Evaluating Legal Interventions Designed to Improve Behavioral Health Outcomes

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EVALUATING LEGAL INTERVENTIONS DESIGNED TO IMPROVE BEHAVIORAL HEALTH OUTCOMES

ABSTRACT

Relatively recent recognition of the significant burden of behavioral health disorders has elevated their status as public health issues in need of population-level interventions. This dissertation focuses on evaluating two types of legal interventions that have enjoyed widespread but heterogeneous adoption and that are aimed at improving behavioral health care and outcomes: mental health parity laws and prescription drug monitoring programs. I further probe the appropriate means of regulatory intervention given the nature of behavioral health challenges targeted by these laws, existing evidence bases, and legal considerations.

Chapter 1, entitled "Association of Federal Mental Health Parity Legislation with Health Care Use and Spending Among Persons with Mental Illness", undertakes a novel examination of the Mental Health Parity and Equity Addiction Act (MHPAEA) of 2008. MHPAEA is a robust federal law that requires equity in insurance coverage between mental health and medical/surgical benefits. I use claims data from a large national commercial health insurer to assess the effects of MHPAEA on health care utilization and out-of-pocket spending among enrollees diagnosed with a mental health disorder. I review state laws that preceded MHPAEA to identify 24 states that exempt small-employer plans from parity requirements. Within these states, I develop a "control" group (of small-employer plan enrollees not subject to parity throughout the study period) and an "exposure" group (of self-insured plan enrollees newly subject to MHPAEA) for assessing the effects of MHPAEA. Employing a difference-in-differences design and propensity score matching techniques, I show that, among the exposure group, the out-of-pocket cost per outpatient mental health visit slightly declined while covered outpatient mental health visits modestly increased (4-6%) after MHPAEA. I also find that total out-of-pocket spending on outpatient mental health services as well as inpatient and emergency

department use are unchanged by the law. I conclude that further investigation is needed to assess whether parity is associated with changes in clinical outcomes.

Chapter 2, a normative piece entitled "Preventing Opioid Misuse with Prescription Drug Monitoring Programs: A Framework for Evaluating the Success of State Public Health Laws" argues that successful policymaking to address prescription opioid misuse requires evaluation against a defined set of criteria. I articulate and synthesize three key criteria with which to dynamically evaluate and justify state prescription drug monitoring programs designed to curb high opioid prescribing and misuse: (1) legal powers to regulate, (2) effectiveness of regulation, and (3) ethical considerations. PDMPs are widespread and promising, but heterogeneous and largely uninformed by robust evidence or a systematic assessment of best practices. I demonstrate my framework's utility in guiding public health lawmaking given the complexities and persistent magnitude of prescription opioid misuse and the rich arsenal of policy options available to address it. I conclude by recommending that PDMPs be implemented with the following features: timely and complete data; strong incentives for prescriber participation; user guidelines and education; integration into clinical work flow; and robust confidentiality and privacy protections. Ongoing evaluation of programs to identify features appropriate for retention and replication also is crucial if PDMPs are to fulfill their potential.

Chapter 3 seeks to assess the impacts of more recent PDMP features and is entitled "Effects of Robust State Prescription Drug Monitoring Programs on Opioid Prescribing and Use." Based on a review of PDMP laws, I identify five "intervention states" with robust PDMPs, as principally identified by the presence of a requirement that prescribers query the data before prescribing opioids. I compare commercial pharmacy claims for enrollees in these intervention states to those in respective controls (with weak or no PDMPs) using an interrupted time series design. I find that the percent of enrollees filling opioid prescriptions and the mean morphine equivalent dosage dispensed per enrollee each decline following robust PDMP implementation in most intervention states relative to controls, with Kentucky exhibiting the most dramatic relative reductions. I recommend that other states seeking to curb high opioid prescribing consider implementing Kentucky's particularly robust PDMP features, which include a use mandate paired with a registration mandate and careful implementation supervision.

CONTENTS

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ASSOCIATION OF FEDERAL MENTAL HEALTH PARITY LEGISLATION WITH HEALTH CARE USE AND SPENDING AMONG PERSONS WITH MENTAL ILLNESS

1.1 Abstract

Importance: Decades-long efforts to require parity between behavioral and physical health insurance coverage culminated in the passage of the comprehensive federal Mental Health Parity and Addiction Equity Act of 2008. The effect of the law on mental health care use and spending is largely unknown.

Objective: To determine the association between the Mental Health Parity and Addiction Equity Act and changes in utilization and out-of-pocket spending on mental health care services among patients with mental health conditions.

Design, Setting, and Participants: Before-after with comparison group design, using administrative data of commercially-insured enrollees aged 18-64 from 2008-2012. Enrollees

with a mental health disorder were drawn from 24 states where self-insured employers were newly subject to parity under the federal law, but small employer plans were exempt both before and after the law and served as the "control" group. Control group enrollees (n=11,326) were propensity score matched (1:1) to similar "exposure" group patients enrolled through self-insured employers (n=11,326), all of whom were continuously enrolled and followed for 1 year before and 1-2 years after the law. Changes in outcomes were calculated using adjusted difference-in-differences analyses.

Exposure: 2010 implementation of the Mental Health Parity and Addiction Equity Act.

Main Outcomes and Measures: Mental health outpatient visits, out-of-pocket spending for these visits, emergency department visits, and hospitalizations.

Results: Relative to controls, mean out-of-pocket spending per outpatient mental health visit declined among exposure enrollees by $0.74 (1.38, 0.09) and $2.12 (3.24, 0.99) in the first and second years after the federal law, respectively. Corresponding annual mental health visits increased by 0.31 (0.12, 0.50; relative: 4.4% [1.6, 7.3]) and 0.45 (0.24, 0.67; relative: 6.6% [3.4, 9.9]) per enrollee. There was no significant difference between groups in emergency department visits, hospitalizations, or total out-of-pocket spending for outpatient mental health visits.

Conclusions and Relevance: In 24 states where self-insured employers were newly subject to federal mental health parity legislation, outpatient mental health visits increased modestly after 2 years. Emergency department visits, hospitalizations, and total out-of-pocket spending on outpatient mental health visits were unchanged. Further investigation is needed to assess whether parity is associated with changes in clinical outcomes.

1.2 INTRODUCTION

About 20% of the adult U.S. population experiences mental illness each year,[1] but in 2012, fewer than of that group half received mental health care.[2] Financial barriers, including inadequate insurance coverage, contribute significantly to suboptimal access.[2,3]

Prior to 2008, a patchwork of state and federal policies was enacted with the goal of making behavioral health insurance coverage as generous as physical illness coverage ("parity"). However, many policies were under-enforced or relatively weak.[3] In addition, none applied to employer-sponsored health plans governed by the federal Employee Retirement Income Security Act (ERISA). Such "self-insured" plans account for approximately 60% of covered workers.[4]

The federal Mental Health Parity and Addiction Equity Act (MHPAEA), passed in 2008,[5] filled this gap by adopting broad parity rules for nearly all group health plans, defined as employee benefit plans that provide medical care (including through insurance) for participants. MHPAEA aims to improve financial protection and increase access to behavioral health services for persons with mental health conditions or substance use disorders—especially enrollees with high use and spending.[6] MHPAEA specifically requires financial and treatment limitation parity between physical and behavioral health benefits, when offered through private employers of 50 or more employees.[6]

The law[6,7] was rolled out over 5 years. Group health plans were expected to be compliant with most MHPAEA requirements beginning in mid-2010.[6] Building on the structure of MHPAEA, the Affordable Care Act (ACA) is anticipated to extend federal parity protections benefits to an estimated 62 million additional people by classifying mental health and

substance use disorder benefits as Essential Health Benefits and by extending parity protections to most individual and small-group plans.[8]

Previous MHPAEA studies have examined substance use disorder service utilization and spending[9,10] and effects of removal of a 30-visit cap,[11] but little is otherwise known about the policy. Research on earlier parity policies found modest decreases in out-of-pocket spending[12-14] and little or modest change in utilization of mental health services or quality.[13-16]

This study investigated changes in mental health care utilization among enrollees covered through "self-insured" employers (i.e., employers that retain risk for payment of claims). These firms were exempt from all parity legislation prior to MHPAEA,[17] then became newly subject to MHPAEA after mid-2010. Enrollees from these self-insured employers were compared to a cohort insured through small employers that were exempt from all parity legislation before and after MHPAEA.

We hypothesized that from before to after MHPAEA, enrollees with mental illness from self-insured employers would experience lower out-of-pocket spending on and increased access to outpatient mental health care visits versus a cohort from small employers. The expected direction of associations between MHPAEA and emergency department (ED) visits or hospitalizations was unclear.

1.3 Methods

We used 2 designs to assess the relationship between MHPAEA and changes in mental health services utilization and spending in a commercially insured population diagnosed with mental health disorders: pre-post with a comparison group and interrupted time series with a comparison series. These designs allowed estimation of the association between MHPAEA and

changes in mental health care spending and utilization independent of other changes to mental health care spending and use. Outcomes included out-of-pocket spending and health care utilization 1 year before ("baseline period") and up to 2 years after ("follow-up period") MHPAEA implementation.

To generate a robust comparison group, 24 states that exempted small employers group plans from state mental health parity laws throughout the study period were identified (Appendix A.1). In those states, small employer-based enrollees, who were not subject to parity laws before or after MHPAEA, served as the comparison group. Within these same states, "exposure" group members were those enrolled through employers that self-insure and were therefore newly subject to MHPAEA in mid-2010.

This research was approved by the institutional review boards at Harvard Pilgrim Health Care Institute and Harvard University. Participant consent was waived for this study of secondary data.

1.3.1 Study Population

Our data were from Optum (Eden Prairie, MN), which includes inpatient, outpatient, and pharmacy claims from a large national health insurer with enrollees in all 50 states. Available demographic information included enrollee gender, year of birth, state of residence, and type of group health plan (fully insured or self-insured). We classified enrollees based on their employer's size and month of plan renewal (Appendix A.1).

Claims in the year preceding and 2 years following the MHPAEA "phase-in" were analyzed (i.e., from late 2008-2012). Under both the MHPAEA statute and "interim final rules," employers were required to comply on their plan renewal dates, i.e., the time when employers

renew or switch the health insurance benefits they offer each year. For all enrollees, the baseline period was the full benefit year that preceded MHPAEA statute implementation (i.e., plan renewal dates starting on October 3, 2009), and the follow-up period was the first full benefit year after interim final rule implementation (i.e., plan renewal dates starting on July 1, 2010). We excluded from analyses a "phase-in" period, defined as the time between statute and interim final rule implementation when many employers were unlikely to have fully complied with MHPAEA. We set the start date for the follow-up period based on interim final rule implementation—rather than "final rule" implementation (i.e., plan renewal dates starting on July 1, 2014)—because it was anticipated that parity effects would be observable once most details regarding plans' obligations for compliance were clarified (Table 1.1).[6,18]

Table 1.1: Mental Health Parity and Addiction Equity Act Implementation: Group Health Plans

Law Component	Passage Date	Effective Date	Salient Features
Statute[12]	October 3, 2008	Plan renewal date starting October 3, 2009	• Sets out barebones parity requirements 1. Financial requirements (e.g., copayments, coinsurance, deductibles, out-of-pocket maximums) 2. (Quantitative) treatment limitations (e.g., annual, episodic, and lifetime inpatient and outpatient visit limits).
Interim Final Regulations[11]	February 2, 2010	Plan renewal date starting July 1, 2010	• Set out an additional required category for parity in insurance benefit design: 1. Nonquantitative treatment limitations (e.g.,prior authorization requirements and medical necessity determinations) • Identify six benefit classifications for parity testing: 1. in-network, outpatient 2. out-of-network, outpatient 3. in-network, inpatient 4. out-of-network, inpatient 5. emergency department 6. prescription drugs • Detail how financial requirement and quantitative treatment limitation testing will be performed • Set forth enforcement accountability
Final Regulations[13]	November 13, 2013	Plan renewal date starting July 1, 2014	• Detail nonquantitative treatment limitation requirements • Clarify plan disclosure requirements and consumer protections

Adults (ages 18-64) from the 24 states of interest who were continuously enrolled from the baseline through at least 1 follow-up year were included in the sample. Children were excluded because their mental health conditions and utilization patterns differ from those of adults, and members over age 64 were excluded because we lacked access to Medicare claims.

The cohort comprised adults who met the inclusion criteria for at least one of the following psychiatric diagnosis categories, which correspond to the ICD-9 diagnosis codes in Table A.9: schizophrenia and other psychoses; bipolar disorder; major depression; anxiety disorders; attention deficit/hyperactivity disorder; adjustment disorders; or other mental health disorders (i.e., all other diagnoses not in the preceding categories). To qualify for inclusion, an individual must have had, in the year *prior* to the baseline period, either (1) ≥2 outpatient or ED claims (on separate dates) within the same diagnosis category (e.g., schizophrenia); (2) ≥1 inpatient claims within a diagnosis category; or (3) ≥1 outpatient or ED claims within a diagnosis category if there was no more than one other claim on a separate date within a different diagnosis category. All diagnoses included in the claims were considered in creating cohorts. The pre-matched cohorts included 70,558 enrollees in self-insured plans meeting mental illness diagnosis criteria and 11,326 counterparts in small employer plans.

To maximize comparability of the exposure and comparison group populations, an enrollee-level propensity score matching[19] approach was used. Each small employer enrollee was matched to a self-insured plan enrollee on fixed demographic characteristics, the Johns Hopkins ACG® System comorbidity score (ACG, version 10.0.1),[20,21] plan renewal month category, and diagnostic qualifying month (Appendix A.1). Propensity score matching improved

balance among enrollees in the 2 groups along gender, comorbidity, diagnosis qualifying month, plan renewal month, race/ethnicity, and neighborhood poverty and education levels. Our final sample included 11,326 enrollees in self-insured plans (exposure group) and 11,326 enrollees in small employer group plans (comparison group) (Table 1.2; Table A.2).

Table 1.2: Unadjusted Baseline Characteristics of Study Population*

	Before Propensity Score Matching		After Propensity Score Matching		
Factor	**Self-Insured Plans (n=70,558)**	**Small Employer Plans (n=11,326)**	**Self-Insured Plans (n=11,326)**	**Small Employer Plans (n=11,326)**	**Standardized Difference[d]**
Age (year) in index mo.	43.8 ± 11.4	43.8 ± 11.8	44.0 ± 11.4	43.8 ± 11.8	-0.01
Female	60.7	56.3	57.9	56.3	0.02
ACG comorbidity score in index mo. (pop. mean=1)	2.5 ± 3.3	2.3 ± 3.1	2.3 ± 3.1	2.3 ± 3.1	-0.00
Diagnosis qualifying mo. (1-12)	6.3 ± 3.5	6.4 ± 3.4	6.4 ± 3.4	6.4 ± 3.4	0.04
Plan renewal mo. (1-12)	2.9 ± 3.1	6.4 ± 3.3	5.8 ± 3.5	6.4 ± 3.3	0.96
Race/ethnicity,[a]					0.04
Hispanic	10.4	7.2	8.1	7.2	
Asian	2.0	1.7	1.7	1.7	
White neighborhood	73.4	77.2	77.0	77.2	
Black neighborhood	1.2	0.9	0.9	0.9	
Mixed neighborhood	13.0	13.0	12.4	13.0	
Neighborhood education,[b]					0.00
High	64.5	64.9	64.8	64.9	
High-middle	20.4	20.0	20.1	20.0	
Low-middle	11.2	11.4	11.5	11.4	
Low	3.9	3.8	3.7	3.8	
Neighborhood poverty,[c]					0.01
Low	50.0	50.6	50.6	50.6	
Low-middle	25.1	24.1	24.3	24.1	
High-middle	17.5	17.5	17.5	17.5	
High	7.4	7.8	7.6	7.8	

Abbreviations: MHPAEA, Mental Health Parity and Addiction Equity Act.

*Data are presented as mean ± SD or %.

[a] Race/ethnicity was derived from a combination of geocoded census-block group level race from the 2000 US Census and surname analysis to identify Asian and Hispanic individuals. Mixed neighborhoods are those that do not meet a 75% threshold for white, black or Hispanic.

[b] Neighborhood education based on geocoded census-block group level data from the 2000 US Census. High denotes neighborhoods with <15% of the population with less than a high school education, high-middle 15%-24.9%, low-middle 25%-39.9%, and low ≥40%.

[c] Neighborhood poverty based on geocoded census-block group level data from 2000 US Census. Low denotes neighborhoods with <5% living below poverty level, high-middle 5%-9.9%, low-middle 10%-19.9%, and high ≥20%.

[d] Standardized difference = difference in means or proportions divided by standard error; a single standardized difference is calculated for binary categorical variables; imbalance defined as absolute value greater than 0.20 (small effect size).

To assess for variation in our outpatient outcomes among key sub-groups, we stratified the exposure and control groups by baseline year mental health outpatient visits quartile, baseline year out-of-pocket mental health outpatient spending quartile, and mental health diagnosis category (Appendix A.3).

1.3.2 Measures

Given that we lacked detailed benefit design information, we examined mean out-of-pocket spending per mental health outpatient visit to determine if the exposure group truly experienced reduced out-of-pocket expenditures. Primary outcomes were annual outpatient mental health visits per enrollee, and corresponding mean out-of-pocket spending per visit, and total annual spending on all outpatient mental health visits (Appendix A.1). An outpatient visit was considered to be mental health-related if (a) the primary diagnosis associated with the claim was categorized as a mental health diagnosis or if there was an evaluation and management code specific to mental health treatment (Table A.3) and (b) a mental health provider code was associated with the claim. We also examined overall inpatient admissions and ED visits.

Covariates included gender, age, neighborhood poverty and education, race/ethnicity, ACG comorbidity score, and plan renewal month. We used validated categorical variables of 2000 U.S. Census block group poverty and educational levels, and we used a combination of 2000 U.S. Census neighborhood characteristics and surname analysis to characterize members' race/ethnicity (Appendix A.1).[22]

1.3.3 Statistical Analyses

We compared baseline characteristics of our study groups using standardized differences (Table 1.2).[23] We used difference-in-differences analysis to estimate changes in outcomes in the exposure group relative to the comparison group in the 2 follow-up years (separately) versus the baseline year. We used generalized estimating equations with a negative binomial distribution to model outpatient mental health visit rates, ED visits, hospitalizations, and out-of-pocket spending, adjusting for individual age, gender, neighborhood education and poverty, race/ethnicity, state of residence, comorbidity, follow-up time, and plan renewal month. The key term of interest was the interaction between indicators of study group (self-insured versus small group) and pre-or post-exposure period. All results reported are based on 2-sided tests of statistical significance defined as $p < 0.05$. We used marginal effects methods (Appendix A.1) to calculate adjusted visit rates and spending, as well as absolute and relative difference-in-differences. We adopted this same approach in sensitivity analyses.

To display and fit estimated interrupted time series trends, we generated differenced outcome rates for monthly time series plots by subtracting mean exposure from comparison group outcomes in each month. We used interrupted time series regression with a linear trend term to model the differenced series, adjusting standard errors for autocorrelation (Appendix A.1). We plotted the monthly rates for each group, the differenced points between the groups, a predicted (from baseline) trend, and separate trends fitted to the actual differenced points in each of the 2 years following MHPAEA implementation (Figures 1.1 and 1.2). We also used the interrupted time series regression models to check that the baseline trends between groups

were not statistically significantly different for all difference-in-differences analyses, because parallel trends are required to generate valid estimates when using this design. We performed analyses using SAS version 9.3 (SAS Institute Inc., Cary, NC) and Stata version 12 (College Station, TX).

1.4 Results

The mean age of enrollees in both groups in the year prior to MHPAEA implementation was 44 and the ACG comorbidity score was 2.3 (compared to a population mean of 1, indicating a higher-than-average morbidity in our study population); 56-58% were female (Table 1.2). The majority of members in both groups were from high-education, low-poverty, and predominantly white neighborhoods (65%, 51%, and 77%, respectively).

In the baseline year (i.e., the year preceding MHPAEA), mean out-of-pocket spending per mental health outpatient visit was $30.81 and $37.03 for the exposure (n=11,326) and comparison (n=11,326) groups, respectively, and corresponding total annual out-of-pocket spending for these visits was $212.15 and $244.82 (Table 1.3) on average. Relative to the comparison group, the exposure group experienced very small but statistically significant declines in mean out-of-pocket spending per visit: $0.74 (1.38, 0.09) in year 1 and $2.12 (3.24, 0.99) in year 2. These corresponded to relative changes of -0.48% (-2.30, 1.34) and -3.22% (-5.98, -0.47). We observed no significant differences in mean total out-of-pocket spending.

Table 1.3: Out-of-Pocket Spending on Outpatient Mental Health Visits among Self-Insured Enrollees (Exposure Group) and Small Employer Enrollees (Comparison Group) in the Propensity Matched Cohort[a]

	Mean Spending ($)						Mean Change From Baseline to Follow-Up, Exposure Group vs Comparison Group			
	Exposure Group (n=11,326)			Comparison Group (n=11,326)			Absolute Spending ($)		Relative, %	
	Pre	Post	Change	Pre	Post	Change	Est. (95% CI)	p-value	Est. (95% CI)	p-value
OVERALL COHORT										
MHPAEA, Year 1										
OOP Spending per Visit	30.81	33.50	2.69	37.03	40.46	3.43	-0.74 (-1.38,-0.09)	0.03*	-0.48 (-2.30,1.34)	0.61
Total OOP Spending per Enrollee	212.15	229.01	16.86	244.82	263.41	18.59	-1.73 (-10.12,6.67)	0.69	0.33 (-3.18,3.84)	0.85
MHPAEA, Year 2										
OOP Spending per Visit	30.81	34.47	3.66	37.03	42.81	5.78	-2.12 (-3.24,-0.99)	<0.001*	-3.22 (-5.98,-0.47)	0.02*
Total OOP Spending per Enrollee	212.15	231.09	18.95	244.82	262.80	17.97	-0.97 (-8.11,10.06)	0.83	1.48 (-2.38,5.34)	0.45
SPENDING QUARTILE 1: LOWEST BASELINE SPENDERS ON MENTAL HEALTH OUTPATIENT VISITS										
MHPAEA, Year 1										
OOP Spending per Visit	19.07	30.75	11.68	23.45	36.20	12.75	-1.07 (-2.61,0.47)	0.17	4.44 (-1.14,10.04)	0.12
Total OOP Spending per Enrollee	26.59	106.44	79.84	29.95	117.70	87.75	-7.91 (-17.39,1.57)	0.10	1.84 (-9.65,13.33)	0.75
MHPAEA, Year 2										
OOP Spending per Visit	19.07	31.99	12.92	23.45	40.56	17.11	-4.19 (-8.85,0.46)	0.08	-3.02 (-14.96,8.91)	0.62
Total OOP Spending per Enrollee	26.59	117.53	90.94	29.95	131.22	101.27	-10.33 (-21.12,0.46)	0.06	0.87 (-10.86,12.60)	0.88
SPENDING QUARTILE 2: LOW-MEDIUM BASELINE SPENDERS ON MENTAL HEALTH OUTPATIENT VISITS										
MHPAEA, Year 1										
OOP Spending per Visit	26.28	31.07	4.79	30.96	36.36	5.31	-0.51 (-1.64,0.61)	0.37	0.93 (-2.61,4.47)	0.61
Total OOP Spending per Enrollee	85.72	138.76	53.03	95.51	162.47	66.96	-13.93 (23.12,-4.75)	0.003*	-4.85 (-10.73,1.04)	0.11
MHPAEA, Year 2										
OOP Spending per Visit	26.28	32.53	6.25	30.96	39.21	8.25	-2.00 (-3.30,-0.70)	0.002*	-2.27 (-5.99,1.46)	0.23
Total OOP Spending per Enrollee	85.72	153.65	67.92	95.51	174.98	79.48	-11.56 (-21.94,-1.17)	0.03	-2.18 (-8.53,4.18)	0.50
SPENDING QUARTILE 3: MEDIUM-HIGH BASELINE SPENDERS ON MENTAL HEALTH OUTPATIENT VISITS										
MHPAEA, Year 1										
OOP Spending per Visit	31.61	33.63	2.02	38.44	40.73	2.29	-0.27 (-1.44,0.90)	0.65	0.41 (-2.85,3.67)	0.81
Total OOP Spending per Enrollee	183.30	210.94	27.64	200.84	233.01	32.17	-4.53 (-16.66,7.59)	0.46	-0.81 (-6.24,4.62)	0.77
MHPAEA, Year 2										
OOP Spending per Visit	31.61	34.67	3.05	38.44	42.35	3.91	-0.86 (-2.17,0.46)	0.20	-0.47 (-4.04,3.10)	0.80
Total OOP Spending per Enrollee	183.30	217.75	34.45	200.84	240.02	39.18	-4.73 (-17.83,8.37)	0.48	-0.60 (-6.34,5.14)	0.84

Table 1.3: Out-of-Pocket Spending on Outpatient Mental Health Visits among Self-Insured Enrollees (Exposure Group) and Small Employer Enrollees (Comparison Group) in the Propensity Matched Cohort[a] (Continued)

	Mean Spending ($)						Mean Change From Baseline to Follow-Up, Exposure Group vs Comparison Group			
	Exposure Group (n=11,326)			Comparison Group (n=11,326)			Absolute Spending ($)		Relative, %	
	Pre	Post	Change	Pre	Post	Change	Est. (95% CI)	p-value	Est. (95% CI)	p-value
SPENDING QUARTILE 4: HIGHEST BASELINE SPENDERS ON MENTAL HEALTH OUTPATIENT VISITS										
MHPAEA, Year 1										
OOP Spending per Visit	42.16	38.88	-3.29	49.93	47.65	-2.28	-1.00 (-2.32,0.32)	0.14	-3.38 (-6.23,-0.48)	0.02*
Total OOP Spending per Enrollee	551.92	424.56	-127.36	640.42	486.93	-153.49	26.13 (2.10,50.15)	0.03*	1.17 (-3.73,6.07)	0.64
MHPAEA, Year 2										
OOP Spending per Visit	42.16	39.14	-3.03	49.93	48.89	-1.04	-1.99 (-3.46,-0.52)	0.008*	-5.21 (-8.35,-2.06)	0.001*
Total OOP Spending per Enrollee	551.92	390.60	-161.32	640.42	444.18	-196.25	34.93 (9.87,59.98)	0.006*	2.04 (-3.34,7.42)	0.46

Abbreviations: MHPAEA, Mental Health Parity and Addiction Equity Act; OOP, out-of-pocket.
[a]All rates and changes estimated using the Stata margins and/or nlcom commands and adjusted for age, gender, race/ethnicity, education level, poverty level, ACG score, state of residence, and plan renewal month.
* $p<0.05$

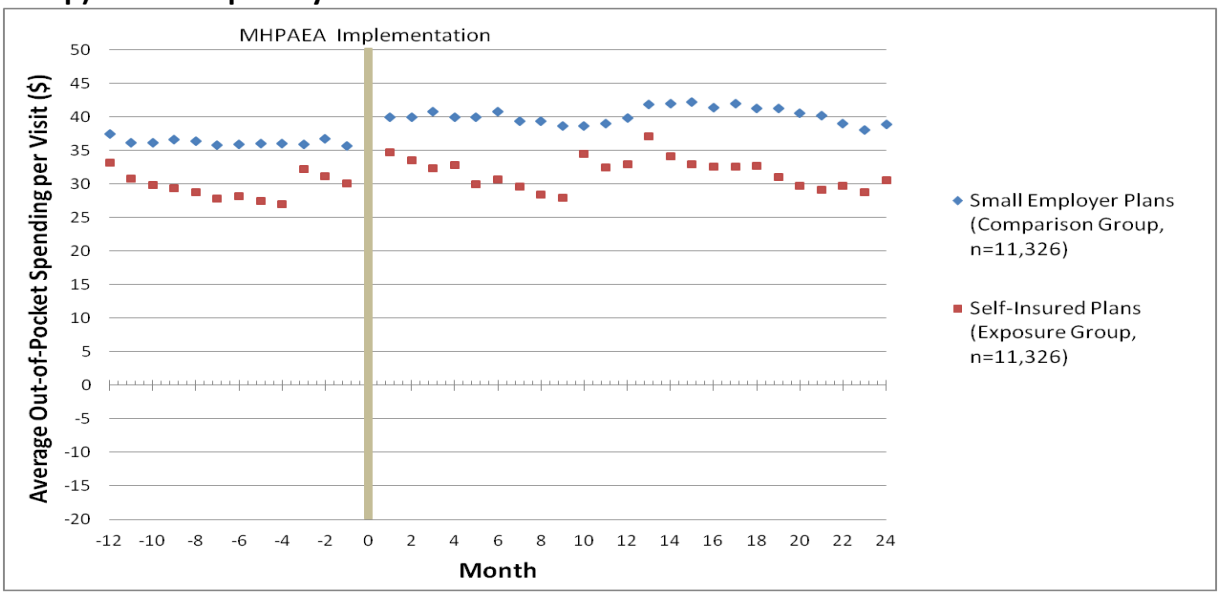
The exposure group had somewhat greater mean outpatient mental health visit rates in the baseline year than the comparison cohort (7.24 versus 6.70 visits per enrollee, Table 1.4). The baseline year ED visit and hospitalization rates (0.27-0.29 and 0.07-0.08 per enrollee, respectively) did not differ significantly between groups. Relative to comparison group enrollees, exposure group enrollees experienced statistically significant increases in outpatient mental health visits of 0.31 visits (0.12, 0.50) in year 1 and 0.45 visits (0.24, 0.67) in year 2, with corresponding relative changes of 4.40% (1.55, 7.25) and 6.64% (3.37, 9.92). We did not detect significant differences in ED visits (mean difference between groups of 0.00 [-0.03, 0.03] in year 1 and 0.01 [-0.02, 0.04] in year 2) or hospitalizations (mean difference between groups of 0.01 [-0.01, 0.02] in year 1 and 0.00 [-0.01, 0.01] in year 2).

