Strategies for Addressing Hepatitis C Prevalence and Treatment in American State Prisons

A Report For the Association of State Correctional Administrators

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Executive Summary

Purpose
The purpose of this memorandum is to provide recommendations to the Association of State Correctional Administration on the management of Hepatitis C in prisons. This document seeks to outline strategies available to correctional administrators in coordinating effective drug provision. It specifically addresses the rising costs of pharmaceuticals and high prevalence of Hepatitis C in incarcerated populations. The recommendation balances the tension of providing optimal healthcare for prisoners and fiscal restraints to provide sustainable solutions.

Dual Policy Recommendation: Disease Management & Bulk Purchasing Agreements
- Incorporate a disease management approach that includes a targeted comprehensive screening for Hepatitis C among inmates as well as an educational awareness campaign.
- Oversee bulk purchasing agreements that band together across facilities and states to leverage market share in discount negotiations with pharmaceutical companies.

A New Approach to Hepatitis C
- The recent development of high impact drugs with high prices for Hepatitis C presents a unique challenge for correctional administrators.
- The management of this disease must be a priority to ensure a healthy prison population.

Prisons and Healthcare in the United States
- Prisons vary in public and private status, medical and health care processes, and budgeting.
- The Affordable Care Act, particularly the expansion of medicaid, has major implications for incarcerated populations.
- Vulnerable populations include intravenous (IV) drug users, those born to a mother with Hepatitis C, those in frequent contact with blood, or those who engage in unprotected sex with individuals infected with Hepatitis C.

What is Hepatitis C?
- Hepatitis C is a viral infection that can begin as acute but develop to a chronic disease over the period of six months.
- If left untreated, chronic Hepatitis C can cause liver damage, cirrhosis (liver scarring), liver failure, or liver cancer within a lifetime.
- Cirrhosis and other symptoms of the disease may not develop for a number of years.

Treatment
- Hepatitis C prevalence in prisons is difficult to measure because many prisons do not mandate Hepatitis C screening upon entry.
- High impact drugs such as Abbvie, Harvoni, and Sovaldi

The Cost of Hepatitis C and the Budget
- Chronic infection requires expensive regulated drug therapy. Other complications, such as liver disease and cancer, require additional costly treatments.
- Drug therapies can costs upwards of $80,000 per treatment per individual.
- Prison budgets simply cannot afford these treatments
Hepatitis C Demographics in Prisons

Hepatitis C is rampant among the incarcerated population. The incidence of Hepatitis C infection within prisons ranges from 13 to 54 percent of inmates. However, the true prevalence of Hepatitis C Virus (HCV) in the incarcerated population is difficult to measure since no mandated screening programs exist. Given that minorities are overrepresented within prison populations, it is likely that they are also disproportionately impacted by the spread of Hepatitis C outside of prison. In 2013, Black males made up 37 percent of America’s incarcerated population; Hispanics, 22 percent; whites made up only 32 percent of the inmate population while totaling over 70 percent of the total population. Similar trends are also seen along the intersections of racial and gender lines; for instance, black females were found to be imprisoned at a rate of 113 per 100,000, more than twice the rate than their white counterparts. The aging prisoners is also a point of concern as inmates 50 and older represent the fastest-growing population in federal correctional facilities. These incarcerated populations bring a heightened demand for healthcare services that must be reconciled with budgets.

Legal Obligations to Provide Healthcare: The Eighth Amendment

In forbidding “cruel and unusual punishment” the 8th Amendment protects prisoners’ right to health care. Estelle v. Gamble (1976) established that the government is obligated to provide healthcare for prisoners to prevent pain and suffering or, at worst, “physical torture or lingering death.” “Deliberate indifference” to a prisoner’s suffering on behalf of a correctional facility constitutes a violation of the Eighth Amendment. However, “deliberate indifference” must be argued and determined in court. In the case of Hepatitis C, a grey area remains concerning “deliberate indifference” as no correctional standard of care has been established.

