Cash-Strapped Prisons Could Save Huge on Hepatitis C Drugs

Existing federal law could permit prisons to negotiate a 90 percent–plus discount—without scaring off pharma.

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Every year, more than 1 million people living with hepatitis C virus (HCV) pass through the nation's prisons and jails. And yet, despite the fact that many of these people are incarcerated long enough to complete a direct-acting antiviral (DAA) regimen to treat the virus, only a tiny fraction ever receives such drug therapy.

This represents a critical missed opportunity to dramatically reduce the number of Americans with hep C and to reduce the spread of the virus as the opioid crisis fuels the viral epidemic and threatens young people in particular with infection.

The problem, first and foremost, is money. Even as prices have fallen in recent years, widespread prescription of DAAs remains prohibitively expensive for prison health care budgets.

"It's not just that the prisons don't want to spend the money," says Anne C. Spaulding, MD, MPH, an epidemiologist at the Rollins School of Public Health at Emory University in Atlanta. "They're not allocated the resources."

The complexities of federal law governing pharmaceutical pricing prevent prisons from negotiating steep enough discounts to enable significant numbers of incarcerated individuals to receive hep C treatment.

But perhaps prison systems are not looking at drug pricing laws closely enough, Spaulding and a group of other researchers have argued in a new paper in the Journal of Correctional Health Care. The team points to existing law that would permit a safety-net provider (those who provide health care regardless of a patient's ability to pay), such as a prison, to secure a greater than 90 percent discount on the average manufacturer price of a medication. Prisons could even obtain such discounts without disrupting the careful financial equilibrium pharmaceutical companies seek to strike when setting drug prices and negotiating discounts on those amounts across the market.

Prison Hep C treatment: By the numbers

Spaulding and her colleagues estimated that 13.5 percent of the 10 million Americans who pass through the nation's prisons and jails each year have hep C. (An estimated 2.4 million Americans are living with the virus. About 41,200 people contracted hep C in 2016, a 21 percent rise since the previous year.) Perhaps 1 in 10 of these inmates with the virus, or 135,000 people, are likely incarcerated long enough—mostly in prisons—to complete the eight to 12 weeks of DAA treatment typically required to cure HCV.

However,given the high cost of the drug regimens, prisons have a considerable financial disincentive to treat hep C—and even to test for the virus.

The DAA market has become increasingly crowded since Gilead Sciences' Sovaldi (sofosbuvir) revolutionized HCV treatment in late 2013. The ramped-up competition between pharmaceutical manufacturers has caused the sticker, or wholesale, price of DAAs to decline from about $70,000 per person per regimen in the fall of 2017 to about $25,000 in 2018. But even at the discounted rate, it would still cost more than $3.3 billion to treat that cohort of 135,000 prime candidates.

Once these institutions learn that an inmate has the virus, they are compelled not to overlook that person's health status. Additionally, while treating hep C earlier likely saves money in the long run, as a result of, for example, averted medical costs associated with advanced liver disease, a prison that pays for a course of DAAs is unlikely to reap savings that tend to accrue years or decades down the line.

Consequently, routine HCV screening in state prisons is the exception rather than the rule.

A primer on drug pricing in the United States:

First you have the average wholesale price, which is essentially the top price.

Next is the average manufacturer price, which is defined by federal law and amounts to the average price at which the drug is actually sold (making it lower than the average wholesale price) to wholesalers and community pharmacies. This figure is reported to federal officials but kept from the general public.

Federal agencies such as the Department of Veterans Affairs as well as Medicare Part D and the Medicaid Drug Rebate Program base the discounts they receive on the average manufacturer price of a medication. Additionally, safety-net hospitals and federally qualified health centers benefit from 340B, a program that secures them the manufacturer's best price for a drug, a discount based on the average manufacturer's price.

Correctional systems typically purchase medications on the open market and through wholesalers, leaving the systems, which are smaller than those major federal programs, in a relatively weak position to negotiate lower prices. At the same time, considering the series of discount calculations that hang on the average manufacturer price of a drug, pharmaceutical companies have a vested interest in keeping that financial benchmark high. This means the companies are disinclined to permit the large-scale purchase of a medication at a discount that would lower the average

manufacturer price and in turn the discounted prices.