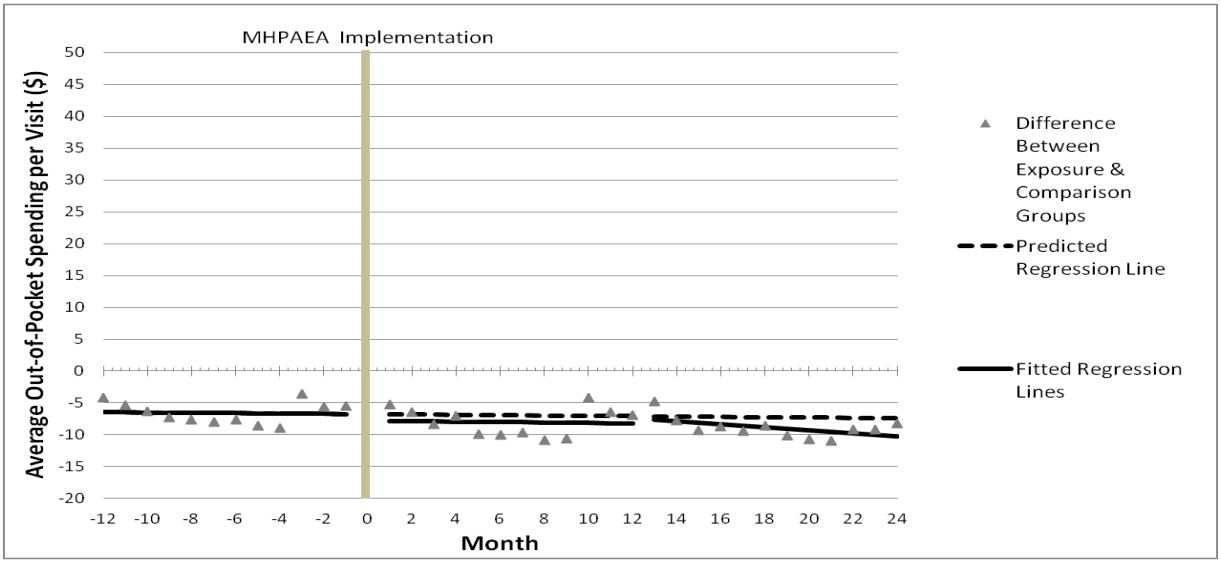
Table 1.4: Health Care Utilization among Self-Insured Enrollees (Exposure Group) and Small Employer Enrollees (Comparison Group) in the Propensity Matched Cohort[a]

	Mean Visits per Enrollee						Mean Change From Baseline to Follow-Up, Exposure Group vs Comparison Group			
	Exposure Group (n=11,326)			Comparison Group (n=11,326)			Absolute, per Enrollee		Relative, %	
	Pre	Post	Change	Pre	Post	Change	Est. (95% CI)	p-value	Est. (95% CI)	p-value
OVERALL COHORT										
MHPAEA, Year 1										
Outpatient Mental Health	7.24	7.49	0.25	6.70	6.64	-0.06	0.31 (0.12,0.50)	0.002*	4.40 (1.55,7.25)	0.003*
Emergency Department	0.29	0.32	0.03	0.27	0.30	0.03	0.00 (-0.03,0.03)	0.93	-0.24 (-9.22,8.74)	0.96
Inpatient	0.08	0.09	0.01	0.07	0.08	0.01	0.01 (-0.01,0.02)	0.40	5.36 (-9.72,20.43)	0.49
MHPAEA, Year 2										
Outpatient Mental Health	7.24	7.51	0.27	6.70	6.52	-0.18	0.45 (0.24,0.67)	<0.001*	6.64 (3.37,9.92)	<0.001*
Emergency Department	0.29	0.33	0.04	0.27	0.30	0.03	0.01 (-0.02,0.04)	0.54	2.10 (-7.50,11.71)	0.67
Inpatient	0.08	0.09	0.01	0.07	0.09	0.01	0.00 (-0.01,0.01)	0.77	1.24 (-13.66,16.14)	0.16
USE QUARTILE 1: LOWEST BASELINE MENTAL HEALTH OUTPATIENT VISITS USERS										
MHPAEA, Year 1										
Outpatient Mental Health	1.31	3.23	1.92	0.82	2.65	1.83	0.09 (-0.12,0.29)	0.42	-24.01 (-31.04,-16.97)	<0.001*
MHPAEA, Year 2										
Outpatient Mental Health	1.31	3.51	2.20	0.82	2.87	2.06	0.15 (-0.11,0.41)	0.27	-23.70 (-31.48,-15.91)	<0.001*
USE QUARTILE 2: LOW-MEDIUM BASELINE MENTAL HEALTH OUTPATIENT VISITS USERS										
MHPAEA, Year 1										
Outpatient Mental Health	3.54	4.67	1.13	3.04	4.11	1.07	0.06 (-.017,0.29)	0.62	-2.41 (-7.58,2.77)	0.36
MHPAEA, Year 2										
Outpatient Mental Health	3.54	5.00	1.46	3.04	4.25	1.21	0.25 (-0.02,0.51)	0.07	0.01 (-0.05,0.07)	0.73
USE QUARTILE 3: MEDIUM-HIGH BASELINE MENTAL HEALTH OUTPATIENT VISITS USERS										
MHPAEA, Year 1										
Outpatient Mental Health	6.68	6.79	0.11	6.36	6.05	-0.31	0.42 (0.14,0.71)	0.004*	6.89 (2.12,11.66)	0.005*
MHPAEA, Year 2										
Outpatient Mental Health	6.68	6.98	0.30	6.36	6.12	-0.25	0.55 (0.24,0.86)	0.001*	8.78 (3.60,13.96)	0.001*
USE QUARTILE 4: HIGHEST BASELINE MENTAL HEALTH OUTPATIENT VISITS USERS										
MHPAEA, Year 1										
Outpatient Mental Health	17.61	14.15	-3.46	16.39	12.30	-4.09	0.63 (0.07,1.20)	0.03*	7.10 (2.83,11.37)	0.001*
MHPAEA, Year 2										
Outpatient Mental Health	17.61	13.11	-4.50	16.39	11.21	-5.19	0.69 (0.75,1.30)	0.03*	8.91 (3.96,13.86)	<0.001*

Abbreviations: MHPAEA, Mental Health Parity and Addiction Equity Act. * p<0.05 [a]All rates estimated using the Stata margins and/or nlcom commands adjusted for age, gender, race/ethnicity, education & poverty level, ACG score, state & renewal month.

Figure 1.1: Unadjusted Mean Out-of-Pocket Spending per Mental Health Outpatient Visit among Self-Insured Enrollees (Exposure Group) and Small Employer Enrollees (Comparison Group) in the Propensity Matched Cohort

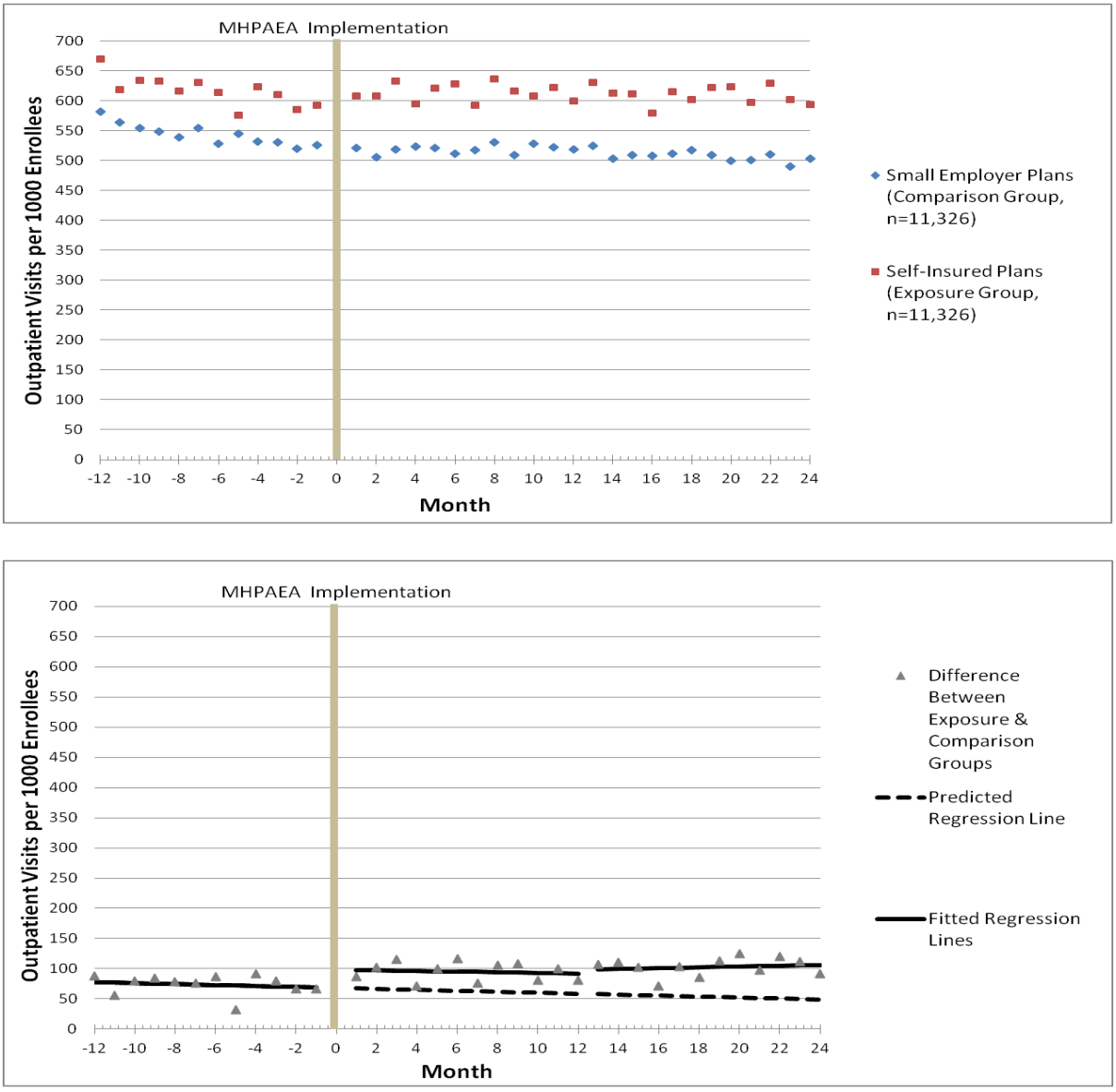




Abbreviations: MHPAEA, Mental Health Parity and Addiction Equity Act.

A fitted regression line shows the difference between exposure and comparison groups in the baseline period and continues as a predicted regression line in the follow-up period. Separate regression lines were fitted for years 1 and 2 of the follow-up period. Regression lines were calculated using unadjusted population-level interrupted time series linear models for the outcomes of interest.

Figure 1.2: Unadjusted Mental Health Outpatient Visit Rates among Self-Insured Enrollees (Exposure Group) and Small Employer Enrollees (Comparison Group) in the Propensity Matched Cohort



Abbreviations: MHPAEA, Mental Health Parity and Addiction Equity Act.
A fitted regression line shows the difference between exposure and comparison groups in the baseline period and continues as a predicted regression line in the follow-up period. Separate regression lines were fitted for years 1 and 2 of the follow-up period. Regression lines were calculated using unadjusted population-level interrupted time series linear models for the outcomes of interest.

Figures 1.1 and 1.2 demonstrate that the study groups had comparable baseline trends in monthly mean out-of-pocket spending per visit and visit rate (per 1000 enrollees) and statistical analyses revealed that baseline trends did not significantly differ. Fitted trends in the

2 years after MHPAEA implementation were consistent with difference-in-differences estimates above.

In analyses stratified by baseline year mental health outpatient use, the higher users in the exposure group experienced the most pronounced increases in utilization post-MHPAEA. Specifically, the third quartile (50-75th percentile in baseline utilization for each group) had mean mental health outpatient visits in the baseline year of 6.68 and 6.36 visits in the exposure and comparison groups, respectively (Table 1.4). In this third quartile, relative to comparison group enrollees, exposure group enrollees experienced statistically significant increases of 0.42 visits (0.14, 0.71; relative 6.89%) in year 1 and 0.55 visits (0.24, 0.86; relative 8.78%) in year 2 (Table 1.4). The fourth quartile (75-100th percentile in baseline utilization for each group) had mean mental health outpatient visits in the baseline year of 17.61 and 16.39 visits in the exposure and comparison groups, respectively (Table 1.4). In this fourth quartile, exposure group enrollees experienced statistically significant increases of 0.63 visits (0.07, 1.20; relative 7.10%) in year 1 and 0.69 visits (0.75, 1.30; relative 8.91%) in year 2, as compared to comparison group enrollees (Table 1.4). In our analyses stratified by baseline mental health outpatient spending, we observed statistically significant decreases in mean out-of-pocket spending per outpatient mental health visits in year 2 after MHPAEA in the second quartile (25-50th percentile in baseline spending) and in the fourth quartile (75-100th percentile in baseline spending) to support our main findings (Table 1.3). In addition, when we stratified by mental health diagnosis, we found significant increases in mental health outpatient visits and decreases in mean spending on these visits among the major depression cohort, although many

of the more severe diagnostic cohorts (e.g., schizophrenia and bipolar disorder) were not reported due to their small sample sizes (Appendix A.3; Table A.12; Table A.13).

Our basic findings were robust to sensitivity analyses. After matching on baseline out-of-pocket spending and visit rate trends, effect estimates for mean out-of-pocket spending per visit, total out-of-pocket spending, and outpatient visits per enrollee were consistent in terms of significance to estimates generated in the main analysis, if somewhat higher in magnitude (Appendix A.2; Table A.5; Table A.6; Figure A.1; Figure A.2). Outpatient visit and out-of-pocket-spending findings were supported by a test for regression to the mean in these sensitivity results (Appendix A.2; Table A.7; Table A.8). Moreover, the main analysis outpatient mental health spending and utilization estimates were consistent with those generated in a sensitivity analysis that excluded enrollees with a substance use disorder diagnosis (Appendix A.2; Table A.10; Table A.11).

1.5 Discussion

This study, one of the first to examine changes in mental health care use and spending after MHPAEA, found that MHPAEA was associated with statistically significant but small decreases in the mean out-of-pocket spending per mental health outpatient visit and increases in these visits for adults with mental health diagnoses. These changes were more pronounced among high utilizers and spenders, as well as in the second year after MHPAEA as compared to the first. MHPAEA was not associated with changes in total out-of-pocket spending on these visits likely because, although spending per visit declined, number of visits increased. We did not detect changes in ED or inpatient use, perhaps because increases in outpatient services were too modest to generate offsets.

Our results differ somewhat from earlier analyses of other (e.g., state or federal employee) parity policies. Our analysis leverages data from almost half of states, uses a rigorous design, and assesses a parity policy of unprecedented scope to find modest increases in outpatient mental health care use among those with mental illness. Most found that parity was associated with no difference in or reduced use of mental health and substance use disorder services, and many identified modest decreases (approximately $14 to $87 annually) in total out-of-pocket spending for those services.[13-16,24] More consistent with our findings is the recent study that found the removal of a 30-visit cap post-MHPAEA had a statistically significant association with increased use of mental health outpatient services by high utilizers.[11] Another study found that federal employee parity encouraged greater use of mental health services among moderate spenders.[25] An analysis of Oregon's 2007 state parity law, which had nonquantitative treatment protections similar to MHPAEA, also found that mental health care utilization increased among those with moderate outpatient need.[15] Other studies, when using survey rather than claims data, found associations between state parity laws and increased mental health service use.[12,17,2627]

MHPAEA was associated with slightly increased financial protection by reducing mean out-of-pocket spending per outpatient mental health visit. This spending result is consistent with a government compliance report which found that between 2009 and 2011, large employers decreased the use of higher cost-sharing (copays and coinsurance) for mental health and substance use disorder care: noncompliance ranged from 10-30% in 2009 and dropped to 0-20% in 2011.[28] Small increases in financial protection—likely in combination with removal of annual mental health outpatient visit caps—were associated with increased use of outpatient

mental health services, particularly among high utilizers, consistent with one of parity's major goals. As above, increased visits along with reduced spending per visit likely accounted for exposure group patients incurring unchanged total out-of-pocket costs while receiving a larger volume of services.

One potential explanation for the differences between our findings and several previous studies is that under prior parity policies, health plans increased supply-side managed behavioral care techniques (e.g., medical necessity determinations) to counteract the potential moral hazard introduced by expanded mental health benefit coverage.[29-33] Most parity policies (except Oregon's) allowed or even encouraged the use of such techniques. MHPAEA, however, required nonquantitative treatment limitation parity as of the interim final rule effective date, although compliance with these provisions is difficult to monitor.[34]

Additionally, previous parity policies reportedly suffered from under-enforcement and noncompliance.[3,35] Consistent enforcement of MHPAEA is also a concern, given decentralized accountability among federal agencies and state governments.[36,37] However, the sweeping and highly publicized nature of MHPAEA, along with early federal oversight, appears to have encouraged plans to comply with many benefit design requirements.[18,28]

Methodological differences may also account for differences between our findings and those of other parity studies. We isolated outpatient mental health visits rather than combining them with mental health inpatient services and drug utilization,[12,13,15,24] on the theory that unmet outpatient need would be most affected by parity. We also examined outcomes at 1 and 2 years after MHPAEA implementation to account for any lag time in plan compliance, whereas most other studies examined only one year or pooled data across 2 years post-parity.[12,13,15,25]

MHPAEA was modestly associated with increased mental health care access. Our findings suggest that mental health specialists and generalist clinicians may see a small or gradual increase in patients presenting for mental health care. Nevertheless, other persistent barriers, such as clinician undersupply[29,38] and stigma,[38,39] may limit opportunities for increased access to care offered by MHPAEA and the ACA.[29,40]

Our analysis has several limitations. Claims data do not provide diagnoses based on structured, standardized clinical interviews. Although it is unlikely that there were systematic changes in the data over time that differed across study groups, any such differences could introduce bias. A further limitation is that 2 years may not be long enough to capture the full extent of changes in spending and use after MHPAEA. Moreover, because psychotropic medication spending is outside of the payment structure for outpatient mental health visits, we did not include it in our measure of total out-of-pocket spending on these visits. However, because MHPAEA requires parity for prescription drug benefits, unlike most precursor policies, future studies should examine MHPAEA's effect on psychotropic medication use and spending.

The Optum data are drawn from a single, national insurer that may not be representative of all insurers in terms of their plans' compliance with MHPAEA. However, this insurer covers a sizeable percentage of the U.S. commercially insured population. Each employer's actual compliance with MHPAEA is uncertain given our lack of detailed benefit design information. Although we have strong reason to believe plans acted based on the interim final regulations,[6,28,34] the MHPAEA final regulations were not released until after our study period. It is therefore plausible that plans were not compliant with the nonquantitative treatment limitation aspects of MHPAEA during the period analyzed.[7] However, we examined

the “real-world” implementation window when employers were expected to comply, so any lack of association between parity and changes in spending and utilization would reflect a policy-relevant failure of compliance and enforcement. Furthermore, the smaller increases in out-of-pocket spending per visit among exposure group members relative to trends in controls suggests benefit design changes favorable to enrollees affected by parity.

In addition, by propensity score matching, we selected a subset of self-insured enrollees who may not have been representative of the entire group. Some self-insured plans may have offered generous mental health benefits prior to MHPAEA. The self-insured enrollees ultimately selected by our matching techniques were more similar to small firm employees not impacted by parity (e.g., along plan design, comorbidity, and gender characteristics). Therefore, MHPAEA-associated changes detected relative to small employer enrollees in the matched self-insured enrollees are arguably more policy relevant than those in the overall self-insured group.

1.6 Conclusions

MHPAEA represents the most sweeping mental health parity legislation adopted prior to the ACA. In 24 states where self-insured employers were newly subject to parity under MHPAEA, parity was associated with a modest relative increase in covered outpatient mental health visits after 2 years, but no changes in emergency department visits, hospitalizations, or total out-of-pocket spending on outpatient mental health visits. The highest baseline users of outpatient mental health visits in the exposure group appeared to experience the greatest increase in these visits associated with MHPAEA. Further investigation is needed to assess whether federal parity or extension of parity requirements to other populations under the ACA are associated with changes in clinical outcomes.

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2

PREVENTING OPIOID MISUSE WITH PRESCRIPTION DRUG MONITORING PROGRAMS: A FRAMEWORK FOR EVALUATING THE SUCCESS OF STATE PUBLIC HEALTH LAWS

2.1 Abstract

The United States is in the midst of a prescription opioid overdose and misuse epidemic. Although many factors have contributed to the escalation of prescription painkiller misuse, it parallels increases in the supply and prescribing of opioids. Prominent state-level regulatory interventions, such as the establishment of prescription drug monitoring programs (PDMPs), recognize prescribers as opioid gatekeepers. Prescribers, who are uniquely situated to distinguish between appropriate use and misuse of opioids, are a natural target for regulation.

PDMPs also target patients who seek to obtain high volumes of prescription opioids for illicit purposes.

PDMP policies are widespread but heterogeneous, largely uninformed by robust evidence or a systematic assessment of best practices. Whether these programs succeed in reducing opioid misuse and overdoses remains unclear. As well, PDMPs present a number of legal and ethical challenges that, along with intervention effectiveness, warrant careful policymaker consideration going forward. This Chapter articulates and synthesizes for the first time key criteria intended to assist state regulators in dynamically evaluating and justifying PDMPs and other public health laws. The criteria focus on the legality of the policy, approaches to measure its effectiveness, and normative considerations that should be factored into good public health laws. Such a framework is crucial for policymakers given the complexities and magnitude of this public health challenge, the rich arsenal of policy options from which to choose, and the slow and uncertain progress in combating prescription painkiller misuse. Concluding recommendations include implementing PDMPs with the following features: timely and complete data; strong incentives for prescriber participation; user guidelines and education; integration into clinical work flow; and robust confidentiality and privacy protections. Ongoing evaluation of programs to identify features appropriate for retention and replication also is crucial if PDMPs are to fulfill their potential to curb prescription opioid overdose and misuse.

2.2 INTRODUCTION

The United States is in the midst of a prescription opioid overdose and misuse crisis. Although only 5% of the world's population lives here, we consume over 80% of the world's

opioid supplies.[1] Drug overdoses, over half of which are related to prescription drugs, are now the leading cause of injury death in the United States.[2] In 2014, opioids were involved in 61% of drug overdose deaths, or 28,647 deaths.[3] The crisis has escalated to such proportions over the past two decades that federal officials now characterize prescription drug misuse and overdose as a national "epidemic."[4]

Prescription opioid deaths are a consequence of non-medically indicated use of opioids. This practice, also termed prescription opioid misuse and abuse (this Chapter uses the term "misuse" to capture both), consists of the unintentional or intentional use of medication without a prescription, in a manner other than as prescribed, or for the feeling or experience it causes.[5] The prevalence of prescription opioid misuse is striking. In 2013 alone, 15.3 million Americans aged 12 and older used prescription drugs non-medically, and 6.5 million had done so in the prior month.[6] Moreover, prescription opioids may serve as gateway drugs: there is

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[1] Jane C. Ballantyne & Andrew Kolodny, *Letter to the Editor: Preventing Prescription Opioid Abuse*, 313 JAMA 1059, 1059 (2015).

