



# **Feasibility and Cost- Effectiveness of Cross- Agency Bulk Purchasing for Direct Acting Antiviral Medications for Hepatitis C**

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**As Required by**

**Rider 40, Article II, 86<sup>th</sup> Legislative  
Session**

**Health and Human Services Commission  
Employees Retirement System  
Teacher Retirement System  
Texas Department of Criminal Justice**



**TEXAS**  
Health and Human  
Services

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# 1. Executive Summary

The Texas Legislature directed the Texas Health and Human Services Commission (HHSC) through Rider 40 of the 2020-2021 General Appropriations Act (Article II, HHSC, 86th Legislature) to work in cooperation with the Texas Department of Criminal Justice (TDCJ), Employees Retirement System of Texas (ERS), and Teacher Retirement System (TRS) to explore the feasibility of implementing a model allowing the state to pay a flat monthly rate for unlimited access to medications or other bulk purchasing or negotiating opportunities to treat individuals with Hepatitis C (HCV) infection who are eligible to have prescriptions provided with state funds. The rider requires HHSC to prepare and submit this report on the cost-effectiveness and projected savings of implementing such a model to the Governor, Legislative Budget Board, and permanent committees in the House of Representatives and the Senate with jurisdiction over health and human services.

In response to this rider, HHSC worked with ERS, TRS, and TDCJ to discuss each agency's drug purchasing methodologies. HHSC and TDCJ use state funds to provide healthcare services, while ERS and TRS use healthcare trust funds that include member premium payments, local school district funds, and state funds.<sup>1</sup> Staff also conducted literature reviews on the use of value-based payments and interviewed key individuals from two states on implementation of this model. These two states, Washington and Louisiana, received Centers for Medicare and Medicaid Services' (CMS) approval in 2019 to implement a bulk purchasing agreement for the acquisition of direct acting antivirals (DAAs) for treating HCV. Significant findings from these interviews and discussion with partner agencies include:

- The purchasing methodologies of individual agencies within states impact contract design;
- Differences in purchasing methodologies among state agencies impact the feasibility of a cross-agency strategy;
- Early engagement with federal partners benefited states' program designs; and
- Cost-effectiveness increases with greater numbers of individuals treated.

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<sup>1</sup> HHSC authored all sections of the report related to TDCJ.

This report provides an overview of the HCV landscape in Texas, a history of the use of DAAs, Washington and Louisiana’s bulk-purchasing agreements, background on how each Texas state agency purchases DAAs and the policies surrounding treatment of HCV, and the feasibility and cost-effectiveness of a bulk-purchasing agreement for the treatment of HCV in Texas. The state’s goals for the treatment of HCV dictate the cost-effectiveness of the bulk-purchasing strategy.

## 2. Introduction

The Texas Legislature directed HHSC through Rider 40 of the 2020-2021 General Appropriations Act (Article II, HHSC, 86th Legislature) to work in cooperation with the Texas Department of Criminal Justice (TDCJ), Employees Retirement System (ERS), and Teacher Retirement System (TRS) to explore the feasibility of implementing a model allowing the state to pay a flat monthly rate for unlimited access to medications or other bulk purchasing or negotiating opportunities to treat individuals with HCV who are eligible to have prescriptions provided with state funds. HHSC was directed to prepare and submit a report on the cost-effectiveness and projected savings of implementing such a model to the Governor, Legislative Budget Board, and permanent committees in the House of Representatives and the Senate with jurisdiction over health and human services.

HCV is a blood-borne disease that is the leading cause of liver-related morbidity, transplantation, and mortality. While HCV was once thought of as a disease that affected the baby boomer generation, new data indicates that it is prevalent across all generations. With the advent of DAAs, there is now promising treatment for this disease. DAAs are medications whose mechanism of action is to inhibit viral replication by interfering with steps in the viral life cycle. When first introduced in late 2013, the second generation DAAs cost approximately \$84,000 for a course of treatment. The price of these drugs has since decreased, but remains costly, leading two states to pursue value-based purchasing strategies to improve access to the medications and increase the number of individuals treated, while maintaining some fiscal predictability in their budgets.

In this report, HHSC evaluates the value-based purchasing strategies of Washington and Louisiana to treat HCV with DAAs in their populations and assesses whether this type of strategy is feasible for implementation across Texas agencies and whether a cross-agency value-based purchasing strategy would be cost-effective and whether cost savings are possible. HHSC, ERS, TRS, and TDCJ purchase HCV drugs differently. HHSC and TDCJ use state funds to provide healthcare services, while ERS and TRS use healthcare trust funds that include member premium payments, local school district funds, and state funds.

### 3. Background

HCV is a significant health problem in the United States (US). It is a blood-borne virus that causes an infection of the liver. Prior to 1992, the virus was transmitted most commonly through exposure to infected blood through transfusion but, today, intravenous drug use is the most common method of transmission. HCV is the most frequently reported blood-borne infection in the US and a leading cause of liver-related morbidity, transplantation and mortality. Based on a 2016 CDC report, HCV kills more Americans than any other infectious disease.<sup>2</sup> The Centers for Disease Control (CDC) estimates that approximately 2.44 million individuals in the US are infected, and the infection is more pervasive than initially thought.<sup>3</sup> This disease was once thought of as a disease that mostly afflicted the baby boomer generation (1946-1964), but new data indicates that it impacts every generation. Of the newly reported infections in 2018, millennials (1981-1996) comprised 36.5 percent, baby boomers comprised 36.3 percent, and Generation X (1965-1980) comprised 23.1 percent of newly reported infections. The United States Preventive Services Task Force (USPSTF) recommends that all adults between the age of 18 and 79 be universally tested for HCV infection, and the CDC recommends every adult be tested for HCV at least once in their lifetime, pregnant women be tested during every pregnancy, and individuals with risk factors be tested on an ongoing basis.<sup>4</sup>

The World Health Organization has set a global goal to eliminate HCV by 2030. Viral hepatitis is one of the three global health sector strategies and aims for a 90 percent reduction in new chronic infections and a 65 percent reduction in mortality for both Hepatitis B and C.

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<sup>2</sup> U.S. Centers for Disease Control (May 4, 2016), Hepatitis C Kills More Americans Than Any Other Infectious Disease, retrieved from [CDC Website](#) on May 14, 2020.

<sup>3</sup> Hepatitis C Questions and Answers for Health Professionals. United States Centers for Disease Control and Prevention. <https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm#Ref01> Accessed on March 11, 2020.

<sup>4</sup> Risk factors include, for example, injection drug use and other high-risk behaviors.

## Health Impacts of Untreated HCV

There are consequences to untreated HCV. Some individuals whose bodies cannot fight off the infection develop chronic HCV infection. Many people infected with the virus are unaware of the infection and have only mild or no symptoms and may unknowingly infect others with the virus. These individuals may not learn of their own infections until years later when diagnosed with cirrhosis or other liver diseases.<sup>5</sup>

Of every 100 people infected with HCV approximately 75 to 85 will develop chronic HCV infection and 10 to 20 will develop cirrhosis over a twenty to thirty-year period. Of the patients who develop cirrhosis:

- One to five percent experience an annual risk of hepatocellular carcinoma, the most common type of cancer that starts in the liver and causes the death of more people in Texas than any other state; and,
- Three to six percent experience an annual risk of hepatic decompensation, for which the risk of death in the following year is 15 percent to 20 percent.<sup>6,7</sup>

There are other notable complications of cirrhosis, including ascites, hyponatremia, spontaneous bacterial peritonitis, hepatorenal syndrome, portopulmonary hypertension, hepatopulmonary syndrome, gastroesophageal varices, and hepatic encephalopathy.<sup>8</sup>

Certain factors increase the rate of progression to cirrhosis, including being male, age over 50 years, moderate to heavy alcohol consumption, nonalcoholic fatty liver disease, coinfection with Hepatitis B or HIV and treatment with immunosuppressive therapy.<sup>9</sup>

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<sup>5</sup> *Viral Hepatitis: Hepatitis C Questions and Answers for Health Professionals*. Centers for Disease Control and Prevention. <https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm#section1>. Updated 01/27/2017. Accessed 10/12/2017

<sup>6</sup> Texas Department of State Health Services (2018). 2018 State Plan for Hepatitis C.

<sup>7</sup> Singal, A. M.D. (2018). Texas than in any other state: How we can Fight Back. University of Texas Southwestern Medical Center. <https://utswmed.org/medblog/hepatocellular-carcinoma/>. Retrieved April 29, 2020.

<sup>8</sup> Centers Nusrat, S., Kham, M.S., Fazili, J., & Madhoun, M.F. (2014). Cirrhosis and its complications: Evidence based treatment. *World Journal of Gastroenterology*, 20, 5442-5460.

<sup>9</sup> [Centers for Disease Control Website](#), retrieved April 24, 2020.

