Coordinating Committee and Work Groups, to cover travel expenses of Coordinating Committee members to attend meetings, to host Hep C Free WA community engagement events) for the continuation of the Hep C Free WA Coordinating Committee and topic specific work groups to improve multi-directional communication among the community, local health jurisdictions, and state agencies in order to advise the Department of Health and other relevant state agencies on the implementation of the Hep C Free WA recommendations.**

1.3 Create Hep C Free WA work groups focused on how to address the HCV prevention, care, and treatment needs of communities disproportionately impacted by HCV as identified by Hep C Free WA data monitoring and analyses (e.g., people who inject drugs, women of transgender experience, men who have sex with men, Native Americans, African Americans). See action item 3.11.

1.4 Create Hep C Free WA community leadership opportunities (e.g., a community leadership program, community engagement events) for and promote the involvement of people affected by HCV and people from communities disproportionately impacted by HCV in the Hep C Free WA coordinating committee and work groups to ensure ongoing engagement in the implementation and refinement of the Hep C Free WA plan over time.

1.5 Align the Hep C Free WA plan with the End AIDS Washington plan[45], the state Opioid Response Plan[46], and other strategic documents related to the syndemics (braided epidemics) of HCV to ensure coordination and communication among these related efforts.



Data and Strategic Information Goals

Goal 2. Identify data sources and strategies to strengthen the characterization of HCV disease burden within Washington State.

2.1 Mandate the reporting of non-positive HCV RNA (viral load) tests to local health jurisdictions, as well as positive ones, to allow tracking of spontaneous HCV clearance and successful HCV curative treatment.

Background: Reactive HCV antibody tests and positive HCV RNA tests must be reported by health care providers, facilities, and laboratories to the local health jurisdiction and to health authorities in Washington State as stated in Washington Administrative Code (WAC) 246-101[47]. The purpose of this reporting is to identify sources of infection and to prevent further transmission from such sources; identify new groups at risk and reduce further cases; inform cases about treatment options; educate cases and contacts about transmission of HCV and how to reduce the risk of transmission; and better understand the epidemiology of HCV infection and the burden of morbidity from chronic infection. The Department of Health is currently working on WAC revisions regarding reporting of negative test results, which would be used to determine when a previously reported case becomes non-infectious; to identify newly acquired infections through identification of a seroconversion window; or to provide information critical for assignment of a case definition. The Department of Health received some push back from labs and the public on reporting of negative antibody tests due to the volume and privacy concerns. A separate system may be needed to house negative test results (similar to the model being used in the state of Utah[48]). Labs could submit aggregate data for screening tests in order for public health to calculate screening rates. Ongoing leadership from entities interested in this policy change is needed as opportunities for public comment on this issue arise in the late summer and fall of 2019.[49]

2.2 Use the All Payer Claims Database and Department of Health HCV surveillance data as primary data sources for statewide monitoring and reporting.

Background: The Washington All Payer Claims Database (WA-APCD) is a health care claims data source, which includes all claims data for Medicaid, Medicare, the Public Employees Benefit Board (PEBB) plan, and about half of private payers. For private payers, the WA-APCD includes all claims for the individual market, but most claims for self-insured plans are not included. The School Employees Benefit Board plan will begin submitting data to the WA-APCD in 2020. The CDC have developed a methodology for using claims data to create an HCV care cascade and Washington should explore creating such a cascade with data from the WA-APCD.[50] The WA-APCD has some limitations. Data from the WA-APCD can allow us to quantify the number of HCV tests conducted and the number of direct-acting antiviral treatments provided, but does not provide information on test results, so we cannot determine if someone is living with HCV or if treatment has resulted in cure.

Department of Health HCV surveillance data are housed in a person-based system within the Washington Disease Reporting System (WDRS). It includes all reported cases of acute, chronic, and perinatal HCV infection in Washington. A proportion of labs that report electronically also submit negative RNA results, which are uploaded into WDRS.

2.3 Use other novel data sources, such as vital records, cancer registries, other infectious disease registries, and data from the Department of Corrections, to strengthen the development of a care cascade for the state and for specific priority populations.

Background: Birth and death records can be matched with the HCV surveillance registry to strengthen the Department of Health's ability to develop an accurate prevalence estimate for Washington and to assist in perinatal HCV case follow up. The Washington State Cancer Registry should be matched with the Department of Health's HCV surveillance records annually in order to illustrate the burden of the progression of HCV to hepatocellular carcinoma in Washington. A routine match between the HCV registry and other relevant infectious disease registries (e.g., HIV and HBV) should be done to understand the burden of co-infections. Because the Department of Corrections provides data on testing and lab results to the Department of Health and fully captures demographic data, including race/ethnicity data (which is often missing from case reports submitted by other facilities), the Departments of Health and Corrections should work together to complete an annual focused analysis in order to create a care cascade for the prisons and to analyze health disparities issues.

Goal 3. Obtain resources and build capacity for continuous data monitoring, evaluation, quality improvement, and reporting.

3.1 Employ a multiagency approach to monitoring progress (including the Health Care Authority, the Department of Health, the Office of Financial Management, the Department of Corrections, the Department of Social & Health Services, the Health Benefit Exchange) and identify and resource an agency (e.g., the Department of Health) to employ staff to analyze all state data and develop an annual HCV data report.

3.2 Add resources and build capacity at the local health jurisdiction level to strengthen data quality and completeness and timeliness of HCV case reporting.

3.3 Add resources for a staff member at the Department of Health to handle increased HCV case reports from local health jurisdictions and link laboratory and case report data.

3.4 Build capacity to allow local health jurisdictions to produce HCV reports to independently create data analytics with prescribed methodology.

3.5 Ensure that all developed metrics will have baseline data, are evaluated at discrete benchmarks, and are monitored continually (see Goals 4 and 5).

3.6 Apply identified metrics, where appropriate and as resources allow, to different populations and sub-populations including the state, Accountable Communities of Health, counties, incarcerated populations, and priority populations (e.g., people who inject drugs, Native Americans, people who are pregnant, men who have sex with men, people born in high prevalence countries).

3.7 Use metrics to develop care cascades for the above populations. Metrics collected and evaluated will be used to develop statewide, Medicaid, Department of Corrections, and other sub-population care cascades.

3.8 Resource a modeling project every other year to track the number of patients needing to be treated annually to achieve 80% elimination by 2030, given current HCV prevalence, incidence, and mortality.

Background: In 2019, the Department of Health received one-time in-kind support from the Association of State & Territorial Health Officials to work with the Center for Disease Analysis Foundation to do this modeling, findings of which are summarized in the table below and provided in full in the report in Appendix A. Resources will be needed to repeat this modeling over time and evaluate progress.

The Center for Disease Analysis Foundation created two treatment scenarios for Washington: 1) Base scenario, the current standard of care assuming a near 40% drop in treatment between 2017 and 2020; and 2) Accelerated Elimination, the levels of intervention necessary to eliminate the disease burden by 2025. The elimination scenario is based on the World Health Organization's (WHO) Elimination Targets, defined as an 80% reduction in new infections, 90% diagnosis of all infections, and a 65% reduction in liver related mortality. This strategy requires the following numbers of people to be diagnosed and treated for HCV:

Scenario	Model parameters	2018	2019	2020	2021	≥2022
Base, WHO targets by 2030	Incident (new) infections	3,000	2,700	2,400	2,300	2,100
	Treated	7,300	7,000	4,900	4,900	4,900
	Newly diagnosed	5,600	5,600	3,900	3,900	1,800
Accelerated, WHO targets by 2025	Incident infections	3,000	2,700	2,200	1,400	800
	Treated	7,300	7,000	5,100	5,100	5,100
	Newly diagnosed	5,600	5,600	3,900	3,600	1,200

Under the base scenario, the number of Washingtonians with HCV peaked in 2000 and will continue to decline by 85% between 2017 and 2030, resulting in 10,700 (95% uncertainty interval, 200-26,700) Washingtonians with HCV by the end of 2030. Liver-related deaths, hepatocellular carcinoma (HCC) (liver cancer), and decompensated cirrhosis will also decrease by 90% as the population ages and a high level of treatment is maintained. Incident cases of HCC will decrease from 280 in 2017 to 20 in 2030 (90% decrease). Incident decompensated cirrhosis cases will decrease from 220 in 2017 to 20 in 2030 (90% decrease). Given the current standard of care in Washington, there would be 340 fewer liver-related deaths by 2030, a 90% decrease from 2017.

Under the World Health Organization elimination scenario, an average of 5,100 patients would need to be treated per year between 2020 and 2025 in order to achieve a 65% reduction in liver related deaths by 2025. Additional harm reduction efforts (i.e., improved access to sterile injection equipment and medication treatment for opioid use disorder) would also be needed to achieve an 80% reduction in new infections by 2025. Doing so would avert 5,800 new infections, 20 cases of decompensated cirrhosis, 25 cases of HCC and 35 liver-related deaths by 2025; and 9,400 new infections, 110 cases of decompensated cirrhosis, 130 cases of HCC and 190 liver-related deaths by 2030 compared to the base scenario.

The report by the Center for Disease Analysis Foundation underscores the need to focus efforts on people who inject drugs and other people at risk for or living with HCV who may be unengaged with health care services. Washington has largely addressed HCV among those easiest to engage in health care and who have access to HCV treatment. Efforts must evolve to address the challenging work ahead in order to ensure HCV elimination efforts reach all disproportionately affected communities.

3.9 Identify and collect qualitative data from populations who may experience barriers to care due to stigma. Collected data will help strengthen our understanding of how stigma impacts individual health outcomes and develop innovative strategies to reduce bias among service providers.

3.10 Develop an interactive dashboard through the Washington Tracking Network[51] to provide publicly available data on HCV and progress toward elimination at the county and Accountable Communities of Health levels.

3.11 Support, where possible, community epidemiological studies to determine the HCV seroprevalence in communities disproportionately impacted by HCV and who experience some of the greatest health inequities in Washington (e.g., women of transgender experience, people engaged in sex work, men who have sex with men, people who inject drugs, Native Americans, African Americans).

3.12 Strengthen bi-directional exchange of HCV surveillance data between healthcare delivery systems, payers of services, and public health systems to support evaluation and strengthen service delivery.

Background: The Department of Health currently provides rapid HCV antibody test kits to the cycle of the Washington-based National HIV Behavioral Surveillance (NHBS) focused on people who inject drugs. Funding permitted, the Department of Health should resource all cycles (e.g., men who have sex with men, high-risk heterosexuals, women of transgender experience) with rapid HCV antibody test kits in order to determine baseline prevalence of HCV antibodies in these communities, as well as support linkage to care services for people who test antibody reactive. Note that successful linkage to care means, at minimum, people living with HCV have attended a first medical appointment for evaluation or treatment.

3.13 Improve coordination among the Department of Health, local health jurisdictions, and community partners to strengthen HCV disease intervention and to assess levels of service needed to optimize outreach services.

3.14 Modernize data collection systems to track the number of unique people accessing services at syringe service programs throughout Washington in order to better understand the use of such programs by people who inject drugs and track improvement in access over time.

Goal 4. Identify and track data metrics using currently available data.

4.1 Identify the following metrics at baseline (i.e. reflecting the "current state") for recent years (e.g., 2017 and 2018) and then track prospectively during the 10-year period of the elimination effort (when possible national metrics and benchmarks, such as the Healthcare Effectiveness Data and Information Set and the National Quality Forum, should be used to make data comparable to other states and national data):

a. **HCV prevalence**. The estimated number of people living with HCV per 100,000 population.

b. **Acute HCV incidence**. The number of newly diagnosed acute HCV cases per 100,000 population.

c. **Chronic HCV incidence**. The number of newly diagnosed chronic cases per 100,000 population. This metric is an approximation, as it relies on newly reported cases (e.g., newly reported cases could have been diagnosed in years prior and may not actually be incident cases).

d. **Number of HCV antiviral treatment regimens**. The number of antiviral treatment regimens prescribed each year (or each six-month period).

e. **Estimated number of HCV cures**. The number of people with lab data to suggest successful HCV treatment (a positive RNA test followed by at least two consecutive negative RNA tests at least 30 days apart).

f. **HCV-associated mortality**. The number and rate of deaths in Washington each year attributed to HCV infections.

g. **All-cause mortality in people living with HCV**. The number and proportion of all-cause deaths in Washington each year among people living with HCV.

h. **Cost of HCV treatment for patients**. Average out-of-pocket costs paid per patient for HCV treatment.

Goal 5. Determine metrics using data not yet available or accessible.

5.1 The following metrics require data that are not currently available and may require additional effort to obtain. As soon as these data are available, these metrics should be identified at baseline and then tracked prospectively:

a. **Number of HCV screenings**. The number of persons screened for HCV during each year (or six-month period).

b. **Number of people at risk for HCV who remain unscreened**. The number (and proportion) of people in Washington at risk for HCV (e.g., Baby Boomers and people who inject drugs) who remain unscreened.

c. **Screening coverage in high-impact settings**. Number of high-impact settings offering routine opt-out HCV screening.

d. **Access to confirmatory testing**. The number of clients who have tested reactive for HCV antibodies that receive a subsequent RNA confirmatory test within three months of their reactive antibody test.

e. **Access to HCV treatment**. The number of providers in Washington prescribing HCV treatment.

f. **Cost of HCV treatment**. The annual cost to the state of Washington and to private payers in Washington to treat HCV.

g. **Cost of HCV-related hospitalizations**. Hospitalization costs related to HCV on an annual basis.

Community-Based Responses and Interventions Goals

Goal 6. Improve access to and use of preventive and health care services in non-clinical settings through expansion and co-location of services.

6.1 **Support the expansion of syringe service programs and medication treatment for opioid use disorder in areas of the state with limited access to such services.**

Background: In order to eliminate HCV among people who inject drugs, access to sterile syringes, access to medication treatment for opioid use disorder (e.g., methadone, buprenorphine), and access to HCV direct-acting antiviral treatment for people who inject drugs all need to scale.[52] [53]

6.2 **Improve access to sterile syringes and other injection equipment by sufficiently resourcing syringe service programs so that they can optimize their open hours and implement needs-based supply access.**[54]

6.3 **Explore innovative strategies for improving sterile syringe access in rural and remote parts of the state, including a mail-order service.**

6.4 **Develop educational materials for community members and clinical stakeholders about the benefits of syringe service programs for individual, community, and population health.**

6.5 **Explore harm reduction interventions for people who inject stimulants.**

Background: "People who inject stimulants need sterile syringes and injecting equipment, although they may need different services from those typically provided by syringe [service] programs to individuals who inject opioids, given the different frequency of injection of these classes of drugs (e.g., injection drug use for stimulants can be periodic instead of consistent intervals such as the case with opioids). As such, [people who use stimulants] often feel that syringe [service] program staff and clients are biased to the needs of heroin/opioid injections and so [people who use stimulants] may elect not to use these vital services. Switching from injecting methamphetamine to smoking is a form of harm reduction and people may be interested in this option… Safer snorting information and equipment should also be provided to [people who use stimulants] to reduce the risks of this practice and/or so that people could consider snorting as a harm reduction option, especially if they frequently inject."[55]

6.6 **Expand the provision of clinical services, including HCV and other infectious disease screening and diagnostic testing (e.g., HIV testing, HBV testing, testing for sexually transmitted infections), linkage to care services, HCV treatment, vaccination (e.g., against HAV and HBV), wound care, overdose education and naloxone distribution in high-impact settings (settings that serve a high proportion of clientele who inject drugs, such as syringe service programs, substance use disorder treatment facilities, opioid treatment programs, organizations serving people experiencing homelessness).**

6.7 **Support strategies for opioid treatment programs to receive reimbursement or bill Medicaid and other health coverage programs for HCV counseling, testing, and linkage to care services.**

6.8 **Ensure non-clinical settings (e.g., syringe service programs, substance use treatment services, other community-based organizations) can secure Medicaid reimbursement for services such as testing, counseling, medical case management, and vaccination services, in order to scale and sustain HCV and related services in community settings.**

Background: This will require defining taxonomy and provider classification for these settings. This aligns with current work underway at the Health Care Authority, in collaboration with the Department of Health, to develop a State Plan Amendment for certain services delivered in the syringe service program setting to become Medicaid reimbursable.

6.9 **Provide resources, including financial resources for Medical Assistant-Phlebotomy training and staff, so that high-impact, non-clinical settings have access to onsite phlebotomy in order to perform immediate blood draws for confirmatory RNA testing for people who have a reactive test result from a point-of-care rapid antibody screening test.**

6.10 **Explore innovative and evolving approaches to HCV testing in non-clinical settings as new platforms receive approval from the Federal Drug Administration, such as dried-blood spot testing to detect RNA and point-of-care antigen testing.**

6.11 **Negotiate with commercial laboratories to reduce the cost of HCV diagnostic laboratory costs for community based organizations providing HCV testing in non-clinical settings.**

6.12 **Incentivize screening, confirmatory testing, and return for HCV care and treatment in high-impact settings, working with the impacted community to understand what incentives would be most meaningful and promote engagement throughout the testing and linkage to care process.**

Background: Research has shown that financial incentives promote testing, engagement, and treatment adherence for infectious diseases, including HCV.[56] [57] [58]

6.13 **Maximize opportunities to integrate HCV services into HIV prevention and care services, such as ensuring that agencies contracted with the Department of Health to provide HIV prevention and/or care services receive education about HCV and share that education with clients, including men who have sex with men, women of transgender experience, and people who inject drugs.**

Background: Evidence suggests that men who have sex with men[59] and women of transgender experience are at elevated risk of acquiring HCV and integrating HCV education into HIV services is an opportunity to raise awareness in these communities, including understanding of sexual transmission of HCV. A study from San Francisco found that women of transgender experience have an HCV prevalence that is nine times higher than San Francisco overall.[60]

6.14 **Ensure that agencies working with the Department of Health to provide non-clinical, rapid HIV antibody testing are trained and resourced to provide non-clinical rapid HCV antibody testing, including resources to provide confirmatory RNA (viral load) testing and HCV linkage to care services; gonorrhea, chlamydia, and syphilis testing and linkage to care services; and HAV and HBV vaccination where feasible.**

6.15 Recognizing the significant impact of homelessness and the lack of housing opportunities for many people experiencing poverty, implement strategies for medication storage in community settings (e.g., at syringe service programs, substance use treatment programs) so that people with no or unstable housing can safeguard their HCV direct-acting antiviral prescriptions and other medications.

