

A Lifesaving Subscription? Evaluating Louisiana's Attempt to Eliminate Hepatitis C *

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ABSTRACT

Hepatitis C is an infectious disease and major public health concern. Break-throughs in pharmaceuticals have the potential to cure Hepatitis C and cause large positive health externalities through reduced transmission. However, the high costs associated of these drugs under traditional reimbursement schemes create large obstacles to care. A recent two-part tariff system in Louisiana aims to circumvent these obstacles using a modified subscription model with an exclusive pharmaceutical provider, where the medication is provided at no marginal cost to the state to cover the Medicaid and incarcerated population. Additionally, Louisiana aims to aggressively test and detect Hepatitis C in order to maximize the benefits of this agreement. We find that detection and treatment of Hepatitis C increased dramatically, with meaningful reductions in Hepatitis C-related mortality.

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1. Introduction

A common theme in American healthcare in recent years has been increasing costs coupled with stagnant or even worsening outcomes (Friedson, 2023). This is particularly true in the case of pharmaceuticals, with Americans paying five to ten times more for insulin than patients in other OECD countries, while U.S. deaths from diabetes rose by over 40% between 2010 and 2022 ((Mulcahy et al., 2020; Murphy et al., 2013; CDC, 2022)). One potential solution to the rising costs of prescription drugs is a two-part tariff system or a subscription-based plan. In these systems insurers pay an upfront fee to gain access to a drug, but then pay the marginal cost for each unit of the drug. This creates an incentive to treat as many people as possible, which would create large positive externalities for drugs which cure infectious diseases, as it could greatly reduce the prevalence of the disease in the population.

Two-part tariffs are commonly used in many markets, with examples including Amazon Prime, country clubs, and membership retail stores like Costco and Sam’s Club, but they are a relatively new idea in the prescription drug market and there is little empirical evidence on their effectiveness. Brekke et al. (2022) analyze two-part tariffs in the pharmaceutical market theoretically, finding that when producers have monopoly power they would be able to extract all the surplus in the market through the subscription fee. However, in contexts with supply-side competition, insurers with large market share are able to extract surplus from producers by threatening to exclude specific suppliers with higher prices.

In 2019, the Louisiana Department of Health implemented a first-of-its-kind two-part tariff system to gain unlimited access to a generic version of the breakthrough Hepatitis C antiviral, Epclusa, for the state’s Medicaid and incarcerated populations. This “modified-subscription system” was the cornerstone of their Louisiana Hepatitis C Elimination Plan (LAHCEP), which had the lofty goal of diagnosing 80% and treating 90% of Hepatitis C patients in Louisiana (Louisiana Department of Health, 2019). In this paper, we evaluate the effects of the LAHCEP on testing and surveillance, prescriptions of DAAs, and HCV-related mortality using both the synthetic control method of Abadie and Gardeazabal (2003) and event-study designs.

Using data from the Centers for Disease Control and Prevention’s (CDC) Na-

tional Center for HIV, Viral Hepatitis, STD, and TB Prevention, we find that, relative to 2018 levels, the LAHCEP increased HCV diagnoses in Louisiana by over 3,000% in 2020, over 4,000% in 2021, and over 1,900% in 2022. The slowdown in diagnoses which occurred in 2022 is consistent with the state reaching diminishing marginal returns to surveillance and testing, which suggests they may have already reached a substantial portion of the HCV positive population. Next, we use data from the Center's for Medicare and Medicaid Services State Drug Utilization Program (SDUD) to estimate the effect of the LAHCEP on prescriptions filled. We find that, relative a synthetic version of Louisiana, the LAHCEP led to an immediate increase of DAA prescriptions of 630%, 1,050%, and 710% in the first three quarters, with increases of over 400% for the next four quarters.

Finally, we use restricted access data from the National Vital Statistics System to measure the effects of the LAHCEP on HCV-related mortality. Because of the slow progression of HCV infection, we would expect the largest effects on mortality to show up between 10-20 years after the start of the plan (Chhatwal et al., 2023), so any effects that we find in the early years are likely to grow over time. Still, we find reductions in HCV related mortality of 11-13% in the first four years, or between 300-400 fewer deaths. This translates to approximately one HCV related death avoided for every 72-95 DAA prescriptions filled between 2019-2022.

This program creates an ideal setting in which to test the benefits of a two-part tariff system in pharmaceuticals for two reasons. First, the potential for positive externalities is large. Hepatitis C (HCV) is a contagious virus that is spread mostly through contact with the blood of an infected person. Because it can take several years for symptoms to show up, as many as 40% of HCV positive patients are not aware of their infection (Gnanapandithan and Ghali, 2023). This makes it virtually impossible to eradicate HCV, even though the breakthrough class of "direct-acting antiviral" (DAA) treatments for HCV are incredibly effective, with cure rates of up to 99% (Asselah et al., 2019; Buggisch et al., 2019). By driving the marginal cost of treatment to effectively zero, a two-part tariff system could allow a public health agency to greatly expand testing and monitoring in order to find and treat patients who do not know they are infected before they have the ability to spread the disease to others. At the time the LAHCEP began, per unit costs of even the generic DAAs still averaged greater than \$20,000 per course of treatment, making it impractical to find and treat asymptomatic patients under a traditional

reimbursement scheme.

Second, the market for DAAs in 2019 closely resembled the ideal setting for consumers/insurers from Brekke et al. (2022). With the introduction of Asegua Therapeutics' generic version of Epclusa, there were ten different DAAs available which all had similar cure rates and minimal side effects, making them closely substitutable. This created an opportunity for the Louisiana Department of Health to negotiate with the various providers and avoid the aggressive surplus extraction that can take place with a monopoly provider. The deal the Louisiana Department of Health negotiated with Asegua Therapeutics capped the state's Medicaid spending on DAAs at 2018 levels while greatly increasing their access to the medications, suggesting that the state could potentially receive substantial surplus.

Our results suggest that there is considerable scope to decrease the public health burden of Hepatitis C by implementing similar subscription-based programs in other states, across the entire U.S., and around the world. The fact that Louisiana was able to increase utilization and reduce the harm of HCV while capping costs at pre-2019 levels suggests that it may actually be cheaper for other health departments to implement two-part tariffs than to maintain the status quo. As plans like these become more common, government agencies may be able to extract more and more surplus as pharmaceutical companies see their prospective pool of single-use DAA clients dwindle, sparking competition to become the exclusive supplier of the drugs.

In addition to the reduction in harm, programs like this have the potential to generate enormous long-run cost savings by treating Hepatitis C early and preventing patients from having to undergo expensive treatments to manage their disease, which could ultimately include organ transplants and dialysis. Both of these treatments are very expensive and typically covered by Medicaid, which means the costs are ultimately born by the U.S. taxpayers. Programs like the LAHCEP also have the potential to generate large spillover benefits onto other groups as well. According to the American Liver Foundation, there are over 11,500 people on the waiting list for a liver transplant, and waits to receive an organ can last from 30 days to over five years (ALF (2022)). By reducing the harm of HCV, this program could reduce the number of new candidates on the waiting list and make it easier for non-HCV patients to get transplants (Callison et al. (2023)).

In addition to providing an empirical application of the effectiveness of a two-

part tariff system in the pharmaceutical market, we also contribute to a growing body of work which looks at the possibility of eliminating HCV as a public health threat. This includes Sood, Ung, et al. (2019), which outlined the novel strategy for increasing access to HCV DAAs through a two-part tariff system that was eventually used in the LAHCEP, as well as Chhatwal et al. (2023), which attempts to estimate the health benefits and cost savings of a national Hepatitis C elimination initiative. The authors of this paper simulate the disease progression, healthcare costs, and eventual mortality with and without a national program designed similarly to the LAHCEP, finding that such an initiative would avert 24,000 deaths, add 220,000 life years, and would save over \$18 billion in direct healthcare spending. While it is far too early to know whether the LAHCEP will eliminate HCV as a public health threat in Louisiana, we demonstrate that it was able to dramatically increase utilization and has already begun to reduce mortality.

This paper will proceed as follows. Section 2 provides background on the health impacts and prevalence of Hepatitis C in the United States, the remarkable class of “direct-acting antiviral” medications which have the potential to eliminate Hepatitis C as a public health concern. This section also covers the barriers to treatment which currently exist and the Louisiana Hepatitis C Elimination Plan, which attempts to overcome these barriers and treat at least 80% of infected patients by 2024. Section 3 outlines the various data sources we use and our empirical strategy for evaluating the effectiveness of this intervention. Section 4 presents our results on Hepatitis C diagnoses, Medicaid prescriptions of DAAs, and Hepatitis C related mortality in Louisiana. Section 5 concludes.

