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Funding Hepatitis C Treatment in Correctional Facilities by Using a Nominal Pricing Mechanism

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Abstract

The cost of treating all incarcerated people who have hepatitis C with direct-acting antiviral agents (DAAs) greatly stresses correctional facility budgets. Complex federal laws bar pharmaceutical companies from simply discounting expensive medications to prices that facilities can afford. This article discusses means by which correctional facilities may qualify under federal law as "safety-net providers" to allow sale of DAAs at a price <10% of the average manufacturer price (AMP). No new laws would need to be enacted to implement this strategy. Using fiscal year 2018 pricing data from the Georgia Department of Corrections, we derived an estimate for the AMP and then used this estimate to calculate a nominal price. The United States would save ~$3 billion if manufacturers sold DAAs at a nominal price to correctional facilities. Use of this strategy would help solve the conundrum of how state and county governments can pay for hepatitis C treatment and would ultimately save money for society.

Keywords

HCV elimination, prison, jail, hepatitis C, Medicaid

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Introduction

Prisons and jails house one third of the hepatitis C epidemic (Varan, Mercer, Stein, & Spaulding, 2014). Injection drug use drives the current hepatitis C virus (HCV) epidemic, and people using illicit drugs often land in a correctional facility (Spaulding, Anderson, Khan, Taborda-Vidarte, & Phillips, 2017). Among the 10 million Americans who pass through a jail or prison annually, we estimate that 18% have antibodies to HCV (Spaulding et al., 2017). Since one-quarter of people with antibodies clear their virus, 13.5%, or 1.35 million, remain with a chronic viral infection (Denniston et al., 2014; Spaulding et al., 2017).

The Department of Health and Human Services' (DHHS) strategy for the elimination of hepatitis C in the United States relies on engaging the criminal justice system in the diagnosis and treatment of HCV (National Academies, 2017). It recommends that treatment with the newest direct-acting antiviral agents (DAAs), which clear HCV infection nearly 100% of the time, be made accessible to incarcerated people.

We estimate that at least 10% of the 1.35 million people with HCV (i.e., 135,000 people) who are incarcerated at some point over a 1-year period have stays long enough to complete an 8- to 12-week course of treatment. Most of these longer stays are in prisons, not in jails. While the mean sentence in a prison (long-term correctional facility) is 3 years (Carson & Sabol, 2016), in jails (short-term facilities) only about 10% of entrants remain more than 3 months (Spaulding et al., 2011).

Treatment for HCV in prisons is cost-effective for society as a whole. Nonetheless, prisons have insufficient funds to buy treatment for all confined people living with HCV. The "sticker price" of DAAs was approximately $70,000 per patient course in the fall of 2017 (see Figure 1). Since then, some manufacturers have lowered prices to approximately $25,000 for a full course of treatment (Andrews, 2017). Nevertheless, the cost of DAAs can still outstrip prison budgets. One recent study of a state correctional system found that its pharmacy budget would need to be 13 times larger to accommodate the added expense of providing DAAs (Nguyen et al., 2015). While different systems may have different HCV prevalence rates and budgets, treatment cost exceeding the total pharmacy budget is very unlikely to be an anomaly. For correctional facilities to collectively provide treatment to the feasible-to-treat fraction (135,000 individuals), this cost translates to more than $3.3 billion, even at the low end of pricing.

The high cost of DAAs, and the lack of financial support to pay for them, creates a disincentive for prisons to implement routine screening for HCV. The legal obligation to systematically screen for a harmful disease such as HCV, for which incarcerated people are at risk, is ambiguous (*Farmer v. Brennan*, 1994). Nonetheless, once the presence of a "serious illness or injury" is known, prison officials cannot remain deliberately indifferent to its presence (*Estelle v. Gamble*, 1976; Spaulding et al., 2012). Furthermore, the downstream cost savings of HCV treatment, compared to the cost of caring for people with advanced liver disease, is generally borne by the society as a whole, not by the prison system. This is because the majority of people behind bars are eventually released back to their communities (He et al., 2016). Hence, few state prison systems implement HCV screening programs despite the high prevalence of the disease (Spaulding et al., 2017).

