Increasing Access to Medication-Assisted Treatment for Opioid Use Disorders

Estimating Costs, Supply, and the Effects of Insurance Expansions

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Abstract

Drug overdose deaths in America exceeded 50,000 in 2015, claiming more lives annually than gun violence and motor vehicle accidents. Of these, more than 63% of overdose deaths were due to opioids. Medication-assisted treatment is regarded as the most effective form of treatment for those struggling with an opioid use disorder. However, medication costs and insurance coverage remain identified barriers to treatment.

My dissertation measures access to buprenorphine, the fastest growing form of medication-assisted treatment, and the effects of demand side interventions aiming to tackle the opioid problem in America. While some supply side interventions have mixed effectiveness or unintended consequences potentially exacerbating the problem, demand side interventions may be more effective in reducing overall demand for opioids and opioid-related deaths. Insurance expansions, such as the federal insurance parity law of 2008 or the 2014 Medicaid expansions associated with the Affordable Care Act, could have increased access to treatment.

The three main insights from this dissertation are: 1) who pays for the medication matters when considering the average cost of buprenorphine maintenance treatment. Patients with public insurance have lower buprenorphine costs compared to those paying with cash-only or with commercial insurance. 2) The federal parity law for substance use disorders (MHPAEA) did not increase access to medication-assisted treatment for opioid use disorders. 3) Out-of-pocket costs for prescription opioids have decreased dramatically while costs for buprenorphine have not declined at similar pace, thus complicating access for those with an opioid use disorder.

Efforts by Congress to push commercial insurers to expand coverage for addiction services have not led to lower costs for opioid treatment, unlike the experience among those with public insurance. Policymakers need to look for other ways to get commercial insurers to lower costs, particularly if further health care reform leads to a reduction in Medicaid funding and enrollment.

Introduction

“The demon of intemperance ever seems to have delighted in sucking the blood of genius and of generosity. What one of us but can call to mind some dear relative, more promising in youth than all his fellows, who has fallen a sacrifice to his rapacity? He ever seems to have gone forth, like the Egyptian angel of death, commissioned to slay if not the first, the fairest born of every family. Shall he now be arrested in his desolating career? In that arrest, all can give aid that will; and who shall be excused that *can*, and will not?”

Abraham Lincoln, *Temperance Address*, 1842

“You need some medication?
The answer's always yes”

La La Land, 2016

A very short overview of the problem

The opioid problem in America is well documented. More people died of drug overdose deaths than from gun violence or motor vehicle accidents. Most of these drug overdose deaths were due to opioids. Despite the urgency to address the issue, policymakers have struggled to design and implement successful policies. Buprenorphine, a type of medication-assisted treatment is regarded as the most effective form of treatment for people with an opioid use disorder but remains underutilized. Combined with behavioral health therapies, such as cognitive behavioral therapy, the use of buprenorphine can significantly increase the chances of surviving an opioid overdose and improve long term recovery. Therefore, it is imperative to understand the reasons why this medication remains underutilized to comprehend the mechanisms through which policy interventions may be able to work. There are several social and regulatory barriers to increasing buprenorphine utilization, including stigma, scarcity of trained providers, and lack of information regarding its use. A frequently stated barrier to accessing buprenorphine is the cost of medication and insurance coverage. As opioid use disorders are considered chronic diseases, even relatively low medication costs can become a burden and restrict utilization of this form of treatment.

What we don't know about measurements and policies that aim to increase treatment for those with opioid use disorders

Better measurement of a problem can lead to better solutions. My dissertation aims to answer three relatively simple questions regarding measurement and policy evaluation: 1) how much does

buprenorphine cost in the United States? A better understanding of the real cost of treatment may lead to effective policies that increase access to buprenorphine. 2) Did the federal insurance parity law of 2008 increase access to buprenorphine? Little is known on whether providing broad substance use disorder parity alone can help address the opioid epidemic. 3) What happened to prices and out-of-pocket costs for prescription opioids and buprenorphine during the years of insurance expansions in America? Documenting changes to the costs of these prescription drugs can add to our knowledge of the mechanisms through which some demand-side interventions can increase access to treatment.

There is no single price for buprenorphine in America (source of payment matters)

The first aim of my dissertation is to shed light on the problem of measuring the cost of buprenorphine treatment in the United States. Efforts to calculate the average cost of treatment for substance abuse (of any type) within the US health care system are influenced by a variety of cost drivers that include (1) where substance use is delivered (inpatient, outpatient or partial outpatient settings); (2) the type of facility in which it is delivered (inpatient hospital settings are different from inpatient opioid treatment programs) and; (3) the additional services that frequently get delivered with the therapy. My first paper, coauthored with Rosalie Liccardo Pacula and Brad Stein, highlights another important source of variation in the cost of treatment, particularly relevant for pharmacotherapies, and that is the variation in negotiated input prices. While some attention has been given to the first three sources of variation listed, far less attention has been paid to differences in negotiated input prices for the exact same therapy. We found very few rigorous real-world analyses of the cost of buprenorphine and most of these presumed that the biggest source of variation in cost is associated with the setting in which therapy is given. For policymakers, it is not clear what is the cost of a daily (or monthly) dose of buprenorphine for a typical US patient. We add to the current knowledge by providing a breakdown of buprenorphine medication costs by type of payer and formulation. Policymakers that know the real cost of treatment by type of payer may be better equipped to design and implement more effective policy interventions.

The Mental Health Parity and Addiction Equity Act did not increase access to buprenorphine

While some supply side interventions have mixed effectiveness or unintended consequences potentially exacerbating the opioid problem in America, demand side interventions may be more effective in reducing overall demand for opioids and opioid-related deaths. Insurance expansions, such as the federal insurance parity law of 2008, also known as MHPAEA, could have increased access to treatment

for opioid use disorders. To date, no study has focused on the effects of state or federal parity laws on access to and cost of medication-assisted treatment for opioid use disorders.

My second paper addresses the gap in the evaluation of MHPAEA's implementation on access to and cost burden of medication-assisted treatment for opioid use disorders. Because of the magnitude of the opioid epidemic and the potential for opioid use disorder treatments to reduce future health care spending, understanding the benefits of improved access to these therapies is especially important for public and private insurers. I extend prior work examining the impact of parity laws, by specifically evaluating whether the 2008 federal parity law, which removed the ERISA exemption, increased access to effective treatments for opioid use disorders. I find that the federal parity law for substance use disorders did not increase access to buprenorphine, measured by standard doses per month, and did not decrease medication costs for patients or payer groups. While I find an overall increase in buprenorphine purchased in all seven states and all payer groups, this increase is not associated with parity. Demand for medication-assisted treatment, driven by the increasing number of people struggling with opioid use disorders, may explain the increase in buprenorphine supply. Together, these results suggest that MHPAEA, while mandating insurance parity for SUD treatment, was inadequate in terms of expanding treatment for opioid use disorders beyond that which was already occurring nationally. In the case of this policy intervention, mandating insurance benefits is not sufficient to increase access because this doesn't necessarily reduce costs for patients.

Public payers may be well suited to increase access to buprenorphine while keeping overall costs down (but commercial insurance remains the largest source of buprenorphine prescriptions)

My third paper focuses on describing cost sharing trends and out-of-pocket costs for outpatient prescription opioids and buprenorphine during the implementation years of MHPAEA and Medicaid expansions. Even with increasing expenditures for outpatient prescription opioids from 1996 to 2014, consumers have seen decreasing expenditures for this class of medications. In contrast to this finding out-of-pocket expenditures for buprenorphine experienced very little decline over time. While the mean total cost of buprenorphine showed a slight decline from 2010 to 2014, this was mostly driven by falling costs paid by insurers, not patients.

I find that variation in cost sharing for buprenorphine among commercial and public payers may offer insights into the role of insurance expansions and the delivery of care by different payers. For public insurers, Medicaid expansions seem to be working in increasing access to buprenorphine. This is not the case for private insurance, where cost sharing is substantially higher and insurers have been reaping the

benefit of price negotiations. Thus, policymakers need to seek alternative ways to expand access among the commercially insured, such as encouraging the placement of buprenorphine formulations in lower-cost sharing tiers of drug formularies, adopting this medication as a first line of treatment for people struggling with opioid use disorders, and encouraging price transparency of the medications being offered to patients.

Policy implications and main contributions to the current knowledge

My dissertation fills an important gap in the current literature by measuring the cost of buprenorphine, evaluating the effects of a federal parity law on access to this medication, and considering differences by type of payer and tracking these differences over time. In doing so, this work helps explain what might at first glance appear to be conflicting results in terms of the effects of policy. I find that insurance mandates like MHPAEA, which expand the benefits of insurance coverage for the commercially insured, are ineffective at increasing buprenorphine utilization and access at a time when opioid abuse was rising tremendously. At the same time, I find that patients in public insurance experienced lower cost sharing and lower costs, leading to greater access overall. By looking at actual cost paid by the patient, it is clear to see why MHPAEA did not expand access to buprenorphine while Medicaid expansions did: out-of-pocket costs of buprenorphine remained high for those with commercial insurance but not for those with public insurance.

Policymakers interested in understanding how to expand access to medication assisted treatment for opioid use disorders should look at policies that affect different payers; commercial insurers do not respond to mandates of coverage in the same way public insurers do. While MAT may be included as a benefit and even offered at parity, other factors can also influence the cost that patients pay. Policymakers need to ask what is driving the difference in costs between public and private payers and look for ways to reduce this difference. For example, it may be that a policy that requires commercial insurers to include at least one generic formulation of buprenorphine (which would presumably be available on a much lower cost-sharing tier) would be a useful strategy for expanding access within commercial insurance. Private sector leaders might want to consider clinical practice guidelines adopted and implemented in public insurers to see if these factors might also be correlated with the cost to the payer as well as the cost to patient. Finally, making prices more transparent to physicians and patients may encourage the adoption of generic formulations of buprenorphine, which are cheaper than Suboxone, and increase the overall utilization of this life saving treatment.

Estimating the costs of substitution therapy for heroin and opioid addiction in the United States: insights and challenges

Ervant Maksabedian¹, Rosalie Liccardo Pacula², and Bradley Stein³

Abstract

We conduct a systematic literature review of the cost of medication-assisted opioid addiction treatments in healthcare settings in the United States and an original analysis of the cost of pharmacotherapy received on an outpatient basis. From the identification of our small set of studies we demonstrate the difficulty in trying to describe the cost of opioid substitution treatment, in that different definitions of ‘treatment episodes’ are used in addition to different standardized doses. We then show, through our own analysis of multi-payer pharmacy data, how even if we focus on a pharmacotherapy that is becoming more widely used in the United States (buprenorphine), a particular stage of treatment (maintenance), and a particular setting (outpatient), there are still big differences in the average cost per dose of this drug because of the different costs negotiated by different US health insurance payers. This study provides an example of how bottom-up estimates for the costs of treatment for opioid addiction in outpatient settings in the United States may vary, for instance, because of the costs of pharmaceuticals.

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Introduction

Background on the US health insurance system and its role in determining access to pharmacotherapies

In the United States, healthcare is financed through a mixed payer system. Potential payers for services include individuals (uninsured), private companies (e.g. employers and/or commercial health plans), and public entities (federal government, state government and other local government agencies). According to recent statistics reported by the Kaiser Family Foundation, the majority of Americans (56 %) in 2015 were covered by private insurance, mostly obtained through (and brokered by) employers (Henry J. Kaiser Family Foundation, 2015). Another 20 % in 2015 were covered by Medicaid, a shared federal-state public insurance program covering individuals on low incomes and with disabilities. Medicare, the federal public health insurance system for the elderly and people with disabilities, provides insurance coverage to another 14 %, while other public insurance, including the Federal Children Health Insurance Plan (CHIP), TRICARE (which provides care for those active in the military and their families), and the Department of Veterans Affairs, which provides care for retired military personnel, provides insurance for another 2 % of the population. In 2015, approximately 9 % of the total population was without any healthcare insurance (Kaiser Family Foundation, 2015).

Although the majority of the American population is covered by private insurance, it pays for less than 13 % of all national substance use disorder treatment expenditures (SAMHSA, 2016). State block grants and other and local spending has covered the largest share of funding (69 %) historically (SAMHSA, 2016), although such funding is likely to diminish in importance in the era of healthcare reforms. State Medicaid, however, which had grown by 2014 to cover about 25 % of total national spending, is expected to rise substantially due to the expansion in eligibility for Medicaid that occurred under the Affordable Care Act (Buck, 2011; Mark et al., 2014). So, state agencies remain an important payer of substance abuse services.

In the United States, it is health insurance carriers that commonly negotiate prices with pharmaceutical companies as part of the process of negotiating the inclusion of specific pharmaceuticals in the health insurance plan's drug formularies, using the size of their enrollee population as a negotiating tool in their bargaining. While insurance companies cannot withhold any particular medicine recommended by a provider from the patient, they do determine whether the insurance company covers some, half, most or all of the cost of a given medication by placing specific drugs in different 'tiers' in

their drug formulary. Therefore, a drug that is being covered entirely by the health insurance company (e.g. vaccines such as flu vaccines), would be placed in the lowest tier (implying lowest cost to the patient). Generic versions of widely used branded prescriptions are also often available at much lower cost to the patient than the branded drug and generally placed in a low tier. Expensive drugs, particularly those still under patent, are often placed in higher tiers, requiring the patient to share more of the cost. Some medications, particularly new drugs that apply to only small patient groups, often do not get included on the insurance plan's drug formulary, in which case the patient is left to cover the full cost of the drug at the price listed by the pharmaceutical company.

The US government negotiates only pharmaceutical prices for patients covered by federal health insurance plans (i.e. Medicare, TRICARE, Veterans Affairs and the Federal Employees Health Benefit group). Separate state agencies negotiate prices for the patients they cover under state insurance plans, including Medicaid and state employee health programs. Private insurance plans or large employers who self-insure negotiate directly with pharmaceutical companies to obtain prices for the prescription drugs that are most frequently used by their insured populations.

Given the substantial reforms that are taking place in the US healthcare system because of the Mental Health Parity and Addiction Equity Act and the Patient Protection and Affordable Care Act, access to MATs is expected to change dramatically in the United States, with public (Medicaid) and private insurance playing an even larger role in terms of its paying for MAT (Barry and Huskamp, 2011; Buck, 2011). This is due, for instance, to federal subsidies encouraging the expansion of eligibility criteria for the state Medicaid population, rules increasing the age at which parents can cover their adult children on their own health insurance (now includes adult dependent children up to age 25), and the required integration of medical and behavioral health services. Hence, regulations that state Medicaid agencies have passed related to access to MAT and the shared cost of the drugs are going to be important factors, and they are far from homogeneous (Burns et al., forthcoming). By 2013, most state Medicaid programs covered methadone and/or buprenorphine (although some states still do not cover both for all Medicaid enrollees more than a decade after buprenorphine's approval), and most listed buprenorphine on their preferred drug lists. However, other Medicaid regulations — related to prior authorization, co-payments and counselling requirements — differ considerably across states and could potentially limit physicians' and clients' use of both these MATs (Mark et al., 2015; Stein et al., 2015; Burns et al., forthcoming).

Government estimates of the cost of opioid substitution therapies

In 2004, the Substance Abuse and Mental Health Services Administration's (SAMHSA's) Center for Substance Abuse Treatment developed a range of cost estimates considered 'reasonable' for the delivery of substance abuse treatment delivered in different treatment modalities to inform policymakers' funding decisions (SAMHSA, 2004a). However, these ranges were generated when buprenorphine and naltrexone were not widely available to clients and the range of cost estimates was so wide that little could be inferred from them, as French and colleagues (2008) pointed out in their update to SAMHSA's work. However, even French and colleagues' update does not provide a breakdown of the costs by type of pharmacotherapy treatment, nor does it clearly distinguish between treatments that are administered through a program with supporting behavioral therapies versus those that are delivered just as pharmacotherapies on an outpatient basis. While pharmacotherapies during induction and stabilization are frequently provided as inpatient services in hospitals, OTPs or other residential locations, maintenance medications, particularly buprenorphine and naltrexone, may be administered as outpatient therapies, meaning that a doctor can simply prescribe the drug for clients to take at home as needed with no additional services. Thus, the cost per modality is not a good indication of the total cost per treatment, as a course of treatment commonly involves detoxification, induction and maintenance and different settings. Current estimates of the cost of treatment for substance abuse are not adequate to properly assess the cost of MAT or even the marginal cost of adding pharmacotherapy to an existing treatment regimen.

Nonetheless, SAMHSA does produce very reliable estimates of the total national spending on treatment of substance abuse disorders. SAMHSA's latest estimate on spending for all substance abuse treatment prescription drugs (including medications for the treatment of alcohol use disorders) was USD 887 million in 2009, or approximately 0.006 % of US GDP in 2009 dollars (SAMHSA, 2013c). Of this amount, almost USD 754 million, or 85 % of total expenditure on prescription drugs for treatment of substance abuse, were spent on combination buprenorphine/naloxone and USD 62 million, or 7 %, on buprenorphine alone ⁽⁴⁾. Estimates for spending on methadone for drug addiction are captured as part of spending for specialty substance abuse centers where methadone is dispensed, rather than with substance abuse prescription drug spending, so it is not possible to identify how much the government spends on methadone vis-à-vis buprenorphine formulations for opioid addiction. So, while total expenditure in substance abuse specialty centers in 2009 was substantially greater than spending on prescription drugs,

⁽⁴⁾ Prescription costs reflect only the cost of the medication, not any overhead or indirect services associated with dispensing the drug given that they can be dispensed in a retail pharmacy.

USD 8 397 million, SAMHSA's data do not permit disaggregation of methadone drug spending from other spending that occurs in these settings.

Despite all types of public and private payers being included in SAMHSA's report, such as Medicaid, Medicare, private insurance, out-of-pocket-spending, and state and local spending, it is not possible to construct an average cost per dose by payer in these data. However, we found that costs per dose estimates are available for some, though not all, types of payers in the United States. For example, per a 2007 study of the Veterans Health Administration (VHA), the average daily cost of methadone (60 to 80 mg/day) in the VHA was USD 0.36 to USD 0.48 (Goodman *et al.*, 2007). Methadone, however, must be administered in an OTP, which is not necessarily available in all locations where buprenorphine is offered. Therefore, once buprenorphine starting being offered in 2003, the VHA started providing typical daily doses (12 to 16 mg) — based on established national non-formulary guidelines for buprenorphine use in office-based practices — at a cost between USD 9.48 and USD 10.10 within the VHA system (Goodman *et al.*, 2007). Consistent with this estimate, one study from 2006, when the VHA approved buprenorphine for formulary status and published criteria for its use, found that a day's supply of buprenorphine, defined as a mean daily dose of 14 mg, would cost USD 9.82 (Barnett, 2009).