2. Background

2.1. *Hepatitis C and Health Outcomes*

Hepatitis C (HCV) is a deadly virus which is typically transmitted through blood. The most common form of infection is through the sharing of contaminated needles for intravenous drug use (Williams et al., 2011), though it can also be transmitted through sexual exposure and via vertical transmission from mother to child (Tibbs (1995)). About a quarter of people infected with HCV will clear the virus spontaneously, with the rest developing chronic infection (Grebely et al. (2012)). HCV infection causes inflammation of the liver, which over time leads to an accu-

mulation of excess protein cells, a condition known as fibrosis. As fibrosis worsens, it leads to scarring of the liver (cirrhosis), liver cancer (hepatocellular carcinoma), liver failure, and death (Bataller and Brenner (2005)).

According to Westbrook and Dusheiko (2014), “Chronic infection with HCV is the leading cause of end-stage liver disease, hepatocellular carcinoma (HCC) and liver related death in the Western world”. Rosenberg et al. (2018) estimates national HCV prevalence in the United States of 0.93% (1 case per 108 Americans), with substantial variation at the state level (0.45% to 2.34%). HCV prevalence is much higher among the incarcerated population, with Spaulding et al. (2023) estimating the prevalence in the state prison population at 8.7%, or over nine times higher than in the non-incarcerated population. Marcus et al. (2020) estimated the life expectancy at age 20 for persons with and without HCV and found that HCV caused a reduction of 12.5 years, or approximately 20%.

Despite the breakthrough HCV treatments which have the potential to eradicate HCV, infection has actually increased in recent years due to the ongoing opioid epidemic (Powell et al., 2019; Zibbell et al., 2018). One of the major public health challenges in dealing with HCV is that because it can take several years for patients to develop symptoms, a large portion of HCV positive patients are unaware of their infection. Denniston et al. (2012) analyzed data from a follow-up survey to the National Health and Nutrition Examination Survey from 2001-2008 and found that just over half (50.3%) of the respondents who tested positive for HCV were unaware that they were infected prior to participating in the survey.

2.2. *Direct Acting Antivirals*

Traditional treatments for HCV, which include interferon and ribavarin (RBV) regimens, were not consistently effective at clearing the virus and could produce adverse side effects, including depression, fatigue, mood disorders, anxiety, and somatic pain (Davoodi et al., 2018; Lin et al., 2020). In December, 2013, the FDA approved the first direct-acting antiviral to treat Hepatitis C, sofosbuvir. Sofosbuvir works by targeting the liver and preventing the HCV RNA polymerase from replicating (Gritsenko and Hughes, 2015). Since then, the combination of sofosbuvir, which is a NS5B protein inhibitor, with an NS5A protein inhibitor¹ has proven

¹These include velpatasvir, which is what is included in the LAHCEP modified subscription model, as well as other drugs like elbasvir, daclatasvir, pibrentasvir, and ledipasvir

remarkably effective at treating HCV infection. Nkuize et al. (2016) described this combination as offering “a new era for the effective treatment of a variety of patients suffering from chronic hepatitis C virus infection.”

A host of clinical trials have demonstrated that sofosbuvir/velpatasvir is safe and remarkably effective at achieving a sustained virologic response (SVR12), meaning that 12 weeks after treatment there is no longer any detectable HCV RNA in the patients bloodstream. These studies have been conducted in several countries and have demonstrated that the drug achieves SVR12 in 95-99% of HCV patients.² Several of these studies have also shown sofosbuvir/velpatasvir to be over 85% effective at achieving SVR12 in patients who have already been diagnosed with cirrhosis or have already had a failed treatment (Miller, 2017; Asselah et al., 2019; Buggisch et al., 2019; Esteban et al., 2018; Ward and Mermin, 2015). This suggests that DAA's are not just effective at reducing harm when taken early in the progression of the disease, but can also improve outcomes for individuals who are already very sick.

2.3. *Barriers to Treatment*

Despite the remarkable efficacy of DAAs in curing hepatitis C, the high cost of treatment has prevented most patients from receiving these lifesaving drugs. Trusheim et al. (2018) found that five years after the introduction of these drugs, only 15% of the estimated population with HCV in the United States had been treated. A quick back-of-the-envelope calculation makes it clear that paying sticker price (originally around \$80,000) for each round of treatment is not a feasible approach to address Hepatitis C. With an estimated 3.5 million HCV positive Americans in 2014 (CDC, 2016), it would cost \$280 billion to treat every HCV positive person. This sum represents about 56% of the total Medicaid budget for 2014 (Burwell, 2014). Clearly, some method of rationing was necessary with such high costs. In many cases, including most state Medicaid programs, treatment with DAAs was limited to people with the most advanced conditions (Daniels and Studdert, 2020) and to those not actively using drugs or alcohol (Liao and Fischer, 2017; Waters and Broder, 2018). Through extensive lobbying and litigation, most Medicaid programs have relaxed

²Isakov et al. (2019) found a 99% SVR12 rate in Russia and Sweden, Izumi et al. (2018) found a 97% SVR rate in Japan, Sood, Duseja, et al. (2019) found a 93% SVR12 rate in India, Buggisch et al. (2019) found a 99% SVR12 rate in Germany, with Miller (2017), Asselah et al. (2019), and Ward and Mermin (2015) all finding a 95-100% rate in the US.

these restrictions leading to increases in utilization (Davey et al., 2024), but there remains a degree of ambiguity over who will ultimately receive treatment since it would be fiscally impossible to treat everyone who would benefit.

2.4. The Louisiana Hepatitis C Elimination Plan

Motivated by the fact that in 2018, less than 3% of the HCV patients on Medicaid or in correctional facilities were able to access DAAs despite spending over \$30 million, the Louisiana Department of Health launched the 2019-2024 Louisiana Hepatitis C Elimination Plan (LAHCEP). The plan included seven broad strategies designed to address the high marginal cost of DAA treatment and the added challenge that a large portion of the HCV positive population of Louisiana was unaware of their infection (Louisiana Department of Health, 2019).

The cornerstone of the LAHCEP was the Modified Subscription Model that Louisiana entered into with Asegua Therapeutics. The general idea of this model is that it could create a mutually beneficial arrangement where instead of Louisiana spending \$30 million across the six pharmaceutical companies who sold DAAs at the time, Louisiana could contract with one company to become the exclusive supplier of DAAs to the state. Asegua would receive the entire \$30 million, which is more than they expected to receive from the state in the absence of the subscription model. In exchange Asegua would provide unrestricted access to their DAA, which is the authorized generic version of Epclusa (Sofosbuvir/Velpatasvir). This agreement effectively drove the marginal cost of DAA use to zero and created an incentive for the state to treat as many infected patients as possible, regardless of disease severity or substance use. It also created an incentive for the state to seek out pre-symptomatic patients who were HCV positive but were not yet experiencing any health problems due to the virus.

The program had a stated goal of curing at least 10,000 Medicaid-enrolled and incarcerated individuals by 2020, and to screen and identify 90% of HCV patients and cure 80% of those identified by 2024. In order to achieve these goals, Louisiana also implemented strategies to educate the public on the availability of the cure, expand HCV screening and link it to treatment, strengthen surveillance activities, and expand provider capacity to treat HCV.

There are a number of reasons why we might expect a program like this to reduce mortality from HCV related illnesses both in the short run and in the long,

with larger effects likely to show up in the long run. This is due to the fact that HCV progresses relatively slowly. Chronic HCV infection moves through four stages of fibrosis of the liver before the most damaging outcomes (cirrhosis, decompensation, liver failure) occur. This means that for many of the patients who receive DAA prescriptions under the LAHCEP, their counterfactual death would not have occurred right away, but would have been several years down the road. The other reason we expect the largest effects to show up in the long run is due to the potential effect of the program on prevalence within the state; patients cured of HCV do not transmit new infections via sexual contact or intravenous drug use.

If enough HCV cases can be cured to lower the prevalence of the virus, then this will create a positive risk externality on the populations who are at risk for becoming infected with HCV in the future. Both of these mechanisms are consistent with the findings of Chhatwal et al. (2023), who perform simulations to quantify the plausible health effects of a national Hepatitis C elimination plan. The authors assume that 90% of all HCV patients in the U.S. will be cured of their infection within five years, and they calculate yearly mortality rates due to HCV related illnesses. They find that the projected reduction in liver-related deaths in years 10-20 of the program are almost twice as large as the reductions in years 1-10.

Although the largest benefits are likely to accrue over the next decade or two, there are also reasons to believe that reductions in HCV-related deaths could manifest almost immediately. First, the patients who are most likely to die in the short run without getting access to DAAs are also the easiest to identify. These will generally be patients whose condition has been deteriorating over a number of years and have progressed through the stages of fibrosis into cirrhosis. Recent evidence has shown that not only can DAAs clear the virus and halt progression of fibrosis/cirrhosis, it can also reverse the damage to the liver which has already been done (Rockey, 2019; Yoo et al., 2022). Overall, this suggests that we may expect to find improvements in the first few years of the program, but that even so, these effects will likely to continue to grow in the medium and long run.