## HCV in Texas

Texas is estimated to have over half a million individuals infected with chronic HCV.<sup>10,11,12</sup> Texas, along with eight other states (California, Florida, New York, Pennsylvania, Ohio, Michigan, Tennessee, and North Carolina), account for over 50 percent of all HCV cases in the U.S.<sup>13</sup> Additionally, Texas has the highest incidence rate and third highest mortality rate for liver and intrahepatic bile duct cancer among states in the US. Liver cancer is the sixth most commonly diagnosed cancer and 50 percent are HCV related. Deaths from liver and intrahepatic bile duct cancers in Texas increased by 36 percent, and new cases of liver and intrahepatic bile duct cancers increased by 3.1 percent from 2010 to 2016. Lack of diagnosis and treatment contribute to prevalent transmission.

## History of DAAs

DAAs boceprevir and telaprevir for treating HCV were first introduced in 2011.<sup>14</sup> In late 2013, the US Food and Drug Administration (FDA) approved second-generation DAAs. They were more effective, easier to tolerate, and had shorter treatment periods. A 12-week treatment course for Gilead's Sovaldi cost \$84,000. Later, Gilead introduced Harvoni at a cost of \$94,500, also for a 12-week supply. Several years later, AbbVie introduced Mavyret at \$26,400 for a treatment course. More recently, the introduction of generic options has lowered the cost of DAAs, yet they remain relatively high-priced, thereby limiting states' abilities to treat all their infected populations. Due to the high cost of the drugs when DAAs for HCV were first introduced, states implemented criteria for accessing the drugs to control costs. Due to scrutiny of criteria limiting access to the drugs, most states relaxed these criteria.

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<sup>10</sup> Hepatitis C in Texas. Texas Department of State Health Services.

<https://dshs.texas.gov/hivstd/info/edmat/HepCinTexas.pdf>. Accessed April 29, 2020.

<sup>11</sup> Price, S. (February 2020). Reaching for the Cure, Texas Medicine.

<sup>12</sup> Texas Department of State Health Services. Hepatitis C in Texas Fact Sheet.

<https://dshs.texas.gov/hivstd/info/edmat/HepCinTexas.pdf>.

<sup>13</sup> Bradley, H., Hall, E.W., Rosenthal, E.M. et al. (2020). Hepatitis C Virus Prevalence in 50 U.S. States and D.C. by Sex, Birth Cohort and Race: 2013-2016. *Hepatology Communications*, 4(3): 355-370.

<sup>14</sup> Bryan-Marrugo, O.L., Ramose-Jimenez, J., Barrera-Saldana, H. et al. (2015). History and progress of antiviral drugs: From acyclovir to direct-acting antiviral agents (DAAs) for Hepatitis C., 17 (68), 165-174.

Prior to the development of sofosbuvir/valpatasvir (SOF/VEL), DAAs were genotype-specific meaning the virus's genotype had to be identified prior to treatment to select the most effective treatment for the specific virus type. There are six major genotypes of HCV and over 50 different subtypes, with each genotype of HCV sharing similar genetic characteristics. Today's modern DAAs can treat all six major genotypes of HCV, which reduces the need for gene testing.

## **The Modified “Netflix” Model**

The high cost of DAAs has motivated states to find different ways to pay for the costly drugs. The modified “Netflix” model is a value-based methodology where the entity (i.e., the state) solicits offers in pursuit of a manufacturer(s) to supply an “unlimited” quantity of its DAA over a specified contract period. The state and the manufacturer negotiate an annual expenditure ceiling, and once the ceiling is reached, each subsequent unit is heavily or fully rebated to result in a nominal net cost. The state is guaranteed an unlimited supply during the contract period. This type of purchasing arrangement has been exercised by different government organizations.

In 2015, Australia (AU) entered into a five-year, AU \$1 billion (US \$766 million) agreement with drug manufacturers for an unlimited supply of HCV drugs. Based on available information, Australia's formulary included seven DAA products. Between March 2016 and February 2018, Australia treated an estimated 47,112 individuals at an average estimated cost of US \$7,352.<sup>15</sup> Similarly, Washington and Louisiana recently executed single-source contracts to eliminate HCV throughout their states more cost-effectively.

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<sup>15</sup> Moon, S., & Erickson, E. (2019). Universal Medicine Access through Lump-Sum Remuneration – Australia's Approach to Hepatitis C. *The New England Journal of Medicine*; 380,7.

## **Louisiana – HCV Treatment**

Louisiana estimates at least 90,900 people in the state are infected with HCV, 39,000 of whom are in the state's Medicaid program or Corrections department. Louisiana Department of Health's (LDH) Medicaid program and Louisiana Department of Corrections (DOC) set a goal to eliminate HCV within five years, while limiting net expenditures on DAAs to the "Total State Spend for Fiscal Year 2018 in both the Medicaid and Incarcerated Populations," which were \$30 million and \$55 million dollars respectively. The Total State Spend is the state's total pre-rebate, annual DAA spend on Medicaid, including federal and state funds, and corrections patients initiating HCV treatment in State Fiscal Year (SFY) 2018 (excluding the Medicare/Medicaid dual eligible and third-party liability populations).

Louisiana argues by engaging in an innovative payment model and negotiating an expenditure cap, the state's costs are predictable, and more people have access to treatment. The agreement also benefits manufacturers because it provides a predictable revenue stream. As a result, patients gain access to treatment while morbidity and mortality are reduced in the population.

Three manufacturers (Gilead, Merck, and AbbVie) responded to Louisiana's request. On June 26, 2019, LDH announced its partnership with Asegua Therapeutics, a wholly owned subsidiary of Gilead, to implement an innovative payment model for the treatment of HCV.<sup>16</sup> Through this partnership, Asegua provides unrestricted access of agSOF/VEL, its authorized generic for EPCLUSA (sofosbuvir/velpatasvir), to Louisiana's Medicaid and incarcerated populations. Sofosbuvir/velpatasvir is indicated for treatment of individuals as young as six years of age with chronic HCV genotypes 1, 2, 3, 4, 5, or 6 infections. Gilead describes EPCLUSA as a pan-genotypic, pan-fibrotic, once-daily, single-tablet regimen with a 12-week dosing for most chronic HCV patients. The contract commenced July 1, 2019 and terminates June 30, 2024. The estimated value of the contract is \$58 million per year for five years.<sup>17</sup> Louisiana's goal is to treat 10,000 of the Medicaid and corrections population by 2020 and to have treated 31,000 of the 39,000 HCV-infected Medicaid patients and inmates by 2024. The cost per treatment has the potential to be less than \$10,000 per person. Once Louisiana reaches the contracted annual expenditure ceiling amount, each subsequent treatment is heavily rebated with supplemental rebates.

Though LDH has one primary contract with Asegua, the differing purchasing methodologies between its Medicaid and correctional facilities necessitated two separate agreements. For the Medicaid population, the manufacturer makes available an unrestricted supply of agSOF/VEL. Once the state's Medicaid Total State Spend reaches the negotiated annual expenditure ceiling amount, the cost of each additional DAA dispensed is offset by supplemental rebates, resulting in a nominal net cost.

<sup>16</sup> The Louisiana Department of Health is comprised of the Medical Vendor Administration (Medicaid), the Office for Citizens with Developmental Disabilities, the Office of Behavioral Health, the Office of Aging and Adult Services, and the Office of Public Health.

<sup>17</sup> [Pharma Sells States on "Netflix Model" To Wipe Out Hep C. But at What Price?](#) Accessed December 9, 2020.

Because of the various requirements regarding eligibility and pricing in the 340B program, Louisiana worked closely with Apexus Compliance, the prime vendor for the federal agency that administers the 340B program, the Health Resources Services Administration (HRSA), to develop a solution that allowed the Department of Corrections to maintain 340B pricing and participate in the modified “Netflix” model. With this new model, the inmate population receives treatment through eight DOC subgrantees. DOC inmates with HCV are not treated at Lallie Kemp Regional Medical Center, a critical access hospital with access to 340B pricing, unless there are infection-related complications that require out-of-facility treatment. DAA treatment within the DOC currently takes place at the facility level.

All HCV DAA purchases are made at 340B ceiling prices, and once the DOC reaches the negotiated Total State Spend for DOC, LDH receives rebates resulting in sub-ceiling prices. Louisiana’s early discussions with federal partners were critical in identifying mechanisms to make this purchasing approach fit within 340B policies.

In pursuit of the treatment goals, on July 15, 2019, Louisiana removed the clinical prior authorization requirements (fibrosis restrictions and substance misuse attestation) for ag-sofosbuvir/velpatavir in Medicaid.<sup>18</sup> LDH also simplified its screening and treatment algorithm. Because ag-sofosbuvir/velpatavir is pan-genotypic they removed the requirement for genotyping the virus prior to treatment.

Louisiana’s Hep C Free Louisiana strategy, a collaboration between the state’s Office of Public Health, Medicaid, DOC, the U.S. CDC, and state and national experts, is guided by a six-step approach to maximize the number of individuals who are screened and treated:

1. Educate the public on availability of cure and mobilize priority populations for screenings;
2. Expand HCV screening and expedited linkage to HCV Cure;
3. Strengthen HCV surveillance to link persons previously diagnosed to Treatment;
4. Expand provider capacity to treat HCV through use of “Sharing the Cure” a training aimed at primary care providers to treat Hep C;
5. Implement harm reduction and complementary treatment strategies; and
6. Extend elimination efforts to all populations within the state.