Literature review of the cost of medication-assisted opioid addiction treatments in healthcare settings in the United States

Given the regulatory complexities regarding the distribution of different pharmacotherapies (i.e. where they can be distributed), and the variation in the willingness of payers to cover such medications, we were interested in seeing the extent to which the literature provides information on the average cost of treatment for each of the FDA-approved therapies in certain health care settings. There have been other reviews of the cost-effectiveness and/or cost-benefit of these pharmacotherapies, with a recent review by Chalk *et al.* (2013) concluding that methadone was the least expensive (USD 30-50 per month of treatment). Oral naltrexone was also fairly inexpensive (about USD 60 per monthly dose). Buprenorphine/naloxone combinations were a bit more expensive at USD 140-160 per month of treatment. Injectable extended release naltrexone, which had only recently become available at that time, was the most expensive (at about USD 700 per month of treatment). A limitation of this review, however, is that it included studies conducted all over the world, and hence the estimate of the average cost of treatment incorporated availability and cost in different healthcare systems, with different levels of cost

sharing transferred to the patient. It does not necessarily reflect the cost of this treatment in the United States, which is what we hope to provide here.

We used the following specific criteria for our systematic review. To be included, studies had to be published in English and consider care delivered within the US healthcare system; the population had to be 18 years or older; the study had to be conducted in or after 2002 (when buprenorphine received FDA approval, as that also had an impact on the delivery of methadone); studies had to include estimations of average dose, estimate cost per dose or cost of treatment and specify the stage of treatment (induction, stabilization, or maintenance); and studies had to be a randomized controlled trial (RCT) or observational or simulation study on cost or cost-effectiveness. Studies could include any type of insurance or payer, provided the care was received in the US healthcare system. The studies could be about MATs that included buprenorphine in any of the following trade names in any formulation used to treat opioid use disorder: Suboxone, Buprenex, Butrans, Subsolve, Bunavail, and generic buprenorphine or buprenorphine HCl. Finally, the search terms used for this systematic analysis were ‘medication assisted opioid treatment’ ‘medication assisted opioid therapy’ ‘medication assisted opioid detox’, ‘opioid treatment’ and ‘opioid therapy’.

Our inclusion criteria yielded a selection of 38 studies, the vast majority of which were studies presenting findings from an RCT. A more careful assessment of these 38 studies revealed that many did not in fact explicitly include acquisition costs for the pharmacotherapies employed. We also excluded studies that used price data prior to 2002 (before buprenorphine was available on the market) or used price data from outside the United States. Studies that did not provide costs per dose or treatment or that did not state the phase of treatment — induction or maintenance — were also excluded from the final sample. Imposing these criteria reduced our discussion to only five papers that presented findings relying on observational or administrative data. While several relevant cost-effectiveness studies that assessed the cost-effectiveness between MAT and MAT plus behavioral therapy might appear to be excluded (e.g. Sindelar et al., 2007), the problem with these studies is that they did not report the price of the pharmacotherapy, as it was being held constant between the treatment and control conditions. However, it is the price of the pharmacotherapy that we are focused on in this study.

This exercise demonstrated to us that in the past 13 years, very few rigorous *real-world* analyses of the cost of buprenorphine, methadone or naloxone have been carried out, as indicated by the relatively small number of included studies. Policymakers looking at these data would have a difficult time understanding exactly what the cost of a daily (or monthly) dose of any of these pharmacotherapies would be for a typical US patient. Table A12.1 in Appendix B provides a snapshot of the key features of each of

the five included studies. A quick glance at the results in the table reveals that the dosages of methadone, buprenorphine and naltrexone administered vary quite a bit across studies and for individuals over time, and they depend on each individual's stage of treatment. Importantly, the perspective of cost also changes from study to study, sometimes reflecting the cost to a state agency, sometimes the client and sometimes the commercial payer. The studies we identified had more or less arbitrary lengths of study period for assessing the maintenance stage of treatment. As a consequence, each study would generate a different cost of treatment, because dosages can and do change over the maintenance period.

An important takeaway from this systematic review is that, while any given study might be able to provide an estimate of the cost of pharmacotherapy, it is important to pay attention to the phase of therapy for which the drug is being used (which is directly tied to the amount being prescribed), the setting of that therapy (inpatient, OTP or other outpatient) and the differential prices negotiated by payers. To date, most presume that the biggest source of variation in cost is associated with the setting in which therapy is given. However, the duration of therapies covered by insurance in each of these settings varies considerably across payers, which suggests that it is important to pay attention to the cost per phase of treatment in a manner that considers the client's costs as well as the agency's cost. The cost (and presumably cost- effectiveness) for what appears to be the same pharmacotherapy might differ significantly if focused on 'treatment', which may include behavioral therapies in addition to pharmacotherapies for some payers or programs but only pharmacotherapies for others. All of these factors make it very difficult to construct an overall estimate of the cost of opioid abuse disorder treatment for the US healthcare system.

Original analysis of cost of a standardized dose of buprenorphine by payer in 2012

In the light of the findings from the published literature, and because of our desire to understand the extent to which costs per standardized dose of a pharmacotherapy can differ across payers being treated in the same phase of treatment (e.g. maintenance), we decided to conduct some original analysis of the cost of pharmacotherapy received on an outpatient basis. Given the complexities of settings and the like, and the fact that there are no publicly available data sources containing information on the cost of drugs distributed through OTPs, we focus only on the drug buprenorphine and its distribution through retail pharmacies. This focus provides a clearer cost of just the drug itself rather than the additional cost of wrap-around services that may be administered during detox (done on an inpatient basis) or with behavioral therapies (if delivered in an OTP). By looking at buprenorphine alone, and standardized doses given during a maintenance phase, we can reduce the noise and complexity caused by considering other therapies, and focus only on the variation created by different payers negotiating prices for the drug.

Information on buprenorphine obtained through a retail pharmacy comes from the Symphony Health Solutions' Integrated Dataverse and relates to a standardized dose (16 mg). The Symphony Health Solutions' Integrated Dataverse includes transactions from approximately 55 000 pharmacies, accounting for over 90 % of US prescription volume. This commercial database obtains and consolidates paid pharmacy transactions, physicians' claims and hospital claims from all payers to create a multi-payer claims database. As we rely in our analysis on information reported solely in retail pharmacies' claims, the cost we are examining represents only the cost of the medication, not the cost of dispensing it, which is absorbed by the retail pharmacy in the United States. We examine prices for the year 2012. We chose 2012 because this was the most recent calendar year before significant expansions in public health insurance took place under the Affordable Care Act (DHHS, 2015).

Our original dataset included 185 835 410 prescriptions administered throughout the year (2012). Of these, approximately 0.13 % (245 678 prescriptions) were for buprenorphine HCl (8 mg buprenorphine sublingual tablets) and Suboxone (oral strips, 8 mg buprenorphine/2 mg naloxone and 4 mg buprenorphine/1 mg naloxone dosages). We collapsed the data by uniquely identified client so that we could identify what the average cost of treatment was per client. For about 9.7 % of these clients information on the cost of the prescriptions received was missing and could not be explained by rejected claims. Thus we dropped these observations. The final dataset contained 41 093 clients for whom we could construct an average cost of buprenorphine per day and month by plan type and buprenorphine formulation during the year.

Table 12.1 presents frequency and percentage of clients by type of payer and for the different forms of buprenorphine products available in the United States. Half (49.87 %) of our sample were individuals who paid for buprenorphine with commercial health insurance, while about one quarter of payers (25.67 %) obtained their medications by paying for them entirely with cash (out-of-pocket expenses). Public programs, such as Medicare and Medicaid, represent almost 14 % of our sample. The remaining 11 % of clients purchased buprenorphine through savings clubs or assistance programs (referred to here as 'mixed', as the payer can be mixed in these).

There are two plausible explanations for the relatively large proportion of commercially insured patients in our sample (vis-à-vis public insurance). First, as stated previously, the Symphony Health data contain only information on prescriptions picked up from retail pharmacies. To the extent that Medicaid- and other publicly insured clients pick up their buprenorphine from community health centers and/or prisons, these prescriptions would not be captured in the data (and hence not reflected in the primary payer). Second, by 2012 key elements of the Federal Mental Health Parity Addiction Equity Act and the

Affordable Care Act had already come into effect, presumably extending substance abuse treatment coverage to more individuals (Nosyk et al., 2013).

Table 12.1. Clients by type of payer in the United States in the year 2012. From the Symphony Health Solutions' Integrated Dataverse

Type of payer	Buprenorphine HCl (sublingual) 8 mg	Suboxone (oral strip) 4 mg/1 mg	Suboxone (oral strip) 8 mg/2 mg	Total (%)
Cash — No insurance	9 913	0	637	10 550 (25.67 %)
Private insurer	17 361	4	3 130	20 495 (49.87 %)
Public entity	4 863	1	777	5 641 (13.73 %)
MIXED	3 414	0	993	4 407 (10.72 %)
Total	35 551	5	5 537	41 093 (100 %)

Table 12.1 also provides a frequency count of the types of buprenorphine products and formulations that were obtained from retail pharmacies by type of plan. Buprenorphine HCl (the generic formulation) is by far the most common form of buprenorphine distributed by pharmacies (over 86.5 % of all prescriptions), with Suboxone (8 mg/2 mg) formulations coming in second (13.5 %). The rest of our analysis will, therefore, focus on these two products.

As different insurance companies have different rules regarding length of treatment covered and clients used varying quantities of buprenorphine by type of product, we created a ‘standard daily dose’ for maintenance in order to calculate cost to individual patients and types of insurance. We set this daily dose at 16 mg to be consistent with FDA guidelines (US Food and Drug Administration, 2014) and because it was within the usual range of dosage for patients on maintenance treatment (SAMHSA, 2004a).

Next, we constructed an average total cost per standard dose of buprenorphine. This was the sum of average cost to clients (shared payments they made or full amounts, depending on whether or not they had any insurance) and plans per client identifier ⁽⁵⁾. Table 12.2 shows the overall costs to clients and plans and total cost of a standard dose of buprenorphine in the United States in 2012. When average costs

⁽⁵⁾ Our sample included observations in which there were negative payments for payers. These could have been reimbursed by pharmacies or paid by the patient. Because we did not want to show negative costs but still reflect the dynamics of payments in the data, we decided to offset these negatives costs through the client payments, thus lowering the client payment and total cost for these observations. Therefore, no information was lost and the visual representation makes more sense.

are considered for all forms together, it would appear that the patient and plan equally share the average cost per daily dose. However, the story changes when the sample is broken down into its generic formulations versus one of its branded formulations (Suboxone oral strip 8 mg/2 mg). In the case of generic buprenorphine, clients pay a larger share of the total cost per daily dose than health plans and the total cost per daily dose is less than USD 10. In the case of branded buprenorphine (Suboxone oral strip 8 mg/2 mg), it is the plans that pay about two thirds of the cost per daily dose, and the total average daily cost overall is close to twice that of the generic formulation.

Table 12.2. Average costs of a standard daily dose of buprenorphine, United States, 2012

	Standard dose of buprenorphine (16 mg)	Mean (USD)	Standard deviation (USD)	Min. (USD)	Max. (USD)	Interquartile range
All formulations	Patient cost per daily dose	5.4	5.0	0.00	44.6	9.3
(n = 41 093)	Plan cost per daily dose	5.6	5.5	0.0	46.4	9.7
	Total cost per daily dose	11.0	6.5	0.0	60.2	9.5
Generic buprenorphine HCl	Patient cost per daily dose	5.3	4.6	0.0	44.6	9.2
(n = 35 551)	Plan cost per daily dose	4.5	4.8	0.0	46.4	7.3
	Total cost per daily dose	9.8	5.6	0.0	48.0	9.1
Suboxone oral strip 8 mg/2 mg	Patient cost per daily dose	6.2	7.2	0.0	27.0	13.3
(n = 5 537)	Plan cost per daily dose	12.5	4.8	0.0	28.7	1.2
	Total cost per daily dose	18.7	6.6	0.0	54.0	6.9

While the difference in total average cost per daily dose between generic formulation and Suboxone is not unexpected, the extent to which there is variation in the average plan cost per daily dose is surprising, particularly in the case of generic buprenorphine, where competition should drive the price down to the cost of production, and hence payers should face relatively stable and similar costs. However, Table 12.2 shows that both the standard deviation and interquartile range for a standard dose of generic buprenorphine paid for by the insurer ('plan') vary substantially, exceeding the mean. Interesting, the standard deviation of the plan cost per daily dose of Suboxone is similar in magnitude, although the interquartile range (75th percentile value – 25th percentile value) is much larger. Because pharmaceutical drugs are not bought and purchased in normal markets — prices are negotiated on the clients' behalf by insurance companies in private — variation remains.

In Table 12.3 we take a closer look at the average cost per dose for generic buprenorphine by type of payer (private insurance, public insurance, and so on) to make this point even clearer. Because small differences in daily dose prices can translate into large differences in monthly drug costs, we show the average cost per monthly dose of buprenorphine, rather than the cost per daily dose, which was shown in Table 12.2. To generate these monthly costs, we multiplied the daily cost by 30.

Table 12.3. Average monthly costs of a standard dose of generic buprenorphine by type of payer in the United States in 2012

Type of payer	Variable	Mean (USD)	Standard deviation (USD)	Min. (USD)	Max. (USD)	Interquartile range
Private insurer (<i>n</i> = 17 361)	Average client cost per monthly dose	129.6	121.6	0.0	1 339.5	202.8
	Average plan cost per monthly dose	175.0	140.3	0.0	1 130.7	226.6
	Average total cost per monthly dose	304.6	179.5	0.0	1 438.8	305.4
Public entity (<i>n</i> = 4 863)	Avg. patient cost per monthly dose	30.0	75.1	0.0	1 110.7	9.3
	Average plan cost per monthly dose	231.6	143.8	0.0	1 393.2	155.8
	Average total cost per monthly dose	261.7	141.9	0.0	1 429.2	184.1
Cash — Out of pocket (<i>n</i> = 9 913)	Average patient cost per monthly dose	233.4	135.3	0.0	959.4	138.2
	Average plan cost per monthly dose	0.0	0.0	0.0	0.0	0.0
	Average total cost per monthly dose	233.4	135.3	0.0	959.4	138.2
Mixed (<i>n</i> = 3 414)	Average patient cost per monthly dose	263.1	80.0	0.0	1 021.3	64.6
	Average plan cost per monthly dose	184.8	98.4	0.0	1 058.6	68.4
	Average total cost per monthly dose	447.9	89.3	33.2	1 266.5	0.0

Note: Average plan and total costs were capped at zero. Some observations had negative values.

Several important insights can be gained from the simple descriptive statistics in Table 12.3. First, private insurers have a higher average total cost per monthly dose of generic buprenorphine than either public insurers (Medicaid/Medicare) or individuals who pay their drug costs without insurance. However, most of those costs are passed on to the patient, because the average plan cost per monthly dose is significantly lower on average for the private insurers than for the public insurers. Second, substantial

variation remains, as indicated by the standard deviation, even within plan type for the same generic medication. Interestingly, however, the standard deviation is similar between public and private insurers from the plan perspective (what the insurer pays). That is not the case in terms of the variation in the client's share of these costs for people with these types of insurance. The variability in average cost to the client among the privately insured is even greater than that for the plan. Finally, mixed programs appear to have the highest average total costs, with clients paying the biggest share of these higher costs. However, the variability in client costs is substantially lower for clients in these mixed programs than if they were paying out of pocket, which suggests that there is indeed some negotiating power associated with receiving the medication through this source instead of paying cash.

Figure 12.1 illustrates the findings from Table 12.3 in graphic form in terms of client components and plan components by primary type of payer (public or private insurance, no insurance and other mixed options), but adds to the graph similar information on the average monthly cost of Suboxone. Here it is easy to see that regardless of the type of plan or insurance, generic buprenorphine is less expensive than Suboxone in terms of plan costs across the board. The cost to the plan is higher but less variable for Suboxone than for the generic formulations, as is indicated by the smaller interquartile range shown in the box and whisker plots. That stands in contrast to the costs paid by the client in each plan, which have greater variability in the case of Suboxone even when median average costs (indicated by the line inside the rectangular boxes) is lower. The higher variability in the client's share of the costs may reflect different total prices of the drugs (so a function of just passing through the higher costs), or the variability may be generated by different private insurance companies placing the branded pharmaceutical in different tiers (requiring different levels of client cost sharing). From this graph alone we cannot tell.

Figure 12.1. Monthly costs using a standard daily dose of generic buprenorphine and Suboxone by type of payer in the United States in 2012

Figure 12.2 combines the total health plan and patient costs by insurance type for each drug and plots the total monthly costs for a standard dose of buprenorphine. Colored asterisks indicate statistically significant differences in mean values in the monthly cost paid *between formulations* of buprenorphine for the same plan type. Thus, we can see statistically significant differences between the costs for Suboxone and generic buprenorphine for all the payer types. That is, total monthly costs for a dose of generic buprenorphine are consistently lower than the total costs for Suboxone for public entity payers, as well as for private insurers, out-of-pocket payers and mixed programs.

Figure 12.2. Total monthly costs for a standard daily dose of generic buprenorphine and Suboxone by type of payer in the United States in 2012

** P -value < 0.01

* P -value < 0.05

What is particularly interesting about Figure 12.2 is that it is possible to see the extent to which total costs per monthly dose (which combines plan and client costs) varies by type of payer in comparison with the variation in pass through to plan or client. While we saw in Figure 12.1 that mixed payers had variability in the plan and client costs for generic buprenorphine separately, we see in Figure 12.2 that there is no variability in the total cost for generic buprenorphine within the mixed insurer category. There is only one value for the total cost per monthly dose (a set price), and what varies is just how that one cost is distributed between the client and the payer that is subsidizing those costs (possibly associated with different cost sharing associated with different coupon or group deals). That is different from total monthly prices faced by clients who pay entirely out of pocket (i.e. without insurance or with other coupons or subsidies). Clients who pay out of pocket entirely for the average monthly dose still see variability in the price paid whether paying for generic buprenorphine or Suboxone. The variation in price is less than that observed when the drug is being paid for primarily through private insurance. Negotiated prices by private insurers clearly vary quite a bit both in the total cost (shown in Figure 12.2) and in the distribution of who pays those costs (as shown in Figure 12.1). And, similarly, we see quite a bit of variation in the average monthly cost of generic buprenorphine paid for by clients with publicly provided insurance. While the average total monthly cost of Suboxone is still higher than that of generic

buprenorphine for those purchasing it with public insurance, the variation in monthly cost per dose for the branded version is quite a bit less than that for the generic among the publicly insured.

The main point illustrated by these figures is that, despite there being a single cost for a pharmaceutical firm to produce these pharmaceuticals, the prices paid for them varies significantly depending on who is negotiating the price, and then the share of that cost that is borne by the insurer versus the client is also highly variable in most instances (with the exception of public insurance). Some of the variability between plan and client within the private insurer category may be due to differential placement of these drugs in their drug formularies (with different tiers requiring different levels of co-payment), or the generic version being excluded entirely from the drug formulary (causing the client to pay the full price). We cannot say from these data alone which factors are driving the bulk variation, only speculate on potential factors that may be causing some of the variation.