3. Data and Methods

3.1. Data Sources

We use data from a variety of sources. First, we use data on state-level testing and prevalence of Hepatitis C from the the Centers for Disease Control and Prevention’s (CDC) National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP). This data includes annual counts of the number of Hepatitis C diagnoses that are made in each state, as well the number of cases per 100,000 residents. The data are incomplete for some state-year combinations, as certain states do not consistently report these counts to the CDC. We focus our analysis on the group of 35 states (including Louisiana) for whom both counts and rates are reported for every year from 2012 through 2022.

Next, we track usage of DAAs in Louisiana and across other states using Medicaid’s State Drug Utilization Data. This dataset contains quarterly counts of prescriptions filled, units reimbursed, and amounts reimbursed for all outpatient drugs covered by Medicaid in each state. Counts are suppressed if there are fewer than 10 prescriptions in a given quarter. We use this data to create quarterly counts of usage of the generic version of Epclusa covered by the LAHCEP, as well as all other FDA-approved DAAs. We combine prescription counts with quarterly counts of state-level Medicaid enrollment from the Centers for Medicare and Medicaid Services in order to calculate the number of DAA prescriptions per 1,000 Medicaid patients in each state.

In order to estimate the effect of the LAHCEP on hepatitis C-related deaths, we use restricted-access mortality data from the National Vital Statistics System. Our dataset contains the universe of death records in the United States from 2012-2022. Each record includes the cause of death, as well as the state and county of residence of the deceased. We code deaths as being hepatitis C-related if the main underlying cause of death is due to cirrhosis of the liver, hepatocellular carcinoma (liver cancer), nephritis, and renal hypertension. In addition to the cause of death, each record includes demographic information about the decedent including their race, ethnicity, age, gender, and marital status, which we use as controls.

3.2. Empirical Strategy

We use several methods to determine the effect of the LAHCEP on diagnoses, DAA prescriptions, and HCV-related mortality. First, we use the synthetic control method (SCM) of Abadie and Gardeazabal (2003) and Abadie, Diamond, et al. (2010). This method allows us to create a ‘Synthetic Louisiana’, chosen as a weighted average of all other U.S. states, with the weights optimized in order to minimize the mean squared error between Louisiana and Synthetic Louisiana. We calculate these weights separately for each outcome. The results of this approach are graphs showing the level and trends in the outcomes for Louisiana and Synthetic Louisiana, using Synthetic Louisiana as a counterfactual.

We also use weighted least squares to estimate difference-in-differences and event study models. By using SCM weights, we create a counterfactual that is most similar to Louisiana in terms of pre-period levels and trends, while also performing hypothesis test on the causal effect of the LAHCEP. Most of our analysis is at the state level, and we use the following estimating equations:

$$y_{st} = \beta_0 + \beta_1 Post_t \times Louisiana_s + \delta_s + \gamma_t + \varepsilon_{st} \quad (1)$$

$$y_{st} = \alpha_0 + \sum_{\tau=-n}^m \alpha^\tau \left(\mathbf{1}[t - b = \tau] \times Louisiana_s \right) + \delta_s + \gamma_t + \varepsilon_{st} \quad (2)$$

Equation 1 is the difference-in-differences estimating equation. The variable y_{st} is an outcome for state s at time t . The coefficient of interest is β_1 , and $Post_t$ takes value one if the LAHCEP is in place (3rd quarter of 2019 or later), and 0 otherwise; $Louisiana_s$ takes value one if the state is Louisiana, and 0 otherwise. We include state (δ_s) and time fixed effects (γ_t). The error term is ε_{st} . This is a standard difference-in-differences approach, as we have a traditional setting with all (one) treated units experiencing the treatment at the same time.³

Equation 2 is the event study estimating equation. Here $\beta_1 Post_t \times Louisiana_s$ is replaced with a series of α^τ and a vector $\mathbf{1}[t - b = \tau]$. The variable τ indicates time relative to implementation of the LAHCEP. Negative τ ’s trace out the difference in trends in outcomes between Louisiana and control states, while positive τ ’s trace out dynamic effects of the LAHCEP.

³Since we are not leveraging variation in treatment timing, the literature regarding potential bias from two-way fixed effect in that context does not apply (Callaway and Sant’Anna, 2021; Goodman-Bacon, 2021; Sun and Abraham, 2021)

Results from equation 2 help support the identifying assumptions of equation 1. One of the main assumptions of the difference-in-differences approach is the parallel trends assumption; in the absence of the LAHCEP, outcomes in Louisiana and the control states would be on parallel paths. However, the counterfactual world where Louisiana did not implement the LAHCEP is not observable, and so the pre-period results from equation 2 are used to show that the pre-trends are similar. This is likely to be the case as we are using weights from the synthetic control method.

Finally, because we have few clusters and only one treated cluster, inference is complicated in our context. We address this in two ways. First, we use Wild Cluster Bootstrap (WCB). Cameron et al. (2008) note that even cluster-robust standard errors over-reject with few clusters, but they propose a cluster bootstrap-t approach. We implement this method to calculate WCB-based p-values. Second, we calculate placebo-base randomization inference p-values.⁴ In order to calculate these p-values, we estimate placebo treatment effects for each of the 49 other states. We do this in two steps. In the first step, we estimate a synthetic control for each state, assuming that the placebo state was treated in the second quarter of 2019 instead of Louisiana. In the second step, we save the weights for each state’s synthetic control and estimate a simple difference-in-difference model with the standard “*TreatXPost*” coefficient. We do this using weighted least squares, with the synthetic control weights used to essentially convert the results of the SCM to a single coefficient estimate. We then look at the distribution of the coefficient estimates to calculate the p-value for Louisiana. We expect the estimated effect of Louisiana to be in the tail of this distribution.

4. Results

4.1. The Effect of the LAHCEP on Diagnoses of HCV

Figure 1 displays data on HCV diagnoses in Louisiana from 2012 through 2022 using data from the CDC’s National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP). The left side of the figure displays the raw count of the number of diagnoses reported. Between 2012 and 2018 there are very few cases reported, with the number rising from 11 in 2012 to 24 in 2015 before dropping

⁴See Cunningham and Shah (2018) for another example of this approach

down to below 10 per year from 2016-18. The number remains flat at eight in 2019, followed by a large spike in reported diagnoses in 2020, up from eight to 281, an increase of approximately 3,500%. There is then a further increase to 308 in 2021 followed by a decline in 2022 to 165, which is still over 20 times larger than the annual number of diagnoses from 2016-2018. The decline in 2022 is also consistent with diminishing marginal returns from the screening and testing program, which may have been able to reach the populations which were most susceptible to HCV infection first, before having to exert more effort to find new cases as the program went on. The right hand side of Figure 1 displays the rate per 100,000 residents of Louisiana, and demonstrates that the large uptick in cases had nothing to do with population change within the state.

Next, Figure 2 display estimates of an event-study specification comparing the log of the number of annual diagnoses in Louisiana to each of the 37 other states for which data was available in every year from 2016 through 2022. The results are consistent with the interpretation of the time series, suggesting that there was not a similar uptick in other states. There is little evidence of divergent trends prior to 2018, with almost no change in 2019 followed by a large increase in 2020. The coefficient estimate is an increase of 355 log points, consistent with an increase of approximately 3,380%.⁵ The coefficient increases to 372 log points (4,023%) in 2021 before reverting to 302 log points (1,949%) in 2022.

There are a few things that merit further discussion from this analysis. First, this data is almost certainly underestimating the burden of HCV in Louisiana. If we apply the national rate of HCV prevalence of 0.93% from Rosenberg et al. (2018) to Louisiana's 2019 population of 4.7 million, this would translate to over 43,000 cases in the state. Even if the majority of these patients are unaware of their infection, this still suggests a large share of confirmed HCV patients are not making it into this national dataset. The main takeaway for our purposes is the large increase in diagnoses that we see in 2020, which suggests that the LAHCEP was effective at increasing diagnoses, though it is possible that the agency simply devoted more resources to *reporting* the cases that were already being diagnosed because of the increased attention being paid to HCV.

It is also interesting that the increase in diagnoses does not materialize until

⁵Percentage changes are calculated using the following transformation: $[\exp^{(0.01x)} - 1] * 100$, where x is the log point difference.

2020 when the subscription model went into effect in 2019. This suggests that any increase in prescriptions that we find in 2019 are likely going to previously diagnosed HCV patients. This would be consistent with the state focusing first on treating the sickest patients before expanding surveillance and testing to patients earlier in the course of the disease. If the patients treated first are also the ones most likely to succumb to the disease in the absence of treatment, we could expect to see reductions in mortality showing up very quickly after the implementation of the policy, even though the typical untreated course of HCV takes years or even decades to result in mortality.