6.16 Work with housing providers (e.g., shelters, supportive housing programs, subsidized housing) to ensure supportive policies that permit residents to possess syringes and to offer access to onsite sharps disposal to promote the use of sterile syringes and proper disposal.

6.17 Ensure HAV and HBV vaccine and vaccination capacity are available in high-impact settings.

6.18 Work with housing providers and organizations serving people experiencing homelessness to support people who inject drugs with education and resources to prevent transmission and acquisition of viral hepatitis, including HAV, HBV, and HCV.

Background: Recent outbreaks of HAV and HBV in Washington have disproportionately impacted people experiencing homelessness and people who inject drugs. People living with HCV who become infected with HAV or HBV are at an increased risk of death due to the synergistic impact of living with multiple forms of viral hepatitis. In addition, people who inject drugs living in close quarters need access to information and resources to prevent transmission and acquisition of viral hepatitis.

Goal 7. Improve access to and use of clinical care and supportive services by sufficiently scaling coverage and widening the scope of community-based navigation and case management programs.

7.1 Develop community navigator programs to empower people who have experienced living with HCV and being cured to support members of their community living with HCV to be linked to HCV care and achieve cure.

Background: Community navigators can help people locate and access community and clinical resources, develop relationships that promote community inclusion, and support people in implementing their individualized plans for addressing HCV and related health and social service needs. Because community navigators come from the population of focus, they can provide culturally relevant services in language their fellow community members understand.

7.2 Expand Title XIX Medical Case Management to HCV, which allows those receiving Medicaid benefits to receive holistic wrap-around services.[61]

7.3 Allocate funding for case management in high-burden counties and/or high-impact settings to support people diagnosed with HCV who are also experiencing mental health issues, challenges with substance use, and/or histories of trauma and incarceration.

7.4 Provide community-based medical case managers in high-impact settings.

7.5 Develop strategies that focus on re-entry community navigators to assist people through the transition between correctional care to community care for HCV and substance use disorder treatment (e.g., the navigator could meet with a person a few weeks prior to reentry to provide connection back into community and to stay connected as they navigate to care services).

7.6 Develop strategies that support people living with HCV who are incarcerated to enroll in Medicaid in order to receive HCV treatment and other health care and social services in the community upon release (e.g., create bridge hubs for re-entry so that people may go to a central location after their release date for comprehensive services such as housing and job placement, primary care, and linkage to substance use disorder treatment and harm reduction services).

7.7 Develop standards for HCV case management, including assessing acuity and intensity of case management needed, and evaluation and documentation of services within and across health systems in order to track client outcomes and avoid duplication of services.

Goal 8. Increase HCV awareness, resources, and education, and reduce stigma.

8.1 **Develop a web-based, searchable HCV provider referral database for people affected by HCV and community navigators and case managers serving them as a centralized repository of health care providers in Washington who treat HCV.**

Background: People living with HCV and community navigators and case managers working with them need a tool to determine which health care providers in their area treat HCV. The database could use a symbol to indicate if a provider offers particular services or competencies (e.g., has specific training or is interested in serving people who use drugs). Resources permitting, the database should include information on where to find the nearest syringe service program, overdose education and naloxone distribution site, substance use treatment facility, and other relevant information that people at risk for or living with HCV might seek.

One option for the database is to expand the existing Washington Recovery Helpline (http://www.warecoveryhelpline.org) to include HCV providers.

8.2 **Support a centralized community education position to improve and sustain community awareness and knowledge of HCV throughout the state.**

8.3 **Establish an online clearinghouse for non-clinical social service providers (e.g., community health workers, HCV care navigators, HCV testing and linkage to care staff) containing training, resources, and technical assistance related to HCV education, prevention, testing, and linkage to care services.**

8.4 **Conduct focus groups and key informant interviews to better understand the impact of stigma on the health and wellbeing of people at risk for and living with HCV.**

8.5 **Develop and implement a standardized tool for measuring stigma towards people who inject drugs and people experiencing homelessness among clinical and support service providers.**

8.6 **Expand HCV, bloodborne infection, and harm reduction education for people experiencing incarceration, which includes the expansion of the peer-educator Project SHIELD (Self Help in Eliminating Life-threatening Diseases) into all prison facilities.**

Background: Initially as part of a research study, the Washington State Department of Corrections, in collaboration with the Hepatitis Education Project, piloted an evidence-based program to reduce drug, tattoo, and sexual risk factors within hard to reach populations both during incarceration and after release. The CDC's HIV risk reduction program, Project SHIELD, was modified to include HCV and was tailored for the correctional setting. The model relies on peer networks to reduce risk behaviors. Participants are trained by 1-2 facilitators to be peer educators during six interactive small-group sessions that involve role-plays, demonstrations, and group discussions. Participants are asked to improve their own health behaviors and promote risk reduction among their social networks and community contacts. The pilot program involved one session at each of four facilities where it was very well received with excellent feedback from participants, prison health staff, and administrators. This modified version of SHIELD, coordinated by Hepatitis Education Project, continues in two Department of Correction facilities.

8.7 **Develop comprehensive HCV community health education materials (e.g., online, printed materials, videos) designed for people at risk for and living with HCV that explain how HCV is transmitted, how HCV is prevented, HCV testing and the difference between antibody and RNA testing, the direct-acting antiviral treatments, and that anyone living with HCV (regardless of substance use or level of fibrosis) is eligible to be treated through Medicaid in Washington.**

8.8 **Resource an HCV social marketing campaign to raise awareness about HCV and promote HCV prevention, testing, and treatment messages.**

8.9 **Provide comments and/or testify on legislation that impacts people at risk for or living with viral hepatitis, including proposed legislation that directly or inadvertently criminalizes people at risk for or living with viral hepatitis.**

8.10 **Ensure approaches to substance use focus on public health approaches and minimize criminalization of people who use drugs (e.g., provide comments on any future proposals related to paraphernalia in the Revised Code of Washington, criminal penalties for drug possession), because criminalization increases risk for infectious diseases, including HCV.**[62]

Clinical Strategies Goals

Goal 9. Improve access to and use of clinical care for marginalized populations at risk for or living with HCV through innovative service delivery models.

9.1 **Support the development of fixed clinical sites where the focus is on delivering interdisciplinary clinical services to people with extensive personal and social barriers to care.**

Background: Models like the MAX Clinic, at Harborview in Seattle, for people living with HIV could be adapted to serve people living with HCV. In addition to flexibility with walk-in hours and robust social and health services, resources are provided to support peoples' attendance at the clinic (e.g., outreach support, financial incentives, snacks, meal vouchers, cell phones, bus passes). Adapting the MAX Clinic model to ensure holistic care to address some of the unique needs of people who inject drugs, such as wound care, podiatry, and dental care, would act as a draw for attracting clientele who would benefit from onsite HCV testing, education, and treatment.

9.2 **Support mobile health clinics where a focus is on meeting people where they are, building trust and rapport, and providing necessary HCV and related infectious disease testing, assessment, and treatment and other health care services in areas with high burden and in remote communities with a lack of access to clinical services.**

9.3 **Explore strategies for incentivizing clinics to serve people who inject drugs referred by syringe service programs for care, including HCV treatment.**

Background: Syringe service programs need adequate referral networks to refer participants to health care services. Clinics may be disincentivized from working with syringe service program participants because of the competing social challenges that may make it difficult for some participants to keep medical appointments. Clinics need to receive reimbursement for missed appointments or some other type of incentive for keeping appointment slots open for syringe service program participants.

9.4 **Support the integration of HCV testing and treatment in opioid treatment programs and office-based buprenorphine treatment programs, and encourage providers to offer medications for HCV in conjunction with medications for opioid use disorder early in the course of substance use treatment.**

Background: Studies suggest that offering HCV treatment has benefits for substance use-related outcomes, and conversely, patients who receive medications for substance use disorder have good HCV treatment outcomes.[63 64 65]

Goal 10. Build the capacity of the health care workforce to diagnose and treat HCV.

10.1 **Scale the availability of easily accessible and low-barrier (e.g., free or low cost, brief) medical education regarding HCV for non-specialist providers and primary care providers, with a special emphasis on screening, diagnosis, treatment, and reinfection education through approachable and easy to understand platforms that offer educational credits to all applicable providers.**

10.2 **Educate providers about risk factors for HCV and encourage providers to implement CDC's updated screening guidance related to both risk-based and routine HCV testing, available at https://www.cdc.gov/hepatitis/hcv/guidelinesc.htm, as well as CDC's updated refugee health guidelines which note, "It is reasonable to screen all adults (≥ 18 years of age) who originated from or have lived in countries with high moderate (2% to 5%) or high (≥ 5%) HCV infection prevalence."[66]**

10.3 **Develop easily accessible and low-barrier provider education materials and information to confront bias and prejudice toward people who use drugs in the medical community, including information on why HCV testing and treatment for people who inject drugs is effective and critical to achieve HCV elimination.**

Background: In 2018, a survey of 1,839 Washington State-licensed medical providers was conducted to assess provider awareness of treatment guidelines and HCV testing and prescribing practices. A primary finding of the survey was that while 1,089 (68%) of respondents had people who inject drugs in their practice, only 739 (68%) provided HCV testing and considered current injection drug use a risk factor for testing. In addition, of the 762 (41%) providers with people who inject drugs living with HCV in their practice, 637 (84%) had heard of direct-acting antivirals, of whom only 46 (13%) had prescribed direct-acting antivirals to a patient who injects drugs in the last three years. Approximately half (48%) were uncomfortable discussing alcohol or drug use during treatment. The most common concern about prescribing direct-acting antivirals to people who inject drugs was not being a specialist/trained (54%). Approximately half (58%) were aware that primary care providers in Washington can prescribe direct-acting antivirals and (52%) that treatment is recommended regardless of risk behavior.[67]

10.4 **Administer an annual or biennial HCV provider survey, like the one described above, to all health care provider types whose scopes of practice include prescribing authority and clinical care management to identify learning opportunities for health care providers and the methods of education preferred.**

10.5 **Develop a provider training program that couples training for prescribing medication treatment for opioid use disorder with training about HCV testing and treatment.**

Goal 11. Improve diagnosis of HCV in primary care settings.

11.1 **Work with all health care systems to implement prompts in their electronic medical records to screen people according to the CDC[68] and United States Preventive Services Task Force (USPSTF) recommendations.[69]**

11.2 **Through opportunities for public comment to the CDC and USPSTF, express Hep C Free WA's support for the expansion of one-time antibody screening for all adults and all people who are pregnant regardless of risk, with follow up RNA testing for anyone who is reactive, and encourage payers to cover this screening.**

Background: Currently the age cohort recommended for a one-time HCV test in the CDC and USPSTF recommendations is Baby Boomers. In addition, while the CDC and USPSTF do not currently recommend HCV testing for all people who are pregnant (only based on risk factors), the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America recommend that all people who are pregnant should be tested for HCV infection, ideally at the initiation of prenatal care (and again in the third trimester for people engaged in behaviors that put them at risk for acquiring HCV). Transmission to children during pregnancy occurs at an overall rate of 5% to 15%, with the number that progress to chronic HCV infection being 3% to 5%.[70] Hep C Free WA anticipates that the CDC and USPSTF recommendations may change in the coming year to include one-time testing for all adults.

11.3 **Work with all labs in Washington that receive specimens for HCV testing to implement reflex testing, ensuring that all specimens that are reactive for HCV antibody are immediately tested for RNA in order to streamline the diagnosis process.**

11.4 **Ensure all HCV antibody testing ordered in health care settings includes a reflex to RNA testing to ascertain current versus past infection and any reactive point-of care test includes an immediate blood draw for performing the RNA test.**

11.5 **Develop a statewide HCV treatment referral management system for primary care providers unable or unwilling to treat HCV in order to refer their patients to HCV treaters, including telemedicine providers, and include such information in the Health Care Authority's master contracts.**

11.6 **Incorporate HCV testing and linkage to care into the Health Care Authority's common measure set[71] so they can be considered for inclusion as value-based quality of care indicators for provider reimbursement through the Health Care Authority.[72]**

Goal 12. Improve HCV disease intervention services.

12.1 **Identify resources to strengthen the scale and scope of public health disease intervention services, to include HBV and HCV, at local health jurisdictions, and ensure that local health jurisdictions are sufficiently staffed with disease intervention specialists to adequately respond to HCV and other infectious diseases (e.g., HIV, STDs, HAV, HBV) and to identify outbreaks.**

Background: Local health jurisdictions receive reports of notifiable conditions from health care providers and laboratories. Given the volume of HCV case reports, no local health jurisdiction in the state has the capacity to investigate newly reported cases and work with people to link them to care and provide testing services to their social networks (e.g., working with a person identified with HCV to understand the settings where they interact with people who inject drugs and/or share injection equipment and to identify sexual partners who may benefit from testing). Only a few local health jurisdictions have any staff specifically tasked to work on HCV disease intervention activities and investigate high-priority cases (e.g., acute cases, cases in people under the age of 30, cases in people who are pregnant).

12.2 **Explore strategies for linking entire social networks into HCV testing and treatment (e.g., injection networks), such as using the support of Epidemic Intelligence Service Officers from the CDC.**[73]

Goal 13. Improve access to HCV treatment and comprehensive health care.

13.1 **Simplify the HCV direct-acting antiviral prior authorization process in Medicaid (Apple Health).**

Background: The Health Care Authority recently released an updated HCV policy that removes some previous restrictions, including a requirement for specialist consultation in order for primary care providers to treat HCV (Appendix C). Some additional strategies for future consideration include:

- Creating a streamlined or expedited prior authorization process for HCV.
- Limiting genotype testing to treatment-experienced patients and those with cirrhosis.[74]
- Reviewing reasons for prior authorization denials and consider removal of prior authorization in the future.

13.2 **Encourage third-party payers to approve HCV treatment for people at high risk of transmitting HCV.**

Background: Most patients who start direct-acting antiviral medication will have an undetectable viral load after four weeks of treatment, which likely means they are not able to transmit the virus to others. Approving treatment for people at high risk of transmitting HCV (e.g., people who inject drugs, men who have sex with men) after a single detectable and quantifiable HCV RNA test (>15 IU/mL) within the last six months, so they can achieve cure as soon as possible, has both an individual and public health benefit.

13.3 **Work with third-party payers to recognize non-physician providers (e.g., NPs, PAs, PharmDs) as prescribers.**

13.4 **Encourage health plans to enroll pharmacists as providers in order to allow for pharmacists to bill for HCV testing, treatment, and prevention counseling.**

13.5 **Support the development and implementation of telehealth models and address policy barriers to telehealth expansion, such as payer requirements for face-to-face visits.**

13.6 **Develop statewide standards of care including, but not limited to, clear guidelines for treating people who inject drugs, information that treatment will be covered for people who experience re-infection, and provider education about re-infection prevention and linkage to supportive services, such as medication treatment for opioid use disorder and syringe service programs.**

13.7 **Improve treatment access and continuity of care for people who are institutionalized (e.g., in jail, prison, state hospitals), such as leveraging the purchasing of HCV medications for jails and a centralized place to deliver medications to jails to ease financial and administrative burden (e.g., this could involve pairing opioid treatment and HCV treatment through these channels), and/or including HCV in the Health Care Authority's 1115 waiver proposal[75] to the U.S. Centers for Medicare & Medicaid Services to continue Medicaid coverage for medication to treat opioid use disorder for people while they are in jail.**

Background: When people are institutionalized their Medicaid coverage is suspended. Washington needs to explore strategies for ensuring people living with HCV can receive HCV direct-acting antivirals during institutionalization, whether they are mid-treatment when institutionalized or start treatment during institutionalization.

13.8 Identify a funding mechanism that provides support for HCV care and treatment for people who are underinsured or uninsured, with a special emphasis on supporting care and treatment for those unable to acquire insurance due to immigration status.

13.9 Ensure people at risk for and living with HCV have access to comprehensive health care, including oral health care, behavioral health services, and hygiene services to improve overall wellness and linkage and retention to HCV services.

Goal 14. Improve the ability of people taking HCV direct-acting antivirals to complete treatment.

14.1 Modify state pharmacy regulations to allow opioid treatment programs to store and administer HCV medications so that they can provide directly observed therapy (DOT) in conjunction with medications to treat opioid use disorder.

14.2 Encourage the use of strategies/tools to improve peoples' ability to take direct-acting antiviral therapy as directed and complete all aspects of treatment (e.g., financial incentives, DOT in opioid treatment programs, smartphone apps for video-DOT, ingestion sensors that confirm treatment was taken, medication storage, etc.).

14.3 Encourage Accountable Communities of Health to offer more flexible policies in care transition (e.g., see the example of the Healthier Here transitional care project[76]).

Goal 15. Improve follow-up clinical care for people who have completed HCV treatment.

15.1 Develop systems to ensure that all patients with cirrhosis receive appropriate follow-up care, which includes screening for hepatocellular carcinoma and portal hypertension.