[2] Ctrs. for Disease Control & Prevention, Prescription Drug Overdose Data (Apr. 30, 2015), http://www.cdc.gov/drugoverdose/data/overdose.html.

[3] Rosa A. Rudd et al., *Increases in Drug and Opioid Overdose Deaths*, 64 MORBIDITY & MORTALITY WKLY. REP. 1378, 1379(2016) (finding that oxycodone and hydrocodone, the most commonly prescribed opioid pain relievers, are involved in more overdose deaths than any other type of opioid, including heroin). *See also* Margaret Warner et al., *Drug Poisoning Deaths in the United States, 1980-2008*, 81 NCHS DATA BRIEF 1 (2011), *available at* http://www.cdc.gov/nchs/data/databriefs/db81.pdf; Li H. Chen et al., *Drug-Poisoning Deaths Involving Opioid Analgesics: United States, 1999-2011*, 166 NCHS DATA BRIEF 1 (2014), *available at* http://www.cdc.gov/nchs/data/databriefs/db166.pdf (specifying that misuse or abuse of prescription drugs is responsible for much of the recent increase in drug-poisoning deaths).

[4] Leonard Paulozzi et al., *CDC Grand Rounds: Prescription Drug Overdoses—a U.S. Epidemic*, 61 MORBIDITY & MORTALITY WKLY. REP. 1, 1-10 (2012) (characterizing the prescription drug abuse as "the fastest growing drug problem in the United States" and prescription drug overdose as "a U.S. Epidemic"); OFFICE OF NATIONAL DRUG CONTROL POLICY, EXECUTIVE OFFICE OF THE PRESIDENT OF THE UNITED STATES OF AMERICA, EPIDEMIC: RESPONDING TO AMERICA'S PRESCRIPTION DRUG ABUSE CRISIS 1 (2011), https://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/rx_abuse_plan.pdf (calling the prescription drug abuse crisis an "epidemic").

[5] Substance Abuse and Mental Health Services Administration, Prescription Drug Misuse and Abuse (Sept. 29, 2014), http://www.samhsa.gov/prescription-drug-misuse-abuse.

[6] SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, RESULTS FROM THE 2013 NATIONAL

some evidence that addicts switch to even deadlier substances, such as heroin, when they can no longer access, afford, or tamper with prescription painkillers.[7]

The rise in prescription painkiller misuse and its consequences are clearly correlated with the increasing supply and prescribing of opioids. The overall sale of opioid analgesic painkillers, which increased nearly four-fold between 1999 through 2010, parallels observed increases in opioid-related overdose deaths, emergency department visits, and treatment admissions.[8] In 2012 alone, providers issued 259 million opioid prescriptions—enough for every adult to have their own bottle of pills.[9]

A heightened focus on pain management starting in the 1980s, spurred by drug industry messages that opioids could be safely used to treat chronic pain, liberalized opioid

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SURVEY ON DRUG USE AND HEALTH: SUMMARY OF NATIONAL FINDINGS, NSDUH Series H-48, HHS Publication No. (SMA) 14-4863. Rockville, MD: Substance Abuse and Mental Health Services Administration (2014) [hereinafter NSDUH].

[7] *See* Ian Frazier, *The Antidote: Can Staten Island's Middle-Class Neighborhoods Defeat an Overdose Epidemic?*, THE NEW YORKER, Sept. 8, 2014, http://www.newyorker.com/magazine/2014/09/08/antidote; Richard C. Dart et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 NEW ENGLAND J. MED. 241, 245-47; Theodore J. Cicero & Matthew S. Ellis, *Abuse-Deterrent Formulations and the Prescription Opioid Abuse Epidemic in the United States: Lessons Learned from OxyContin*, 72 JAMA PSYCHIATRY 424, 426-48 (2015). *But see* Rose A. Rudd et al., *Increases in Heroin Overdose Deaths—28 States, 2010-2012*, 63 MORBIDITY & MORTALITY WKLY. REP. 849, 849-52 (2014) ("[a]lthough some persons might be discontinuing prescription opioids and initiating heroin use as a replacement, results from this study indicate that recent heroin death rate increases were not significantly associated with decreases in [opioid pain reliever] overdose mortality."); Wilson M. Compton et al., *Relationship between Nonmedical Prescription-Opioid Use and Heroin Use*, 374 NEW ENG. J. MED. 154, 154-161 (2016) (finding that although a subgroup of non-medical prescription opioid users may transition to heroin use – especially those persons with frequent non-medical use and those with opioid abuse or dependence—the timing of policy-driven efforts to curb prescription opioid availability (which predated the increase in the rates of heroin use) makes it unlikely that the policies induced a substitution effect to heroin use).

[8] Ctrs. for Disease Control & Prevention, *Vital Signs: Overdoses of Prescription Opioid Pain Relievers – United States, 1999-2008*, 60 MORBIDITY & MORTALITY WKLY. REP. 1487, 1488-91 (2011).

[9] Christopher M. Jones et al., *Sources of Prescription Opioid Pain Relievers by Frequency of Past-Year Nonmedical Use: United States, 2008-2011*, 174 JAMA INTERNAL MEDICINE 802, 802-03 (2014); Ctrs. for Disease Control and Prevention, *Vital Signs: Variation Among States in Prescribing of Opioid Pain Relievers and Benzodiazepines—United States, 2012*, 63 MORBIDITY & MORTALITY WKLY REP. 563 (2014).

prescribing.[10] But in responding to the public health problem of under-treatment of pain, prescribers paradoxically have had a major role in creating another public health problem: the growth in prescription drug misuse. Almost twenty-four percent of non-medical prescription painkiller users obtained their drugs directly from a doctor's prescription, while 53% of users accessed drugs from family or friends (87% of whom had gotten their prescriptions from a doctor).[11] In other words, the vast majority of misused prescription drugs are sourced directly or indirectly from prescribers.[12]

Prescribers are uniquely situated to distinguish between appropriate use and misuse of opioids and prescribe accordingly. Several state regulatory interventions, including most prominently the establishment of prescription drug monitoring programs (PDMPs), recognize prescribers as opioid gatekeepers.[13] PDMPs also target "doctor shoppers" (patients with particularly high opioid consumption patterns) and diverters (individuals who transfer their prescribed drugs to others for illicit use). PDMPs have been adopted in all but one state, and the Centers for Disease Control and Prevention describes them as "among the most promising

[10] Andrea M. Garcia, *State Laws Regulating Prescribing of Controlled Substance: Balancing the Public Health Problems of Chronic Pain and Prescription Painkiller Abuse and Overdose*, 41 J. LAW, MED. & ETHICS (SUPP. 1) 42, 42-43 (2013); Tatyana Lyapustina & G. Caleb Alexander, *The Prescription Opioid Addiction and Abuse Epidemic: How it Happened and What We Can Do About It*, THE PHARMACEUTICAL JOURNAL, June 11, 2015, http://www.pharmaceutical-journal.com/opinion/comment/the-prescription-opioid-addiction-and-abuse-epidemic-how-it-happened-and-what-we-can-do-about-it/20068579.article (discussing the rise in global prescribing of opioids for pain starting in the 1990s, and claiming that the increased morbidity and mortality from opioids has resulted from the degree to which they have been prescribed).

[11] NSDUH, *supra* note 6.

[12] *See also* Jones et al., *supra* note 9, at 802-03 (observing that those at highest risk of overdose, or those who use prescription opioids non-medically on a chronic basis (i.e., for 200 or more days/year), were at the highest risk to obtain their drugs directly from a doctor (27% of the time)).

[13] *See* Barath Chakravarthy et al., *Prescription Drug Monitoring Programs and Other Interventions to Combat Prescription Opioid Abuse*, 13 WESTERN J. OF EMERG. MED. 422, 424 (2012).

state-level interventions to improve painkiller prescribing, inform clinical practice, and protect patients at risk."[14]

Although early evidence is emerging regarding the impact of these interventions on opioid prescribing, misuse, and overdoses, the rapid proliferation of heterogeneous PDMPs has been largely uninformed by robust evidence or a systematic assessment of best practices. Instead, state replication of PDMPs has exemplified disorganized policymaking in the face of a serious public health crisis. Moreover, PDMPs present a number of legal and normative challenges that, along with intervention effectiveness, warrant careful policymaker consideration going forward. Thus, existing PDMPs offer an opportunity to reflect upon how state public health policymaking in this area can follow a more deliberate path towards success.

This Chapter argues for the use of state PDMPs with the following features: timely and complete data; strong incentives for prescriber participation; user guidelines and education; integration into clinical workflow; and strong confidentiality protections—including a requirement that law enforcement officials and licensing boards access individual-identifying data only with a court-issued warrant or subpoena. Ongoing evaluation of PDMPs to improve understanding of best practices is also needed. To arrive at these recommendations, this Chapter articulates and synthesizes key criteria intended to assist state regulators in dynamically evaluating and potentially justifying public health laws like PDMPs. The criteria focus on the *form* that regulation should take, based on analysis of the policy's legality, measurement of law effectiveness, and normative considerations that ought to be factored into

[14] Ctrs. for Disease Control & Prevention, Prescription Drug Monitoring Programs (PDMPs) (May 5, 2015), http://www.cdc.gov/drugoverdose/pdmp/index.html.

good public health policy. Such a streamlined framework is a critical tool for state regulators, given the complexities and scope of prescription opioid misuse, the rich arsenal of policy options available to address it, and slow and uncertain progress in combating this problem. Although used to guide PDMP policymaking, this framework also can be applied to interventions designed to tackle public health threats that exhibit similar characteristics to prescription drug misuse—i.e., those of significant magnitude and that may be addressed using a number of available policy options, the success of which is not yet obvious or common knowledge.[15]

This Chapter proceeds as follows. Part 2.3 describes the current prescription drug misuse crisis, establishing it as a public health threat of substantial magnitude that evolved from a history of ebbing and flowing in opioid prescribing in the United States. Part 2.3 also outlines the panoply of regulatory interventions available to address this epidemic, including, most prominently, PDMPs implemented by state governments. Part 2.4 then lays out a framework for evaluating public health laws implemented by the states, which bear great responsibility to protect population health, and applies it to PDMPs. Key criteria are articulated that probe legal powers to regulate (including legal barriers to implementation), the effectiveness of the law at achieving identified primary and secondary health outcomes, and salient ethical issues raised by public health regulation. Finally, specific recommendations for

[15] The framework may also be used after identifying "critical opportunities" for public health lawmaking, or those areas "in which law is under-performing as a public health tool in relation to the problem of interest." Law can under-perform because legal interventions are few (or nonexistent) or because they are executing poorly, such as causing undesirable consequences. A critical opportunity satisfies three criteria: (1) it targets a significant public health threat; (2) its etiology is well-understood to support the use of law as an intervention; and (3) one or more plausible legal interventions are available to address the threat but are not being used to their full advantage. Michelle M. Mello et al., *Critical Opportunities for Public Health Law: A Call for Action*, 103 AM. J. PUBLIC HEALTH 1979, 1979-80 (2013).

PDMPs, generated by application of the evaluative framework, are set forth, with the goal of maximizing the chances that these policies will be a public health success.

2.3 Prescription Drug Misuse: A Public health epidemic

The current prescription drug misuse and overdose epidemic evolved from over a century of ebbing and flowing in prescription drug use in America. This is the third wave of misuse, following two earlier eras of problematic opioid use and regulatory responses.[16] The first escalation in misuse occurred in the late 19th century during a time when opioids were altogether unregulated.[17] Opioids, including heroin, were commonly prescribed for menstrual pain, among other maladies, often resulting in medically-induced morphine addiction.[18] Regulation ensued, in the form of the 1906 Pure Food and Drug Act, which required the content of drugs (including opioids) to be listed on their labels, and the 1914 Harrison Narcotics Act, which regulated physicians by mandating that they write prescriptions for opioids, taxing them for such prescriptions, and requiring that they maintain records of drugs dispensed.[19] The Harrison Narcotics Act moreover restricted the quantity of opiates that could be contained in medicines.[20] Regulation, and increased medical education and treatment options, had the intended effect of reducing opioid overprescribing.[21]

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[16] Austin Frakt, *The Upshot: Painkiller Abuse, a Cyclical Challenge*, N.Y. TIMES, Dec. 22, 2014, http://www.nytimes.com/2014/12/23/upshot/painkiller-abuse-a-cyclical-challenge.html?abt=0002&abg=1.
[17] *Id.*
[18] *Id.*; Andrew Kolodny et al., *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, 36 ANN. REV. PUBLIC HEALTH 559, 561 (2015) (discussing the limited options, other than opium and morphine, available to physicians in this era when treating pain symptoms).
[19] *Id.*; Ellen M. Weber, *Failure of Physicians to Prescribe Pharmacotherapies for Addiction: Regulatory Restrictions and Physician Resistance,* 13 J. HEALTH CARE L. & POL'Y 49, 57 (2010).
[20] Weber, supra note 19, at 57.
[21] Kolodny et al., *supra* note 18, at 562.

The second wave of misuse came in the mid-1950s as reports of increases in opioid use and overdose deaths proliferated across the country.[22] Regulatory responses included laws permitting involuntary hospitalizations of addicts, the establishment of methadone clinics for treating addiction under the Controlled Substances Act (CSA), and formation of the Drug Enforcement Administration (DEA) to coordinate federal anti-drug efforts.[23]

In the decades after this second wave, the under-treatment of pain was increasingly recognized as a serious public health challenge that necessitated changes to prescribing behavior. The United Nations even declared access to pain medication a human right in 1961.[24] This swing toward the liberalization of opioid prescribing contributed substantially to the current misuse and overdose epidemic. In response, various stakeholders—including state and federal regulators, insurers, drug manufacturers, and providers—have adopted a panoply of interventions targeting the supply of, demand for, and misuse of opioids.

2.3.1 The Liberalization of Opioid Prescribing for Pain

Under-treatment of pain is itself a serious public health challenge in the United States. An Institute of Medicine committee estimated that every year chronic pain affects about 100 million people and costs up to $560–635 billion in lost productivity and medical treatment.[25] Starting in the 1980s, inadequate treatment of chronic pain received heightened scrutiny. Before this time, physicians prescribed narcotics for short-term, acute pain, or for pain related

[22] Frakt, *supra* note 16.
[23] *Id*.
[24] *Id*.
[25] INSTITUTE OF MEDICINE, RELIEVING PAIN IN AMERICA: A BLUEPRINT FOR TRANSFORMING PREVENTION, CARE, EDUCATION AND RESEARCH 1 (2011), http://www.iom.edu/Reports/2011/Relieving-Pain-in-America-A-Blueprint-for-Transforming-Prevention-Care-Education-Research.aspx. The Institute of Medicine is now known as the National Academy of Sciences.

to cancer or end-of-life care.[26] Two medical journal articles—the first published in 1980 in the *New England Journal of Medicine*, and the second in *Pain* in 1986—opened the door to more liberal prescribing of painkillers.[27] Both studies concluded that narcotics can be safely prescribed for chronic pain to many patients with little risk of inducing addiction.[28]

In 1995, Purdue Pharma introduced an extended-release, highly potent form of the painkiller oxycodone known as OxyContin, which marked the onset of increased opioid use.[29] Around the same time, drug manufacturers began to market their opioid drugs for chronic, non-cancer pain via advertisements in well-respected journals, through continuing medical education courses for doctors, and by contributing financial support to not-for-profit organizations, such as the American Academy of Pain Management, the American Pain Society, and the Federation of State Medical Boards.[30] Highly-regarded physicians, such as Dr. Russell Portenoy (co-author of the aforementioned *Pain* study and director of the American Pain Society), served as the faces behind many of these drug company promotions.[31] In 1996, the American Pain Society launched an aggressive campaign entitled "Pain as the Fifth Vital Sign," the message of which was embraced by the Veterans Affairs health system and The Joint Commission (which accredits health care organizations, including hospitals).[32] In 2004, the Federation of State Medical Boards passed a model policy on the use of controlled substances

[26] Celine Gounder, *Who is Responsible for the Pain Pill Epidemic?*, THE NEW YORKER, Nov. 8, 2013, http://www.newyorker.com/business/currency/who-is-responsible-for-the-pain-pill-epidemic.
[27] *Id*.; Frakt, *supra* note 16.
[28] *Id*.
[29] Kolodny et al., *supra* note 18, at 562.
[30] *Id.*; Frakt, *supra* note 16.
[31] Gounder, *supra* note 26.
[32] Kolodny et al., *supra* note 18, at 562.

to treat pain.[33] The policy encouraged state medical boards to consider under-treatment of pain an equally serious violation of the standard of care as over-treatment.[34]

Also over the past several decades, more subtle forces have encouraged doctors to generously prescribe opioids. Patient satisfaction assessments pervade the modern practice of medicine (and even impact payment under pay-for-performance schemes), thereby motivating certain physicians to prescribe opioids if requested by patients.[35] The medical insurer practice of reimbursing well for prescription pain medications further reinforces the use of opioids to treat subjective pain.[36] Cumulatively, stakeholder group activities, financial incentives, and patient satisfaction considerations have contributed significantly to sharp increases in opioid prescribing observed in the 1990s–2000s that laid the foundation for misuse.

During this same period, a number of academics proposed legal strategies to promote opioid prescribing for pain. Building upon one prominent case in which a physician was found to have committed elder abuse by a California court for failing to prescribe drugs adequately to manage a patient's pain,[37]some academics advocated for increased state court recognition of tort claims against physicians who under-prescribe painkillers[38] or institutions for failing to

[33] Garcia, *supra* note 10, at 43.
[34] *Id*.; Gounder, *supra* note 26.
[35] Anna Lembke, *Why Doctors Prescribe Opioids to Known Opioid Abusers*, 367 NEW ENG. J. MED. 1580, 1580-1581 (2012);
[36] *Id*.; Aleksandra Zgierska et al., *Patient Satisfaction, Prescription Drug Abuse, and Potential Unintended Consequences*, 307 JAMA 1377, 1377-78 (2012).
[37] Garcia, *supra* note 10, at 42-43.
[38] *See* Michael J. Reynolds, *Note: Morphine or Malpractice: Should Courts Recognize a Legal Duty to Prescribe Opiates for Treating Chronic Pain*, 15 ST. JOHN'S J.L. COMM. 79 (2000); Barry R. Furrow, *Pain Management and Provider Liability: No More Excuses*, 29 J. L. MED. & ETHICS 28, 30-36 (2001); Gilah R. Mayer, *Comment: Bergman v. Chin: Why an Elder Abuse Case is a Stride in the Direction of Civil Culpability for Physicians Who Undertreat Patients Suffering from Terminal Pain*, 37 NEW ENG. L. REV. 313 (2003).

satisfy a standard of care for effective pain relief.[39] Other have recommended the development of a comprehensive, coordinated national policy to address the inadequate management of pain, rather than the patchwork of state and federal policies in existence.[40] Still others have questioned the appropriateness of criminal liability for prescribers under the CSA and instead supported an increased role for state medical boards in policing physician controlled substance prescribing.[41] Many of these viewpoints, however, relied on older science that supported the effectiveness of opioids for treating chronic, non-cancer pain—a clinical viewpoint that is now regularly challenged and up for debate.[42] Concerns with under-prescribing now must be balanced with those about over-prescribing, given our current epidemic of prescription drug misuse.

2.3.2 The Rise of Prescription Painkiller Misuse

Prescription opioid misuse in the United States has risen to epidemic proportions in recent years. Non-medical use[43] of prescription drugs occurs in four therapeutic classes (pain relievers, tranquilizers, stimulants, and sedatives); opioid pain relievers are, however, the most

[39] Furrow, *supra* note 38, at 37-42; Ben A. Rich, *The Politics of Pain: Rhetoric or Reform?* 8 DEPAUL J. HEALTH CARE L. 519 (2005).

[40] Amy J. Dilcher, *Damned if They Do, Damned if They Don't: The Need for a Comprehensive Public Policy to Address Inadequate Management of Pain*, 13 ANN. HEALTH L. 81 (2004).

[41] Diane E. Hoffmann & Anita J. Tarzian, *Achieving the Right Balance in Oversight of Physician Opioid Prescribing for Pain: The Role of State Medical Boards*, 31 J.L. MED. & ETHICS 21 (2003); Diane E. Hoffmann, *Treating Pain v. Reducing Drug Diversion and Abuse: Recalibrating the Balance in Our Drug Control Laws and Policies*, 1 ST. LOUIS J. HEALTH L. & POL'Y 231 (2008).

[42] *See* NAT'L INSTITUTES OF HEALTH, PATHWAYS TO PREVENTION WORKSHOP: THE ROLE OF OPIOIDS IN THE TREATMENT OF CHRONIC PAIN, Sept. 29-30, 2014, https://prevention.nih.gov/docs/programs/p2p/ODPPainPanelStatementFinal_10-02-14.pdf (suggesting that for most patients, there are likely to be more effective approaches to managing chronic pain than opioid therapies); Deborah Dowell, Tamara M. Haegerich, & Roger Chou. *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, JAMA, March 15, 2016, available at http://jama.jamanetwork.com/article.aspx?articleid=2503508.

[43] For a definition of "non-medical use", *see supra* note 5 and accompanying text.

commonly misused medication by far.[44] The percentage of Americans aged twenty and older who non-medically use pain relievers in a month has held relatively stable at around 7% over the past decade, after increasing from 5% in 1999–2002.[45] However, this statistic fails to capture an increase in the intensity of use and misuse. For example, from 1999–2002 to 2011–2012, the percentage of opioid analgesic users who used a stronger-than-morphine equivalent opioid (per dose) in the past 30 days increased from 17% to 37%.[46]

Moreover, adverse health consequences resulting from prescription drug misuse—including overdose events, emergency department (ED) visits, and inpatient admissions—have escalated dramatically. Fatal opioid overdoses exploded from 1.4 per 100,000 people in 1999 to 9.0 per 100,000 people in 2014.[47] The rate of emergency department visits involving nonmedical use of prescription drugs—primarily of opioids—more than doubled from 214 visits per 100,000 people in 2004 to 458 in 2011.[48] About half of these deaths and ED visits involved another drug, including benzodiazepines, cocaine, or heroin.[49] The proportion of substance misuse treatment admissions citing pain reliever misuse also more than quadrupled from 1998 and 2008.[50]

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[44] NSDUH, *supra* note 6, at 15-18.

[45] Steven M. Frenk et al., *Prescription Opioid Analgesic Use Among Adults: United States, 1999-2012*, 189 NCHS DATA BRIEF 1, 1-2 (2015), *available at* http://www.cdc.gov/nchs/data/databriefs/db189.htm.

[46] *Id*. at 2.

[47] Chen et al., *supra* note 3, at 2; Rudd et al., *supra* note 3, at 1378.

[48] SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, THE DAWN REPORT: HIGHLIGHTS OF THE 2011 DRUG ABUSE WARNING NETWORK (DAWN) FINDINGS ON DRUG-RELATED EMERGENCY DEPARTMENT VISITS (2013), http://archive.samhsa.gov/data/2k13/DAWN127/sr127-DAWN-highlights.htm.

[49] *Id*.; Warner et al., *supra* note 3, at 1.

[50] OFFICE OF NATIONAL DRUG CONTROL POLICY, EXECUTIVE OFFICE OF THE PRESIDENT, 2010 NATIONAL SURVEY ON DRUG USE AND HEALTH: HIGHLIGHTS 1 (2011), http://www.whitehouse.gov/sites/default/files/ondcp/Fact_Sheets/nsduh_fact_sheet_9-7-11_0.pdf.

Prescription opioid use and misuse persists among people from diverse demographic backgrounds, albeit certain groups exhibit slightly higher rates of use and overdose risk. Adults aged 40 and older are slightly more likely to use opioid analgesics than adults aged 20-39; women are slightly more likely than men to use opioids; and non-Hispanic white adults are more likely to use prescription painkillers than Hispanic adults.[51] People at heightened risk for opioid overdose include women, those consuming high daily doses of opioids, those taking medication for chronic pain, "doctor-shoppers,"[52] users of multiple abusable substances, and those with substance abuse or other mental health issues.[53]

There is little room for optimism. Evidence from 2011–2013 did indicate a leveling off in opioid prescribing rates and overdoses nationally,[54] which some researchers attributed to the August 2010 reformulation of OxyContin to a more tamper-resistant form.[55] However, more

[51] Frenk et al., *supra* note 45, at 3-6.
[52] Clinical definitions of "doctor shoppers" differ. *See, e.g.,* Scott G. Weiner et al., *Characteristics of Emergency Department "Doctor Shoppers"*, 48 J. EMERG. MED. 424, 424 (2015) (defining "doctor shoppers" as patients that had 8 or more Schedule II-V prescriptions filled from 8 or more providers in 1 year); Douglas C. McDonald & Kenneth E. Carlson, *Estimating the Prevalence of Opioid Diversion by "Doctor Shoppers" in the United States*, 8 PLOS. ONE e69241 (2013) (using different thresholds to define "doctor shoppers" to estimate opioid diversion prevalence). *See also* Joseph Logan et al., *Opioid Prescribing in Emergency Departments: The Prevalence of Potentially Inappropriate Prescribing and Misuse*, 51 MED. CARE 646 (2013) (identifying the following as indicators of potential inappropriate use: opioid prescriptions overlapping by 1 week or more; overlapping opioid and benzodiazepine prescriptions; high daily doses of ≥ 100 morphine milligram equivalents; long-acting/extended-release (LA/ER) opioids for acute pain; and overlapping LA/ER opioids).
[53] Kate M. Dunn et al., *Opioid Prescriptions for Chronic Pain and Overdose: A Cohort Study*, 152 ANNALS INTERNAL MED. 85, 87-91 (2010); Amy S. Bohnert et al. *Association Between Opioid Prescribing Patterns and Opioid Overdose-Related Deaths*, 305 JAMA 1315, 1315-1321 (2011); Alan G. White et al. *Analytic Models to Identify Patients at Risk for Prescription Opioid Abuse*, 15 AM. J. MANAGED CARE 897, 897-906 (2009); Barth L. Wilsey et al., *Profiling Multiple Provider Prescribing of Opioids, Benzodiazepines, Stimulants, and Anorectics*, 112 DRUG & ALCOHOL DEPENDENCE 99 (2010). *See also*, Anupam B. Jena et al., *Opioid Prescribing by Multiple Providers in Medicare: Retrospective Observational Study of Insurance Claims*, 348 BRIT. MED. J. g1393 (2014) (finding that concurrent opioid prescribing by multiple providers in Medicare patients is associated with higher rates of opioid-related hospital admissions).
[54] *See* Richard C. Dart et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 NEW ENGL. J. MED. 241 (2015).
[55] *Id*.; Marc R. Larochelle et al., *Rates of Opioid Dispensing and Overdose After Introduction of Abuse-Deterrent Extended-Release Oxycodone and Withdrawal of Propoxyphene*, 175 JAMA INTERNAL MED. 978 (2015); Theodore J.

recent evidence shows that national prescription opioid overdose death rates again significantly increased from 2013–2014,[56] suggesting that existing policy interventions may not be sufficient to tackle to epidemic. Over this same period, moreover, heroin abuse rates increased, suggesting that some—though not all—prescription drug misusers switched to an illegal, cheaper, and deadlier alternative when they could no longer access prescription opioids.[57]

2.3.3 Regulatory Responses

Federal and state policymakers, among others, have responded with a multitude of interventions to address opioid misuse and overdoses. Table 2.1 catalogues prominent interventions and identifies the stakeholders that typically take these measures. Although not exhaustive, this list illustrates the many strategies available and the complex array of implementers. These strategies are characterized within the public health prevention paradigm used for epidemiologic responses to other communicable and non-communicable diseases. Opioid addiction, or the compulsive opioid seeking and use despite the often negative consequences,[58] is the chronic disease that can result from prescription opioid misuse.[59]

Cicero & Matthew S. Ellis, *Abuse-Deterrent Formulations and the Prescription Opioid Abuse Epidemic in the United States: Lessons Learned from OxyContin*, 72 JAMA PSYCHIATRY 424 (2015).