4.2. Medicaid DAA Prescriptions

Appendix Table A.1 displays summary statistics for the ten different FDA-approved DAAs which appear in the SDUD between 2014-2022. For each DAA, we include the first year it appears, the year where the largest number of Medicaid prescriptions for the drug were reimbursed, the total number of prescriptions, and the average amount that was reimbursed per prescription. Some suggestive general trends emerge. First, state Medicaid offices are able to negotiate substantial discounts off of the list prices (initially as high as \$86,000) of all these drugs. Second, as new DAAs enter the market they appear to be competing on price, as newer DAAs are being reimbursed at lower average rates, causing reimbursement rates to fall over time. Third, state Medicaid offices appear to be price sensitive, as lower-priced drugs quickly win considerable market share. DAAs that accept lower reimbursement rates than the incumbent drugs (Epclusa, Zepatier, Mavyret, Generic Epclusa) all receive tens of thousands of prescriptions while DAAs that maintain similar or even higher reimbursement rates than the incumbents (Viekira, Technivie, Vosevi, Generic Harvoni) all struggle to gain traction.

We now show how the LAHCEP shifted prescribing behavior for Louisiana Medicaid patients receiving a DAA prescription. Figure 3 displays quarterly numbers of prescriptions filled of the four most popular DAAs in Louisiana over the period of our study. These include Mavyret, Epclusa, Zepatier, and the generic for Epclusa which was included in the modified subscription plan with Asegua Therapeutics. In the period two to three years prior to the LAHCEP, Epclusa and Zepatier were the most popular DAAs in the state, with list prices of \$75,000 and \$60,000 for a 12-week course, respectively (Early and Maxted, 2017; Sokol, 2017).

Then, in the third quarter of 2017, Mavyret came onto the market, initially priced at \$26,000 for an eight week course and \$56,000 for a 16 week course (Grover and Erlich, 2018). Mavyret quickly increased its market share, presumably due to the lower cost and comparable effectiveness of the other two drugs.

In January of 2019, Asegua Therapeutics released its generic version of Epclusa, with an initial list price of \$24,000. Initially, there are no Medicaid-covered prescriptions in Louisiana for this generic. In the third quarter of 2019, when the LAHCEP begins under the modified subscription model, the generic Epclusa immediately takes almost complete market share and drastically increases the number of overall prescriptions being filled in the state. At the same time, prescriptions of all other DAAs in the state drop below 20 per quarter by the first quarter of 2020. Clearly, the LAHCEP altered the mix of DAAs being used in Louisiana and looks to have increased prescriptions overall. Next, we compare trends in overall DAA usage in Louisiana to what was happening over this period nationwide.

Figure 4 displays the quarterly number of Medicaid prescriptions filled for any DAA in Louisiana compared with the national average for the 20 quarters leading up to the LAHCEP and the fifteen quarters after it. This period runs from the second quarter of 2014 through the first quarter of 2023. Louisiana tracks fairly closely with the national average from the start of the period until about four quarters before the LAHCEP, where there is a slight increase from about 0.3 prescriptions per 1,000 Medicaid patients to about 0.45 prescriptions per 1,000 Medicaid patients. This number reverts back to about .3 in quarters one and two of 2019 before the LAHCEP begins in quarter three. In quarter three there is an immediate spike in prescriptions up to 1.9 per 1,000, which increases to 2.3 in quarter four before returning to 1.9 in the first quarter of 2020. After the initial spike, the rate levels off to between 1.1 and 1.2 for the next four quarters before declining further to about 0.7 prescriptions for the rest of the window.

The results of the synthetic control method are displayed in Figure 5. There is a close match in the pretreatment DAA prescriptions paid for by Medicaid, but the synthetic version of Louisiana shows no sign of the dramatic increase that takes place in the state immediately after the LAHCEP goes into effect. If anything, the control group shows a slight downward trend over the first four quarters, leaving a large gap between the two. Compared with the synthetic control, the LAHCEP appears to have caused increases in utilization of 630%, 1,050%, and 710% in the first

three quarters, with increases of over 400% for the next seven quarters. Though somewhat larger, our results are roughly consistent with Auty et al. (2021), which estimated the effect of the LAHCEP on prescriptions for the first four quarters of the program, finding an average increase of over 530% per quarter. We extend their analysis and demonstrate that prescriptions in Louisiana remained elevated relative to its synthetic control for at least six additional quarters after the first year of the program.

Next we turn to randomization inference. The DiD estimate for Louisiana is 1.175 DAA prescriptions per 1,000 Medicaid patients, which is more than double the absolute value of the next largest coefficient of 0.514 for Wisconsin. This translates to a p-value of $\frac{1}{51} = 0.0196$. A histogram of the placebo coefficient estimates is displayed in Appendix Figure A.1.

Finally, we estimate an event-study model using the weights from the synthetic control method. Results from this are displayed in Figure 6. In each of the ten quarters leading up to the intervention, coefficient estimates are within 0.05 of zero, and none of the pre-treatment leads has a p-value less than 0.5. Then, in the first quarter after the program began, the coefficient estimate jumps to 1.7, before rising to 2.2 and returning to 1.7, and then leveling off around 1.0 for the next four quarters. Each of the first nine posttreatment coefficients has a p-value of less than 0.001.

4.3. *Effect of LAHCEP on Mortality from Hepatitis C Related Conditions*

Figure 7 displays a synthetic control estimate of the effect of the LAHCEP on mortality due to Hepatitis C related conditions. The left-hand side variable is the percent of all deaths in each state which are Hep C related. There is a reasonably close pre-treatment match, with both Louisiana and Synthetic Louisiana remaining relatively stable at just under six percent from 2012 through 2018. There is a slight divergence in 2019, with Synthetic Louisiana rising slightly while Louisiana declines somewhat. This trend continues into 2020, with a gap of about 1 percentage point opening up between the two. Both groups rise slightly in 2021 and 2022, with the gap between the two remaining relatively steady.

Appendix Figure A.2 displays the distribution of placebo DiD estimates of the effect of the LAHCEP on hepatitis C related mortality. The DiD estimate for Louisiana is negative 0.01, or a reduction of one percentage point. This estimate is the third

largest in magnitude and second largest reduction of all 50 states, for a p-value of .06. Alaska has the largest estimate in magnitude, with an increase of HCV related deaths of 1.34 percentage points. Vermont is the only state with a bigger reduction in HCV related deaths than Louisiana at 1.03 percentage points. After Louisiana, the next largest estimate in magnitude is South Carolina, at 0.76 percentage points.

Figure 8 displays a series of event-study estimates of the effect of the LAHCEP on HCV related mortality in Louisiana. In each case, the event-study uses the weights from a synthetic control specification to construct the control group, and standard errors are clustered at the state level. The top left graph displays estimates on individual-level data on the percentage of deaths in each state due to HCV related illnesses. There is a slight downward trend between 2014 and 2017, though only the 2015 coefficient is statistically significant. The 2017 estimate is a precisely estimated zero, indicating that trends in the treated and control group are parallel in the year leading up to the LAHCEP. There is then a small but statistically significant decrease in HCV related mortality in 2019, followed by larger decreases in each of the next three years.

The top right graphs repeats this exercise, only using state-level counts instead of individual data. With a smaller number of observations, confidence intervals are larger, but the overall story is very similar. The parallel trends assumption actually appears slightly more reasonable in this specification, as there is less of a downward trend from 2014-2017 and there is even a slight increase from 2016 to 2017. Of the six pretreatment leads, only 2015 is significantly different than zero, whereas all of the posttreatment lags are negative and significant at .1.

One concern with using the percentage of deaths due to HCV related illnesses is that this period includes the COVID-19 pandemic, which caused a large shock to the denominator of this ratio. If HCV patients in Louisiana were less likely to die from COVID-19 than patients in other states, reductions occurring in 2020-2022 could be spurious. To address this concern, the bottom two graphs instead estimate the effect of the LAHCEP on the log of the number of HCV related deaths (bottom left) and sum of HCV related deaths (bottom right). In both groups, there is support for the equal counterfactual trends assumption, as there is little movement in the pretreatment leads. In the bottom left, there are negative and significant estimates in 2019, 2020, and 2022. On the bottom right, the only significant posttreatment estimate occurs in 2019, though all of the lags are negative and economically

meaningful.

4.4. Robustness Checks

We now explore the robustness of our main results to a series of modifications to address potential concerns about our identification. The four panels of Table 1 displays a series of difference-in-difference estimates of the effect of the LAHCEP on HCV related mortality in Louisiana. For each regression in Table 1, we run a version of the standard two-way fixed effects (TWFE) model using the weights from the synthetic control version, and then we iteratively add controls for demographic characteristics. This method leaves us with relatively few clusters, which can lead to over-rejection, so we also estimate p-values using the Wild Cluster Bootstrap (WCB) method proposed by Cameron et al. (2008).