15.2 Ensure those with risk factors for re-infection are monitored post-cure (e.g., people who currently inject drugs who have been cured should be counseled about reinfection prevention and receive RNA testing annually).

Implementation Phase and Next Steps

The development of the "Hep C Free WA Plan to Eliminate Hepatitis C by 2030" marks the beginning of Washington's efforts to eliminate the public health threat of HCV by the year 2030. Now that this initial planning phase is complete, the Hep C Free WA initiative moves into the implementation phase.

The Hep C Free WA Coordinating Committee, with support from the Department of Health as the backbone organization, will continue meeting on a quarterly basis. The Committee will focus on:

1. Disseminating best practices and identifying promising approaches and potential demonstration projects;
2. Shared accountability, an important tenet of collective impact initiatives, including monitoring implementation of the recommendations, evaluating progress toward elimination, and refining the plan over time as efforts evolve;
3. Reviewing progress on the recommendations, producing an annual, written progress report, and revising recommendations as necessary;
4. Refining its structure and defining governance, including how to ensure effective communication with the Governor, Secretary of Health, and other relevant state leaders to ensure bi-directional communication and to discuss progress and roadblocks toward realization of the Governor's Directive (Appendix B); and
5. Investigating opportunities for raising funds to support activities to help Washington achieve HCV elimination.

The three Hep C Free WA topic-specific work groups — Data & Strategic Information, Community-Based Responses & Interventions, and Clinical Strategies — will also meet on a quarterly basis, to ensure accountability related to their group's recommendations. At the quarterly Coordinating Committee meetings, each work group will report back on opportunities and challenges. An additional work group focused on community engagement and outreach will form and meet monthly to build leadership among people affected by HCV and from communities disproportionately impacted. This group will also coordinate Hep C Free WA community engagement events throughout the state.

The tools exist to eliminate the public health threat of HCV in Washington, but we must act swiftly and provide the resources necessary to achieve this goal.

Conclusion

Hepatitis C is a public health crisis in Washington State. Illness and death among aging Baby Boomers from HCV-related causes is on the rise. New infections are occurring at alarming rates among younger people who inject drugs, largely related to increases in opioid and other drug injection. Stigma and lack of accurate knowledge about HCV among affected communities and healthcare providers impede appropriate preventive services, testing, diagnosis, linkage to care, and treatment. The tools exist to eliminate the public health threat of HCV in Washington, but we must act swiftly and provide the resources necessary to achieve this goal. By working together to implement the Hep C Free WA recommendations, we can fulfill the Governor's Directive to eliminate the public health threat of HCV by 2030.

Appendices

Appendix A

Report by the Center for Disease Analysis Foundation, Public health impact of a population based approach to HCV treatment in Washington

Appendix B

Directive of the Governor 18-13

Appendix C

Washington State Health Care Authority, Hepatitis C Clinical Policy

Appendix D

Glossary

Public health impact of a population based approach to HCV treatment in Washington

This is a summary of the key outcomes of a hepatitis C virus (HCV) disease burden analysis undertaken by the CDA Foundation's Polaris Observatory, in collaboration with ASTHO, CDC and the Washington State Department of Health

This analysis was funded by a CDC cooperative agreement with ASTHO.

Contents

Executive Summary and Key Recommendations

Hepatitis C virus (HCV) is a blood borne infectious disease that causes substantial liver related morbidity and an increased risk of liver cancer and liver-related death.[1] HCV is often known as a "silent disease", as there are few noticeable symptoms, especially in early stage infection.[2] Because of this, many infected individuals are unaware of their HCV status until more serious, late stage complications arise. Treatment is available for HCV, with success measured by the sustained viral response (SVR) rate at 12-24 weeks post treatment. Prior to 2014, an average of 48-70% of patients achieved SVR with the available therapies; however, recent therapeutic advances mean that SVR rates in 2018 have increased to more than 95%.[3] Achieving SVR can reverse the effects of early stage fibrosis and slow the progression of cirrhosis into decompensation or hepatocellular carcinoma (HCC).[4,5] This reduces liver related mortality by 20-fold and all-cause mortality by 4-fold.[6] Transmission of HCV can be prevented by avoiding direct exposure to contaminated blood or blood products, including objects that may have come in contact with contaminated blood, such as needles and syringes.

Over the last 14 years, the HCV epidemic has drastically changed in the US. Originally a disease affecting "baby boomers" (people born between 1945 and 1965), HCV has reemerged as a syndemic with opioid misuse, overdose and HIV.[7] In 2010, approximately 3.5 million Americans were infected with chronic HCV[8] and, according to CDC data; HCV now kills more Americans than any other infectious disease.[9] Additionally, HCV is the leading cause of cirrhosis and liver cancer, and the most common reason for liver transplantation in the US.[10] In 2013, HCV-related deaths surpassed the total combined numbers of deaths from 60 other infectious diseases reported to the CDC, including HIV and tuberculosis; and in 2014, HCV-related deaths reached an all-time high with more than 19,600 deaths reported.[11] At the same time, there has been a marked simultaneous increase in the number of persons newly diagnosed with HCV across the US, particularly among people with a history of injection drug use.[12] Increases in acute HCV and hospital admissions for opioid injection were seen between 2004 and 2014, with the number of persons newly diagnosed with HCV more than doubling between 2010 and 2014.[13]

National-level programs to control the burden of HCV have focused primarily on the older cohort of previously infected individuals. These programs include screening for HCV in the baby boomer birth cohort (1945-1965) as well as programs through the Veteran's Administration (VA) to diagnose and cure all veterans infected with HCV. Despite these efforts, barriers to treatment still exist at the state Medicaid level, as evidenced in many states by fibrosis requirements that preclude treatment for patients with early stage liver disease.[14] Universal procedures exist to prevent HCV transmission in medical settings across the US (though localized outbreaks may still occur when procedures fail). However, the recent opioid crisis presents a new challenge for HCV prevention efforts. At present, policies to prevent transmission among drug users are entirely state-specific, and in many states these policies are non-existent.[15]

This report presents the outcomes of a multi-stakeholder collaboration to assess the HCV disease burden in the state of Washington. This work follows a standard methodology (modified Delphi process) developed and facilitated by the CDA Foundation's Polaris Observatory staff. It engages local stakeholders, including the Washington State Department of Health, doctors from the Department of Veterans Affairs and University of Washington, local health jurisdictions (Tacoma Pierce County Health Department and Public Health – Seattle & King County), the Washington State Department of Corrections, the Hepatitis Education Project, the Washington State Office of Financial Management and Washington State Health Care Authority, to ensure the data used in the analysis represent the best available and to develop momentum and consensus toward a common goal. The tool used in this work is a Microsoft Excel based

Markov model, populated with consensus estimates, which can answer the basic questions needed for HCV policy development.

Key Insights and Recommendations

Who is affected?

- At the beginning of 2018, there were 59,100 (95% uncertainty interval 32,500-71,500) HCV-RNA+ (viremic) infections in Washington. Approximately 80%, of infections were diagnosed previously (n= 46,500) with 5,600 infections diagnosed annually, and 12% of persons infected (n=7,330) were initiated on treatment annually. There were an estimated 2,950 new infections annually, an incidence rate of 39.9 per 100,000 in 2018.
    - 52% of total infections were in the 1945 to 1965 birth cohort*
    - 18% of total infections were among women of child bearing age*
    - 25% of total infections were among people who inject drugs*
    - 5% of the HCV infected population were among incarcerated people
    - The percent of the HCV infected population on Medicaid was unknown

    *Percentages do not sum to 100% because overlap exists across groups and not all subpopulations are considered here

What is the impact of current policies?

- If currently policies continue and there is no change to the HCV treatment paradigm in Washington, the total number of HCV infections will decline 85% by 2030; liver related deaths, hepatocellular carcinoma (HCC), and cirrhosis will decrease by 90% as the infected population ages.

What needs to be done to eliminate HCV in Washington?

- Under the current standard of care, Washington is projected to eliminate HCV (defined by the WHO as an 80% reduction in new infections, 90% diagnosis of all infections, and a 65% reduction in liver related mortality) by 2030. Between 2019 and 2030, a total of 61,400 treatments are needed, an average of 5,100 patients annually.
- Eliminating HCV on an accelerated timeline (2025) would require 1,500 *fewer* total treatments than in the base scenario but at a slightly higher rate in years 2020-2025. Additionally, prevention efforts would need to continue to lower the incidence rate from 39.9 per 100,000 cases in 2018 to around 6.6 per 100,000 by 2030.
    - As discussed below, Washington already has some prevention programs in place providing access to sterile needles and syringes and treating persons who are actively injecting drugs.

Background

HCV globally

Today, an estimated 71 million individuals globally are infected with Hepatitis C, a curable disease that can lead to cirrhosis, liver cancer, and liver related death. Approximately 400,000 people die each year from causes related to HCV, which can be eliminated through coordinated efforts for prevention and treatment. Unfortunately, as of 2017, only 20% of those infected patients have ever been diagnosed, and, currently, only 2% of total infected patients are being treated for the disease annually.

The CDA Foundation and the Polaris Observatory

The CDA Foundation (CDAF) is a non-profit organization that specializes in the study of complex and poorly-understood diseases in order to provide countries and states with the data and information to create and implement successful elimination strategies. The Polaris Observatory, an initiative of CDAF, provides epidemiological data, modeling tools, training and decision analytics to support eliminating Hepatitis B and C globally by 2030. The observatory offers the most up-to-date estimates for the HCV, hepatitis B virus disease burden and economic impact, and offers strategies for elimination of each virus, along with financing options. An independent advisory board with representatives from global health organizations, academia, civil societies and donors oversees the activities of the observatory. The Polaris Observatory's teams of epidemiologists work directly with stakeholders in over 100 countries to assess the current – and future – disease burden of hepatitis, model economic impact, and develop strategies that can achieve country or state-defined targets to eliminate it. By developing partnerships at country and regional levels, the observatory collects and analyzes data for its platform and publishes key findings to enable policies around hepatitis elimination.

How this model has been used globally

This work has resulted in the adoption of national hepatitis elimination strategies in countries such as Egypt and Mongolia. In Egypt, this included an economic analysis that accounted for both direct costs (healthcare, screening, diagnostic and antiviral therapy costs) and indirect costs (costs based on disability-adjusted life years). The analysis showed that it would cost Egypt US$90 billion over a 15-year period if the government kept the status quo. A plan of action was then developed beginning in 2014 with a goal of treating 300,000 patients annually, including cost subsidies for four years. After seeing successes, the plan continued each year. In 2016, Egypt treated 577,000 patients and the plan expanded to include patients at all stages of disease, even those without any HCV-related consequences.

In Mongolia, CDAF and its Polaris Observatory team worked with the World Health Organization's Regional Office for the Western Pacific (WPRO) to first design an economic analysis and understand the disease burden. Working with partners including WPRO, the president of the Mongolian Association on Study of Liver Diseases, a physician professor and a group of other researchers, the team developed the co-payment method based on income level. The Mongolian government subsidized part of drug treatment and as prices declined, treatment became even less expensive for patients. CDAF also worked with the WPRO to develop a national screening program in urban and rural areas after reaching the conclusion that, even if the prevalence of HCV goes down in the next decade, there will still be more transmission and deaths unless there is an increase in screening and diagnosis.

How this model has been used in the United States

In 2014, this work expanded to include state-based analyses within the US. Through collaborations with a combination of state health departments, the CDC Foundation, Association of State and Territorial Health Officials (ASTHO) and state collaborators this model has been used to encourage the removal of Medicaid fibrosis restrictions (Colorado), to publish the HCV epidemiology and an elimination scenario (Rhode Island) and to inform the development of state elimination strategies (District of Colombia and New York, *in progress*). Additionally, the results for ten states (California, Colorado, Georgia, Iowa, Louisiana, New Mexico, Pennsylvania, Rhode Island, Tennessee and Washington) are included on the Polaris Observatory Website (http://cdafound.org/polaris-hepC-dashboard/). Ongoing analyses include collaborations with ASTHO, CDC and state partners to identify the disease burden and associated elimination strategies in Washington.

Hepatitis C related disease burden – Washington

Washington is a Pacific Northwest US state that is larger than average both geographically and in population size. Washington has demonstrated the capacity to treat as many as 7,900 HCV patients in a year, has implemented some of the nation's first harm reduction programs among high-risk populations and has developed a funding mechanism for future statewide treatment scale-up.[16]

The analysis presented here represents the work of stakeholders from the Washington State Department of Health, the Department of Veterans Affairs, the University of Washington, local health jurisdictions (Tacoma Pierce County Health Department and Public Health – Seattle & King County), the Washington State Department of Corrections, the Hepatitis Education Project, the Washington State Office of Financial Management and Washington State Health Care Authority, ASTHO, CDC and CDAF. The primary objectives were to quantify the current and future disease burden of HCV in Washington and identify the level of effort necessary to eliminate HCV in the state.

Based on the Edlin et al. adjustments of NHANES data, scaled specifically to Washington, it was estimated that 1.1% (range 0.8%-1.5%) of the population of Washington was chronically infected (RNA positive) with HCV in 2010. This equates to approximately 77,100 (range 55,000-103,500) infected individuals in 2010. [17]

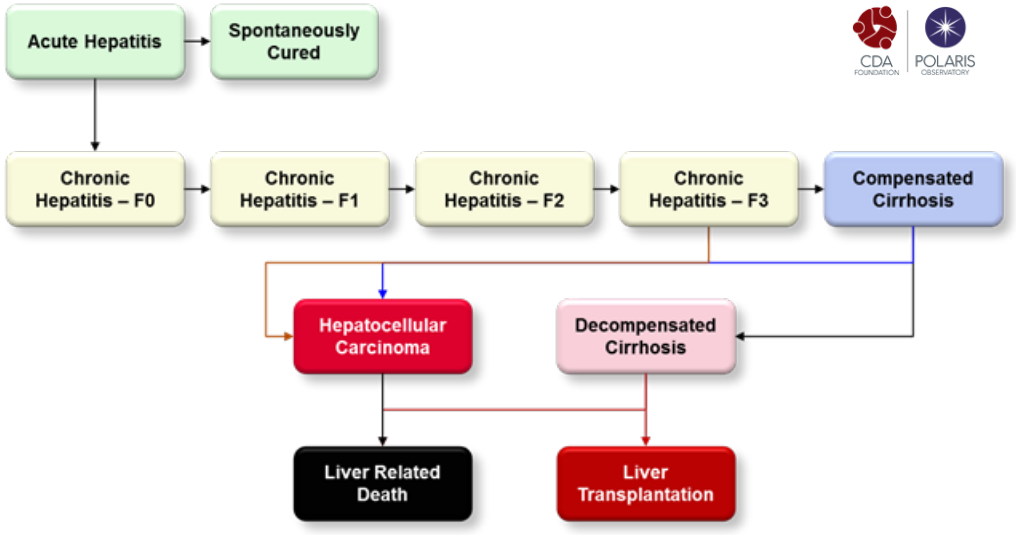
Achieving a sustained virologic response (SVR) to HCV treatment can reverse the effects of early stage fibrosis and slow the progression of cirrhosis into decompensation or HCC.[18,19] This reduces liver related mortality by 20-fold and all-cause mortality by 4-fold.[20] Direct acting antivirals (DAA) can achieve SVR in >95% of patients with HCV.

Similar to the United States as a whole, in Washington, almost 70% of individuals infected have genotype 1 (unpublished surveillance data from the Washington DOH).[21] Though previously genotype 1 chronic infection was the most difficult to treat, DAAs have become the standard of care and are safe for the treatment of genotype 1 patients. For this modeling exercise, based on input from expert meetings, we assumed an SVR rate of 95% for all genotypes.

The model

The mathematical model is an Excel based disease progression model which was calibrated using reported, state-specific, epidemiologic data. The progression is as follows (Figure 1):

Figure 1.



The details of the model have been described previously in Blach 2016.[22] Briefly, a Markov disease progression model grounded in population, mortality, and state-specific HCV data was developed. The model captures new (acute) infections by age and sex starting in 1950, and then follows the annual progression from acute to spontaneous clearance or through the stages of chronic infection. Additionally, the model accounts for age-specific mortality as well as patients who maintain a sustained virological response (SVR). Based on state-specific inputs, the model is used to forecast the disease burden by HCV-sequelae, including fibrosis, cirrhosis, decompensated cirrhosis, hepatocellular carcinoma (HCC), and liver related death from 1950-2030.

Input data

The following epidemiologic data were input into the model (Table 1):

Table 1.