<sup>18</sup> Pan-genotypic means the drug is United States Food and Drug Administration (FDA)-approved to treat all genotypes (1, 2, 3, 4, 5, and 6) of Hepatitis C.

To maximize the cost-effectiveness of the modified “Netflix” model, increasing the number of eligible individuals who are treated is important. Between July 15, 2019 and November 23, 2020, Louisiana has treated 6,321 Medicaid and corrections patients.<sup>19</sup>

## Washington – HCV Treatment

Washington State also implemented a modified “Netflix” model for the purchase of DAAs to treat HCV. In 2018, Washington State Governor Jay Inslee issued a directive for the elimination of HCV in Washington.<sup>20,21</sup> Washington is estimated to have over 65,000 individuals who are infected. Between 2009 and 2017, HCV infections increased by 60 percent, mostly due to increased intravenous drug use. Approximately 30,000 of the state’s infected population are covered by one of the state agency health plans. Washington estimated that, in Fiscal Year 2018, its annual Medicaid HCV drug expenditure would be \$140 million all funds (\$68 million agency costs) and it would treat 3,300 individuals. Between 2014 and 2018, Washington treated 10,377 people, at an average cost of \$37,259 per treatment.<sup>22</sup>

Washington State Health Care Authority (HCA), the state agency that oversees state programs including Medicaid and the Public Employees Benefit Board (PEBB), initiated a Request for Proposals for a drug manufacturer(s) to provide the state with DAAs to eliminate HCV in the state by 2030. HCA, in coordination with other state agencies, implemented the modified “Netflix” purchasing strategy, which included other state-purchased healthcare programs:

- HCA (Medicaid, Public Employees Benefits, and School Benefits programs)
- Department of Corrections (DOC)
- Department of Social and Health Services
- Department of Labor and Industries

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<sup>19</sup> Taking Control of Hep C. <http://ldh.la.gov/assets/hepc/prod/>. Accessed 04.29.2020.

<sup>20</sup> Elimination is different from eradication. 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.

<sup>21</sup> Office of the Governor of Washington. (2018, September 28). *Eliminating Hepatitis C in Washington by 2030 through combined public health efforts and a new medication purchasing approach*. [Directive of the Governor 18-13](#).

<sup>22</sup> Aleccia, J., Ostrov, B.F., & Blankship, G. (October 2010). Pharma sells Washington state and others on “Netflix model” to wipe out Hep C. But the cost is being kept from the Public. [Seattle Times](#). Accessed 04.29.2020.

In June 2003, the Washington State legislature created the Prescription Drug Program, a consortium that brought together the state agencies to use a single pharmacy benefit manager to manage one vendor. The Program brought together the HCA, the Department of Corrections, and the Department of Labor and Industries, with HCA as the program administrator. HCA coordinates prescription drug purchasing for Medicaid fee-for-service, state public employee, and workers compensation. The use of a single pharmacy benefit manager allowed Washington to pursue a single manufacturer to address HCV across the state healthcare programs. Washington State pooled purchasing across agencies and maintains a combined preferred drug list for its Medicaid, public employee, and worker compensation programs.

Washington announced AbbVie as the apparently successful vendor in April 2019 and signed the contracts with AbbVie June 1, 2019 for the purchase of HCV DAA Mavyret. They entered into two contracts, one for the Medicaid program and one for the non-Medicaid programs where Mavyret is the preferred drug under both subcontracts. The subcontract for the Medicaid program is a value-based supplemental rebate agreement. Like Louisiana, HCA and AbbVie negotiated an annual threshold, based on the approved state budget, and any additional units above the annual threshold receive supplemental rebates resulting in a nominal net cost to the state for the contract year. Washington, also under CMS's guidance, implemented this value-based strategy through a value-based supplemental rebate agreement and a Medicaid state plan amendment.

The non-Medicaid contract is a pharmaceutical discount and rebate agreement that provides a discount on Mavyret to non-Medicaid state agency health plans for DOC, Department of Social and Health Services, HCA (self-insured options offered through the Employee and Retiree Benefits Programs), and Department of Labor and Industries. These agencies purchase DAAs both directly and indirectly for the individuals they serve. DOC and the Department of Social and Health Services have facilities that directly purchase DAAs and distribute them to HCV-infected individuals within those facilities. The self-funded health plans administered under the Employee and Retiree Benefits Programs and the Department of Labor and Industries use group programs and reimburse pharmacies for DAAs dispensed to individuals covered by their respective programs. These programs would purchase DAAs at the single best Guaranteed Net Unit Price for all non-Medicaid programs. DOC and the Department of Social and Health Services receive an upfront discount through their wholesale pharmaceuticals distributors. PEBB and the Department of Labor and Industries receive rebates on Mavyret.

Washington's goal is to treat twice as many individuals for the same annual expenditure. The value of the contract is estimated at more than \$321 million with a goal to treat 30,000 individuals over four years; this results in an estimated average treatment cost just under \$11,000. Washington expects that through these contracts, their cost per treatment will be approximately 40 percent lower than prior to the implementation. Like Louisiana, Washington's starting position for negotiation was to maintain approximately the same level of funding for HCV for each program for the length of the contract.

AbbVie also engages in public health activities to help Washington reach its elimination goals, including finding untreated populations through community outreach, educating the healthcare workforce about screening and providing curative treatments, and addressing barriers to care.

Potential savings through these contracts is unknown given their recent execution, the unavailability of final contract terms, or the current lack of detailed actuarial expenditure data under the contract.

## 4. Scope and Treatment of HCV in HHSC

HHSC oversees the Medicaid program, the state hospital system, and state-supported living centers; approximately 4.5 million individuals are enrolled in the Medicaid and CHIP programs.

### Medicaid and CHIP

In SFY 2019, 3.99 million Texans were enrolled in Medicaid and 408,000 in the Children’s Health Insurance Program (CHIP), with a total of 20,967 unique Medicaid clients and 13 CHIP clients identified as having chronic HCV (see Table 1). The numbers presented here represent known infected populations who have sought care and do not include the sizeable percentage of individuals estimated to be infected and undiagnosed. The United States Centers for Disease Control (CDC) estimates that for each new acute HCV case that is reported in the United States, approximately 13.9 actual new acute HCV cases (reported and unreported) have occurred.<sup>23,24</sup> Other studies estimate that Texas has a prevalence rate ranging between 0.84 percent to 1.0 percent.<sup>25</sup> Based on an estimate of 4.5 million Medicaid recipients, between 37,800 and 45,000 of those recipients are estimated to have HCV. These estimates reflect that a significant number of individuals are living with HCV but are undiagnosed, which significantly raises the risk of infecting other individuals.

**Table 1: HCV Among the Texas Medicaid Population SFY 2017-2019**

SFY	Number Infected	Newly Diagnosed	Number Treated	All Funds Expenditures for DAAs
2017	23,379	8,678	810	\$ 52,758,839
2018	22,793	7,810	1,137	\$ 49,212,899
2019	20,967	6,671	884	\$ 30,983,897

<sup>23</sup> HCV Epidemiology in the United States, [Hepatitis C Online](#).

<sup>24</sup> HCV Epidemiology in the United States, [Hepatitis C Online](#). Approximately 15 percent of acute Hepatitis C cases become chronic and require treatment.

<sup>25</sup> Rosenberg, E.S., Rosenthal, E.M., Hall, E.W., et al (2018). Prevalence of Hepatitis C Virus Infection in US States and the District of Columbia, 2013 to 2016. [Journal of American Medical Association Network Open](#), 2018, 8.

To participate in the Medicaid program, drug manufacturers are required to participate in the federal Medicaid Drug Rebate Program to help offset federal costs of most outpatient prescription drugs dispensed to Medicaid patients. The federal rebate amount for each unit of a drug is based on statutory formulas to ensure Medicaid pays a net price that is consistent with the best price that manufacturers charge other payers for the drug. Drug manufacturers and labelers enter into supplemental rebate contracts to have their products considered for preferred status on the state's preferred drug list (PDL).<sup>26</sup> The Texas Drug Utilization Review Board reviews classes of drugs on a quarterly basis and recommends drugs for preferred or non-preferred status on the PDL based on efficacy, clinical significance, cost effectiveness, and safety. In addition to federal rebates, States and manufacturers can negotiate further discounts called supplemental rebates. Rebates help states manage the cost of drugs. Rebates are shared between the state and the federal government.

The CHIP rebate program is a voluntary state rebate program that began in March 2002. Because of the Medicaid "best price" requirements included in Section 1927 of the Social Security Act, CHIP rebate rates are below the Medicaid rates to protect manufacturer's Medicaid best price and incentivize participation.