The top panel includes individual level regressions which look at whether the share of deaths in Louisiana that is attributable to HCV related illness declines after the rollout of the LAHCEP. The first column includes the standard TWFE version of this model, with no control aside from the year and state fixed effects. The point estimate of -0.0088 indicates that the share of deaths due to HCV related illnesses in Louisiana declines by almost a full percentage point after 2018, with this effect being significant at the 0.1% level. The second column adds controls for the race and ethnicity of the individuals who passed away. The point estimate and statistical significance are unchanged, though the standard errors increase slightly. Finally, the third column also adds controls for the gender, age, and marital status of each individual. The sample size shrinks slightly (by $< 1\%$) due to some observations missing these characteristics. The point estimate is relatively unchanged, though the standard error is once again slightly larger, causing the estimate to only be significant at 1%. For all three specifications, the WCB p-value is larger than the TWFE effects version, but remains significant at 10%.

The second panel again estimates the effect of the LAHCEP on the share of deaths due to HCV related illness, but first collapses observations up to the state-year level. This helps prevent correlations of observations within state-year clusters from causing the standard errors to be artificially small (Bertrand et al., 2004). The economic interpretation of the results is unchanged. The point estimates are all similar or slightly larger, and while the standard errors increase slightly, two of the three estimates are still significant at 0.1%, while the third is still signifi-

cant at 5%. As in Panel A, the WCB p-values are larger, but each estimate remains significant at 10%.

Panels C and D address concerns about COVID-19 causing a shift in the denominator by replacing the share of deaths due to HCV on the left hand side with the log of of deaths and the count of deaths due to HCV related illness. In Panel C, the estimates indicate a reduction of deaths from HCV related illness of between 11.3 and 13 percent with all three coefficients significant at 5% in both the TWFE version and WCB version. Panel D replaces the log of HCV deaths with the count of HCV deaths. The estimate in the first column indicates that there were about 300 fewer HCV related deaths in Louisiana following the LAHCEP, but the estimate is noisy and only significant at the 10% level and is insignificant using the WCB method ($p=0.182$). Interestingly, the estimate grows in both magnitude and precision as controls are added. The estimates in columns two and three suggest reductions of around 400 deaths, with column three significant at the 5% level for TWFE ($p=0.182$ for WCB) and column three significant at the 0.1% level and with a WCB p-value of <0.001 .

5. Conclusion

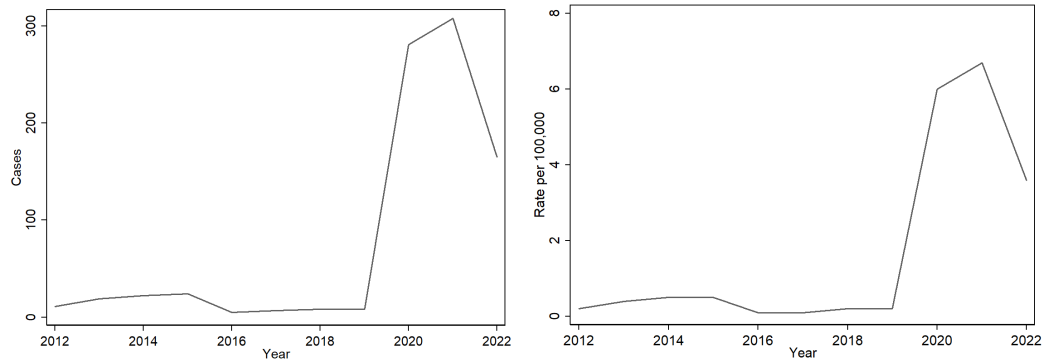
This paper studies the impact of a first-of-its-kind two-part tariff subscription model applied to the pharmaceutical market for Hepatitis C antiviral drugs. The subscription model was the cornerstone of a larger program designed to eliminate Hepatitis C as a public health threat in the state of Louisiana. In addition to the subscription, the intervention also included surveillance efforts to seek out and diagnose potential Hepatitis C patients who may have been unaware of their infection. This allowed the public health agency to both treat them in the early stages of their disease progression as well as to prevent them from unknowingly spreading the illness to others. A similar national program has been endorsed by the Biden administration, which makes it vital to understand how effective this program was and what lessons might be applied to a larger scale version to cause the greatest reduction in harm.

We document large increases in both diagnoses of Hepatitis C and prescriptions of direct-acting antiviral medications, though interestingly we find that prescriptions increase immediately after the subscription became active in 2019 while

diagnoses do not spike until 2020. This suggests that the first round of DAAs went to patients who were already sick and perhaps at more advanced stages in their illness as the Louisiana Department of Health ramped up its surveillance efforts. In line with this, we also find an immediate reduction in mortality due to Hepatitis C related illness in Louisiana relative to control states, which suggests that many of the patients who were treated first must have been quite sick at the time they were treated.

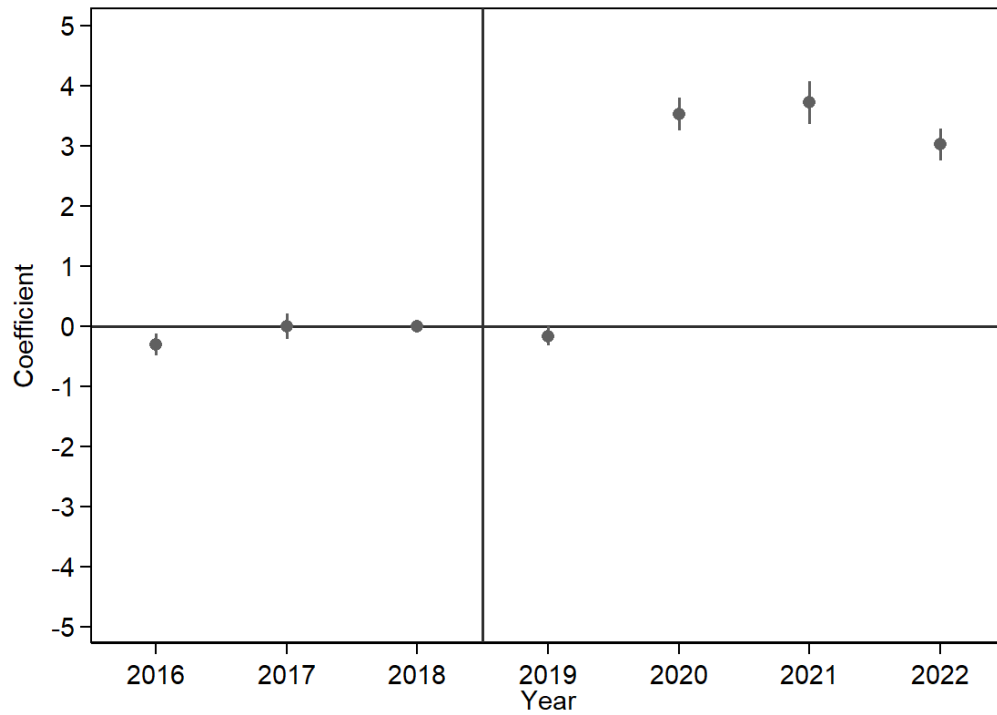
While this immediate reduction in mortality is important, it is far too early to estimate the full impact of this program. As Hepatitis C typically takes many years and even decades to progress to the point of causing fatal illness, the mortality effects we find here are likely to grow over time. Future work should also investigate the extent to which this program succeeds in eliminating Hepatitis C as a public health threat in the state. If the program was able to treat most of the patients with Hepatitis C in the state, this could halt the transmission of the virus even as intravenous drug use is on the rise due to the ongoing opioid epidemic. On the other hand, Louisiana does not exist in a vacuum, and Hepatitis C infected individuals from outside the state could come to Louisiana and spread the disease. There is much to be learned about whether it is possible to eliminate the threat of such a disease, which an individual can carry and spread for many years without experiencing any symptoms, by monitoring what happens with Hepatitis C in Louisiana in the coming years.

Figure 1 — Time Series of HCV Diagnoses in Louisiana - 2010-2022



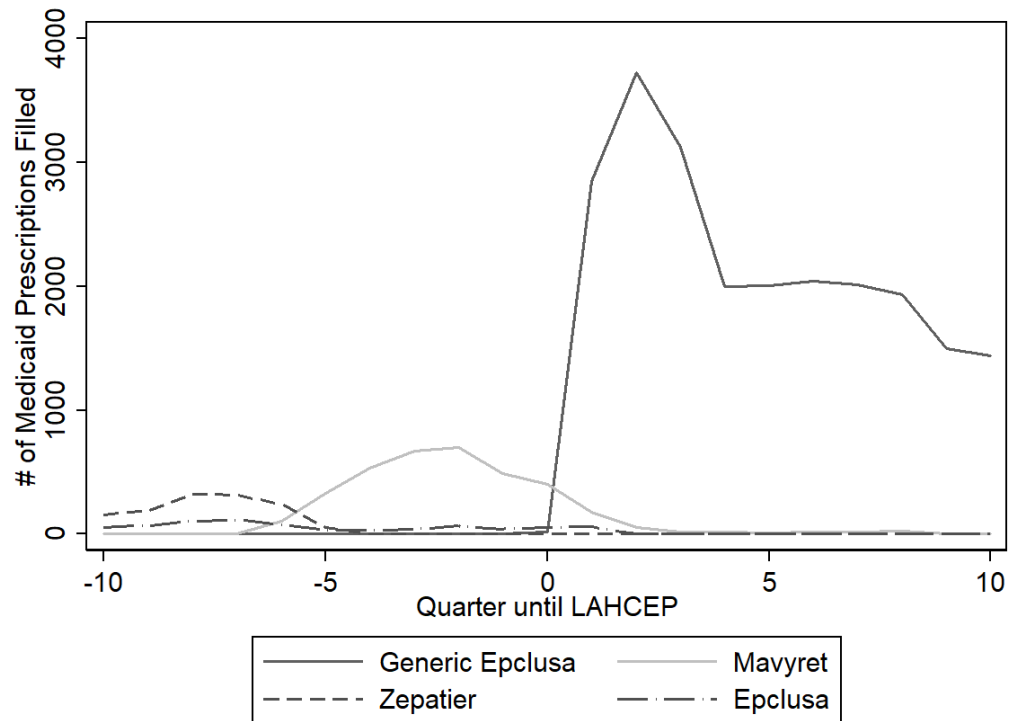
Note: This figure displays data on HCV diagnoses in Louisiana from 2012 through 2022 using data from the CDC’s National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP). The left side of the figure displays the raw count of the number of diagnoses reported, while the right side displays the number of cases per 100,000 residents of Louisiana.

