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How well do doctors know their patients? Evidence from a mandatory access prescription drug monitoring program

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Abstract

Many opioid control policies target the prescribing behavior of health care providers. In this paper, we study the first comprehensive state-level policy requiring providers to access patients' opioid history before making prescribing decisions. We compare prescribers in Kentucky, which implemented this policy in 2012, to those in a control state, Indiana. Our main difference-in-differences analysis uses the universe of prescriptions filled in the two states to assess how the information provided affected prescribing behavior. We find that a significant share of low-volume providers stopped prescribing opioids altogether after the policy was implemented, though this change accounted for a small share of the reduction in total volume. The most important margin of response was to prescribe opioids to fewer patients. Although providers disproportionately discontinued treating patients whose opioid histories showed the use of multiple providers, there were also economically meaningful reductions for patients without multiple providers and single-use acute patients.

KEYWORDS

opioid prescribing, physician behavior, prescription drug monitoring programs

JEL CLASSIFICATION

I18; H75; I11; I12

1 | INTRODUCTION

The number of prescription opioids filled in the United States increased by roughly 300% in the first decade of the twenty-first century (Kunins, Farley & Dowell, 2013), contributing to a similarly dramatic increase in overdose deaths (Chen, Hedegaard & Warner, 2014; Dart et al., 2015; Rudd, Aleshire, Zibbell & Matthew Gladden, 2016). Although the total volume of prescriptions has declined since 2010, nearly two million Americans had an opioid addiction in 2015 (Han et al., 2017). Although illicitly imported or manufactured narcotics are now a significant contributor, the epidemic has its roots in the misuse of prescriptions legally obtained from medical professionals. Thus, a number of policy responses to the opioid epidemic have targeted prescribing behavior.

Among the most significant policy responses to this public health crisis are state-level prescription drug monitoring programs (PDMPs). These systems track all purchases of Drug Enforcement Agency (DEA) scheduled drugs in the state and were originally designed to identify inappropriate or suspicious utilization, often for law enforcement. Current programs are designed to influence the behavior of health care practitioners by providing comprehensive and timely information about patients' prescription histories. Forty-nine states have established a PDMP, and many have strengthened their programs over time.

Historically, most PDMPs relied on providers to take the initiative to access patient prescription histories. Evidence from several states suggests that when PDMPs are voluntary, provider engagement is low (Haffajee et al., 2015). This may explain results from several studies, which find no effect of PDMPs on a variety of opioid-related outcomes (Brady et al., 2014; Jena et al., 2014; Li et al., 2014; Paulozzi, Kilbourne & Desai, 2011). According to the National Association of Model State Drug Laws, by 2019 more than 40 states have sought to increase provider engagement via "mandatory access" laws. These policies require prescribers to consult the PDMP in certain circumstances before prescribing opioids and other DEA-scheduled drugs. Recent studies suggest that such mandates reduce the volume of opioids prescribed and indicators of misuse (Bao et al., 2018; Buchmueller & Carey, 2018; Dowell et al., 2016; Grecu et al., 2019; Haffajee et al., 2018; Meinhofer, 2018; Strickler et al., 2019; Wen, Hockenberry, Jeng & Bao, 2019; Wen, Schackman, Aden & Bao, 2017).

The first comprehensive mandatory access policy was enacted and implemented in Kentucky in 2012. It required all providers in the state, with limited exceptions, to check the PDMP before prescribing opioids to new patients and at intervals for continuing patients. In contrast, previous mandates in other states applied only to certain types of providers or circumstances. Since it implemented its mandate in 2012, Kentucky's PDMP has been held up as a model program (Shatterproof, 2016). Subsequently, a majority of other states enacted similar laws. Thus, Kentucky represents an excellent case study for investigating the impact of comprehensive mandatory access legislation on opioid prescribing.

We examine how this policy altered the prescribing behavior of Kentucky providers compared with providers in neighboring Indiana, which represents a good counterfactual for Kentucky for several reasons. Both states were among the top ten in opioid prescriptions per capita in 2012 (Paulozzi, Mack & Hockenberry, 2014). The two states are also very similar in terms of demographics, economic conditions, health systems, and health insurance coverage during the period of our analysis. Furthermore, until Kentucky's 2012 reform, the two states' PDMPs and other opioid policies were quite similar, as detailed in Section 2.

We estimate the policy's effect on the total morphine-equivalent dosage (MED) prescribed by each provider in each quarter. We find that after the policy went into effect, Kentucky providers significantly decreased MED prescribed relative to Indiana providers. To shed light on the changes providers made, we estimate the effect of the policy on four distinct margins: (1) whether the provider writes any opioid prescriptions, (2) the number of patients to whom they prescribe opioids, (3) the number of days supplied per patient, and (4) the average MED per day.

Our results suggest that providers primarily responded along the first two margins. After the policy went into effect, there was a 3.8 point decline in the percentage of providers writing opioid prescriptions in Kentucky (relative to the change in Indiana). Among providers that wrote any opioid prescriptions in a quarter, there was a roughly 16% decline in the number of patients. Decreases in the days per prescription and MED per day were smaller in magnitude and sensitive to specification.

There is substantial variation in provider practice style related to opioid prescribing (Makary, Overton & Wang, 2017; Schnell & Currie, 2018; Thiels et al., 2017). To test for heterogeneous policy effects, we sort providers into quartiles based on their prescribing in the 6 months prior to the mandatory access policy. Like previous research, we observe substantial variation in opioid prescribing across providers. In our data, prior to the policy change, providers in the top quartile account for 97% of total MED supplied, whereas, conditional on prescribing, the modal provider in the lowest quartile had only one patient with an opioid prescription. The heterogeneity analysis reveals that the decrease in the percentage of providers writing any opioid prescriptions was largely limited to low-volume providers. Low-volume providers experience a five percentage point (41%) reduction in the probability of any opioid prescribing. Among high-volume providers, the main response to the policy was to prescribe opioids to fewer patients.

A key question is what type of patients were affected. Ideally, increasing provider PDMP engagement will not simply reduce opioid prescribing, but will result in more appropriate prescribing. Providers who access PDMP records will be alerted to patients with utilization patterns that are consistent with misuse or diversion. We thus investigate whether providers targeted their reductions on patients with histories suggestive of high-risk use. We characterize patients using three mutually exclusive categories. The first consists of "single use" patients who fill a single prescription in a quarter and none in the following quarter. This utilization pattern suggests post-surgical acute care and is generally considered low risk. We divide patients who fill multiple prescriptions into two groups, depending on whether or not they exhibit behaviors consistent with "shopping," which we define as obtaining opioids from three or more prescribers or pharmacies in a quarter.

The results from this part of the analysis suggest that providers target their reductions on those who meet the shopping criteria. The average provider reduced the total number of patients with opioid prescriptions by 19% and the

number of "shoppers" by one-third. Providers reduce opioid supply to other patient types by a smaller but statistically significant amount. Prescriptions to single-use patients fell by 12%. Thus, although prescriptions to "shoppers" were most affected, the mandatory access policy may have induced a broader "chilling" effect on opioid prescribing.

An important strength of our analysis is that it is based on the "universe" of DEA scheduled prescriptions in Kentucky and Indiana. By comparison, most of the research on PDMPs uses insurance claims datasets or state-level aggregate data. Administrative claims datasets are limited to the enrollees of a particular payer, such as Medicare (Buchmueller & Carey, 2018), Medicaid (Wen et al., 2017), or a private insurer (Haffajee et al., 2018). Our PDMP dataset includes prescriptions purchased with all insurance types plus cash purchases. The use of cash correlates with measures of misuse such as doctor-shopping (Cepeda et al., 2013). Not only is our data representative of the entire population but also the completeness of the PDMP data allows us to account for all of the provider's patients and to conduct a provider-level analysis. This is important given that the policy is designed to affect provider behavior. With our provider-level analysis, we are able to not only estimate the overall effect of the policy on opioid prescriptions but also to investigate in more detail the provider behavior driving the results.