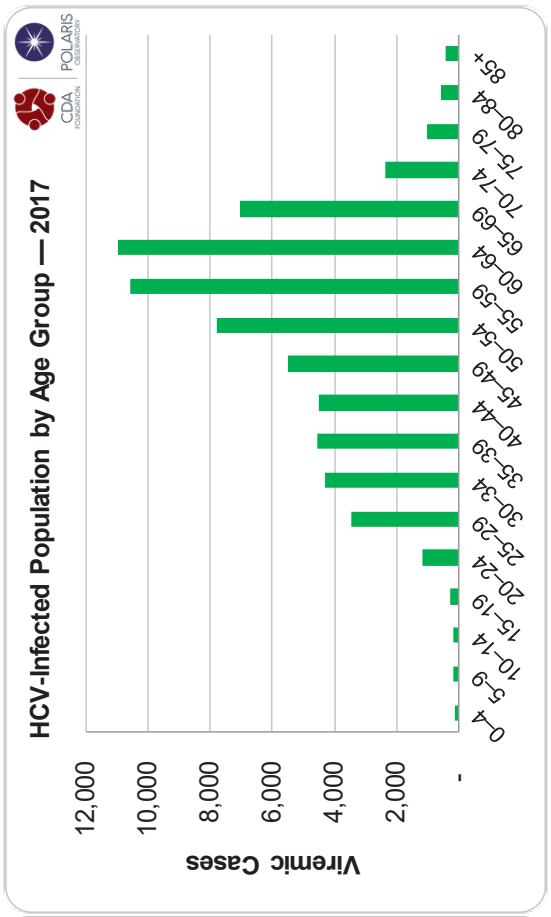
Historical Input	Estimate (Range)	Estimate Year	Source	Source Description
HCV-RNA+ Infections	77,100 (55,000-103,500)	2010	[23]	Edlin 2015
Anti-HCV Prevalence by Age and Sex	See Figure 2	2017	[24,25]	Notification data provided by the Washington State Department of Health scaled to the WA prevalence population
HCV-RNA Prevalence by Age and Sex	See Figure 3	2017	[26]	Notification data provided by the Washington State Department of Health scaled to the WA prevalence population
HCV Genotype	See Table 2	2018-2019	[27]	Unpublished surveillance data from the WDOH
Total Diagnosed (HCV-RNA)	33,294	2010	[28,29]	Based on analyses of NHANES data, ~45% of the US infected population has been previously diagnosed, scaled to the WA population
Annual Newly Diagnosed (HCV-RNA)	7,889	2017	[30]	Notification data provided by the Washington State Department of Health
Annual Number Treated	7,957	2017	[31]	All Payers Claims Data provided by the Washington State Office of Financial Management

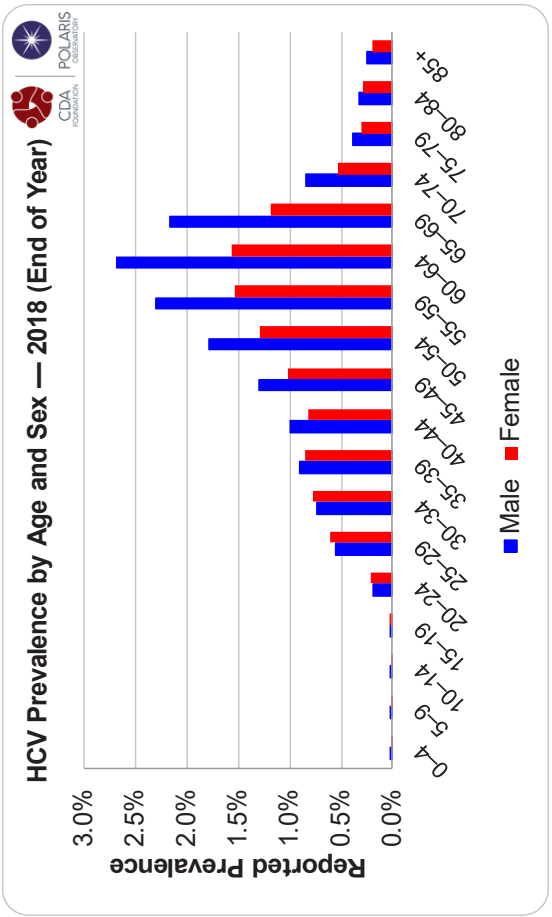
HCV Prevalence

Prevalence of HCV in Washington was estimated for 2010 based on adjustments made to the National Health and Nutritional Examination Survey (NHANES) data. Edlin et al. details several high-risk groups (such as incarcerated, homeless, active military, etc.) that were excluded from the NHANES data, and based on this analysis, it was estimated that 1.1% (range 0.8%-1.5%) of the population, or approximately 77,100 (range 55,000-103,500) individuals, were chronically infected with Hepatitis C in 2010. [32] Uncertainty intervals from Edlin et al. were used in the sensitivity analysis.

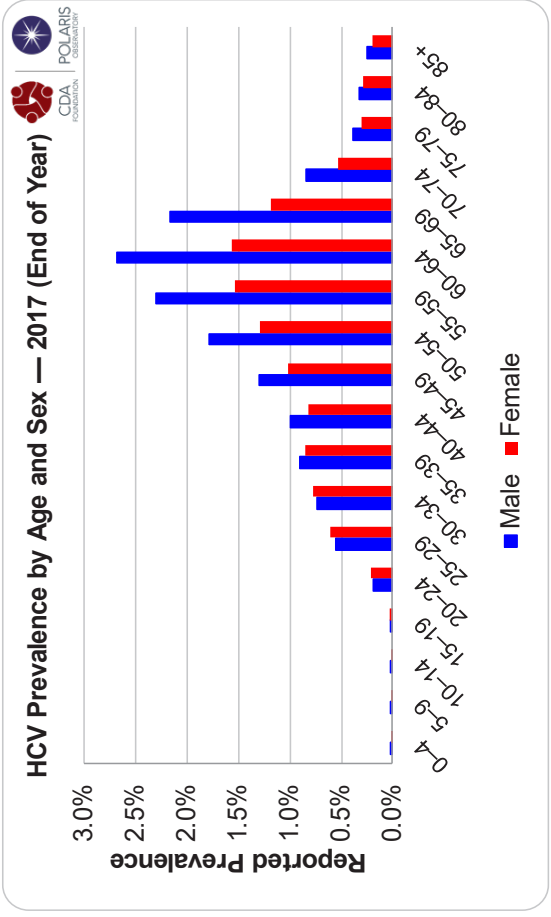
The historical age and sex distribution of the infected population in Washington was estimated using state notification data by age and sex collected from 2000-2017.[33] The data were aggregated and aged over time while adjusting for viremia (75%, except for 2016-2017 where actual RNA+ cases were reported), age- and sex-standardized mortality rates, and the number of patients cured each year (in total, 40,475 treated and 32,190 cured). Next, this distribution was scaled to match the overall number of HCV infections estimated in 2017 (Figures 2a and 2b). The resulting prevalence by age curve was bell-shaped in 2006 with a peak in 50-54 year olds (model output). This was similar to the US as a whole according to data reported from NHANES 2003-2010.[34]

The distribution of total viremic patients by age group for Washington in 2018 can be seen in Figure 3a. As the opioid epidemic grows in the United States, we see an increase in the number of infected individuals between the ages of 25-39. More so, in Figure 3b, we see that females are slightly more likely to be infected than males in ages younger than 35 years.





Figures 3a and 3b.



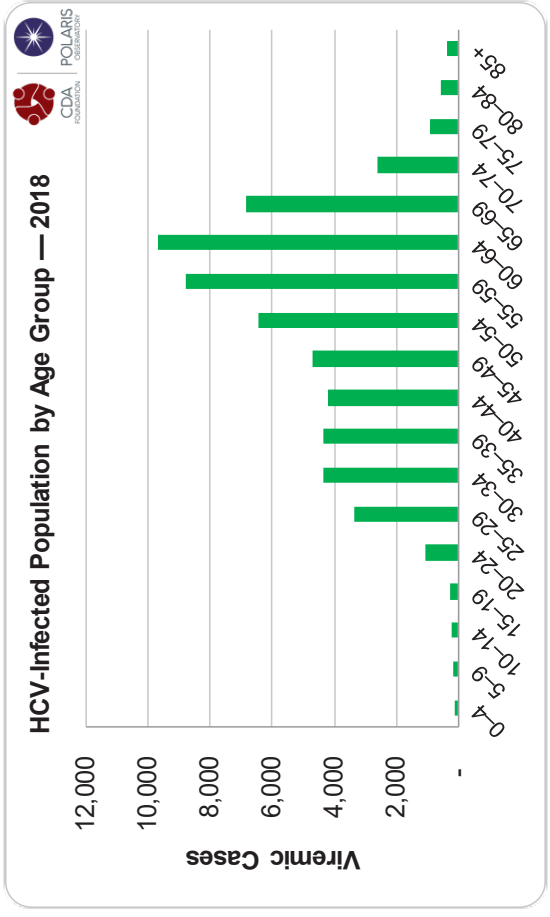


Figure 2a and 2b.

Genotype

The genotype distribution in Washington was based on unpublished surveillance data collected from 2018-2019 and provided by the WDOH (n=5,423). [35]

Table 2.

Genotype	G1	G2	G3	G4	G5	G6	Mixed/ Other
WDOH (2018-2019)	66.0%	14.9%	17.3%	0.9%	0.0%	0.5%	0.4%

Incidence

Prior to 2007, the incidence trend in Washington was assumed to mirror that of the entire United States. [36] Starting in 2008, it was then assumed that incidence increased to reflect increasing use of drugs by injection and sharing of injection equipment in Washington.

Diagnosis

According to US national estimates, ~45% of the infected population was diagnosed by the end of 2009.[37,38] This rate was applied to the Washington infected population in 2010, resulting in an estimated 33,300 previously diagnosed cases in that year. After 2010, WDOH notification data was used to inform the number of patients annually diagnosed.[39]

In 2017 alone, WDOH received reports of 8,813 Washingtonians who tested positive for HCV, and 7,889 of those patients were also confirmed to be RNA+.[40]

Treated

The number of patients treated each year between 2008 and 2014 was estimated using annual US treatment rates applied to the Washington population. The Washington State Office of Financial Management was able to provide Washington-specific All Payers Claims Data (APCD) which reported number of treatment initiations in years 2015-2017 stratified by Medicaid, Medicare and commercial.[41] Adjustments were made to these data to account for employees of large companies (e.g. Microsoft, Amazon, etc.) and those who are self-insured by applying the commercial treatment rate from the APCD to this population. Additionally, data on the number of prisoners treated were provided by the Washington State Department of Corrections and added to the adjusted APCD. Other potential points of care for treatment of HCV that would not be captured by the APCD include the Department of Veterans Affairs and tribal health providers, however these data could not be collected. According to these estimates, which were agreed to by expert consensus, 7,960 patients were treated in 2017.

Subpopulations

Approximately 30% of the total population of Washington is currently on Medicaid.[42] The prevalence of HCV in the Medicaid population was unavailable at the time of the analysis.

Routine opt-out screening for anti-HCV in the prison populations began in 2010 for all incoming men and women.[43] In 2018, almost 90% of the intake population was screened for anti-HCV with a 23.7% positivity rate for HCV exposure with an estimated 11-14% living with chronic infection.[44] About 7,000-8,000 people enter the Washington prison system each year and at any one time the prison population is estimated at 19,000.[45] The number of people who are incarcerated being treated for HCV has been increasing annually. Whereas ~90 people received treatment in 2015, over 250 will be treated in fiscal year 2019.[46]

There were an estimated 33,300 people who inject drugs (PWID) in Washington in 2017 (0.5% of the population). Based on the National HIV Behavioral Survey in 2016, it was assumed that approximately 66% of this population was anti-HCV positive. [47]

In 2017, approximately 23% of the total population in Washington was women of child bearing age (WoCBA) (females aged 15-49 years). The prevalence of HCV in this population was unavailable at the time of this analysis but could be estimated by the HCV disease burden model.

Results

Past and Present Burden of Disease

Annual incidence was modeled with expert input to peak in 1989, around the time systematic blood screening began. It was then modeled to increase again in 2007 in order to capture the increase in transmission of HCV due to high rates of unsterile opioid use in Washington. In 2018, it was estimated that there were approximately 2,950 Washingtonians who acquired HCV (39.9 per 100,000).

At the beginning of 2018, 79%, or 46,500, of the 59,100 (95% uncertainty interval 32,500-71,500) viremic infections were diagnosed. Of the total infected population, 12% (7,300) were treated. Of the 7,300 treated, 95% (7,000) were cured. This cascade of care in 2018 can be seen in Figure 4. The distribution of Washingtonians with HCV by fibrosis stage, which is calculated by the model, can be seen in Figure 5. Almost 30% of patients in 2018 were estimated to be fibrosis stage F1, while more than 40% were F2, F3, or cirrhotic.

The prevalence in subpopulations was also considered. Within the incarcerated population there close to 2,700 RNA+ infections in 2018. This was calculated by applying the anti-HCV prevalence (23.7%) and a viremic rate (71%) to the number of incarcerated persons (16,000). At the start of 2018, 4.6% of all viremic infections (2,700/59,100) were among persons who are incarcerated.

The prevalence among people who inject drugs (PWID) was also estimated. Assuming 33,300 total PWID in Washington and applying an anti-HCV rate of 66% and a viremic rate of 75% there would be a total of 16,500 HCV-RNA+ PWID, approximately 25% of all viremic infections at the beginning of 2018. [48]

The model was used to calculate the prevalence among WoCBA and in baby boomers (persons born in the 1945 to 1965 birth cohort). The prevalence by age in the WoCBA population ranged from 0.05%-0.92% in 2018, with the peak prevalence in those aged 45-49. In total, 18% of all viremic infections at the start of 2018 were estimated to be WoCBA. The prevalence by age in the baby boomer population ranged from 0.88%-2.03% in 2018. In total, 52% of all viremic infections in the same year were estimated to be among baby boomers.

Figure 4.

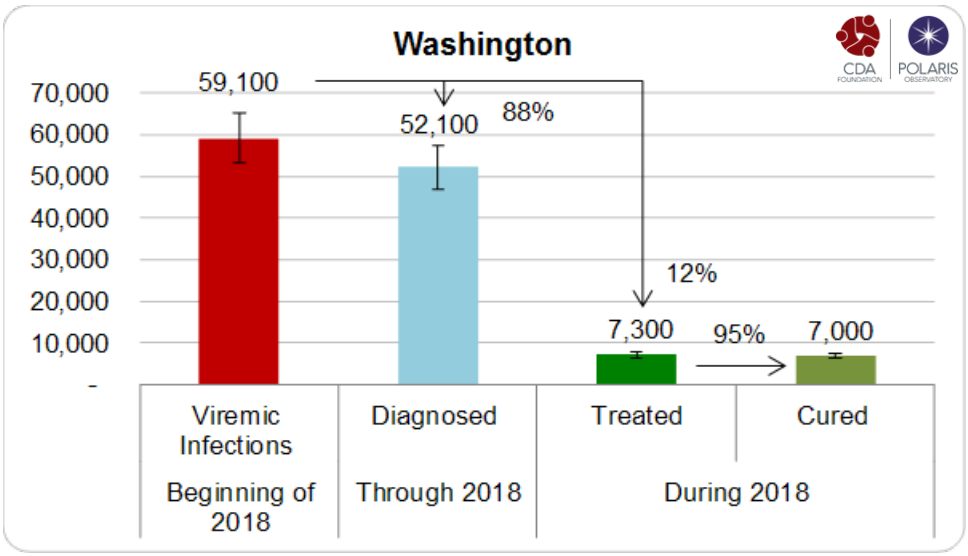
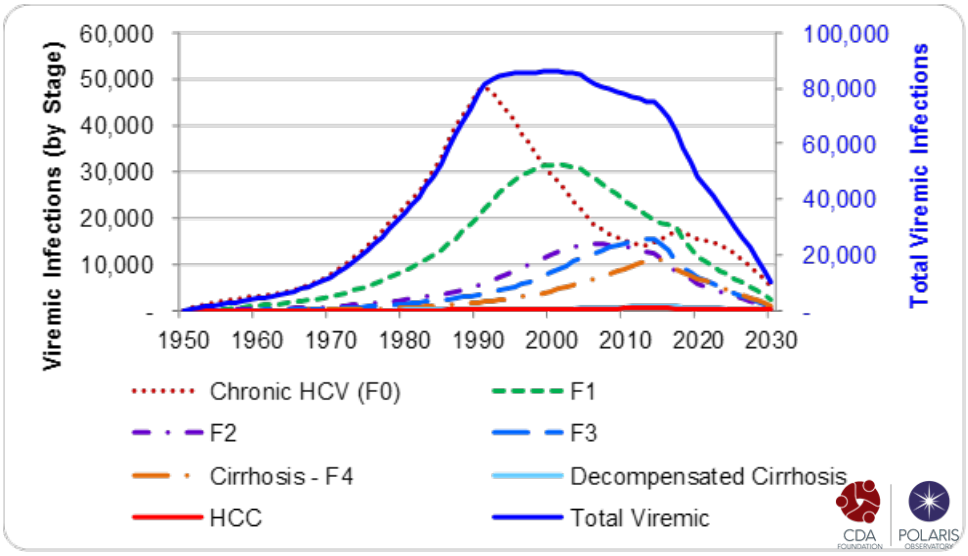

Washington
CDA FOUNDATION
POLARIS OBSERVATORY
70,000
60,000
50,000
40,000
30,000
20,000
10,000
-
59,100
52,100
88%
12%
7,300
95%
7,000
Viremic Infections
Diagnosed
Treated
Cured
Beginning of 2018
Through 2018
During 2018

Figure 5.