Recent lawsuits have led to a debate about how to apply the Eighth Amendment to treating those with Hepatitis C. A lawsuit by two Minnesota inmates seeking high-impact Hepatitis C drugs was filed by the International Humanitarian Law Institute (IHLI) and is currently pending. Many healthcare policy experts agree with IHLI arguments that inmates have been denied access “in deliberate indifference” to their serious medical needs. Some reference the majority opinion in Estelle that the care and treatment provided to the prison population reflect the degree of professionalism of correctional medicine and are hallmarks of a civilized society. However, there is debate on whether specialized treatment requiring high impact drugs is protected by the 8th Amendment. Moreover, some prison administrators conclude that under current budgets it is fiscally impossible to treat the large prison population affected by Hepatitis C.

Public and Private Healthcare Systems

State prisons have varied health care systems that dictate the services they provide for inmates. Currently, 36 of 50 states contract some, if not all, of their correctional health care services to private firms. Correctional Healthcare contracts help prisons manage cost and care for prisoners. Contracted services range from comprehensive overhauls, ranging from mental health care to specialized services such as dialysis and
Hepatitis C treatment. During the 2013 fiscal year, private correctional healthcare companies provided states an estimated $1.9 billion in services. The large cost of providing healthcare may be reduced through changes created by the Affordable Care Act and purchasing negotiations.

How the Affordable Care Act Affects Corrections
The Affordable Care Act (ACA) may lower prison healthcare costs by improving entering inmate health, but it may also place responsibility on prisons for continuity of care. ACA expands Medicaid to many people without insurance, a category overrepresented in prison. The expansion will cover about 33.6 percent of inmates released annually and another 23.6 percent eligible for subsidized insurance through health insurance exchanges. The newly insured entering prison should face fewer acute conditions due to prior treatment that they have received. Thus the burden on prison healthcare budgets would be reduced. However, prisons may be expected to continue courses of treatment started prior to incarceration and this could increase costs. Federal Medicaid funding will not cover incarcerated individuals except in certain cases of temporary hospitalization. Inmates eligible for Medicaid can apply while in prison or suspend their existing insurance while in prison. This allows them to easily resume coverage, to secure care upon reentry, and to avoid costly gaps in treatment.

Part II: What is Hepatitis C?

Introduction
Correctional administrators need to understand Hepatitis C in order to address the disease, its frequency among the prison population and its costs of treatment. The Hepatitis C infection is caused by a powerful virus of the Hepacivirus genus, which has six different genotypes that do not mutate. The most common of these strands is genotype one. The virus successfully avoids the immune system in 75 to 85 percent of cases leading to chronic diseases in the majority of cases.

Characteristics of Symptoms

- Of those who develop acute infections 80% do not experience any symptoms
- Around 6 to 10 weeks after the initial infection, the other 20 percent experience symptoms, “with anorexia, vague abdominal discomfort, nausea and vomiting, fever and fatigue”
- Symptoms usually appear 4-12 weeks after infection
- Even if symptoms are present, they are not easy to read by infected individuals or healthcare professionals—thus delaying crucial diagnosis and treatment

Acute to Chronic: Hepatitis C Conditions & Development
Hepatitis C begins as acute, but if left untreated, progresses to a chronic disease. Due to the long asymptomatic period of the Hepatitis C virus, many individuals unwittingly progress to the more severe chronic stage of infection. While early treatment can be highly effective, less complicated, and less costly, the concealed symptoms prevent many individuals from accessing these treatments. Screenings, especially upon entry to prison, are necessary as they allow earlier intervention for Hepatitis C treatment.

Lifetime consequences arise for infected individuals whose bodies do not remove the virus early. Those who do not naturally clear the infection and do not receive prompt medical
care can develop a chronic HCV infection after 6 months of carrying the virus. This chronic infection can last a lifetime and cause liver damage, cirrhosis (liver scarring), liver failure, or liver cancer.¹⁵ Liver disease develops over several decades—often without symptoms. The path to cirrhosis begins with inflammation of the liver and eventually progresses to the hardening and scarring of the organ. 20 percent of those afflicted by chronic Hepatitis C develop cirrhosis in the liver after 15 to 20 years.¹⁶

Due to the long incubation period for chronic Hepatitis C, symptoms of cirrhosis and other liver issues may not develop for years. Thus, many patients discover their infections through blood tests performed for other concerns. The impact of HCV infections is felt inside- and out of prisons. Chronic Hepatitis C infections are currently the most common reason for liver transplants in the United States.¹⁷ Approximately 2.7 million persons in the United States have a chronic HCV infection. Those born between 1945-1965 are the most affected by this in regards to developing the later stages of Hepatitis C. Hepatitis C creates a range of responses within infected individuals. Sixty percent of adults infected with HCV develop some type of chronic liver disease and experience fluctuating levels of liver enzymes.¹⁹ The various conditions that infected persons develop over the decades following HCV infection require specific targeted measures for adequate treatment depending on the disease stage and type. The challenges of treating this infection stem from the various modes of infection, the variable progress the virus can make, and the virus’s long potential latency period. Thus, in discussing approaches to health care for prisoners with Hepatitis C, the direction should be specific to the individual.