We explore the impact of the provision of a particular type of information—opioid prescribing histories—across the full distribution of providers. This research complements other recent field experiments that examine the change in prescribing by providers in response to information. One such experiment provided "peer comparison" information to providers prescribing opioids at extremely high levels in Medicare; this experiment concluded that such information had no effect on prescribing and ruled out meaningfully sized impacts (Sacarny et al., 2016). However, a similar experiment targeting prescribing of antipsychotics to dementia and Alzheimer patients found large decreases in prescribing, including substantial effects on clinically appropriate psychiatric patients (Sacarny et al., 2018). This finding echoes our observation that the provider response, while larger among shopper patients, also reduced prescribing to single-use patients. Finally, a small experiment found that providers who were informed of the overdose death of an opioid patient prescribed 10% less MED in the following 3 months compared with matched prescribers who were not informed (Doctor et al., 2018).

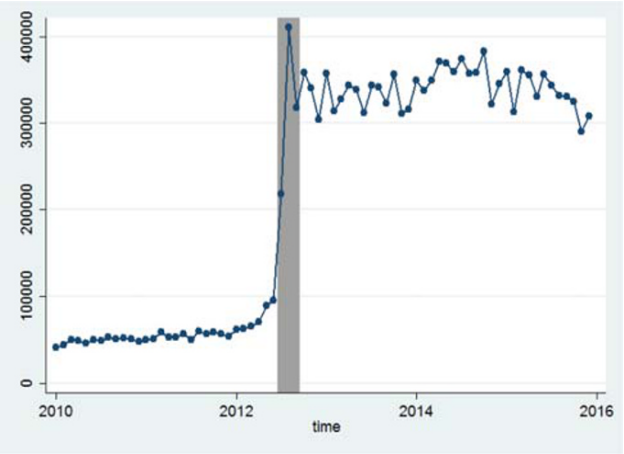
2 | PDMP AND OTHER OPIOID POLICIES IN KENTUCKY AND INDIANA

By 2012, both Kentucky and Indiana had well-established PDMPs. The Kentucky All Schedule Prescription Electronic Reporting (KASPER) system first became operational, with its data available to providers and dispensers, in July 1999. Indiana's PDMP, known as the INSPECT system, was established 1year earlier, but access was initially limited to state regulators; providers and dispensers gained access in March 2009. Law enforcement agencies in both states are allowed to access the data in connection with ongoing investigations. Both systems capture data on prescriptions for DEA Schedule II–V drugs. During our entire sample period, physicians in both Indiana and Kentucky could delegate access to the PDMP to a nurse or other employee.

Kentucky's mandatory access requirement was established by House Bill 1 (HB 1), which was passed in April 2012 and went into effect that July. The law requires all providers who are licensed to prescribe DEA-scheduled drugs to register with the PDMP and refers noncompliers to the Kentucky Board of Medical Licensure. With limited exceptions, providers are also required to query the PDMP the first time they order any Schedule II prescription (and Schedule III containing hydrocodone) for a patient and at least every 3 months thereafter. During the period we analyze, providers in Indiana faced no such requirements.

It is important to note that the Kentucky mandatory access requirement did *not* change any aspect of the reporting of controlled substance prescriptions to the Kentucky PDMP. Over the entire sample period, pharmacies reported all fills of DEA-scheduled prescriptions to KASPER using established procedures, which are unrelated to provider registration or querying behavior.

Indiana makes a useful comparator for Kentucky due to its similarity on numerous dimensions, including other policies that might affect the demand for and supply of prescription opioids. The states have similar demographics, income, and employment over the time period (see Table A1 in the supporting information). They ranked 35th (KY) and 37th (IN) in physicians per capita (Center for Workforce Studies, 2013). Neither state allowed the medical or recreational use of marijuana. During the period of our analysis, Indiana did not have a law allowing third-party prescribing and lay administration of naloxone. In Kentucky, such a law went into effect in June 2013. Neither state had a "good samaritan law" providing immunity from prosecution for drug possession to anyone who seeks emergency medical assistance in the event of a drug overdose.



Note: Monthly administrative count, obtained via personal communication with KASPER staff. Shaded area represents implementation quarter 2012q3.

FIGURE 1 Requests for Kentucky All Schedule Prescription Electronic Reporting (KASPER) reports, 2010–2015. [Colour figure can be viewed at wileyonlinelibrary.com]

One difference between the two states is that HB 1 also included a provision regulating pain clinics.[1] The law limits ownership of pain clinics to physicians (though there is a grandfather provision for facilities established prior to July 2012) and a physician with appropriate board certification must be on-site practicing medicine at least 50% of the time. The law also requires that clinics accept private insurance and prohibits payments from parties other than a patient, their spouse, parent/guardian, or insurer. Pain clinic physicians are required to complete 10 hours of continuing medical education in pain management during each registration period.

According to KASPER, between mid-2012, when the policy went into effect, and mid-2015, 24 pain clinics closed. Although we cannot definitively disentangle the effect of the mandatory access policy from these pain clinic provisions, previous research using national data suggests that the independent effect of pain clinic laws is minimal and that the estimated effect of a PDMP mandate is not sensitive to how the analysis controls for such laws (Buchmueller & Carey, 2018; Dowell, Zhang, Noonan & Hockenberry, 2016). Later, we provide several pieces of evidence that suggest that Kentucky's pain clinic regulations are not the predominant cause of the decline in opioid prescribing in the state.

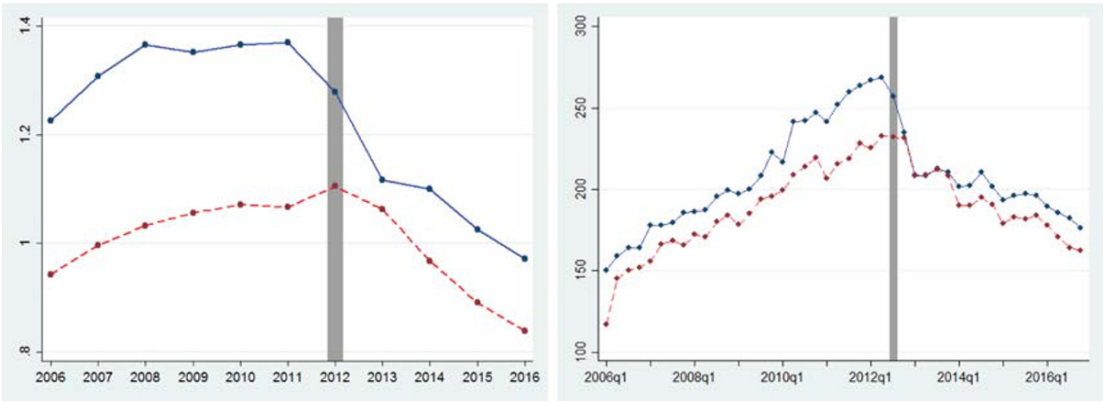
Horwitz et al. (2018) argue that research on the impact of PDMPs is often hampered by ambiguity about when exactly programs became operational. From Figure 1, it should be clear that there is no such problem dating when Kentucky's access mandate went into effect. The figure presents raw administrative data on the monthly number of requests for KASPER records between 2010 and 2016. The gray bar is at 2012q3, when the mandatory access policy was implemented. Prior to that, there were 60,000–70,000 requests made per month. Apart from a slight increase in the 2 months before implementation, there was very little trend in the number of monthly requests. The figure shows a fivefold increase in KASPER requests coincident with the policy implementation. Similarly, the number of providers registered with KASPER rose from 37% of DEA registrants in June 2012 to 97% a year later (Freeman et al., 2015). Available evidence suggests that during the period of our analysis, PDMP queries in Indiana were comparable with pre-period usage in Kentucky (Allain, 2012).