Viremic Infections (by Stage)
Total Viremic Infections
60,000
50,000
40,000
30,000
20,000
10,000
-
100,000
80,000
60,000
40,000
20,000
-
1950 1960 1970 1980 1990 2000 2010 2020 2030
Chronic HCV (F0)
F1
F2
F3
Cirrhosis - F4
Decompensated Cirrhosis
HCC
Total Viremic
CDA FOUNDATION
POLARIS OBSERVATORY

Treatment Scenarios

We created two treatment scenarios: 1) Base, the current standard of care assuming a near 40% drop in treatment between 2017 and 2020; and 2) Accelerated Elimination, the levels of intervention necessary to eliminate the disease burden by 2025. The elimination scenario is based on the WHO Elimination Targets, defined as an 80% reduction in new infections, 90% diagnosis of all infections, and a 65% reduction in liver related mortality. This strategy requires the following numbers of people to be diagnosed and treated for HCV:

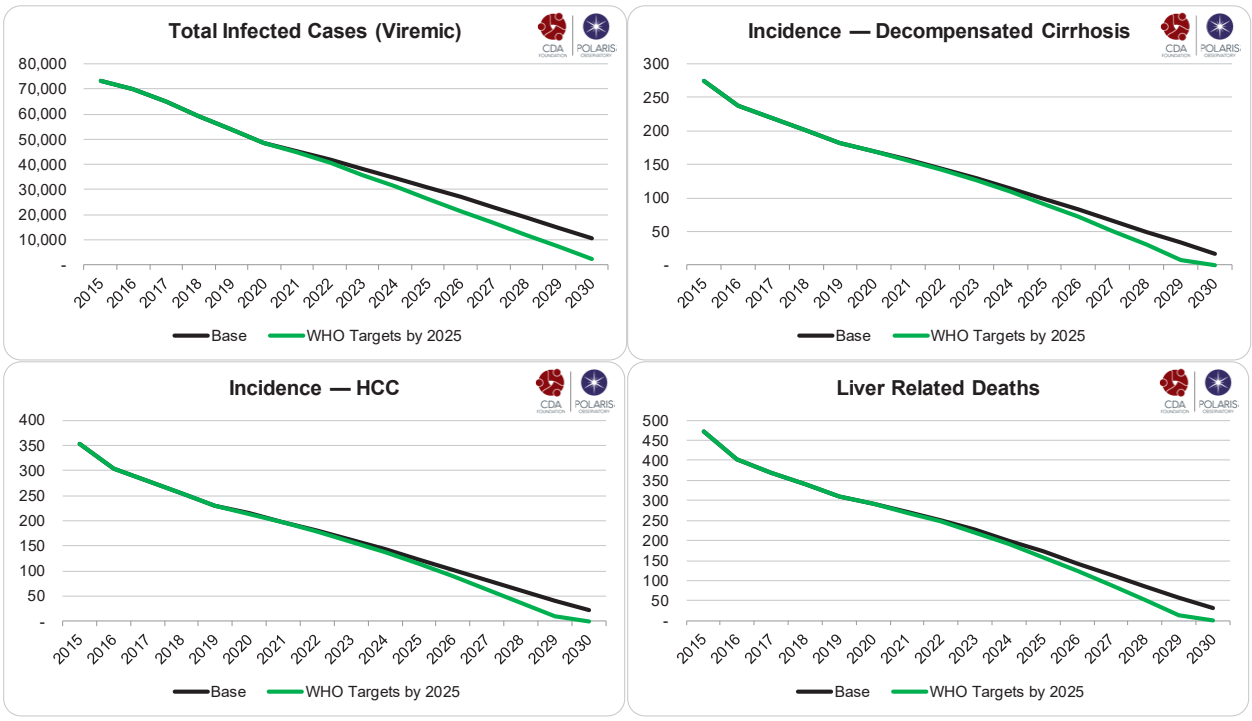
Table 3.

Scenario	Model Parameter	2018	2019	2020	2021	≥2022
Base	Incident Infections	3,000	2,700	2,400	2,300	2,100
	Treated	7,300	7,000	4,900	4,900	4,900
	Newly Diagnosed	5,600	5,600	3,900	3,900	1,800
	Fibrosis Stage	⩾F0	⩾F0	⩾F0	⩾F0	⩾F0
	Treated Age	15+	15+	15+	15+	15+
	SVR	95%	95%	95%	95%	95%
WHO Targets by 2025	Incident Infections	3,000	2,700	2,200	1,400	800
	Treated	7,300	7,000	5,100	5,100	5,100
	Newly Diagnosed	5,600	5,600	3,900	3,600	1,200
	Fibrosis Stage	⩾F0	⩾F0	⩾F0	⩾F0	⩾F0
	Treated Age	15+	15+	15+	15+	15+
	SVR	95%	95%	95%	95%	95%

Under the base scenario, the number of Washingtonians with viremic HCV peaked in 2000 and will continue to decline by 85% between 2015 and 2030, resulting in 10,700 (95% uncertainty interval 200-26,700) Washingtonians with HCV by the end of 2030. Liver related deaths, hepatocellular carcinoma (HCC), and decompensated cirrhosis will also decrease by 95% as the population ages and a high level of treatment is maintained. Incident cases of HCC will decrease from 350 in 2015 to 20 in 2030 (90% decrease). Incident decompensated cirrhosis cases will decrease from 280 in 2015 to 20 in 2030 (90% decrease). Given the current standard of care in Washington, there would be 440 fewer liver related deaths by 2030, a 95% decrease from 2015.

Under the WHO Elimination scenario, an average of 5,100 patients would need to be treated per year between 2020 and 2025 in order to achieve a 65% reduction in liver related deaths by 2025. Additional harm reduction efforts would also be needed to achieve an 80% reduction in new infections by 2025. Doing so would avert 5,800 new infections, 20 cases of decompensated cirrhosis, 25 cases of HCC and 35 liver related deaths by 2025 and 9,400 new infections, 110 cases of decompensated cirrhosis, 130 cases of HCC and 190 liver related deaths by 2030 compared to the base scenario.

Figure 6. Scenario Outcomes


Total Infected Cases (Viremic)
80,000
70,000
60,000
50,000
40,000
30,000
20,000
10,000
-
2015 2016 2017 2018 2019 2020 2021 2022 2023 2024 2025 2026 2027 2028 2029 2030
Base
WHO Targets by 2025
Incidence — Decompensated Cirrhosis
300
250
200
150
100
50
-
2015 2016 2017 2018 2019 2020 2021 2022 2023 2024 2025 2026 2027 2028 2029 2030
Base
WHO Targets by 2025
Incidence — HCC
400
350
300
250
200
150
100
50
-
2015 2016 2017 2018 2019 2020 2021 2022 2023 2024 2025 2026 2027 2028 2029 2030
Base
WHO Targets by 2025
Liver Related Deaths
500
450
400
350
300
250
200
150
100
50
-
2015 2016 2017 2018 2019 2020 2021 2022 2023 2024 2025 2026 2027 2028 2029 2030
Base
WHO Targets by 2025

Discussion

The ability to forecast the HCV disease burden in the presence and absence of interventions allows policy makers the ability to test hypotheses and quantify the impact of decisions. Using a Microsoft Excel based Markov model a team of state collaborators was able to develop consensus estimates to answer three primary questions - 1) Who in the state is most affected by HCV? 2) How do current policies positively or negatively impact indicators such as HCV prevalence, and HCV-related liver cancer and mortality? 3) What level of effort will be necessary to eliminate HCV?

Currently in Washington, it is estimated that more patients are being treated annually than are newly infected with HCV. Alongside increased mortality from an aging infected population, this means that the number of persons living with HCV is declining in the state. At the same time, the aging population is progressing to costly advanced liver disease, which can be prevented through timely treatment. Although the number of new infections occurring annually is low compared with the number of patients being treated, most people who are newly infected are not diagnosed for many years. While Washington has identified an estimated 80% of viremic infections, the remaining undiagnosed cases will be challenging to identify without an active screening campaign. If undiagnosed, they could remain silent carriers for decades, and may continue to transmit the virus and progress in their liver disease.

Overall, the disease burden in Washington is declining at a pace that is projected to achieve the WHO elimination targets by 2030 and almost by 2025 even with the expectation of a decline in treatment over the next several years. This is mainly due to a relatively high proportion of viremic cases previously diagnosed and high annual rates of diagnosis and treatment. Treating an annual average of 5,100 patients between 2020 and 2025 (36% less than the number treated in 2017) will achieve the targets.

Over the past several years Washington has treated HCV patients at high volumes, implemented harm reduction efforts such as needle exchanges and made efforts to open first-in-the-nation safe injections sites. Still, scale-up of these efforts would be required to achieve the goal of reducing new infections by 80% by 2025. The scale-up of treatment in the prison system would be another way to reduce new infections. Incarcerated people largely overlap with some of the most at-risk populations who are also the hardest to link to health care. Establishing a point of care in prisons would create an opportunity to prevent future infections through treatment of an otherwise difficult to reach population often with high transmission rates. Universal opt-out screenings upon intake are already conducted with an antibody test positivity rate of 24% in 2018.[49] Because the incarcerated population is very dynamic (mean length of stay is 15 months for women and 25 months for men), there is a constant flow of patients living with HCV and treatment opportunities.[50] Successfulness of such an intervention would thus need to be measured by treatment and cure statistics and not by prevalence rate at intake.

While Washington is currently on pace to meet the WHO Targets by 2030, future efforts are imperative to maintain the necessary diagnosis and treatment rates. Achieving these rates will become more challenging as the remaining infected population will consist primarily of those with limited access to care. Screening campaigns targeting at-risk communities and programs to address barriers to care will be necessary. Washington has taken significant steps towards eliminating HCV by removing treatment restrictions based on fibrosis stage in the Medicaid population, establishing harm reduction and test and treat programs and demonstrating the capacity to diagnose and treat high volumes of HCV patients. These strengths should not be taken for granted but should be maintained and bolstered moving forward in order to eliminate HCV in Washington.

Appendix A: Expert Panel Participants

The following individuals contributed to the content of this report through their participation in the expert panel discussions and in report revisions and we are grateful for their efforts:

Contributors	Affiliation
Hillary Armstrong, MPH	Public Health – Seattle and King County
Amanda Avalos, MPA	Washington State Health Care Authority
Kim Desmarais	Tacoma Pierce County Health Department
Tessa Fairfortune, MPH	Washington State Department of Health
Mary Fliss, MHA	Washington State Health Care Authority
Emalie Huriaux, MPH	Washington State Department of Health
George Ioannou, MD, MS	VA Puget Sound Health Care System, University of Washington
Thea Mounts, MA	Washington State Office of Financial Management
Meaghan Munn, MPH	Public Health – Seattle and King County
Michael Ninburg	Hepatitis Education Project
Deepinder Singh, MPA	Washington State Health Care Authority
Jon Stockton	Washington State Department of Health
Lara Strick, MD, MSc	Washington State Department of Corrections
Mona Doshani, MD	Epidemiologist, Clinical Interventions Team, Division of Viral Hepatitis, NCHHSTP, CDC
Geetika Nadkani, MPH	Director, Infectious Diseases, Association of State and Territorial Health Officials
Sarah Blach, MHS, CPH	CDA Foundation
Jonathan Schmelzer, MPH	CDA Foundation

[1] Stanaway JD, Flaxman AD, Naghavi M, et al., The global burden of viral hepatitis from 1990 to 2013: findings from the Global Burden of Disease Study 2013. Lancet 2016; 388: 1081-88.
[2] National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. Viral Hepatitis. https://www.cdc.gov/hepatitis/hcv/index.htm
[3] Afdhal N, Zeuzem S, Kwo P, Chojkier M, Gitlin N, Puoti M, et al. ION-1 Investigators. Ledipasvir and sofosbuvir for untreated HCV genotype 1 infection. N Engl J Med. 2014;370:1889–98. doi: 10.1056/NEJMoa1402454
[4] Poynard T., McHutchison J., Manns M., et al., "Impact of pegylated interferon alfa-2b and ribavirin on liver fibrosis in patients with chronic hepatitis C." *Gastroenterology*. 2002. 122(5):1303-1313. Available at https://www.ncbi.nlm.nih.gov/pubmed/11984517. Accessed 5-01-2018.
[5] Aleman S., Rahbin N., Weiland O., et al. "A risk for hepatocellular carcinoma persists long-term after sustained virologic response in patients with hepatitis C-associated liver cirrhosis." *Clin. Infect. Dis*. 2013. 57(2): 230-236. Available at https://www.ncbi.nlm.nih.gov/pubmed/23616492. Accessed 5-01-2018.
[6] van der Meer AJ., Veldt BJ., Feld JJ. Et al., "The number needed to treat to prevent mortality and cirrhosis-related complications among patients with cirrhosis and HCV genotype 1 infection." *J Viral Hepat*. 2013. 21(8):568-77. Available at https://www.ncbi.nlm.nih.gov/pubmed/24118177. Accessed 5-01-2018.
[7] Perlman DC, Jordan AE. The Syndemic of Opioid Misuse, Overdose, HCV, and HIV: Structural-Level Causes and Interventions. Curr HIV/AIDS Rep. 2018;15(2):96-112.
[8] Edlin BR, Eckhardt BJ, Shu MA, et al., Toward a more accurate estimate of the prevalence of hepatitis C in the United States. Hepatology. 2015: 62(5):1353-63.
[9] National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. Hepatitis C Kills More Americans than Any Other Infectious Disease. Centers for Disease Control and Prevention. May 4, 2016.
[10] National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. Increase hepatitis C infections linked to worsening opioid crisis. Centers for Disease Control and Prevention. December 21, 2017.
[11] ibid
[12] ibid
[13] ibid
[14] National Viral Hepatitis Roundtable. Hepatitis C: The State of Medicaid Access. Preliminary Findings: National Summary Report. November 2016. Available at: https://www.chlpi.org//wp-content/uploads/2013/12/HCV-Report-Card-National-Summary_FINAL.pdf. Accessed 5-01-2018.
[15] Campbell CA, Canary L, Smith N, Teshale E, Blythe Ryerson A, Ward JW. State HCV Incidence and Policies Related to HCV Preventive and Treatment Services For Persons Who Inject Drugs - United States, 2015-2016. Am J Transplant. 2017;17(7):1945-8.
[16] Washington State Health Care Authority. Eliminating Hepatitis C. 2019; Available from: https://www.hca.wa.gov/about-hca/clinical-collaboration-and-initiatives/eliminating-hepatitis-c.
[17] Edlin BR, Eckhardt BJ, Shu MA, et al., Toward a more accurate estimate of the prevalence of hepatitis C in the United States. Hepatology. 2015: 62(5):1353-63.
[18] Poynard T., McHutchison J., Manns M., et al., "Impact of pegylated interferon alfa-2b and ribavirin on liver fibrosis in patients with chronic hepatitis C." *Gastroenterology*. 2002. 122(5):1303-1313. Available at https://www.ncbi.nlm.nih.gov/pubmed/11984517. Accessed 5-01-2018.
[19] Aleman S., Rahbin N., Weiland O., et al. "A risk for hepatocellular carcinoma persists long-term after sustained virologic response in patients with hepatitis C-associated liver cirrhosis." *Clin. Infect. Dis*. 2013. 57(2): 230-236. Available at https://www.ncbi.nlm.nih.gov/pubmed/23616492. Accessed 5-01-2018.
[20] van der Meer AJ., Veldt BJ., Feld JJ. Et al., "The number needed to treat to prevent mortality and cirrhosis-related complications among patients with cirrhosis and HCV genotype 1 infection." *J Viral Hepat*. 2013. 21(8):568-77. Available at https://www.ncbi.nlm.nih.gov/pubmed/24118177. Accessed 5-01-2018.
[21] Centers for Disease Control and Prevention National Center for Health Statistics. National Health and Nutrition Examination Survey Data, 2003-2014. Hyattsville, MD: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention.; 2015.

[22] Blach S, Zeuzem S, Manns M, et al., "Global prevalence and genotype distribution of hepatitis C virus infection in 2015: a modelling study." *The Lancet Gastroenterology & Hepatology*. 2017. 2(3): p. 161-176. Available at https://www.ncbi.nlm.nih.gov/pubmed/28404132. Accessed 5-01-2018.
[23] Edlin BR, Eckhardt BJ, Shu MA, et al., Toward a more accurate estimate of the prevalence of hepatitis C in the United States. Hepatology. 2015: 62(5):1353-63.
[24] ibid
[25] Washington State Department of Health. Notified Cases 2000-2017. Unpublished.
[26] ibid
[27] Washington State Department of Health, *Genotype Surveillance Data, 2018-2019*. 2019: Unpublished.
[28] Volk, M.L., et al., Public health impact of antiviral therapy for hepatitis C in the United States. Hepatology, 2009. 50(6): p. 1750-1755.
[29] Denniston MM, Klevens RM, McQuillan GM, Jiles RB. Awareness of infection, knowledge of hepatitis C, and medical follow-up among individuals testing positive for hepatitis C: National Health and Nutrition Examination Survey 2001-2008. Hepatology. 2012;55(6):1652-61.
[30] Washington State Department of Health. Notified Cases 2000-2017. Unpublished.
[31] Washington State Office of Financial Management, All Payers Claims Data, 2015-2017. 2019: Unpublished.
[32] Edlin BR, Eckhardt BJ, Shu MA, et al., Toward a more accurate estimate of the prevalence of hepatitis C in the United States. Hepatology. 2015: 62(5):1353-63.
[33] Washington State Department of Health. Notified Cases 2000-2017. Unpublished.
[34] Denniston MM., Jiles RB., Drobeniuc J., et al., "Chronic hepatitis C virus infection in the United States, National Health and Nutrition Examination Survey 2003 to 2010." *Ann Intern Med.* 2014;160(5):293-300. Available at https://www.ncbi.nlm.nih.gov/pubmed/24737271. Accessed 5-01-2018.
[35] Washington State Department of Health, *Genotype Surveillance Data, 2018-2019*. 2019: Unpublished.
[36] Armstrong, GL., Alter MJ., McQuillan GM., Margolis HS., "The past incidence of hepatitis C virus infection: implications for the future burden of chronic liver disease in the United States." *Hepatology*. 2000;31(3):777-82.
[37] Volk, M.L., et al., Public health impact of antiviral therapy for hepatitis C in the United States. Hepatology, 2009. 50(6): p. 1750-1755.
[38] Denniston MM, Klevens RM, McQuillan GM, Jiles RB. Awareness of infection, knowledge of hepatitis C, and medical follow-up among individuals testing positive for hepatitis C: National Health and Nutrition Examination Survey 2001-2008. Hepatology. 2012;55(6):1652-61.
[39] Washington State Department of Health. Notified Cases 2000-2017. Unpublished.
[40] ibid
[41] Washington State Office of Financial Management, All Payers Claims Data, 2015-2017. 2019: Unpublished.
[42] ibid
[43] Assoumou, S.A., et al., Hepatitis C Testing and Patient Characteristics in Washington State's Prisons Between 2012 and 2016. Am J Prev Med, 2019. 56(1): p. 8-16.
[44] Washington Department of Corrections, Incarcerated Population Data. 2019: Unpublished.
[45] ibid
[46] ibid
[47] Banta-Green, C.J., A. Newman, and S. Kingston, *Washington State Syringe Exchange Health Survey: 2017 Results*. 2018, Alcohol and Drug Abuse Institute, University of Washington.
[48] Ibid
[49] Washington Department of Corrections, *Incarcerated Population Data*. 2019: Unpublished.
[50] Assoumou, S.A., et al., Hepatitis C Testing and Patient Characteristics in Washington State's Prisons Between 2012 and 2016. Am J Prev Med, 2019. 56(1): p. 8-16.