This chronic infection can last a lifetime and cause liver damage, cirrhosis (liver scarring), liver failure, or liver cancer.
According to the Centers for Disease Control and Prevention (CDC), of every 100 persons infected with HCV, approximately:

- 75–85 will go on to develop chronic infection
- 60–70 will go on to develop chronic liver disease
- 5–20 will go on to develop cirrhosis over a period of 20–30 years
- 1–5 will die from the consequences of chronic infection

While the timeframe of development for chronic liver disease can be up to several years after infection, serious symptoms can appear at any moment after exposure. Thus, understanding how the disease is transmitted is an important first step in creating approaches to disease management. Stem from the various modes of infection, the variable progress the virus can make, and the virus’s long potential latency period. Thus, in discussing approaches to health care for prisoners with Hepatitis C, the direction should be specific to the individual.

**Hepatitis C Transmission: Risk factors & Vulnerable Populations**

Although less than one percent of Americans have chronic HCV infections, infections are most prevalent in specific communities. Individuals most at risk are those:

- With a history of injection drug use, infection from donated blood and blood products - especially if done before 1992
- Born to an HCV-infected mother and exposure to blood through sexual transmission
- In frequent contact with blood (e.g. healthcare workers)
- Who have engaged in unprotected sex with infected individuals

Because HCV infections are more common in areas where contaminated needles and syringes are shared, there is a higher risk of exposure in America’s lower-income, urban areas where intravenous (IV) drug use is more prevalent. 50 to 80 percent of drug users test positive for the Hepatitis C antibody within one year of beginning IV drug use. Additionally, IV drug users account for about 50 percent of all new cases of the disease.
Populations from low-socioeconomic backgrounds are also at a higher risk for developing a disease than other communities because of lesser access to health care and a longer delay for diagnosis and treatment. The HCV positive population is disproportionately comprised of people of color—an inequality that further destabilizes urban, low-income communities.

Prevalence of Hepatitis C in Prisons
Hepatitis C is prevalent in correctional facilities due to both prison demographics and conditions. Hepatitis C disproportionately affects the prison population as a result of the drug epidemics of the 1970s and 1980s when needle sharing was widespread and the dangers were unknown. Because the Hepatitis C virus is transmitted through blood-to-blood contact, individuals with a history of IV drug use are more affected by the infection. Moreover, Hepatitis C is more than three times more prevalent than HIV among this population. According to the Drug Policy Alliance, “people of color are far more likely to be stopped, searched, arrested, prosecuted, convicted and incarcerated for drug law violations than are whites” despite similar rates of drug use and dealing among racial groups. In addition, adults in prisons and other correctional facilities are at an increased risk to have and to carry HCV. This occurs because inmates commonly share equipment used for drug injection, tattooing and piercing with other people who are already infected often without knowledge by both the giving and receiving party.

For this reason, prisons should screen for Hepatitis C for those persons who:

• were born between 1945 and 1965
• have ever injected illegal drugs, even those who have only injected once many years ago
• have had exposure to HCV such as health care workers working with needles involving HCV positive blood
• were recipients of blood or organs from a donor who later tested HCV positive
• have an HIV infection
• are individuals in the prison population overall, due to the heavy prevalence of IV drug usage, tattooing and HCV infections

While inmates are guaranteed healthcare under the 8th amendment and are at the hands of these total institutions, conditions within the prison may also contribute to the spread of this blood-borne virus that is already so rampant in these institutions.

Part III: Treatment Options

Acute Stage
Treatment options during the acute infection phase are limited because spontaneous clearance can occur anytime within the six months following infection. Testing for the HCV antibody is recommended in case of possible exposure to HCV or the onset of symptoms. Once the infection is identified, rest, fluids and a balanced diet may be sufficient treatment to stall progression to chronic infection.