Discussion and conclusions

Despite modest declines in prescription opioid overdose deaths since 2010, more than 33 000 lives are lost annually to opioids (Rudd *et al*, 2016b). Thus, the prescription drug problem remains significant in the United States. Increasing access to effective treatment is a major strategy proposed for dealing with the opioid epidemic in the United States but the US treatment system is not well situated to deal with this problem because the primary payers — not private insurers — are not well informed about the real cost of treatment. Efforts to calculate the average cost of treatment for substance abuse (of any type) within this system are influenced by a variety of cost drivers that include (1) where substance use is delivered (inpatient, outpatient or partial outpatient settings); (2) the type of facility in which it is delivered (inpatient hospital settings are different from inpatient OTPs) and; (3) the additional services that frequently get delivered with the therapy. This chapter highlights yet another important source of variation in the cost of treatment, particularly relevant for pharmacotherapies, and that is the variation in negotiated input prices. While some attention has been given to the first three sources of variation listed, far less attention has been paid to differences in negotiated input prices for the exact same therapy, which by definition influences average cost.

Even when we focus on just the pharmaceutical cost of providing OST, we find that a variety of factors can influence the negotiated price paid, including the particular type of drug offered, the dose required (which varies depending on the stage of treatment) and the payer. We demonstrate in the last section of this chapter that, even when comparing standardized dosages and comparing the same stage of treatment, the anticipated payer matters when considering the average cost of the treatment. Looking at the data collected, we can see clearly that individuals with different types of insurance are paying

different amounts for their daily and monthly doses of buprenorphine. While there are some general trends (branded pharmaceuticals are more expensive than generic ones), considerable variability in the prices paid within these categories remains, some of which are completely absorbed by the plans (in the case of public insurance) and some of which are more likely to be absorbed by the patient (in the case of private insurance).

The study has several limitations that need to be considered when drawing conclusions from it. First, we have focused here only on the cost of the pharmacotherapy portion of treatment, not any additional services that may make pharmacotherapy more or less effective. Second, we have only been able to examine variation in the cost of one pharmacotherapy (buprenorphine) that is prescribed and administered through retail pharmacies. This study cannot say anything about the variation in the cost of buprenorphine or other pharmacotherapies offered in other healthcare settings (community health clinics, hospitals, OTPs). Third, we have looked only at the cost of a standardized dose of a drug offered in the maintenance stage, which may not be the most important or expensive aspect of a full treatment episode (particularly if detoxification or induction into treatment is largely done in inpatient settings). Fourth, we could only provide information on the cost of this pharmaceutical for clients who continued taking the drug. If clients were less likely to stay on a particular formulation because the costs were prohibitive, then our sample may be biased by people who had lower average costs in the first place (and hence were willing to stay on it for longer periods of time).

Even with these limitations, this study provides some useful insights and cautions for policymakers interested in drawing comparisons regarding the relative cost or cost-effectiveness of pharmacotherapies received in the United States to those countries that operate healthcare at a national level. The unique healthcare environment in which these services are currently being delivered may heavily influence the relative cost of the care received, but so too might the payer of the services (for instance, when purchasing power by large entities, such as government or large private networks, can affect the final price of these medications and their cost-effectiveness). Thus, it will be important for researchers to think of ways to standardize information across countries in a meaningful way so that meaningful direct comparisons of costs across countries can be made. To the extent that international comparisons of the cost of treatment are made including countries with a single public payer, it would be wise to use information on the cost of treatment paid by our public insurers (Medicaid/Medicare) rather than private insurers, as the cost paid for the exact same therapies in the United States clearly differs depending on the bargaining power of the payer.

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Appendix A

US regulations and clinical guidelines regarding the delivery of opioid agonist therapy in the United States

Prior to 2002, methadone and levo-alpha-acetyl methadol (or LAAM) were the only federally approved and supported OSTs available in the United States and both had to be distributed in certified OTPs. Methadone was first introduced on a national scale in the early 1970s, while LAAM, manufactured by Roxane Laboratories, received FDA approval in July 1993 (Center for Substance Abuse Treatment, 1995) but was taken off the market in 2004, when Roxane Laboratories stopped producing LAAM because of an increased risk of cardiac complications (Center for Substance Abuse Treatment, 2005).

Methadone treatment dosage, like that of the other pharmacotherapies, is expected to vary based on the stage of treatment. Regulation 42 CFR § 8.12 (h)(3)(ii)) states that, in the case of methadone, initial doses should not exceed 30 mg and the total dose for the first day should not exceed 40 mg unless the client's opioid withdrawal symptoms do not dissipate (SAMHSA, 2015b). For clients in the maintenance stage stage, there is no agreement on optimal dosages for patients. However, a common conclusion from several studies is that patients receiving higher methadone doses report better outcomes than those on lower maintenance doses (Leavitt, 2003). Only oral forms of methadone are allowed to be dispensed for opioid addiction treatment, non-oral forms are strictly prohibited. At one point, only liquid formulations could be dispensed, but current regulations have removed the liquid-only restriction and now permit solid forms of the medication (SAMHSA, 2015).

A major limitation of methadone (and LAAM) is that it can be administered only within an OTP. Thus patients who would not or could not routinely attend OTPs for geographical, ideological or practical considerations are not well served by it (Fiellin and O'Connor, 2002; Oliva et al., 2011). It was not until the Drug Addiction Treatment Act of 2000 (that the FDA allowed Schedule III-V medications, such as buprenorphine, to be prescribed for opioid use disorder treatment in non-OTP settings. Buprenorphine was approved by the FDA as a drug for the treatment of opioid addiction in 2002 (Kleber, 2007), and was expected to have an immediate impact on the utilization of MAT (Ducharme and Abraham, 2008; O'Brien, 2008) Under the Drug Addiction Treatment Act (Civic Impulse, 2017) waived physicians were permitted to prescribe or dispense buprenorphine to no more than 30 patients for the treatment of opioid use disorder at any one time. The Office of National Drug Control Policy Reauthorization Act of 2006 modified restrictions to grant approval for treating up to 100 patients at a time to physicians who

had been waived for at least a year, who were currently treating patients with buprenorphine and who opted to apply for the higher patient limit (Office of National Drug Control Policy Reauthorization Act, 2006).

In the case of buprenorphine as treatment for opioid use disorder, the optimal dosage for individuals also varies based on the stage of treatment (induction — also known as detoxification — stabilization or maintenance). When approved the recommended initial (i.e. first day) dose for someone in the induction phase is between 2 and 8 mg, and the usual stabilization dosage is 12-24 mg per day (US Department of Health and Human Services, 2010). As clinical experience with buprenorphine has increased, there has been greater appreciation of the nuances of prescribing buprenorphine reflected in more recent guidelines (Farmer et al., 2015; Kapman and Jarvis, 2015), but there remains a consensus that the recommended daily dose for most individuals receiving maintenance treatment lies between 12 and 16 mg per day (US Food and Drug Administration, 2014), with little clinical support for doses above 32 mg.

Naltrexone, approved by the FDA in tablet form in 1984 for treatment of opioid dependence, was not frequently administered to patients in pill form because of patient compliance problems as well as noteworthy side effects, now prominently featured on medication labels (Tai et al., 2001; SAMHSA, 2009; Rinaldo and Rinaldo, 2013). That changed in October of 2010 when the FDA approved Vivitrol, a long-lasting injectable slow-release formulation that lasts for approximately 30 days. Naltrexone implants, which also provide sustained doses to a patient over several months, are available in other countries, but have not yet been approved by the FDA for use in the United States.

Patients using naltrexone pills may receive an initial dose of 25 mg during the detoxification (or induction) stage and then transition to 50 mg pills (one each day) during maintenance phase. However, those patients at risk of adverse events (young people, women, those with a shorter period of abstinence) may need lower daily doses, from 12 to 25 mg, building up to 50 mg per day (SAMHSA, 2009). The recommended dose of Vivitrol, the extended-release injectable formulation of naltrexone, is 380 mg, to be delivered intramuscularly once a month.

Our systematic review of studies examining the average cost of various substitution therapy pharmaceuticals identified only five studies in which information on the average dose of the pharmacotherapy was available (in real-world settings where these drugs were being paid for entirely through the usual market system). These studies, and the key characteristics of each, which are described in detail in the main chapter, are shown in Table A12.1.

Table A12.1. Previous cost estimates of substitution therapy using buprenorphine, combined buprenorphine/naloxone and methadone in the United States

Study	Year	RCT, observational, or simulation?	Purpose: maintenance or induction (detox)	Insurance (payers)	Average dose	Average cost per dose (in constant 2015 USD)
Jackson et al.	2015	Simulation using cost data from 11 state Medicaid programs and single-state agencies	Maintenance (six months total)	State addiction treatment payers	Flexible doses for methadone, buprenorphine and extended-release naltrexone (simulation)	N/A. Only costs per day of treatment are available: 13.31 for methadone, 21.16 for buprenorphine and 48.36 for extended-release naltrexone
Schackman et al.	2012	Simulation using cost data from an observational study	Maintenance (excluding first six months of treatment)	N/A	8 mg buprenorphine/2 mg naloxone	8.33 for four tablets of 2 mg buprenorphine/0.5 mg naloxone and 0.93/mg for a 8 mg buprenorphine/2 mg naloxone tablet. Authors adjusted for discounts frequently available to large public and private insurers using the published local discount for all Medicaid drugs (14 % discount plus 3.15 dispensing fee per 30-day prescription). Original data in 2010 dollars (7.62 for four tablets of buprenorphine/naloxone and 0.85 per 8 mg tablet)
Polsky et al.	2010	RCT	Induction and maintenance (12 weeks total)	Six community out-patient treatment programs in New Mexico, North Carolina, Maryland, Maine and Pennsylvania	No average dose was provided	Adjusted average acquisition cost of buprenorphine/naloxone. No costs per dose were provided although substance abuse costs were 87.48 and 26.01 for buprenorphine administration during the induction and maintenance phases (74 and 22 in 2006 dollars from original data)
Jones et al.	2009	RCT	Maintenance after one year of stabilization period (six months total)	Clinical trial (analysis assumed patients did not incur costs for medications)	17 mg per day of buprenorphine (range: 6-24 mg); 69 mg per day (range: 20-100mg) for clinic-based (MC) methadone; and 70 mg per day (range:25-100 mg) for office-based (MO) methadone.	Buprenorphine: 10.02 per daily dose (original data in 2006 dollars: 8.48 using 0.53 per mg as base) Clinic methadone: 3.56 per daily dose (original data in 2006 dollars: 3.01 using 0.05 per mg as base) Office methadone: 3.39 per daily dose (original data in 2006 dollars: 2.87 using\$0.05 per mg as base)
Kaur et al.	2008	Observational (using administrative data)	Initiation (fixed observations for six calendar months) and maintenance (fixed observations for 12 calendar months)	Commercial health maintenance organization, point-of-service, preferred provider organization, direct access, medical savings account, and traditional indemnity plans in a New Jersey managed care organization	Between 4 and 24 mg of buprenorphine with a range from < 4 to 48 mg (authors calculated per individual prescription per day using the following formula: number of tablets divided by days supply multiplied by the strength of buprenorphine naloxone filled	19.4 per patient per day during six-month initiation period and 3.44 per patient per day during 12-month follow-up (15.9 for six-month initiation and 2.82 for 12-month follow-up in original price data. Note: authors did not specify dollar years, assumed 2005 dollars

The Effects of Insurance Parity on Access to Medication Assisted Treatments for Opioid Use Disorders.⁶

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Abstract

Drug overdose deaths in America exceeded 50,000 in 2015, claiming more lives annually than gun and motor vehicle accidents since 2009. Of these, more than 33,000 overdose deaths were due to opioids, signifying an upward trend in opioid-related morbidity and mortality that has occurred over the past two decades. While opioid agonist therapy is regarded as the most effective treatment for opioid use disorders, only 4 out of 10 people receive this type of therapy. Health insurance parity laws and regulations, like the Mental Health Parity and Addiction Equity Act of 2008, could help increase the adoption and implementation of opioid agonist therapies, a form of medication assisted treatment (MAT), for opioid use disorders. This paper addresses the gap in research by evaluating the effect of MHPAEA's implementation on access to MAT. Using prescription-level data from a commercial pharmacy database, this paper describes how purchases of buprenorphine and the costs for patients and insurers changed following MHPAEA's implementation in different states. Specifically, I use data from prescription transactions at the retail level obtained from a random sample of 8,365 physician prescribers in seven U.S. states to examine the effects of the federal parity law on the amount of buprenorphine supplied and the costs to patients and insurers. I estimate the effects of insurance parity on access to MAT in states with no previous parity laws relative to those with pre-existing parity laws using difference-in-difference-in-differences (DDD). I find that the federal parity law for substance use disorders did not increase access to buprenorphine and did not decrease medication costs for patients or payer types. My findings suggest that the implementation of the federal parity law did not successfully expand treatment for people with opioid use disorders, beyond the growth that was already occurring nationally. Because insurance parity regulations do not explicitly mandate coverage for opioid use disorders, they may not increase access to treatment as much as opioid specific policies. Policymakers should evaluate whether parity will be adequate to meet the treatment needs caused by the current opioid epidemic in light of the changing healthcare policy landscape in America.

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1. Introduction

Drug overdose deaths in America exceeded 50,000 in 2015, claiming more lives annually than gun and motor vehicle accidents since 2009. Of these, more than 33,000 overdose deaths were due to opioids (Rudd, 2016). Moreover, the National Survey on Drug Use and Health (NSDUH) reports that nearly 2 million Americans meet criteria for opioid use and dependence (Hedden, 2015). These numbers are the culmination of an upward trend in opioid-related morbidity and mortality that has occurred over the past two decades. From just 1999 to 2014 alone, the number of fatal poisonings due to prescription pain medications quadrupled, paralleling a similar increase in the distribution of opioid pain medications (Dowell, Haegerich and Chou, 2016).

Treatments for drug use disorders, especially those that combine medications with behavioral interventions, significantly reduce drug use. Further, they help ameliorate health problems in individuals and decrease hospitalization rates, reduce health care costs, increase employment and functioning on the job (Saxon and McCarty, 2005), reduce criminal activity, and create overall savings for society (Volkow and Li, 2005). Medication-assisted treatments (MAT) for opioid use disorders (Barthwell et al., 2016) may increase retention in treatment, reduce the risk of infectious-disease transmission, and engage less in criminal activity (Volkow et al., 2014). In addition to their clinical benefits, private and public insurers, as well as society as a whole, would increase savings and be better off by providing and paying for MAT access (Thomas et al., 2014).

Despite the evidence for treating people with MAT, few have access (Oliva et al., 2011). While opioid agonist therapy is regarded as the most effective treatment for opioid use disorders (Fiellin et al., 2004), recent figures shows that a relatively low number of patients receive it (Volkow et al., 2014). Less than 40% of Americans with a diagnosis for OUD and who were 12 years old or older received MAT in 2012 (Volkow et al., 2014). Adoption of MAT as a form of OUD treatment in the private sector treatment is below 50%; among those programs that adopted MAT, only about a third of patients received them (Knudsen, Abraham and Roman, 2011). Furthermore, there is a considerable gap between OUD treatment needs and national and state level capacities (Jones et al., 2015) and medication coverage nationwide (Mark et al., 2015).

Expanding access to treatment for opioid use disorders is considered an essential component of a comprehensive response to the current public health problem (Dowell, Haegerich and Chou, 2016). The 2002 FDA approval of buprenorphine, an effective evidence-based MAT for opioid use disorders, was expected to expand access to treatment. Some studies have documented an expansion in certain measures of access for some specific populations, such as Medicaid patients in Massachusetts (Clark et al., 2011) or

increased numbers of waived physicians (Stein et al., 2012; Stein et al., 2015). However, medication costs and insurance coverage remain identified barriers to broader access as late as 2010 (Roman, Abraham and Knudsen, 2011; Knudsen, Abraham and Roman, 2011). Because OUD is considered a chronic disease, lifetime costs of buprenorphine medication can become a barrier to treatment adherence and recovery for patients, particularly when the medication is not covered by insurance (Maksabedian *et al*, forthcoming).

A patient's ability to pay for their medication is essential for pharmacotherapy treatment to work. Along with stigma related to the use of opioid agonist medications, the current scarcity of prescribers, policy and regulatory barriers to access have hindered the expansion of MAT (Busch et al., 2014; Volkow et al., 2014; Stein et al., 2015). Existing research has focused on some of the structural barriers. These include access to training and medical staff, state regulations, inadequate treatment capacity, and expansion of waivers for physicians (Knudsen, Abraham and Roman, 2011; Stein et al., 2015). Studies have focused on subgroups of the entire patient universe, such as state Medicaid or other state-funded treatment programs (McBride et al., 2008). However, less attention has been paid to financial barriers and medication cost burdens for patients.

The federal and state governments have pursued public and private sector policies aimed at expanding OUD treatment by reducing its cost through insurance (Barry and Sindelar, 2007). While some states have enacted and implemented parity laws, which reduce cost by including treatment services as a covered insurance benefit, limited coverage and exclusions may have hindered the policy goals of increasing access to treatment and lowering costs for people with SUD (see section 1.1 for more detail). The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act (MHPAEA) is a federal SUD parity law passed in 2008 that expanded benefit coverage for addiction therapy beyond state parity laws. The law did not require that all forms of addiction treatment be covered and did not mandate coverage for addiction treatment, as it only applied to insurers that chose to cover substance use disorder benefits (Goplerud, 2013). Given the magnitude of the opioid epidemic in the U.S. today, which grew after individual states adopted addiction parity laws (Volkow et al., 2014), there are legitimate questions as to whether insurance parity, even the more comprehensive federal parity law, can meaningfully improve access to and reduce the cost of OUD-specific therapies.

To date, no study has focused on the effects of state or federal parity laws on access to and cost of OUD treatments specifically. Research on the impact of state and federal addiction parity laws examines overall substance use disorder treatment costs, utilization, and enrollment, particularly among some insured groups, such as federal employees and families with children with mental health care needs (Gilmer et al., 2010). Other studies suggest parity improved insurance protection, measured by the

increased probability of being diagnosed with a substance use disorder or by eradicating quantitative treatment limits for MH/SUD treatment, but had little impact on utilization, costs for plans, or quality of care (Azzone et al., 2011; Haffajee et al., 2015; McDaid, 2011; Amber Gayle Thalmayer et al., 2016). All addiction treatments were jointly examined by these studies, so alcohol and/or tobacco treatment, which represent the vast majority of treatment therapies paid for by insurers, likely dominated the results (Barry and Ridgely, 2008; Busch, 2012).

Could broad insurance parity requirements for addiction lead to an increase in access to MAT for opioid use disorder treatment specifically? In this paper, I use data from the Symphony Health Integrated Data Verse Prescription Patient Claims Database to examine the effects of the federal parity law on a few measures of access to buprenorphine. Specifically, I examine the effects of insurance parity on access to MAT in states with no previous parity laws relative to those with pre-existing parity laws. By using difference-in-difference-in-differences (DDD), I estimate changes to the amount of buprenorphine supplied, measured by standard doses of buprenorphine per month per 100,000 people, as well as the costs to patients and insurers (i.e., payer groups) before and after MHPAEA's implementation.

This paper addresses the gap in the evaluation of MHPAEA's implementation on access to and cost burden of MAT for opioid use disorders. Because of the magnitude of the opioid epidemic and the potential for opioid use disorder treatments to reduce future health care spending, understanding the benefits of improved access to these therapies is especially important for public and private insurers. I extend prior work examining the impact of parity laws, by specifically evaluating whether the 2008 federal parity law, which removed the ERISA exemption, increased access to effective treatments for opioid use disorders (Gilmer et al., 2010; Azzone et al., 2011; Haffajee et al., 2015; McDaid, 2011; Barry and Ridgely, 2008; Busch, 2012).