3 | DATA AND DESCRIPTIVE ANALYSIS

3.1 | Aggregate state-level data

Data from Indiana's PDMP begin in the first quarter of 2012; only two quarters before mandatory access went into effect in Kentucky. Thus, it is not possible with our main data sources to test for parallel pre-trends in the two states. We address this issue by considering other data sources. Figure 2 presents annual data from the Centers for Disease Control

[1]The law defines pain clinics as facilities where a majority of patients receive pain medications and either the primary practice component is the treatment of pain or the facility advertises any type of pain management services. The regulations do not apply to hospital-owned facilities, hospices, or long-term care facilities.



(a) Annual Prescriptions Per Capita
Source: CDC

(b) Quarterly MED Per Capita
Source: ARCOS

Note: Shaded area represents implementation period (2012 for CDC and 2012q3 for ARCOS.) Blue solid line represents KY and red dashed line represents IN.

FIGURE 2 Opioid utilization per capita in Indiana and Kentucky, 2006–2016. [Colour figure can be viewed at wileyonlinelibrary.com]

(CDC) on opioid prescriptions per capita and quarterly data from the DEA's Automation of Reports and Consolidated Orders System (ARCOS) database on MED[2] per capita for the years 2006 to 2016.

Both sources indicate that opioid prescriptions in Kentucky and Indiana were trending in a roughly parallel fashion from 2006 through 2011. The ARCOS series, but not the CDC series, shows a level shift up in MED beginning with 2010q2. This level shift is due entirely to oxycodone, which jumps up in Kentucky and continues a near-linear trend in Indiana. The timing of the shift in oxycodone shipments to Kentucky coincides with two important events related to this commonly abused drug.

One is the reformulation of the extended release version of the drug, Oxycontin. Although this change had a large effect on the demand for oxycodone products and their substitutes, there is little reason to expect a large positive effect on shipments to Kentucky relative to Indiana. Alpert et al. (2018) show that Kentucky and Indiana had the same rates of Oxycontin misuse before the reformulation and thus were similarly exposed to it.

The other change that occurred around this time is a major crackdown on pill mills in Florida (Kennedy-Hendricks et al., 2016). These clinics were widely reported to be a source of drugs sold in other states. Indeed, Interstate 75, which runs through both Florida and Kentucky, was dubbed the "Oxy Express." Evans, Lieber & Power, (2019) develop a measure for cross-state comparisons that suggests Kentucky was obtaining considerably more opioids from Florida than Indiana was prior to the crackdown. Thus, it is very plausible that as the supply from Florida was reduced, the demand for oxycodone from in-state providers increased more in Kentucky than Indiana.

Table 1 examines trends in aggregate quarterly per capita MED consumption in Kentucky and Indiana using ARCOS data from 2006q1 to 2012q2. The models in columns 1 and 2 include just an indicator for Kentucky, a linear trend and the interaction of the two. In columns 3 and 4, we include a second Kentucky intercept to capture the level shift in oxycodone shipments after the Florida pill mill crackdown.

Using the logged outcome (column 1), the results indicate that in both states, the volume of opioids grew by roughly 8% per quarter over the 7-year period. When the dependent variable is specified in levels, the simpler specification suggests stronger growth in Kentucky in the pre-period. However, when we include a second intercept for Kentucky from 2010q2 onwards, we no longer find a difference in the time trends between Kentucky and Indiana. This suggests that indeed there was simply a level shift in Kentucky rather than different trends over the full pre-policy period.

Table 2 reports difference-in-differences estimates using quarterly MED per capita for 2006q1 to 2013q4, before and after Kentucky's implementation of the mandatory access policy (but prior to the Affordable Care Act expansions). Because the implementation quarter (2012q3) is partially treated, we allow its own dummy. In these results, we again consider the impact of allowing Kentucky a second intercept for the period beginning in 2010q2. Including this, additional variable does not alter the results in a qualitative sense. The first column suggests that the PDMP mandate

[2]We converted ARCOS and PDMP opioid prescriptions to their morphine equivalents using conversion factors from the following three sources: Palliative.org (2016); CMS (2015); Ohio Bureau of Workers' Compensation (2016).

TABLE 1 Pre-period trends in aggregate morphine-equivalent dosage (MED) per capita (Automation of Reports and Consolidated Orders System [ARCOS] data), 2006q1–2012q2

Variable	Log	Level	Log	Level
KY	0.143**	37.35**	0.0917**	19.45**
	(0.0232)	(3.466)	(0.0320)	(5.067)
KY#Post2010q2			0.0462*	16.21**
			(0.0185)	(3.366)
Time	0.0840**	15.17**	0.0840**	15.17**
	(0.00740)	(0.899)	(0.00747)	(0.909)
KY#Time	0.00748	3.884**	−0.00219	0.492
	(0.00774)	(0.997)	(0.00908)	(1.220)
2nd intercept for KY	No	No	Yes	Yes
Observations	52	52	52	52

Note. Table reports pre-trends analysis of quarterly aggregates MED per capita for Kentucky and Indiana from ARCOS. Models include a constant (not shown) and end in the quarter prior to Kentucky's implementation of a mandatory access policy. Columns 1 and 3 use logged outcomes. Columns 3 and 4 include a binary variable for Kentucky 2010q2 to 2012q2. Robust Huber–White standard errors.
**$p<0.01$.
*$p<0.05$.

TABLE 2 Difference-in-differences analysis of aggregate MED per capita (ARCOS data), 2006q1–2013q4

Variable	Log	Level	Log	Level
KY	0.116**	23.27**	0.0987**	17.13**
	(0.00871)	(2.027)	(0.0108)	(1.423)
KY#Post2010q2			0.0491**	17.73**
			(0.0123)	(2.120)
KY#2012q3	−0.0141	1.560	−0.0462**	−10.04**
	(0.00871)	(2.027)	(0.00588)	(1.572)
KY#Post2012q3	−0.111**	−22.20**	−0.143**	−33.80**
	(0.00929)	(2.155)	(0.00672)	(1.737)
2nd intercept for KY	No	No	Yes	Yes
Quarterly fixed effects	Yes	Yes	Yes	Yes
Observations	64	64	64	64

Note. Table reports a difference-in-differences analysis comparing aggregate quarterly MED per capita for Kentucky and Indiana from ARCOS before and after Kentucky's implementation of a mandatory access policy in 2012q3. KY#2012q3 corresponds to implementation period. Robust Huber–White standard errors.
**$p<0.01$.

reduced the volume of opioids in Kentucky by 11%. Allowing Kentucky to have a second intercept (similar to beginning the analysis in 2010q2) increases our estimate of the policy impact to 14%. Similarly, when the dependent variable is specified in levels both specifications indicate that the effect of Kentucky's PDMP mandate was statistically and economically significant.