Unfortunately, the infection is rarely diagnosed and is able to progress because in most instances the patient does not experience symptoms during this stage. The same antiviral drug therapy used for chronic infections may also be used for acute infections, but the cost of antiviral drug therapy is high and the patient may not truly need the treatment.

Chronic Stage
Antiviral medication is a viable approach for patients dealing with chronic Hepatitis C.
Since HCV infection is a chronic disease that progresses slowly over many years, there is a long treatment window in which antiviral therapy could be initiated and therapy can be effective. Further, there are six genotypes of the HCV. While genotype one is the most common form of the virus, understanding the different genotypes and identifying the form carried by an individual patient is critical to developing an effective treatment regimen of the disease.

So far, results have shown that “Individuals with genotypes two and three are almost three times more likely than individuals with genotype 1 to respond to therapy.” This breakdown of genotypes complicates matters in making comprehensive policy decisions concerning future treatment, and it is important to understand all available options.

For chronic Hepatitis C infection, treatment requires regulated drug therapy that may come from one of the few available options on the market. Additionally, the health issues that develop from Hepatitis C infection, including liver disease and cancer, also require their own directed approach to care. For example, for end-stage liver disease, the only effective approach a liver transplant.

**Vaccines**
Currently there is no approved Hepatitis C vaccine due to the difficulty of the following: finding at-risk subjects for trial, the variability of the Hepatitis C virus relative to Hepatitis A and B, and the uncertainty about its efficiency given the unique qualities of Hepatitis C. One vaccine is currently being assessed, and, if approved, would be available to the public in 2016.

**FDA Approved Drugs**
In the treatment of chronic Hepatitis C infection, 2014 brought to the market oral regimens with significantly higher cure rates. Viekira Pak, Harvoni, Olysio (in combination with sofosbuvir), and Sovaldi were all approved by the U.S. Food and Drug Administration (FDA) in late 2014 for patients with chronic Hepatitis C.

### VIEKIRA PAK with or without Ribavirin (RBV): A Short-Course Treatment for Chronic Genotype 1 (GT1) Hepatitis C Virus (HCV) Patients

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Treatment</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>GT1A, WITHOUT CIRRHOSIS</td>
<td>VIEKIRA PAK + RBV 12</td>
<td>12</td>
</tr>
<tr>
<td>GT1A, WITH CIRRHOSIS</td>
<td>VIEKIRA PAK + RBV 12</td>
<td>24</td>
</tr>
<tr>
<td>GT1B, WITHOUT CIRRHOSIS</td>
<td>VIEKIRA PAK - RBV 12</td>
<td>12</td>
</tr>
<tr>
<td>GT1B, WITH CIRRHOSIS</td>
<td>VIEKIRA PAK + RBV 12</td>
<td>12</td>
</tr>
</tbody>
</table>

*Source: About Viekira Pak* 2015
Cost-Benefit Analyses of Available Drugs

While Sovaldi and Harvoni have competed in 2015 for the same demand from health care providers, Viekira Pak has recently emerged as a preferred option by many providers. The cost for a 12-week treatment course with Viekira Pak is $83,319.\(^{34}\)

The newer Viekira Pak treatment can treat genotype one of Hepatitis C through an oral regimen made up of four different medications - ombitasvir, paritaprevir, ritonavir and dasabuvir. With Viekira Pak, the length of treatment is dependant on the genotype one subtype and the presence or absence of cirrhosis.\(^{35}\) Viekira Pak's approach to treatment attacks the virus at three points in its lifecycle in order to stop the virus from reproducing.

Results from multiple populations, including those considered difficult to treat, showed 91 to 100 percent of participants who received Viekira Pak at the recommended dosage achieved Sustained Virologic Response (SVR) -- when they have achieved a continuous undetectable status for 12 to 24 weeks after therapy.\(^{36}\) However, it is important to note that Viekira Pak should not be used in patients with severe hepatic impairment due to risk of potential toxicity.\(^{38}\) While Viekira Pak has emerged as a treatment of choice because of its effectiveness in eliminating Hepatitis C and cirrhosis, costs remain a prohibitive factor.