JAY INSLEE
Governor

STATE OF WASHINGTON
OFFICE OF THE GOVERNOR
P.O. Box 40002 • Olympia, Washington 98504-0002 • (360) 902-4111 • www.governor.wa.gov

DIRECTIVE OF THE GOVERNOR
18-13

September 28, 2018

To: Washington State Executive and Small-Cabinet Agencies

From: Governor Jay Inslee

Subject: Eliminating Hepatitis C in Washington by 2030 through combined public health efforts and a new medication purchasing approach

This year, an estimated 65,000 Washingtonians are living with the chronic Hepatitis C Virus (HCV), but fortunately, we now have a cure. HCV is the leading cause of liver cancer and liver transplants. The virus also causes other health problems, including debilitating fatigue, which can significantly impact the quality of life of those affected.

HCV is the most common blood-borne disease in the United States, and in Washington, from 2012 to 2017, nearly 40,000 new cases of HCV were reported, increasing each year. And while deaths from other infectious diseases have steadily declined over the past decade, HCV-related deaths continue to rise, now exceeding all deaths from other reportable infectious conditions combined.

Newly acquired HCV-infection reports show a 126% increase in Washington between 2013 and 2017 when compared to the prior five years, an increase linked to the opioid crisis. And while the disease has historically impacted Baby Boomers (those born between 1945 and 1965), younger people are now contracting the disease with greater frequency, again related to opioid use. Ultimately, Washington's HCV-related hospitalization charges totaled $114 million between 2010 and 2014.

Confronting the HCV crisis is challenging because many Washingtonians living with HCV do not know they are infected. So, to reach affected communities, we must make enhanced public health efforts, including efforts to improve education, preventive services, and early detection of HCV to treat and cure existing infections and curb the onward transmission of the virus.

Fortunately, we see an opportunity to take action against HCV. In 2017, the National Academies of Sciences, Engineering, and Medicine released "A National Strategy" outlining how the United States can save nearly 30,000 lives from HCV-related deaths and eliminate HCV by 2030. Moreover, medications now exist to cure HCV in nearly all people appropriately linked to, and retained in, care. HCV drugs are expensive, but we can drive down costs by applying new purchasing strategies in which state agency health care purchasers collaborate with

manufacturers in combination with using key public health interventions to reduce the costs of treating and ultimately curing HCV.

In curing HCV, we can stem the tide of liver disease and liver cancer and save individuals the physical, emotional, and financial damage caused by HCV infection. Curing this disease will also support HCV-affected persons to engage in healthy behaviors, such as accessing treatment for opioid-use disorder, general primary care, and mental health services, which will help them live full, satisfying, and productive lives. This is an important part of the opioid response plan.

Accordingly, I direct my health sub-cabinet and the health and human service state agencies under my authority to begin immediately to work with Tribal governments, local public health officials, and other partners across the state, to develop and implement a statewide HCV elimination plan. The Department of Health (DOH) shall lead the effort to develop the elimination plan as part of this comprehensive public health response. The Health Care Authority (HCA) shall lead and coordinate with DOH and other agencies and purchasers, in a corresponding effort to establish a comprehensive procurement strategy for the purchase of HCV medications that also includes financing the needed public health interventions to affordably eliminate HCV by 2030. Furthermore, I direct the following:

1. DOH, in collaboration with any other relevant state agencies that it identifies, shall convene and facilitate an HCV-elimination coordinating committee comprised of stakeholders from various sectors, including individuals personally affected by HCV. The committee shall draw on existing efforts, best practices, and community knowledge to develop, by July 2019, a comprehensive strategy to eliminate the public health threat of HCV in Washington by 2030. The strategy will address needed improvements to the public health systems to help ensure that all people living in Washington who have or are at risk for contracting HCV, have access to preventive services, know their status, and connect to care and ultimately the cure. The elimination strategy shall include a major public health communications plan financed, to the extent possible, by the funds saved through the purchasing strategy described below.

2. HCA shall collaborate with the Department of Corrections, Office of the Insurance Commissioner (OIC), Department of Labor and Industries, Department of Social and Health Services, Department of Veterans Affairs, DOH and Tribal governments, to initiate an innovative strategy to purchase curative HCV medications and ensure timely access to curative treatment for Washingtonians with HCV. Given that several state agencies each year purchase HCV treatment medications for over 4,000 people, by January 2019, HCA shall collaborate with these agencies and issue a single request for proposals for a joint value-based purchasing agreement for curative HCV medications from one or more pharmaceutical manufacturer(s). This joint purchasing agreement shall aim to reduce the costs of the drug(s) and incorporate key known public health strategies to address the needs described above.

3. HCA, in collaboration with DOH, shall request that the Centers for Medicaid and Medicare Services (CMS) enter into a shared-savings agreement for Medicare-program-cost avoidance resulting from the implementation of the state's HCV prevention and

treatment strategy. Our state program will save Medicare significant costs by not only treating people sooner, alleviating Medicare from needing to pay for HCV medications, but also the dire costs of liver disease and cancer and other health effects that would occur later in one's life while they are covered under Medicare.

4. HCA and DOH shall work with CMS, the Centers for Disease Control and Prevention, the Surgeon General, Veterans Affairs, other federal agencies, and Tribal governments to consider additional health care purchasing and disease elimination strategies, especially for rural and underserved populations—including Vietnam veterans living in rural areas—to address HCV in a cost-effective manner.

5. HCA, in collaboration with other state agencies shall, as the next phase of this plan, engage a multi-state or national organization to develop a strategy to assess the interest and ability of extending our purchasing and public health strategy to not only Washington's other major purchasers of health care and commercial insurers, but also other states or purchasers. As part of this next phase, HCA shall work with Washington's Health Benefit Exchange and OIC to explore purchasing options for the health insurance markets.

6. DOH and HCA shall also use data and information to detect cases of HCV, monitor HCV-related morbidity and mortality, monitor HCV-curative treatment access, and evaluate the impact of interventions and activities designated by this directive.

7. DOH and HCA shall develop a communications plan for this project. This communications plan shall include filing quarterly reports to my office and the health committees of the legislature to ensure the status and outcomes herein.

Washington State Health Care Authority

Antivirals - Hepatitis C Treatment

Medical policy no. 12.35.30.99 Effective July 1, 2019

Medical necessity

Drug	Medical Necessity
Preferred **Glecaprevir/pibrentasvir (MAVYRET)** *Non-preferred* Daclatasvir dihydrochloride (DAKLINZA) Elbasvir/grazoprevir (ZEPATIER) Ledipsvir/sofosbuvir (HARVONI) Ombitasvir/paritaprevir/ritonavir (TECHNIVIE) Ombitas/paritapr/riton and dasab pak (VIEKIRA) Sofosbuvir (SOVALDI) Sofosbuvir/velpatasvir (EPCLUSA) Sofosbuvir/velpatasvir/voxilaprevir (VOSEVI)	Antivirals: Hepatitis C treatment may be considered medically necessary for the treatment of chronic Hepatitis C infection when the clinical criteria listed below are met. Non-preferred products will be considered on a case-by-case basis when treatment with Mavyret is not indicated. Requests for brand-name medications with a generic equivalent available must also meet the criteria described in the **Brands with Generic Equivalents** policy (Non-Clinical Policy No. 0001).

Clinical policy:

Drug	Clinical Criteria (Initial Approval)
Daclatasvir dihydrochloride (DAKLINZA) Elbasvir/grazoprevir (ZEPATIER) **Glecaprevir/pibrentasvir (MAVYRET)** Ledipsvir/sofosbuvir (HARVONI) Ombitasvir/paritaprevir/ritonavir (TECHNIVIE) Ombitas/paritapr/riton and dasab pak (VIEKIRA) Sofosbuvir (SOVALDI) Sofosbuvir/velpatasvir (EPCLUSA) Sofosbuvir/velpatasvir/voxilaprevir (VOSEVI)	1. Patient has confirmed diagnosis of Hepatitis C and a quantifiable HCV RNA test >15 IU/mL within the last 12 months. 2. Required documentation and lab tests: a. HCV Genotype. b. Current HCV RNA Viral Load less than 12 months old. c. Fibrosis staging test (e.g. FibroScan® or FibroSURE®) to determine liver fibrosis level required to ensure the appropriate treatment regimen is used (e.g. patients with cirrhosis and/or decompensation may require longer treatment and/or ribavirin). Fibrosis staging test results must be less than 2 years old. d. Documentation of decompensation (or previous episodes of decompensation) if fibrosis level is F4 or cirrhosis. e. Documentation of treatment-experienced status including prior treatment regimen, length of treatment, response, and dates of treatment.

	f. Lab reports, if available, documenting presence or absence of resistant mutations in treatment-experienced patients. 3. Patients with the following conditions are not eligible for HCV treatment until the condition is resolved. Patients who: a. Are taking medications that are contraindicated with or that have a severe drug interaction with the prescribed HCV treatment. b. Are pregnant or planning on becoming pregnant. c. Have severe end organ disease and are not eligible for transplantation (e.g. heart, lung, kidney) d. Have a clinically-significant illness or any other major medical disorder that may interfere with patients' ability to complete a course of treatment. e. In the professional judgment of the primary treating clinician, would not achieve a long-term clinical benefit from HCV treatment (e.g. patients with multisystem organ failure, receiving palliative care, with significant pulmonary or cardiac disease, or with malignancy outside of the liver not meeting oncologic criteria for cure). f. Have a MELD score <20 and one of the following: i. Cardiopulmonary disease that cannot be corrected and is a prohibitive risk for surgery ii. Malignancy outside the liver not meeting oncologic criteria for cure iii. Hepatocellular carcinoma with metastatic spread iv. Intrahepatic cholangiocarcinoma v. Hemangiosarcoma vi. Uncontrolled sepsis
	Criteria (Reauthorization)
	See treatment experienced dosing guidelines below.

Preferred therapies:

Drug Name	Preferred For:
Glecaprevir/pibrentasvir (MAVYRET)	**Patients with or without compensated cirrhosis (Child-Pugh A) that are:** • treatment naïve patients with genotypes 1, 2, 3, 4, 5, and 6; or • patients with genotypes 1, 2, 3, 4, 5, and 6 with prior treatment with peg-interferon, ribavirin, or sofosbuvir, but no prior treatment with an NS5A inhibitor or an NS3/4A protease inhibitor; or • patients with genotype 1 with prior treatment with an NS5A inhibitor but not an NS3/4A protease inhibitor; or • patients with genotype 1 with prior treatment with an NS3/4A protease inhibitor but not an NS5A inhibitor.

Sofosbuvir/velpatasvir (EPCLUSA) **Sofosbuvir/velpatasvir/voxilaprevir (VOSEVI)**	Will be considered on a case-by-case basis when treatment with Mavyret is not indicated.

Dosage and quantity limits

Drug Name	Dose and Quantity Limits

Glecaprevir/pibrentasvir (MAVYRET)	**Treatment Naïve Genotypes 1, 2, 3, 4, 5, 6**
	• 8 weeks without cirrhosis
	• 12 weeks with compensated cirrhosis
	
	Treatment Experienced
	• With peg-interferon, ribavirin, or sofosbuvir, but no prior treatment with an NS5A inhibitor or an NS3/4A protease inhibitor
	  ○ Genotypes 1, 2, 4, 5, 6
	  ▪ 8 weeks without cirrhosis
	  ▪ 12 weeks with compensated cirrhosis
	  ○ Genotype 3
	  ▪ 16 weeks with or without compensated cirrhosis
	• With an NS5A inhibitor without an NS3/4A protease inhibitor
	  ○ 16 weeks for Genotype 1 with or without compensated cirrhosis
	• With an NS3/4A protease inhibitor without an NS5A inhibitor
	  ○ 12 weeks for Genotype 1 with or without compensated cirrhosis

Sofosbuvir/velpatasvir (EPCLUSA) Sofosbuvir/velpatasvir/voxilaprevir (VOSEVI)	Will be determined on a case-by-case basis when treatment with Mavyret is not indicated.

References

1. American Association for the Study of Liver Disease (AASLD). Recommendations for testing, managing, and treating Hepatitis C. 2014; Available at: http://www.hcvguidelines.org/full-report-view. Accessed January 14, 2014.
2. Fabrizi F, Martin P, Dixit V, Messa P. Meta-analysis of observational studies: Hepatitis C and survival after renal transplant. *J of Viral Hepas*. 2014; 21: 314-324.
3. Berenguer M, Schuppan D. Progression of liver fibrosis in post-transplant Hepatitis C: mechanisms, assessment, and treatment. *J Hepatol.* 2013; 58: 1028-1041.
4. Curry MP, Forns X, Chung RT, et al. Sofosbuvir and ribavirin prevent recurrence of HCV infection after liver transplantation: An open-label study. *Gastroenterology*. 2015; 148: 108-17.
5. Flamm SL, Everson GT, Charlton MR, Denning JM, Arterburn S, Brandt-Sarif T. Ledipasvir/Sofosbuvir with ribavirin for the treatment of HCV in patients with decompensated cirrhosis: Preliminary results of a prospective, multicenter study. 65th Annual Meeting of the American Association for the Study of Liver Disease (AASLD). November 7-11, 2014. Boston, MA. Available at: http://www.natap.org/2014/AASLD/AASLD_36.htm.
6. Dove LM, Brown RS. Liver transplantation in adults: Patient selection and pretransplantation valuation. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on December 4, 2014.)
7. Gilead Science. Sofosbuvir (Sovaldi™). Product Label. 2014. Accessed January 20, 2015.
8. Gilead Science.Ledipasvir/Sofosbuvir (Harvoni™). Product Label. 2014. Accessed January 20, 2015.

9. AbbVie. Ombitasvir/Partiaprevir/Ritonavir/Dasabuvir (Viekira Pak™). Product Label. 2014. Accessed January 20, 2015.
10. Kowdley K, Gordon S, Reddy R, et al. Ledipasvir and sofosbuvir for 8 or 12 weeks for chronic HCV without cirrhosis (ION3). *N Engl J Med*. 2014; 370: 1879-88.
11. Feld JJ, Kowdley KV, Coakley E, et al. Treatment of HCV with ABT-450/r/ombitasvir and dasabuvir and ribavirin (SAPPHIRE-I). *N Engl J Med.* 2014; 370: 1594-1603.
12. Zeuzem S, Jacobson IM, Baykal T, et al. Retreatment of HCV with ABT-450/r-ombitasvir and dasabuvir with ribavirin (SAPPHIRE-II). *N Engl J Med.* 2014; 370: 1604-1614.
13. Ferenci P, Berstein D, Lalezari J, et al. ABT-450/r-ombitasvir and dasabuvir with or without ribavirin for HCV (PEARL-III/IV). *N Engl J Med.* 2014; 370: 1983-1992.
14. Afdhal N, Zeuzem S, Kwo P, et al. Ledipasvir and sofosbuvir for untreated HCV genotype 1 infection (ION1). *N Engl J Med*. 2014;370: 1889-98.
15. Poordad F, Hezode C, Trinh R, et al. ABT-450/r-ombitasvir and dasabuvir with ribavirin for Hepatitis C with cirrhosis (TURQUOISE-II). *N Engl J Med.* 2014; 370: 1973-1982.
16. Afdhal N, Reddy R, Nelson D, et al. Ledipasvir and sofosbuvir for previously treated HCV Genotype 1 Infection (ION2). *N Engl J Med*. 2014; 370: 1483-93.
17. Bourlier M, Sulkowski M, Omata M, et al: An integrated safety and efficacy analysis of > 500 patients with compensated cirrhosis treated with ledipasvir/sofosbuvir with or without ribavirin. 65th Annual Meeting of the American Association for the Study of Liver Disease (AASLD). November 7-11, 2014. Boston, MA. Available at: http://www.natap.org/2014/AASLD/AASLD_15.htm.
18. Andreone P, Colombo MG, Enejosa JV, et al. ABT-450, ritonavir, ombitasvir, and dasabuvir achieves 97% and 100% sustained virologic response with or without ribavirin in treatment-experienced patients with HCV genotype 1b infection (PEARL-II). *Gastroenterology*. 2014; 147:359-365.
19. Jacobson I, Gordon S, Kowdley K, et al. Sofosbuvir for Hepatitis C genotype 2 or 3 in patients without treatment options (POSITRON/FUSION). *N Engl J Med.* 2013; 368: 1867-1877.
20. Zeuzem S, Dusheiko G, Salupere R, et al. Sofosbuvir and ribavirin in HCV genotypes 2 and 3 (VALENCE). *N Engl J Med.* 2014; 370: 1993-2001.
21. Lawitz E, Poordad F, Brainard D, et al. Sofosbuvir with Peginterferon-ribavirin for 12 weeks in previously treated patients with Hepatitis C genotype 2 and 3 and cirrhosis. *Hepatology.* 2014 doi: 10.1002/hep.27567.
22. Gane EJ, Stedman CA, Hyland RH, et al. Nucleotide polymerase inhibitor sofosbuvir plus ribavirin for Hepatitis C (ELECTRON). *N Engl J Med.* 2013; 368:34-44.
23. Gane E, Hyland R, An D, et al. Ledipasvir/Sofosbuvir fixed-dose combination is safe and effective in difficult-to-treat populations including GT3 patients, decompensated GT1 patients, and GT1 patients with prior sofosbuvir experience. International Liver Congress. 2014. London UK.
24. Gane EF, Hyland RH, An D, et al. High efficacy of LDV/SOF regimens for 12 weeks for patients with HCV genotype 3 or 6 infection. . [Abstract LB11.] 65th Annual Meeting of the American Association for the Study of Liver Disease (AASLD). November 7-11, 2014. Boston, MA. Available at: http://www.natap.org/2014/AASLD/AASLD_27.htm.
25. Lawitz E, Mangia A, Wyles D, et al. Sofosbuvir for previously untreated chronic Hepatitis C infection (FISSION/NEUTRINO). *N Engl J Med.* 2013; 368: 1878-1887.
26. Ruane PJ, Ain D, Riad J, et al. Sofosbuvir plus ribavirin in the treatment of chronic HCV genotype 4 infection in patients of Egyptian ancestory. 64th Annual Meeting of the American Association for the Study of Liver Disease (AASLD). November 1-4, 2013. Washington DC.
27. Kapoor R, Kohli A, Sidharthan S, et al. All oral treatment for genotype 4 chronic Hepatitis C infection with sofosbuvir and Ledipasvir: Interim results from the NIAID SYNERGY trial. [Abstract 240.] 65th Annual Meeting of the American Association for the Study of Liver Disease (AASLD). November 7-11, 2014. Boston, MA. Available at http://www.natap.org/2014/AASLD/AASLD_76.htm.