I find that the federal parity law for substance use disorders did not increase access to buprenorphine, measured by standard doses per month, and did not decrease medication costs for patients or payer groups. While I find an overall increase in buprenorphine purchased in all seven states and all payer groups, this increase is not associated with parity. Demand for MAT, driven by the increasing number of people struggling with OUD, may explain the increase in buprenorphine supply. Together, these results suggest that MHPAEA, while mandating insurance parity for SUD treatment, did not help expand treatment for opioid use disorders beyond that which was already occurring nationally.

My findings suggest that the federal policy that aimed to expand treatment and improve patient outcomes for people with substance use disorders did not itself improve access for those suffering from OUD specifically. If the goal is to expand access for opioid use disorder treatment in particular, then

policymakers should consider expanding insurance parity regulations to explicitly address OUD treatment. In addition, in light of the probable repeal of the Affordable Care Act, parity laws could be augmented with mandates to provide coverage for MH/SUD among those plans that currently do not offer them. Focusing on implementation and evaluation of said parity laws would help measure their effectiveness, track their progress, and make sure their targets are met.

1.1. State parity laws and MHPAEA: how do they differ?

Insurance parity laws seek to reduce the discrimination and inequality that have existed in insurance policies regarding mental health or substance use disorder benefits relative to other types of medical benefits (Barry, Huskamp and Goldman, 2010; Barry and Sindelar, 2007). Evidence from the RAND Health Insurance Experiment showed that mental health and substance use care may present greater moral hazard than other types of medical care (Keeler et al., 1982; Wells et al., 1982). This incentivizes insurers to limit these types of services more severely than other medical or surgical benefits, either through higher co-insurance, copayments, maximum dollar expenditures, and sometimes separate deductibles (Lohr et al., 1986; Wells et al., 1982; Keeler, Manning and Wells, 1988). Substance use disorder parity laws, initially passed by some states in the late 1990's and finally by Congress in 2008, attempt to reduce this disparity and thus the patient's cost of addiction treatment (Wen et al., 2013). Insurance parity ensures that if mental health or substance use disorder benefits are being offered, these are covered at equal to medical or surgical benefits. However, the limitations of state SUD parity laws were the same as those experienced by state mental health parity laws implemented in the previous decades. While policies mandating general coverage of MH/SUD benefits can be passed by state and federal policymakers, it is the insurance carriers themselves that determine whether OUD therapies are specifically included as part of the "addiction services" covered under the benefits or not. There are additional restrictions to state parity laws; those that the Employee Retirement Income Security Act of 1974 (ERISA) enabled self-insured companies (i.e., most large employers who offer health insurance) to be exempt from state mental health and addiction parity mandates (Ridgely and Goldman, 1995).

On October 3, 2008, Congress enacted The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act (MHPAEA) in order to expand the scope of the Mental Health Parity Act of 1996. While the previous 1996 Mental Health law provided for parity in the application of aggregate lifetime dollar limits and annual dollar limits between mental health benefits and medical/surgical benefits, MHPAEA extended the parity protections to substance use disorder benefits. MHPAEA also expanded the parity requirements to apply beyond aggregate dollar limitations to include financial requirements and treatment limitations (both quantitative and non-quantitative).

MHPAEA preempts existing state parity laws to some extent. Any previous state laws must meet the minimum requirements imposed by the federal parity ruling. If any state has more comprehensive parity laws, then these are not superseded and the states only have to ensure their laws meet the minimum standards set by MHPAEA (Goplerud, 2013).

1.2. Source of identification

I exploit two sources of variation: group level and state level variation in MHPAEA implementation. MHPAEA was implemented for some groups of insured individuals but not others. The law states that health insurance benefits for people who receive insurance through their employer, who insure over 50 people, and choose to offer substance use disorder benefits must be on parity with the medical/surgical benefits. Parity is also applicable to Medicaid Managed Care Plans. Although MHPAEA provides significant new protections to participants in group health plans, it does not mandate that a plan provide MH/SUD benefits. Rather, if a plan provides medical/surgical and MH/SUD benefits, it must comply with the MHPAEA's parity provisions. Also, MHPAEA does not apply to issuers who sell health insurance policies to employers with 50 or fewer employees or who sell health insurance policies to individuals. MHPAEA required group health plans and health insurance issuers to ensure that financial requirements (such as co-pays, deductibles, and coinsurance) and treatment limitations (such as visit limits) applicable to mental health or substance use disorder (MH/SUD) benefits are no more restrictive than the predominant requirements or limitations applied to substantially all medical/surgical benefits.

The second source of variation is the state level differences in parity laws for SUD. Some states, such as New York (New York Insurance Law, 2006)⁸ and Massachusetts (Massachusetts General Law, Part I, 2008)⁹, had passed and implemented parity laws related to substance use disorder prior to MHPAEA. Others, like California, Texas, Florida, Pennsylvania, and Michigan, had no substance use disorder parity laws before MHPAEA's IFR were implemented in July 2010. I use this state-level variation in implementation of parity in order to understand its effect on MAT utilization and cost burdens to patients and insurance plans.

Crucially, states with existing strong parity laws only had to show that they complied with MHPAEA's minimum requirements. This means that there is no "additional" parity requirements (i.e.

⁸ New York Insurance Law § 3221 Sections 5 and 6. Group or blanket accident and health insurance policies; standard provisions.

⁹ Massachusetts General Law M.G.L. c. 32A, §22; M.G.L. c. 175, §47B; M.G.L. c. 176A, §8A; M.G.L. c. 176B, §4A; M.G.L. c. 176G, §§4 4M.

“treatment”) for a state that could show it had previous parity laws that were no less generous than the federal law. This provision allows a clear identification of treatment and control states.

Massachusetts insurance parity law included substance use disorders as part of its parity legislation for large and small fully-insured plans, individual plans, and state employee plans to provide MH/SUD treatment coverage on a “non-discriminatory basis” for certain conditions. The law explicitly applies to substance use disorders and required that annual limits, lifetime limits, and other quantitative treatment limits (QTL’s, such as medication and treatment copays, deductibles, and coinsurance) for SUD to be the same as they are for other medical conditions (ParityTrack)¹⁰. The Massachusetts parity law of 2006, amended in August 2008 to include SUD benefits parity, became effective July 1, 2009; this meant starting on January 1, 2010 for most insurance plans (An Act Relative To Mental Health Parity, 2008). SUD parity in Massachusetts was implemented, as required by law, before the federal law regulations were legally binding. New York’s parity legislation of 2006, also known as Timothy’s Law, aimed to provide mental health coverage parity (S08482 -"Timothy's Law", 2006). Along with this legislation, the state of New York also required all group health insurance plans (but not the self-insured) to provide coverage for substance use disorder treatment as defined by the insurance policies¹¹. While neither of these state laws fully implemented SUD parity with other surgical/medical benefits, I argue that they serve as appropriate controls in my study. This view is supported by the lack of additional state legislation designed to increase compliance with the federal parity law after 2008¹². The existence of previous parity laws in New York and Massachusetts lets me utilize this variation in implementation at the state- and treated group (i.e., by payer type) levels to estimate causal effects of MHPAEA on MAT utilization. However, there is a potential attenuating factor in these estimates: the provisions of the Employee Retirement Income Security Act (ERISA) law of 1974 on employer-sponsored insurance.

Part of the Federal ERISA law of 1974 stated that self-insured payers, such as employers, did not have to follow state mandates, including state parity laws. Because Section 514 of ERISA pre-empts state

¹⁰ An in-depth view of parity legislation by state can be consulted at Parity Track, funded by The Kennedy Forum and The Scattergood Foundation.

¹¹ New York Insurance Law § 3221 Section 6(A), states that “Every insurer delivering a group or school blanket policy or issuing a group or school blanket policy for delivery, in this state, which provides coverage for inpatient hospital care must make available and, if requested by the policyholder, provide coverage for the diagnosis and treatment of chemical abuse and chemical dependence, however defined in such policy, provided, however, that the term chemical abuse shall mean and include alcohol and substance abuse and chemical dependence shall mean and include alcoholism and substance dependence, however defined in such policy.”

¹² Although this changed after it became apparent that implementation and enforcement of the MHPAEA provisions were poor, and thus compliance of federal parity itself was not being achieved (see Discussion section for more).

law relating to employee benefits, states with strong parity laws prior to MHPAEA implementation may still have a large number of insurance groups that did not have to comply with the state law. Through a complicated series of pre-emption clauses, ERISA regulations limit states from attempting to regulate self-insured employee benefit plans by treating these plans as insurers (Ridgely and Goldman, 1995). Therefore, state mandates on SUD parity may not have been as effective in providing parity for mental health and substance use disorder benefits. This all changed with MHPAEA. Since it is a federal, not state, law, MHPAEA's provisions are not bound by ERISA's section 514. Even strict state-level parity laws will not affect most people (Pacula and Sturm, 2000). This will bias the difference of access to MAT between comparison groups toward zero.

Implementation of MHPAEA occurred in three phases: statutory provisions, interim final regulations (IFR), and final regulations. MHPAEA's statutory provisions were self-implementing and generally became effective for plan years beginning after October 3, 2009 (for plans starting on January 1, 2010). However, the requirements of the interim final regulations, which were not known until they were announced on February 2nd, 2010, generally became effective on the first day of the first plan year beginning on or after July 1, 2010 (or January 1, 2011 for most insurance plans). Final regulations applied to group health plans and health insurance issuers offering group health insurance coverage on the first day of the first plan year beginning on or after July 1, 2014 (plans starting on January 1, 2015). Appendix A, figure A.1 shows a stylized timeline of MHPAEA implementation.

This paper focuses on the implementation after the Interim Final Regulations (IFR) took effect on July 1, 2010. The implementation of the IFR is important because these are the regulations that finally provided guidance on the application of parity to financial, quantitative, and non-quantitative treatment limitations (NQTLs), which were not addressed in the initial passage of the law or the statutory provisions. Because MHPAEA's statutory provisions, which were effective on October 2009, were self-enforcing, insurers were not legally obligated to comply with them. Moreover, the IFR clarified several regulatory uncertainties that the statutory provisions didn't address fully, such as financial requirements and quantitative treatment limitations (i.e., limits that can be expressed numerically as a dollar, a percentage, or number of visits or episodes, such as medication and treatment copays, deductibles, and coinsurance). The IFR also specified classification of benefits with parity required for each: inpatient in-network, inpatient out-of-network; outpatient in-network; outpatient out-of-network; emergency care; and prescription drugs (Goplerud, 2013). Therefore, using July 2010 as the implementation date for most of MHPAEA's regulations makes sense in the context of my research questions. While July 1, 2014, when MHPAEA's Final Rules became effective, could arguably be seen as the 'true' date of parity implementation; I argue that this is not the case. A concern with using the IFR would be that most of the

parity rulings of MHPAEA would not be adopted by insurers until the Final Rules were published. However, independent reviews of parity implementation found that most plans had mostly complied with parity requirements, at least as reported by them, by 2011 (Goplerud, 2013; Horgan et al., 2015). According to these studies, even in 2010, only a very small percentage of plans were using separate deductibles and confirmed that the use of higher co-payments and coinsurance for inpatient mental health and substance use disorder services declined rapidly in large employer plans following implementation of MHPAEA's IFR.

For a parity law to be effective it has to be enforced and the groups affected by the regulations must comply with them. It is not clear that commercial insurance payers ever fully adhered to federal parity or that the federal and state agencies tasked with its regulation and enforcement did so in an effective way (Christensen, 2013).

2. Empirical Strategy & Data

2.1. Empirical Strategy

This paper estimates the effect of MHPAEA's IFR on access to buprenorphine as a way to evaluate the efficacy of the federal parity law on increasing access to treatments for opioid use disorders. I use a difference-in-difference-in-differences (DDD) analysis in order to evaluate the effects of the federal parity law. Difference-in-difference-in-differences has been used in previous research addressing the effects of parity laws on utilization and health outcomes (Barry and Ridgely, 2008; Bao and Sturm, 2004). This method is useful to distinguish the effects of federal parity from those of other policies (such as the passage and implementation of the ACA) or state- or time-specific trends (e.g., the increase in OUD diagnoses across the country starting in 2002 and the implementation of state Prescription Drug Monitoring Programs).

A triple difference is necessary because: (1) some states already had parity laws, making those in group health plans (i.e., those that were not self-insured) not treated by the federal law. These states may have been experiencing upward trends in buprenorphine utilization for reasons independent of the federal law. These would have nothing to do with the MHPAEA but rather, for example, preferred use of pharmacotherapy over psychotherapy or possibly due to other state or federal policies that affect everyone's utilization of buprenorphine; and (2) due to ERISA, there were some populations even in these state parity law states that became affected by the federal parity law.

MHPAEA applied to all states that had no substance use parity laws or whose laws fell below the minimum requirements provided by the federal law. These would act as treatment states. Crucially, states

with existing parity laws only had to show that they complied with MHPAEA’s minimum requirements. That is, if they showed that the parity for substance use treatment in their state was already in place, then these states could be said to have been “treated” before the federal law was implemented in the other states.

Massachusetts and New York had strong parity laws in effect before MHPAEA. These early adopters become the “control” states, allowing me to see what happens to the “treated” states that are exposed to SUD parity for the first time through the federal law. Moreover, because the state laws applied only to some insured groups within the state, I construct a within-state ‘treatment’ and ‘control’ groups before and after MHPAEA. This is because, after the federal law was implemented, every group affected within the early adopting states had to comply with the law. This setup allows me to estimate the effect of the federal parity law on access and cost of buprenorphine using both within- and between-state variations in exposure to the policy. My main specification is:

$$\log(y_{gst}) = \sum_{s \cdot t=1}^{s \cdot t=M} \gamma_{st} + \sum_{g \cdot t=1}^{g \cdot t=N} \lambda_{gt} + \sum_{g \cdot s=1}^{g \cdot s=K} \theta_{gs} + \delta \cdot (Payer_g \cdot MHPAEA_s \cdot Post_t) + \varepsilon_{gst} \quad (1)$$

Where y_{gst} measures an outcome of interest (e.g., purchased buprenorphine standard doses per 100,000 inhabitants, cost to patient, cost to insurance plan) for a given payer type g (i.e., commercial insurance, cash-only payers, Medicaid, Managed Medicaid, Medicare, or Assistance Program/Coupons) on a given state s on a given month t . γ_{st} , θ_{gs} , and λ_{gt} are vectors of interactions for state-month ($s=7$ states, $t=54$ months, $M=378$), payer-state ($g=6$ payers, $s=7$ states, $K=42$), and payer-month ($g=6$ payers, $t=54$ months, $N=324$) effects to flexibly control for common factors that might influence the outcome of interest. In other words, these non-parametric controls are constructed using the interaction between state and month, payer group and state, and payer group and month. This approach controls for three kinds of potentially confounding trends: changes in buprenorphine utilization by the treated groups across states (that would have nothing to do with MHPAEA), changes in payer groups over time, and changes in buprenorphine utilization of all people living in the MHPAEA-affected states (possibly due to other state or federal policies that affect everyone’s utilization of MAT, or state-specific changes in the economy that affect everyone’s utilization). I cluster standard errors at the payer-by-state level to allow for correlation

across payer groups within states and serial correlation over time. I also cluster at the state level for all outcomes of interest for added robustness checks.

The coefficient of interest is δ , which measures the change in the outcome of interest in the year after the implementation of MHPAEA's Interim Final Regulations on July 2010 for payer groups affected by the federal parity law (commercial insurance and managed Medicaid). $Payer_g$, $MHPAEA_s$, and $Post_t$, are dummy variables that turn on when a payer group is affected by the federal parity law, on a state with no previous parity laws (CA, MI, FL, PA, and TX), and on any month after June 2010, respectively. It is necessary to have month as the relevant time variable, as opposed to yearly data, because of the timing in MHPAEA's IFR implementation.

I also use a standard difference-in-differences specification to estimate whether MHPAEA had any effects at the state level, in the log of total standard doses of buprenorphine adjusted by 100,000 inhabitants, in the year after the regulations took effect. The specification is as follows:

$$\log(y_{gst}) = \sum_{s=1}^S \rho_s + \sum_{t=1}^T \tau_t + \phi \cdot (MHPAEA_s \cdot Post_t) + \varepsilon_{st} \quad (2)$$

Where ρ_s and τ_t are vectors of fixed effects to flexibly control for common factors in a given state or month. The coefficient of interest is ϕ , which measures the change in the outcome of interest in the states affected after the implementation of MHPAEA's IFR. While the difference-in-differences estimation does not identify groups affected by MHPAEA within states, it provides a basic robustness check, on direction and magnitude, to those estimated from the DDD specification.

In addition to the DDD and DD estimates, I use a non-parametric event study model. This tests whether there is a structural break in the payer groups in the states affected by MHPAEA relative to the trend of groups not affected by federal parity around the time of the IFR implementation on July 2010. I control for permanent differences across payer groups, states, and time effects (in months) with vectors of two way interaction terms, γ_{st} , θ_{gs} , and λ_{gt} , respectively. $Payer_g$ and $MHPAEA_s$ are dummy variables that turn on when a payer group is affected by the federal parity law, on a state with no previous parity laws (CA, MI, FL, PA, and TX), respectively. I cluster standard errors at the payer-by-state level. I also cluster at the state level for added robustness checks. The coefficients of interest are included in the vector of ψ_t , where each ψ_t gives the change in the affected payer group on buprenorphine dose difference between month t and the (omitted) reference month of January 2010. The specification is as follows:

$$\log(y_{gst}) = \alpha + \sum_{s:t=1}^{s:t=M} \gamma_{st} + \sum_{g:t=1}^{g:t=N} \lambda_{gt} + \sum_{g:s=1}^{g:s=K} \theta_{gs} + \sum_{t=1}^T \psi_t \cdot (\text{Payer}_g \cdot \text{MHPAEA}_s) + \varepsilon_{st} \quad (3)$$

2.2. Symphony Health data

The *Symphony Health Solutions Integrated Dataverse* (henceforth “Symphony Health”) restricted pharmacy data are a collection of prescription transactions at the retail (i.e., pharmacy) level in the U.S. This database is collected electronically by a commercial provider, Symphony Health Solutions, and includes transactions from approximately 55,000 pharmacies, accounting for over 90% of US prescription volume. Symphony Health obtains and consolidates paid pharmacy transactions, physician claims, and hospital claims from all payers to create a multi-payer claims database. While the Symphony Health database cannot claim to be a representative sample of all pharmacy transactions in the country, it is an administrative dataset with a large number of recorded daily transactions. This is appealing in the context of studies focusing on provider- or population-level trends and is especially useful with carefully constructed samples for analyses such as the one presented in this paper.