3.2 | Prescription records

Via data use agreements with KASPER and INSPECT, we obtained the states' complete PDMP records. Each record contains the following fields: encrypted identifiers for patients, providers and pharmacies, National Drug Code (from which we derive ingredient, strength, and route of administration), number of units, days supply, patient zip code, and provider location. For most physicians with prescriptions recorded in KASPER, we also know their specialty.[3]

Our analysis period begins in 2012q1. Though PDMP data for both states are available through 2016, we end our sample period in 2013q4 to avoid a possible confounding effect of the Affordable Care Act (ACA). Kentucky

[3]Physician specialty is observed for all physicians who registered with KASPER between 2010 and 2018. In our sample, physician specialty is known for 96% of Kentucky prescriptions.

implemented the ACA Medicaid expansion in January 2014 and also established its own marketplace. Indiana did not expand Medicaid until 2015 and participated in the Federal Healthcare.gov marketplace. Whereas in 2013, a similar percentage of each state's population was uninsured (14.3% in Kentucky and 14.0% in Indiana), between 2013 and 2014, the percent uninsured declined by 5.8 percentage points in Kentucky compared with only 2 percentage points in Indiana (Smith & Medalia, 2015).

A key advantage of PDMP administrative data over other opioid utilization data is that we observe all or substantially all of an in-state provider's outpatient opioid prescribing,[4] which allows us to conduct a provider-level analysis. By comparison, analyses of aggregate opioid supply (e.g., ARCOS data) do not report data at the provider level, and claims from a subsample of patients (e.g., Medicare data) do not fully capture a provider's prescribing behavior. In particular, our PDMP data include all cash purchases, which is predictive of other suspicious behaviors (Cepeda et al., 2013).[5] Therefore, analyses based on PDMP data yield the maximal insight on how providers respond to mandatory access policies.

We limit our sample to providers who practiced in Kentucky or Indiana. Prescriptions filled in Kentucky and Indiana but written by out-state providers are disregarded because those providers are subject to other states' opioid regulations. Our main analyses are done on a balanced panel consisting of quarterly observations of providers who wrote at least one opioid prescription in any quarter between 2012q1 and 2013q4.

3.3 | Hypotheses and outcome measures

There are several possible provider responses to a PDMP use mandate. The requirement that providers have an active account and check the database before prescribing opioids introduces fixed compliance costs. Some providers may cease prescribing opioids altogether rather than bear the cost associated with learning to navigate the system. Therefore, we test whether the policy induced a change on the extensive margin of writing any opioid prescriptions in a quarter.

Fundamentally, PDMPs are designed to alert providers to possible doctor shopping and other suspicious patterns of patient behavior. Previous research based on Medicare claims data finds that mandatory access policies significantly reduce the number of patients receiving prescriptions from multiple providers and the number of "new patient" visits (Buchmueller & Carey, 2018). Thus, we hypothesize that among providers who continue to prescribe opioids, the strongest effect of a mandatory access policy will be on the number of patients to whom they prescribe.

It is possible that a provider encountering a PDMP report that suggests a patient is overusing opioids may not refuse to prescribe to that patient, but rather will write a weaker prescription in hopes of weaning the patient off high-dosage or chronic opioid use. Additionally, the mandate may indirectly affect prescribing intensity. In a survey of Kentucky prescribers, roughly three quarters of respondents said they believed they were being more closely monitored after the policy went into effect (Freeman et al., 2015). This perception may have led some to prescribe more conservatively. And checking the PDMP more often may affect prescribing intensity by raising the salience of safe prescribing practices. We analyze two measures of prescribing intensity: days supplied per patient and the average MED per day.

Table 3 presents summary statistics for these outcomes aggregated to the provider×quarter level. In the pre-period (2012q1 and 2012q2), the percentage of providers prescribing any opioids was identical in Indiana and Kentucky (74%). Conditional on prescribing opioids, the average Kentucky provider prescribed to more patients (60.2 vs. 54.5). MED per provider is higher in Kentucky because of the difference in the number of patients; the baseline means for days/patient and MED/day were essentially identical in the two states. Figure 3, which presents the provider-level distribution of log MED prescribed for the pre-period, also indicates that prescribing patterns were quite similar in the two states before Kentucky's policy change.

After the policy change, the number of Indiana providers writing any opioid prescriptions increased by 2 percentage points, whereas the percentage in Kentucky fell by 2 points. The number of patients per provider fell in both states, but

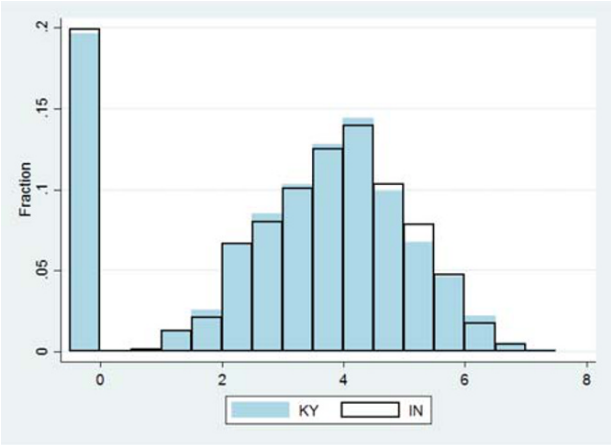
[4]KASPER and INSPECT capture about 95% of the total MED shipped to a state (as reported by ARCOS) or about 95% of all prescriptions filled in the state (as reported by the CDC). We expect the PDMP to capture less than 100% of the ARCOS volume, which includes opioids administered to hospital inpatients (not reported to PDMPs). The CDC data are based on a sample of retail pharmacies; the CDC does not give detailed information about its methods.

[5]Although our PDMP datasets always report prescriptions purchased with cash, information on the source of payment is not available in Kentucky until 2015. In 2015, after both states had expanded their Medicaid programs, 8% of prescriptions in KASPER and 10% of INSPECT prescriptions were purchased with cash. Prior to Medicaid expansion, 14% of Indiana's prescriptions were purchased with cash.

TABLE 3 Sample means of quarterly provider-level outcomes

	Indiana			Kentucky			Kentucky		
	All prescribers			All prescribers			Excl. pain mgmt.		
Outcome	Pre	Post	Change	Pre	Post	Change	Pre	Post	Change
MED (1000s)	56.1	55.9	−0.2	62.6	56.7	−5.9	49.2	41.8	−7.5
Any prescription	0.74	0.76	0.02	0.74	0.72	−0.02	0.74	0.72	−0.02
Unique patients | Any	54.5	52.1	−2.4	60.2	54.2	−6.1	56.4	49.5	−6.9
Days/patient | Any	18.5	18.6	0.1	18.9	19.3	0.4	18.4	18.8	0.4
MED/day | Any	35.6	35.5	−0.1	34.6	34.3	−0.3	34.4	34.1	−0.3

Note. This table reports means of quarterly provider-level measures based on PDMP data. The column marked "pre" refers to 2012q1 & 2012q2; the column marked "post" refers to 2012q4 through 2013q4. The first set of columns reports on all prescribers in Indiana, the second on all prescribers in Kentucky, and the third on Kentucky prescribers excluding pain management specialists.
Abbreviation: MED, morphine-equivalent dosage.



Note: Figure depicts distribution of providers in Kentucky (blue) and Indiana (outline) based on the logged (base 10) total MED they prescribe in 2012h1, with those who prescribe zero mapped to -0.5.

FIGURE 3 Distribution of logged (Base 10) total morphine-equivalent dosage (MED) prescribed by provider, 2012h1 (0 mapped to −0.5). [Colour figure can be viewed at wileyonlinelibrary.com]

more so in Kentucky (−6.1 vs. −2.4). There was essentially no change in either intensity measure in either state. Overall, the mean MED per provider fell by 9.4% in Kentucky and by 0.4% in Indiana.