Prices for DAAs need to drop dramatically for correctional health care services to realize a substantial return on an investment in routine screening and treatment for all incarcerated people infected with HCV. We propose a solution to DAA pricing for correctional facilities that takes advantage of the federal law on nominal pricing. This strategy has the potential to cut the cost of HCV treatment delivered to a substantial portion of infected people in prisons from $3.3 billion to $337.5 million, saving U.S. taxpayers approximately $3 billion.

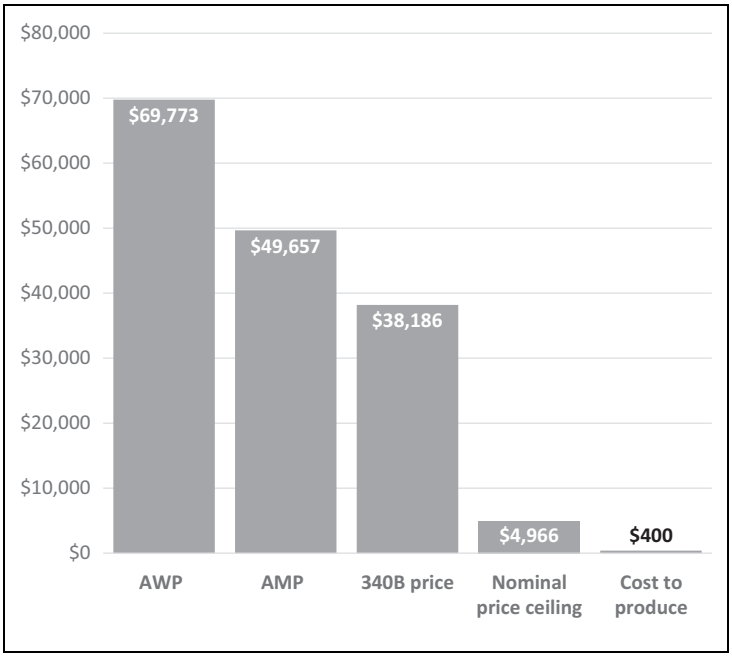

Figure 1. Estimated price per course of hepatitis C treatment in prisons, direct-acting agents for hepatitis C. *Source*: Authors' analysis as outlined in Method section, based on data supplied by Georgia Department of Corrections, November 2017. Modified from Spaulding et al. (2018).

Policy Background

Correctional systems usually buy medications through wholesalers at high prices on the open market. Their markup is one of the greatest in the U.S. drug market (Beckman et al., 2016; Rosenthal & Graham, 2016). Due to the market repercussions of various federal laws, prisons face barriers in negotiating a lower price with the manufacturer. As a stand-alone transaction, a lower price may benefit both parties. However, if a manufacturer discounts prices below a certain amount, it may have to change prices sold to other customers.

The price for medications bought by federal entities is pegged to the average price of the drug, usually the average manufacturer price (AMP), or is based on the "best price" of the drug in the market (see Table 1). AMP is defined by federal law: It represents the manufacturer's average price across the United States for a drug within the retail class of trade (Public Health, 2010b; The Public Health and Welfare, 2008). Manufacturers must report AMP for all drugs quarterly to federal officials, but this price is not disclosed to the general public. The "federal ceiling price" to which certain government purchasers—Department of Veterans Affairs, Department of Defense, Public Health Service, and Coast Guard—are entitled and the average sales price formula used by Medicare Part D to reimburse providers are both based on AMP. The Medicaid Drug Rebate Program (MDRP), as well as the 340B program for safety-net hospitals and federally qualified health centers, by statute must access the manufacturer's best price. This best price mechanism is especially challenging. Instead of incrementally decreasing the prices, the mechanism can cause a sudden plummet in pricing, set off by a single transaction.

These federal pricing policies dampen the incentive for manufacturers to lower the cost of DAAs to a price point that would allow correctional facilities to implement systematic screening and treatment. The prison market is smaller than the markets of the federal programs. It does not make

fiscal sense for pharmaceutical manufacturers to prioritize it above the federal programs. If a correctional facility successfully negotiated substantial discounts, those discounts would then, by law, lower profits from their drugs within the larger federal programs.