[56] Rudd et al., *supra* note 3, at 1378-79.

[57] Dart et al., *supra* note 55; Larochelle et al., *supra* note 55; Brian Owens, *Tackling Prescription Drug Abuse,* THE PHARMACEUTICAL JOURNAL, Jun. 11, 2015, http://www.pharmaceutical-journal.com/news-and-analysis/features/tackling-prescription-drug-abuse/20068685.article?adfesuccess=1; Compton et al., *supra* note 7.

[58] NATIONAL INSTITUTE ON DRUG ABUSE, RESEARCH REPORT SERIES: PRESCRIPTION DRUG ABUSE 3 (2014), https://d14rmgtrwzf5a.cloudfront.net/sites/default/files/prescriptiondrugrrs_11_14.pdf. Addiction can also include physical dependence, or where an individual experiences withdrawal symptoms when use of a drug is suddenly stopped or reduced. *Id*.

[59] Kolodny et al., *supra* note 18, at 565.

Table 2.1: Interventions to Curb Prescription Drug Misuse

Stage	Objective	Examples of Interventions	Implementing Stakeholders

Primary prevention	Prevent initiation of prescription opioid addiction	Opioid prescriber education & guidelines*	• State & local governments
			• Health care providers
			• Federal government
			  ○ CDC Guidelines on Opioid Prescribing for Chronic Pain[60]
			  ○ U.S. Food & Drug Administration (FDA): Risk Evaluation & Mitigation Strategy (REMS)[61] required of extended-release/ long-acting (ER/LA) opioid drug sponsors

		Pain management clinic (i.e., "pill mill")[62] regulation*	• State governments • Federal government ○ Drug Enforcement Agency

		Opioid drug approval*	• Federal government
			  ○ FDA:REMS required for ER/LA opioids
			  ○ FDA: Black box warnings for immediate-release opioid pain medications[63]

		Abuse-deterrent drug formulations*	• Opioid drug developers
		Medication take-back or disposal programs*	• Federal government ○ DEA • State or local governments • Retail pharmacies

[60] Dowell et al., *supra* note 42.

[61] Under the Food and Drug Administration Amendments Act (FDAAA) of 2007, REMS was introduced as a risk-management strategy intended to reduce known or serious safety hazards associated with a drug or biologic product. The FDAAA grants the FDA authority to require sponsors to submit a REMS prior to drug approval if it determines that such a measure is necessary to ensure that drug benefits outweigh risks, or after approval if new safety information emerges to necessitate such a strategy. INSTITUTE OF MEDICINE, ETHICAL AND SCIENTIFIC ISSUES IN STUDYING THE SAFETY OF APPROVED DRUGS 42-43 (2012), http://www.nap.edu/catalog/13219/ethical-and-scientific-issues-in-studying-the-safety-of-approved-drugs.
See infra note 149 for a discussion of the REMS for ER/LA opioid medications.

[62] "Pill mills" are those facilities where pain management is the primary practice component, or which provide pain treatment to a majority (>50 percent) of patients, or both. Ctrs. for Disease Control and Prevention, Menu of Pain Management Clinic Regulation (Sept. 28, 2012), http://www.cdc.gov/phlp/docs/menu-pmcr.pdf

[63] U.S. Food and Drug Administration, *FDA Announces Enhances Warnings for Immediate-Release Opioid Pain Medications Related to Risks of Misuse, Abuse, Addiction, Overdose and Death*, March 22, 2016, available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm.

Table 2.1: Interventions to Curb Prescription Drug Misuse (Continued)

Stage	Objective	Examples of Interventions	Implementing Stakeholders
Secondary prevention	Identify & treat prescription opioid addiction after onset but before serious complications develop	Prescription drug monitoring programs**	• State governments • Insurers
		Urine testing for drugs**	• Health care providers • Insurers
		Drug supply management ** • Formulary development • Quantity limits • Reimbursement incentives	• Insurers • Pharmacy benefit managers
		Anti-"doctor shopping" laws[64]	• State and local governments
Tertiary prevention	Address firmly established opioid addiction through therapeutic or rehabilitative measures	Opioid addiction treatment	• Insurers • Health care providers • Governments (federal, state, local)
		Access to opioid overdose reversal drugs	• State and local governments • Insurers and PBMs
		Syringe exchange programs	• State and local governments • Non-governmental organizations

* These interventions also can be considered secondary prevention measures.
** These interventions could be considered primary, secondary, or tertiary prevention measures, because they aim to identify misusers and diverters and prevent them from accessing opioids (which can then be passed on to "unexposed" persons) and can also be used to direct misusers into treatment programs.

Prevention of addiction can be organized into strategies that focus on (1) *primary prevention* of new cases of opioid addiction, (2) *secondary prevention* to identify and treat early cases of addiction, and (3) *tertiary prevention* to effectively treat those already addicted.[65] The goal of primary prevention is to reduce the incidence of disease—in this case, to prevent the initiation of opioid addiction. Prescriber guidelines, such as those recently issued by the Centers for Disease Control and Prevention (CDC) on Opioid Prescribing for Chronic Pain,[66] are an

[64] "Doctor shopping" is defined as a patient obtaining controlled substances from multiple healthcare providers without the prescriber's knowledge of the other prescriptions. Ctrs. for Disease Control and Prevention, Doctor Shopping Laws, (Sept. 28, 2012), http://www.cdc.gov/phlp/docs/menu-shoppinglaws.pdf.
[65] *Id*. at 565-69.
[66] Dowell et al., *supra* note 42.

example of primary prevention, because they seek to encourage more informed opioid prescribing. Secondary prevention measures aim to identify and treat a serious health condition after onset but before serious complications ensue,[67] such as detecting doctor shoppers by means of a PDMP. Finally, tertiary prevention measures provide therapy and rehabilitation once a disease is firmly established.[68] Access to the opioid overdose reversal drugs (e.g., naloxone) is an example of tertiary prevention.

Undoubtedly, some combination of these prevention measures is required to comprehensively address prescription opioid-related morbidity and mortality—but which specific interventions are most worthwhile to pursue? This Chapter focuses on a specific type of intervention: prescription drug monitoring programs. Other prevention measures are unquestionably key components to comprehensively addressing the epidemic, but PDMPs are a popular, state-level, legal mechanism that have gained the reputation as having incredible promise for addressing opioid misuse.[69] They primarily target prescribing, a significant upstream driver of prescription opioid misuse because it serves as the prerequisite to most opioid addiction—whether by initial prescription, repeat prescriptions, or obtaining drugs from friends/family members or diverters.[70] And PDMPs have experienced widespread—albeit disorganized—roll-out among the states, such that policies exhibit widely varying features not rigorously informed by evidence or systematic criteria for determining their success.

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[67] Kolodny et al., *supra* note 18, at 565-69.
[68] *Id*.
[69] Chakravarthy et al., *supra* note 13, at 424.
[70] Wilson M. Compton et al., *Prescription Opioid Abuse: Problems and Responses*, PREVENTIVE MED. (2015), doi:10.1016/j.ypmed.2015.04.003. *See also* Jones et al., *supra* note 9, at 802-03 (underscoring the need to target prescribers, as they commonly source opioids to frequent users).

2.3.3.1 State Prescription Drug Monitoring Programs

State PDMPs are the most prevalent state policy mechanism used to address prescription drug misuse, with forty-nine states and the District of Columbia having enacted programs.[71] PDMPs digitally store controlled substance dispensing information in a centralized, statewide database and make that information accessible to "authorized users," including prescribers, pharmacists, and sometimes law enforcement officials and state medical boards.[72] When they query the system about a patient, authorized users typically see the dose, supply, and prescriber of scheduled drugs that the patient has recently filled.[73] Authorized users can only access the data with log-in credentials provided upon registering with the PDMP.

PDMPs seek to satisfy many goals, most prominently to support providers in facilitating the legitimate medical use of controlled substances, while avoiding prescription drug misuse.[74] Armed with PDMP information supplied about a patient, prescribers and pharmacists can communicate with the patient about his or her prescription histories, address potentially dangerous co-prescribing of substances, refrain from supplying opioids to a doctor shopper[75] or diverter, comfortably provide prescription drugs to an individual who doesn't raise concerns about misuse, and direct individuals into substance abuse treatment therapy when clinically

[71] NATIONAL ALLIANCE FOR MODEL STATE DRUG LAWS, ANNUAL REVIEW OF PRESCRIPTION MONITORING PROGRAMS 2 (2014), http://www.namsdl.org/library/3449DDCF-BB94-288B-049EB9A92BAD73DF/ [hereinafter NAMSDL Review].
[72] PRESCRIPTION DRUG MONITORING PROGRAM CENTER OF EXCELLENCE AT BRANDEIS, BRIEFING ON PDMP EFFECTIVENESS 3 (2014), http://www.pdmpexcellence.org/sites/all/pdfs/Briefing%20on%20PDMP%20Effectiveness%203rd%20revision.pdf [hereinafter COE Briefing].
[73] Rebecca L. Haffajee et al., *Mandatory Use of Prescription Drug Monitoring Programs*, 313 JAMA 891 (2015).
[74] KRISTIN M. FINKLEA ET AL., CONG. RESEARCH SERV., PRESCRIPTION MONITORING PROGRAMS 3 (2014), https://fas.org/sgp/crs/misc/R42593.pdf (additionally identifying public health trend surveillance as a PDMP purpose).
[75] *See supra* note 52 and accompanying text.

indicated.[76] When enough providers share dispensing information and access patient profiles via PDMPs, opioid misusers and diverters have a harder time "gaming" the system by seeking drugs from multiple providers or pharmacies. As well, PDMPs are intended to help regulators in investigating clinicians with inappropriate prescribing and dispensing patterns and patients with drug fill behaviors indicative of misuse or diversion.[77] In sum, PDMPs aim to promote individual as well as population health, by improving prescribing (and dispensing) decisions made for each patient and by limiting the negative externalities generated by the over-supply of opioids.[78]

State legislatures create PDMPs by statute and outline program details by regulation, often leaving many of the operational particulars to the executive agency in which the program is housed.[79] Advances in information technology facilitated state implementation of electronic PDMPs in the 1990s–2000s.[80] These programs succeeded earlier, less-widespread paper prescription monitoring systems (also known as carbon copy or triplicate paper programs), the first of which was created in California in 1939.[81] Since the first electronic PDMP was established in Oklahoma in 1990, these programs have rapidly proliferated.[82] In 2001, sixteen

[76] Haffajee et al., *supra* note 73, at 891.
[77] Finklea et al., *supra* note 74, at 3.
[78] *See* G. Caleb Alexander et al., *Rethinking Opioid Prescribing to Protect Patient Safety and Public Health*, 308 JAMA 1865, 1865-6 (2012) (suggesting that a public health approach to the treatment of pain calls for greater clinical judiciousness in prescribing of opioids given the harmful effects that clinicians' treatment decisions have on other individuals beyond the patient being treated).
[79] PDMPs are most commonly housed within health agencies or boards of pharmacy, although some are housed within law enforcement or other agencies. The housing agency distributes PDMP data to individuals authorized under state law to receive the information. Richard A. Deyo et al., *Measures Such as Interstate Cooperation Would Improve the Efficacy of Programs that Track Controlled Drug Prescriptions*, 32 HEALTH AFF. 603, 604 (2013).
[80] *Id*.
[81] *Id*.
[82] THOMAS CLARK ET AL., PRESCRIPTION DRUG MONITORING PROGRAM CENTER OF EXCELLENCE AT BRANDEIS, PRESCRIPTION DRUG MONITORING PROGRAMS: AN ASSESSMENT OF THE EVIDENCE FOR BEST PRACTICES 3 (2012), http://www.pdmpexcellence.org/sites/all/pdfs/Brandeis_PDMP_Report_final.pdf

states had authorized the creation of a program by statute; and by June 2012, forty-nine states and one territory had passed such laws (with forty-one states having an operational program).[83] Today, all states except Missouri have an operational PDMP.[84]

PDMPs vary widely along a number of dimensions,[85] including: who can query the data (and for what purposes);[86] whether unsolicited reports are sent to users;[87] whether prescribers and/or dispensers can delegate access to an authorized agent;[88] whether notification of a patient is required when his/her data is accessed;[89] the extent to which data is shared with other states;[90] how frequently the data are updated;[91] and whether training is required of users.[92] PDMPs increasingly monitor (or track) drugs that are included in Schedules II through V of the DEA's controlled substances schedules.[93] Recent innovations gaining traction with states

[83] *Id*. at 5.
[84] NAMSDL Review, *supra* note 71, at 2.
[85] *See generally* Deyo et al., *supra* note 79, at 605-07. *See* NAMSDL Review, *supra* note 71, for an updated comparison of program features.
[86] Forty-eight states include prescribers, dispensers, licensing boards, and law enforcement officials as "authorized users". Only 18 states require law enforcement to access the data only with a warrant, subpoena, or other judicial process, whereas 30 states allow such access pursuant merely to an active investigation. NAMSDL Review, *supra* note 71, at 25-26 & 31.
[87] Fort-five states send unsolicited reports to individuals varying from prescribers, to law enforcement officials, to licensing officials. The triggers for and information included in these reports vary widely. *Id*. at 45.
[88] In 34 states, prescribers and/or dispensers can delegate access to an agent who can log into the system on their behalf. Agents can include a physician's assistant, nurse practitioner, pharmacy technician, or other health personnel. *Id*. at 21.
[89] Patients must be notified when their PDMP data is accessed in 11 states. *Id*. at 9.
[90] Although 45 states have authorized interstate data sharing, only 32 states currently share data. *Id*. at 34; Prescription Drug Monitoring Program Training and Technical Assistance Program, Interstate Data Sharing (Aug. 2015), http://www.pdmpassist.org/pdf/Interstate_Data_Sharing.pdf.
[91] Over half of state PDMPs update the data weekly or less frequently, while only one program offers real-time data. NAMSDL Review, *supra* note 71, at 12-13.
[92] PDMP training is required of authorized users in only a handful of states (13), although most states offer optional training. *Id*. at 36.
[93] Schedule I drugs have high abuse potential and are not prescribed legally (they have no current medically accepted use in the United States)—thus they cannot be tracked (e.g., heroin, Ecstasy). Schedule II drugs are those with a high potential for abuse but a medically accepted use (e.g., oxycodone, morphine, stimulants). Schedule III drugs are those with moderate abuse potential and a medically accepted use (e.g., buprenorphine, hydrocodone). Schedule IV drugs are those with low abuse potential and a medically accepted use (e.g., benzodiazepines,

are mandates that clinicians query the data for information regarding a patient (under specified circumstances).[94] Also on the PDMP policy horizon is the integration of PDMP data into clinical workflow (i.e., electronic medical records) and improved interstate sharing of data to track those individuals who travel across state lines in pursuit of prescription drugs.[95]

PDMPs are perhaps so attractive because they hold the potential to both facilitate legitimate prescribing of controlled substances and also mitigate prescription drug misuse.[96] The appropriate prescribing of controlled substances can reduce their misuse and diversion. At the same time, law enforcement, licensing board, and surveillance efforts can protect the public's health by limiting diversion.[97]

Despite these best intentions, we do not have a firm understanding of PDMPs' effectiveness nor of the potential for unintended PDMP consequences (or other legal or ethical quagmires). Interest groups, however, have attempted to identify a number of PDMP "best practices" to help guide their implementation. They include a comprehensive list of drugs monitored; unsolicited reporting to providers; medical provider education on PDMP use; a wide array of authorized users; real-time or frequent data collection; interstate sharing of data; and

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hypnotics). Finally, Schedule V drugs are those with the lowest abuse for potential and a medically accepted use (e.g., cough syrups with codeine, anti-diarrheals). THE CONTROLLED SUBSTANCES ACT, 21 U.S.C. § 801, *et seq*.

[94] NAMSDL Review, *supra* note 71, at 3 & 40 (identifying 24 states as having some form of mandate, although conditions and exemptions vary widely). *See* Haffajee et al., *supra* note 73, at 891-92 (outlining the pros and cons of requiring prescribers to participate in querying PDMP systems and arguing that while mandates may be called for, given the magnitude of prescription drug abuse and early indications of mandate effectiveness, more robust evidence and guidelines to support their implementation are necessary to avoid potentially dire unintended consequences—such as under-prescribing of opioids for legitimate pain).

[95] NAMSDL Review, *supra* note 71, at 3.

[96] *Id*.; Clark et al., *supra* note 82, at 5.

[97] *Id*.

disclosure of de-identified data for research purposes.[98] These characteristics appear to be identified largely based on face validity and anecdotal or associative observations, rather than rigorous evidence.[99] In short, justification for these features is wanting. The framework presented herein can assist in systematically analyzing PDMP effectiveness, legality, and normative appeal, with the goal of identifying desirable features that, if adopted, could facilitate the achievement of public health goals and increase the likelihood that these policies will succeed.

2.4 A FRAMEWORK FOR EVALUATING PRESCRIPTION DRUG MONITORING PROGRAM SUCCESS

State policymakers stand to benefit from an evaluative framework to assess the success of PDMP efforts to curb prescription drug misuse for several reasons. First, the rapid escalation and magnitude of the prescription drug misuse and overdoses—with forty-four people in the United States now dying every day from prescription painkiller overdose[100]—are remarkable and somewhat unprecedented. Such a crisis warrants a robust and effective response, which has led to rapid dissemination of new legal approaches, including PDMPs, across the states before their effects have been thoroughly evaluated. Second, the intervention possibilities—from various PDMP features to other types of interventions altogether (see Table 2.1 for a non-exhaustive list)—are numerous and could be overwhelming to policymakers. Third, some

[98] Clark et al., *supra* note 82; NATIONAL CONFERENCE OF INSURANCE LEGISLATORS, BEST PRACTICES TO ADDRESS PRESCRIPTION DRUG ABUSE, MISUSE AND DIVERSION 1-4 (2013), https://www.ncoil.org/HomePage/2013/2007964d.pdf.
[99] Clark et al., *supra* note 82 (reviewing the PDMP evidence comprehensively but failing to differentiate between studies appropriate for causal inference—i.e., those that demonstrate effects attributable to PDMPs—and those of a merely associative or anecdotal nature). *See infra* Part 2.4.2.2 & Part 2.4.2.3 for further discussion of evaluating PDMP effectiveness.
[100] Ctrs. for Disease Control and Prevention, Injury Prevention & Control: Prescription Drug Overdose: Understanding the Epidemic (Apr. 30, 2015), http://www.cdc.gov/drugoverdose/epidemic/index.html.

indications of a leveling of opioid prescribing and misuse from 2011-2013 are encouraging, but naturally beg the question: can we attribute any of these changes to state PDMPs?

It is incumbent upon policymakers at all levels to implement the most prudent set of interventions possible to target prescription opioid misuse, given current knowledge and limited resources. The states are a reasonable and critical locus for policymaking.[101] This Chapter does not mean to imply that states are the exclusive or always optimal level at which to regulate.[102] Indeed, the federal government is very involved in regulation of controlled substances, particularly under the CSA, through DEA oversight of prescribing, and via FDA drug approval-related activities (see Table 2.1). However, the states have broadly regulated to address prescription drug misuse and overdose using their plenary powers to police the health, safety, and welfare of their citizens.[103] As compared to the federal government, states are closer in proximity to these issues: they can better target prevention strategies to the specific nature of and variation in prescribing and misuse risks across their jurisdictions and are directly accountable to their citizens when it comes to adverse health and related consequences.[104]

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[101] Garcia, *supra* note 10, at 43.

[102] *See* Joanna Shepherd, *Combating the Prescription Painkiller Epidemic: A National Prescription Drug Reporting Program*, 40 AM. J.L. & MED. 85 (2014) (advocating for a national prescription drug reporting program that builds upon pharmacy benefit manager networks to crack down on prescription drug abuse). *See also* Roger S. Magnusson, *Mapping the Scope and Opportunities for Public Health Law in Liberal Democracies*, 35 J. L. MED. & ETHICS 571, 572 (2007) (noting that public health regulatory functions are "shared" between different tiers of government, and together these elements at the national and sub-national levels create a range of specific laws, processes, and remedies for improving health outcomes).

[103] States have initiated many prominent laws to address prescription drug abuse and overdose, beyond PDMPs. Other legal strategies include pain clinic (or "pill mill") laws; drug dose and limit laws; physical examination requirements; doctor shopping laws; tamper-resistant form requirements; prescription drug identification laws; and Good Samaritan laws that provide protection to those who reasonably assist others experiencing abuse or overdose. *See* Ctrs. for Disease Control and Prevention, State Laws on Prescription Drug Misuse and Abuse (Apr. 20, 2015), http://www.cdc.gov/phlp/publications/topic/prescription.html.

[104] LAWRENCE O. GOSTIN. PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT. Berkeley: University of California Press 118 (2008); Scott Burris & Evan Anderson, *Legal Regulation of Health-Related Behavior: A Half Century of Public Health Law Research*, 9 ANN. REV. L. SOC. SCI. 95, 107 (2013).

Moreover, states have typically assumed authority over the practice of medicine and other health professions as well as health more generally,[105] and thus the prescribing of controlled substances (the source of most prescription drugs that are misused) falls squarely within their purview. This Chapter addresses the balance of regulation between state and federal governments as it relates to how states can best target PDMPs,[106] but it does not cover non-governmental-based initiatives.

The separation of public health powers among different branches of government, albeit fundamental to the way policies are conceived and carried out, is not a focus of this Chapter. "State policymakers" or "state regulators," as referred to herein, signify members of both the legislative and executive branches of state governments. Members of the legislature, who are elected and politically accountable to the public, are typically responsible for creating health policy and allocating resources required to carry it out.[107] Executive agencies, most notably departments of public health,[108] assume increasingly expansive public health functions in the states—ranging from proposing laws to the legislature, to issuing rules to carry out policy, to enforcing policy.[109] The framework proposed views state policymakers as a monolithic group, capable of dividing and delegating public health powers as between themselves efficiently and in accordance with administrative law requirements.

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[105] *See* Barsky v. Board of Regents, 347 U.S. 442, 449 (1954); Michelle M. Mello & Kathryn Zeiler, *Empirical Health Law Scholarship: The State of the Field*, 96 GEO. L. J. 649, 654 (2008) (noting that states have been the primary site of lawmaking for important aspects of health markets, including public health-related areas such as seatbelt and workplace wellness, tobacco and alcohol, and unhealthful food and beverages in schools).
[106] *See infra* Part 2.4.1.2.
[107] Gostin, *supra* note 104, at 83.
[108] *Id*. at 161.
[109] *Id*. at 83-84 & 166-169.

This discussion also focuses on state *public health laws*,[110] namely PDMPs, rather than other types of interventions.[111] Law is increasingly recognized as an important determinant of health and a valuable and effective tool in the public health arsenal.[112] Law has been shown to have a powerful impact in a number of public health domains, such as motor vehicle safety, including when based on robust evidence.[113] Specifically, state laws are starting to proliferate in public health: the adoption of legal interventions in a number of areas (PDMPs included) over the past several decades has followed a steep curve from initial adoption in one jurisdiction to nearly fifty-state saturation.[114] Non-legal interventions are also critical to addressing opioid misuse, and the public's health more generally, but the use of PDMP laws—"on the books" (such as constitutions, statutes, rules, judicial opinions) and as implemented in practice[115]—by policymakers to address opioid misuse constitutes the focus of this discussion.

[110] "Public health law" has been famously defined by Lawrence O. Gostin as "the study of the legal powers and duties of government to assure the conditions for people to be healthy (e.g., to identify, prevent, and ameliorate risks to health in the population), and the limitations on the power of the state to constrain the autonomy, privacy, liberty, proprietary, or other legally protected interests of individuals for protection or promotion of community health." *Id*. at 4. Themes that emerge from this definition and that will recur throughout this Chapter include: (1) government power and duty, (2) coercion and limits of state power, (3) government partners in the "public health system," (4) the population focus, (5) communities and civic participation, (6) the prevention orientation, and (7) social justice. Lawrence O. Gostin, *A Theory and Definition of Public Health Law*, 10 J. HEALTH CARE L. & POL'Y 1, 1 (2007).

[111] Magnusson, *supra* note 102, at 572 (observing that law is only one of a multitude of "modes" of regulation that reflect different strategies towards compliance and enforcement).

[112] Mello et al., *supra* note 15, at 1979 (discussing law's recent success in preventing childhood lead poisoning and workplace injuries). *See also* Scott Burris et al., *Making the Case for Laws that Improve Health: A Framework for Public Health Law Research*, 88 THE MILLBANK Q. 169, 170 (2010); Wendy E. Parmet, *The Individual Mandate: Implications for Public Health Law*, J. L. MED. & ETHICS 401, 411 (2011).

[113] Burris & Anderson, *supra* note 104, at 107.

[114] *Id*.

[115] Burris et al., *supra* note 112, at 174-75. "Legal interventions", as discussed herein, may include a full range government use of legal authority, such as adoption of new laws, amendments or clarifications to existing laws, and removal of laws thought to be ineffective. Mello et al., *supra* note 15, at 1980.