4 | ECONOMETRIC ANALYSIS

4.1 | Overall impact of Kentucky's mandatory access provision

We estimate the overall impact of Kentucky's mandatory access policy in a difference-in-difference framework. Our estimating equation is

$$Y_{it}^{j} = \alpha^{j} KYpost_{it} + \beta^{j} KY \times 2012q3_{it} + \delta_{t}^{j} + \delta_{i}^{j} + \varepsilon_{it}^{j}, j = 1,2,3,4, \quad (1)$$

where i indexes providers, t indexes calendar quarters, and the j superscript indexes the four distinct decisions that providers make regarding opioids: whether to write any opioid prescriptions; the number of patients; days supply per patient; and MED per day. The product of these four outcomes is the total MED prescribed by a provider in a quarter.

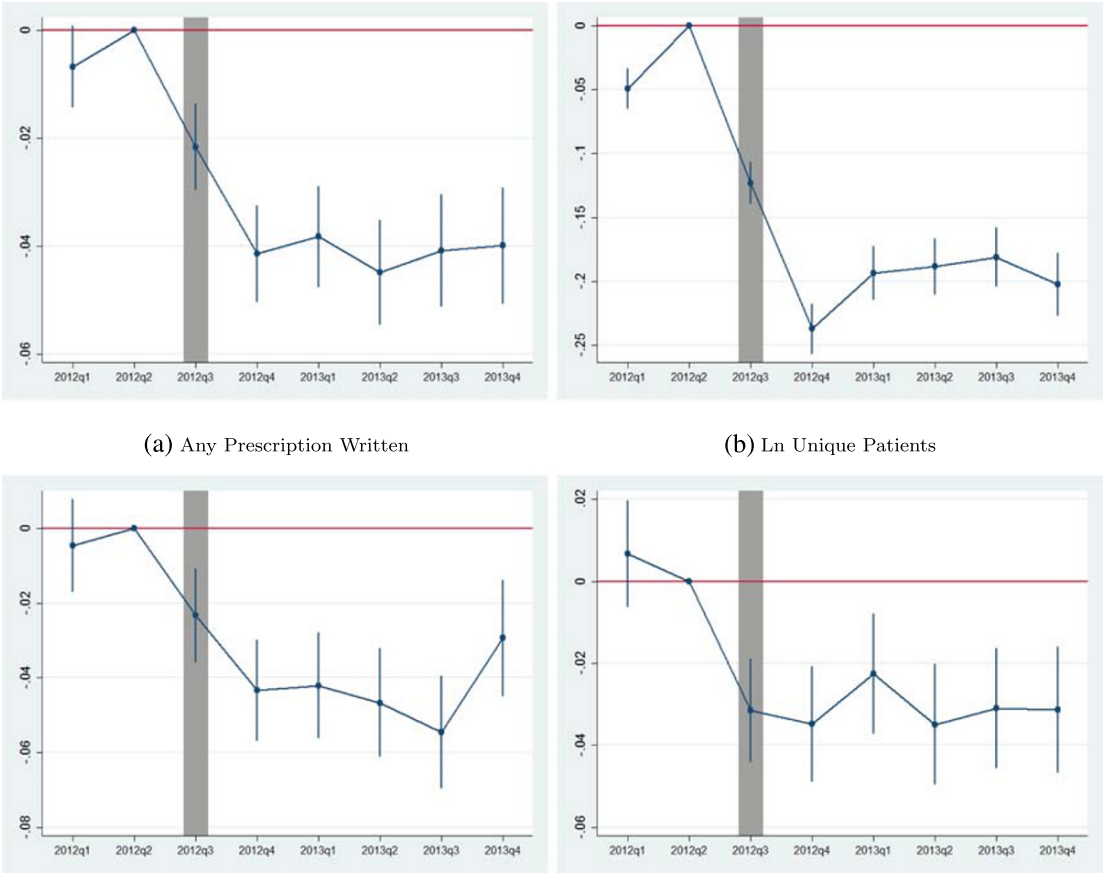
The policy variable, *KYpost*, equals 1 for Kentucky providers beginning in 2012q4 and 0 elsewhere; Kentucky's partially treated implementation quarter, 2012q3, is accounted for with its own dummy variable. Because the data from both states include encrypted provider identifiers, we are able to condition on provider fixed effects (δ_i). Our models also include quarter fixed effects (δ_t). We cluster ε_{it} at the provider level. With only two states, asymptotics for

consistency will not apply if standard errors are clustered at the state level. However, clustering at the provider level will account for much of the serial autocorrelation in errors, which is the main concern that Bertrand et al. (2004) identify for difference-in-differences models. We explore inference under two alternative models in Section 4.B.

Y^1 is an indicator variable that equals one if a provider wrote at least one prescription in the quarter and zero otherwise. Because of the fixed effects, we specify this equation as a linear probability model. For the continuous outcomes, we report two sets of models, one with the dependent variable in levels, the other in natural logs. As shown in Figure 3, the distribution of MED prescribed by providers in the pre-period appears to be approximately lognormal. Intuitively, we expect the policy to have a proportional effect on the number of patients, which points to the log model as the preferred specification. For the other continuous outcomes, it is less clear a priori whether logs or levels should be preferred. Tests for model specification recommended by Deb et al. (2017) suggest that the log model fits our data better for all three continuous outcomes.

In addition to the basic difference-in-differences specification, we also estimate an event study version of the model in which an indicator variable for Kentucky is interacted with each time dummy. Because we have a very short pre-period, we rely on the previous analysis of ARCOS and CDC data to provide evidence on pre-period trends. We primarily use this specification to confirm that the estimated treatment effect coincides with the quarter when HB 1 was implemented and to examine the dynamics of the treatment effect in the post-period.

The event study results are presented graphically in Figure 4. Each of the four variables exhibits a sharp decline in 2012q3 relative to the previous quarter, with the full impact realized by 2012q4. The fact that the movement in the variables is so tightly linked to the policy timing is reassuring. The pattern in these event studies—a sharp change in prescribing behavior followed by parallel trends in the post-period—is well-captured by a difference-in-differences framework.



(a) Any Prescription Written

(b) Ln Unique Patients

(c) Ln Days Per Patient

(d) Ln MED Per Day

Note: In these event study figures, coefficients represent the deviation from the mean difference between Kentucky and Indiana in each quarter 2012q1 to 2013q4, with 2012q2 normalized to zero. Regressions include provider and quarter fixed effects. Standard errors clustered at provider level. Shaded area represents implementation quarter 2012q3. Bar represents 95 percent confidence interval.

FIGURE 4 Provider-level prescribing behavior: event study, 2012q1–2013q4. [Colour figure can be viewed at wileyonlinelibrary.com]

TABLE 4 Difference-in-differences estimates of the effect of Kentucky's mandatory access Prescription Drug Monitoring Programs (PDMP) law

Variable	(1) Any prescription	(2) Patients	(3) Days/patient	(4) MED/day
	Results with dependent variables 2–4 in logs			
KYPost	−0.0377**	−0.177**	−0.0409**	−0.0343**
	(0.00379)	(0.00913)	(0.00536)	(0.00513)
Observations	290,464	215,409	215,328	215,328
Number of providers	36,308	36,308	36,294	36,294
Mean of LHS in KY pre (levels)	0.739	60.20	18.85	34.61
Treatment effect in levels	−0.0377	−10.73	−0.805	−1.211
	Results with dependent variables 2–4 in levels			
KYPost	−0.0377**	−6.466**	−0.0334	−0.418*
	(0.00379)	(0.607)	(0.113)	(0.187)
Observations	290,464	215,409	215,328	215,328
Number of providers	36,308	36,308	36,294	36,294

Note. Table reports difference-in-difference coefficients from estimation of Equation 1 on a panel of quarterly provider-level measures 2012q1 to 2013q4. Outcomes in second, third, and fourth column are conditional on the provider having any prescribing in the quarter. Outcomes in the third and fourth column are further conditional on having information on days supply. Standard errors clustered at provider level.
Abbreviation: MED, morphine-equivalent dosage.
**$p<0.01$.
*$p<0.05$.