The initial dataset requested from Symphony Health contained prescription-level data originating from a random sample of 13,801 physicians from any specialty who prescribed buprenorphine at least once between January 2010 and June 2014 in the U.S. This sample contained over 900 million prescriptions for any medication. Symphony Health Solutions provided the data based on the following criteria: (a) for each physician selected in the sample, there is at least one prescription claim for buprenorphine in 2010 for a total of 962,370¹³ buprenorphine prescriptions of any kind; (b) the physicians selected also have at least one written prescription during the first and last quarter of every year of the analysis, that is, January 2010 through June 2014 (54 months). Symphony Health contains de-identified information on each prescription: geographical location (3-digit ZIP code provided), a record of the prescription's transaction date, the name of drug purchased, an indicator for generic brand, the drug's strength, drug formulation, quantity per package (e.g., 10 tablets per package), the quantity purchased (e.g., 1 package), the amount the patient and payer plan (if any) paid for the drug, the name of the insurer or plan of each patient¹⁴, the type of payment by the plan or insurer, and the number of supply days each

¹³ These are non-rejected, non-reversed buprenorphine from any retail pharmacy, which represent about 92.5% of all prescriptions in the sample. Appendix B presents the counts and percentages of approved, rejected, and reversed claims in Symphony Health data.

¹⁴ No information is available for the type of plan in the case of commercial insurance. Further, I am not allowed to identify them by merging or cross-referencing these names with other databases per a signed DUA.

purchase has (e.g., 3-day supply, 30-day supply). There is no patient-specific data beyond a unique identification number that cannot be linked to other databases, per a signed database use agreement (DUA). Similarly, a physician's National Provider Identifier (NPI) number cannot be used to link prescriptions to geographical locations at aggregation levels below state. Despite these data limitations, the price and quantity data of buprenorphine available in Symphony Health are particularly useful for estimating utilization and cost burden for patients and payers.

A key advantage of the Symphony Health database is the information on health plans (i.e., payers) as it allows me to look at intra-state payers affected by the federal parity ruling. The granularity of this dataset facilitates the identification of payer types that were affected by the federal parity law within each state, thus allowing the DDD approach to estimate the effect of MHPAEA on buprenorphine access.

I have access to data for several U.S. states. However, only physicians in New York, Massachusetts, California, Pennsylvania, Michigan, Florida, and Texas were randomly selected¹⁵. Table 1 presents prescription counts by year for the final sample used in this analysis, which includes New York, Massachusetts, California, Pennsylvania, Michigan, Florida, and Texas. Prescriptions from these states reflect a random sample of 8,365 unique physicians. In total, 71,962 unique patients purchased 864,207 buprenorphine prescriptions in these states between January 2010 and June 2014. Data management (cleaning, merging files, and creation of a subset of data for buprenorphine prescriptions only) on the original Symphony Health files was done using SAS version 9.4. Data management and analysis on the final Symphony Health data sample was done using Stata 14.

¹⁵ A separate analysis using only 5 states, CA, MI, TX, NY, and MA, yielded the same overall results (not shown). Potential reasons to exclude Pennsylvania and Florida were the following: (1) a violation of the parallel trends assumption in the comparison group. Florida's legislative actions in 2010 through 2012, from crackdown on pain clinics to the establishment of its Prescription Drug Monitoring Program (which began operating in 2011 and included buprenorphine, schedule III drug), may confound the results of the analysis if this state is included. Some studies have shown that these policies had a significant effect on reducing opioid prescriptions, hospitalizations and deaths in Florida during the years of MHPAEA implementation (Rutkow et al., 2015; Kennedy-Hendricks et al., 2015). (2) As a consequence of the previously mentioned supply-side policies, drug overdose deaths and total standard doses of buprenorphine per month per 100,000 inhabitants in Florida declined compared to other states in the sample, thus a comparison with the rest of the states affected by MHPAEA might not be adequate. (3) Pennsylvania experienced a significant increase in drug overdose deaths and in total standard doses of buprenorphine per month per 100,000 inhabitants compared to the rest of the states in the sample. Despite these concerns, the DDD specification allows identification of treated groups within states, and so the concern of differential pre trends between states is eased. Similarly, the effects of supply side policies and other external shocks are accounted for in DDD estimation (see Methods).

Table 1. Number of Buprenorphine Prescriptions in Selected States in Symphony Health Dataset, Jan. 2010-June 2014

State	Year					Total
	2010	2011	2012	2013	2014	
California	23,254	34,644	39,872	41,286	24,397	163,453
Florida	37,941	61,451	63,093	74,475	42,418	279,378
Massachusetts	5,867	9,074	11,313	14,425	7,911	48,590
Michigan	3,928	7,341	9,782	14,930	10,111	46,092
New York	6,698	11,163	14,022	21,929	12,291	66,103
Pennsylvania	12,958	30,132	45,278	54,474	28,091	170,933
Texas	10,895	16,395	19,093	26,712	16,563	89,658
Total	101,541	170,200	202,453	248,231	141,782	864,207

Note: Data for 2014 available between January-June.

Table 2 presents a frequency count of the number of buprenorphine prescriptions obtained from retail pharmacies by type of plan. Commercial insurance plans paid for the majority of all buprenorphine prescriptions in the Symphony Health sample with approximately 59% of all prescriptions. Payments in cash (those paid without insurance) are the second most common purchases available in the data, with 22% of all prescriptions. Payments with coupons –also labeled ‘assistance programs’ comprised approximately 10% of all observations. Finally, payments made by public payers, such as Medicare and Medicaid, are the least common form of payment in the data, with only 9.4% of all buprenorphine prescriptions.

Table 2. Number of Buprenorphine Prescriptions by Type of Payer. Symphony Health Data, Jan. 2010-June 2014.

Payer Type	Freq.	Percent	Cum.
Assistance Prog. - Coupons	87,887	10.17	10.17
Cash	189,683	21.95	32.12
Commercial Plan	505,720	58.52	90.64
Managed Medicaid	32,637	3.78	94.41
Medicaid	19,737	2.28	96.7
Medicare	28,543	3.3	100
Total	864,207	100	

Note: Data for 2014 available between January-June.

Table 3 presents a frequency count of the types of buprenorphine formulations that were obtained from retail pharmacies by type of plan. Buprenorphine HCL (the generic formulation) is by far the most common form of buprenorphine distributed by pharmacies (over 93% of all prescriptions), with the two formulations for Suboxone (8mg buprenorphine-2mg naloxone and 4mg buprenorphine-1mg naloxone) as the second-most prescribed type of buprenorphine (6.3% of all prescriptions).

Table 3. Number of Buprenorphine Prescriptions by formulation and type of payer. Symphony Health Data, Jan. 2010-June 2014.

Payer type	Drug name					Total
	Generic bup 8mg (tablet w/2 mg naloxone)	Butrans 15mg (patch)	Suboxone 4mg (oral strip w/1 mg naloxone)	Suboxone 8mg (oral strip w/2 mg naloxone)	Suboxone 2mg (tablet w/.5 mg naloxone)	
Assistance Prog. – Coupons	79,680	155	5,686	2,366	0	87,887
Cash	182,768	192	3,839	2,882	2	189,683
Commercial Plan	471,482	2,140	19,297	12,800	1	505,720
Managed Medicaid	29,953	93	2,148	443	0	32,637
Medicaid	18,066	36	756	879	0	19,737
Medicare	24,588	506	2,868	581	0	28,543
Total	806,537	3,122	34,594	19,951	3	864,207

Since different commercial insurance plans may have different rules regarding length of covered treatment and patients used varying quantities of buprenorphine by type of product, I created a ‘standard daily dose’ for maintenance in order to calculate cost to individual patients and types of insurance. I set this daily dose at 16 mg to be consistent with physician usual practices, FDA guidelines (FDA, 2014), and because it was within the usual range of dosage for patients on maintenance treatment (SAMHSA, 2004). In order to compare buprenorphine access and costs across states, I constructed a measure of standard daily dose of buprenorphine of 16 mg adjusted by 100,000 inhabitants¹⁶.

Figure 1 shows the growth in the log of total standard daily doses of buprenorphine adjusted by population for each of the seven states in the sample before and after the implementation date of MHPAEA’s Interim Final Rule. While all experienced growth in buprenorphine doses between 2010 and 2014, Massachusetts, Florida, and Pennsylvania had higher baseline levels of prescriptions relative to other states. This could be explained by three things: 1) Massachusetts was one of the early adopters of methadone in the early 1990’s and buprenorphine in the early 2000’s; 2) Massachusetts adopted a state-wide health insurance in 2007, which might have increased coverage for OUD treatments in general, and buprenorphine access in particular; and 3) Pennsylvania and Florida experienced significant problems with OUD with respect to other states in America, and thus had a higher demand for MAT than others (Rudd et al., 2016; Rutkow et al., 2015; Kennedy-Hendricks et al., 2015). However, as long as these

¹⁶ See Appendix C, figures C.1 and C.2 for growth and relative growth of standard daily doses of buprenorphine by state. See figure C.3 for growth of the unadjusted total number of prescriptions by state.

differences between states do not vary significantly over the period prior to MHPAEA's IFR implementation, a DDD analysis can still provide an estimate of the effect of this policy on buprenorphine access.

Figure 1. Log of total number of standard monthly doses (16mg per day) of buprenorphine per 100,000 inhabitants. All payer groups. Symphony Health data, 2010-2014.

Figure 2 shows the population adjusted growth in the log of total standard daily doses of buprenorphine for the seven “treatment” and “control” states in the sample (California, Michigan, Florida, Pennsylvania, and Texas, and New York & Massachusetts)¹⁷. A key identifying assumption in a difference-in-difference analysis is common trends. There seems to be a relatively parallel trend in buprenorphine growth for both groups during the year before MHPAEA's IFR implementation and no obvious change in the July 2010 mark. Further, the level difference between groups does not seem to increase over time. This suggests that no real changes in buprenorphine doses purchased occurred after federal parity implementation.

¹⁷ Where Appendix D shows payer-by-group trends for all states analyzed in the dataset.

Figure 2. Growth over time for treatment and control states in log of total standard monthly doses of buprenorphine adjusted by 100,000 inhabitants. All payer groups. Symphony Health data, 2010-2014.

While the Symphony Health dataset provides detailed information on individual patients on the amount of buprenorphine prescribed (doses, days of coverage, refills) as well as the cost to the insurer and patient for the drug, it does not include information on methadone. This is because methadone can only be legally prescribed through methadone clinics (not retail clinics or pharmacies). Therefore, I use a different dataset to check the validity of my results.

2.3. ARCOS data

As Symphony Health contains convenience sample of physicians in seven US states, I might not capture the full effect of MHPAEA on access to MAT. Furthermore, I am only looking at buprenorphine, omitting methadone. To test whether the data source and sample selection drive the estimates from (1) and (2), I use a completely different dataset: the Drug Enforcement Agency's (DEA's) *Automation of Report and Consolidated Orders System* (henceforth "ARCOS"). This is an alternate data source that allows the evaluation the robustness of the results from Symphony Health. The ARCOS dataset tracks the quantities of all controlled substances (including methadone and buprenorphine) distributed to hospitals,

pharmacies, clinics and doctor offices. As reported by the Drug Enforcement Agency, the ARCOS database is a “reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level - hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions” (DEA, 2012). It contains summarized annual state level data of total amount of controlled substances, in milligrams, for a variety of medications and opiates (such as morphine, fentanyl, oxycodone, methadone, and buprenorphine, among others). While the purpose of ARCOS is to accumulate transactions in order to create reports identifying the diversion of controlled substances into illicit channels of distribution for investigators in federal and state government agencies, the database can also be used to estimate the total amount of a controlled substance available legally in a given U.S. state. Since different medications, such as methadone and buprenorphine, may have varying quantities morphine, all quantities are converted to morphine equivalent doses (i.e., MED) by state-month for ease of comparison and aggregation. Data are available from 2000 to 2011 for all 50 states in the U.S., plus the District of Columbia. All data management and analysis on the ARCOS dataset was done using Stata 14.

The addition of the ARCOS data adds value to this analysis because it allows me to look at the same states as the Symphony Health database and check whether my results change using a different data source. Unlike Symphony Health, it does not contain data for different payers within states, as it only provides summarized annual state-level data, so a DDD analysis is not possible. However, the ARCOS database contains the entire universe of buprenorphine and methadone supply in each state. By using a difference-in-differences (DD) approach to examine the variation in the amounts of these drugs distributed to the various outlets in which patients might receive them in my original sample of seven states, findings from the Symphony Health data might be more believable.

In order to check if my analysis may have generalizability issues, I use the full ARCOS data for all states, plus DC. I utilize a DD approach to estimate the effect of MHPAEA’s IFR implementation on total supply of buprenorphine and methadone in states with previous parity laws to those only affected by MHPAEA. This analysis addresses the generalizability concerns regarding the sample selection of seven states in the Symphony Health data presented in this paper.

The additional analysis using ARCOS provides a robustness check to the DDD estimates using Symphony Health data. If the two sample analyses show consistent stories, the concern of unique results driven by data source and data selection might be ameliorated. As for parallel trends concerning the supply between treatment and control states before MHPAEA's implementation, I use data from ARCOS to test whether or not this occurred. My approach is more likely to have internal validity if this is the case.

While ARCOS data contain the total annual supply of methadone and buprenorphine distributed to each state, both quantities are converted to morphine equivalent doses (i.e., an estimate or standard based on morphine against which most opioid medications can be compared) for data harmonization purposes. Morphine equivalent dose measurement ignores the properties of partial opioid agonist medications, such as buprenorphine, which partially bind to the opioid receptors in the brain, and do not exactly match the properties of fully binding opiates such as methadone. However, morphine equivalent dose measurements allow for easy comparisons between these two opioid medications. With these annual state estimates of morphine equivalent doses, I am able to construct a sample of the total supply of buprenorphine, methadone, and MAT (buprenorphine plus methadone) in the original sample of seven states from the Symphony Health database and evaluate whether the common trends assumption holds (see Figure 3 and 4 for buprenorphine and methadone; Appendix E figure E.1 for total MAT supply).

Figure 3. Log of total buprenorphine supply over time for treatment and control states in total morphine equivalent doses adjusted by 100,000 inhabitants. ARCOS data, sample of 7 states, 2002-2011.

As in Figure 2, it seems like the control states had a higher baseline of buprenorphine doses compared to the treatment states. In addition, Massachusetts and New York experienced a marked

increase in MAT supply in 2002, which was the first year buprenorphine became available for OUD treatment in America. This is probably due to Massachusetts being an early adopter of buprenorphine. The years after 2002 seem to mark a relatively parallel increase in MAT adoption by these two groups of states. Unfortunately, ARCOS does not provide more granular data, so it is not possible to ascertain whether there are differential growth rates by commercial or public payers in these states.

Figure 4. Log of total methadone supply over time for treatment and control states in total morphine equivalent doses adjusted by 100,000 inhabitants. ARCOS data, sample of 7 states, 2000-2011.

Figure 4 shows the growth in methadone supply for both groups of states between 2000 and 2011. Despite the marked increase in supply early in the decade, there is no appreciable difference between the two groups starting in 2006, suggesting parallel trends between these.

Finally, Figures 5 and 6 presents the fifty states (plus DC) sample of the total supply of buprenorphine and methadone (Appendix E figure E.2 for total MAT supply). I used data from the National Conference of State Legislatures ("Mental Health Benefits: State Laws Mandating or Regulating.," 2015) to classify the treatment and control states in the sample (12 control states, 39 treated

states)¹⁸. Those classified into the “control” group were only those states that specifically enacted SUD parity laws (not just mental health parity) prior to MHPAEA. As in the restricted, seven state-only sample, there are no obvious differential trends in MAT supply prior to MHPAEA implementation. In order to estimate the magnitude of the changes after MHPAEA implementation, I turn to regression analysis.

Figure 5. Log of total buprenorphine supply over time for treatment and control states in total morphine equivalent doses adjusted by 100,000 inhabitants. ARCOS data, sample of 50 states plus DC, 2002-2011.

¹⁸ Previous state parity laws (“control” states): Connecticut, Indiana, Maine, Maryland, Massachusetts, Minnesota, New York, North Carolina, Oregon, Rhode Island, South Carolina, and West Virginia.
No previous state parity laws (“treatment” states): Alabama, Alaska, Arizona, Arkansas, California, Colorado, Delaware, DC, Florida, Georgia, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana, Michigan, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, North Dakota, Ohio, Oklahoma, Pennsylvania, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington State, Wisconsin, and Wyoming.

Figure 6. Log of total methadone supply over time for treatment and control states in total morphine equivalent doses adjusted by 100,000 inhabitants. ARCOS data, sample of 50 states plus DC, 2000-2011.

3. Results

3.1.1 Measure of Access: Buprenorphine Doses

3.1.1.1 Difference-in-differences and Difference-in-difference-in-differences Analysis

Prior to the implementation of the Interim Final Regulations, the combined states of California, Michigan, Florida, Pennsylvania, and Texas had higher access to buprenorphine, as measured by standard doses of buprenorphine (Figure 2). However, it is not clear that any changes occurred after federal parity implementation in the states, and particularly groups, targeted by this policy. To test this in the Symphony Health database, I use a standard difference-in-differences specification to estimate whether MHPAEA had any effect at the state level, measured in log of total standard doses of buprenorphine per month adjusted by 100,000 inhabitants, several months after federal parity took effect. Then, I estimate the DDD model to look for any effects on payer types affected by MHPAEA's implementation (see Table 4).

Table 4. Effect of MHPAEA's IFR on buprenorphine doses to payer types affected by federal parity. Symphony Health data, 2010-2014.

	(1)	(2)	(3)
Log of std. doses of buprenorphine per month per 100,000 inhabitants	Diff-in-diff	DDD	DDD
MHPAEA x Post	0.00 (0.39)		
Payer x MHPAEA x Post		-1.12 (0.74)	-1.12 (0.70)
Observations	2,198	2,198	2,198
R-squared	0.70	0.98	0.98
State FE	YES	YES	YES
Payer FE	NO	YES	YES
Month FE	YES	YES	YES
Clustered Std. Err.	Yes-by state	Yes-by state	Yes-by payer and state

Robust standard errors in parentheses

*** p<0.01, ** p<0.05, * p<0.1

Note: Two-way interactions for state-month, payer-state, and payer-month effects are included in the DDD specification to flexibly control for common factors that might influence the outcome of interest

I find no effect of MHPAEA's IFR on the total number of standard doses of buprenorphine, a measure of access, on the groups affected by the federal parity law a year after implementation when clustering at the state level, as seen in columns (1) and (2). This result changes remains robust when clustering the standard errors at the payer type by state level. I argue that errors should be clustered at this level (more on discussion section below).

3.1.1.2 Event Study Analysis

The coefficients of the event study analysis from equation (3) are reported in Figure 7. Affected payer groups in states with no previous parity laws appear to have had the same buprenorphine prescription trends before and after MHAPEA's IFR implementation, as reflected in the statistically insignificant coefficients in the months before and after July 2010.

Figure 7. Event study analysis of the log of total standard monthly doses of buprenorphine adjusted by 100,000 inhabitants for treatment and control states. All payer groups. Symphony Health data, 2010-2014.