Figure 2 — Event Study of the Effect of the Louisiana Hepatitis C Elimination Plan on the Log of the Number of Annual HCV Diagnoses in Louisiana - 2016-2022



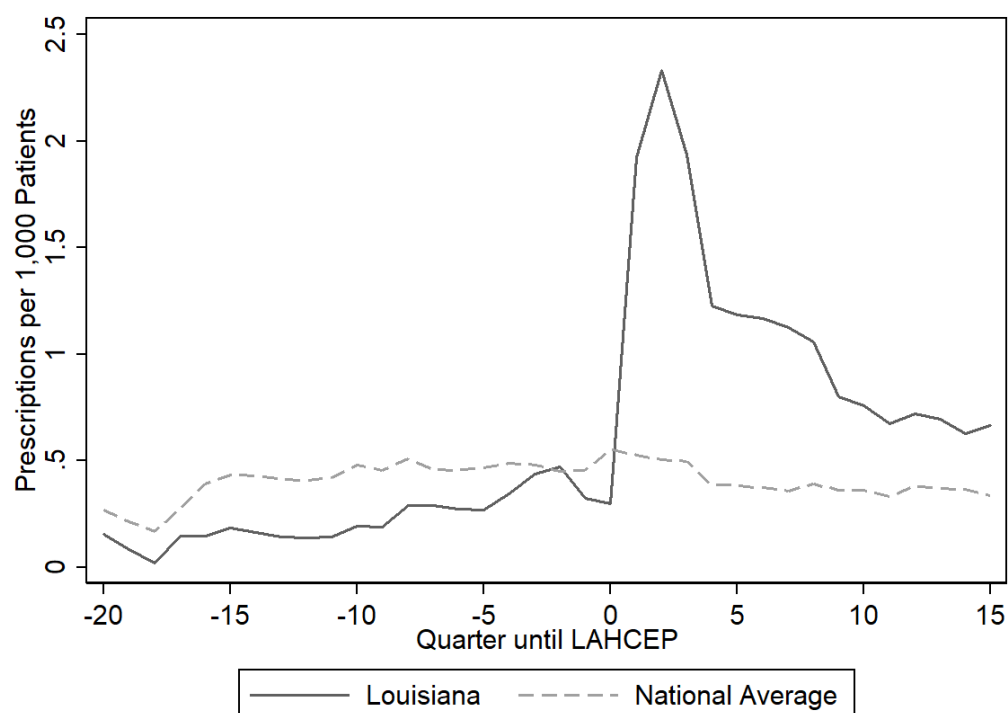
Note: This figure displays event-study estimates of the effect of the Louisiana Hepatitis C Elimination Plan on annual hepatitis C diagnoses, using data from the CDC's National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP). All 36 of the other states which reported data on diagnoses for each year from 2016-2022 are included as controls.

Figure 3 – Quarterly Rates of Prescriptions of Various Direct-Acting Antivirals
Louisiana: 2016-2021



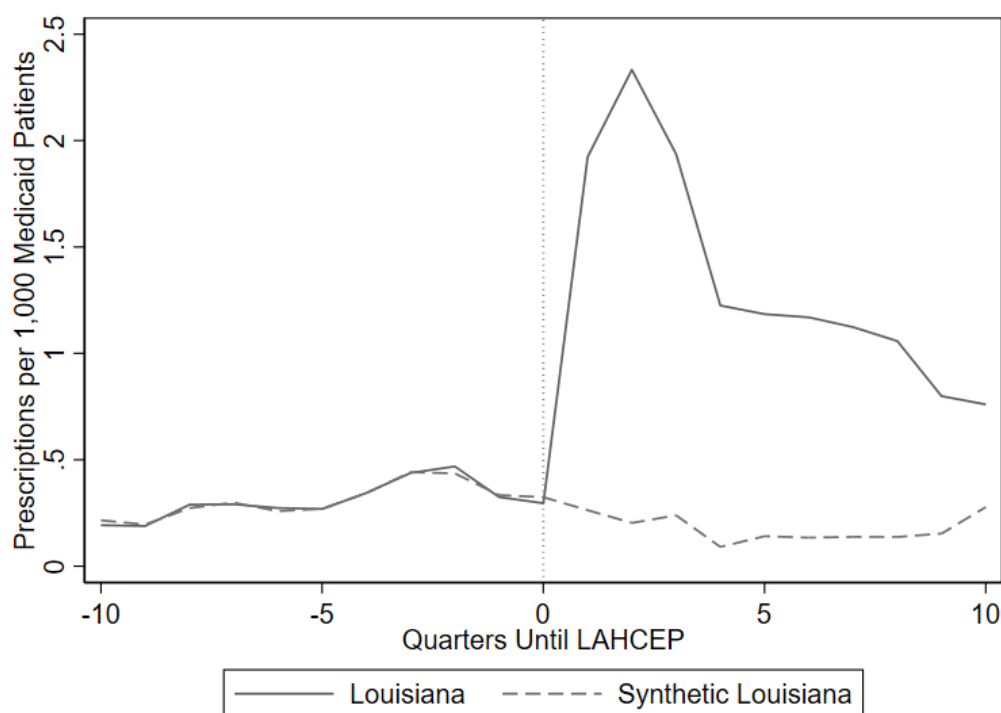
Note: This figure uses data from Medicaid’s State Drug Utilization Data (SDUD) to display the quarterly number of Medicaid prescriptions of various direct-acting antivirals (DAAs) in Louisiana, spanning from the fourth quarter of 2016 to the fourth quarter of 2021.

Figure 4 — Quarterly Rates of Direct-Acting Antiviral Prescriptions in Louisiana Compared with the National Average: 2014-2023



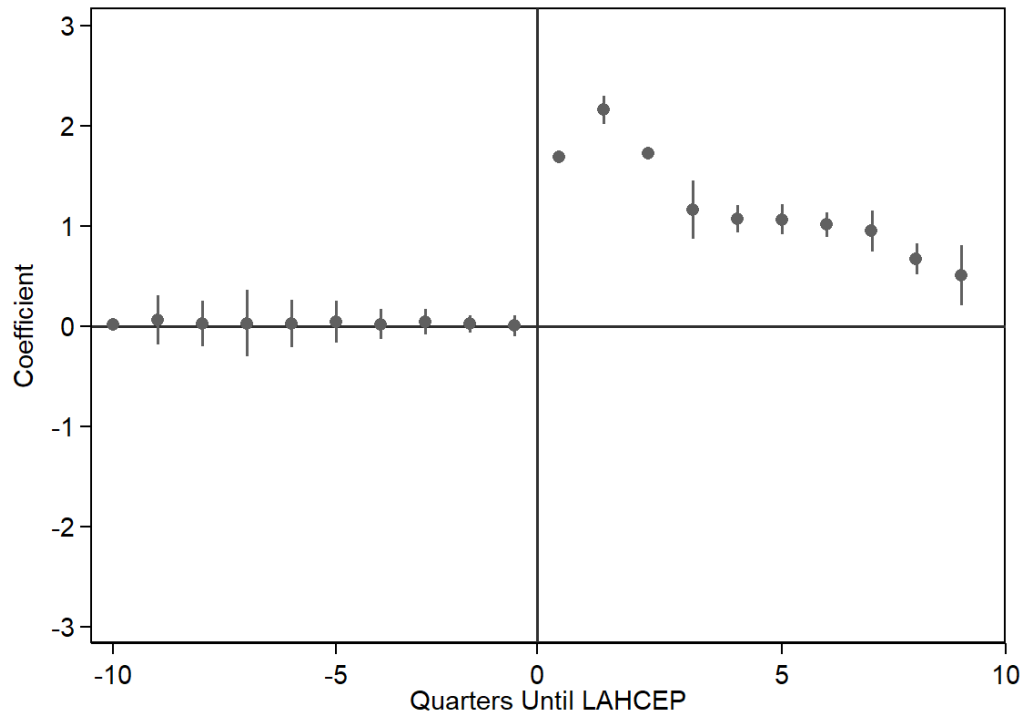
Note: This figure uses data from Medicaid’s State Drug Utilization Data (SDUD) to display the quarterly average number of Medicaid prescriptions of direct-acting antivirals (DAAs) per 1,000 Medicaid patients in Louisiana compared with the national average for the 20 quarters leading up to the Louisiana Hepatitis C Elimination Plan and the 15 quarters following it, spanning from the second quarter of 2014 to the first quarter of 2023.