28. Pol S, Reddy KR, Baykal T et al. Interferon-free regimens of ombitasvir and ABT-450/r with or without ribavirin in patients with HCV genotype 4 infection: PEARL-I study results. [Abstract 1928.] 65th Annual Meeting of the American Association for the Study of Liver Diseases (AASLD). November 7-11, 2014; Boston, MA.
29. Sulkowski MS, Naggie S, Lalezari J, et al. Sofosbuvir and rivabirin for Hepatitis C in patients with HIV coninfection (PHOTON-I). JAMA. 2014; 312(4): 353-361.
30. Molina JM, Orkin C, Iser DM, et al. Sofosbuvir plus ribavirin for the treatment of Hepatitis C infection in patients coinfected with HIV (PHOTON-2): A multicenter, open label, nonrandomized, phase 3 study. Lancet. Published online February 4, 2015. Accessed February 16, 2015.
31. Townsend K, Osinusi A, Nelson A, et al. Use of Ledipasvir/sofosbuvir fixed dose combination for treatment of HCV genotype-1 infection in patients coinfected with HIV (ERADICATE). [Abstract 84.] 65th Annual Meeting of the American Association for the Study of Liver Disease (AASLD). November 7-11, 2014. Boston, MA. Available at: http://www.natap.org/2014/AASLD/AASLD_01.htm.
32. Wyles D, Sulkowski MS, Eron JJ, et al. TURQUOISE-I: 94% SVR12 in HCV/HIV-1 coinfected patients treated with ABT-450/r/ombitasvir and dasabuvir and ribavirin. [Abstract 1939.] 65th Annual Meeting of the American Association for the Study of Liver Disease (AASLD). November 7-11, 2014. Boston, MA. Available at: http://www.natap.org/2014/AASLD/AASLD_28.htm.
33. Charlton M, Gane E, Manns MP, et al. Sofosbuvir and ribavirin for treatment of compensated recurrent Hepatitis C virus infection after liver transplantation. *Gastroenterology*. 2014; doi:10.1053/j.gastro2014.10.001.
34. Reddy KR, Everson GT, Flamm SL, Denning JM, Arterburn S, Brandt-Sarif T. Ledipasvir/Sofosbuvir with ribavirin for the treatment of HCV in patients with post-transplant recurrence: Preliminary results of a prospective, multicenter study. [Abstract 8.] 65th Annual Meeting of the American Association for the Study of Liver Disease (AASLD). November 7-11, 2014. Boston, MA. Available at http://www.natap.org/2014/AASLD/AASLD_16.htm.
35. Kwo PY, Mantry PS, Coakley E, et al. An interferon-free antiviral regimen for HCV after liver transplantation (CORAL-I). *N Engl J Med*. 2014; 371: 2375-2382.
36. Flamm SL, Everson GT, Charlton MR, et al. Ledipasvir/sofosbuvir with ribavirin for the treatment of HCV in patients with decompensated cirrhosis: Preliminary results of a prospective multicenter study. 65th Annual Meeting of the American Association for the Study of Liver Disease (AASLD). November 7-11, 2014. Boston, MA. Available at http://www.natap.org/2014/AASLD/AASLD_36.htm.
37. Bristol-Myers-Squibb. Daclatasvir (Daklinza™). Product Label 2015. Accessed August 12, 2015.
38. AbbVie. Ombitasvir/Partiaprevir/Ritonavir/ (Technivie™). Product Label 2015. Accessed August 12, 2015.
39. Nelson DR, Cooper JN, Lalezard JP, et al. All-Oral 12-Week 12-week treatment with daclatasvir plus sofosbuvir in patients with hepatitis C virus genotype 3 infection: ALLY-3 phase III study. Hepatology. 2015; 61: 1127-1135.
40. Hézode C, Asselah T, Reddy KR, et al. Ombitasvir plus paritaprevir plus ritonavir with or without ribavirin in treatment-naïve and treatment-experienced patients with genotype 4 chronic hepatitis C virus infection (PEARL-I): a randomized, open-label trial. Lancet. 2015; 385: 2502-2509.
41. Sulkowski MS, Gardiner DF, Rodriquez-Torres M, et al. Daclatasvir plus sofosbuvir for previously treated or untreated chronic HCV infection. NEJM. 2014; 370(3): 211-221.
42. Jacobson IM, Dore GH, Fried MW, et al. Simeprevir with pegylated interferson alfa 2a plus ribavirin in treatment-naïve patients with chronic hepatitis C virus genotype 1 infection (QUEST-1): a phase 3, randomized, double-blind, placebo-controlled trial. Lancet. 2014; 384; 403-413.
43. Manns M, Marcellin P, Poordad F, et al. Simeprevir with pegylated interferson alfa 2a or 2b plus ribavirin in treatment-naïve patients with chronic hepatitis C virus genotype 1 infection (QUEST-2): a randomized, double-blind, placebo-controlled, a phase 3 trial. Lancet. 2014; 384; 414-426.

44. Lawitz E, Poordad F, Brainard DM, et al. Sofosbuvir with peginterferon-ribavirin for 12 weeks in previously treated patients with Hepatitis C and genotype 2 or 3 and cirrhosis. Hepatology. 2015; 61: 769-775.
45. Foster GR, Pianko S, Brown A, et al. Efficacy of sofosbuvir plus ribavirin with or without peginterferon-alfa in patients with hepatitis C virus genotype 3 infection and treatment-experienced patients with cirrhosis and hepatitis C virus genotype 2 infection. Gastroenterology. 2015; 1-9. doi: 10.1053/j.gastro.2015.07.043.
46. Doss W, Shiha G, Hassany M, et al. Sofosbuvir plus ribavirin for treating Egyptian patients with hepatitis c genotype 4. J Hepatology. 2015; 63: 581-585.
47. Ruane PJ, Ain D, Stryker R, et al. Sofosbuvir plus ribavirin for the treatment of chronic genotype 4 hepatitis C virus infection in patients with Egyptian ancestry. J Hepatology. 2015; 62: 1040-1046.
48. Kohli A, Kapoor R, Sims Z, et al. Lepdipasvir and sofosbuvir for hepatitis C genotype 3: a proof-of-concept, single centre, open-label phase 2a cohort study. Lancet. 2015; 15: 1049-1054.
49. Kwo P, Gitlin N, Nahass R, et al. A phase 3, randomized, open-label study to evaluate the efficacy and safety of 8 and 12 weeks fo Simeprevir (SMV) plus sofosbuvir (SOF) in treatment-naïve and experienced patients with chronic HCV genotype 1 infection without cirrhosis: OPTIMIST-1. 50th Annual Meeting of the European Association for the Study of the Liver (EASL). April 22-26, 2015; S270; Vienna, Austria.
50. Abergel A, Loustaud-Ratti V, Mitivier S, et al. Ledipasvir/sofosbuvir for the treatment of patients with chronic genotype 4 or 5 HCV infection. 50th Annual Meeting of the European Association for the Study of the Liver (EASL). April 22-26, 2015; Vienna, Austria.
51. Foster GR, McLauchlan J, Irving W, et al. Treatment of decompensated HCV cirrhosis in patients with diverse genotypes: 12 weeks sofosbuvir and NS5A inhibitors with/without ribavirin is effective in HCB genotypes 1 and 3. [Abstract O002] 50th Annual Meeting of the European Association for the Study of the Liver (EASL). April 22-26, 2015; Vienna, Austria. Available at http://natap.org/2015/EASL/EASL_34.htm
52. Wyles DL, Ruane PJ, Sulkowski MS, et al. Daclatasvir plus sofosbuvir for HCV in patients coinfected with HIV-1. NEJM. 2015; 373(8): 714-725.
53. Poordad F, Schiff ER, Vierling JM, et al. Daclatasvir, sofosbuvir, and ribavirin combination for HCV patients with advanced cirrhosis or post-transplant recurrence: ALLY-1 phase 3 study. [Abstract L08] 50th Annual Meeting of the European Association for the Study of the Liver (EASL). April 22-26, 2015; Vienna, Austria.
54. Bourliere M, Bronowicki J, de Ledinghen V, et al. Ledipasvir/sofosbuvir fixed dose combination is safe and efficacious in cirrhotic patients who have previously failed protease-inhibitor based triple therapy. [Abstract LB-6.] 65th annual Meeting of the American Association for the Study of Liver Diseases (AASLD). November 7-11, 2014; Boston, MA.
55. Charlton M, Everson GT, Flamm SL, et al. Ledipasvir and sofosbuvir plus ribavirin for treatment of HCV infection in patients with advanced liver disease. Gastroenterology. 2015; 149: 649-659.
56. Pungpapong S, Werner KT, Aqel B, et al. Multicenter experience using sofosbuvir and Simeprevir with/without ribavirin to treat HCV genotype 1 after liver transplantation. [Abstract 9] 65th Annual Meeting of the American Association for the Study of Liver Disease (AASLD). November 7-11, 2014; Boston, MA.
57. Pockros PJ, Reddy KR, Mantry PS, et al. Safety of ombitasvir/paritaprevir/ritonavir plus dasabuvir for treating HCV GT1 infection in patients with severe renal impairment or end-stage renal disease: the RUBY-1 study. [Abstract L01] 50th Annual Meeting of the European Association for the Study of the Liver (EASL). Aprill 22-26, 2015; Vienna, Austria.
58. Merck. Elbasvir/grazoprevir (Zepatier™) Product Label. 1/2016. Accessed June 6, 2016.
59. Gilead. Sofosbuvir/velapatasvir (Epclusa®) Product Label. 6/2016. Accessed September 9, 2016.
60. Abbvie. Glecaprevir/pibrentasvir (Mavyret™) Product Label. 8/2017. Accessed November 2, 2017.

History

Date	Action and Summary of Changes
06-07-2019	• Updated policy for preferred therapies and formatting.

07-08-2019	• Placed in updated policy format • Removed prescriber specialty requirement • Removed proof of chronic HCV infection • Added all drugs to the policy • Mavyret only preferred agent • Added treatment regimens

Glossary

- **Accountable Communities of Health** (ACHs): Organizations that bring together leaders from multiple health sectors around the state with a common interest in improving health and health equity. As ACHs better align resources and activities, they support wellness and a system that delivers care for the whole person. There are nine ACHs. Their boundaries align with Washington's Medicaid regional service areas. (https://www.hca.wa.gov/about-hca/healthier-washington/accountable-communities-health-ach)
- **Baby Boomers**: People born between 1945 through 1965. According to the CDC, Baby Boomers in the U.S. are five times more likely than other adults to have HCV.
- **Backbone Organization**: The backbone organization pursues six common activities to support and facilitate collective impact which distinguish this work from other types of collaborative efforts. Over the lifecycle of an initiative, they: 1) Guide vision and strategy; 2) Support aligned activities; 3) Establish shared measurement practices; 4) Build public will; 5) Advance policy; and 6) Mobilize funding.
- **Collective Impact**: The commitment of a group of actors from different sectors to a common agenda for solving a specific social problem, using a structured form of collaboration. The concept of collective impact was first articulated in the 2011 Stanford Social Innovation Review article "Collective Impact," written by John Kania, Managing Director at FSG (https://www.fsg.org/areas-of-focus/collective-impact), and Mark Kramer, Kennedy School at Harvard and Co-founder FSG.
- **Centers for Disease Control & Prevention** (CDC): The CDC is one of the major operating components of the U.S. Department of Health and Human Services and the health protection agency for the nation. The CDC's mission is to work 24/7 to protect America from health, safety and security threats, both foreign and in the U.S. Whether diseases start at home or abroad, are chronic or acute, curable or preventable, human error or deliberate attack, the CDC fights disease and supports communities and citizens to do the same.
- **Direct-acting antiviral**: Current HCV treatments are made up of combinations of drugs called direct-acting antivirals (DAAs). DAAs directly target the hepatitis C virus in different ways to stop it from making copies of itself. DAAs have a cure rate of over 95%. For most people who take DAAs, treatment is eight to twelve weeks and there are few side effects.
- **Elimination**: In the case of HCV, elimination is defined as a state where HCV is no longer a public health threat and where those few who become infected with HCV learn their status quickly and access curative treatment without delay, preventing the forward spread of the virus.
- **Eradication**: Elimination is distinct from eradication. Eradication is reduction of the worldwide incidence of a disease to zero as a result of deliberate efforts, obviating the necessity for further control measures. True eradication usually entails eliminating the microorganism itself or removing it completely from nature.
- **High-impact settings**: Settings that serve a high proportion of clientele who are at high risk for acquiring or transmitting HCV (e.g., syringe service programs, substance use disorder treatment centers, opioid treatment programs, programs serving people experiencing homelessness, jails, prisons).

- **Linkage to care**: Ensuring that people with a reactive HCV antibody test receive an HCV RNA (viral load) test, and those with current HCV infection (HCV RNA positive) are linked to a health care provider who is prepared to provide counseling services and comprehensive curative treatment. Successful linkage to care means people living with HCV have attended a first medical appointment for evaluation or treatment.
- **Local health jurisdictions**: Washington has 31 county health departments, three multi-county health districts, and two city-county health departments, referred to as local health jurisdictions. They are local government agencies. Local health jurisdictions carry out a wide variety of programs to promote health, help prevent disease, and build healthy communities. They are an important part of the state's public health system.
- **Non-clinical settings**: Community-based settings, such as outreach sites, syringe service programs, non-medication-based substance use treatment programs, shelters, organizations serving people experiencing homelessness, supportive housing programs, social service programs, and other locations outside of a clinical setting. These are locations that are easy to access and useful for people who might not be willing or able to access medical services regularly.

Endnotes

[1] Centers for Disease Control & Prevention. "Surveillance for Viral Hepatitis – United States, 2016." Available online at: https://www.cdc.gov/hepatitis/statistics/2016surveillance/commentary.htm.

[2] Lydia Tang, Lauren Marcell, and Shyam Kottilil, "Systemic manifestations of hepatitis C infection," Infectious agents and cancer, 11, 29 (2016). Available online at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4878040/.

[3] Baligh Yehia, Asher Schranz, Craig Umscheid and Vincent Lo Re, "The Treatment Cascade for Chronic Hepatitis C Virus Infection in the United Stated: A Systematic Review and Meta-Analysis," PLoS ONE 9, 7 (2014). Available online at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4079454/.

[4] Centers for Disease Control & Prevention, "Testing Recommendations for Hepatitis C Virus Infection." Available online at: https://www.cdc.gov/hepatitis/hcv/guidelinesc.htm.

[5] AK Varan, DW Mercer, MS Stein, and AC Spaulding, "Hepatitis C Seroprevalence Among Prison Inmates Since 2001: Still High but Declining," Public Health Reports, 129 (2014): 187-195. Available online at: https://www.ncbi.nlm.nih.gov/pubmed/24587554.

[6] BR Edlin, BJ Eckhardt, MA Shu, and MA Shu. "Toward a more accurate estimate of the prevalence of hepatitis C in the United States," Hepatology, 62, 5 (2015): 1353-63.

[7] Varan et al., op cit.

[8] Lara Strick, Personal communication, July 7, 2019.

[9] BR Yehia, RS Herati, JA Fleishman, JE Gallant, AL Agwu, SA Berry, PT Korthuis, et al."Hepatitis C virus testing in adults living with HIV: a need for improved screening efforts," PLoS ONE, 9, 7 (2014):e102766. Available online at: https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0102766.

[10] PR Spradling, JT Richardson, K Buchacz, AC Moorman, L Finelli, BP Bell, and JR Brooks, HIV Outpatient Study Investigators, "Trends in hepatitis C virus infection among patients in the HIV Outpatient Study, 1996–2007," J Acquir Immune Defic Syndr, 53 (2010):388–396.

[11] Centers for Disease Control and Prevention, "Viral Hepatitis Surveillance—United States, 2015," (2017). Available online at: https://www.cdc.gov/hepatitis/statistics/2015surveillance/pdfs/2015HepSurveillanceRpt.pdf.