Texas Medicaid began covering two types of DAAs, Sovaldi (Gilead) and Olysio (Johnson and Johnson), in 2015. Currently, Texas Medicaid covers the following DAAs:

- EPCLUSA (Asegua): on the state's preferred drug list, pan-genotypic, and approved to treat people age six and older;
- Mavyret (AbbVie): on the state's preferred drug list, pan-genotypic, and approved to treat people age twelve and older;
- Vosevi (Gilead): on the state's preferred drug list and approved to treat people age 18 and older;
- Harvoni (Gilead): non-preferred on the state's preferred drug list and approved to treat people age three and older;
- Solvadi (Gilead): non-preferred on the state's preferred drug list and approved to treat people age three and older;

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<sup>26</sup> Texas Government Code sections 530.070 and .072 specify that, with limited exceptions, Texas Medicaid's preferred drug lists may contain only drugs provided by a manufacturer or labeler that has reached a supplemental rebate agreement with the state.

- Zepatier (Merck): non-preferred on the state’s preferred drug list and approved to treat people age 18 and older;
- Viekira (Abbvie): non-preferred on the state’s preferred drug list and approved to treat people age 18 and older;
- sofosbuvir/velpatasvir (Asegua): EPCLUSA’s generic, pan-genotypic, and approved to treat people age six and older; and
- ledipasvir/sofosbuvir (Asegua): Harvoni’s generic and approved to treat people age three and older.

To access the DAAs, Medicaid recipients must satisfy multiple prior authorization (PA) criteria.<sup>27</sup> Three primary PA criteria are:

- A METAVIR<sup>28</sup> Fibrosis score of F3 (advanced fibrosis) or F4 (cirrhosis), a liver transplant recipient, or a patient with hepatocellular carcinoma; and
- Prescription from a board-certified gastroenterologist, hepatologist, or infectious disease physician, or another prescriber who is under the supervision of one of the specialists; and
- A drug screening within 90 days prior to the request for HCV treatment.

In the fall of 2018, HHSC added HCV DAA drugs into the managed care organizations’ (MCO) capitation payments. Before Fall 2018, HHSC reimbursed MCOs for these drugs with a non-risk payment. Non-risk payments are paid in addition to the pharmacy capitation payment and are limited to the actual amounts MCOs paid to pharmacy providers for these drugs as represented in “Net Amount Due” field (Field 281) on the National Council for Prescription Drug Programs encounter transaction up to the Fee-for-Service reimbursement amount. Over 90 percent of Texas Medicaid members, and all CHIP members, received their care through MCOs.

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<sup>27</sup> CHIP formulary is similar to the Medicaid formulary and operates under similar policies as the Medicaid program.

<sup>28</sup> The METAVIR score is a tool used to evaluate the severity of fibrosis seen on a liver biopsy sample from a person who has Hepatitis C. The grade indicates the amount of inflammation in the liver, and the stage represents the amount of scarring or fibrosis.

MCOs manage the prescription drug benefits of their members but, until 2023,<sup>29</sup> are required to adhere to the state's formulary and the state's preferred drug list. Under Texas Government Code § 533.005 (a)(23)(D)(i), the MCO may not negotiate rebates with drug companies for pharmaceutical products. HHSC or its designee will negotiate rebate agreements. If the MCO or its pharmacy benefit manager (PBM) has an existing rebate agreement with a manufacturer, all Medicaid and CHIP outpatient drug claims, including provider-administered drugs, must be exempt from such rebate agreements. The federal rebates and supplemental rebates are shared between federal and state governments.

Only a small percentage of Medicaid clients remain in fee-for-service (FFS) Medicaid. In the FFS model, the Medicaid Vendor Drug Program (VDP) contracts with pharmacies to dispense drugs for its FFS members. The VDP then reimburses the contracted pharmacies directly for the cost of its FFS members' prescription drugs.

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<sup>29</sup> See Tex. Gov't Code §533.005(a-1).

## State Hospitals and State Supported Living Centers

Between the state hospitals and state-supported living centers (SSLCs), over three hundred individuals are identified to have the HCV infection; the majority of whom are in the state hospitals. The two entities share contracts for both the pharmacy wholesaler and the Group Purchasing Organization (GPO), which is part of an interstate drug purchasing pool. The GPO negotiates the price on behalf of its participants, and the entity orders medications through the pharmacy wholesaler. Currently available DAAs that are specific to and curative in the treatment of HCV that are covered by this policy include: Viekira Pak (combination of ombitasvir, paritaprevir, ritonavir, and dasabuvir), Sovaldi (sofosbuvir), Olysio (simeprevir), Harvoni (combination of ledipasvir and sofosbuvir) and EPCLUSA (sofosbuvir and velpatasvir). Only clinicians at the facility may prescribe these medications. Both the SSLCs and state hospitals prioritize access to DAAs to the following:

- METAVIR Score of F3 or F4 or presence of a co-existing diagnosis, liver transplant recipient, or a patient with hepatocellular carcinoma or behavior that puts staff, peers, or general public at risk of infection with HCV; and,
- Prescription from a board-certified gastroenterologist, hepatologist, or infectious disease physician, or another prescriber who is under the supervision of one of the specialists; and
- A negative drug screening within 90 days prior to the request for HCV treatment.

Table 2 below represents the number of individuals in state hospitals who received treatment.

**Table 2. HCV DAA Treatment in State Hospitals**

SFY	Number Infected	Number Treated	General Revenue Expenditures for DAAs	Average Cost Per Treatment
2017	416	12	\$408,208.00	\$34,017.33
2018	391	8	\$201,046.85	\$25,130.86
2019	337	11	\$211,230.00	\$19,202.73

As in the Medicaid program, the average cost per treatment has declined due to the introduction of generic versions of DAAs.

## 5. Scope and Treatment of HCV in TDCJ

The Texas Department of Criminal Justice (TDCJ) is the state agency responsible for the care of over 123,000 inmates across 102 prison units. The healthcare of inmates is governed by the Correctional Managed Health Care Committee (CMHCC). CMHCC is authorized by Chapter 501, Subchapter E of the Texas Government Code.<sup>30</sup> The CMHCC was originally established by the 73rd Legislature in 1993 to address the rising costs and operational challenges involved in providing healthcare to prisoners confined in the Texas Department of Criminal Justice (TDCJ).

The CMHCC is composed of nine voting members and one non-voting member as follows:

- one member employed full-time by TDCJ, and appointed by the executive director;
- one member who is a physician and employed full-time by the University of Texas Medical Branch (UTMB) at Galveston, appointed by the president of the medical branch;
- one member who is a physician and employed full-time by the Texas Tech University Health Sciences Center (TTUHSC), appointed by the president of the university;
- two public members who are physicians, each of who is employed full-time by a medical school other than UTMB or TTUHSC, appointed by the governor;
- two members appointed by the governor who are licensed mental health professionals;
- two members appointed by the governor who are not affiliated with TDCJ or with any contracting entity, at least one of whom is licensed to practice medicine in this state; and
- the state Medicaid director or a person employed full-time by HHSC and appointed by the Medicaid director, is to serve as an ex-officio non-voting member.

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<sup>30</sup>[Texas Government Code Subchapter E, Chapter 501.](#)

The CMHCC coordinates the development of statewide policies for the delivery of correctional healthcare and serves as a representative forum for decision-making in terms of overall healthcare policy. TDCJ, TTUHSC, and UTMB, under the guidance and direction of CMHCC, work collaboratively to ensure TDCJ inmates have access to quality healthcare while maintaining costs.

## **Screening and Treatment of HCV**

The Correctional Managed Health Care Infection Control Manual outlines policies related to HCV screening and treatment. TDCJ HCV policy recommends that all inmates be screened at intake for risk factors related to HCV infection, and the presence of signs and symptoms of infection to determine whether an anti-HCV antibody test should be offered.<sup>31</sup>

The policy also recommends that, regardless of risk factors, certain inmates be screened; they include inmates:

- Born between 1945 and 1965;
- Diagnosed with Chronic Hepatitis B or Human Immune Deficiency Virus (HIV) infection, because inmates must be tested for HCV as part of the baseline evaluation of these conditions;
- With persistently abnormal alanine aminotransferase levels (ALT);
- Who have ever received hemodialysis; and
- Who may have been exposed to HCV.

Inmates may be tested for anti-HCV antibody once every 12 months. Those with an AST/Platelet Ratio Index (APRI) score greater than 0.5 are candidates for referral to be evaluated for HCV treatment. The APRI score refers to the aspartate aminotransferase to platelet ratio index and is a way to measure liver fibrosis. Though all inmates diagnosed with HCV are eligible for DAA treatment, patients are prioritized according to liver disease severity (F3-F4 are given priority over F0-F2) and co-morbid conditions. As of September 1, 2020, approximately 11,000 inmates are known to be infected with HCV.

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<sup>31</sup> Risk factors include: injection drug use, intranasal illicit drug use, needlestick injuries, perinatal transmission, sharing of personal items contaminated with blood, unprotected sex, sharing instruments, receipt of blood transfusions prior to 1992, and use of clotting factors prior to 1987.