3.2. Measure of Access: Costs to Patients and Plans

If the federal insurance parity law had no effect on the number of prescriptions, then it is necessary to examine other possible transmission channels of parity on access. As noted before, financial barriers and medication cost burdens for patients are structural barriers to access and expansion for MAT. I look at the effect of MHPAEA's IFR on costs to patients, to payers, and total costs of buprenorphine as a second measure of buprenorphine access. If federal parity increased access to MAT coverage through insurance, then we should observe lower patient costs after MHPAEA and a reduction in cash-only

payments. Table 5 shows the DDD estimates of the effect of MHPAEA on these measures. Column (1) shows estimates for the effect of parity on patient costs for a standard monthly dose of buprenorphine; column (3) for plan cost; and (5) for total costs when clustering at the state level. Similarly, columns (2), (4), and (6) show estimates with clustered standard errors at the payer type-by-state level for patient costs, plan costs, and total costs, respectively.

Table 5. Effects of MHPAEA's IFR on buprenorphine costs to payer types affected by federal parity. Symphony Health data, 2010-2014.

	(1)	(2)	(3)	(4)	(5)	(6)
Cost of std. dose of buprenorphine per month per 100,000 inhabitants	Mean Patient Cost	Mean Patient Cost	Mean Plan Cost	Mean Plan Cost	Mean Total Cost	Mean Total Cost
Payer x MHPAEA x Post	0.91 (1.61)	0.91 (0.92)	-0.61 (1.06)	-0.61 (0.94)	0.29 (2.11)	0.29 (1.44)
Observations	2,198	2,198	2,198	2,198	2,198	2,198
R-squared	0.98	0.98	0.96	0.96	0.98	0.98
Two-way interactions	YES	YES	YES	YES	YES	YES
Clustered Std. Err.	Yes-by state	Yes-by payer and state	Yes-by state	Yes-by payer and state	Yes-by state	Yes-by payer and state

Robust standard errors in parentheses

*** p<0.01, ** p<0.05, * p<0.1

Note: Two-way interactions for state-month, payer-state, and payer-month effects are included in the DDD specification to flexibly control for common factors that might influence the outcome of interest

I find no significant effect of federal parity on costs of standard doses of buprenorphine per month to either patients or plans. In terms of practical significance, the magnitude of these estimates is close to one dollar per doses per month. There is also little evidence of declining cash-only payments over time for buprenorphine, therefore strengthening the interpretation that

many insurance plans did not provide coverage for OUD (Appendix D, figure D.5). Taken together, the results from Tables (4) and (5), as well as those presented from the event study analysis in Figure (7), suggest no real effect of federal parity on access to buprenorphine.

3.2.1. Discussion

In general, I find no effects of MHPAEA's IFR on access to buprenorphine, both in measures of number of doses and costs of the medication paid by patients and plans. Both of these results reinforce the conclusion that MHPAEA did not directly address two of the structural barriers for access to this form of MAT. The results remain robust regardless of clustering levels. As there is additional information in each payer type by state that is not captured by state level clustering, I argue that clustering done at the payer type-by-state level is the appropriate way to add precision to these estimates. Further, a sensitivity analysis using January 2011 as the first month of parity compliance using Symphony Health data found no significant differences in the estimates shown above (Appendix F).

3. Robustness checks

3.1. Lagged dependent variable-model

The DDD estimators above are based on assumptions of time- or group invariant omitted variables (Angrist and Pischke, 2008). However, this way of modeling might not be suitable when estimating the effects of a certain policy on groups of interest (Ashenfelter and Card, 1984). Past standard doses of buprenorphine purchased may be a time-confounding variable that is not absorbed by fixed effects. For example, it is possible that previous efforts in the states of Massachusetts and New York to control and reduce the opioid epidemic are what best explains the growth in access to buprenorphine for payers in these two states. To test whether the assumptions in the DDD model drive the results, I use a lagged dependent-variable model that takes the form:

$$y_{gst} = \alpha + \sum_{t=1}^T \tau_t + \sum_{h=1}^H [\theta_{gst-h}] + \delta \cdot (Payer_g \cdot MHPAEA_s \cdot Post_t) + \varepsilon_{gst} \quad (4)$$

Where y_{gst} measures my outcome of interest (i.e., purchased buprenorphine standard doses per 100,000 inhabitants) for a given payer type g (i.e., commercial insurance, cash, Medicaid, Managed Medicaid, Medicare, or Assistance Program/Coupons) on a given state s on a given month t . τ_t is a vector of time fixed-effects, θ_{gst} is a vector of lagged buprenorphine standard doses for the H previous months, and α is a constant. I cluster standard errors at the state and payer-by-state level. The coefficient of interest is δ_{gst} , which measures the change in the outcome of interest after the implementation of MHPAEA's Interim Final Regulations for payer groups affected by the federal parity law. I use a 3-month and 6-month model to account for short- and medium-term lags (in this case, H is 3 and 6 months).

Since DDD and lagged dependent-variable models are not nested, the estimates shown below provide both robustness to the original results from (1) and 'bracket' the DDD estimates of the effect of MHPAEA on the total number of buprenorphine doses. Table 6 shows that the dose in the previous month is the best predictor of future monthly doses of buprenorphine. Again, I find no effect of MHPAEA's Interim Final Regulations on buprenorphine doses on those payers affected by the federal parity law.

Table 6. MHPAEA's IFR on the log of Buprenorphine Doses to Payer Types Affected by Federal Parity with a Lagged Dependent Variable-Model. Symphony Health data, 2010-2014.

	(1)	(2)	(3)	(4)
Log of std. doses of buprenorphine per month per 100,000 inhabitants	3-month lagged dep. variable	3-month lagged dep. variable	6-month lagged dep. variable	6-month lagged dep. variable
Payer x MHPAEA x Post	0.00 (0.02)	0.00 (0.02)	0.00 (0.02)	0.00 (0.02)
Std. dose: 1-month lag	0.74*** (0.06)	0.74*** (0.07)	0.75*** (0.05)	0.75*** (0.06)
Std. dose: 2-month lag	0.04 (0.04)	0.04 (0.05)	0.05 (0.04)	0.05 (0.05)
Std. dose: 3-month lag	0.19*** (0.05)	0.19*** (0.04)	0.19*** (0.06)	0.19*** (0.04)
Std. dose: 4-month lag			-0.00 (0.06)	-0.00 (0.07)

Std. dose: 5-month lag			-0.05 (0.04)	-0.05 (0.05)
Std. dose: 6-month lag			0.04 (0.04)	0.04 (0.04)
Observations	2,030	2,030	1,891	1,891
R-squared	0.97	0.97	0.97	0.97
Month FE	YES	YES	YES	YES
Clustered Std. Err.	Yes-by payer and state	Yes-by state	Yes-by payer and state	Yes-by state
Lag in months	3	3	6	6

Robust standard errors in parentheses

*** p<0.01, ** p<0.05, * p<0.1

3.1.2. Discussion

The estimates that arise from an alternate specification under the assumption of a time-varying omitted variable, past buprenorphine purchases by a payer type in a given state, are broadly similar to those obtained in the DDD estimation. If the DDD specification is wrong, and the most important omitted variables are time-varying, then the magnitude of the estimates of the effect of MHPAEA will tend to be too big. However, if the DDD specification identifying assumptions are correct, then the estimates under the lagged dependent-variables specification will be too small (Guryan, 2004). Consistent with this interpretation, the estimates in the DDD tend to be bigger, albeit non-significant, than those in Table 7. Taken together, estimates from equations (1), (2), (3), and (4) suggest that the implementation of MHPAEA's IFR had no effect on access to buprenorphine on those affected by the parity law.

3.2. Difference-in-differences using ARCOS data

3.2.1. Difference-in-differences with seven state sample

As mentioned previously on section 2.3, I use the ARCOS dataset in order to check the robustness of my findings from the Symphony Health data. I utilize a difference-in-differences (DD)

approach, specified on equation (2), to estimate the effect of MHPAEA on access to MAT¹⁹. The ARCOS dataset, which reports the total supply of the two opioid agonist medications used for the treatment of opioid use disorders, provides a check to the DDD estimates using Symphony Health data. If estimates derived from these two different data sources are similar, the concern of unique results driven by the original data source selection might be ameliorated. My approach is more likely to have internal validity if this is the case. Table 7 presents results for the difference-in-differences specification described in section 2.1. I find no significant effects of MHPAEA's IFR on total state supply of methadone, buprenorphine, or the combination of both opioid agonists.

Table 7. Effects of MHPAEA's IFR on MAT supply (buprenorphine, methadone, and methadone buprenorphine) in states affected by federal parity. ARCOS data, sample of 7 states, 2000-2011.

Log of morphine equivalent doses per year per 100,000 inhabitants	(1) Buprenorphine & methadone supply	(2) Methadone supply only	(3) Buprenorphine supply only
MHPAEA x Post	0.01 (0.11)	0.03 (0.10)	-0.27 (0.19)
Observations	84	84	70
R-squared	0.98	0.98	0.98
State FE	YES	YES	YES
Year FE	YES	YES	YES
Clustered Std. Err.	Yes-by state	Yes-by state	Yes-by state

Robust standard errors in parentheses

*** p<0.01, ** p<0.05, * p<0.1

Notes: No available ARCOS data for buprenorphine prior to 2002 (FDA approval)

¹⁹ Using year fixed effects instead of month fixed effects due to the nature of the ARCOS dataset.

Because the implementation of federal parity took effect in the middle of the year, a weighted model, such as (5), may provide better estimates of the effect of MHPAEA on MAT supply. Equation (5) is a weighted DD model of the form:

$$\log(y_{gst}) = \frac{1}{2} \phi_{2010} \cdot (MHPAEA_s \cdot Post_{2010}) + \phi_{2011} \cdot (MHPAEA_s \cdot Post_{2011}) + \sum_{s=1}^S \rho_s + \sum_{t=1}^T \tau_t + \varepsilon_{st} \quad (5)$$

I explore a treatment indicator measuring the fraction of each period that a state operates under the policy. Treatment equals zero if the year is 2009 or earlier; equal to 0.5 in 2010; and equal to one in 2011. Table 8 presents the estimates for the effect of MHPAEA implementation on MAT supply using a weighted DD model.

Table 8. Effects of MHPAEA’s IFR on MAT supply (buprenorphine, methadone, and methadone buprenorphine) in states affected by federal parity using a weighted DD model. ARCOS data, sample of 7 states, 2000-2011.

Log of morphine equivalent doses per year per 100,000 inhabitants	(1) Buprenorphine & methadone supply	(2) Methadone supply only	(3) Buprenorphine supply only
MHPAEA x Post	0.12 (0.16)	0.15 (0.13)	-0.34 (0.24)
Observations	70	70	70
R-squared	0.98	0.98	0.98
State FE	YES	YES	YES
Year FE	YES	YES	YES
Clustered Std. Err.	Yes-by state	Yes-by state	Yes-by state
Robust standard errors in parentheses			
*** p<0.01, ** p<0.05, * p<0.1			

Notes: No available ARCOS data for buprenorphine prior to 2002 (FDA approval). Weighting of 2010 and 2011 based on a dose-response model.

3.2.2. Difference-in-differences with a sample of fifty states (plus DC)

I use a sample of fifty states plus DC from the ARCOS dataset to estimate the effects of MHPAEA’s IFR on total state supply of methadone, buprenorphine, or the combination of both opioid agonists. I used data from the National Conference of State Legislatures to classify the treatment and control states in the sample. Those classified into the “control” group were only those states that specifically enacted SUD parity laws (not just mental health parity) prior to MHPAEA. In total, 12 states with previous SUD parity laws are classified into the control group, whereas 39 states with no previous parity laws are classified into the treatment group.

Table 9. Effects of MHPAEA’s IFR on MAT supply (buprenorphine, methadone, and methadone buprenorphine) in states affected by federal parity. ARCOS data, sample of 50 states plus DC, 2000-2011.

Log of morphine equivalent doses per year per 100,000 inhabitants	(1) Buprenorphine & methadone supply	(2) Methadone supply only	(3) Buprenorphine supply only
MHPAEA x Post	0.15** (0.07)	0.16** (0.07)	0.00 (0.12)
Observations	612	612	496
R-squared	0.97	0.97	0.98
State FE	YES	YES	YES
Year FE	YES	YES	YES
Clustered Std. Err.	Yes-by state	Yes-by state	Yes-by state
Robust standard errors in parentheses			
*** p<0.01, ** p<0.05, * p<0.1			

Notes: No available ARCOS data for buprenorphine prior to 2002 (FDA approval)

Table 9 presents results from the non-weighted DD model (2). Consistent with previous estimates, I find no effect of MHPAEA on the supply of buprenorphine on the states newly affected by a SUD parity law. While there is a small but significant increase in total methadone supply after the implementation of MHPAEA (about 17%), this effect on methadone disappears when weighting the year of implementation of parity, 2010. Table 10 presents results from the weighted DD model using (5). Under this specification, the implementation of parity did not have any effect on buprenorphine or methadone supply at all.

Buprenorphine was not available prior to 2002. During these years, methadone supply between treatment and control states differed sharply, followed by a substantial increase after 2001. In Appendix G, Table G.1, I test whether the first two years of data available, 2000 and 2001, drive the results for methadone or total MAT supply. When this is done as an added robustness check, the effect of MHPAEA

on methadone supply ceases to be significant. Finally, Appendix G. Table G.2 shows estimates when the transition year 2010 is excluded from the analysis. Again, the effects of parity on buprenorphine supply remain robust and equal to zero, while methadone supply is positively affected by MHPAEA. Overall, the estimates for buprenorphine are robust to the changes in specifications, relative to the 2011 start date for treatment, while methadone supply estimates are not. This suggests that the implementation of federal parity and the changes in methadone supply may not be related to each other.

Table 10. Effects of MHPAEA's IFR on MAT supply (buprenorphine, methadone, and methadone buprenorphine) in states affected by federal parity using a weighted DD model. ARCOS data, sample of 50 states plus DC, 2000-2011.

Log of morphine equivalent doses per year per 100,000 inhabitants	(1) Buprenorphine & methadone supply	(2) Methadone supply only	(3) Buprenorphine supply only
MHPAEA x Post	0.04 (0.08)	0.06 (0.08)	0.01 (0.16)
Observations	510	510	496
R-squared	0.99	0.99	0.98
State FE	YES	YES	YES
Year FE	YES	YES	YES
Clustered Std. Err.	Yes-by state	Yes-by state	Yes-by state

Robust standard errors in parentheses

*** p<0.01, ** p<0.05, * p<0.1

Notes: No available ARCOS data for buprenorphine prior to 2002 (FDA approval). Weighting of 2010 and 2011 based on a dose-response model.

4. Conclusion and Limitations

I find that the implementation of MHPAEA did not increase access to buprenorphine, measured by standard doses per month, or decrease medication costs for patients and payer groups affected by the federal parity law. These findings remain robust to different implementation dates of the parity law and model specification. While I find an overall increase in buprenorphine purchased in all seven states and all payer groups, this increase is not associated with parity. Demand for MAT, driven by the increasing number of people struggling with OUD, may explain the increase in buprenorphine supply. Together, these results suggest that MHPAEA, while mandating insurance parity for SUD treatment, did not help expand treatment for opioid use disorders at a time when the opioid crisis in America was expanding.

This paper has several limitations. First, it is difficult to say whether the broad implementation of MHPAEA had any effect in the years beyond 2011; especially for the Final Rules of MHPAEA, effective for most plans on January 2015. While the preferred specification of this paper, the DDD analysis, can provide more reliable estimates of the effect of parity on the groups affected by this law, these become harder to disentangle from other policies over time. Disentangling the effects of federal parity from other health policies and supply side regulations, such as the passage and implementation of various policies of the Affordable Care Act and the establishment and operation of Prescription Drug Monitoring Programs, makes the estimates after 2014 less reliable. It may be difficult to expect for MHPAEA to have an effect on the affected payer groups beyond the first few years of implementation, especially on the number of doses, without the ACA provisions. This is supported by an independent evaluation of MHPAEA implementation (Goplerud, 2013). The evaluation found that most insurers and payer groups did not change or drop out coverage in the years after MHPAEA took effect. This suggests most of the effect, if any, of federal parity should have occurred early after the law was implemented.

While the Symphony Health dataset is very granular, it does not contain patient or plan characteristics. Further, it does not allow for identification of these characteristics by linking the data to other sources. This is problematic for two reasons: (a) it is not possible to control for observable characteristics of the payer groups on the DD or DDD estimations; and (b) I cannot determine if some commercial payer groups are included in the under-fifty employee threshold for MHPAEA provisions to be legally binding. However, this concern decreases when taking into account that nearly two thirds of the US population under 65 years old have insurance through their employers (Stanton, 2004) and that about 66% of all employed people work in places with one hundred or more employees (U.S.CensusBureau, 2017).

As previously mentioned, the ERISA exemption on state laws may bias my estimates toward zero. This paper presents what are probably conservative estimates of the impact of parity in these states

rather than a true measure of the effect because of the self-insured insurance plans that did not have to comply with state laws. However, growth of buprenorphine and methadone supplies seemed to have leveled off by the mid 2000's in both the treatment and control states, suggesting no real change after the implementation of parity. In addition, my findings boost the claims from government regulators, health researchers, and other reports that have long acknowledged little to no impact of the parity law on increased access to treatment (Christensen, 2013).

Another limitation in the Symphony Health data is the lack of observations pre-2010. This could mask an absence of parallel trends between treatment and control states used in the analysis. While the ARCOS data contains observations for 10 years before the implementation of MHPAEA's IFR, the lack of more granular data may also hide an absence of parallel trends. However, the consistency in trends and results in these two data sources provide more credibility to the parallel trends assumption crucial to a DD setup.

Using MHPAEA's Interim Final Regulations as cutoff for the implementation of parity may also be problematic. A concern regarding this is that insurance plans or payer groups affected by federal parity may have altered their behavior (e.g., dropped coverage or altered the contents of their insurance policies) because of MHPAEA requirements. According to a study sponsored by HHS, only a very small percent of plans dropped mental health or substance use disorder benefits after the implementation of MHPAEA and there is no clear evidence they did so because of MHPAEA (Goplerud, 2013). Another concern with using the IFR as cutoff is that not all of the parity requirements stipulated by MHPAEA may have taken effect by the date of implementation on July 2010. This concern is somewhat reduced in light of the findings of a survey commissioned by the American Society of Addiction Medicine, which found that by early 2013 "most commercial plans were covering medications for opiate dependence and that this coverage was complex" (Rinaldo and Rinaldo, 2013). Additionally, the survey found that coverage not always meant access to patients due to additional utilization management requirements, limiting medications to detoxification only, limiting duration of treatment with medications, and restricting access to in-network providers only. This suggests that even after the IFR took effect, some QTLs and NQTLs may still have been in place after implementation of the interim regulations. However, my choice of parity implementation is consistent with that of other studies evaluating MHPAEA (Ettner et al., 2016; McGinty et al., 2015), thus supporting the choice of IFR as the appropriate starting date for parity implementation. Finally, the effects of parity on buprenorphine access presented in this paper are robust to different implementation months and years, which suggests that my results are not driven by choice of the implementation date.

Even with these limitations, this paper addresses an important gap in the evaluation of MHPAEA's implementation and its impact in decreasing barriers to access MAT and expanding treatment for those who need it. I extend prior work examining the impact of parity laws, by specifically evaluating whether the 2008 federal parity law, which removed the ERISA exemption, increased access to effective treatments for opioid use disorders (Gilmer et al., 2010; Azzone et al., 2011; Haffajee et al., 2015; McDaid, 2011; Barry and Ridgely, 2008; Busch, 2012).