[12] Shikha Garg, John Brooks, Qingwei Luo, and Jacek Skarbinski, "Prevalence of and Factors Associated with Hepatitis C Virus (HCV) Testing and Infection Among HIV-infected Adults Receiving Medical Care in the United States," Infectious Disease Society of America (IDSA), Philadelphia, PA, 2014. Available online at: https://www.researchgate.net/publication/267530237_Prevalence_of_and_Factors_Associated_with_Hepatitis_C_Virus_Testing_and_Infection_Among_HIV-infected_Adults_Receiving_Medical_Care_in_the_United_States.

[13] Yehia et al., op. cit.

[14] Spradling et al., op. cit.

[15] Centers for Disease Control and Prevention, op. cit.

[16] Panel on Opportunistic Infections in HIV-Infected Adults and Adolescents. Guidelines for the prevention and treatment of opportunistic infections in HIV-infected adults and adolescents: recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. Available at http://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf.

[17] P Telfer, C Sabin, H Devereux, F Scott, G Dusheiko, C Lee, "The progression of HCV-associated liver disease in a cohort of haemophilic patients," Br J Haematol, 87, 3 (1994):555–561.

[18] B Soto, A Sanchez-Quijano, L Rodrigo, JA del Olmo, M Garcia-Bengoechea, J Hernadez-Quero, C Rey, et al., "Human immunodeficiency virus infection modifies the natural history of chronic parenterally-acquired hepatitis C with an unusually rapid progression to cirrhosis," J Hepatol, 26, 1 (1997):1–5.

[19] Y Benhamou, M Bochet, V Di Martino, F Charlotte, F Azria, A Coutellier, M Vidaud M, et al., "Liver fibrosis progression in human immunodeficiency virus and hepatitis C virus coinfected patients," Hepatology, 30, 4 (1999):1054–1058.

[20] CS Graham, LR Baden LR, E Yu E, et al. "Influence of human immunodeficiency virus infection on the course of hepatitis C virus infection: a meta-analysis," Clin Infect Dis., 33, 4 (2001):562–569.

[21] AIDSinfo, "Fact sheet: HIV and hepatitis C." Available online at: https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/26/88/hiv-and-hepatitis-cExternal.

[22] Jen Reuer, Personal communication, June 24, 2019.

[23] C Ramière, C Charre, P Miailhes, F Bailly, S Radenne, AC Uhres AC, C Brochier, et al, "Patterns of HCV transmission in HIV-infected and HIV-negative men having sex with men," Clin Infect Dis, online edition (2019).

[24] Gonche Danesh, Victor Virlogeux, Christophe Ramiere, Caroline Charre, Samuel Alizon, Laurent Cotte, et al. "Phylodynamics of HCV acute infection in men having sex with men." CROI 2019, Seattle, Abstract Number 594.

[25] Maxine Denniston, Ruth Jiles, Jan Drobeniuc, R. Monina Klevens, John Ward, Geraldine McQuillan, and Scott Holmbery, "Chronic Hepatitis C Virus Infection in the United States, National Health and Nutrition Examination Survey 2003 to 2010," Annals of Internal Medicine, 4 March (2014). Available online at: https://annals.org/aim/fullarticle/1834167/chronic-hepatitis-c-virus-infection-united-states-national-health-nutrition.

[26] Brigg Reilley and Jessica Leston, "A Tale of Two Epidemics-HCV Treatment among Native Americans and Veterans," N Engl J Med, 377 (2017):801-803. Available online at: https://www.nejm.org/doi/full/10.1056/NEJMp1705991.

[27] U.S Department of Health and Human Services Office of Minority Health, "Hepatitis and American Indians/Alaska Natives." Available online at: https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=35.

[28] SM Hatcher, S Joshi, and T Weiser. "Hepatitis C mortality among American Indians and Alaska Natives in the Northwest, 2006-2012." Council of State and Territorial Epidemiologists. June 3-8, 2017. Boise, ID.

[29] Rui Marinho and David Pires Barreira, "Hepatitis C, stigma and cure," World J Gastroenterolg, 19, 40 (2013): 6703-6709. Available online at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3812468/#B41.

[30] World Health Organization. Combating hepatitis B & C to reach elimination by 2030. (Geneva: World Health Organization, 2016). Available online at: https://www.who.int/hepatitis/publications/hep-elimination-by-2030-brief/en/.

[31] Centers for Disease Control and Prevention), "National Progress Toward Hepatitis C Elimination – Georgia, 2015-2016,"Morbidity & Mortality Weekly Report, 65, 41 (2016):1132-1135. Available online at: https://www.cdc.gov/mmwr/volumes/65/wr/mm6541a2.htm.

[32] Burnet Institute (Australia), "Eliminate Viral Hepatitis." Available online at: https://www.burnet.edu.au/centres/24_eliminate_hep_c.

[33] John Dillon, "Scottish Hepatitis C Action Plan, Version 4.0." (2015). Available online at: http://regist2.virology-education.com/2015/1euhep/11_Dillon.pdf.

[34] National Academies of Sciences, Engineering, and Medicine. A national strategy for the elimination of hepatitis B and C. (Washington, DC: The National Academies Press, 2017). Available online at: http://nationalacademies.org/hmd/Reports/2017/national-strategy-for-the-elimination-of-hepatitis-b-and-c.aspx.

[35] Department of Health and Human Services, "National Viral Hepatitis Action Plan 2017-2020" (Washington, DC, US Department of Health and Human Services, 2017). Available online at: https://www.hhs.gov/sites/default/files/National%20Viral%20Hepatitis%20Action%20Plan%202017-2020.pdf.

[36] Northwest Portland Area Indian Health Board and Cardea, "Universal screening Cherokee Nation to eliminate hepatitis C." Available online at: http://www.npaihb.org/wp-content/uploads/2018/06/J.Iwasaki_Lummi.pdf.

[37] Healio, "Universal screening Cherokee Nation to eliminate hepatitis C," Hepatology/Hepatitis C, August 8, 2017. Available online at: https://www.healio.com/hepatology/hepatitis-c/news/online/%7Bb0771a05-bc35-46d1-8b18-a08a7ba6ff6f%7D/universal-screening-in-cherokee-nation-aims-to-eliminate-hepatitis-c.

[38] End Hep C SF, "End Hep C SF strategic plan 2017-2019" (San Francisco: End Hep C SF, 2017). Available online at: http://www.endhepcsf.org/wp-content/uploads/2017/07/EndHepC_FINAL_for_e-distribution.pdf and www.endhepcsf.org for additional information on the End Hep C SF initiative.

[39] Miranda Sedillo, "New Mexico Hepatitis C Elimination Project Slides", University of New Mexico/ECHO, May 10, 2017. Available online at: https://som.unm.edu/education/cme/2017/files/miranda-sedillo.pdf.

[40] NYS Hepatitis C Elimination Campaign, "HEP C Ends With Me". Available online at: https://www.endhepcny.org/ and Governor's Press Office, "NY Governor Announces Nation's First State-Level Hep C Elimination Strategy,"Hepfree.NYC. Available online at: https://hepfree.nyc/ny-governor-announces-nations-first-state-level-hep-c-elimination-strategy/.

[41] AASLD/IDSA, "Overview of Cost, Reimbursement, and Cost-Effectiveness Considerations for Hepatitis C Treatment Regimens." Hepatitis C Guidelines.org. Available online at: https://www.hcvguidelines.org/evaluate/cost.

[42] Washington State Health Care Authority purchases health care for more than two million Washington residents through Apple Health (Medicaid), the Public Employees Benefits Board (PEBB) Program, and, beginning in 2020, the School Employees Benefits Board (SEBB) Program. The Health Care Authority is the largest health care purchaser in the state.

[43] Washington State Health Care Authority, "Eliminating hepatitis C." Available online at https://www.hca.wa.gov/about-hca/clinical-collaboration-and-initiatives/eliminating-hepatitis-c.

[44] Collective Impact Forum, "Collective impact brings people together in a structured way, to achieve social change." Available online at: https://www.collectiveimpactforum.org/what-collective-impact.

[45] Washington State Department of Health, "End AIDS Washington." Available online at: https://www.doh.wa.gov/YouandYourFamily/IllnessandDisease/HIV/EndAIDSWashington.

[46] Washington State Department of Health, "Opioids." Available online at https://www.doh.wa.gov/CommunityandEnvironment/Opioids.

[47] Washington State Department of Health, "Hepatitis C," Available online at: https://www.doh.wa.gov/ForPublicHealthandHealthcareProviders/NotifiableConditions/HepatitisC.

[48] State of Utah, RULE: R386-702-4

1. *Electronic reporting of negative results: Electronic reporting shall include negative as well as positive results for tests ordered for the following conditions: Chlamydia, Gonorrhea, Hepatitis A, Hepatitis B, Hepatitis C, including viral loads, Human Immunodeficiency Virus (HIV), including viral loads and confirmatory tests, Salmonellosis, STEC, Tuberculosis.*
2. *Negative test results reported for these conditions will be used for the following purposes as authorized in Utah Health Code Section 26-1-30(2)(c),(d), and (f):To determine when a previously reported case becomes non-infectious; To identify newly acquired infections through identification of a seroconversion window; or To provide information critical for assignment of a case definition.*
3. *Information associated with a negative test result will be retained by the Utah Department of Health for a period of 18 months. At the end of the 18 month period, if the result has not been appended to an existing case, personal identifiers will be stripped and expunged from the result. The de-identified result will be added to a de-identified, aggregate dataset which will be retained for use by public health to analyze trends associated with testing patterns* and case distribution, enabling identification and establishment of prevention and intervention efforts for at-risk populations, and assessment of trends over time in those populations, as authorized by Utah Health Code 26-1-30(2)(f).

[49] Washington State Board of Health. "Notifiable Conditions Update". January 9, 2019. Available online at: https://sboh.wa.gov/Portals/7/Doc/Meetings/2019/01-09/Tab06a-Notifiable%20Conditions%20Update.pdf.

[50] C Isenhour, S Hariri, and C Vellozzi, "Monitoring the Hepatitis C Care Cascade Using Administrative Claims Data," Am J Manag Care, 24, 5 (2018): 232-238.

[51] Washington State Department of Health, Washington Tracking Network, Available online at: https://www.doh.wa.gov/DataandStatisticalReports/EnvironmentalHealth/WashingtonTrackingNetworkWTN.

[52] Peter Vickerman, Hannah Fraser, Thomas Hoerger, Carolina Barbosa, Susan Hariri, Claudia Vellozzi, Alex Kral, Jon Zibbell, and John Ward, "Impact and cost-effectiveness of scaling up HCV treatment and prevention interventions for PWID in the U.S." Presentation at the CDC Viral Hepatitis Summit, Atlanta, April 2017.

[53] Natasha Martin, Peter Vickerman, Graham R. Foster, Sharon J. Hutchinson, David J. Goldberg, and Matthew Hickman, "Can antiviral therapy for hepatitis C reduce the prevalence of HCV among injecting drug user populations? A modeling analysis of its prevention utility." Journal of Hepatology, 54 (2011):1137–1144.

[54] Washington State Department of Health. "Recommendation: Needs-Based Syringe Access." (Olympia: Washington State Department of Health, 2019. Available online at: https://www.doh.wa.gov/Portals/1/Documents/Pubs/150-122-WADOHSyringeAccessRecommendation2019.pdf.

[55] Drug Policy Alliance, "Stimulant Use: Harm Reduction, Treatment, and Future Directions Conference Report." September 2017. Available online at: http://www.drugpolicy.org/sites/default/files/dpa_report_stimulantharmreduction_0.pdf.

[56] David Wohl, Andrew Allmon, Donna Evon, Christopher Hurt, Sarah Reifeis, Harsha Thirumurthy, Becky Straub, Angela Edwards, and Katie Mollan, "Financial Incentives for Adherence to Hepatitis C Virus Clinical Care and Treatment: A Randomized Trial of Two Strategies," Open Forum Infectious Diseases, Spring (2017). Available online at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5499638/.

[57] Audrey Pettifor, Catherine MacPhail, Nadia Nguyen, and Molly Rosenberg, "Can money prevent the spread of HIV? A review of cash payments for HIV prevention," AIDS Behav., October (2012). Available online at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3608680/.

[58] CK Malotte, JR Hollingshead, and F Rhodes. "Monetary versus nonmonetary incentives for TB skin test reading among drug users," American Journal of Preventive Medicine, 16, 3 (1999):182-188.

[59] AASLD/IDSA, "HCV in Key Populations: Men Who Have Sex With Men," HCV Guidelines. Available online at: https://www.hcvguidelines.org/unique-populations/msm.

[60] Erin Wilson, Jessica Lin, Caitlin Turner, San Francisco Department of Public Health and University of California, San Francisco, Unpublished data from "The Trans*National Study." Available online at: https://static1.squarespace.com/static/56e34aadd210b8a4c7ea4a9c/t/5c5db94ab208fcb27d0b86d4/1549646175796/Trans+Health+Summit+31Oct2017+HCV+and+transwomen_8Nov17+for+upload.pdf.

[61] Washington State Health Care Authority, "Medicaid (Title XIX) State Plan." Available online at: https://www.hca.wa.gov/about-hca/apple-health-medicaid/medicaid-title-xix-state-plan.

[62] Kora DeBeck, Tessa Cheng, Julio Montaner, Chris Beyrer, Richard Elliott, Susan Sherman, Evan Wood, and Stefan Baral, "HIV and the criminalisation of drug use among people who inject drugs: a systematic review," The Lancet HIV, 4, 8 (2017). Available online at: https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018(17)30073-5/fulltext.

[63] BL Norton, A Beitin, M Glenn, J DeLuca, AH Litwin, and CO Cunningham, "Retention in Buprenorphine Treatment is Associated with Improved HCV Care Outcomes," J Subst Abuse Treat. 75 (2017): 38–42.

[64] Maria Stepanova, Alexander Thompson, Joseph Doyle, Issah Younossi, Leyla de Avila, and Zobair M Younossi, "Hepatitis C Virus–Infected Patients Receiving Opioid Substitution Therapy Experience Improvement in Patient-Reported Outcomes Following Treatment With Interferon-Free Regimens," The Journal of Infectious Diseases, 217, 7 (2018):1033–1043.

[65] AASLD and IDSA. "Key Populations: Identification and Management of HCV in People Who Inject Drugs," HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C (2019). Available online at https://www.hcvguidelines.org/unique-populations/pwid.

[66] Centers for Disease Control and Prevention, "Screening for Viral Hepatitis During the Domestic Medical Examination of Newly Arrived Refugees." Available online at: https://www.cdc.gov/immigrantrefugeehealth/guidelines/domestic/hepatitis-screening-guidelines.html.

[67] Vanessa McMahan, Sarah Deutsch, Chelsie Porter, Madi McPadden, Lisa Talbott, Nicole Dronen, and Shilo Jama, "Awareness of HCV Treatment Guidelines and Testing and Prescribing Practices for Patients who Inject Drugs Among Washington State Providers," unpublished findings.

[68] Centers for Disease Control & Prevention, "Testing Recommendations for Hepatitis C Virus Infection." Available online at: https://www.cdc.gov/hepatitis/hcv/guidelinesc.htm.

[69] U.S. Preventive Services Task Force, "Hepatitis C: Screening," Available online at: https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/hepatitis-c-screening.

[70] AASLD and IDSA. "HCV in Pregnancy," HCV Guidelines. Available online at: https://www.hcvguidelines.org/unique-populations/pregnancy.

[71] Health Care Authority, "Washington State Common Measure Set, 2019 (PMCC Approved, December 2018)." Available online at: https://www.hca.wa.gov/assets/program/washington-state-common-measures-2019.pdf.

[72] Washington State Health Care Authority, "Value-based purchasing" Available online at: https://www.hca.wa.gov/about-hca/value-based-purchasing.

[73] Centers for Disease Control and Prevention, "Epidemic Intelligence Service 2019 Annual Update," Available online at: https://www.cdc.gov/eis/index.html.

[74] Jordan Feld, "Simplifying HCV Assessment and Treatment," Hepatitis Annual Update June 5, 2010, Clinical Care Options. Available online at: https://www.clinicaloptions.com/hepatitis/programs/ccohep2019/downloadable-slidesets/slides-1.

[75] Centers for Medicare & Medicaid Services, "About section 1115 Demonstrations," Available online at: https://www.medicaid.gov/medicaid/section-1115-demo/about-1115/index.html.

[76] Healthier Here. "Our work." Available online at: https://www.healthierhere.org/our-work/.

Hep C Free Washington Community Partners

To date, 16 community partners have signed on to the Hep C Free WA initiative. These partners have agreed that they share the goal of HCV elimination in Washington State, driven by broad-based prevention addressing social determinants of health, education, testing, linkage, and treatment strategies. Partners provide expertise and, in many cases, staff time in initiative meetings and Hep C Free WA events.

As a collective impact initiative, participation from representatives of these various organizations helps ensure Hep C Free WA is leveraging a variety of expertise in service of a common agenda for change.

Please email HepCFreeWA@doh.wa.gov if your organization would like to officially sign on to be a Hep C Free WA Community Partner.

HEP Hepatitis Education Project

Lifelong

NWIH Integrated Health

FHRA

pcaf

Providence Centralia Hospital

Public Health Seattle & King County

Spokane Regional Health District

Tacoma Needle Exchange — A Dave Purchase Initiative

Tacoma-Pierce County Health Department — Healthy People in Healthy Communities

Department of Corrections Washington State

Washington State Department of Health

Washington State Health Care Authority

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College of Pharmacy and Pharmaceutical Sciences — Washington State University

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