Sovaldi offers a cost-comparable option to Viekira Pak that also attempts to eliminate the virus and limit its reproduction. The wholesale list price for sofosbuvir is $1,000 per 400 mg pill. Accordingly, the cost for the sofosbuvir component in a 12-week treatment course is $84,000.\(^{3}\)

Although most cases of Hepatitis C in the United States are of genotype one, Sovaldi holds an advantage over Viekira Pak because the latter does not treat the Hepatitis genotypes two or three. And while the costs of Sovaldi and Viekira Pak are similar, the need to combine Sofosbuvir (Sovaldi) with other medications also raises the price of treatment.

In December 2014, the Infectious Diseases Society of America (IDSA) and the American Associations for the Study of Liver Diseases (AASLD), in collaboration with the International Antiviral Society-USA (IAS-USA), outlined guidelines for the treatment of patients with chronic HCV infection.\(^{41}\)

The guidelines propose that priority should be given to those with the most urgent need because all patients cannot receive treatment immediately upon the approval of new agents. The recommendations include the following:

- Patients with advanced fibrosis, those with compensated cirrhosis, liver transplant recipients, and those with severe extrahepatic hepatitis are to be given the highest priority for treatment
- Based on available resources, patients at high risk for liver-related complications and severe extrahepatic Hepatitis C complications should be given high priority for treatment
- Treatment decisions should balance the anticipated reduction in transmission versus the likelihood of reinfection in patients whose risk of HCV transmission is high and in whom treatment may result in a reduction in transmission (e.g., men who have high-risk sex with men, active injection drug users, incarcerated persons, and those on hemodialysis).\(^{42}\)
Part IV: The Cost of Hepatitis C and the Budget

Specialty drugs make up a larger percentage of pharmaceutical costs
Highly effective and specialized drugs are being sold in the U.S. market with high mark-ups. Spending on these specialized drugs is expected to increase by 6 percent by the end of 2015 and quadruple over the next three years. This strategy was implemented by the pharmaceutical industry after it faced decreased profits and shifted its focus from cures for common illnesses to the production of highly effective drugs for rare ailments. This approach may seem promising for citizens whose ailments require these highly effective drugs. However, the budgetary constraints must be overcome in order to assure access to these treatments is available to those who need them.

The high costs of highly effective drugs
The prison population has a high prevalence of Hepatitis C; as a result, providing Sovaldi to one prisoner would equal the current health-care costs of about 17 prisoners. This is due to the fact that only about $5,000 are set aside per inmate for health-related costs and each Sovaldi treatment costs upwards of $84,000 per 12 week-long treatment.

Rhode Island as a case study for budgetary constraints
The following table uses Rhode Island as an example to estimate potential budget constraints for Sovaldi treatments.

| ESTIMATED PHARMACY AND OVERALL BUDGET IMPACT OF HCV TREATMENT GUIDELINES BY TREATMENT STRATEGY |
|-------------------------------------------------|-------------------------------------------------|-------------------------------------------------|
| Treat all (n = 32)                               | Treatment (n = 29)                              | Treat advanced fibrosis (n = 119)                |
| Estimated cures                                 | Estimated total drug costs \(^a\)                |                                                  |
| 315                                             | $34,170,053                                     | 115                                             |
| $34,170,053                                     | $31,454,139                                     | $15,188,440                                     |
| Budget impact \(^b\)                             | Proportion of pharmacy expenditures             |                                                  |
| RIDOC 2014 pharmacy budget:                     | 1254%                                           | 558%                                            |
| $2,723,669                                       | RIDOC 2014 overall healthcare budget:           |                                                  |
| $119,889,269                                     | $119,889,269                                    |                                                  |
| Proportion of overall healthcare expenditures   | 172%                                            |                                                  |
| 158%                                            | Estimated cost per patient cured:               |                                                  |
| $110,000 – $130,000                              |                                                  |                                                  |

\(^a\) Total drug costs estimated from interferon-free regimes (SO + RBV and SO + D/TVR)

\(^b\) Budget impact calculations based on public record of RIDOC 2014 expenditures

As table 4 shows, it would cost the state of Rhode Island $34,170,063 to treat all of its patients with Sovaldi. This would effectively make up 1254 percent of Rhode Island’s pharmaceutical budget and 172 percent of its overall correctional healthcare budget. In order to trim costs, the study then explored how much money would be spent on Sovaldi if only prisoners with signs of any fibrosis were treated with the drug. With this slight restriction, the costs would still add up to 158 percent of Rhode Island’s correctional healthcare budget.