Table 4 reports difference-in-differences regressions for each of our four outcomes. The first column indicates that mandatory access reduced the probability of any opioid prescribing by nearly 4 percentage points. This significant effect on the extensive margin is consistent with the hypothesis that fixed compliance costs may have led some providers to stop prescribing scheduled drugs altogether. We provide further support for the fixed-cost hypothesis in the next section.

We hypothesize that requiring providers to check a PDMP before prescribing opioids will have the strongest effect on the number of patients receiving prescriptions. The regression results indicate a large provider response along this margin. The log specification implies that among providers writing any opioid prescriptions in a quarter, Kentucky's mandatory access policy reduced the number of patients by 16% ($exp(-0.177) - 1 = -0.162$). Specifying the model as linear in levels also yields a significant policy effect, though, relative to the sample mean, the percent effects are slightly smaller (−11%). The results for Y^1 and Y^2 can be combined to estimate the total effect on the number of patients treated using standard methods for two-part models (Deb et al., 2017). Because the change in the extensive margin was concentrated among very low volume providers, the reduction in the number of patients among providers writing any opioid prescriptions in a quarter accounts for roughly 95% of the total decline in the number of patients per provider.

Estimated effects for the average days per patient and MED per day are smaller and more sensitive to specification. In the log model, the mandatory access policy is estimated to reduce days per patient by 4%, whereas the levels model implies essentially no change. Similarly, for MED per day, the log model implies a statistically significant 3% to 4% reduction, whereas the corresponding levels model implies smaller and less precisely estimated reductions. As noted, any effects on these margins are likely to be indirect. The changes observed for these outcomes may also reflect a change in the composition of patients receiving opioids after the policy change. As we show below, the effect of the policy on the patient margin was strongest for patients who filled multiple prescriptions. Reducing the number of high-use patients will have the effect of also reducing measures of prescribing intensity. Because of this and the sensitivity of the estimates to specification, we are reluctant to conclude that providers responded to the policy by reducing the number of days or MED per day.

We calculate the overall effect on MED supplied by combining the estimates from our four outcomes, which can be multiplied to yield total MED. When the outcome variables are in levels, we find a 10.2% reduction in MED after the policy in Kentucky relative to Indiana. Our estimate is in line with the simple comparison of sample means, which implies a 9% reduction, and the ARCOS regressions, which imply a 10%–14% reduction. We find a somewhat larger impact when we specify the dependent variables in logs, but the log model is not ideal for calculating the overall effect

TABLE 5 Impact of excluding providers in border counties

	(1) Any prescription	(2) Ln patients	(3) Ln days/patient	(4) Ln MED/day
All providers				
KYPost	−0.0377**	−0.177**	−0.0409**	−0.0343**
	(0.00379)	(0.00913)	(0.00536)	(0.00513)
Observations	290,464	215,409	215,328	215,328
Number of providers	36,308	36,308	36,294	36,294
No KY-IN border counties				
KYPost	−0.0415**	−0.177**	−0.0497**	−0.0293**
	(0.00446)	(0.0107)	(0.00637)	(0.00592)
Observations	228,672	171,221	171,155	171,155
Number of providers	28,584	28,584	28,572	28,572
No KY-IN border counties, no KY border counties				
KYPost	−0.0398**	−0.186**	−0.0491**	−0.0303**
	(0.00523)	(0.0130)	(0.00749)	(0.00696)
Observations	203,304	152,736	152,692	152,692
Number of providers	25,413	25,413	25,408	25,408

Note. The first panel repeats the analysis of Table 4. The next panel excludes all providers located in a county on the Indiana–Kentucky border (in either state). The next panel excludes all providers located in a county on the Indiana–Kentucky border as well as any other Kentucky border county.

Abbreviation: MED, morphine-equivalent dosage.

**$p<0.01$.

on MEDs. The calculation with the log model requires retransformation to levels, which can be inaccurate if there is treatment effect heterogeneity because of the Duan smearing factor (Deb et al., 2017).[6]

4.2 | Robustness and specification checks

Because Kentucky implemented its mandatory access policy near the time when it implemented regulations on pain clinics, our difference-in-difference estimates could be driven by the pain clinic regulation. To examine this possibility, we isolate the group of physicians most likely to be affected by pain clinic regulation using the information on specialties that we observe for Kentucky physicians. In the third set of columns in Table 3, we report the pre- and post-period averages for Kentucky physicians in general and excluding the roughly 1% reporting a pain management specialty. The pre-post differences for each variable are weakly greater in the sample that excludes pain management specialists. This is the opposite of the pattern we would expect if pain clinic regulation is the cause of our estimates.

One advantage of the fact that the two states we analyze are neighbors is that they are more likely to be subject to similar economic shocks. At the same time, there are possible disadvantages. A significant population center, Louisville, lies close to the Indiana border, giving rise to a region known as "Kentuckiana." To the extent that some Kentucky patients respond to the PDMP mandate by seeking prescriptions in Indiana, our estimates will be biased away from zero, representing the combined effect of a decrease in prescriptions in the treatment state and an increase in the control state.

To test the sensitivity of our results to border-crossing, we re-estimated all models on two subsets. The first excludes all counties in either state along the Kentucky–Indiana border, and the second further excludes all counties along any Kentucky border. Results from this robustness check are reported in Table 5. The results are statistically indistinguishable from the full sample result and nearly the same to the hundredth place. Although cross-border contamination need not be limited to the counties that lie along the border, we are reassured by the fact that the results are so similar when excluding the individuals for whom border effects are likely to be largest.

[6]We note that the 10% overall reduction is not inherently inconsistent with the 16% decrease in the number of patients estimated by the log model. The log model measures the average change in logs, which corresponds to the average percentage change across providers. The log model weights the percent change from a low volume prescriber the same as the percent change from a high volume prescriber.

Another issue with analyzing only two states (neighbors or not), is that asymptotics for consistency will not apply if standard errors are clustered at the state level. As a robustness check to test the sensitivity of our inferences, we follow the suggestion of Bertrand et al. (2004) and collapse the data to create a single pre- and post-period observation for each provider, to account for residual serial correlation in the errors. Results from this exercise are reported in Table A2 in the supporting information. Estimating the model on this data set yields similar point estimates and standard errors that are roughly 30% larger than those obtained using quarterly data. For the extensive margin of prescribing any opioids (Y^1) and the number of patients (Y^2), this difference does not qualitatively change our inferences: the estimates remain statistically significant at the 1% level.

In addition, we conduct an exercise recommended by Donald and Lang (2007) to assess whether we are overrejecting the null hypothesis of no effect. They suggest estimating the difference-in-differences coefficient for every consecutive two periods within the sample period. If standard errors are severely underestimated, these placebo tests will return statistically significant results. Table A3 in the supporting information implements this exercise, reporting the coefficients and *t*-statistics for all four outcomes across all seven possible two-quarter intervals. Our implementation period is 2012q3, and the two regressions that include that period are bolded for reference. The placebo regressions are generally, though not always null. However, the*t*-statistics for the implementation period average more than five times the *t*-statistics for the placebo tests. This suggests that even if the standard errors are somewhat too large, inference is likely to be robust to smaller standard errors.

4.3 | Heterogeneity across providers by pre-period prescribing volume

We hypothesize that the Kentucky law had different impacts for higher and lower volume providers. Low-volume providers may be most reluctant to pay the costs of mandatory access compliance, because opioid prescribing is not critical to their practice. Additionally, low-volume providers may not be sufficiently familiar with opioid prescribing histories to confidently interpret a PDMP record (Carey et al., 2018). Thus, we expect that low-volume providers are more likely than high-volume providers to stop prescribing.