This Chapter articulates a framework to assist state lawmakers' decision-making when considering whether and how to respond to a significant public health threat, and uses it to directly guide PDMP implementation.[116] The framework, which can be generalized to contexts beyond prescription drug misuse, sets forth key criteria with which to justify and assess public health laws—both when considering initial policy enactment and in evaluating regulations once implemented. The goal is to identify the optimal *form* that a public health law should take, once a serious public health challenge has been identified. Broadly, the evaluative criteria include (1) legal powers to regulate and barriers to implementation; (2) effectiveness of regulation; and (3) ethical/normative considerations.

This evaluative framework integrates and builds upon earlier public health law scholarship, including work on evidence-based lawmaking[117] and justificatory conditions for public health legal interventions.[118] Mello and Zeiler outline an ideal iterative process of research and policymaking that a health law, informed by evidence, would take—a so-called "lifecycle" for an empirical health law success story.[119] In their lifecycle, society first identifies a significant public health risk factor derived from clear epidemiological evidence.[120] Risk factors are exposures or attributes that are associated with an increased likelihood of developing a

[116] Gostin has outlined at least five models, or levers, for legal intervention designed to prevent injury and disease and promote the public's health: (1) the power to tax and spend; (2) the power to alter the informational environment; (3) direct regulation of individuals (e.g., motorcycle helmet laws), professionals (e.g., licenses), or businesses (e.g., inspections); (4) indirect regulation through the tort system; and (5) deregulation. Lawrence O. Gostin, *Public Health Law: A Renaissance*, 30 J. L. & MED. & ETHICS 136, 137-38 (2002) [hereinafter Gostin, *Renaissance*]. This Chapter deals primarily with the first three intervention levers, or affirmative regulatory acts engaged in by policymakers.
[117] *See generally* Mello & Zeiler, *supra* note 105; Burris et al., *supra* note 112.
[118] *See generally* Gostin, *supra* note 104.
[119] Mello & Zeiler, *supra* note 105, at 668-69.
[120] *Id. See also* Gostin, *supra* note 104, at 55.

disease or injury.[121] *Significant* risk factors can be characterized as variables that greatly increase the risk of developing a disease, or those that are associated with severe harm. Second, in response to such risks, policymakers, researchers, or other key stakeholders may propose and experiment with innovative legal solutions, among other types of policy responses.[122] Third, these experiments should be evaluated by researchers and policymakers, ideally in cooperation. Finally, those public health laws identified as successful should be retained, strengthened, and replicated in additional jurisdictions, while those deemed unsuccessful should be abandoned (or amended) in favor of policy alternatives.[123]

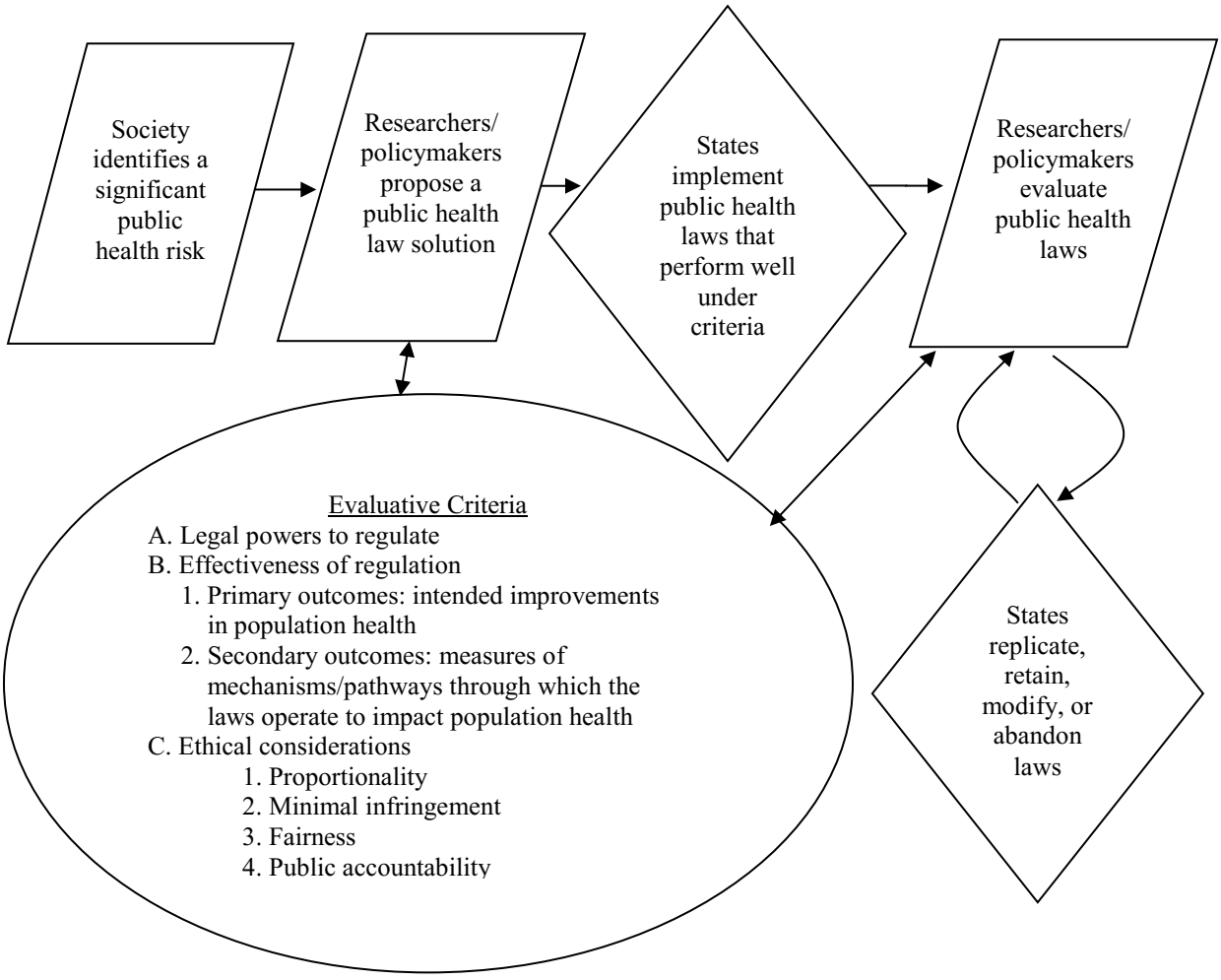
Lawrence Gostin has articulated certain prerequisite conditions for public health laws, reminding us that regulation is not justified merely in the name of population health.[124] Such laws should be defended given that they incur public and private costs and can impact future policymaking legitimacy.[125] Gostin thus proposes five criteria with which to evaluate whether a public health regulation is warranted: significant risk, effectiveness, economic cost, burden on individuals, and fairness.[126]

Figure 2.1 lays out the four stages articulated in Mello and Zeiler's lifecycle,[127] but goes a step further to specify the specific criteria with which to actually evaluate policy experiments and the ways in which these criteria should be applied to justify any particular law's existence. Innovative concepts incorporated into Figure 2.1 include: (1) that evaluative criteria should be

[121] World Health Organization, Health Topics: Risk Factors, http://www.who.int/topics/risk_factors/en/ (last visited July 7, 2015).
[122] Mello & Zeiler, *supra* note 105, at 669.
[123] *Id*.
[124] Gostin, *supra* note 104, at 43-76.
[125] *Id*.
[126] *Id.* at 55.
[127] Mello & Zeiler, *supra* note 105, at 668.

applied both at the law adoption stage as well as the retrospective evaluation (of existing policy) stage; (2) that the evaluation should be an ongoing process, rather than a one-time occurrence; and (3) that states should revisit a policy upon each round of evaluation to consider whether to retain, amend, or abandon a law.

Figure 2.1: Framework for Evaluating State Public Health Laws



Moreover, the specific evaluative criteria set forth in Figure 2.1 differ from Gostin's in several key regards. First, whereas Gostin does not focus on a particular level of authority or jurisdiction, these criteria are intended to organize *state* policymaker inquiries with respect to implementing public health laws. Second, the criteria explicitly recognize legal standards as necessary threshold to be incorporated into evaluation. Third, they re-characterize and substantially expand upon the inquiries regarding policy effectiveness and ethical appeal, drawing upon principles of research design and practice-based public health ethics, respectively. Apart from satisfying baseline legal requirements, the key evaluative criteria further detailed below are aspirational and do not necessarily need to be "satisfied" per se, but should be considered carefully and compared between policy options (if multiple exist). Performing favorably under these criteria lends validity to public health laws and enhances state policymaker and stakeholder confidence in their value. Consideration of these criteria also may help to address issues of antiquity, inconsistency, redundancy, and ambiguity that can render state public health laws ineffective.[128] In the discussion that follows, the three criteria will be outlined and directly applied to PDMPs in an effort to organize and inform this policymaking agenda.

2.4.1 Legal Powers to Regulate

A threshold inquiry for state policymakers when considering PDMPs and other public health laws is whether the requisite legal powers to regulate exist, and/or whether legal

[128] Gostin, *Renaissance*, *supra* note 116, at 136-7 (discussing entrenched problems with state public health laws—i.e., that they are often outdated, built up in layers over varying periods of time, and very fragmented among the fifty states—that call for reform so that law conforms with modern scientific and legal standards, is consistent across jurisdictions, and is more uniform in how it addresses different types of health threats).

barriers may frustrate implementation. This inquiry drives to the heart of longstanding debates about the appropriate balance of public health powers between federal and state levels of government, and constitutional limits to such powers in the name of civil liberties. Legal powers and restraints, to use Gostin's terms,[129] define the space available for public health intervention and should be considered dynamically, given the potential for changes in judicial interpretation of these parameters. State policymakers should specifically ask (1) whether they have the affirmative constitutional power to act to promote or protect the public's health, (2) whether the actions planned or taken exceed their powers by encroaching upon regulatory territory already occupied by the federal government, and (3) whether the law in question infringes upon protected individual rights.[130]

In general terms, state implementation of PDMPs stands on solid legal footing. Nevertheless, the ways in which PDMPs are designed raise a number of legal issues that warrant consideration, including the federal government's possible role in program implementation, privacy issues associated with the retention of personal health information in the databases, and the use of the data by law enforcement and licensing boards.

2.4.1.1 Federalism and the Power to Regulate the Public's Health

Federalism divides available lawmaking power between two levels of government: federal and state.[131] As articulated in what is widely viewed as a leading judicial decision in

[129] Gostin, *supra* note 104.
[130] *See* James G. Hodge, Jr., *The Role of New Federalism and Public Health Law,* 12 J.L. & HEALTH 309, 311 (1997/1998).
[131] The federal government acts with enumerated, limited powers granted by the Tenth Amendment, while the remaining powers, including the police power, are left to the states. Hodge, *supra* note 130, at 311. State governments have long held the authority, and sometimes duty, to protect and preserve public health, a critical role which dates to the *Federalist Papers* and pre-existed the Constitution. Wendy E. Parmet, *After September 11:*

public health, *Jacobson v. Massachusetts* (1905), state police powers include broad powers to pursue reasonable regulations that promote the public health, safety, welfare, or morals.[132] While *Jacobson* dealt with infectious disease—namely, the power of the City of Cambridge, Massachusetts to require smallpox vaccination—a vast array of state public health laws, ranging into areas of non-communicable disease and injury, extend the police power articulated therein.[133] Beyond the police power, states also possess *parens patriae* powers to act as guardians of those who cannot protect themselves legally, namely children and incompetent persons.[134]

Although the states possess significant power to police and protect the public's health, they do not exclusively inhabit the domain.[135] Rather, the federal government has a role to play

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Rethinking Public Health Federalism, 30 J.L. MED. & ETHICS 201, 202 (2002); Hodge, *supra* note 130, at 314; Gibbons v. Odgen, 22 U.S. 1, 87 (1824) ("[t]he constitution gives nothing to the States or to the people. Their rights existed before it was formed, and are derived from the nature of sovereignty and the principles of freedom."). *See also* Jacobson vs. Massachusetts, 197 U.S. 11 (1905).

The Constitution is largely cast in negative terms, particularly with respect to public health protection among the states. *See, e.g.,* DeShaney vs. Winnebago County Department of Social Services, 489 U.S. 189 (1989) (holding that the Wisconsin State Department of Social Services had no affirmative duty to provide protection to a 4-year-old boy who was beaten severely and incurred permanent brain damage after the Department received reports of the abuse and took no action).

There are, however, certain instances whereby the Constitution creates an affirmative duty for the government to protect people from harm or provide health services, including: (1) for persons held in state custody (e.g., prisons, mental institutions) who have been deprived of their liberty and are thus unable to care for themselves; or (2) if the state increased the threat of harm, and is responsible for creating danger. Gostin, *supra* note 104, at 87.

[132] Gostin, *supra* note 104, at 78 & 121-26 (quoting Justice Harlan's decision in *Jacobson v. Massachusetts*, to say that "[t]he safety and the health of the people of Massachusetts are, in the first instance, for that Commonwealth to guard and protect. They are matters that do not ordinarily concern the National Government.").

[133] Wendy E. Parmet et al., *Individual Rights versus the Public's Health—100 Years after* Jacobson v Massachusetts, 352 NEW ENG. J. MED. 652, 653 (2005).

[134] This power is typically invoked by a state to make decisions on behalf of those who cannot make decisions for themselves, or to justify the state's more general interest in societal welfare and health. *See* Gostin, *supra* note 104, at 95-98.

[135] Parmet, *supra* note 131, at 202.

in the areas in which it has clearly articulated jurisdiction under the Constitution.[136] If there is overlap between federal and state laws in these arenas, then federal law supersedes (or preempts) that of the states—even where states have acted appropriately within their police powers.[137] In short, the federal government can serve as a limiting factor to state public health regulation.

The pendulum of power to regulate to promote the public's health has swung between state and federal governments over the course of the 20th century. Federal authority in the public health arena increased during the New Deal era when the Supreme Court broadened its interpretations of the commerce, taxing, and spending powers with national interests in mind—evidencing the so-called "death" of federalism.[138] Most recently, state powers have been newly invigorated by a series of cases that restrict federal power. Specifically, the Court has curtailed

[136] Federal public health powers typically are found in the United States Congress's powers to tax, spend, regulate interstate commerce, and employ the means reasonably necessary to achieving other federal objectives (implied under the Necessary and Proper Clause). U.S. CONST. art. I, § 8. For a more in-depth discussion of the federal enumerated powers relevant to public health, *see* Gostin, *supra* note 104, at 98-109; Parmet, *supra* 131, at 203-07; Hodge, *supra* note 130, at 330-228; Lawrence O. Gostin. *Public Health Theory and Practice in the Constitutional Design*, 11 H. MATRIX 265 (2011); James G. Hodge, Jr., *Implementing Modern Public Health Goals through Government: An Examination of New Federalism and Public Health Law*, 14 J. CONTEMP. H. L. & POL'Y 93 (1997).

[137] U.S. CONST. art. VI, par. 2 ("[t]his Constitution, and the Laws of the United States which shall be made in Pursuance thereof; … shall be the supreme Law of the Land."). *See* Gostin, *supra* note 104, at 80 (discussing the different types of federal preemption, including (1) express preemption, where a federal statute explicitly declares that it preempts state or local law; and (2) implied preemption, where Congress's intent to supersede state or local law is clearly implied in legislative language or history. Implied preemption is further subdivided into two categories: (a) field preemption, whereby federal regulation is so encompassing as to dominate an entire field and leave no space for state or local action; and (b) conflict preemption, whereby compliance with state law would frustrate or make impossible compliance with federal law). Federal action in an area of public health regulation need not necessarily invalidate any state regulation, however. Federal laws often serve as a floor, above which state regulation can impose more stringent standards. *See, e.g.,* Interim Final Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, 45 CFR Part 146, 75 Fed. Reg. 5,410, 5,418 & 5,430 (Feb. 2, 2010).

[138] *Id*. 311-12 (quoting Joseph Lesser, THE COURSE OF FEDERALISM IN AMERICA – AN HISTORICAL OVERVIEW, IN FEDERALISM: THE SHIFTING BALANCE 11 (Janice C. Griffith, ed. 1987)).

Congress's power to "commandeer" the states to carry out federal programmatic objectives[139] and has limited the scope of the commerce power.[140] Although national public health goals are unifying, they must be accomplished without infringing on state sovereignty.[141]

2.4.1.2 State and Federal Authority to Monitor Prescription Drugs

Regulating controlled substances to prevent misuse and associated health and safety problems falls squarely within states' police powers and their *parens patriae* powers to act as guardians for those unable to protect themselves, although the question of federal preemption arises as a potential limitation to that exercise. Several state attorneys general have successfully brought *parens patriae* lawsuits against Purdue Pharma, the maker of OxyContin, under negligent marketing and public nuisance theories to assert their state's "quasi-sovereign" interests in the health, safety, and welfare of its citizens.[142] State police power also has been exerted in numerous ways in the context of prescription opioid misuse, including via law enforcement activities to identify doctor shoppers, diverters, and high-volume prescribers, as well as through regulation of health care professionals involved in prescribing and

[139] *See, e.g.,* New York v. U.S., 505 U.S. 144 (1992) (striking down a "take title" provision of the Low-Level Radioactive Waste Management Act Amendments of 1985, which required states to take ownership of and assume liability for waste if they did not dispose of radioactive wastes in a particular way); Nat'l Fed'n of Indep. Bus. v. Sebelius, 132 U.S. 2566 (2012) (ruling that Congress exceeded its powers by requiring in the Affordable Care Act that states expand Medicaid eligibility up to 133% of the federal poverty level in order to receive any Medicaid federal funds). *But see* South Dakota v. Dole, 483 U.S. 203 (1987) (upholding a federal law withholding 5% of federal highway funds from states that allowed people under 21 to buy alcoholic beverages).

[140] *See, e.g.*, U.S. vs. Lopez, 514 U.S. 544 (1995) (holding that Congress lacked the authority, under the commerce powers, to make gun possession around schools under the Gun-Free School Zones Act of 1990 a federal criminal offense); U.S. v. Morrison, 529 U.S. 598 (2000) (finding that Congress lacked the authority to enact the Violence Against Women Act under the commerce clause).

[141] Hodge, *supra* note 130, at 356 (referring to this trend as signifying a "new federalism" era in which public health action must be balanced among federal and state levels of government).

[142] *See* Richard C. Ausness, *The Role of Litigation in the Fight Against Prescription Drug Abuse*, 116 W. VA. L. REV. 1117, 1146-56 (2014).

dispensing.[143] States have significantly expanded their legislative efforts in this area since the 1970s, enacting myriad laws that have generally gone unchallenged as valid exercises of state police powers.[144] Against this backdrop, there is little debate that PDMP general establishment falls squarely within the purview of state authority, to the extent PDMPs regulate the clinical practices of prescribing and dispensing of narcotic medicines. That said, and as discussed in Part 2.4.1.4, PDMPs do raise certain privacy objections related to the storage and use of prescription data.[145]

Although the states implement PDMPs with the requisite police power authority, the federal government possesses concurrent authority to regulate prescription drugs together with the states, a power derived from the Commerce Clause.[146] The Supreme Court has found narcotic drugs may be federally regulated under the Commerce power, as they are "things"

[143] *See Barsky*, 347 U.S. at 449 (1954) ("It is elemental that a state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there. …The state's discretion in that field extends naturally to the regulation of all professions concerned with health."). The authority of the states to regulate the practice of medicine is longstanding and extends to the field of narcotic prescribing. *See* Edward P. Richards, *The Police Power and the Regulation of Medical Practice: A Historical Review and Guide for Medical Licensing Board Regulation of Physicians in ERISA-Qualified Managed Care Organizations*, 8 ANN. HEALTH L. 201, 201-23 (1999) (providing a history of the police power and the regulation of medical practice).

[144] *See infra* note 103 and accompanying text. Certain states have sought to regulate the *supply* of a certain controlled substance, for example when Governor Deval Patrick of Massachusetts issued a public health emergency declaration that empowered the public health commissioner to use emergency powers to prohibit the prescribing and dispensing of hydrocodone-only medication (Zohydro, Zogenix), which had been recently approved by the Food and Drug Administration. This type of action, however, encroaches upon the federal government's (specifically, the FDA's) supreme role in drug safety approval and was found unconstitutional when challenged by Zogenix. *See* Rebecca Haffajee, Wendy E. Parmet & Michelle M. Mello, *What is a Public Health "Emergency"?*, 371 NEW ENG. J. MED. 986, 986-88 (2014).

[145] *See infra* Part 2.4.1.4.

[146] U.S. CONST., art. I, § 8, cl. 3. Under the Commerce Power, the U.S. Congress may regulate (1) the channels of interstate commerce, (2) the instrumentalities of commerce (including persons and things in interstate commerce), or (3) economic activities that have a substantial effect on interstate commerce. Perez v. United States, 402 U.S. 146, 150 (1971).

that flow through an interstate supply chain (from manufacturer to distributor to pharmacy to patient), the distribution of which impacts this interstate flow.[147]

Congress's regulation of controlled substances dates back to the early 1900s.[148] But it truly expanded with the enactment of the CSA in 1970 and creation in 1973 of the DEA, an agency charged with policing the issuance and dispensing of controlled substances, including prescription drugs.[149] To prescribe controlled substances in Schedules II through V, licensed prescribers must register with the DEA every three years and follow other administrative requirements.[150] To avoid criminal liability under the CSA, a prescriber may issue controlled substance prescriptions only "for a legitimate medical purpose" when "acting in the usual course of his professional practice."[151]

Despite this expansive federal oversight of controlled substances and jurisprudence relating to the Commerce Power, the federal government has not chosen to use its Commerce

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[147] *See* Michael C. Barnes & Gretchen Arndt, *The Best of Both Worlds: Applying Federal Commerce and State Police Powers to Reduce Prescription Drug Abuse*, 16 J. HEALTH CARE L. & POL'Y 271, 283-92 (2013) (describing in detail the Supreme Court's application of the Commerce Power in the context of federal regulation of narcotics to advocate for a national prescriber education to reduce prescription drug abuse).

[148] *See* Shepherd, *supra* note 102, at 101.

[149] *See* Drug Enforcement Administration, DEA Mission, http://www.dea.gov/about/mission.shtml (last accessed Jul. 30, 2015). In addition, the federal government also established the FDA, which in 2012 used its powers to require ER/LA opioid manufacturers to develop a REMS given that the potential risks of the drugs outweighed the benefits. The REMS policy requires these drug developers to manage the risk of accidental or intentional misuse and risks to patients who are prescribed the drugs but do not clinically need them, primarily by financing the education of prescribers and patients regarding opioid risks and proper prescribing, storage, and disposal practices. Valerie Blake, *Fighting Prescription Drug Abuse with Federal and State Law*, 15 VIRTUAL MENTOR 443, 443-44 (2013). *See generally* John F. Peppin et al., *Issues and Critiques of the Forthcoming Risk Evaluation and Mitigation Strategy (REMS) for Opioids in Pain Management*, 27 ISSUES L. & MED. 91 (2011) (suggesting that REMS is unlikely to reduce the bulk of prescription drug abuse that occurs with non-patients); Heather Homenko, *Rehabilitating Opioid Regulation: A Prescription for the FDA's Next Proposal of an Opioid Risk Evaluation and Mitigation Strategy (REMS)*, 22 HEALTH MATRIX 273 (2012).

[150] 21 U.S.C. §§ 823, 827-829 (2012). *See infra* note 93 for a summary of the federal controlled substance Schedules.

[151] 21 C.F.R. § 1306.04(a) (2013). Prescribers may also be held liable under certain state controlled substance acts for unauthorized prescribing practices.

Power to create any national prescription monitoring program or curtail state plenary powers to do so.[152] Instead, it supports the states in monitoring prescription drugs, thereby lending additional support to the idea that Congress has little intention of preempting state PDMP creation. Specifically, the United States Department of Justice has encouraged state PDMPs by creating the Harold Rogers Prescription Drug Monitoring Program in 2002 to fund program creation, the National Alliance for Model State Drug Laws to help with policy coordination, and a Prescription Drug Monitoring Program Center of Excellence at Brandeis University to identify best practices.[153] None of this federal activity would be construed as commandeering of the states, as the funds and support provided for PDMPs relate directly to these programs and do not require program establishment or operation.[154]

The federal government, however, has not ceded this entire arena to the states. As a reciprocal gesture for its support for PDMPs, the federal government has elicited state cooperation with investigative activities relating to prescription drug misuse. The DEA has requested certain state PDMP data pursuant to administrative subpoenas, as authorized under the CSA, to investigate drug crimes—an action that raised supremacy issues that ultimately went unresolved in *Oregon Prescription Drug Monitoring Program v. U.S. DEA*.[155] In this case,

[152] In other words, the federal government has neither expressly preempted state PDMPs nor enacted other controlled substance monitoring laws that would impliedly preempt state *creation* of PDMPs. *See* Barnes & Arndt, *supra* note 147, at 292-95 (discussing circuit court decisions that reaffirm the constitutionality of CSA regulations, but that have also found such regulations do not invalidate state police powers to regulate medicine).
[153] Deyo et al., *supra* note 79, at 604-05.
[154] *See infra* note 139.
[155] Or. Prescription Drug Monitoring Program v. DEA, 998 F.Supp. 957 (D. Or. Mar 31, 2013). The DEA appealed the District Court's ruling and is awaiting a decision from the 9th Circuit Court of Appeals. The ultimate outcome of the case could influence the standards across jurisdictions regarding DEA (and state law enforcement) access to PDMP data.

the DEA was attempting to use its administrative subpoena power to access Oregon PDMP records for an individual patient and for all drugs prescribed by two physicians, absent a warrant.[156] The Oregon PDMP refused to comply with these subpoenas on the basis that doing so would violate Oregon law, which says that PDMP data constitutes protected health information and law enforcement can only access the data pursuant to a *valid court order based on probable cause* for an authorized drug-related investigation involving an individual.[157] In a former instance when the Oregon PDMP objected to a DEA request for PDMP data (pursuant to an administrative subpoena) on all Schedule II through IV controlled substance prescriptions issued by a particular physician over a seven-month period, a United States Magistrate judge found Oregon's court order requirement to be preempted by the CSA.[158] In *Oregon Prescription Drug Monitoring Program*, the court never reached the Supremacy issue presented, however, instead deciding that DEA's use of administrative subpoenas violated the Fourth Amendment, as discussed below in Part 2.4.1.4.