Figure 5 — Synthetic Control Estimate of the Effect of the Louisiana Hepatitis C Elimination Plan on DAA Prescriptions Among Medicaid Patients



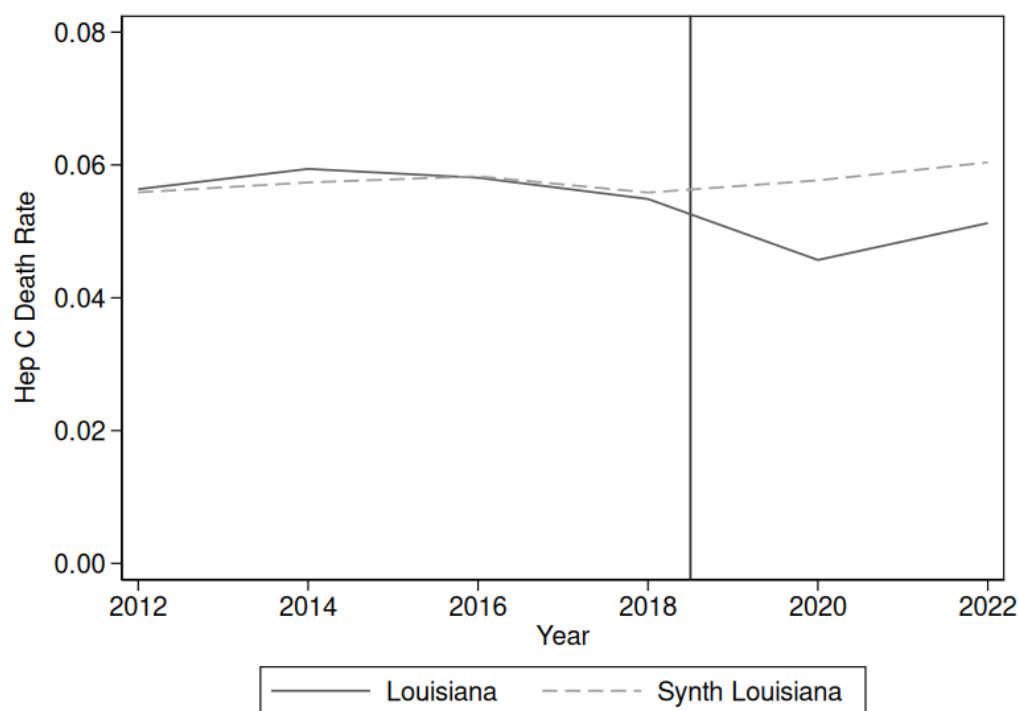
Note: This figure uses data from Medicaid’s State Drug Utilization Data (SDUD) to display the quarterly average number of Medicaid prescriptions of direct-acting antivirals (DAAs) per 1,000 Medicaid patients in Louisiana compared with a synthetic version of Louisiana, where synthetic Louisiana is made up of a weighted average of the other 49 U.S. states, where the weights are chosen to minimize the difference in quarterly prescription rates for the ten quarters leading up to the Louisiana Hepatitis C Elimination Plan.

Figure 6 — Event-Study Estimate of the Effect of the Louisiana Hepatitis C Elimination Plan on DAA Prescriptions Among Medicaid Patients



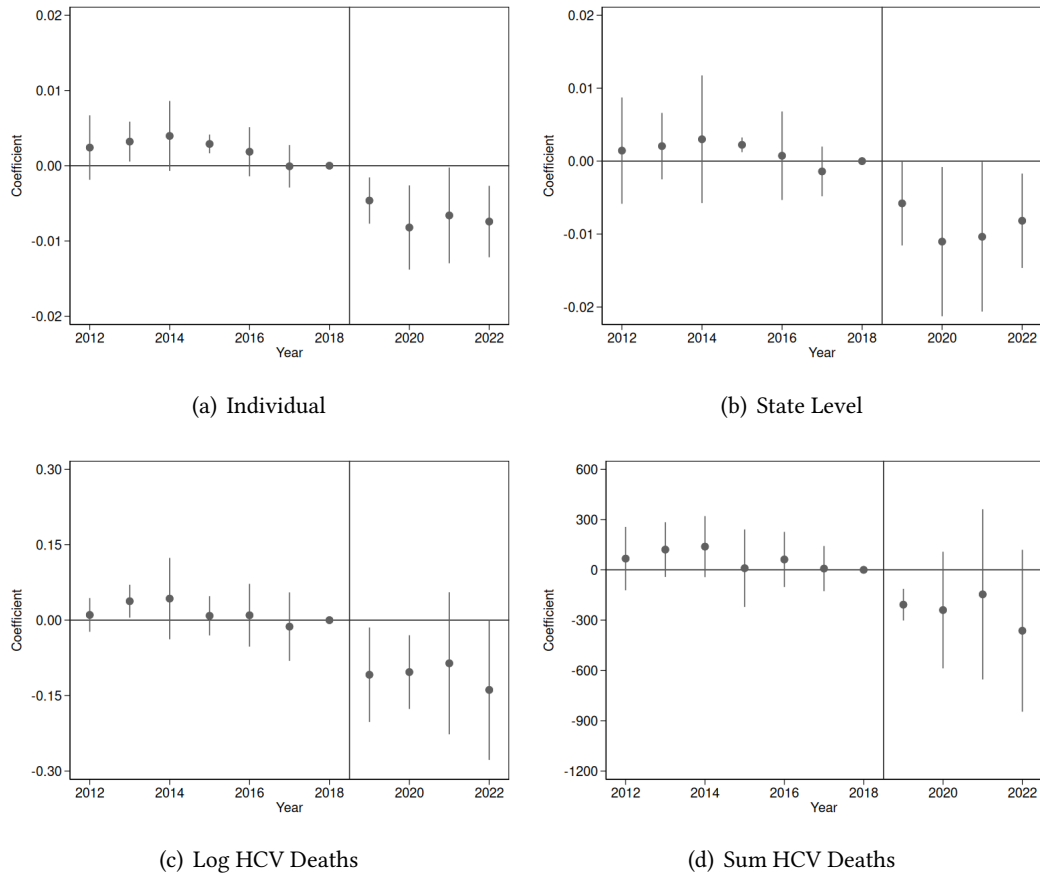
Note: This figure displays event-study coefficient estimates of the effect of the Louisiana Hepatitis C Elimination plan on quarterly Medicaid prescriptions of direct acting antivirals in Louisiana using data from Medicaid’s State Drug Utilization Data (SDUD). Each coefficient includes a 95% confidence interval. The event-study regression uses the weights from the synthetic control method, where the weights were chosen to minimize the squared difference between Louisiana and its synthetic control in the ten quarters leading up to the Louisiana Hepatitis C Elimination Plan. Standard errors are clustered at the state level.

Figure 7 — Synthetic Control Estimate of the Effect of the Louisiana Hepatitis C Elimination Plan on Hepatitis C Related Mortality



Note: This figure displays the synthetic control estimate of the effect of the Louisiana Hepatitis C Elimination plan on annual Hepatitis C-related mortality in Louisiana, using restricted-access data from the National Vital Statistics System (NVSS). The black line displays the rate for Louisiana, while the dashed line displays the weighted average of the rates of the synthetic control states, where the weights are chosen in order to minimize the sum of the squared difference in the pretreatment rates of Hepatitis C-related mortality.

Figure 8 — Event-Study Estimates of the Effect of the Louisiana Hepatitis C Elimination Plan on Hepatitis C Related Mortality



Note: This figure displays the event-study estimates of the effect of the Louisiana Hepatitis C Elimination plan on annual Hepatitis C-related mortality in Louisiana, using restricted-access data from the National Vital Statistics System (NVSS). The top left graph displays the estimate of the share of overall mortality attributable to Hepatitis C related causes, using records at the individual level. The top right graph estimates this share after first collapsing records to the state-year level. The bottom left graph uses the log of the total number of Hepatitis C related deaths as the dependent variable, while the bottom right graph uses the count of Hepatitis C related deaths as the dependent variable.