It is less obvious which types of providers will reduce the number of patients the most. High-volume providers treat hundreds of patients every quarter and are more likely to be pain specialists. Because chronic pain patients are at high risk for opioid misuse, pain specialists may be most likely to learn of suspicious behavior when they begin using the PDMP. On the other hand, these providers may *already* use the PDMP prior to the mandatory access provision. And of course, some high-volume providers may engage in illicit opioid distribution, and thus may be insensitive to the information contained in the PDMP.

To estimate heterogeneous policy effects by volume, we divide the provider sample into quartiles based on the total MED prescribed in the 6months before Kentucky's policy went into effect. Table 6 provides summary statistics on providers in each quartile. All of the outcome variables that we analyze increase monotonically across the quartiles, with the differences being most pronounced for the number of patients treated. The first quartile is made up of infrequent

TABLE 6 Provider-level outcomes by pre-period provider volume

	All	Quartile 1	Quartile 2	Quartile 3	Quartile 4
Total MED in 2012H1 (000s):					
Minimum	0	0	0.136	3.652	31.024
Maximum	14,639	0.135	3.652	31.022	14,639
Average quarterly outcomes in pre-period:					
Any prescriptions in quarter: mean (%)	73.9	12.1	85.0	98.7	99.8
Number of patients: mean	41.9	0.17	4.7	35.4	127.4
Percent single use (%)	29	61	51	47	23
Percent multiple use non-shoppers (%)	57	29	36	38	63
Percent multiple use shoppers (%)	14	9	12	15	13
Days per patient	18.6	5.83	9.9	12.3	33.7
MED per day	35.2	14.73	28.9	34.7	43.5

Note. This table reports means of pre-period provider-level measures by provider volume quartile, based on MED prescribed in pre-period (2012h1.) Sample statistics correspond to quarterly averages in in the pre-period.
Abbreviation: MED, morphine-equivalent dosage.

prescribers. Only 12% wrote an opioid prescription in each quarter in the pre-period and the modal provider who did so had only one patient. Conditional on prescribing, mean days per patient and MED per day are low for providers in quartile 1 relative to other providers. This is consistent with lower-volume providers treating opioid-naive patients with short-term pain. Quartiles 2 and 3 differ mainly in terms of the number of patients to whom opioids are prescribed. Quartile 4 appears to include many pain specialists. The average provider in this quartile prescribes to a high number of patients and writes prescriptions with longer durations.

For each quartile, we estimate a separate set of regressions. These results are reported in Table 7, the first column of which repeats the full sample results from Table 4. For brevity, we report only the log models for the continuous outcomes, and show the level models in Table A4 in the supporting information.

The first panel reports the effect of mandatory access on the probability of writing any opioid prescriptions in a quarter. We find that the lowest-volume prescribers are 5 percentage points less likely to write a prescription due to the policy change. Relative to the pre-period mean, this is a 41% decline. The estimated coefficient is slightly larger for quartile 2, though in percentage terms the effect is smaller. The vast majority of providers in quartile 3 and 4 continue to prescribe after the policy change.

The results by provider quartile support the hypothesis that low-volume providers view the fixed costs of mandate compliance as excessive relative to the benefits. As a further test of the fixed cost hypothesis, we also examine whether the number of providers who never again write an opioid prescription increases. The results, reported in Table A5 in the supporting information, suggest that Kentucky's access mandate did lead low-volume providers to "exit the

TABLE 7 Difference in differences estimates by provider quartile

Sample	(1) All	(2) Quartile 1	(3) Quartile 2	(4) Quartile 3	(5) Quartile 4
Total MED 2012 H1	**0+**	**0–135**	**136–3652**	**3652.5–31022**	**31024+**
	Any prescription				
KYPost	−0.0377**	−0.0533**	−0.0644**	−0.0232**	−0.00957**
	(0.00379)	(0.00892)	(0.00729)	(0.00472)	(0.00311)
Observations	290,464	72,696	72,536	72,616	72,616
Number of providers	36,308	9,087	9,067	9,077	9,077
Mean of LHS in KY pre (levels)	0.739	0.129	0.850	0.989	0.998
	Ln patients				
KYPost	−0.177**	−0.0824+	−0.180**	−0.190**	−0.167**
	(0.00913)	(0.0470)	(0.0189)	(0.0150)	(0.0148)
Observations	215,409	24,264	51,585	68,426	71,134
Number of providers	36,308	9,087	9,067	9,077	9,077
Mean of LHS in KY pre (levels)	60.20	1.329	5.251	35.85	142.1
	Ln days/patient				
KYPost	−0.0409**	−0.00134	−0.0616**	−0.0505**	−0.0183**
	(0.00536)	(0.0460)	(0.0133)	(0.00844)	(0.00683)
Observations	215,328	24,217	51,559	68,421	71,131
Number of providers	36,294	9,073	9,067	9,077	9,077
Mean of LHS in KY pre (levels)	18.85	5.659	10.04	12.50	34.98
	Ln MED/day				
KYPost	−0.0343**	−0.167**	−0.0542**	−0.0340**	−0.00802
	(0.00513)	(0.0580)	(0.0134)	(0.00738)	(0.00553)
Observations	215,328	24,217	51,559	68,421	71,131
Number of providers	36,294	9,073	9,067	9,077	9,077
Mean of LHS in KY pre (levels)	34.61	16.69	29.95	35.03	40.68

Table reports difference-in-difference coefficients from estimation of Equation 1 on a panel of quarterly provider-level measures 2012q1 to 2013q4 by quartile of provider MED in 2012h1. Outcomes in second, third, and fourth panel are conditional on the provider having any prescribing in the quarter. Standard errors clustered at provider level.

Abbreviation: MED, morphine-equivalent dosage.

**$p<0.01$.

*$p<0.05$.

+$p<0.1$.

market." We find that high-volume Kentucky prescribers are *not* more likely to cease prescribing than their Indiana counterparts. This is further evidence that the closure of pain clinics is not the main driver of our results.

Among providers who continue to prescribe opioids, there is a substantial decline in the number of patients by between 15% and 17% for providers in quartiles 2 through 4. For providers in the first quartile, the log-linear model implies a smaller percent decline (8%), and the linear model indicates no significant change. A weak effect for the lowest volume providers is not surprising given that for this group, the bulk of the variation is at the extensive margin.

Results for the two measures of prescribing intensity, days per patient and MED per day, are reported in the bottom two panels. As in the full sample analysis, these results are mixed, providing less clear evidence for an effect of the policy. Effects on log days per patient are absent for the lowest volume providers, who already write very short duration prescriptions, and small for the highest volume providers. When measured in levels, none of the estimates are statistically significant. The magnitude of the effect sizes for the natural log of MED per day is monotonically decreasing. Among providers in the fourth quartile, who account for the vast majority of all opioid prescriptions, we see no significant reduction in MED per day.

4.4 | Prescribing reductions by patient type

The goal of PDMPs is to alert providers to possible drug-seeking and other indicators of high-risk use. We now examine whether providers target reductions on patients with suspicious opioid histories that would be revealed in PDMP records. We are also interested in whether providers reduce prescribing to patients *without* suspicious behaviors. Such a finding would suggest that mandatory access was associated with a general chilling effect, which potentially could have inhibited clinically appropriate prescribing.