Given the concurrent jurisdiction of federal and state governments to monitor prescription drugs, what is the appropriate balance of powers—particularly when presented with a complex and serious public health problem like prescription opioid misuse? Strong arguments can be made for federal intervention, given markedly heterogeneous programs

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The CSA empowers the Attorney General, and executive agencies acting pursuant to his/her authority (including the DEA), with broad authority to issue administrative subpoenas for information "relevant or material" to an investigation relating to his functions "with respect to controlled substances." 21 U.S.C. § 876(a) (2012).

[156] Or. Prescription Drug Monitoring Program, 998 F.Supp. at 960-61.

[157] *Id*.; O.R.S.§ 431.966(2)(a)(C)).

[158] U.S. v. Or. Prescription Drug Monitoring Program, 3:12-mc-00298 (D.Or. Aug. 27, 2012). In other words, the magistrate judge found the DEA's investigatory authority reigned supreme over Oregon state law's data access requirements.

across states, limited state resources, and the interstate components of drug prescribing and dispensing involved. State PDMPs exhibit widely varying features, most of which appear chaotically conceived and uninformed by rigorous studies of effectiveness (as most programs were adopted before much of an evidence base existed). State authorities may lack the resources or expertise to operationalize PDMPs optimally, even with federal assistance.[159] Furthermore, prescription drug misuse is not confined within state borders, as demonstrated by growing evidence of doctor shopping across state lines[160] and mail order pharmacies that can send controlled substances across states.[161] All of these factors weigh in favor of uniform federal standards that could, in theory, more comprehensively and deliberately address prescription drug misuse.[162]

While the federal government has the authority and a set of justifications to have its own PDMP, the creation of such a program would require a major overhaul of deeply entrenched state programs. State PDMPs represent huge investments; replacing them with a federal system would seem wasteful and counter-productive just as we are beginning to detect what may be promising health results.[163] State governments (and local governments to which they may delegate power) are closer to the issues and have more flexibility than the federal

[159] Clark et al., *supra* note82 , at 57-62. *See* Gostin, *supra* note 104, at 81.
[160] *See, e.g.*, Douglas C. McDonald & Kenneth E. Carlson, *The Ecology of Prescription Opioid Abuse in the USA: Geographic Variation in Patients' Use of Multiple Prescribers ("Doctor Shopping")*, 23 PHARMACOEPIDEMIOLOGY & DRUG SAFETY 1258 (2014) (estimating that 30% of doctor shoppers obtained prescriptions across state lines); Ken Lammers, Jr., *Rise of the Pills*, 15 UDC-DCSL L. REV. 91, 102 (2011) (providing anecdotal evidence of doctor shopping across state lines).
[161] *See* Anupam B. Jena et al., *Prescription Medication Abuse and Illegitimate Internet-Based Pharmacies*, 155 ANNALS INTERNAL MED. 848 (2011).
[162] Gostin, *supra* note 104, at 81; Parmet, *supra* note 131**Error! Bookmark not defined.**, at 208.
[163] *See infra* Part 2.4.2.3 for a discussion of the PDMP effectiveness literature.

government to cater the programs to their citizenry's public health needs, opinions, and geographies—all of which can serve to enhance PDMP results.[164] Certain states may wish to implement specific features or PDMPs in combination with other interventions—for example, Florida chose to combine a PDMP with regulation of pill mills, given the high concentration of these practices—for a greater impact.[165] States also can function as "laboratories" to test new interventions and inform evidence-based policy in other jurisdictions.[166] The progressive, widespread adoption of PDMPs from the 1990s through 2000s provides rich heterogeneity in programs across states to allow for natural experiments that test different features for the best results. In sum, leaving state PDMPs intact for continued evaluation and, potentially, improvement seems preferable. As a stronger evidence base about effective PDMP practices emerges, there will be room for increased federal influence to achieve some consistency across programs: the federal government should condition future state PDMP funding on adoption of these identified practices.[167] But at the moment, while states seem an appropriate level at which to implement PDMPs, policymakers face tough decisions with respect to the form that these laws take, as guided by consideration of individual liberties, effectiveness, and other ethical dimensions.

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[164] *See* Gostin, *supra* note 104, at 81; Hodge, *supra* note 130, at 356.

[165] *See, e.g.*, Lainie Rutkow et al., *Effect of Florida's Prescription Drug Monitoring Program and Pill Mill Laws on Opioid Prescribing and Use*, JAMA INTERNAL MED. (Aug. 17, 2015), doi:10.1001/jamainternmed.2015.3931 (finding that Florida's PDMP and pill mill laws were associated with modest decreases in total opioid volume supplied, as well as in morphine milligram equivalents per transaction and opioid prescriptions).

[166] Mello & Zeiler, *supra* note 105, at 654 & 671-79 (discussing that state-based law provides the opportunity for evaluation thanks to time-varying adoption of reform across jurisdictions, often for reasons unrelated to the outcome variable of interest. The federal National Minimum Drinking Age Act, which tied the minimum drinking age to national highway funds, was adopted after studies of state innovations attributed beneficial health impacts to higher drinking ages).

[167] *See* South Dakota v. Dole, 483 U.S. 203 (1987).

2.4.1.3 Constitutional Limits to Public Health Regulation

Although state governments have broad authority to act in ways that limit private interests in favor of the greater community,[168] these infringements do have legal bounds. Individual liberty, autonomy, privacy, and economic freedom enjoy protection under the Bill of Rights, as well as state constitutions and laws, from certain government intrusion.[169] *Jacobson v. Massachusetts*, in addition to articulating the breadth of state authority to protect the public's health, was the first case to carefully articulate a framework for the protection of individual liberties in the exercise of police power, which has evolved in subsequent case law interpreting the Constitution.[170] The permissibility of public health laws turns on scientific justification and the manner in which they are applied.[171] Specifically, public health powers are constitutional only if exercised in accordance with the following legal principles: (a) extraterritoriality; (b) necessity; (c) reasonableness; (d) due process rights, and (e) equal protection principles.[172] Freedom of expression principles further impose significant barriers to public health regulation. For general framing purposes, the above principles are outlined in brief and then applied in detail as relevant to PDMPs.

[168] Parmet, *supra* note 112, at 401-11(discussing the interdependency of health and the public good nature of many interventions as justifications for public health interventions, such as the individual mandate in the Affordable Care Act).
[169] Gostin, *supra* note 104, at 85-86, 114-16. State constitutions and laws also provide parameters for policymaker actions, but are too plentiful to be addressed comprehensively in this Chapter.
[170] Wendy K. Mariner et al., Jacobson v. Massachusetts: *It's Not Your Great-Great-Grandfather's Public Health Law*, 95 AM. J. PUB. HEALTH 581 (2005) (tracing the evolution of conceptions of state police powers and individual liberty over the century since *Jacobson*, finding that the Court's recognition of the relative importance of liberty has strengthened over time).
[171] Parmet et al., *supra* note 133, at 654.
[172] Although the facts in *Jacobson* did not require the Supreme Court to articulate equal protection as a constitutionally required limitation, this standard had previously been articulated in *Jew Ho v. Williamson* in 1900. Gostin, *supra* note 104, at 128.

For any given public health law, state policymakers should undertake a careful constitutional analysis to anticipate private objections that could frustrate implementation. First, states can regulate matters within their borders, but not extraterritorially.[173] Second, the exercise of police power should be necessary to prevent an actual or looming threat to public health, rather than a potential or hypothetical one.[174] Third, the exercise of state power must be reasonable. Here a policymaker would ask two questions: will the legal action taken plausibly be effective in achieving its objective (i.e., are the means rationally related to the ends)? And are there any obviously less burdensome alternatives that could have been implemented instead?[175]

Furthermore, individual rights to due process and equal protection are constitutionally protected and must be considered in the affirmative government exercise of public health powers. Individuals are free from unwanted intrusions—including searches and seizures—in places in which they have a legitimate expectation of privacy (e.g., their body or property).[176] Under the Fourth Amendment, a search is usually found unreasonable absent a warrant from a

[173] The police power is a state's "recognized authority to enact…all laws that relate to matters completely within its territory and which do not by their necessary operation affect the people of other states." Jacobson, 197 U.S. at 27.

[174] Gostin, *supra* note 104, at 126-27 (the subject of compulsory intervention must pose an actual, demonstrable threat to the community); Jacobson, 197 U.S. at 39 (not requiring that the vaccination be administered against anyone who "with reasonable certainty" can show that he is not the "fit subject of vaccination …, by reason of his then condition, would seriously impair his health or probably cause his death.").

[175] Jacobson, 197 U.S. at 31; Gostin, *supra* note 104, at 127.

[176] Gostin, *supra* note 104, at 403. The Fourth Amendment guarantees "the right of the people to be secure in their persons, houses, papers, and effects against unreasonable searches and seizures," and is extended to state governments via the Fourteenth Amendment. *See* Wilson v. Health & Hospital Corp. of Marion County, 620 F.2d 1201 (7th Cir. 1980) (finding that health official searches absent warrants or consent violated individual's reasonable expectation of privacy under the Fourth Amendment).

judge showing probable cause,[177] with limited exceptions.[178] The concept of liberty is also protected under the Fifth Amendment[179] and can be framed as two separate obligations: procedural due process[180] and substantive due process.[181] Furthermore, any state government-drawn distinction between similarly situated persons—for example, between persons of different races/ethnicities[182]— requires justification based on equal protection principles.[183] And although not raised in *Jacobson* or yet in the context of PDMPs, freedom of speech is relevant to the evaluative framework and policymaking calculus in other public health law

[177] *See, e.g.,* Camara v. Municipal Court, 387 U.S. 523 (1967) (holding that a housing inspection of an apartment was a violation of the Fourth Amendment absent a warrant or consent); See v. City of Seattle, 387 U.S. 543 (1967) (finding the fire inspection of a business to be unconstitutional without a warrant or consent).

[178] Gostin, *supra* note 104, at 403-404 and 468-69. If obtaining a warrant is impractical, the courts will conduct an individualized assessment using reasonableness standards—probing the importance of the state interest, the degree of privacy invasion, and whether the state had a reasonable suspicion or special need. *Id*. at 403-404. *See* Board of Education v. Earls, 536 U.S. 822, 829 (2002) (holding that drug testing high school extracurricular activity participants is reasonable given the important state interests in protecting children's health, the minimal intrusion associated with urine testing, and the reduced expectation of privacy that schoolchildren possess). A special need must be something aside from merely enforcing laws, although this standard has been interpreted more generously over time. *See, e.g.,* Ferguson v. City of Charleston, 532 U.S. 67 (2001) (finding that state hospital performance of urine tests on pregnant women without their consent to obtain evidence for law enforcement purposes constituted unconstitutional searches under the Fourth Amendment. No special need was recognized given that the testing was linked to the state's general interest in law enforcement.); Loder v. City of Glendale 14 Cal.4th 846 (Cal. 1997) (in which mandatory drug tests for all city employees seeking promotions was struck down because they had already been tested, whereas drug tests for new applicants were permissible given the lack of prior knowledge of their drug use).

[179] The Fifth Amendment to the United States Constitution states: "No person shall … be deprived of life, liberty, or property, without due process of law." The Fifth Amendment has been extended to the state under the Fourteenth Amendment to the United States Constitution.

[180] Procedural due process entitles individuals to fair procedures—typically, notice, a fair hearing, and counsel—when the government deprives them of life, liberty, or property. *See, e.g.,* Greene v. Edwards, 263 S.E.2d 661 (W.Va. 1980).

[181] Substantive due process relates to the protected zone of individual liberty or privacy, where the government cannot enter without adequate justification. *See, e.g.,* Lawrence v. Texas, 539 U.S. 558 (2003) (finding a liberty right to engage in private acts, particularly intimate acts in nonpublic locations, such as the home).

[182] *See, e.g.,* Jew Ho v. Williamson, 103 F. 10 (C.C.N.D. Cal. 1900) (finding that the quarantine of an entire district in San Francisco to contain a bubonic plague epidemic was used as a guise to discriminate against Chinese people who populated most of the area, the health of whom was actually placed at greater risk by the quarantine); Yick Wo v. Hopkins, 118 U.S. 356 (1886) (striking down a facially neutral ordinance restricting the washing of clothes in public laundromats after 10 p.m. as it was enforced with discriminatory intent only against Chinese owners).

[183] For further discussion of substantive due process, equal protection, and levels of constitutional review, *see* Gostin, *supra* note 104, at 135-42.

contexts, such as regulating the advertising of tobacco products. State regulators should be mindful that courts afford exceptional protection to speech under the First Amendment, and the trend has been toward increasing protection of commercial speech, in particular.[184]

2.4.1.4 Liberty Issues Raised by PDMPs

Certain features of heterogeneous PDMPs have the potential to infringe upon individual rights and freedoms and may, therefore, be subject to legal challenge. PDMPs, as typically implemented, meet the extraterritoriality and necessity requirements for public health laws articulated in *Jacobson*.[185] Each program operates within its state's borders, collecting data on controlled substances dispensed within the state and permitting prescriber, pharmacist, and sometimes regulator use of that data.[186] Some interstate exchanging of information to authorized users (typically, prescribers or pharmacists) or PDMPs in other states occurs and is increasingly encouraged,[187] but any information transmitted across state boundaries is usually shared reciprocally, subject to the originating state's requirements for authorized use, and intended to complement public health efforts in both states. Furthermore, sharing of data

[184] *Id.*; *See, e.g.*, Lorillard Tobacco Company v. Reilly, 533 U.S. 525 (2001) (holding that Massachusetts' outdoor and point-of-sale advertising restrictions targeting smokeless tobacco and cigars violate the First Amendment); Thomson v. Western States Medical Center, 535 U.S. 357 (2002) (holding that a provision of the FDA Modernization Act that exempts certain compounded drugs from having to satisfy drug approval requirements if the drug is not advertised or promoted unconstitutionally restricts pharmacists' commercial speech); Sorrell v. IMS Health Inc., 564 U.S. 2653 (2011) (finding that a Vermont state statute banning the sale, use or transmission of prescriber-identifiable data (absent prescriber consent) violated data miner free speech rights); R.J. Reynolds Tobacco Co. v. Food & Drug Administration, 696 F.3d 1205 (D.C. Cir. 2012) (holding that the FDA rule requiring graphic warning images on cigarette packages and advertisements violates the First Amendment).

For academic discussion of this evolving and expansive body of law, *see*, *e.g.*, David Orentlicher, *The Commercial Speech Doctrine in Health Regulation: The Clash between Public Interest in a Robust First Amendment and the Public Interest in Effective Protection from Harm*, 37 AM. J. L. & MED. 299 (2011); Micah L. Berman, *Manipulative Marketing and the First Amendment*, 103 GEORGETOWN L.J. 497 (2015).

[185] *See supra* note 173 and accompanying text.

[186] NAMSDL Review, *supra* note 71, at 4.

[187] National Alliance for Model State Drug Laws, Interstate Sharing of Prescription Monitoring Database Information (2014), http://www.namsdl.org/library/BCBEC7B0-C951-08A4-2141E943AC8ECE71/.

across state lines can be justified given the sometimes interstate nature of prescribing, drug fills, and diversion.[188] There is little debate that the exercise of police power is necessary to address opioid misuse and overdose, a public health threat of significant and increasing magnitude.[189]

Further, the programs appear reasonable.[190] PDMPs bear a real and substantial relation to the protection of public health and safety: they aim to inform optimal prescribing as well as to address patients and prescribers with outlier fill and prescribing patterns, respectively. Given that the vast majority of drugs misused originate from prescribers (either directly or indirectly),[191] prescribing is a reasonable level at which to intervene to address the epidemic. Also, because a small percentage of prescribers source the majority of opioids, and because a small percentage of patients receive disproportionately large amounts of opioids,[192] outliers in each of these categories are reasonable targets for intervention. If challenged, a court would likely view a state's decision to implement a PDMP in lieu of or in addition to other available interventions that target prescription drug misuse (e.g., pain clinic laws[193]) with deference, finding it neither arbitrary nor totally unreasonable.

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[188] *Id*.
[189] *See supra* note 174 and accompanying text, and *see* Part 2.3 for a discussion of the public health significance of opioid abuse.
[190] *See supra* note 175 and accompanying text.
[191] *See supra* note 11-12 and accompanying text.
[192] U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ADDRESSING PRESCRIPTION DRUG ABUSE IN THE UNITED STATES: CURRENT ACTIVITIES AND FUTURE OPPORTUNITIES 15-17 (2013), *available at* http://www.cdc.gov/drugoverdose/pdf/hhs_prescription_drug_abuse_report_09.2013.pdf.
[193] Laws that regulate "pill mills", or pain management clinics that source large quantities of prescriptions, aim to prevent these facilities from inappropriately prescribing controlled substances. Such laws typically provide for state oversight of pill mills and contain other requirements pertaining to ownership and operation of the facility. For instance, a law may set forth personnel and operational requirements, inspection and licensure procedures, standards of care, and/or patient billing procedures. *See* Ctrs. for Disease Control and Prevention, *supra* note 62.

The heart of challenges to PDMPs revolves around informational privacy rights. These rights can be located in the Fourteenth and Fourth Amendments, as well as in federal and state confidentiality laws. Because statewide prescription dispensing data are aggregated in a database that can be widely accessed by many types of authorized users and even linked to other PDMPs or medical record databases, PDMPs present new possibilities for security breaches in which private information is disclosed to the general public, as well as for law enforcement and licensing body use of the data. The potential for broad data access raises privacy concerns among patients and prescribers and could reduce their drug seeking and prescribing behaviors, respectively. Some such behavior changes may be desirable, given that a central purpose of PDMPs is to have a deterrent effect on over-prescribing, doctor shopping, and diversion. But other behavioral changes may be unintended[194] and undesirable, such as the chilling of appropriate prescribing or patient access to legitimately needed painkillers. Courts seek to balance the competing state and individual privacy interests in determining the legality of PDMPs and access to prescription information contained therein.

The Supreme Court addressed the right to informational privacy in prescription records under the Due Process Clause of the Fourteenth Amendment in *Whalen v. Roe*.[195] In this case, the Court considered whether New York's paper prescription monitoring program (which also collected the prescription information in a computerized database) violated individual interests in (a) avoiding disclosure of personal matters, and/or (b) independence in important decision-

[194] For additional consideration of unintended consequences of PDMPs under the evaluative framework, *see infra* sections III.B and III.C.
[195] Whalen v. Roe, 429 U.S. 589 (1977).

making.[196] The Court admitted that the monitoring program could have a chilling effect on opioid prescribing and use. Nonetheless, it found that the program adequately safeguarded physicians' and patients' right to informational privacy, emphasizing the extensive security protections in place to keep private information from being disclosed and the fact that the decision whether to prescribe or use a drug is still left to patient and doctors.[197] Subsequent state courts have considered the right to informational privacy in prescription records housed in individual pharmacies (rather than statewide databases) and relied on the *Whalen* precedent to find no constitutional violations.[198] Although not yet squarely addressed by any court, it seems unlikely an electronic PDMP would infringe upon Fourteenth Amendment privacy rights if adequate safeguards were in place to protect the data from public disclosure.[199]

Patient (and prescriber) Fourth Amendment privacy rights are also implicated by warrantless searches of PDMP data by law enforcement officials and other regulators. In almost

[196] *Id*. at 591, 599-600.

[197] *Id*. at 600-602, 604 (noting protections, including a receiving room protected by a locked wire fence and alarm system, limited access to a small number of people, and serious penalties for unlawful release). The Court also found that any physician claim regarding potential disclosure of patient information was "derivative from, and therefore no stronger than, the patients'" – in other words, rejecting physician privacy rights violations in this context. *Id*. at 604.

[198] *See, e.g.*, Nebraska v. Wiedeman, 835 N.W.2d 698 (Neb. 2013) (finding no violation of the Fourteenth Amendment after "weighing the State's significant interest in the regulation of potentially dangerous and addictive narcotic drugs against the minimal interference with one's ability to make medical decisions and the protections from broader dissemination to the general public"); Stone v. Snow, 593 N.E.2d 294 (Ohio 1992) (holding that the Ohio statutes permitting warrantless inspection of prescriptions, orders, and records to law enforcement officials and regulators did not violate doctor, patient, or pharmacist rights to privacy as they did not allow disclosure to the general public and included adequate safeguards).

[199] In a *Whalen v. Roe* concurrence, Justice Brennan did express concerns with the computerized storage of sensitive information, leaving open the possibility that the Court would view electronic PDMPs, whereby data are shared across a wide network of authorized users, as a heightened invasion of privacy. David B. Brushwood, *Maximizing the Value of Electronic Prescription Drug Monitoring Programs*, 31 J.L. MED. & ETHICS 41, 43 (2003). *But see* Amy J. Dilcher, *Damned if They Do, Damned if They Don't: The Need for a Comprehensive Public Policy to Address Inadequate Management of Pain*, 13 ANN. HEALTH L. 81 (2004) (suggesting it is unlikely that the Supreme Court will invalidate electronic PDMPs on general privacy grounds).

all states, professional licensing bodies and law enforcement officials can access PDMP data for the respective purpose of conducting administrative searches and pursuing criminal investigations against patients, prescribers, or pharmacists.[200] What differs from state to state is whether these officials can access the data simply pursuant to an active investigation, or whether they need to satisfy the more stringent standards of accessing the information only with a court-issued search warrant, subpoena, or order.[201] While the stated goals of PDMPs vary—and many programs explicitly do aim to prevent criminal activities such as diversion and doctor shopping[202]—a common primary goal is to improve health care by reducing drug misuse and facilitating appropriate prescribing.[203] If law enforcement and licensing officials are given access to the files absent any probable cause or reasonable restrictions around terms of access, PDMPs could easily turn into tools primarily used to troll for criminal or medical misconduct. This shift in emphasis could induce a chilling effect on prescribing and prescription drug use in ways that actually interfere with optimal medical care.

The *Whalen* Court did not decide whether a centralized state database housing prescription records implicates the Fourth Amendment right to privacy.[204] However, other state and federal courts have addressed this right in the context of pharmacy-housed prescription

[200] NAMSDL Review, *supra* note 71, at 5, 25-26. In a handful of states, the PDMP is actually housed within a law enforcement or professional licensing agency, as opposed to a health agency, thereby giving these regulators and officials unfettered access to the records. *Id*. at 25-26.
[201] *Id*.
[202] Corey S. Davis et al., *Overdose Epidemic, Prescription Monitoring Programs, and Public Health: A Review of State Laws*, 105 AM. J. PUB. HEALTH e9, e9-e10 (2015).
[203] *Id.*
[204] The Court declined to address the Fourth Amendment arguments brought by physician and patient plaintiffs because the case did not "involve affirmative, unannounced, narrowly focused intrusions into individual privacy during the course of criminal investigations." Whalen, 429 U.S. at 604 n.32.

records, generally finding that although patients have a subjective expectation of privacy in their prescription records, they do not have a privacy right that society is prepared to recognize as (objectively) reasonable[205]—as is also required to invoke Fourth Amendment protections.[206] Some courts have justified patients' (and prescribers') reduced expectation of privacy in pharmacy records on the basis that most states have laws that explicitly allow certain officials access to these records without a warrant.[207] Other courts have recognized pharmaceuticals as a pervasively regulated industry[208] and thus applied the three-pronged test set out in *New York v. Burger* to determine whether a warrantless search is reasonable.[209] In applying the *Burger* test, courts have typically found that allowing searches of prescription data furthers substantial and well-established government interests in regulating prescription drugs, and that notice requirements are met if these searches are conducted during reasonable hours.[210] Most courts have found the warrant exception applies to administrative inspections of pharmacy records,

[205] *See, e.g.*, Nebraska v. Wiedeman, 835 N.W.2d at 710-711; State v. Russo, 790 A.2d 1132, 1152 (Conn. 2002); Stone v. Snow, 593 N.E.2d at 300-301.
[206] Katz v. U.S., 389 U.S. 347, 361 (1967) (Harlan, J., concurring).
[207] *See, e.g.*, State v. Underwood, No. K2/98-0485A, 1999 WL 47159, at *5 (R.I.Super. Jan. 20, 1999); Douglas v. Dobbs, 419 F.3d 1097, 1102 (10th Cir. 2005); Murphy v. State, 62 P.3d 533, 536 (Wash. App. 2003); State v. Russo, 790 A.2d at 1141; Gettel v. State, 449 So.2d 413, 414 (Fl.App. 2 Dist. 1984). *See also* National Alliance for Model State Drug Laws, *Prescription Monitoring Programs, Pharmacy Records and the Right to Privacy* 21-37 (2014), http://www.namsdl.org/library/2450F09A-1C23-D4F9-749781734E3A333F/ (providing a catalogue of these pharmacy records access laws) [hereinafter NAMSDL Privacy].
[208] In its close level of regulation, the pharmaceutical industry is distinguishable from certain other areas of health. *See, e.g.*, Tucson Women's Clinic v. Eden, 379 F.3d. 531 (9th Cir. 2004) (holding that an Arizona regulation that required abortion clinics to submit to warrantless inspections by the Arizona Department of Human Services violated the Fourth Amendment. The Ninth Circuit determined that the administrative search exception was inapplicable because abortion services are not a closely regulated business.).
[209] New York v. Burger, 482 U.S. 691 (1987). To determine whether a warrantless search is reasonable, three criteria must be met: (1) there must be a substantial government interest in regulating this area, (2) the regulatory scheme must further that government interest, and (3) the regulation must provide a constitutionally adequate substitute for a warrant—in other words, it must provide comprehensive notice to the target of the search and appropriately limit the time/place/scope of the search. *Id*. at 702.
[210] *See, e.g.*, State v. Welch, 624 A.2d 1105, 1110-1112 (Vt. 1993); Terraciano v. Montanye, 493 F.2d 682, 683-85 (2d Cir. 1974); Stone v. Snow, 593 N.E.2d at 300-301.

such as those conducted by pharmacy boards, though some also have applied it to searches conducted pursuant to criminal investigations.[211]

PDMPs, however, raise unique issues with respect to unfettered searches, particularly when conducted by law enforcement or licensing officials, which justify different data access standards from those applied to pharmacy-housed records. PDMPs centralize *all* dispensing data generated within a state (and sometimes across states), rather than that from a single pharmacy. They are fully electronic and searchable, for instance by prescriber, pharmacy, or patient name—or conceivably by controlled substance or prescribing volume. Under the mosaic theory, the aggregation of prescription information in PDMPs should be covered by a reasonable expectation of privacy under the Fourth Amendment, even if each individual pharmacy-housed record may not be.[212] Moreover, although the third-party doctrine suggests that when certain records are turned over and maintained by third-parties, they are no longer

[211] State v. Welch, 624 A.2d at 1112; Stone v. Snow, 593 N.E.2d at 300-301; State v. Jarvis, No. 16388, 1998 WL 57342, at *4-5 (Ohio App. 2 Dist. Feb. 13, 1998) (finding that inspectors were not required to ignore evidence of criminality discovered during a warrantless administrative search conducted with independent administrative justification). *But see* State v. Penn, 576 N.E. 2d 790 (Ohio 1991); Commonwealth v. Frodyma, 436 N.E. 2d 925 (Mass. 1982) (refusing to extend the warrant exception to criminal investigations). *See also* State v. Desper, 783 N.E.2d 939 (Ohio App. 7 Dist. 2002) (finding that once a search stopped being administrative in nature and a criminal investigation commenced, a warrant was required); State v. Penn, 576 N.E. 2d 790 (Ohio 1991) (upholding a lower court's grant of a motion to suppress evidence uncovered during a joint inspection by the state pharmacy board and police, given that the search was undertaken for general criminal purposes. The court stated that the "board cannot act as a surrogate for the police to obviate the constitutional duty of obtaining a search warrant.").