Table 1 – Difference-in-Differences Specifications of the Effect of the Louisiana Hepatitis C Elimination Plan on Hepatitis C Related Mortality - 2012-2022

Panel A: Individual-Level Regressions			
	HCV Related	HCV Related	HCV Related
Louisiana x Post	-0.0088*** (0.0010)	-0.0088*** (0.0013)	-0.0089** (0.0015)
Wild Cluster P-value	0.032	0.060	0.060
Observations	4,079,992	4,079,992	4,041,165
Panel B: State-Level Regressions			
	HCV Related	HCV Related	HCV Related
Louisiana x Post	-0.0100*** (0.0015)	-0.0097*** (0.0013)	-0.0088* (0.0024)
Wild Cluster P-value	0.018	0.066	0.048
Observations	77	77	77
Panel C: Log of Total HCV Related Deaths			
	Ln(HCV)	Ln(HCV)	Ln(HCV)
Louisiana x Post	-0.1228** (0.0275)	-0.1223** (0.0161)	-0.1074** (0.0192)
Wild Cluster P-value	0.000	0.030	0.030
Observations	66	66	66
Panel D: Count of HCV Related Deaths			
	# of HCV	# of HCV	# of HCV
Louisiana x Post	-297.15 (139.02)	409.97* (110.81)	-413.38*** (46.40)
Wild Cluster P-value	0.182	0.182	0.000
Observations	55	55	55
TWFE	Y	Y	Y
Race/Ethnicity	N	Y	Y
Sex/Age/Marital	N	N	Y

Note: This table displays the difference-in-differences (DID) estimates of the effect of the Louisiana Hepatitis C Elimination plan on annual Hepatitis C-related mortality in Louisiana, using restricted-access data from the National Vital Statistics System (NVSS). Each panel includes the DID estimate with no controls in the first column, with controls for race and ethnicity in the second column, and with additional controls for gender, age, and marital status in the third column. Below each estimate is the Wild-cluster p-value for that estimate, along with the total number of observations included in the regression. Panel A displays the estimate of the share of overall mortality attributable to Hepatitis C related causes, using records at the individual level. Panel B estimates this share after first collapsing records to the state-year level. Panel C uses the log of the total number of Hepatitis C related deaths as the dependent variable, while the Panel D uses the count of Hepatitis C related deaths as the dependent variable.

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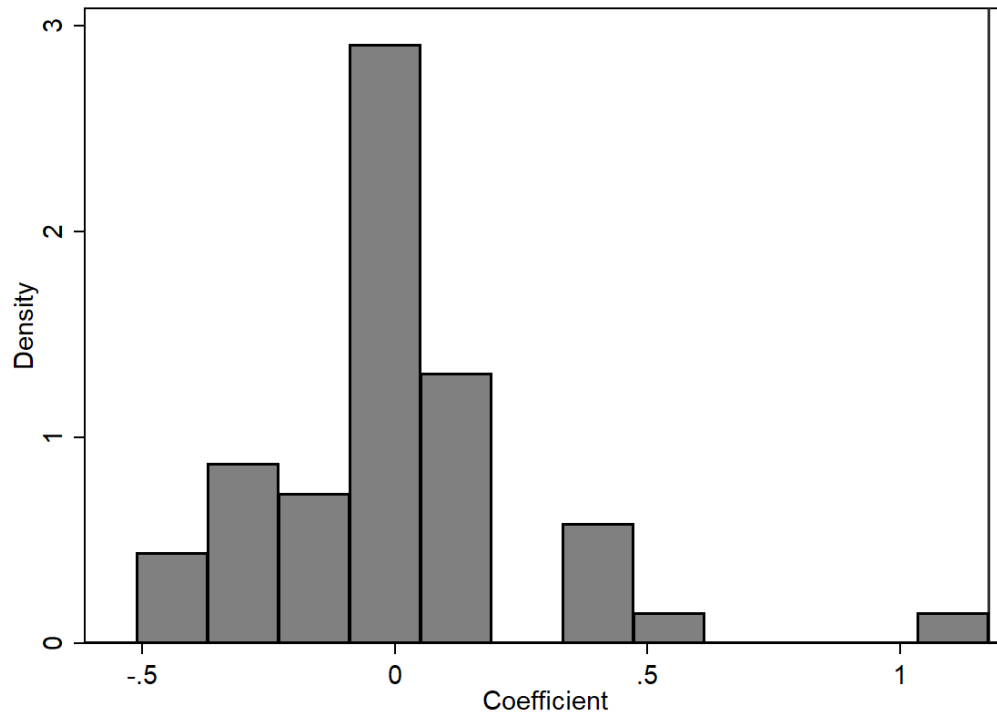
A. Online Appendix (Not for Publication)

Table A.1 — Summary Statistics of Various Direct-Acting Antivirals from the State Drug Utilization Data: 2014-2022

Name	First Year	Peak Year	Total Prescriptions	Avg. Reimbursement
Sovaldi	2014	2014	101,933	25,250
Harvoni	2014	2016	222,855	27,592
Viekira	2015	2016	23,381	23,925
Technivia	2015	2015	102	23,997
Zepatier	2016	2017	64,058	15,511
Epclusa	2016	2017	139,482	21,951
Mavyret	2017	2018	337,018	12,266
Vosevi	2017	2018	10,910	22,027
Generic Epclusa	2019	2022	174,892	7,717
Generic Harvoni	2019	2019	2,891	11,593

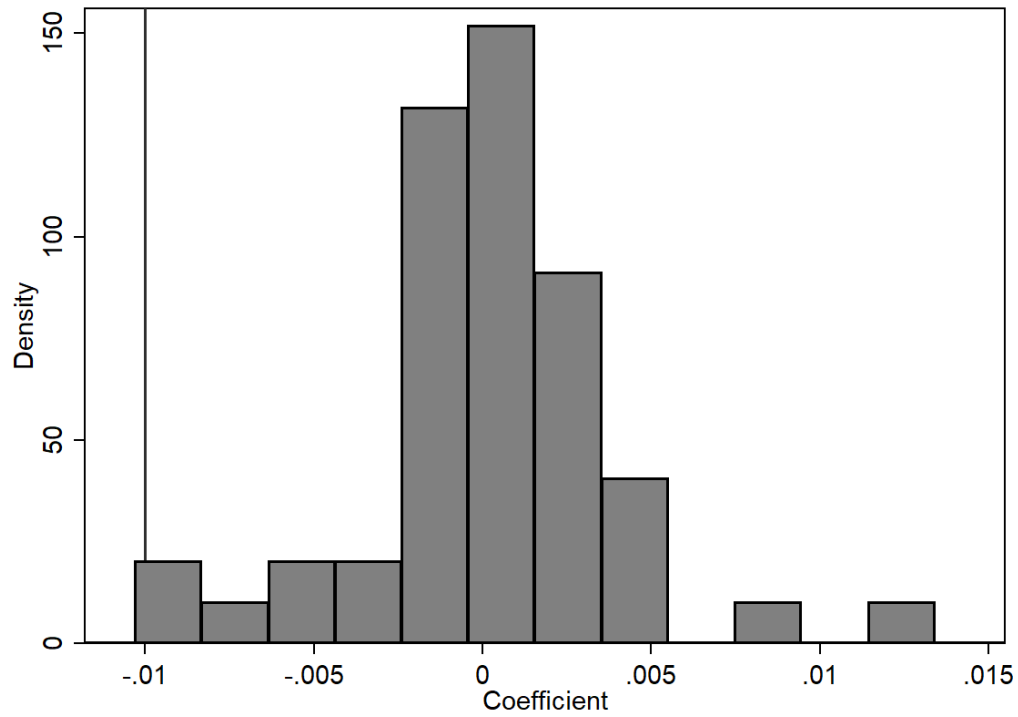
Note: This table compares ten different FDA-approved direct-acting antiviral (DAA) medications used to treat Hepatitis C using data from the Centers for Medicare and Medicaid Services State Drug Utilization Data (SDUD). The first column includes the brand name of each drug. The second column displays the first year the drug shows up in the SDUD data. The third column displays the year in which the drug received the most Medicaid prescriptions. The fourth column displays the total number of prescriptions for the drug in the SDUD data from 2014-2022. The fifth column displays the average amount reimbursed for the drug.

Figure A.1 – Distribution of Placebo DiD Estimates for the Effect of the Louisiana Hepatitis C Elimination Plan on DAA Prescriptions.



Note: This figure displays the distribution of placebo synthetic control estimates for the effect of the Louisiana Hepatitis C Elimination Plan on the quarterly number of direct acting antiviral prescriptions to Medicaid patients using data from the State Drug Utilization Data (SDUD). The vertical line displays the true Louisiana treatment effect.

Figure A.2 — Distribution of Placebo DiD Estimates for the Effect of the Louisiana Hepatitis C Elimination Plan on Hepatitis C Related Mortality.



Note: This figure displays the distribution of placebo synthetic control estimates for the effect of the Louisiana Hepatitis C Elimination Plan on the Hepatitis C related mortality, using restricted-access mortality data from the National Vital Statistics System (NVSS). The vertical line displays the true Louisiana treatment effect.