TDCJ contracts with UTMB to provide healthcare services to inmates. UTMB provides managed healthcare for inmates in 84 adult and juvenile correctional facilities throughout the state and offers medical, dental, and health services to more than 110,000 patients, or some 80% percent of the state's inmate population. UTMB provides healthcare services to TDCJ inmates at several TDCJ units, including Hospital Galveston, which is a secure prison hospital facility located adjacent to UTMB's John Sealy Hospital in Galveston, Texas. TDCJ provides all necessary security for the prison hospital, while UTMB provides the medical personnel. The hospital includes operating room facilities, radiology services, physical and occupational therapy services, a clinical laboratory, specialty clinics, and an outpatient department.

TDCJ also contracts with TTUHSC to provide coverage for nearly 25,000 inmates in North and West Texas. TTUHSC's correctional health services are provided through three primary approaches: On-Site Health Services, Off-Site Health Services, and Correctional Telemedicine. The On-Site Health Services address medical, dental, and mental health needs on the correctional units. The Off-Site Health Services typically provide for outpatient, emergency room, and inpatient care using an extensive network of negotiated contracts with community medical resources.

As a disproportionate share hospital (DSH), UTMB, including Hospital Galveston, receives special discount pricing on outpatient drugs through the 340B program.<sup>32</sup> Through its partnership with UTMB and Hospital Galveston, the majority of TDCJ inmates have access to discounted drugs (e.g., HCV DAAs). However, as a DSH, UTMB is prohibited by federal law from participating in a group purchasing organization for covered outpatient drugs.<sup>33</sup> TDCJ estimates that it has saved over \$102 million in SFY 2018, and \$110 million in SFY 2019 through UTMB's participation in the 340B drug discount program. The discounts are critical for TDCJ as its annual appropriation for pharmacy benefits is \$75 million in general revenue.

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<sup>32</sup> A disproportionate share hospital is a hospital that serves a significantly disproportionate number of low-income patients and receive payments from the Centers for Medicaid and Medicare Services to cover the costs of providing care to uninsured patients. Disproportionate share hospitals are defined in Section 1886(d)(1)(B) of the Social Security Act.

<sup>33</sup> Other entities prohibited from participating group purchasing organization pricing are cancer hospitals and children's hospitals.

HCV DAAs available to inmates include:

- Velpatisvir/Sofosbuvir (EPCLUSA®)
- Sofosbuvir/Velpatsavir/Voxilaprevir (Vosevi®)
- Ribavirin

Drug selection regimen is based on patient specific characteristics including prior HCV treatment, genotype, degree of cirrhosis, and co-morbidities.<sup>34</sup>

In SFY 2019, expenditures for HCV DAAs to treat TDCJ inmates were \$13.25 million, and the average cost per treatment course was \$14,000.

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<sup>34</sup> [Correctional Managed Care Formulary](#), 25<sup>th</sup> edition, 2019. Accessed May 5, 2020.

## **6. Scope and Treatment of HCV in the ERS Texas Employees Group Benefits Program (GBP)**

ERS administers the Texas Employees Group Benefits Program (GBP), which includes health insurance benefits for roughly 500,000 employees, dependents and retirees employed by 114 state agencies, 47 universities, 19 junior and community colleges, and four local governmental entities. These health benefits are funded with trust funds, which include a combination of benefit contributions from employers who received them as state appropriations, monthly member premium contributions, investment proceeds, and member cost sharing (deductibles, copays, and coinsurance).

The Texas Employees Group Benefits Program (GBP) prescription drug coverage is provided through various programs, depending on the participant's medical coverage selection. The GBP offers two primary prescription drug plans for the majority of participants, those not enrolled in the two regional HMOs:

- HealthSelect<sup>SM</sup> Prescription Drug Plan covers participants in the HealthSelect and Consumer Directed HealthSelect plans; and
- HealthSelect<sup>SM</sup> Medicare Rx covers retirees who are Medicare-primary participants.

Both prescription drug plans are self-funded, meaning the state – not an insurance carrier – assumes financial responsibility for the plans. In 2016, ERS awarded the primary prescription drug benefits administrator contract to UnitedHealthcare Services (referred to as Optum Rx) through a competitive procurement. The resulting contract began January 1, 2017. As the HealthSelect Prescription Drug Program PBM, Optum Rx provides a network of pharmacies, negotiated rates and rebates with drug manufacturers, and prescription drug management to ensure patients are receiving safe, appropriate and cost-effective medications for medically diagnosed conditions. ERS estimates the contract with Optum Rx will save \$1.6 billion during the full six-year contract period due to better ingredient cost guarantees and higher drug rebates than were available under the previous contract, among other factors.

## **ERS Treatment of HCV**

The ERS health plans do not determine the most appropriate drug treatment for individual patient needs. That decision is made by the physician and the patient to address specific medical needs. The health plan defines the payment reimbursement structure for covered benefits, including the member's out-of-pocket costs for various types of treatment and treatment protocols.

ERS's PBM drug formulary currently covers 13 medications (including 10 DAAs) to treat and cure patients with HCV at various stages of the disease and does not limit treatment based on disease stage. The PBM authorizes coverage of HCV drugs according to guidelines published by the federal Food and Drug Administration and the American Association for the Study of Liver Diseases.

Prescribing criteria assess many factors, including:

- HCV genotype status;
- Absence or presence of liver cirrhosis;
- Prior HCV treatment and patient's response to the treatment; and
- Prescription by, or in consultation with, a medical specialist that has experience with HCV treatments.

After assessing a patient using the above criteria, the physician determines the most medically appropriate drug treatment for the specific patient and prescribes the medication. If a physician believes that a more appropriate non-formulary medication is medically necessary for a specific patient, either the patient or physician may appeal and, based on that review, a coverage decision is made. For specialty drugs like HCV medications, the PBM provides high-touch patient services including patient monitoring to encourage treatment adherence. PBM clinical staff are part of the treatment team involved with HCV patients.

## **ERS Spending on Treatment for HCV**

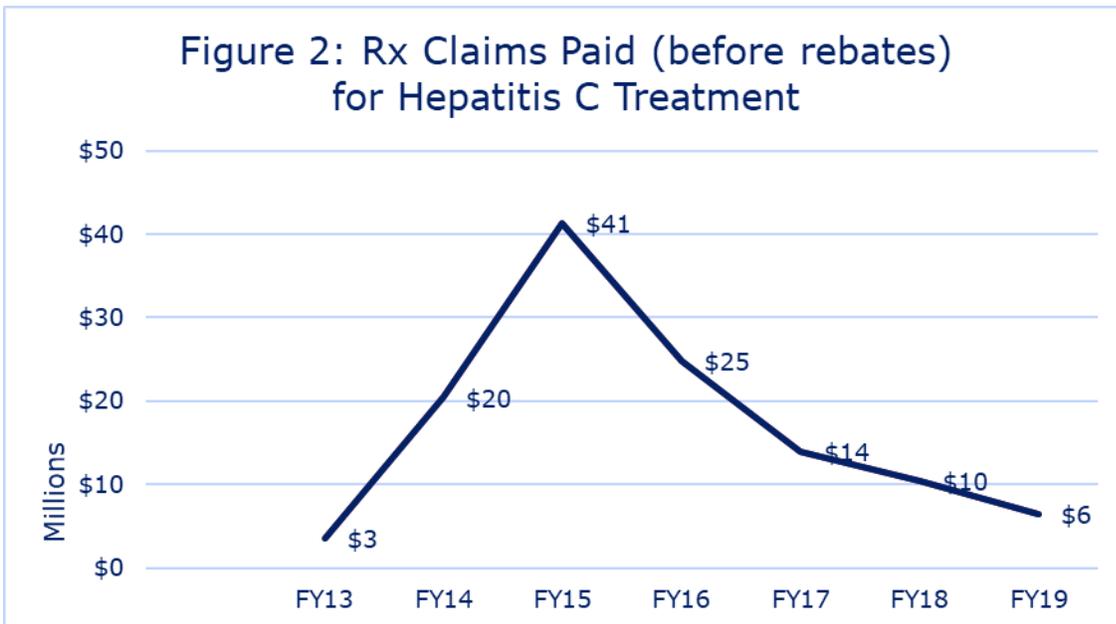
New HCV medications were introduced in FY 2013. Following an initial increase in the number of participants receiving HCV treatments, ERS self-funded plans experienced a steady decline in treatments since 2015, with 136 participants receiving HCV medications in FY 2019. The decline in HCV treatments since FY15 is partially due to ERS's commitment to treating all diagnosed cases with appropriate drugs (see Figure 1).

**Figure 1: Drug Claimants with HCV**



Pharmacy costs for HCV treatments in FY 2019 were \$6.5 million before application of pharmacy rebates (see Figure 2). This represents 0.6 percent of the more than \$1 billion in gross pharmacy spend across ERS self-funded plans. Based on information provided by Optum Rx, about 60 percent of the cost of this group of drugs is subject to rebate, resulting in an estimated net cost of about \$2.6 million for HCV medications during FY 2019, representing 0.5 percent of net pharmacy spend.