To provide insight on how different types of patients were affected by the policy, we define three mutually exclusive patient types. In contrast to our prescriber volume quartiles, which are defined using only pre-period data, we categorize patients contemporaneously because many obtain a prescription in only a single quarter. "Single use" patients fill a single prescription in a quarter and none in the following quarter. As shown in Table 6, in the pre-period, 29% of the average provider's patients (about 12 patients) were single-use patients. Among patients observed filling multiple prescriptions we distinguish between "shoppers" and "non-shoppers." Shoppers are defined as patients who receive prescriptions from three or more providers or fill prescriptions at three or more pharmacies in a given quarter.[7] In the pre-period, 6% of patients in either state meet our definition of "shoppers." However, because these patients appear in the patient pools of multiple providers, roughly 14% of each provider's patients meet the standard, as is reported in Table 6. Individuals exhibiting shopping behavior comprised a similar share of providers' patient set across the volume quartiles. However, because high-volume providers account for the bulk of all prescriptions, most shoppers (more than two-thirds) obtain opioids from these prescribers. The most common consumption pattern was filling multiple prescriptions but not meeting our shopping criteria. Presumably, many of these individuals are chronic pain patients.

We use our categorization to examine whether providers targeted reductions in opioid prescriptions on high risk patients. For simplicity, we report for each patient type an overall effect on the number of patients that combines the effect on any prescribing (extensive margin) and the effect on the number of patients (intensive margin Deb et al., 2017).

Table 8 reports estimated policy effects by patient type, as well as bootstrapped standard errors (Belotti et al., 2015). Consistent with the goal of the policy, the effect of the policy was largest in percentage terms for shoppers and smallest for single-use patients. The average provider prescribed to 2.6 fewer shoppers, which represents a 34% effect. Reductions in prescribing to shopping patients are exactly what we expect from the provision of PDMP information; without a PDMP, it is difficult for a provider to observe prescriptions written by other providers.

However, there are meaningful declines for the other patient types. A 17% decline in non-shopping patients, and a 12% decline in single-use patients is consistent with providers imperfectly targeting the reductions in patients. It is possible these patients were adversely affected by a chilling effect. At the same time, the PDMP may include other

[7]Most analyses of opioid misuse define measures of multiple use of providers and pharmacies over a longer period, such as a 6 months or a year (Buchmueller & Carey, 2018; GAO, 2011; Jena et al., 2014). We use a quarterly measure to investigate whether patterns consistent with provider and pharmacy shopping change shortly before compared to after the policy change. Of the patients who obtain a prescription from 3+ providers in a quarter, roughly three quarters obtain prescriptions from four or more providers in a year.

TABLE 8 Change in number of patients seen by a provider by patient type

	(1)	(2)	(3)	(4)
	All	Single-use	Multiple use	
			Non-shoppers	Shoppers
Total effect in levels	−9.483**	−1.689**	−5.523**	−2.584**
	(0.510)	(0.127)	(0.334)	(0.0905)
Implied effect in percent	−19.4	−12.2	−17.1	−33.9

Note. Single-use patients defined as patients who receive one prescription in current period and none in next period. Multiple-use shoppers defined as patients who fill a prescription from 3+ providers or at 3+ dispensaries in a quarter. Remaining patients are multiple-use non-shoppers. Estimates based on a two-part model combining a linear probability model of any prescribing to the patient type with an ordinary least squares regression of the log number of patients of the given type. For ease of interpretation, the combined effect is reported in both percentage change and levels. All regressions include provider fixed effects. Bootstrapped standard errors based on 1,000 replications, which are sampled with replacement at the provider level.

**$p<0.01$.

information suggesting that an opioid prescription would be contraindicated, such as prescriptions for benzodiazepines (Dasgupta et al., 2016). The number of patients with overlapping claims for opioids and benzodiazepines fell by 5% in Kentucky after the mandatory access policy went into effect, whereas there was no change in Indiana.

5 | DISCUSSION: STUDY LIMITATIONS AND STRENGTHS

It is important to acknowledge several possible limitations of our analysis. With any analysis that focuses on a single state, questions can be raised about the external validity of the particular "case study." We first consider whether the policy that is being examined representative of an approach that other states might adopt. Kentucky was the first state to implement a comprehensive PDMP mandate and shortly after its law went into effect other states enacted similar legislation. Whether the other states explicitly based their PDMP mandates on the Kentucky policy or they just adopted best practices, the subsequent legislation followed Kentucky's model, and we expect that if more states implement mandates, they will look like Kentucky's. Our one-state case study also has an advantage compared to studies that use data on all states. Such studies define the "treatment group" based on multiple states with policies of varying strength (e.g., Buchmueller & Carey, 2018). The average effects estimated using such an approach may not correspond directly to specific policies that states are considering.

A second threat to external validity is special circumstances that would affect replicability. As we have noted, the legislation that established the PDMP mandate also introduced new regulations governing pain clinics, raising the possibility that our results represent the combined effect of these two reforms. Although it is not possible to precisely disentangle the separate effects of these two policies, several patterns we observe suggest that our results are not merely the effect of the pain clinic law. First, the overall prescribing reductions in Kentucky are the same or greater if we exclude the pain management specialists most likely to be affected by the pain clinic closures. Second, if opioid prescriptions fell because of pain clinic closures, we would expect to see a significant reduction in the number of high-volume providers writing any opioid prescriptions in Kentucky relative to Indiana. We do see a policy effect on the extensive margin, but it is low-volume providers who "exit the market." The largest effects we find are on the number of patients to whom opioid prescriptions are written. Again, if this effect was driven by stricter pain clinic laws it would be concentrated among the highest volume providers, as Rutkow et al. (2015) find in an analysis of Florida pain clinic closures. Yet, for this outcome, we find roughly comparable effects for all but the lowest volume providers.

Our analysis also has limitations that have possible implications for internal validity. With any analysis using a difference-in-differences research design, the internal validity of the results depends on whether the "control group" represents a plausible counterfactual. It is standard practice to assess the plausibility of this assumption by testing for parallel trends in the period before the policy went into effect. If outcomes trended similarly in treatment and control states during the pre-period, the assumption that control states are a good counterfactual is more plausible. Because we have limited PDMP data prior to the implementation of Kentucky's mandate, we cannot assess pre-trends in that data. However, we are able to assess pre-trends using other state-level data. The results are generally supportive of the parallel trends assumption. Moreover, the fact that the two states are so similar not only in terms of prescribing

characteristics right before Kentucky's mandate but also in terms of demographic and economic characteristics provides further support for the use of Indiana as a control group.

6 | CONCLUSION

PDMPs have the potential to decrease inappropriate prescribing of opioids. But PDMPs will only be effective if health care providers access the data. In an effort to increase provider engagement, several states have recently enacted policies requiring providers to query the state's PDMP before prescribing opioids. This paper evaluates the first comprehensive PDMP mandatory access policy, which was enacted by Kentucky in 2012. We find that providers responded to this policy in two main ways. Some, who prescribed low volumes of opioids before the policy went into effect, stopped prescribing the drugs altogether. This is consistent with the idea that the policy introduced fixed compliance costs that low-volume providers were not willing to bear. Higher volume providers continued to prescribe but wrote prescriptions to fewer patients.

We also assess what types of patients were affected. Ideally, PDMP data will help providers identify doctor shoppers and other high risk patients. Our results suggest that providers reduced prescriptions to patients whose prescription histories suggest possible doctor or pharmacy shopping. We find large reductions (in percentage terms) in the number of such patients receiving opioid prescriptions. At the same time, we find economically significant reductions in the number of patients without suspicious prescribing histories. These decreases suggest there may also be patients with a clinically justified need for pain relief who lose access to treatment as a result of the policy.

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CONFLICT OF INTEREST

The authors have no conflicts of interest to disclose.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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