By focusing on a federal parity law, looking only at MAT for opioid use disorders, and by addressing different types of payers (private, public, and even cash payers), this paper adds to the current knowledge by providing evidence asserting that SUD parity alone did not help address the opioid epidemic. Specifically, it finds little evidence of increased access of buprenorphine due to the implementation of the federal parity law. These results are consistent with other evaluations of MHPAEA using administrative databases, which found little evidence that the federal parity law significantly increased utilization of behavioral health services (Ettner et al., 2016; McGinty et al., 2015).

Given the scale of the US opioid epidemic and the demonstrated effectiveness of MAT, understanding the consequences of expanding insurance in a manner that includes access to MAT is especially policy relevant now, when federal and state policy makers are looking for ideas that can help fight the epidemic. While significant policy attention has been paid to expanding the number of waived doctors prescribing buprenorphine (Stein et al., 2015), increasing supply of physicians able to prescribe buprenorphine does little if people cannot afford to pay for the treatment because it is not covered by their insurance. Some state Medicaid agencies have expanded benefit coverage by including buprenorphine on state drug formularies, but these policies only apply to those with Medicaid insurance, and the opioid epidemic is not specific to the poor.

The results of this paper may be of use to stakeholders that need to know if simply providing "addiction" coverage is sufficient to expand treatment and improve patient outcomes for those suffering from OUD. Some of these stakeholders include private and public health insurers, patient advocacy groups, medical practitioners, and state and federal policymakers. I show that expanding broad addiction benefits may be inadequate in the case of OUD treatments. Therefore, the stakeholders need to consider other policies or mandates that more explicitly address ability to pay for buprenorphine and other MAT therapies.

My findings suggest that the federal policy that aimed to expand treatment and improve patient outcomes for people with substance use disorders did not itself improve access for those suffering specifically from OUD. If the goal is to expand access for opioid use disorder treatments in particular,

then policymakers should consider expanding insurance parity regulations to explicitly address these treatments. In light of the probable repeal of the Affordable Care Act, parity laws could be augmented with mandates to provide coverage for MH/SUD among those plans that currently do not offer them. Focusing on implementation and evaluation of said parity laws would help measure their effectiveness, track their progress, and make sure their targets are met. Until such policies are designed, executed, and enforced, it is unlikely that insurance parity will benefit patients struggling with opioid addictions and help end the current opioid epidemic.

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Appendix A. MHPAEA Timeline

Figure A.1. MHPAEA Timeline

Figure A.2. Identification of States and Payer Groups Affected by MHPAEA

Appendix B. Prescription Claim Status in Symphony Health data. 2010-2014

Table B.1. Prescription Claim Status in Original Symphony Health dataset

Prescription Claim status	Freq.	Percent	Cum.
0	31,359	3.01	3.01
1	962,370	92.45	95.46
2	47,230	4.54	100
Total	1,040,959		100

Note: Claim status codes: 0 = Rejection, 1 = Approval, 2 = Reversal. Pharmacists reverse claims when a patient fails to pick up a medication. The pharmacy is required to reverse the claim and credit the payer the amount originally billed.

Appendix C. Symphony Health dataset. Prescriptions by state. Symphony Health dataset, 2010-2014.

Figure C.1. Total number of standard daily doses (16mg) of buprenorphine per 100,000 inhabitants. All payer groups. Symphony Health dataset, 2010-2014.

Figure C.2. Relative growth of buprenorphine standard monthly doses by state. Symphony Health dataset, 2010-2014.

Figure C.3. Prescription growth over time for 7 U.S. states. Symphony Health dataset, 2010-2014.

Appendix D. Symphony Health Final dataset: Treatment and Control by Payer Type

Figure D.1. Treatment and Control States for Assistance Program/Coupon Payers. Symphony Health dataset, 2010-2014.

Figure D.2. Treatment and Control States for Managed Medicaid. Symphony Health dataset, 2010-2014.

Figure D.3. Treatment and Control States for Medicaid (excl. Managed Medicaid). Symphony Health dataset, 2010-2014.

Figure D.4. Treatment and Control States for Medicare. Symphony Health dataset, 2010-2014.

Figure D.5. Treatment and Control States for Cash-Only Payers. Symphony Health dataset, 2010-2014.

Figure D.6. Treatment and Control States for Commercial Payers. Symphony Health dataset, 2010-2014.

Appendix E. ARCOS Dataset: total MAT supply

Figure E.1. Total MAT (buprenorphine plus methadone) supply in 7 U.S. States. ARCOS dataset, 2000-2011.

Figure E.2. Total MAT (buprenorphine plus methadone) supply in 50 U.S. States plus DC. ARCOS dataset, 2000-2011.

Appendix F. Estimates of access to buprenorphine using January 2011 as first date of federal parity implementation. Symphony Health data, 2010-2014.

Table F.1. Effect of MHPAEA's IFR on buprenorphine doses to payer types affected by federal parity (January 2011 implementation date). Symphony Health data, 2010-2014.

	(1)	(2)	(3)
Log of std. doses of buprenorphine per month per 100,000 inhabitants	Diff-in-diff	DDD	DDD
MHPAEA x Post	0.17 (0.39)		
Payer x MHPAEA x Post		-1.03 (0.75)	-1.03 (0.62)
Observations	2,198	2,198	2,198
R-squared	0.70	0.98	0.98
State FE	YES	YES	YES
Month FE	YES	YES	YES
Two-way interactions	NO	YES	YES
Clustered Std. Err.	Yes-by state	Yes-by state	Yes-by payer and state

Robust standard errors in parentheses

*** p<0.01, ** p<0.05, * p<0.1

Note: Two-way interactions for state-month, payer-state, and payer-month effects are included in the DDD specification to flexibly control for common factors that might influence the outcome of interest

Table F.2. Effects of MHPAEA's IFR on buprenorphine costs to payer types affected by federal parity (January 2011 implementation date). Symphony Health data, 2010-2014.

	(1)	(2)	(3)	(4)	(5)	(6)
Cost of std. dose of buprenorphine per month per 100,000 inhabitants	Mean Patient Cost	Mean Patient Cost	Mean Plan Cost	Mean Plan Cost	Mean Total Cost	Mean Total Cost
Payer x MHPAEA x Post	0.75 (1.22)	0.75 (0.71)	-1.46 (0.94)	-1.46 (0.88)	-0.71 (1.63)	-0.71 (1.14)
Observations	2,198	2,198	2,198	2,198	2,198	2,198
R-squared	0.98	0.98	0.96	0.96	0.98	0.98
Two-way interactions	YES	YES	YES	YES	YES	YES
Clustered Std. Err.	Yes-by state	Yes-by payer and state	Yes-by state	Yes-by payer and state	Yes-by state	Yes-by payer and state

Robust standard errors in parentheses

*** p<0.01, ** p<0.05, * p<0.1

Note: Two-way interactions for state-month, payer-state, and payer-month effects are included in the DDD specification to flexibly control for common factors that might influence the outcome of interest

Appendix G. Robustness of estimates of access to MAT in 50 states plus DC. ARCOS data.

Table G.1. Effects of MHPAEA's IFR on MAT supply (buprenorphine, methadone, and methadone buprenorphine) in states affected by federal parity. ARCOS data, sample of 50 states plus DC, 2002-2011.

Log of morphine equivalent doses per year per 100,000 inhabitants	(1) Buprenorphine & methadone supply	(2) Methadone supply only	(3) Buprenorphine supply only
MHPAEA x Post	0.06 (0.07)	0.07 (0.07)	0.00 (0.12)
Observations	510	510	496
R-squared	0.99	0.99	0.98
State FE	YES	YES	YES
Year FE	YES	YES	YES
Clustered Std. Err.	Yes-by state	Yes-by state	Yes-by state
Robust standard errors in parentheses			
*** p<0.01, ** p<0.05, * p<0.1			

Table G.2. Effects of MHPAEA's IFR on MAT supply (buprenorphine, methadone, and methadone buprenorphine) in states affected by federal parity. ARCOS data, sample of 50 states plus DC, 2002-2011, excluding transition year 2010.

	(1)	(2)	(3)
Log of morphine equivalent doses per year per 100,000 inhabitants	Buprenorphine & methadone supply	Methadone supply only	Buprenorphine supply only
MHPAEA x Post	0.16** (0.08)	0.17** (0.08)	0.01 (0.14)
Observations	561	561	445
R-squared	0.97	0.97	0.98
State FE	YES	YES	YES
Year FE	YES	YES	YES
Clustered Std. Err.	Yes-by state	Yes-by state	Yes-by state
Robust standard errors in parentheses			
*** p<0.01, ** p<0.05, * p<0.1			

Divergent Trends in Cost Sharing for Opioids and Buprenorphine in the United States²⁰

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Abstract

This paper focuses on cost sharing trends for opioids and buprenorphine during a time when the opioid epidemic was sweeping through America. Using prescription-level data from a commercial pharmacy database and the Medical Expenditure Panel Survey (MEPS), this paper describes how opioid and buprenorphine costs for patients and insurers have evolved in the past decade and a half. While total expenditures for prescription opioids has increased since 1996, the share of payments for these drugs made by patients has decreased significantly since then. Buprenorphine prices and share of expenditures paid by patients has not declined at a similar rate to those of prescription opioids. However, variation in cost sharing for buprenorphine among commercial and public payers may offer insights into the role of insurance expansions and the delivery of care by different payers. For public insurers, Medicaid expansions seem to be working in increasing access to buprenorphine. In the case of commercial insurance, public and private policymakers should encourage placing buprenorphine formulations in lower-cost sharing tiers and adopting this medication as a first line of treatment for people struggling with opioid use disorders.

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More than 33,000 people died due to opioid overdose deaths in America in 2015 (Rudd, Aleshire, Zibbell, & Matthew Gladden, 2016). This continues an upward trend in opioid-related morbidity and mortality over the past two decades (CDC, 2011a, 2011b, 2015; Kochanek, Murphy, Xu, & Tejada-Vera, 2016). While consumption of opioids has increased almost fourfold since 1999, the share of payments for these drugs made by patients has decreased significantly since then (Zhou, Florence, & Dowell, 2016). Reductions in patient out-of-pocket expenditures for prescription opioids are likely to drive up the number of people initiating use and the total number of prescription opioid users. Empirical evidence from the RAND Health Insurance Experiment, the Oregon Health Insurance Experiment, and other studies suggest that when people pay a lower share of out-of-pocket (OOP) prices for a medication, they generally increase their utilization (Finkelstein, Taubman, Wright *et al.*, 2012; Gemmill, Thomson, & Mossialos, 2008; Gerdtham & Johannesson, 1996; Gianfrancesco, Baines, & Richards, 1994; Gibson, Mark, McGuigan, Axelsen, & Wang, 2006; Gibson, McLaughlin, & Smith, 2005; Gibson, Ozminkowski, & Goetzel, 2005; Goldman, Joyce, & Karaca-Mandic, 2006; Goldman, Joyce, O'Brien *et al.*, 2004; Goldman, Joyce, & Zheng, 2007; Manning, Newhouse, Duan, Keeler, & Leibowitz, 1987)

An increase in the supply of prescription opioids will inevitably grow the pool of those susceptible to misuse these medications and increase the potential for more opioid use disorders (Powell, Pacula, & Taylor, 2015). Of approximately 97.5 million past year users of prescription opioids, about 12.5 million misused them, and 2 million people had an opioid use disorder (Hughes, Williams, Lipari *et al.*, 2016). Evidence from the CDC and the National Survey on Drug Use and Health, NSDUH, documented an upwards trend in both the total number of prescription opioids dispensed and people with opioid use disorders in recent years (Guy Jr, Zhang, Bohm *et al.*, 2017; Hughes *et al.*, 2016). This does not necessarily imply that a reduction in the supply of prescription opioids will reduce the existing number of people with an OUD or decrease overdose deaths. People might substitute from one type of opioid to another, such as heroin or fentanyl, thus making opioid use potentially more dangerous (Alpert, Powell, & Pacula, 2017; Bonnie, Kesselheim, & Clark, 2017). A balanced approach to reducing the supply of and demand for prescription opioids is needed. Such an approach should curtail the number of prescription opioids dispensed for some patients while ensuring that those with legitimate needs can still access these medications. (Bonnie *et al.*, 2017; Dowell, Haegerich, & Chou, 2016; Bradley D. Stein, Gordon, Dick *et al.*, 2015).

Expanding access to treatment for opioid use disorders is considered an essential component of a comprehensive response to the current public health problem (Bonnie *et al.*, 2017; Dowell *et al.*, 2016; Bradley D. Stein *et al.*, 2015). However, not enough people struggling with an opioid use disorder have access to treatment (C. M. Jones, Campopiano, Baldwin, & McCance-Katz, 2015). Per NSDUH

estimates, approximately 1.2 million people struggling with an OUD lacked access to any type of treatment in 2015 (Hughes *et al.*, 2016).

Medication-assisted treatment (MAT) is one of the most cost-effective treatments for opioid use disorders (Fiellin & O'Connor, 2002; Sordo, Barrio, Bravo *et al.*, 2017). Buprenorphine is a cost-effective evidence-based MAT that reduces morbidity, mortality, hospitalizations and emergency visits associated with relapse, and increases retention in treatment among those with an opioid use disorder, (Clark, Samnaliev, Baxter, & Leung, 2011; Doran, Shanahan, Mattick *et al.*, 2003; E. S. Jones, Moore, Sindelar *et al.*, 2009; Manhapra, Rosenheck, & Fiellin, 2017; Mattick, Ali, White *et al.*, 2003; Mattick, Kimber, Breen, & Davoli, 2008; Polsky, Glick, Yang *et al.*, 2010; Sordo *et al.*, 2017). Despite its proven effectiveness, the supply of these medications did not keep pace with the increase in people with OUD in America (C. M. Jones *et al.*, 2015; Pacula, Gordon, Dick *et al.*, 2015; Volkow, Frieden, Hyde, & Cha, 2014). Because people diagnosed with an OUD may need to pay for these medications for an extended period, as is the case for patients with other chronic diseases, financial costs may be one of the most important barriers to treatment. (Gemmell *et al.*, 2008; Gibson, Ozminkowski, *et al.*, 2005; Goldman *et al.*, 2007; Grogan, Andrews, Abraham *et al.*, 2016; Mojtabai & Olfson, 2003; Rinaldo & Rinaldo, 2013; Winkelmann, 2004).

Insurance expansions, such as the Mental Health Parity and Addiction Equity Act (MHPAEA) of 2008 and the Medicaid expansions following the implementation of the Affordable Care Act (ACA) in January of 2014, could have increased the demand for medication-assisted treatment by lowering the out-of-pocket price faced by consumers (Barry & Sindelar, 2007). There is evidence of a modest impact of insurance parity on utilization of broad behavioral and substance use disorder treatments, with some indication of decreased financial costs burdened by patients following the implementation of MHPAEA (Ettner, Harwood, Thalmayer *et al.*, 2016; McGinty, Busch, Stuart *et al.*, 2015). However, there is no evidence of increased access to or utilization of buprenorphine for the treatment of opioid use disorders for those affected by the implementation of MHPAEA (Maksabedian, 2017). In the case of the Affordable Care Act, some studies have documented increases in buprenorphine expenditures and treatment utilization following the 2014 Medicaid expansion (Clemans-Cope, Epstein, & Kenney, 2017; Clemans-Cope, Lynch, Epstein, & Kenney, 2017; Maclean & Saloner, 2017).

While emerging research and evaluations have documented increases in buprenorphine access and utilization following MHPAEA and Medicaid expansions, none have estimated buprenorphine costs at a time when these insurance expansions took place. This paper adds to the current literature by describing cost sharing trends and out-of-pocket costs for outpatient prescription opioids and buprenorphine during the implementation years of MHPAEA and Medicaid expansions. Using prescription level data from a commercial pharmacy database and the Medical Expenditure Panel Survey

(MEPS), this study describes how opioid and buprenorphine costs for patients and insurers have evolved over time. The first focus of this paper is on out-of-pocket costs and share of costs paid by patients for prescription opioids and buprenorphine from 2010 to 2014, the years during which MHPAEA and Medicaid expansions took place. If the Medicaid expansions decreased prices of buprenorphine to consumers, then this would partly explain the increase in utilization documented by others. This study also examines the variation in out-of-pocket costs and cost sharing for buprenorphine by type of commercial and public insurers, as this may offer a glimpse of potential avenues for increasing access to buprenorphine treatment. The last section of this paper discusses how insurance expansions, specifically Medicaid expansions after the implementation of the ACA, may have improved access to buprenorphine for those with an OUD.

Data

This study focuses on the costs of prescription opioids and buprenorphine using two sources of data. The database used to estimate expenditures for prescription opioids is the Medical Expenditure Panel Survey (MEPS) Household Component and Prescribed Medicines Data files from 1996 through 2014. This is a nationally representative longitudinal dataset administered by the Agency for Healthcare Research and Quality (AHRQ) and the National Center for Health Statistics. Estimated expenditures, defined as the sum of payments for all opioid prescriptions, are for all outpatient prescribed opioids for the U.S. civilian noninstitutionalized population. As this is an annual survey, expenses are calculated on a yearly basis. In the case of opioid prescriptions, this is reported as the mean annual out-of-pocket expenditures. Following established methodology, this study includes refills and original prescriptions for opioids in expense estimates and adjusts them using the GDP Price Index, with 2014 as the base year (Stagnitti, 2015; Zhou *et al.*, 2016). Both methadone and buprenorphine prescriptions are included in the MEPS sample. Observed methadone prescriptions are included as pharmacy prescriptions for this medication are dispensed for pain management, not treatment of opioid use disorders. Buprenorphine prescriptions were not excluded from the sample to maintain the representativeness of MEPS data using person-level weights. As prescriptions for buprenorphine were only observed in 2014 and comprised less than 0.02% of the total sample, including buprenorphine in this analysis does not alter any of the results or modify the trends for observed prices.

For medication-assisted treatment estimates, this study focuses solely on buprenorphine and its distribution through retail pharmacies. Buprenorphine is not the only pharmacotherapy available for the treatment of opioid use disorders. However, this drug has been the focus of federal efforts to expand treatment availability since regulatory barriers make methadone harder to access (Clemans-Cope, Lynch, *et al.*, 2017). Methadone for the treatment of OUD is not available for purchase in pharmacies and is not

included in this study because of the lack of publicly available data sources containing information on the cost of drugs distributed through Opioid Treatment Programs (OTP). The data used to estimate buprenorphine costs for this study is the *Symphony Health Solutions Integrated Dataverse* ("IDV Integrated Dataverse ", 2015), henceforth "Symphony Health". Symphony Health is a restricted pharmacy database collected electronically by a commercial provider, Symphony Health Solutions. This database is a collection of prescription transactions at the retail (i.e., pharmacy) level from more than 80% of all pharmacies in the country, and containing information on approximately 90% of prescriptions filled at retail pharmacies in the United States. Missing pharmacies are generally independent or part of small chains. Symphony obtains pharmacy data directly from prescription drug claim processors and payers, using the same data that get verified against standard reporting information to the US government (B. D. Stein, Sorbero, Dick *et al.*, 2016). Symphony Health data allows the estimation of the cost of buprenorphine itself without additional costs of wrap-around services that may be administered during detoxification or induction (done on an inpatient basis) or with behavioral therapies (if delivered in an OTP). Prescription data for this study was drawn from a representative random sample of 8,365 physicians who wrote at least one prescription for buprenorphine and resided in one of seven states: New York, Massachusetts, California, Pennsylvania, Michigan, Florida, and Texas. These states were selected because they contain approximately 42% of the US population. They also represent diversity in terms of the opioid problem in America. States like Florida, and Massachusetts have had consistently higher rates of opioid overdose deaths compared to the national average from 1999 through 2015. In contrast, states like California and Texas had lower opioid overdose deaths compared to the national average in the same period (KFF, 2017b). For this sample, 71,962 unique patients purchased 864,207 buprenorphine prescriptions in these seven states between January 2010 and June 2014.