Since both of the aforementioned scenarios are not financially feasible, the Federal Bureau of Prisons encourages correctional administrators to prioritize treatment for prisoners with advanced fibrosis. Many states’ Medicaid programs have already chosen to place this type of restriction on Sovaldi. If this strategy were to be implemented it would cost 76 percent of Rhode Island’s correctional healthcare budget.

Implementing this treatment regimen is still not financially feasible without discounts from the companies that produce Hepatitis C drugs and/or an increase in the correctional budget. At the moment producers of Sovaldi are refusing to provide discounts to providers who restrict the population to which they provide the treatment. However, there is an alternative drug, Viekira Pak, with comparable costs and cure rates, that is currently negotiating discounts with certain states. It costs roughly $83,319 per treatment. Additionally, the drug trials showed a 90 percent cure rate. Producers of Viekira Pak have agreed to provide the state of Missouri with a 30 to 40 percent discount rate and the state expects to save $4.2 million next year from switching to this drug. In Rhode Island, implementing this strategy would mean that Viekira Pak treatments would cost 45.6 to 53.2 percent of the state’s correctional healthcare budget.

Part V: Policy Recommendations

Disease Management Recommendation
We recommend that state correctional administrators implement a comprehensive screening program involving full screening of current prisoner populations and establishing mandatory testing procedures upon entry and exit. The screening procedure follows the Hepatitis C screening guidelines created by the Centers for Disease Control.

Recommended Testing Sequence for Identifying Current Hepatitis C Virus (HCV) Infection

![Testing Sequence Diagram]

Comprehensive screening is necessary to establish baseline disease levels of Hepatitis C. Comprehensive screening for Hepatitis C gives administrators the necessary information to properly allocate treatment. Currently, the majority of Hepatitis C tests in prisons are done on a targeted basis depending on risks factors of IV drug use, receiving transfusions or organ transplants. A small minority of prisons have routine testing, while the majority of prisons test for Hepatitis C on an opt-in basis through inmate request, or physician request.\(^{43}\)

Risk-based screening underestimates the Hepatitis C virus prevalence in correctional facilities because it requires that inmates disclose stigmatized behaviors within the correctional setting.\(^{44}\) Furthermore, targeted screening misses infected prison populations including non-intravenous drug users and women with high-risk sexual behavior.\(^{45}\)

The benefits of mandatory screening outweigh the costs

Mandatory screening provides correctional administrators with options to treat inmates at earlier stages of Hepatitis C, reducing overall treatment costs. Earlier stage diagnosis of Hepatitis C can be managed through risk-reduction counseling; vaccination for hepatitis A and B virus; and treatment evaluations that incorporate partnerships with community health care providers to treat prisoners following release.\(^{46}\)

Hepatitis C screening is cost-effective for high prevalence populations like the prison inmate population.\(^{47}\) Therefore the initial input cost for the comprehensive screening program will be recouped through savings in treatment options and proper allocation of the high cost Hepatitis C drug on inmates with more severe cases of Hepatitis C.

CDC guidelines for HIV screening in prisons provide a screening model for Hepatitis C

The CDC advocates for mandatory HIV testing because the process preserves public health and medical staff resources, greatly increases the proportion of inmates tested due to the streamlined consent and counseling processes, and normalizes HIV testing.\(^{48}\) Considering that HIV and Hepatitis C are similarly blood-borne viruses highly prevalent in prison populations, the same screening practice can be justified for Hepatitis C. Evaluations of the mandatory HIV screening policy in Rhode Island state prisons have shown that these policies have resulted in a greater proportion of the HIV positive prison population being accurately identified.\(^{49}\) The implementation of a mandatory screening for Hepatitis C could potentially bring down HIV screening costs because prisons systems could collect enough blood to simultaneously conduct a HIV and Hepatitis C test.