[212] *See* Benjamin J. Priester, *Five Answers and Three Questions after* United States v. Jones *(2012), the Fourth Amendment "GPS Case"*, 19-28 (March 28, 2012), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2030390 (noting five Justices' express support in *U.S. v. Jones* for the "mosaic theory", or the idea that the aggregation of information may be covered by a reasonable expectation of privacy, even though each discrete piece of information standing alone would not. The mosaic theory, which suggests the Fourth Amendment protection can be triggered when the sheer quantity of information becomes great, applies both to information presented to the public and that turned over to a third-party, like PDMP data. However, the precise parameters of how this theory will be applied by the Court remain uncertain.) For additional arguments in favor of the mosaic theory, *see* Wayne A. Logan, *"Mosaic Theory" and Megan's Laws*, 2011 CARDOZO L. REV. DE NOVO 95 (2011).

private and not protected by the Fourth Amendment when exposed to others, significant support for patients' expectation of privacy in *medical* records exists.[213] Because PDMP data, by virtue of their comprehensive nature, are akin to medical records, there is a strong argument that such records are entitled to some measure of protection from unfettered access by government officials.

Indeed, the heightened Fourth Amendment privacy concerns associated with PDMPs were recognized in *Oregon Prescription Drug Monitoring*. In this leading case in the area, the American Civil Liberties Union (ACLU) intervened on behalf of the PDMP to raise arguments about individual physician and patient Fourth Amendment privacy rights in their PDMP information. Notwithstanding federalism issues discussed above in Part 2.4.1.2, the federal district court decided for the ACLU and held that the Fourth Amendment was violated by the DEA's use of administrative subpoenas (rather than a court-issued warrant) to obtain PDMP records for an individual patient's prescriptions and for all drugs prescribed by two physicians.[214] The court found both patients and physicians have subjective *and* objective expectations of privacy in PDMP records for the Schedule II through IV drugs at issue.[215] The court found that although patients must expect that medical personnel will access their prescription files, it is reasonable for patients to expect that law enforcement will not have access to the PDMP records—given the intensely personal nature of the data (often revealing a

[213] *See, e.g.,* State v. Skinner, 10 So. 3d 1212 (La.2009) (finding that the Fourth Amendment requires a search warrant before a search of medical or prescription records for criminal investigative purposes can be undertaken); Doe v. Broderick, 225 F.3d 440,. 451 (*4th Cir*. 2000) (holding that a patient at a methadone clinic had a legitimate expectation of privacy in the records on file there, given their intimate and private nature).
[214] Or. Prescription Drug Monitoring Program, 998 F.Supp. at 967.
[215] *Id*. at 964-67.

person's medical condition and treatment patterns) and information on the PDMP's website that emphasized the protection of confidential information.[216]Although the district court's decision is not binding in other jurisdictions and a few state courts have held alternately,[217] PDMPs are beginning to follow *Oregon Prescription Drug Monitoring* guidance by increasingly requiring a search warrant or a court-issued subpoena for law enforcement officials to access PDMP data.[218]

Privacy protections for PDMP data can also be located in non-constitutional sources, such as the Health Insurance Portability and Accountability Act (HIPAA) and state privacy laws.[219] The HIPAA "Privacy Rule" creates a national standard for the protection of individually

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[216] *Id*. at 966-67. The District Circuit found it "difficult to conceive of information that is more private or more deserving of Fourth Amendment protection" than prescription drug information that would reveal if a patient is being treated for gender identity disorder—as would be captured by PDMP records. Prescribing records of this kind are protected against government intrusion by a "heightened privacy interest rendering the use of administrative subpoenas unreasonable." *Id.* The court also dispensed with the DEA's assertion that the "third-party doctrine" undermines the patient/prescriber expectations of privacy because (a) PDMP records are inherently personal and private and (b) doctors and patients do not voluntarily convey the information to the PDMP—rather it is required by law that all dispensing information be included. *Id*.

[217] Williams v. Commonwealth, 213 S.W.3d 682 (Ky. 2007) (finding that the Kentucky statute authorizing warrantless searches of PDMP data is facially constitutional and does not amount to a "search", because limited data of Schedules II-V controlled substances that did not reveal a patient's medical condition or treatment were conveyed); Michael H. Lambert v. R.J. Larizza, as State Attorney for the Seventh Judicial District Circuit of the State of Florida, Case No. 13-314-2-CICI (Fla.Cir.Ct. Feb 13, 2014) (holding that the production of PDMP prescription records for 3,300 patients to state and federal law enforcement officials pursuant to a warrantless request did not violate Florida's constitution because there is a reduced expectation of privacy in prescription records). *See also* Jodie Tillman, *California High Court to Consider Limits on Regulators' Access to Prescription Database*, LOS ANGELES DAILY NEWS, Apr. 26, 2015, http://www.dailynews.com/general-news/20150426/california-high-court-to-consider-limits-on-regulators-access-to-prescription-database (describing the decision of a California state appeals court that found medical board use of PDMP data to identify a physician with outlier prescribing trends that led to his administrative probation does not violate the patients' rights to privacy under the state constitution. The court found that medical records are not comparable to prescription records from a privacy standpoint, as the latter are subject to regular scrutiny by law enforcement and regulatory agencies.).

[218] NAMDSL Review, *supra* note 71, at 2. *See also* Devon T. Unger, *Minding Your Meds: Balancing the Needs for Patient Privacy and Law Enforcement in Prescription Drug Monitoring Programs,* 117 W. VA. L. REV. 345 (2014) (arguing that patients have a legitimate interest in personally identifiable PDMP data and that the Fourth Amendment requires law enforcement to obtain a warrant before accessing these data). Still, 30 states allow law enforcement to conducted searches of PDMP data merely pursuant to an active investigation, and many also allow licensing boards to do the same. NAMDSL Review, *supra* note 71, at 25-26.

[219] Unger, *supra* note 218, at 362-64.

identifiable health care information from disclosure by "covered entities" (or health care providers), with limited exceptions that may apply to PDMP data.[220] For example, a covered entity may disclose health information that identifies a patient without receiving permission from that individual for enumerated exceptions germane to PDMPs, including: disclosures required by law; public health activities; health oversight activities; law enforcement purposes; and for treatment, payments, and health care operations.[221] Moreover, HIPAA does not preempt state law (including state privacy and PDMP laws) if the Secretary of Health and Human Services determines that the state provision serves a compelling public health need or has as its principal purpose the regulation of any controlled substance, among other aims.[222] All this suggests that HIPAA should not prevent the sharing of information via PDMPs—either by dispensers when initially logged into the PDMP or to authorized users of PDMPs—given the compelling public health need for prescribers and dispenser to view aggregated prescribing information, so long as the information shared is limited to the minimum necessary to achieve this intended purpose.[223]

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[220] 45 C.F.R. §§ 160, 164 (2012). "Covered entities" include medical or health care service providers, such as physicians and pharmacists, who electronically transmit individually identifiable information in connection with financial or administrative activities related to health care. 45 C.F.R. §§ 164.501, 164.506, 164.512.

[221] 45 C.F.R. §§ 164.501, 164.506, 164.512.

[222] HIPAA does not preempt state law (including a PDMP law) if the Secretary of Health and Human Services determines that the provision serves a compelling public health need, or has as its principal purpose the regulation of the manufacture, registration, distribution, dispensing or other control of any controlled substance; or provides for reporting of disease or injury . . . or for the conduct of public health surveillance, investigation or intervention 45 C.F.R. §§ 160.203(a)(1)-(2) & 160.203(c). *See* National Alliance of Model State Drug Laws, Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and Prescription Drug Monitoring Programs (PMPs) (2010), http://www.namsdl.org/library/BB52D3BB-1372-636C-DD90AC3AAB8D724F/ hereinafter, NAMSDL HIPAA].

[223] 45 C.F.R. § 164.502(b)(1). At least one federal lawsuit charges that access by a local police department of a man's prescription history without probable cause, a subpoena, or court order is a violation of HIPAA. Mollie Bryant, *Brandon Denies Police Violated HIPAA*, THE CLARION LEDGER (Jan. 25, 2016), http://www.clarionledger.com/story/news/2016/01/25/brandon-denies-bpd-violated-hipaa/79313188/.

Moreover, some states include explicit privacy protections in their PDMP laws. These steps are advisable for all programs and include: exempting PDMP data from public records requests;[224] imposing criminal or civil penalties for unauthorized disclosure of PDMP data;[225] limiting authorized users of the data to a select set of professionals; and explicitly requiring that the housing entity comply with all relevant state and federal privacy and confidentiality laws.[226] States also should put into place substantial data security protections to avoid disclosure of PDMP information, especially if data are shared across state lines. These measures include password-protected access (and careful authentication of all users), data encryption software, preventing unauthorized downloads of the data, and monitoring for potential security breaches.

While some states set forth stricter conditions for law enforcement and licensing official access PDMP files, as compared to pharmacy-housed files, the majority still allow warrantless searches.[227] The *Oregon Prescription Drug Monitoring* decision to require law enforcement officials to obtain a warrant based on probable cause strikes a reasonable balance between facilitating federal and state law enforcement drug investigations and protecting physician-patient interests and medical privacy. These data access requirements should be extended to licensing bodies also, given their analogous role to law enforcement and ability to sanction medical professionals by revoking or suspending medical licenses. Otherwise, unfettered access

[224] Thirty-one states currently exempt PDMP data from public records laws. NAMDSL Review, *supra* note 79, at 41.
[225] Thirty-eight states currently have such penalties for disclosing or obtaining PDMP data without authorization. *Id*. at 42. However, enforcement of these penalties is not well-documented.
[226] NAMDSL HIPAA, *supra* note 220. *See also* Unger, *supra* note 218, at 379-82 (proposing that all data be personally de-identified before disclosure to law enforcement officials).
[227] *See* NAMSDL Privacy, *supra* note 207, at 22-37; National Alliance for Model State Drug Laws, Types of Authorized Recipients—Professional Licensing or Regulatory Boards (2014), http://www.namsdl.org/library/BD1A41D1-CDF1-B6B6-ACB4543F7F8D2DC7/.

to prescription records by law enforcement and licensing officials runs a higher risk of hampering prescribing and/or opioid use to an extent that compromises legitimate pain management. State rules that house the data within a health agency and limit PDMP authorized users to those who use the data for clinical purposes—and provide the data (absent a warrant) to others (e.g., researchers, law enforcement, licensing bodies) only on a de-identified basis—run the least risk of running afoul of privacy laws or interfering with the doctor-patient relationship. Moreover, requiring law enforcement and licensing bodies to obtain a warrant does not substantially interfere with their duties and is therefore reasonable.[228]

In summary, states seem to be the appropriate level for PDMP implementation and a federal PDMP is neither a realistic option on the horizon nor a necessary one. However, certain features of state PDMPs can infringe upon protected individual rights and should be carefully considered going forward. Given the potential for broad PDMP data access that could hinder optimal medical care by affecting doctor and patient behavior around opioid prescribing and drug seeking, PDMPs should be guarded carefully by the housing entity and available to a limited subset of users under select circumstances. Most notably, law enforcement and licensing officials should only obtain the data pursuant to warrant based on probable cause. Penalties for unauthorized data disclosure should be clear, strong, and enforced.

2.4.2 Effectiveness of Regulation

[228] *See* People v. Curco Drugs, Inc., 350 N.Y.2d 74, 84 (N.Y. Crim. Ct., 1973) ("obtaining a warrant would not have seriously undermined the [statute allowing administrative inspections of pharmacy premises without a warrant]'s purpose of deterring violations. Clearly, it would have been only a minimal interference with their duties to obtain a warrant.").

Even if a PDMP seems likely to withstand privacy challenges, policymakers should further inquire into the effectiveness of a particular approach. This second consideration when considering public health laws is empirical in nature: will (or does) the regulation in question—either proposed or already implemented—effectively address the immediate public health threat? State regulators specifically should ask: (1) what are the public health outcomes this law seeks to impact?, (2) do these outcomes align with pre-defined primary and secondary health outcomes we seek to target?, and (3) does sufficient, credible evidence exist to suggest that the law will achieve (or has achieved) intended public health outcomes when applied to the context and environment at hand? (4) Is the predicted or actual ratio of intended to unintended consequences high enough to warrant implementation?

The level of certainty desired to deem a regulation effective can vary. As a general matter, policymakers should aim to identify robust evidence, generated using optimal designs for establishing causality, to support a particular regulatory approach. In other words, does the law itself *cause* intended changes in targeted health outcomes? This question can and should be assessed at different stages.[229] If a policy is being newly considered for implementation, regulators can consider evidence generated from comparable contexts to support law initiation.[230] Alternatively, if the law is already implemented, regulators can focus on

[229] *See* J. Frank Wharam & Norman Daniels, *Toward Evidence-Based Policy Making and Standardized Assessment of Health Policy Reform*, 298 JAMA 676, 677 (2007) (identifying the need for systematic and *ongoing* evaluations of new health policies, the lack of which has led to the discovery of unintended consequences years after policy implementation, and presenting a framework for maximizing the effectiveness and ethical characteristics of health policy. The four essential elements identified in the framework include: "(1) [r]eview to ensure that the policy's fundamental precepts are ethical, … (2) [t]argeted pilot projects or timely retrospective assessments to address benefits and harms for stakeholders, … (3) [s]tudies to determine if unintended consequences can be satisfactorily minimized,… [and] (4) [f]eedback systems to maintain acceptable outcomes after policy implementation.").
[230] Burris et al., *supra* note 112, at 187.

retrospective evaluations of the specific law as well as literature reviewing similar policies to determine whether the law should be retained, revised, or abandoned in favor of other policy options (Figure 2.1). Policymakers might also consider a package of laws or a law intervention paired with a different type of policy, such as a PDMP combined with prescriber education initiatives, in which case they should seek evidence to support the interactive effects of these multiple interventions.[231]

Fortunately, in contemporary times, research on public health law effectiveness is increasingly available.[232] Public health law research (PHLR) may be generated from within the legal academy, where there has been an explosion of empirical work in recent years, or from researchers in other social science fields (e.g., economics, health services research, political science, public policy) that "use systematic methods within an explicit theoretical framework to collect and analyze data."[233] The translation of available scientific evidence (i.e., research) into public health policy and law, though a critical step, has historically been under-emphasized and constitutes a key criteria in the framework for evaluating public health law success (Figure 2.1).[234] Moreover, evidence included for this translation should be selected with care, based on

[231] *See* Nancy E. Kass, *An Ethics Framework for Public Health*, 91 AM J. PUB. HEALTH 1776, 1778 (2001) (observing that if a law is one of multiple and varied interventions that together are designed to reduce health risks and poor health, then interventions and studies must be designed with the awareness of the relationship between this program of interventions and ultimate reduction in morbidity and mortality).
[232] For example, the Robert Wood Johnson Foundation funded a large Public Health Law Research initiative starting in 2008, to promote the scientific study of the relation between laws and legal practices to population health. Burris et al., *supra* note 112, at 171.
[233] *Id*. at 172 (in other words, they engage in "research").
[234] See Jonathan E. Fielding et al., *How Do We Translate Science into Public Health Policy and Law?*, 30 J. L. MED. & ETHICS 22 (2002). *See also* Kass, *supra* note 231, at 1780 (noting that, due to the all-too-common situation in which public health research findings are not translated into policy, benefits can fail to accrue from the research. Institutional review boards allow research to proceed with the expectation that a benefit to research subjects or communities will emerge. Without translation into policy, the risk-to-benefit ratio of the research will rarely weigh in favor of research proceeding.). *But see* Burris & Anderson, *supra* note 104, at 107-08 (discussing the influential

some hierarchy of rigor and robustness, to avoid regrettable health policy decisions based on inadequate or misleading research.[235]

2.4.2.1 Outcome Variables of Interest

Intended outcomes that signify improved public health should be pre-defined by policymakers based on policy needs and health risks targeted. Public health targets of interventional laws can be categorized as primary and secondary outcomes, as described below. Other, non-health-related or process-oriented benefits of legal interventions may accrue and are important, such as increased employment or community building in the process of carrying out the law, but these benefits are ancillary to the main goals of public health regulation.[236] At the forefront of policymakers' minds when considering public health regulation should be stated goals of improving population health.[237]

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nature of PHLR on policymaking, in both a top-down and bottom-up fashion. Research funding so crucial to creating a robust PHLR base, however, has been disproportionately light in comparison to its wide use and impact.). Some of this policy translation has failed to occur for reasons outside of the effectiveness evidence, such as budget constraints and public support. *See infra* Part 2.4.3. *See also* Stephanie Zaza et al., *Using Science-Based Guidelines to Shape Public Health Law*, 31 J. L. MED. & ETHICS (SPECIAL SUPP.) 65, 66 (2003) (observing that legislators often shy away from evidence-based decision-making simply because they lack the knowledge to understand the science or because they lack confidence in the actual health benefits and effectiveness of a proposed intervention); Beverly Gard et al., *Connecting Public Health Law with Science*, 32 J. L. MED. & ETHICS (SPECIAL SUPP.) 100, 100 (2004).

[235] *See* Sumit R. Majumdar & Stephen B. Soumerai, *The Unhealthy State of Health Policy Research*, 28 HEALTH AFF. w900 (2002) (discussing examples, such as in the field of health information technology, where researchers failed to adopt core principles of study design prerequisite to producing valid evidence, which arguably led to the adoption of ineffective interventions. Worse, such an evidence base could lead to the unintended consequence of population harm.). *See also* Stephen B. Soumerai et al., *How Do You Know Which Health Care Effectiveness Research You Can Trust? A Guide to Study Design for the Perplexed*, 12 PREVENTING CHRONIC DISEASE 1 (2015).

[236] Kass, *supra* note 231, at 1778. These incidental benefits may play a role in balancing of benefits and harms when considering whether regulation should be undertaken.

[237] Kass, *supra* note 231, at 1778 ("…a reduction in morbidity and mortality need not and could not be the goal of every individual public health intervention or program; however, individual public health programs should not be undertaken that are not part of a larger package of programs whose combined goals is the reduction of morbidity and mortality.").

Population health improvements can be measured in terms of primary outcomes or secondary outcomes. Primary outcomes are ideal measures of public health law effectiveness, as these directly reflect population health sought to be addressed by the law. Those considered of value to state policymakers include population-level morbidity and mortality measures.[238] Pre-defined and "clinically significant" improvements in primary outcomes typically include reductions in diagnosed illnesses or deaths. In the PDMP context, primary outcomes targeted that signify improved health include reduced opioid-related overdoses, substance abuse treatment admissions, emergency department visits, and rates of addiction.

Secondary outcomes considered in public health law evaluations include proximal or intermediate outcomes that lie along the pathways of effect. Such proxy outcome variables include changes to environments and behaviors that expose individuals to health risks.[239] PDMP proximal outcomes include changed prescriber and patient behavior, reduced controlled substance supply, and enhanced law enforcement or other surveillance activity. Changes in prescribing behavior indicative of reduced opioid misuse and overdose risk include, for example, lower rates of prescribing of high-morphine-equivalent dosages[240] or less co-prescribing of opioids and benzodiazepines.[241] Reduced rates of doctor shopping[242] and drug

[238] Burris et al., *supra* note 112, at 177-78; Kass, *supra* note 231, at 1777.
[239] *Id*.
[240] Jane A. Baumblatt et al., *High-Risk Use by Patients Prescribed Opioids for Pain and Its Role in Overdose Deaths*, 174 JAMA INTERNAL MED. 796 (2014); Nathaniel Katz et al., *Usefulness of Prescription Monitoring Programs for Surveillance –Analysis of Schedule II Opioid Prescription Data in Massachusetts, 1996-2006*, 19 PHARMACOEPIDEMIOLOGY & DRUG SAFETY 115 (2010); Logan, *supra* note 52; Wilsey, *supra* note 53.
[241] Logan, *supra* note 52; Wilsey, *supra* note 53; Dunn, *supra* note 53.
[242] *See infra* note 64 for a definition of "doctor shopping".

diversion reflect changes in patient behaviors and/or law enforcement activity, from which lowered opioid adverse health effects may follow.

While primary outcome measures are the ultimate measure of public health law effectiveness, a focus on intermediate (or secondary) outcomes is often necessary or reasonable for several reasons.[243] First, the time horizon required to detect changes in population health often can be lengthy,[244] because reduced morbidity and mortality attributable to a policy take time to manifest and measure. Take opioid misuse, for instance: even if a PDMP reduces incident opioid addiction by erecting appropriate barriers to individuals obtaining prescriptions, reductions in population-level overdoses and mortality will take some time to manifest because an already-addicted population will continue to experience these adverse health outcomes in the short-term. Also, ultimate health outcomes like opioid-related overdoses and hospitalizations are so rare that they must be observed over some time to detect policy-attributable changes (if there are any). It is thus more practicable and still telling to measure changes in prescribing patterns as a proxy for changes in the environment that ultimately would contribute to reduced opioid adverse health outcomes. Second, because ultimate health outcomes are often attenuated from laws or policies, understanding mechanisms that may lead to changes in these outcomes increases confidence that any effects observed are indeed attributable to a particular intervention. Access to and measurement of intermediary variables along the causal pathway avoids exclusive use of sometimes unpersuasive ecological studies, not uncommon to the PHLR literature.[245]

[243] Burris et al., *supra* note 112, at 177-79.
[244] *Id*.
[245] Burris & Anderson, *supra* note 104, at 108.

2.4.2.2 Assessing the Evidence

Policymakers and researchers should explicitly identify the intended and/or anticipated pathways of effect from law to health outcomes. Research supporting or refuting aspects of this pathway can be located within a causal model, [246] while gaps in the research base may also become apparent. But how can regulators identify empirical research worth including in the evidence base to either support or call into question public health laws? PHLR can be good science, but this is not true across the field. Furthermore, some laws lend themselves to evaluation better than others.[247] Principles of research design can be used to guide policymakers—even those with limited empirical training—in identifying scientific evidence worth incorporating into policy.[248]

A wide array of research methods are available for studying the effects of public health laws,[249] ranging from qualitative research,[250] to observational studies,[251] to quasi-experiments,[252] to randomized controlled experiments.[253] Study design types within these

[246] *See* Jeffrey W. Swanson & Jennifer K. Ibrahim, *Picturing Public Health Law Research: The Value of Causal Diagrams, in* PUBLIC HEALTH LAW RESEARCH: THEORY AND METHODS 217-36 (ed. Alexander C. Wagenaar & Scott Burris, San Francisco: John Wiley & Sons, 2013).
[247]Burris & Anderson, *supra* note 104, at 107-08.
[248] Soumerai, *supra* note 235, at 14-15.
[249] *See generally,* PUBLIC HEALTH LAW RESEARCH: THEORY AND METHODS (Alexander C. Wagenaar & Scott Burris eds., San Francisco: John Wiley & Sons, 2013).
[250] Robert Drislane & Gary Parkinson, *Qualitative Research*, *in* Online Dictionary of the Social Sciences (2011), *available at* http://bitbucket.icaap.org/dict.pl (defining "qualitative research" as "[r]esearch using methods such as participant observation or case studies which result in a narrative, descriptive account of a setting or practice.").
[251] WILLIAM R. SHADISH, THOMAS D. COOK, & DONALD T. CAMPBELL. EXPERIMENTAL AND QUASI-EXPERIMENTAL DESIGNS FOR GENERALIZED CAUSAL INFERENCE. Belmont (CA): Wadsworth Cengage Learning 12 (2002) (synonymous with a correlational study, an observational study is one "that simply observes the size and direction of a relationship among variables").
[252] *Id*. ("[a]n experiment in which units are not assigned to conditions randomly").
[253] *Id*. ("[a]n experiment in which units are assigned to receive the treatment or an alternative condition by a random process such as the toss of a coin or a table of random numbers").

broad categories of research can be characterized by the inter-related concepts of rigor, suitability for causal inference, and capacity to control for common biases.[254]

A simplified hierarchy of designs can assist policymakers (ideally in coordination with researchers) in organizing PHLR to assess whether sufficient evidence exists to support law adoption or continued existence. The quantity of evidence is important here,[255] although less so than the quality of evidence used to determine policy effectiveness and the generalizability of the evidence to the context in question. Table 2.2 suggests a way to organize studies, generally arranged from the strongest to weakest designs for causal inference (i.e., to demonstrate that effects were *caused* by the policy studied). Randomized controlled experiments, the "gold-standard" for inferring a causal relationship between the law and an outcome,[256] are quite rare in PHLR.[257] Thus, natural experiments, or those where the intervention is not randomly assigned, are important to consider.[258] The hierarchy presented is by no means exhaustive of the different types of studies that policymakers may encounter. Rather it is intended as a starting point to assist in assessing the value of PHLR for policy incorporation.

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[254] *See, e.g.,* Soumerai et al., *supra* note 235, at 15; Mello & Zeiler, *supra* note 105, at 657-62 (providing a helpful catalogue of methodological approaches to empirically study health laws, from strongest to weakest designs, and also displaying the rating system used by the United States Preventive Services Task Force in considering whether sufficient evidence exists to support a preventive health measure).

[255] Kass, *supra* note 231, at 1778-79 (suggesting that the greater the burdens posed by a program, the stronger the evidence base must be to support that a program will achieve its stated goals).

[256] Because the law is "randomly assigned" to an intervention group and not the comparison group, the two groups theoretically are comparable on every other dimension, and effects found, therefore, can be attributed to the intervention rather than confounding variables. Confounding variables are those that could be related to both the intervention and the outcome variable, and could thus explain any changes in outcomes observed.