Correctional facilities have some existing strategies to obtain lower prices. Some prisons have been able to partner with a safety-net hospital or a federally qualified health center to reduce the price they pay for DAAs. By having the prison's patients treated at these 340B-eligible facilities, the patients are eligible to receive 340B discounted drugs. However, most correctional facilities do not have access to 340B pricing. The Federal Bureau of Prisons can buy medications according to the Federal Supply Schedule (FSS), at a price lower than that offered to state facilities. Even with access to 340B and FSS discounts, the budget needed to treat all inmates exceeds what most prisons can afford at present. To the best of our knowledge, no U.S. correctional system currently offers DAA treatment to all hepatitis C patients.

A mechanism exists to navigate around the stipulation that certain federally supported programs receive the best price for a drug. To arrive at an official best price, a manufacturer is not required to consider prices that are merely "nominal" in amount (The Public Health and Welfare, 2008). Federal law defines a nominal price as a price below 10% of AMP (Public Health, 2010a) and paid by an entity listed in Section 1927(c)(1)(D)(i) of the Social Security Act or any facility determined to be a "safety-net provider" by the DHHS Secretary (The Public Health and Welfare, 2008). The Secretary has at his or her discretion the right to approve nominal pricing for prisons. The decision could be based on the services provided or the population served (The Public Health and Welfare, 2008). The nominal pricing exemption to best price calculations was included in Medicaid reform in the 1990s. The purpose was to continue to encourage manufacturers to provide drugs at low prices to organizations that served populations with limited access to health care. Because this mechanism does not require the U.S. Congress to change laws, nominal pricing puts DAA treatment within reach of all correctional systems. We propose that correctional systems explore this opportunity.

Method

Some prices, such as AMP, are not publicly available. In order to calculate approximations of unpublished prices and estimate what a nominal price would be, we obtained fiscal year (FY) 2018 pricing data from the Georgia Department of Corrections (GDC).

Back Calculating From Known Prices

When GDC contracts with a safety-net hospital, it receives the 340B rate of $38,186 for a full course of treatment. This is more favorable to GDC than the average wholesale price (AWP or sticker price) for DAAs of $69,773. We know that the maximum 340B price is 23.1% below AMP. Thus knowing the 340B rate permits us to calculate AMP. Nominal pricing is then 10% (or less) of this AMP estimate.

Using the GDC System as an Example

For the most recent year for which complete data are available (FY2017), 219 GDC patients completed HCV treatment. We estimated the cost of treating these 219 patients under AWP, 340B, and nominal pricing and the savings that could accrue if manufacturers sold DAAs at a nominal price. We compared how many people could be treated if the dollars spent using AWP were instead spent on a 340B or nominal pricing program. For an estimate of the anti-HCV antibodies prevalence in the Georgia prison system as a whole, we extrapolated from studies of exit testing of people leaving the GDC. The estimated population prevalence of anti-HCV antibodies in

Table 1. Explanation of Pricing Levels.

AWP (average wholesale price): This is a drug-specific published price. It was originally intended to represent the average price paid to wholesalers by pharmacies, doctors, and other customers (including correctional pharmacies). Today, it is considered more like a "sticker" or "list" price than an actual market price.

AMP (average manufacturer price): The average price paid to a manufacturer by wholesalers for the manufacturer's drugs distributed to retail community pharmacies and by retail community pharmacies that purchase the drug directly from the manufacturers, subject to certain exceptions. Pharmaceutical companies are required to report this price quarterly to the federal government.

340B (maximum price that can be charged to a 340B-covered entity): The 340B ceiling price is calculated quarterly by the drug's manufacturer by subtracting the Medicaid Drug Rebate Program (MDRP) rebate amount from AMP. The minimum MDRP rebate for brand-name drugs is AMP $\times$ 23.1%.

Nominal price (price that is less than 10% of AMP; Public Health, 2010a): Five categories of purchasers and a sixth category of "safety-net providers" approved by the Department of Health and Human Services' Secretary are allowed to use this mechanism. These entities can negotiate and pay a nominal price, without establishing a new best price for purposes of the MDRP and 340B programs (Public Health and Welfare, 2008).

Cost to produce: $400 or less (Hill et al., 2014; van de Ven et al., 2015).