Co-Implementation of Hepatitis C Awareness Campaign would reduce transmission within prisons

Along with comprehensive screening, we recommend conducting an awareness campaign to educate prisoners on the risk factors, symptoms and treatment process for Hepatitis C. The educational campaign will reduce incidence of Hepatitis C within prisons because prisoners will understand the severity of the disease and also the behavior that puts them at risk of contracting the disease. Fundamentally the most affordable method of dealing with Hepatitis C is preventing the contraction of the disease.

Follow the Standards for Hepatitis C Treatment Set by Medicaid and the Federal Bureau of Prisons

Our disease management and treatment recommendations align with standard practices implemented by state Medicaid programs and the Federal Bureau of Prisons. In its 2013
Guidelines for Clinical Practices, the Federal Bureau of Prisons recommends screening asymptomatic inmates for the Hepatitis C antibody if they meet certain risk factors. These include a history of injection drug use, HIV or Hepatitis B infection, and tattoo or piercing receipt while in prison. We recommend expanding screening procedures beyond this standard to all prisoners due to the necessity of rationing new, expensive Hepatitis C treatments. Currently, states limit the use of Sovaldi and Harvoni. As of November 2014, 42 states explicitly offered Medicaid reimbursement for Sovaldi. Within this group, 74 percent of the states limit Sovaldi coverage to people suffering from advanced fibrosis or cirrhosis and 88 percent require abstinence from drug or alcohol usage.

Given significant budget constraints, correctional facilities should follow the Federal Bureau of Prisons and state Medicaid programs in limiting high-impact Hepatitis C drug coverage to people with advanced liver damage and those who either abstain from drug use or enroll in substance abuse treatment programs. Prioritizing advanced cirrhosis or fibrosis ensures that patients with the most severe illness receive treatment. Limiting coverage to those abstaining from or working towards abstaining from drugs coincides with controlling transmission of Hepatitis C. The CDC’s “Hepatitis C and Incarceration” fact sheet warns patients not to use alcohol or drugs as this exacerbates liver damage.

Within prisons, requiring enrollment in substance abuse monitoring and treatment alongside Hepatitis C medication is wholistically managing the illness. To maximize the long term impact of treatment in prisons on the communities in which inmates will return, correctional facilities should complement the healthcare system of the state in which they operate. For states that have expanded Medicaid under the Affordable Care Act, inmates that re-enter their community have medical coverage to continue their treatment regimen.

*Bulk Purchasing Recommendations*

We recommend correctional administrators pursue bulk purchasing agreements to negotiate lower drug pricing.

Pharmaceutical companies producing Hepatitis C treatments secure market share by providing discounts in return for exclusive or preferred offering of their drug. The Federal Bureau of Prisons has already managed to achieve a 44 percent discount on Gilead’s Sovaldi through a Department of Veteran’s Affairs arrangement (U.S. Senate Committee on Finance 2014).

Negotiating prices for high-impact Hepatitis C treatments is possible. In late 2014, the state of Missouri negotiated a deal with AbbVie for Viekira Pak, a rival treatment to Gilead’s Harvoni and Sovaldi. 25 other states are also negotiating with AbbVie. Missouri offers preferred status to AbbVie by limiting Medicaid recipients with Hepatitis C to Viekira Pak except in the 15 to 20 percent of patients for which Sovaldi would work better. The state projects $4.2 billion in savings corresponding to a 30 to 40 percent reduction in the cost of Hepatitis C treatments. This reflects the 23 percent discount that state Medicaid programs receive by law plus an estimated 20 to 30 percent discount negotiated in return for preferred treatment status. Express Scripts, the largest pharmacy benefits manager in the United States, agreed to exclusively prescribe Viekira Pak. AbbVie’s Chief Medical Officer stated that the price would roughly match the price of Sovaldi in Western Europe—$51,373 to $66,000. Responding to this competition for market share from AbbVie, Gilead began offering discounts to various insurance companies averaging 46 percent.
Strategies for Negotiation

Negotiations will need to balance the strategy of prioritization outlined earlier with treating a large enough volume of patients for sizeable leverage in price negotiations with pharmaceutical companies. Budget constraints necessitate targeting and limiting who receives high-impact drugs according to disease severity and compliance with substance abuse treatment. Pharmaceutical companies will push to remove all restrictions on who gets treatments to maximize market share. For example, the discount deal between AbbVie and Express Scripts entailed that all patients, regardless of the stage and severity of their Hepatitis C, get coverage for Viekira Pak.\textsuperscript{56} Likewise, Gilead recently eliminated discounts for insurance companies that limit Sovaldi and Harvoni based on degree of fibrosis and drug testing–two criteria that we recommend using to target treatment. Gilead also eliminated discounts for insurance companies that use step-therapy, a process of trying one intervention before the next.\textsuperscript{57} Despite these challenges, correctional administrators have a strong case for large discount negotiations:

- About 1.8 million incarcerated people have Hepatitis C (approximately one-third of all Hepatitis C cases in the United States).
- About 58 percent of U.S. inmates reside in state correctional facilities (Senate Committee on Finance 2014).\textsuperscript{58}

Increasing the number of prisons entering into a bulk purchasing agreement would increase negotiation power without abandoning the prioritization strategy.

Moreover, prisons can threaten to walk away from negotiations if the pharmaceutical companies demand too much coverage expansion or inadequate discounts.

A June 2014 report specifically addressing Hepatitis C states, “it is reasonable to postpone treatment for cases with less advanced fibrosis, pending the expected availability of better treatments in the very near future”.\textsuperscript{59} A study from the Center for Evidence-based Policy at the Oregon Health and Science University found that this concern applied to Sovaldi. “Gilead produced limited results from a small body of research over a relatively small period of time under an accelerated FDA ‘breakthrough drug’ path, which focuses more on quickly bringing the drug to the market than on effectiveness”.\textsuperscript{60} A 2015 study of over 4,000 veterans by the Veterans Affairs Palo Alto Health Care System found that Sovaldi was more effective than older treatments but less effective than in the clinical trials.\textsuperscript{61} Note that the results of clinical trials will likely overstate the effects on subsets of the population in reality, whether this pertains to veterans or inmates.

Ultimately, \textit{Estelle v. Gamble} (1976) does not mandate that correctional facilities embrace every cutting-edge treatment. Emphasize in negotiation that you have choice. Your decisions to cover the high-impact Hepatitis C drugs are motivated not by legal necessity but by your desire to excel as professional facilities within bounds of fiscal feasibility. The pharmaceutical companies need your business rather than the other way around.
Glossary

**Abbvie:** Pharmaceutical Company that produced Hepatitis C Drug Viekira-Pak

**Acute Hepatitis C:** short-term illness that occurs within the first 6 months after someone is exposed to the Hepatitis C virus. For most people, acute infection leads to chronic infection.

**Chronic Hepatitis C:** long-term illness that occurs when the Hepatitis C virus remains in a person’s body. Hepatitis C virus infection can last a lifetime and lead to serious liver problems, including cirrhosis (scarring of the liver) or liver cancer.

**Genotype:** A genotype is a classification of a virus based on the genetic material in the RNA (Ribonucleic acid) strands of the virus. Generally, patients are only infected with one genotype, but each genotype is actually a mixture of closely-related viruses called quasi-species.

**Gilead:** Pharmaceutical Company that produced Hepatitis C drugs: Sovaldi and Harvoni

**Harvoni:** High impact Hepatitis C drug treatment marketed in 2014 (Drugs: Ledipasvir and Sofosbuvir)

**Sovaldi:** High impact hepatitis C treatment first marketed in 2013 (Drugs: Sofosbuvir)

**Spontaneous clearance:** A person infected with HCV (2 & 3) who is able to gain control of their infection, by means of weapons from the host’s own immune system. However, it remains unclear what exactly distinguishes a successful from an unsuccessful cellular immune response and how critical a role other parts of the immune system have in HCV control.

**Viekira-Pak:** High impact Hepatitis C treatment first marketed in 2014 (Drugs: Dasabuvir, Ombitasvir, Paritaprevir, and Ritonavir)
8 Christopher Snowbeck, Minnesota Prison inmates sue to gain access to costly hepatitis C Medications,” Star Tribune, Web (2015)


Figure 1. Recommended Testing Sequence for Identifying Current Hepatitis C Virus (HCV) Infection. Adapted from “Testing for HCV infection: An update of guidance for clinicians and laboratorians.” by the Centers for Disease Control.


“Grassley, Charles E. and Ron Wyden. U.S. Senate Committee on Finance. Letter to Dr. John C. Martin, Chairman and Chief Executive Officer of Gilead Inc. 11 July 2014. TS.