Some correctional facilities do, however, outsource their treatment of inmates with HCV to safety-net hospitals or federally qualified health centers. This allows these institutions to take advantage of those health care facilities' access to 340B drug pricing.

A proposed solution:

Spaulding and her colleagues suggest that correctional systems already have at their disposal a workaround that could afford them rock-bottom prices for DAAs.

When calculating the average manufacturer price, pharmaceutical companies are not required, according to federal law built into Medicaid reform in the 1990s, to consider a "nominal" price. This is defined as a price below 10 percent of the average manufacturer price. Such a heavily discounted price may be secured by a safety-net provider, a designation that the Department of Health and Human Services (DHHS) Secretary—currently, Alex M. Azar II—has the authority to make at his or her discretion.

For a theoretical test case of how the use of nominal pricing could benefit prison systems and pharmaceutical companies alike, the paper's authors considered 2017 data from the Georgia Department of Corrections and the fact that the average wholesale price for a DAA regimen was $69,773 at that time. Since the department paid $38,186 at the 340B rate when contracting with a safety-net hospital and that rate is 23.1 percent less than the average manufacturer price, the researchers presumed that the average manufacturer price was $49,657. Ten percent of that figure provides a nominal-pricing ceiling of $4,956 to treat hep C in one person.

In 2017, Georgia paid for 219 inmates to receive HCV treatment—a drop in the bucket given that about 3,000, or 6 percent of the state's prison population of some 50,000, likely had the virus. The new paper's authors calculated that treating those 219 people would have cost $15.3 million if the DAAs were sold according to the average wholesale price. Under 340B pricing and taking into account the $452 per person in additional funds needed to ferry inmates to outside health care facilities, the total cost would be $8.5 million. The use of nominal pricing, in which the prison system negotiated a discount of $4,000 per regimen, would lower the bill to just $876,000.

A one-year budget of $15.3 million for the treatment of HCV among Georgia's prison population could cover 400 people under 340B pricing and 3,820 people under nominal pricing—a respective 9.5-fold and 17.4-fold increase in the patient population over the group of 219.

Would pharma bite? Will prisons test for HCV?

In theory, given the multiple players in the hep C pharmaceutical market, at least one company could agree to a nominal price discount. Doing so would ensure that this company would edge out a competitor to sell its product to prisons en masse, while also raising the number of people treated. Of course, companies could wager that it would be more profitable to wait until inmates seek treatment outside prison, where drug costs would be much higher than with nominal pricing.

But those ex-inmates could wind up taking other companies' medications.

The economics of such nominal-pricing negotiations operate under the assumption that pharma companies have already recouped their research and development costs for DAAs, which given the drugs' extraordinarily high prices and how long they have been on the market, is likely the case. And because the cost of manufacturing a DAA regimen is likely just $400, even charging only $4,000 represents a 10-fold markup.

If prison systems could secure much more affordable prices for DAAs through nominal pricing, they could possibly be coaxed into conducting widescale HCV testing among inmates. However, it is also possible that such systems would find themselves compelled to pay for treatment for more people than their budgets would permit—even with nominal pricing of DAAs. That said, Spaulding and her coauthors predict that enough DAA-eligible inmates would opt not to receive treatment, thus mitigating the budgetary risk of broad-based screening of the virus.

A win-win:

Dollars and cents aside, curing hep C is associated with numerous health benefits, including the potential for arrested and even dialed-back liver disease progression as well as a lower risk of diabetes, cardiovascular and kidney disease, recurrence of liver cancer and death. Beating the virus is also associated with improved quality of life.

Considering the high rate of substance abuse disorders among inmates with HCV and their considerable likelihood of experiencing relapse after release, curing their virus while they are incarcerated likely benefits public health by preventing them from transmitting hep C to others through the sharing of injection drug equipment once they are out of jail or prison.

"Nominal pricing," the paper's authors conclude, "is a win-win situation for both pharmaceutical companies and incarcerated patients. The time is now to seek authorization from the DHHS secretary to use the mechanism."

"I'm optimistic. I believe it is one viable option," says Spaulding of the nominal pricing strategy. "The advantage of it over other proposals would be that no laws need to be changed."

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