**Figure 2: Rx Claims Paid (before rebates) for Hepatitis C Treatment**



## **7. Scope and Treatment of HCV in the TRS Texas Employees Group Benefits Program Overview**

The Teacher Retirement System of Texas (TRS) has a long history of delivering health benefits to public education affiliated participants. Since 1986, TRS has provided health coverage to retirees through TRS-Care. Starting in 2003, TRS has also offered coverage to public education employees through TRS-ActiveCare. In fiscal year 2019, TRS provided health coverage to 712,888 people, including 483,113 public education employees and their families and 229,775 retirees and their families. Health benefits offered by TRS are funded by employee and retiree contributions, as well as funding from schools and the legislature. The TRS Board of Trustees adjusts benefits and determines the total cost of premiums.

TRS participants' prescription coverage varies depending on the plan they are enrolled in. Active employees and their families have two plan choices: TRS-ActiveCare 1-HD, a high deductible health plan, with an integrated medical and drug deductible, and TRS-ActiveCare Select, a plan with copays for generic drugs and coinsurance for brand and specialty medications. Retirees and dependents not yet eligible for Medicare have drug coverage through the TRS-Care Standard, a high deductible plan, and retirees and dependents with Medicare have drug coverage through the TRS-Care Medicare Rx plan, which has low, predictable copays for medications.

TRS strives to maximize the value of every health care dollar, and this includes competitively bidding its contracts to ensure public school employees, retirees and their families are getting the highest value health benefits. Similar to ERS, prescription coverage is self-funded, and drugs claims are paid for directly from the TRS-ActiveCare and TRS-Care funds. In 2017, the TRS Board of Trustees awarded new contracts for pharmacy benefit administrators for the active and retired public school employee health benefit programs to CVS Caremark. The contract began in 2018 with a projected savings to TRS of \$450 million over the first two years.

CVS Caremark provides a network of pharmacies, contracted rates for drugs, and utilization management processes such as pre-authorization to ensure participants receive cost-effective, appropriate medications for medical conditions.

## 8. Treatment of HCV on TRS Health Plans

TRS does not employ clinicians and relies on CVS Caremark to verify the genotype of each patient's virus. TRS health plans cover eight different DAA medications. Based on the genotype the virus belongs to, there may be one to two preferred products. CVS Caremark reviews the physician's drug selection to ensure that medication and dosage the physician prescribed meets the drug manufacturer's guidelines. CVS Caremark also has an exception process for any patients that cannot use the preferred products for specific reasons. TRS covers HCV treatment regardless of fibrosis level.

### Spending related to HCV Treatment in TRS Health Plans

In FY15, after the drugs came to market, 127 participants in TRS-ActiveCare health plan were identified as having a condition treatable by new direct-acting antiviral (DAA) medications. In 2016, the number of participants with a diagnosis of HCV across TRS-ActiveCare decreased to 94 (see Figure 3). For all TRS self-funded plans, 66 participants received HCV medications in FY19.

Figure 3: Drug Claimants with Hepatitis C



\*FY15 – FY 17 are for TRS-ActiveCare claims only.

The total gross costs for DAA medications totaled \$12 million in FY 2015 for TRS-ActiveCare and \$4 million in FY 2019 for both TRS-ActiveCare and TRS-Care before application of pharmacy rebates. For FY 2015 this represents 3.6 percent of the more than \$331 million in pharmacy paid before rebates by TRS-ActiveCare self-funded plan, and 0. percent of the more than \$557 million in pharmacy paid before rebates by TRS self-funded plans. For FY 2019, 75 percent of the cost paid for DAAs was returned in rebates, resulting in an estimated net cost of about \$918,000 for DAAs during FY 2019, representing 0.3 percent of net pharmacy spend (see Figure 4).

**Figure 4: Rx Claims Paid (before rebates) for Hepatitis C Treatment**



\*FY15 – FY 17 are for TRS-ActiveCare claims only.

## Considerations

The rates of HCV diagnoses among TRS’s population and costs for DAAs have declined since the introduction of these medications. Only 66 individuals were treated by DAAs in FY 2019. TRS contracts with CVS Caremark and negotiates rebates that significantly reduce the costs of DAAs. In FY 2019, the costs of DAAs made up less than one-third of 1% of TRS’s overall spending on prescription drugs after rebates.

Implementing a single-source subscription model for TRS's health plans would have adverse effects. Moving to a subscription model that covers a single DAA medication would mean participants may not be able to access the optimal treatment based on the virus genome without going through an exception process. In addition, including TRS in a multi-agency subscription model would require TRS to source DAA medications outside existing agreements with its PBM. Removing DAA medications from these contracts would result in less favorable rebate guarantees for a broader swath of drugs than just DAAs increasing drug costs for TRS health plans.

## 9. Feasibility and Cost Effectiveness of Cross-Agency Bulk Purchasing – HHSC, TDCJ, ERS, and TRS

This section of the report assesses the feasibility and cost-effectiveness of bulk purchasing of HCV DAA drugs jointly across the four agencies (HHSC, TDCJ, ERS, and TRS) by evaluating the administrative complexity of the implementation against the cost-effectiveness achieved. There are potential challenges with implementing a bulk-purchasing strategy jointly across all four agencies. First, the coordination of drug purchasing across different agencies is challenging because each agency purchases drugs differently and is guided by differing policies and need to be aligned for a bulk-purchasing strategy to operate. Second, the untreated population in two of the agencies, ERS and TRS, is low. These variables must be weighed against the benefits that may be achieved.

### Differing Purchasing Methodologies Poses Challenges

HHSC, TDCJ, ERS, and TRS provide access to DAAs for the clients they serve; however, each agency's approach to making the drugs available is different. As described above, ERS and TRS are self-funded programs and use a PBM to negotiate drug prices and rebates on behalf of each agency. TDCJ, through its contractual relationship with UTMB, has access to 340B pricing, and there is a specific federal limitation that prohibits UTMB from participating in a group purchasing arrangement.<sup>35</sup> In the Medicaid program, manufacturers that wish to participate in Medicaid must participate in the Medicaid Drug Rebate Program. The Medicaid program also negotiates supplemental rebates with certain manufacturers. The state hospitals and SSLCs participate in GPO pricing for their medications. These different methods for purchasing drugs create challenges with bringing the four agencies together to engage in a single procurement aimed at one type of drug. The contractual arrangements in ERS and TRS also pose unique challenges to a cross-agency approach.

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<sup>35</sup> 42 U.S.C. § 256b(a)(4)(L)(iii); see HRSA Release No. 2013-1 (Feb. 7, 2013) (statutory prohibition on GPO participation), *available at* <https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/prohibitio nongpoparticipation020713.pdf> (last accessed Dec. 4, 2020).

ERS is in the third year of a six-year contract, which is expected to save the state approximately \$1.6 billion due to negotiated rebates and better ingredient cost guarantees. Similarly, TRS is in the third year of its contract with its selected pharmacy benefit administrators for the active and retired public school employee health benefit programs and is projected to save TRS \$450 million over the first two years. HCV DAAs are just one of the many drugs that their respective PBMs have negotiated on their behalf. Carving out one drug or one drug type from the larger contract is challenging for the self-funded health insurance programs.

An unintended consequence of carving out this class of drug treatments from ERS's PBM contract is the potential disruption of contractual rebate agreements currently in place. These agreements contribute significant savings to ERS health plans: \$365 million in FY 2019 alone. Removing DAAs from these contracts would potentially result in less favorable rebate agreements for a broader class of drugs than just the specific medication awarded a single contract. This could negate any savings by increasing other drug costs for ERS health plans. It is unclear how ERS would be able to operationalize a single-source statewide contract for an HCV drug under the existing PBM contract structure without reopening the contract award.

Similarly, it is not clear that TRS would be able to implement a statewide contract for a single drug within the current PBM contract structure without reopening the existing contract agreement. Moving to a single-source model or subscription model that carves DAAs out of current negotiated agreements with TRS's PBM would result in less favorable rebate guarantees for DAAs. In addition, because rebate discounts are negotiated at the drug class level and not for individual drugs, this means the less favorable contract terms would likely apply to a broader set of drugs than DAAs alone, resulting in higher drug costs for multiple medications. Engaging in negotiations related to a portion of the PBM contract may result in other portions of the contract being revisited, potentially resulting in disadvantageous terms for TRS. Including TRS in a multi-agency subscription model would require TRS to source DAA medications outside existing agreements with its PBM. Removing DAA medications from these contracts would result in less favorable rebate guarantees for a broader swath of drugs than just DAAs, increasing drug costs for TRS health plans.

## **Reductions in Infected Populations and Treatment Costs**

The introduction of new DAAs has lowered the cost of treatment. Whether the lowered costs of the drugs can be further offset with the implementation of a cross-agency bulk purchasing agreement is an important consideration. Furthermore, the number of HCV diagnoses experienced within the self-funded plan populations continues to fall.