The costs of buprenorphine examined in this study represent only the cost of the medication, not the cost of dispensing it, as this analysis uses information reported only in pharmacy claims. However, looking at standardized buprenorphine doses given during the maintenance phase, this study can focus on the variation in costs incurred by patients and payers over time.

This study uses monthly costs of buprenorphine, derived from a 'standard daily dose' for buprenorphine maintenance, to calculate OOP costs to patients and types of insurance. Since different payers have different rules regarding length of treatment covered and clients can purchase varying quantities of buprenorphine by type of formulation, this measure is constructed to provide reliable comparisons across payers and formulations over time. The daily dose of buprenorphine is set at 16 mg to be consistent with national guidelines (Kampman & Jarvis, 2015) and because it is within the usual range of dosage for patients on maintenance treatment (SAMHSA, 2004). To generate monthly costs, the estimated daily cost is multiplied by 30. Total costs of buprenorphine are the sum of patient costs plus

third payer costs. Shares of out-of-pocket costs for patients are calculated as a percentage of the total cost of buprenorphine. All cost estimates were adjusted using the GDP Price Index, with 2014 as the base year. Data management and analysis on both MEPS and Symphony Health data samples were conducted using Stata 14.

Declining out-of-pocket costs for prescription opioids but no similar reductions for buprenorphine

Even with increasing expenditures for outpatient prescription opioids from 1996 to 2014, consumers have been paying less and less for this type of medication. Mean OOP expenditures have experienced a steady decline over time. Figure 1 illustrates the declining out-of-pocket expenditures as well as the increasing shift in expenditures paid by insurers, both public and private, in 2014 dollars. Expenditures for prescription opioids paid by insurers rose steadily over time, from a mean expense for outpatient prescribed opioids of \$21.7 in 1996 to a high of \$223.7 in 2011. The sharp increase in third party payments in 2006 is largely attributed to increases in spending by Medicare and commercial insurers due to the implementation of Medicare part D (Nudelman, 2016; Powell *et al.*, 2015; Zhou *et al.*, 2016). It remains to be seen if the decrease in third party expenses observed after 2011 signals the beginning of a new trend or just a blip in the long-term trajectory of prices for these medications.

Initially, OOP expenditures kept pace with those of third party payer expenses for prescription opioids, specifically from 1996 through 2001. However, patients have been paying less, in real terms, for their opioid prescriptions for over a decade. While mean patient expenditures for opioid prescriptions were \$84.9 in 2002, they dropped to \$37.1 in 2014. This represents a 56.3% reduction in inflation-adjusted dollars in OOP expenditures for prescription opioids.

Figure 1. Mean out-of-pocket and third payer expenses for outpatient prescribed opioids. MEPS, 1996-2014.

Note: Medical Expenditures Panel Survey data. 1996-2014

Out-of-pocket expenditures for prescription opioids have not only decreased in real terms but also as a share of total expenditures. While this is somewhat apparent from Figure 1, the precipitous drop in OOP share paid by patients as a percentage of total prescription opioids expenses over time is clearer in Figure 2. Patients paid about 62% of the total cost for their outpatient prescription opioids in 1998. By 2014, their share of total costs decreased to 18.4%. Given that demand curves slope downwards, it is perhaps unsurprising that the amount of outpatient prescribed opioids has paralleled the decrease in the cost of these medications faced by patients (Stagnitti, 2015). All differences between estimates previously discussed are statistically significant at the 0.05 level.

Figure 2. Mean out-of-pocket share for outpatient prescribed opioids. MEPS, 1996-2014.

Note: Medical Expenditures Panel Survey data. 1996-2014

The mean total cost for a monthly dose of buprenorphine decreased from 2010 through 2014, as figure 3 indicates. This reduction is driven mostly by falling costs paid by third party payers, not patients. Mean patient costs for buprenorphine experienced a slight decline over time. They paid, on average, \$215.7 for a monthly dose of buprenorphine in 2010. This amount had declined slightly by 2014, to an average of \$188.1, or a 12.8% decrease. For third party payers, the cost for a monthly dose of buprenorphine decreased significantly more. In 2010, the cost of a monthly dose of buprenorphine was \$222.1 for a third party payer; by 2014, a monthly dose of buprenorphine was \$162.7, a 26.8% reduction. These differences in means were statistically significant at the 0.01 level.

Even with a slight decrease for a monthly dose of buprenorphine for patients, financial barriers remain a significant concern for access to these medications. The costs for buprenorphine contrast with those for prescription opioids presented above, where patients experienced steep declines in out-of-pocket costs and third party payers saw increases in the same period.

Figure 3. Mean monthly out-of-pocket and third payer costs for a standard dose of outpatient prescribed buprenorphine. Symphony Health data, 2010-2014.

Figure 4 shows that buprenorphine out-of-pocket costs as a share of total costs have increased, albeit slightly, over time. While patients paid 52.2% of the total cost of a monthly dose of buprenorphine in 2010, their share of total costs had increased to 58.5% by 2014. This difference was statistically significant at the 0.01 level. Available evidence suggests that increasing levels of prescription drug cost sharing decreases the consumption of prescription drugs and may produce treatment disruptions and outcomes of care for people who are chronically ill (Gibson, Ozminkowski, *et al.*, 2005; Goldman *et al.*, 2007). However, figures 3 and 4 may hide variation in cost sharing by type of third party payer in the US.

Figure 4. Mean monthly out-of-pocket share for a standard dose of outpatient prescribed buprenorphine. Symphony Health data, 2010-2014.

Out-of-pocket expenditures vary substantially by type of payer

Figure 5 shows that commercial insurance payers essentially split the cost of a monthly dose of buprenorphine with patients. Despite this, the OOP share paid by patients increased over time. In the case of patients with commercial insurance, they paid an average of 48.5% of out-of-pocket share of costs in the period between January 2010 and June 2014. This share exhibits a consistent increase over time, from 38.8% in 2010 to 47.9% in 2014. Similarly, patients on assistance programs (i.e. coupons) experienced an increase in their share of cost sharing for buprenorphine. Their out-of-pocket share of costs for a monthly dose of buprenorphine increased steadily from 43% in 2010 to 78.8% in June 2014.

Unlike those with commercial insurance, patients with public insurance paid much lower out-of-pocket shares for their monthly doses of buprenorphine while experiencing very little growth in the same period. On average, patients with Medicare paid 13.7% of the share of total monthly costs of buprenorphine from 2010 to 2014. This share exhibits a small but statistically significant increase over

time, from 11.5% in 2010 to 13.6% in 2014. People with Medicaid and Managed Medicaid paid 3.4% and 5.6%, respectively, of the total share of buprenorphine between January 2010 and June 2014. For patients with Medicaid, their share of out-of-pocket costs experienced a small increase in this period from 3.4% in 2010 to 4% in 2014. For those with Managed Medicaid, their share of out-of-pocket costs experienced a small decrease in this period from 6.2% in 2010 to 5.5% in 2014. All differences previously discussed were statistically significant at the 0.01 level. In terms of differences between payers, all were statistically significant at the 0.01 level.

Figure 5. Mean monthly out-of-pocket shares for a standard dose of outpatient prescribed buprenorphine by type of payer. Symphony Health data, 2010-2014.

Note: Standard dose of buprenorphine defined as 16 mg per day.

Figure 6 presents OOP monthly costs for a standard dose of buprenorphine by type of payer. Again, there is significant variation in costs from one type of payer to another. Mean OOP monthly costs for buprenorphine were significantly higher among patients using coupons (\$253.2), cash-only (\$279.9), and private insurance (\$183.9) compared to those with public insurance. Mean OOP monthly costs for patients with Medicare (\$39.5), Medicaid (\$11.8), and Managed Medicaid (\$16.5) were substantially lower. All differences in monthly means between payers are statistically significant at the 0.01 level.

Significant within-plan variation remains for a monthly dose of buprenorphine even though all OOP costs experienced a modest decline between 2010 and 2014. In the case of patients with commercial insurance, their out-of-pocket costs experienced a decrease from \$201.1 in 2010 to \$168.8 in 2014. Similarly, out-of-pocket costs for patients on assistance programs (i.e. coupons) saw a small decrease from \$271.4 in 2010 to \$243.7 in 2014. For those without insurance (i.e., cash only payers), their OOP costs also decreased from \$305.9 in 2010 to \$275 in 2014.

Patients with public insurance paid much lower out-of-pocket costs for their monthly doses of buprenorphine with a wide range of changes in mean costs in the same period. On average, patients with Medicaid paid \$12.9 in 2010 for a monthly dose of buprenorphine. This out-of-pocket cost exhibits a small but statistically significant increase over time, to \$16.7 in 2014. In contrast, people with Managed Medicaid saw a 47% reduction in out-of-pockets costs for a monthly dose of buprenorphine from \$22 in 2010 to \$11.7 in 2014. For patients with Medicare, they also saw decreases in their out-of-pocket costs from \$51.6 in 2010 to \$34.7 in 2014. All differences previously discussed were statistically significant at the 0.01 level.

Although pharmaceutical firms incur in a single average cost to produce each of these medications, findings from figures 5 and 6 suggest that the amount paid for them varies significantly depending on the payer negotiating prices. Patients with public insurance programs pay significantly less for a standard dose of buprenorphine than those with commercial insurance or the uninsured while total costs remaining similar between public and private payers. This suggest that some of the cost reductions are not being passed on to the consumer in the case of private insurance. Private and public policies should consider their roles in addressing the opioid epidemic through a systemic approach in the health care landscape in America.

Figure 6. Mean monthly out-of-pocket costs for a standard dose of outpatient prescribed buprenorphine by type of payer. Symphony Health data, 2010-2014.

Note: Standard dose of buprenorphine defined as 16 mg per day.

Medicaid expansion increased access to buprenorphine treatment

Medicaid expansion increased access to buprenorphine and is aiding in the fight against the opioid epidemic. A growing body of evidence suggests that the Medicaid expansions under the Affordable Care Act increased buprenorphine prescriptions and spending (Clemans-Cope, Epstein, *et al.*, 2017; Clemans-Cope, Lynch, *et al.*, 2017; Maclean *et al.*, 2017; Wen, Hockenberry, Borders, & Druss, 2017). Even though Medicaid already covers 30% of all people diagnosed with an OUD (KFF, 2017a), it will also become the largest payer of substance use treatment with its spending projected to increase from \$5 billion to \$12 billion by 2020 (Andrews, Grogan, Brennan, & Pollack, 2015). With Medicaid programs providing coverage for buprenorphine in all states and the District of Columbia, albeit with quantitative and non-quantitative limits, this insurance expansion may be one of the few successful policies that increase access to medication-assisted treatment.

None of the previous studies have examined the role of price on buprenorphine utilization. Figure 7 shows that total costs (patient plus plan costs) of buprenorphine decreased substantially for both Medicaid and Managed Medicaid three years before the implementation of the expansion under the Affordable Care Act. Despite increased enrollment following the expansion in January 2014, total buprenorphine costs remained essentially steady after that. This finding, combined with the fact that OOP and OOP share of costs remained the lowest among patients with Medicaid and Managed Medicaid, suggests that public payers may be well suited to increase access to affordable MAT while keeping overall costs (to patients?) down. A concern regarding public insurance expansion is that utilization could shift from one payer to another.

Research by the Urban Institute and the IMS Institute for Health Care Informatics acknowledge that part of the growth in buprenorphine prescriptions covered by Medicaid could have shifted payments away from other insurers (Clemans-Cope, Epstein, *et al.*, 2017; Clemans-Cope, Lynch, *et al.*, 2017; IMS, 2016). Despite this, the total increase in buprenorphine supply and number of prescriptions suggests that this share-shifting may only explain part of the increase in Medicaid expenditures. The reductions in cash-only buprenorphine payments, while shares for other sources remaining stable, indicate that part of this shift may have benefitted the previously uninsured (IMS, 2016).

Through reductions in financial barriers to buprenorphine treatment and by reaching the population the needs it the most, insurance expansions that target specific populations may be able to achieve greater treatment access at lower costs compared to commercial insurers. However, public policies aiming to curb the opioid epidemic need to consider the role of commercial insurance. As the largest providers of buprenorphine medication in the country, commercial insurers may be the key drivers in bridging the treatment gap.

The promise of commercial insurance as a provider of buprenorphine

Per analysis by the IMS Institute for Healthcare Informatics, commercial insurance plans covered 57% of all buprenorphine prescriptions in 2016. This was followed by public funding (Medicaid plus Medicare), which paid about 32% of total buprenorphine prescriptions (IMS, 2016). The Symphony Health data sample used in this analysis provides a similar picture, with commercial payers representing 58.5% of all buprenorphine prescriptions in the study period available. Results from this study show that buprenorphine patients covered by private insurance have not seen a decrease in cost sharing for this type of medication from 2010 until the first half of 2014 while total costs decreased continuously during the same period while seeing only a slight decline in actual costs. At the same time, commercial insurers are able to negotiate lower prices compared to most public payers, with little evidence of cost reductions passed on to the consumer (Maksabedian, Pacula, & Stein, forthcoming). Figure 7 shows that total costs

for buprenorphine, patient plus third payer costs, were essentially equal for all public and private payers by the end of 2014. This further suggests that insurance coverage for substance use disorder treatment benefits for commercial providers, encouraged by insurance expansions like MHPAEA and the ACA, is not enough to increase utilization if prices faced by patients do not decrease.

Figure 7. Mean monthly total costs for a standard dose of outpatient prescribed buprenorphine by type of payer. Symphony Health data, 2010-2014.

Note: Standard dose of buprenorphine defined as 16 mg per day.

The lack of a decline in cost sharing for buprenorphine relative to prescription opioids may indicate that buprenorphine bills for commercial insurers are being placed on higher cost-sharing tiers. This may occur even after they have generic competitors, as is the case for buprenorphine. Policies aimed at increasing access to medication-assisted treatment through commercial insurers should focus on the classification of buprenorphine in drug formularies, emphasizing the need for at least some lower-cost sharing options to be available, particularly in light of the availability of generic buprenorphine. These policies should also make sure that essential provisions of MHPAEA, like reductions in non-quantitative

treatment limitations, such as preauthorization and ‘fail first’ regulations, for buprenorphine be assessed in terms of their implementation within commercial insurers.

Policy Implications

Research shows that insurance expansions can have unintended consequences on population health, both negative and positive. Medicare Part D contributed to the opioid epidemic through increased opioid prescriptions and diversion to illegal drug markets (Powell *et al.*, 2015). Despite MHPAEA’s attempts to reduce benefit disparities between substance use disorder treatment and other medical services, it largely failed at increasing buprenorphine utilization and access following its implementation. However, it appears what failed in the commercial system seemed to work relatively well for public payers, as states that expanded Medicaid post ACA do appear to demonstrate increased access to buprenorphine treatment for those with an opioid use disorder (Clemans-Cope, Epstein, *et al.*, 2017; Clemans-Cope, Lynch, *et al.*, 2017; Maclean *et al.*, 2017). Moreover, my findings here show that this was done at lower cost to the public insurers and patients. Policymakers looking to increase access to buprenorphine for opioid use disorder treatment should consider how and why these two alternative types of insurers had such dramatically different experiences with this drug.

Limitations

This study has several limitations. First, MEPS data did not contain enough observations to analyze prices and expenditures for buprenorphine over time. While Symphony Health provides information on costs and prescriptions of buprenorphine, the lack of data prior to 2010 makes cost comparisons between opioid prescriptions and MAT before this date impossible. In addition, some states in the Symphony Health data did not implement Medicaid expansions (Texas and Florida), or did so later (Michigan in April of 2014; Pennsylvania in January of 2015), so estimates for buprenorphine OOP costs and shares for Medicaid may mask additional variation between these states. Finally, the seven state sample included in Symphony Health data represent approximately 42% of the US population. While this is a large percentage of the total population, results derived from this sample may not be nationally representative. Despite these limitations, this study adds to the current literature by estimating buprenorphine costs and cost sharing trends by type of payer at a time when the MHPAEA and Medicaid insurance expansions took place. Variation in cost sharing and total costs of buprenorphine are important for understanding overall access, and the differences identified among commercial and public payers may offer insights into the role of insurance expansions and the delivery of care by different payers.

Conclusions

Even with increasing expenditures for outpatient prescription opioids from 1996 to 2014, consumers have been paying less and less for this type of medication, both in out-of-pocket expenditures and as a share of their total cost. In contrast to this finding and a time when the opioid epidemic was sweeping through America, out-of-pocket expenditures for buprenorphine experienced very little decline over time. While the mean total cost of buprenorphine showed a slight decline from 2010 to 2014, this was mostly driven by falling costs paid by insurers, not patients.

Importantly, the share of out-of-pocket expenditures for buprenorphine varies substantially by type of payer. Research shows that insurance expansions contributed to worsening the opioid epidemic, in the case of Medicare Part D, and increased access to buprenorphine treatment for those with an OUD, in the case of state Medicaid expansions. Policymakers should consider the variation in the roles that public and private insurance play in providing substance use disorder treatment when designing policies that aim to tackle the opioid epidemic. For public insurers, Medicaid expansions seem to be working in increasing access to buprenorphine, while Medicare Part D should be closely monitored to prevent excessive opioid prescriptions and diversion to illicit markets. In the case of commercial insurance, public and private policymakers should encourage placing buprenorphine formulations in lower-cost sharing tiers and adopting this medication as a first line of treatment for people struggling with opioid use disorders.

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Appendix

Figure A1. Mean out-of-pocket and commercial insurance shares for outpatient prescribed buprenorphine. Symphony Health data, 2010-2014.

Note: Standard dose of buprenorphine defined as 16 mg per day.

Figure A2. Mean out-of-pocket share and Medicare shares for outpatient prescribed buprenorphine. Symphony Health data, 2010-2014.

Note: Standard dose of buprenorphine defined as 16 mg per day.

Figure A3. Mean out-of-pocket and Medicaid shares for outpatient prescribed buprenorphine.
Symphony Health data, 2010-2014.

Note: Standard dose of buprenorphine defined as 16 mg per day.

Figure A4. Mean out-of-pocket and Managed Medicaid shares for outpatient prescribed buprenorphine. Symphony Health data, 2010-2014.

Note: Standard dose of buprenorphine defined as 16 mg per day.

Figure A5. Mean out-of-pocket and assistance programs (coupons) for outpatient prescribed buprenorphine. Symphony Health data, 2010-2014.

Note: Standard dose of buprenorphine defined as 16 mg per day.