GDC is 12% (Taborda Vidarte, Anderson, Khan, Phillips, & Spaulding, 2017). GDC's population averages 50,000. We estimated the proportion of people in the GDC with active HCV infection by assuming that 75% of people with antibodies are viremic. We then calculated the estimated number of patients missed with each pricing scheme. Additional cost considerations were included: (1) transportation—to qualify for 340B pricing, patients in prisons spread across Georgia are brought to the safety-net hospital, with a cost of $452 per patient for each such trip; and (2) cost for screening—HCV testing price is negligible ($8 per antibody assay and $64 per reflex RNA assay to detect people with active HCV infection) for overall cost and equivalent under each pricing scheme, and thus not included in the price comparisons.

Results

Back Calculating From Known Prices

Using data from the Georgia prison system, whose 340B rate for DAAs in 2017 was $38,186 per course, we estimate that the AMP for DAAs was $49,657. At this price, the 340B price would represent a 23.1% discount from the AMP. This AMP estimate allowed us to calculate the nominal price.

Nominal Price Ceiling

We estimate that drug manufacturers could use nominal pricing to supply DAAs to the GDC for less than $4,966 per course of treatment (see Figure 1). In FY 2017, when 219 people with chronic HCV were treated within the GDC, the cost using the AWP would have been $15,280,287 (see Table 2). Under nominal pricing, using the figure of $4,000 per course of treatment, the cost to treat the same 219 people would have been reduced by 94% from the cost of AWP.

Nominal pricing could increase access to HCV treatment for people with HCV living in prisons 9.5-fold compared to when systems use the 340B strategy and 17.4-fold compared to when drugs are purchased at AWP (see Figure 2).

Table 2. Cost of Treating 219 Patients With Hepatitis C Under Three Schema—Average Wholesale Price (AWP), 340B, and Nominal Pricing[a]—Using Fiscal Year 2018 Georgia Department of Corrections Data.[b]

	Pricing Program		
Budget Items	AWP	340B	Nominal
Expenses			
Medications	$15,280,287	$8,362,734	$876,000
Transportation		$98,988	
Total	$15,280,287	$8,461,722	$876,000
Savings compared to AWP	—	$6,818,565	$14,404,287

Source: Based on Georgia Department of Corrections data, supplied November 2017.
[a] Estimated at $4,000 per course of treatment. [b]Population 50,000, 12% hepatitis C virus (HCV) antibody positive, 9% HCV viremic.

Figure 2. Number of persons with chronic hepatitis C hypothetically treated and missed under three pricing strategies. The total amount of $15,280,287 can treat 219 people when cost is AWP ($69,773), 400 people when treated under 340B pricing ($38,186), and 3820 people when nominally priced ($4,000). *Source*: Georgia Department of Corrections, fiscal year 2017 to 2018.

Discussion

We have shown that manufacturers could sell DAAs to state prisons for an estimated nominal price of $4,000 without disrupting the rest of the market. Each year, 1.35 million people with hepatitis C find themselves in a jail or prison. At least 135,000 stay long enough to complete a full course of treatment. Using nominal pricing could make treating these 135,000 affordable. We do not believe that pharmaceutical manufacturers would lose money on this strategy. Pricing DAAs at $4,000 per regimen, or an even further reduced cost such as $2,000, could still permit sales of the medications for a profit. The manufacturers would still be selling DAAs to correctional facilities at a price several fold greater than the cost to manufacture these drugs (Hill, Khoo, Fortunak, Simmons, & Ford, 2014; van de Ven et al., 2015). Manufacturers could afford to extend nominal pricing to prisons once research and development costs have been recouped. Since DAAs have been in the market for some time already, we assume these costs have been covered.

Using nominal pricing faces some hurdles. First, manufacturers need to be willing to sell DAAs at the nominal price point. Because pharmaceutical companies are currently unable to entice state