ERS health plans have experienced both falling demand and reduced costs for HCV treatments. Possible savings generated from ERS's use of a single-source state contract would be minimal at best, at significant benefit reduction to the ERS membership. HCV drug treatments account for 0.5 percent of the plans' net drug cost, with the number of treated patients falling from 429 in FY 2015 to 136 in FY 2019. For ERS plans, current rebates for HCV drug treatments recover approximately 60 percent of the gross cost to the plan. This brings the net cost of all HCV drug treatments in FY 2019 to \$2.6 million, a number that continues to decline along with the patient population.

Given these trends, ERS is unable to determine whether locking in terms and pricing with a single-source contract for such medications would yield additional savings not already available under the current PBM contract structure. Any potential savings would be small and likely offset by a restructuring off the existing rebate guarantees.

The population in TRS health plans that is diagnosed with HCV also continues to decline as does the cost impact of the DAA medications used to treat the condition. Only 66 individuals across all TRS health plans were treated by DAAs in FY 2019. TRS contracts with CVS Caremark and negotiates deep pharmacy rebates that significantly reduce the costs of DAAs. The total gross costs for DAA medications totaled \$4 million in FY 2019 for both TRS-ActiveCare and TRS-Care before application of pharmacy rebates. For FY 2019, 75 percent of the cost paid for DAAs was returned in rebates. After rebates, the cost was less than \$11 million, representing less than 1/3 of 1 percent of all pharmacy spending in TRS health plans. For FY 2015 this represents 3.6 percent of the more than \$331 million in pharmacy paid before rebates by TRS-ActiveCare self-funded plan, and 0.7 percent of the more than \$557 million in pharmacy paid before rebates by TRS self-funded plans.

Implementing a single-source subscription model for TRS's health plans would have adverse effects. Moving to a subscription model that covers a single DAA medication would mean participants may not be able to access the optimal treatment based on the virus genome without going through an exception process. In addition, a statewide subscription model would require TRS to source DAA medications outside existing agreements with its PBM. Removing DAA medications from these contracts would result in less favorable rebate guarantees for a broader swath of drugs than just DAAs increasing drug costs for TRS health plans.

## **Other Important Considerations**

The state's ERS administered plans place a high value on the physician-patient relationship. This relationship and related health plan administration processes have resulted in a high incidence of patients who complete their course of treatment. While certain drugs work for all genotypes, no one drug works the same way for all patients; appropriate treatments for HCV vary by genotype, effectiveness and patient medical history, and new drugs are in constant development. GBP pharmacy plans cover a variety of treatments and provide an appeals process that allows for exceptions based on medical determinations, if the prescribing physician believes it is necessary for a successful treatment outcome. If a new contract limits the treatments available to GBP health plan participants from current options, participants would see a reduction in existing benefits.

Because ERS does not maintain in-house medical or pharmacological expertise, the agency relies on prescribing physicians and the oversight of clinical staff to verify that prescribed high-cost treatments are both appropriate for a particular patient and can support patients in completing their specific treatment. For specialty drugs like HCV medications, the PBM provides high-touch patient services including patient monitoring to encourage treatment adherence. PBM clinical staff are part of the treatment team involved with HCV patients.

Similarly, implementing a single-source subscription model for TRS's health plans has the potential for adverse effects. Moving to a subscription model that covers a single DAA medication would mean participants may not be able to access the optimal treatment based on the virus genome without going through an exception process.

TRS currently treats HCV with DAAs at competitive pricing while allowing physicians and clinicians flexibility in determining the best course of treatment including which DAA medication is the best option for the participant. TRS, through clinical experts provided by its PBM, ensures the prescribed agent meets the drug manufacturer's guidelines and is indicated for the specific genome of the virus. The implementation of a subscription model that limits the available DAA medications would narrow the treatment options physicians have to provide care to TRS participants with HCV.

Given the low prevalence of the condition among TRS health plan participants, the cost-effective strategies TRS has in place, the robust options for treatment as well as the feasibility challenge a single-source model poses for TRS's existing PBM contract structure, the adverse impact of implementing a subscription model are likely to outweigh potential gains.

If a single-source contract precludes coverage of any of the drugs currently available to plan participants, physicians would be limited in their ability to prescribe effective treatments to plan participants and serve the medical needs of ERS health plan participants. A final patient concern surrounding single-source contracting is limiting access to new treatments and medications currently in development from alternate manufacturers, as well as the PBM patient services that accompany the use of currently available HCV drug treatments.

An additional important consideration with a bulk-purchasing agreement with a single manufacturer that is important to note is that limiting availability with a single-source contract would be particularly concerning if the supply chain to the drug manufacturer selected were disrupted.

## **Cost-Effectiveness**

One of the benefits of a bulk-purchasing arrangement is fiscal certainty to state budgets for the length of the contract period. Second, the benefit of a cross-agency bulk-purchasing agreement is the financial gains obtained by treating many individuals while holding constant the ceiling price. The strategy is cost-effective if the administrative costs to implement the cross-agency model and the cost of the contract yield a net cost or a per person cost of treatment that is less than the cost would have been absent the agreement and absent the cost to create a cross-agency purchasing approach.

Both ERS and TRS already have treated most of their infected populations under their current arrangements. ERS has had a steady decline in the number of infected who need treatment. ERS is already committed to treating all its infected population, as there are no limitations on who can be treated, and ERS does not have a backlog of infected individuals who are waiting for criteria to change to be treated. With the small number of individuals in the ERS and TRS systems remaining to be treated, their inclusion in a bulk purchasing strategy would not be cost-effective due to the administrative complexity of creating the joint purchasing system. ERS and TRS would have to either carve out a single DAA or a set of DAAs from its existing agreement with Optum Rx or the four agencies would have to consider a cross-agency drug purchasing system for all outpatient drugs. The latter approach would require a broader discussion and analysis and direction from the state Legislature.

## 10. Feasibility and Cost Effectiveness of Cross-Agency Bulk Purchasing - TDCJ and HHSC

Though a cross-agency approach including all four state agencies (ERS, TRS, TDCJ, and HHSC) in a bulk-purchasing strategy with a single-source vendor would be difficult to implement due to administrative complexity and the limited value that would come from the effort, a value-based approach of either HHSC alone, or jointly between TDCJ and HHSC, may be feasible. The population of HCV-infected individuals in both agencies is great. Together the two agencies account for over 40,000 known infections, and potentially an even a larger number of unknown infections.

### Federal Approval Is Required

A challenge with TDCJ participating in a value-based purchasing strategy is due to the Correctional Managed Health Care arrangement at TDCJ whereby inmates receive care and gain access to discount drug pricing through UTMB, a DSH and a 340B-covered entity.<sup>36</sup> Covered entities that are also a DSH are prohibited from participating in group purchasing arrangements.<sup>37</sup>

Though 340B prohibitions against group purchasing arrangements for DSHs pose a potential challenge for TDCJ to participate with HHSC in a bulk-purchasing strategy, early conversations with federal partners may be beneficial to identifying solutions to the policy restrictions. Louisiana and Washington both strongly encouraged Texas to initiate conversations with federal partners (CMS for Medicaid and HRSA for 340B) as early as possible. The two states indicated that their conversations with the federal partners were critical to developing solutions to policy-related implementation challenges.

To participate in a bulk-purchasing agreement such as the modified “Netflix” model, HHSC would have to first adopt policies and prior authorization criteria that align with CMS guidance. Similar to Louisiana and Washington, HHSC would also need to engage in a competitive procurement, which requires CMS approval of the RFP and the resulting value-based purchasing contract.

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<sup>36</sup> A DSH hospital is a hospital that serves a large number of Medicaid and uninsured individuals.

<sup>37</sup> See note 38 *supra*.

## Feasibility of Bulk-Purchasing – HHSC Alone

HHSC is recommending pursuing a single-source contractor alone to open up treatment access to all chronic Hepatitis C clients because of the number of individuals in Medicaid, CHIP, state hospitals, and SSLCs requiring treatment.<sup>38</sup> This option may be feasible and cost-effective for HHSC alone to pursue, though additional work is required to assess how the state Medicaid program can coordinate with the state hospitals and SSLCs, which purchase drugs through a GPO. However, drug manufacturers may find a contract that includes both HHSC and TDCJ more attractive than HHSC alone.

As described earlier, Louisiana and Washington have awarded single-source contracts under a modified “Netflix” model to purchase DAA for HCV in their Medicaid populations.<sup>39</sup> Both Louisiana and Washington included their incarcerated populations; Washington also included their self-funded insurance programs and individuals receiving care in facilities. CMS approved Louisiana and Washington’s state plan amendments to use value-based arrangements with drug manufacturers, allowing the states to negotiate their own supplemental rebate agreements. Though it is feasible for Texas to similarly implement this type of model in its Medicaid and CHIP populations, HHSC will need to:

- Align policies and prior authorization criteria with CMS guidance.<sup>40</sup>
- Engage CMS, conduct a competitive procurement, and receive approval on a value-based agreement.
- Prepare providers to maximize their capacity to identify and treat patients.
- Engage with the Department of State Health Services on a public health campaign for HCV outreach and identification.

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<sup>38</sup> Though only a small percentage of Medicaid clients remain in fee-for-service, any bulk-purchasing agreement would have to include both the fee-for-service and managed care populations.

<sup>39</sup> Washington includes its state hospitals and other facility-based entities in its modified “Netflix” model for DAAs.

<sup>40</sup> HHSC has submitted an exceptional item for consideration by the 87th legislature that would provide funding for DAA access to all HCV-infected individuals when the PA criteria of METAVIR score, a drug screening 90-days prior to request, and specialist prescription are removed.

## Cost Effectiveness - TDCJ and HHSC Jointly or HHSC Alone

The cost-effectiveness of the bulk purchasing model can be evaluated in two ways: assessing whether the net cost to the state under this model is less than the net cost to the state without this model or comparing whether the per person cost under this model is less than the per person cost without the model.

Between TDCJ and HHSC, there are over 40,000 individuals with known HCV infections. In SFY 2019, TDCJ expenditures for HCV DAAs was \$13.25 million general revenue at an average treatment cost of \$14,000 per person.

Texas Medicaid expenditures as reported on claims/encounters for DAAs was approximately \$49 million all funds to treat 1,137 individuals in SFY 2018 and \$31 million all funds to treat 884 individuals in SFY 2019 (see the Table 3 below). The all funds cost per treatment decreased from approximately \$54,000 to \$42,000 between SFY 2018 and 2019.

**Table 3: Medicaid HCV Treated Numbers and Expenditures**

SFY	Number Infected	Newly Diagnosed	Number Treated	All Funds Expenditures for DAAs
2017	23,379	8,678	810	\$ 52,758,839
2018	22,793	7,810	1,137	\$ 49,212,899
2019	20,967	6,671	884	\$ 30,983,897

Among the inmate population, in SFY 2018, over 60,000 were released into the public, and over 60,000 were received into the system. Although intake has been lower due to COVID-19, based on a recent observational study, UTMB found the prevalence at intake for TDCJ inmates to be 9.4%. Therefore, if intake reaches the pre-COVID-19 level of 60,000 inmates per year, approximately 5,640 would be infected with HCV. Currently, TDCJ can treat approximately 1,200 inmates per year offenders. Given these statistics, the influx of new inmates potentially infected with HCV will far exceed the number who are treated for HCV in a given year, making it challenging for the agency to gain a foothold on treating the disease. The agency will continuously be paying for HCV treatment because there always will be more newly identified patients and untreated patients with HCV than those being treated.

HHSC has on average, treated approximately five percent of the Medicaid-infected population each year. However, the yearly number of newly diagnosed exceeds the number who are treated annually. In SFY 2018, for example, 7,810 individuals were newly diagnosed, and 1,137 were treated. Under existing policies, the state will continuously pay for DAAs because there will always be more newly identified patients and untreated patients with HCV than those being treated. Until the state treats all people with HCV, the cost of treating the limited population will continue to remain a significant and constant expenditure. These individuals represent known cases of HCV and does not include the infected but undiagnosed cases. The bulk-purchasing strategy would be a mechanism for both agencies to maximize treatment at a defined predictable cost.

Though the true cost of Louisiana's and Washington's contracts with each of the winning manufacturers is not publicly available, Louisiana's solicitation for offers stated that Louisiana was seeking an unrestricted supply of DAAs "at an annual cost not to exceed the Total State Spend on HCV medications in the Medicaid population, estimated to be \$30 million dollars, and the Total State Spend on HCV medications in the Corrections population, estimated to be \$5 million dollars, for SFY 2018." Washington took a similar approach in its request for proposal and stated, "A key objective of this request for proposals is to work with a drug manufacturer to bring down the cost of medications to enable the state, and ultimately other purchasers, to eliminate HCV without exceeding current expenditures." Washington reported spending \$80.4 million to treat 3,300 individuals across five agencies (Medicaid, Department of Corrections, Labor and Industry, Public Employees Benefit and School Employees Benefit Program, and Department of State Health Services). Both states are engaging in aggressive public health campaigns to treat as many people as possible to lower their average cost per person.

HHSC alone, or TDCJ and HHSC jointly together, may consider using a similar approach; evaluating the cost-effectiveness of the model based on the ability to negotiate a contract with a manufacturer that would not result in a net cost to the state that is greater than prior expenditures. Using an approach like Washington's and Louisiana's, each agency's annual expenditure (\$31 million for HHSC and \$13.25 million for TDCJ) could be a starting point for the two agencies' negotiations. Or, the two agencies may negotiate a higher annual guaranteed contract with a single manufacturer but aim to treat more people to result in an average net cost to the state that is less than current average cost per treatment (approximately \$43,283 to \$35,050 all funds between SFY 2018 and 2019 for HHSC, and approximately \$14,000 for TDCJ in SFY 2019).

The benefit of this strategy is that by pursuing a value-based purchasing strategy such as the modified "Netflix" model:

- the purchasing strategy incentivizes the state to treat more individuals within a limited time frame,
- each additional person treated reduces the average cost per person;
- HCV-related medical costs should diminish as the population of infected individuals decreases over time thereby offsetting future expenditures; and
- the state's DAA costs are fixed based on the length of the agreed contract.

Because this option requires a competitive procurement, it cannot be implemented quickly. To be cost-effective, the challenge of this strategy lies in the state having a strong public health campaign to ensure that enough of the infected population is treated. By ensuring enough infected individuals are treated, the state drives down the per unit cost of treatment compared to the traditional purchasing methodology and reduces expenditures associated with non-treatment of HCV.

Furthermore, this would minimize the state's expenditures on future costs associated with not broadening treatment of chronic HCV. In SFY 2019, approximately half of Medicaid/CHIP recipients diagnosed with chronic Hepatitis C incurred medical costs associated with the disease - \$6.9 million all funds (AF) in inpatient hospital care for 895 cases involving HCV-infected recipients and \$3.48 million AF in outpatient or professional costs related to the disease. This is over \$10.2 million AF in costs to provide care to HCV-infected persons who did not receive a DAA. The data presented here are annual costs and do not reflect the cumulative cost to the system. Some of these costs can be averted. Untreated HCV infections are expensive to the system because of the costs associated with treating advanced liver diseases such as liver failure and cancers.

## 11. Conclusion

ERS, TRS, TDCJ, and HHSC provide access to HCV DAA to the clients they serve; however, each agency's approach to making the drugs available is different. The number of individuals in ERS and TRS that may benefit from this arrangement is limited, and because of the administrative complexity that would be involved in carving out a single drug (the DAA) from each of the agency's existing PBM contracts, the inclusion of these two agencies in the bulk-purchasing agreement may not be cost-effective. Washington was able to negotiate a broad contract that included all its agencies because it had coordinated drug purchasing across its agencies in 2006. The move towards the use of a single PBM allowed Washington to pursue a single-source contract with AbbVie to bulk purchase the DAA to address HCV across the four state healthcare programs. The purchasing differences pose challenges to developing a cross-agency approach to procure a single-source contract to purchase DAAs in Texas.

With over 20,000 cases of known HCV among the Medicaid, CHIP, state hospital, and state-supported living center populations, and approximately 11,000 known cases among the inmate population in Texas, a modified "Netflix" model coupled with a robust public health campaign within TDCJ and HHSC may be a cost-effective approach to reduce the per-person cost of treatment. Even if TDCJ is not included, the agency has recommended that the "Netflix" model is the best option for the State to pursue given all the reasons outlined above. Early treatment may also help to forego immediate and long-term costs associated with untreated HCV. In summary, a clear identification of the agencies' goals relating to HCV will provide a clearer picture of the cost-effectiveness and savings associated with proceeding with a modified "Netflix" model.

## **List of Acronyms**

<b>Acronym</b>	<b>Full Name</b>
agSOF/VEL	authorized generic for EPCLUSA, sofosbuvir/velpatasvir
ALT	abnormal alanine aminotransferase levels
CHIP	Children’s Health Insurance Plan
CMHCC	Correctional Managed Health Care Committee
CMS	Centers for Medicare and Medicaid Service
DAA	Direct Acting Antivirals
DOC	Department of Corrections
DSH	Disproportionate Share Hospital
ERS	Employee Retirement System
FDA	Food and Drug Administration
FFS	Fee-For-Service
FY	Fiscal Year
GBP	Group Benefits Program
GPO	Group Purchasing Organization
HCA	Health Care Authority
HCV	Hepatitis C Virus
HRSA	Health Resources Services Administration
HHSC	Health and Human Services Commission
LDH	Louisiana Department of Health
PEBB	Public Employees Benefit Board
PDL	Preferred Drug List
TDCJ	Texas Department of Criminal Justice
TRS	Teacher Retirement System
TTUHSC	Texas Tech University Health Science Center
SFY	State Fiscal Year
UTMB	University of Texas Medical Branch
US	United States
VDP	Vendor Drug Program