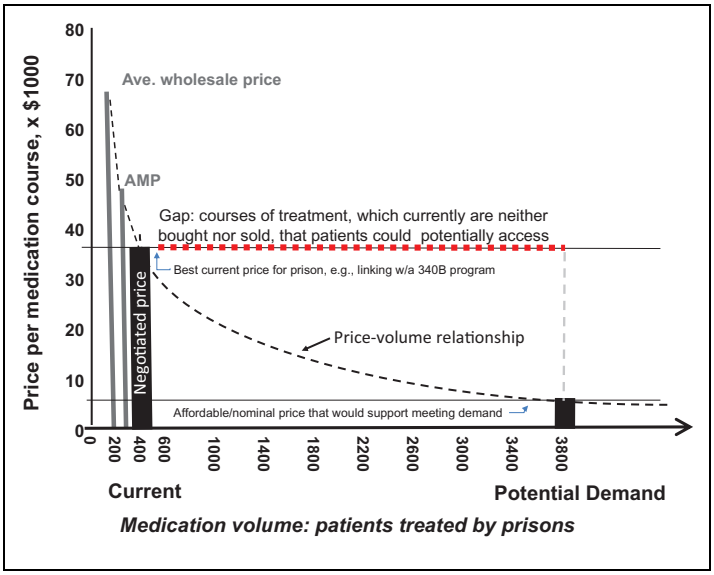

Figure 3. Price–volume curve for hepatitis C virus medications, for a U.S. prison system, 2017, showing gap between potential/actual access to medications.

prison systems to treat all potentially eligible people (Beckman et al., 2016), we believe it might be in a manufacturer's best interest to extend nominal pricing to the systems. Doing so would enable reaching the remaining niches of the U.S. market (see Figure 3). Companies could gamble that not extending discounts to prisons and waiting until patients are released and charged higher prices under community-based regimens would allow them to reap greater profits. However, in the rapidly evolving hepatitis C market, deferring treatment might mean a competitor would sell their product to the prison. Waiting until after release risks losing the opportunity to have the patient cured with their drug. Offering avenues for prisons to access DAAs, similar to access programs for developing nations, could build goodwill for companies.

Second, DHHS has to determine that correctional facilities are safety-net providers within the meaning of Section 1927(c)(1)(D)(i)(VI) of the Social Security Act. If so, then when manufacturers agree to sell their DAAs to prisons at a nominal price, that sale will not set a new best price and thereby reduce the payments expected within the MDRP and 340B markets. Extending nominal pricing to state prisons and local jails would help state and county government institutions, which currently are not able to afford medications. Not treating patients while incarcerated shifts the burden to Medicaid or Medicare. These entitlement programs would cover the cost of curing the same patients later, when more advanced—and more costly—liver disease and liver cancer risk rises. There is ongoing precedent for extending nominal pricing to governmental and other nonprofit agencies: In the year 2016 alone, 648 companies that label pharmaceuticals sold 135 unique drugs using nominal pricing (Centers for Medicare & Medicaid Services. 2018, March 8). We believe a strong case can be made to the DHHS Secretary to approve use of nominal pricing for DAAs purchased by state prisons and local jails.

Lastly, with costs per patient slashed, prisons may face added pressure to test and treat more patients than before. In doing so, they could expend even more for an HCV program than currently budgeted. For example, GDC could treat 3,802 people with nominal pricing for what is spent treating 219 people using AWP. However, if GDC increases screening, orders more tests for

evaluation such as for cirrhosis, and finds 4,500 patients to treat (the upper limit of people who we estimate await treatment), the overall outlay increases. The major expense would still be the drugs rather than the evaluation. This rapid expansion is unlikely, given that not every eligible person opts to start DAAs while incarcerated. Also, while general medical providers can prescribe the new agents, the existing health care infrastructure in prisons could limit how fast the system can reach everyone.

HCV prevalence varies state by state (Spaulding et al., 2017), but all state prison systems would benefit if treatment costs fall. We can treat many people in the carceral setting now by adopting nominal pricing. Treating people who inject drugs and are sentenced to prison will likely halt future transmission. Incarcerated people are not a static population: More than 99% of entrants eventually leave. Although drug treatment is available in prisons, substance use disorder is a relapsing illness. Many people living with HCV could spread their infection in the community after release if not cured in prison (He et al., 2016). Treating a community's most active injectors has the greatest effect on reducing transmission of HCV to others in networks of drug users (Martin et al., 2013). Doing nothing will mean a continuation of rising HCV incidence (Campbell et al., 2017).

Conclusion

At current pricing for treatment, corrections cannot afford to screen for HCV and treat everyone infected. Drug manufacturers could use nominal pricing to supply DAAs to correctional facilities at $200 to $4,000 a course, which could turn the tide. Prisons are an undertapped market for manufacturers. At lower prices, more medication would be available for people in prison, who are at highest risk of transmitting HCV to the broader community once released. Nominal pricing 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.

Authors' Note

This article is a synopsis of an article by Spaulding, Adee, Lawrence, Chhatwal, and von Oehsen (2018).

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