[257] Mello & Zeiler, *supra* note 105, at 660. *But see* Alan S. Gerber et al., *Evaluating Public Health Law Using Randomized Experiments, in* PUBLIC HEALTH LAW RESEARCH: THEORY AND METHODS 283-306 (ed. Alexander C. Wagenaar & Scott Burris, San Francisco: John Wiley & Sons, 2013).

[257] Shadish, Cook & Campbell, *supra* note 251, at 171-206.

[258] *See* Alexander C. Wagenaar & Kelli A Komro, *Natural Experiments: Research Design Elements for Optimal Causal Inference Without Randomization*, PUBLIC HEALTH LAW RESEARCH: THEORY AND METHODS 307-324 (ed. Alexander C. Wagenaar & Scott Burris, San Francisco: John Wiley & Sons, 2013).

Table 2.2: Hierarchy of Public Health Law Research Designs

Category	Design Type	Brief Description	Strengths	Validity Threats[259]
Experimental	Randomized controlled trial	Experiment in which units are assigned to receive a legal intervention or no intervention by a random process (e.g., toss of a coin or lottery).[260]	• "Gold standard" of evidence for identifying causal relationships. • If randomization is successful, the risk of unmeasured confounding variables is minimized.	• External validity (i.e., generalizability to other contexts, populations) is limited. • Quite rare in PHLR.
Quasi-Experimental	Interrupted time series	Study that specifies a time at which an intervention occurred to "interrupt" the prior situation (e.g., time at which a law is effective) and observes outcomes over multiple time points pre- and post-interruption.[261] Stronger design if it includes a comparison group or outcome not exposed to interruption.	• Displays graphically baseline trends and any changes in level or trend of the outcome variable at time of interruption in the intervention group.	• Co-occurring interventions or indeterminate intervention time periods threaten validity. • Requires adequate observations pre- and post-interruption to establish seasonality or secular trends.
	Regression discontinuity	Study participants are assigned to a condition (e.g., health insurance coverage) on the basis of a cutoff score (e.g., income). Outcome variable is measured before and after assignment.[262]	• Minimizes differences (i.e., confounders) between groups, but for the cutoff score.	• Possible manipulation of the cutoff criteria (e.g., lying about income). • Generalizable only to populations close to the cutoff.
	Difference-in-differences (or) controlled pre-post	Study that compares outcomes before and after the intervention in a group exposed compared to a group not exposed to an intervention.	• Minimizes concern that effects merely reflect secular trends.	• Not accounting for differing baseline trends of groups.[263]

[259] Study validity can be characterized in a number of ways. This table and accompanying discussion focus on internal validity and external validity. "Internal validity" refers to the validity of inferences about whether observed covariance between treatment (intervention) and outcome variables reflects a *causal* relationship. "External validity" refers to the validity of inferences about whether the cause-effect relationship holds over variation in persons, settings, treatment variables, and measurement variables. Shadish, Cook & Campbell, *supra* note 251, at 33-102.

[260] *Id*. at 12-13.

[261] *Id*. at 171-206.

[262] *Id*. at 207-43.

[263] Soumerai et al., *supra* note 235, at 15.

Table 2.2: Hierarchy of Public Health Law Research Designs (Continued)

Category	Design Type	Brief Description	Strengths	Validity Threats
Observational	Uncontrolled pre-post	Study measures outcome variable before and after the intervention, but without a comparison group. Stronger design adjusts for potential confounding variables (i.e., uses multivariate regression).[264]	• Can rule out that effects are caused by other confounding variables rather than the law of interest by including these variables in the model.	• Cannot rule out that secular changes in the environment may introduce confounding variables responsible for effects.
	Cross-sectional designs	Study is descriptive only, measuring outcome variable at one point in time after the intervention (i.e., no baseline measure). Stronger designs adjust for confounding variables (i.e., use multivariate, instead of univariate or bivariate regression).[265]	• Can describe the relationship between two variables. Precision in the measure of this relationship is enhanced if other variables that relate to both (i.e., confounders) are included in the model.	• No baseline measure(s) to provide a basis for comparison to outcome measures after the intervention, so no cause-effect relationship can be identified.
Qualitative	Surveys, interviews, focus groups	Systematic content analysis (and sometimes quantitative analysis) of questions answered by multiple study participants.	• Can provide rich context to the factors affecting policy effectiveness.	• Subjective and susceptible to response bias.[266] • Not generalizable given typically small sample sizes.
	Case studies	Description of policy intervention experience using a particular example or set of examples.	• Can provide rich information about particular example(s) of policy effectiveness.[267]	• Example(s) selected may be unique and not generalizable to other contexts.[268]

In addition to the above categories of designs for individual studies, other types of research aim to aggregate the findings of multiple primary studies and may be very valuable to policymakers. Systematic reviews use explicit methods to identify and critically review research relating to a particular outcome or set of outcomes and evaluate the strength of their findings

[264] Mello & Zeiler, *supra* note 105, at 659-60; Soumerai et al., *supra* note 235, at 15.
[265] Mello & Zeiler, *supra* not 105, at 658-60.
[266] *Id*. at 658.
[267] *Id*.
[268] *Id.*

to arrive at a general conclusion about the literature.[269] Meta-analyses apply quantitative statistical analyses to pool and analyze findings from different studies to arrive at effect estimates of similar interventions across the literature.[270] There are certain collaborative entities, such as the Cochrane Collaboration, Campbell Collaboration, and The Community Guide (of the Centers for Disease Control and Prevention) pioneering the work in these areas, although relatively few systematic-type reviews are available relative to the numerous and varied types of public health laws in existence.[271] Finally, "comparative effectiveness" studies do not necessarily encompass a specific study design type, but are defined as those that compare methods to "prevent, treat, and monitor a clinical condition or to improve the delivery of care," and to inform decision-making by policymakers, among others.[272] This definition can potentially include head-to-head comparisons of community- and population-level interventions to improve health conditions, such public health law approaches to treating prescription opioid misuse.[273] Comparative effectiveness research, although in its infancy in the United States, is enjoying substantial federal funding[274] and may be increasingly available and relevant to public health policymaking in the future.

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[269] Moulton et al., *The Scientific Basis for Law as a Public Health Tool*, 99 AM J PUB HEALTH 17, 17 (2009); Mello & Zeiler, *supra* note 105, at 661.
[270] *Id.*
[271] *See* Moulton et al., *supra* note 269, at 17 for a detailed discussion and catalogue of systematic reviews available for interventional public health laws, as well as identification of notable gaps in the field. *See also* Mello & Zeiler, *supra* note 105, at 661.
[272] Jane H. Thorpe, *Comparative Effectiveness Research and Health Reform: Implications for Public Health Policy and Practice*, 125 PUBLIC HEALTH REP. 909, 909 (2010) (quoting the Institute of Medicine's definition of comparative effectiveness research).
[273] *Id*.
[274] *Id*. at 909-10.

2.4.2.3 PDMP Effectiveness

The body of research investigating PDMP effectiveness is beginning to generate information about whether these policies impact opioid-related primary health outcomes or proximal outcomes. Although the literature is growing and of a respectable size, many studies are not rigorous enough to warrant policy incorporation or replication, when compared against the hierarchy of research designs presented in Table 2.2. Several more recent studies, though, use long-term data from multiple states and assess specific PDMP features to draw conclusions about PDMP impacts. As these kinds of stronger studies proliferate, a clearer sense of PDMP effectiveness will emerge.

The Table B.1 catalogues key studies of PDMPs that shed light on identified primary and secondary outcomes (Appendix B).[275] Table B.1 summarizes the results of a search of social science and medical peer-reviewed literature[276] for studies that measure the effects of state-based, electronic PDMPs.[277] Included in Table B.1 are the published analyses that employ quasi-experimental and observational designs (*see* Table 2.2). Although this review does not focus on

[275] *See supra* Part 2.4.2.1 for identification of these outcomes.

[276] The helpfulness of unpublished PDMP evaluations, such as those conducted internally by states, for informing policy is limited by the widespread use of uncontrolled designs (i.e., the studies fail to include a comparison group for reference when evaluating a particular PDMP) and contexts which are difficult to generalize across states. Further, these evaluations are not subject to the peer-review process.

Also, evaluations of PDMPs in other countries, most notably Canada, are not included in the literature presented. Extrapolating results from these studies presents numerous challenges given differing health care systems, prescribing norms, patient behaviors, and PDMP features. *See* Yoko Murphy et al., *Prescription Opioid Use, Harms and Interventions in Canada: A Review Update of New Developments and Findings since 2010*, 18 PAIN PHYSICIAN E605, E610-611 (2015).

[277] There is a decent-sized literature on paper PDMPs, particularly focusing on their impact on benzodiazepine prescribing. However, this literature is not included in Appendix Table because paper PDMPs were a substantially different intervention from electronic PDMPs and were implemented during a different prescribing era. This literature thus may have limited generalizability to electronic PDMPs. *See* Tamara M. Haegerich et al., *What We Know, and Don't Know, About the Impact of State Policy and Systems-Level Interventions on Prescription Drug Overdose*, 145 DRUG & ALC. DEPENDENCE 34, 37-38 (2014), for a summary of these paper PDMP studies.

them, qualitative studies can offer further insights into the relationship between PDMPs and health outcomes and should supplement policymaker considerations. Table B.1 should not be considered exhaustive of research bearing on PDMPs, but it includes the best candidate studies currently available for drawing causal inferences about the public health effects of PDMPs.

Although some have interpreted the PDMP literature as providing strong evidence of program effectiveness,[278] the story is far from clear.[279] We still lack a robust understanding of whether PDMPs reduce opioid-related overdose deaths, the ultimate health outcome of interest. The best available study uses national mortality data from the Centers for Disease Control and Prevention to find no association between PDMPs and overdose mortality.[280] However, the data used are somewhat outdated (1999-2005) and span a period when PDMPs were not very robust.[281] On the other hand, states with PDMPs do seem to experience fewer opioid-related treatment admissions and poisonings, based on two strong quasi-experimental studies.[282] These analyses used national poisoning and treatment admission data cumulatively spanning from 1997 through 2009 and characterized states of study based on the presence or

[278] *See, e.g.,* COE Briefing, *supra* note 72, at 3; Julie Worley, *Prescription Drug Monitoring Programs, a Response to Doctor Shopping: Purpose, Effectiveness, and Directions for Future Research*, 33 ISSUES IN MENTAL HEALTH NURSING 319, 326 (2012).

[279] *See* Haegerich, *supra* note 277, at 37-38 (presenting an astute but limited review of the PDMP evaluation literature from 1946-2014. The authors conclude that "later studies … have not clearly established significant effects on total opioid prescribing or health outcomes with PDMPs. The largest limitation is the lack of detailed data on prescribing volume and patterns prior to PDMP implementation, which forced the use of cross-section, observational study designs. The effect sizes in the most recent studies have been small, making it conceivable that the differences are due to unaddressed confounding variables. There is yet little data to settle the question of whether specific actions of PDMPs (e.g., proactive reporting) add to their effectiveness.") No rigorous systematic reviews study PDMP effects.

[280] *See* Leonard J. Paulozzi et al., *Prescription Drug Monitoring Programs and Death Rates from Drug Overdose*, 12 PAIN MED. 747 (2011).

[281] *Id*.

[282] Lisa M. Reifler et al., *Do Prescription Monitoring Programs Impact State Trends in Opioid Abuse/Misuse?*, 13 PAIN MED. 434 (2012); Richard M. Reisman et al., *Prescription Opioid Usage and Abuse Relationships: An Evaluation of State Prescription Drug Monitoring Program Efficacy*, 3 SUBSTANCE ABUSE 41 (2009).

absence of a PDMP.[283] Reifler et al. went a step further and conducted sub-analyses of "superior" PDMP features (i.e., program was in effect for a long time, sent unsolicited reports, and monitored comprehensive drug schedules) to find consistent results.[284] Although further study of all primary health outcomes is warranted, these studies suggest that PDMPs are at least associated with decreased poisonings and admissions.

However, the mechanism of effect (or secondary outcomes) to explain reduced treatment admissions and poisonings is uncertain. The literature findings are mixed as to whether state PDMPs reduce opioid supply or prescribing. Several quasi-experimental studies use national opioid supply data spanning 1997 through 2008 to draw different conclusions regarding whether PDMPs are associated with reduced supply. Another quasi-experimental study conducted by Rutkow et al. found that Florida's (voluntary) PDMP and pill mill law combined to drive modest decreases in total opioid fills and morphine concentration per dose (but not days' supply of drugs) among the highest baseline users and prescribers, respectively.[285] This strong analysis nevertheless suffers from an imperfect comparison state (Georgia—which had much lower prescribing at baseline) and an inability to isolate PDMP effects from those of another intervention.[286] Weaker observational studies have drawn mixed conclusions about the effect of PDMPs on prescribing behavior and typically include small sample sizes, which limit their generalizability.[287] Finally, there is very little evidence to suggest

[283] *Id*.
[284] Reifler et al., *supra* note 282.
[285] *See* Rutkow et al., supra note 165.
[286] *Id*.
[287] *See* David F. Baehren et al., *A Statewide Prescription Monitoring Program Affects Emergency Department Prescribing Behaviors*, 56 ANNALS EMERGENCY MED. 19 (2010); Chris Ringwalt et al., *The Effects of North Carolina's Prescription Drug Monitoring Program on the Prescribing Behaviors of the State's Providers*, 36 J. PRIMARY

that PDMPs reduce doctor shopping or diversion, given that the few studies available on these outcomes do not lend themselves to causal inference.[288]

Although the evidence base to support PDMPs is growing, it requires significant further exploration and rigor. Weaknesses in the literature are numerous. First, many of the more rigorous studies were conducted during a period when PDMPs were less comprehensive policies—for instance, through the early 2000s, programs typically monitored only Schedule II substances and were seldom queried—and thus need updating. Second, most studies are not rigorous, with no randomized controlled trials and few quasi-experimental studies available. Many studies also lack a comparison group, fail to measure outcomes before a policy went into effect, or include small sample sizes. Third, studies typically do not account adequately for many other, co-occurring prescription drug misuse policy interventions (such as pill mill laws, or opioid drug reformulations), and thus could falsely attribute effects to PDMPs instead of to these policies. Finally, mixed results could be attributable to divergent PDMP policies, which are typically not carefully characterized in studies. Studies could do a much better job of differentiating the PDMP interventions based on policy strength.

PREVENTION 131 (2015); Matthew W. McAllister et al*., Impact of Prescription Drug-Monitoring Program on Controlled Substance Prescribing in the ED*, 33 AM. J. EMERGENCY MED. 781 (2015); Scott G. Weiner et al., *Clinician Impression Versus Prescription Drug Monitoring Program Criteria in the Assessment of Drug-Seeking Behavior in the Emergency Department,* 62 ANNALS EMERGENCY MED. 281 (2013).

[288] *See*, e.g., Linda Simoni-Wastila & Jingjing Qian, *Influence of Prescription Monitoring Programs on Analgesic Utilization by an Insured Retiree Population*, 21 PHARMACOEPIDEMIOLOGY & DRUG SAFETY 1261 (2012); Hillary L. Surratt et al., *Reductions in Prescription Opioid Diversion Following Recent Legislative Interventions in Florida*, 23 PHARMACOEPIDEMIOLOGY & DRUG SAFETY 314 (2014).

A major drawback in PDMP studies, moreover, is the typical failure to account for actual levels of PDMP *use* by prescribers, which is still thought to be quite low.[289] The median PDMP *registration* rate among providers who issued at least one controlled substance prescription was 35% from 2009–2012,[290] and not all enrolled prescribers regularly query PDMPs. A recent national study found that only 53% of primary care physicians reportedly use their state's PDMP.[291] Although studies do suggest that PDMP awareness is high and that use is increasing over time,[292] database queries are still sufficiently low that not incorporating this measure into studies may dilute any potential findings of effect. Also, further investigation is required into whether targeting increased use among a subset of high-volume prescribers, rather than all physicians or controlled substance prescribers, is warranted.

Because so many varied PDMPs have been implemented, policymakers and researchers should now look to evidence from multi-state, retrospective, comparative evaluations of their

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[289] *But see* Ringwalt et al., *supra* note 287; Chris Delcher et al., *Abrupt Decline in Oxycodone-Caused Mortality After Implementation of Florida's Prescription Drug Monitoring Program*, 150 DRUG & ALC. DEPENDENCE 63 (2015) (which incorporates a measure of PDMP queries into the intervention variable).

[290] PETER KRIENER ET AL., BUREAU OF JUSTICE ASSISTANCE PRESCRIPTION DRUG MONITORING PROGRAM PERFORMANCE MEASURES REPORT: JANUARY 2009 THROUGH JUNE 2012 (2013), http://www.pdmpexcellence.org/sites/all/pdfs/BJA%20PDMP%20Performance%20Measures%20Report%20Jan%202009%20to%20June%202012%20FInal_with%20feedback.pdf. The percentage of prescribers who registered with the program (among prescribers who issued at least one controlled substance prescription in the prior three months) from 2009-2012 ranged from one to 82% based on the state. *Id*. at 15-16.

[291] Lainie Rutkow et al., *Most Primary Care Physicians Are Aware of Prescription Drug Monitoring Programs, But Many Find the Data Difficult to Access*, 34 HEALTH AFF. 484, 487 (2015).

[292] *See, e.g.,* Jeanmarie Perrone et al., *Prescribing Practices, Knowledge, and Use of Prescription Drug Monitoring Programs (PDMP) by a National Sample of Medical Toxicologists*, 8 J. MED. TOXICOLOGY 341 (2012); Lance Feldman et al., *Awareness and Utilization of a Prescription Monitoring Program among Physicians*, 13 PAIN MED. 908 (2012); Lance Feldman et al., *Influencing Controlled Substance Prescribing: Attending and Resident Physician Use of a State Prescription Monitoring Program*, 25 J. PAIN & PALLIATIVE CARE PHARMACOTHERAPY 313 (2011); Kirstin Barrett & Ashby Watson, *Physician Perspectives on a Pilot Prescription Monitoring Program*, 19 J. PAIN & PALLIATIVE CARE PHARMACOTHERAPY 5 (2005).

effectiveness.[293] This evidence base needs updating, using longer-term data from before and after program implementation, now that sufficient time has passed since electronic PDMPs were implemented in many jurisdictions. Identifying appropriate comparison jurisdictions to enable quasi-experimental designs is somewhat of a challenge, given that 49 states have adopted their own PDMPs. Thus, time variation in PDMP adoption or implementation of certain features offers opportunities for comparative studies. For instance, the impact of relatively recent "strong" PDMP mandates (requiring that prescribers check the systems regularly) on reduced opioid prescribing shows promise in the handful of states that have adopted this policy lever,[294] but requires additional empirical support. Also, comparison outcomes offer new avenues. For example, researchers can compare opioid prescribing for acute pain or headaches (indications where opioids have been shown to have limited utility) versus that for cancer (where opioid prescribing receives little scrutiny). One would hypothesize that PDMPs would reduce opioid prescribing in the former case, but not the latter.

The literature would benefit from a greater interdisciplinary focus by incorporating prescribers, pharmacists, program administrators, law experts, and health services researchers into informing and designing studies. Prescribers and pharmacists can provide clinical expertise germane to generating hypotheses about which PDMP features are likely to impact prescribing behavior and to identifying appropriate comparison outcomes (see above example). Law

[293] Twenty PDMPs currently require that evaluations be reported to the legislature at least annually regarding the effectiveness of the programs and how they are impacting prescribing. NAMDSL Review, *supra* note 79, at 11. These types of reporting requirements would offer a prime opportunity for policymakers to work with researchers and program administrators to enhance the evidence base, particularly by conducting studies using comparison states or comparison outcomes.

[294] Linda Rasubala et al., *Impact of Mandatory Prescription Drug Monitoring Program on Prescription of Opioid Analgesics by Dentists*, 10 PLoS ONE e0135957 (2015) (for a strong assessment of the impact of the New York i-STOP mandate on opioid prescribing among dentists). *See* Haffajee*, supra* note 94.

experts can assist in categorizing PDMPs as robust or weak for comparison purposes, based on assessment of their policy features or enforcement. Policymakers can identify key outcomes of interest with regard to PDMP effectiveness. Program administrators can provide PDMP data for study and an understanding of the operational particulars of the programs (such as user-ship). And health services researchers can help to design the best studies feasible, using available data.

Finally, comparative effectiveness studies that compare PDMPs to other state interventions targeting opioid misuse, such as pill mill laws or access to opioid antagonists, would provide timely information to regulators regarding how to best invest their limited resources to tackle prescription opioid misuse. If PDMPs are implemented concurrently with other interventions, as was the case in Florida where PDMPs and other policies were pursued in quick succession, it may be practically difficult to separate out PDMP independent effects, and thus co-effects that are less generalizable to other jurisdictions must be considered.[295] Exploration into all these areas would assist policymakers to most effectively address prescription drug misuse and would serve to facilitate decisions regarding whether to retain, amend, or abandon PDMPs.

2.4.3 *Ethical Considerations*

A third broad inquiry for state policymakers asks whether ethical objections advise against public health law implementation or perpetuation. Even if a policy falls within the

[295] *See* Rutkow et al., supra note 165 (studying the interactive effects of the Florida PDMP law and pill mill laws on opioid prescribing and total opioid volume). *But see* Delcher et al., *supra* note 289 (attempting to "control" for three co-interventions that impacted Florida (including the Florida pill mill law, DEA pill mill crackdown, and OxyContin reformulation) in the multivariate regression model).

appropriate legal parameters for state action and seems likely (or is proven) to be effective in addressing the public health problem, there may be ethical objections that, if substantial, should bar its implementation or continued existence.

The community-level focus of public health calls for a set of justificatory considerations distinct from those used in clinical medical settings where the treatment and cure of individual patients are paramount.[296] Instead, public health is primarily concerned with the well-being of populations, the broader social and environmental determinants of health, and prevention of ill societal health.[297] Practice-based public health ethics frameworks emerged from an explicit recognition of these distinguishing features and unique moral considerations in public health.[298] Rather than try to provide a comprehensive philosophical approach to public health in practice, they rely upon the foundational values of rights (positive and negative) and social justice.[299] Specifically, a code of public health ethics should emphasize the negative rights of citizens to noninterference, affirmative societal obligations to improve the health of the overall population, and the need to fulfill these obligations with special focus on the needs of the most

[296] Kass, supra note 231, at 1776 ("[c]odes of medical and research ethics generally give high priority to individual autonomy, a priority that cannot be assumed to be appropriate for public health practice. … A framework of ethics is needed, both to provide practical guidance for public health professionals and to highlight the defining values of public health, values that differ in morally relevant ways from values that define clinical practice and research."). *See also* Lisa M. Lee, *Public Health Ethics Theory: Review and Paths to Convergence*, 34 J. L. MED. ETHICS 85, 87 (2012); James F. Childress et al., *Public Health Ethics: Mapping the Terrain*, 30 J.L. MED. & ETHICS 170, 170 (2002); Ross E.G. Upshur, *Principles for the Justification of Public Health Intervention*, 93 CANADIAN J. PUBLIC HEALTH 101, 101 (2002).

[297] Upshur, *supra* note 296, at 101. The Institute of Medicine has defined public health as "what we, as a society, do collectively to assure the conditions in which people can be healthy." INSTITUTE OF MEDICINE, THE FUTURE OF PUBLIC HEALTH . Washington, DC: National Academy Press (2006).

[298] *Id*.

[299] Lee, *supra* note 296, at 87-90; Kass, supra note 231, at 1777.

disadvantaged.[300] The principles proposed provide practical guidance for practitioners faced with public health ethical quandaries,[301] including policymakers implementing public health laws.[302]

Public health ethics principles set forth by Kass[303] and Childress[304] provide useful guideposts for the ethical implementation of public health laws. These conditions do not explicitly include, but instead, complement and assume favorable performance under those criteria already set forth herein (i.e., the legal permissibility and effectiveness of a law designed to address a significant public health threat).[305] Although not an exact algorithm to resolve conflicts between the goal of public health and other moral considerations, the following ethical conditions can help guide determinations about the appropriateness of public health interventions, and include: (1) proportionality, (2) minimal infringement, (3) fairness, and (4) public accountability.[306] A brief discussion of the principles follows, and each is applied to the

[300] Kass, supra note 231, at 1777; Gostin, *supra* note 104, at 10-11 (discussing the social justice moral impulses that animate public health: (a) to advance human well-being by improving health, and (b) to do so by particularly focusing on the needs of the most disadvantaged. To satisfy these aims succeeds in bringing the good of health to *all* members of the population).
[301] Lee, *supra* note 296, at 87-88.
[302] Kass, supra note 231, at 1777 ("Indeed, it is in great part *because* such power is vested in public health by law that a code or framework of ethics designed specifically for public health is so very important.").
[303] Kass, supra note 231.
[304] Childress et al., *supra* note 296.
[305] Several of the justificatory conditions included in public health ethics frameworks proposed by other scholars actually overlap with legal requirements set forth in Part 2.4.1 *supra* and the general requirement of effectiveness set forth in Part 2.4.2 *supra*. For example, James Childress et al., require that a public health policy be *necessary*, *effective*, and *minimally infringing*. Childress et al., *supra* note 296, at 173. Nancy Kass requires that a public health policy be *effective* at reducing mortality and morbidity and *minimally infringing*. Kass, supra note 231, at 1778-80. Richard Upshur requires that the program be minimally restrictive. Upshur, *supra* note 296, at 102. Minimal infringement is included in the present framework as an ethical principle because, depending on the type of policy, the law requires varying degrees of inquiry into the level of infringement and whether less restrictive alternatives are available. By including minimal infringement as an ethical principle, an inquiry must be made into the reasonableness of the intrusiveness of the law, not merely whether an *obviously* less restrictive means is available. *See infra* Part 2.4.1.1.
[306] Childress et al., *supra* note 296, at 173.

PDMP context—although it is important to bear in mind that every state PDMP is unique and must be assessed on a case-by-case basis.

2.4.3.1 Proportionality

First, it is critical to demonstrate that the benefits of a public health law outweigh the costs or infringements associated with its implementation.[307] Proportionality requires that societal benefits be considered against burdens, to help assess whether this particular law is the best use of available resources.[308] There are two dimensions of proportionality: one that considers societal benefits against individual burdens and another that considers societal benefits against societal burdens. (Individual burdens, such as liberty and privacy, will be further addressed below in the discussion of "minimal infringement."[309]) The societal benefits of PDMPs include changes in the primary and secondary outcomes outlined above: reducing opioid-related adverse health outcomes, improving prescribing, and reducing diversion or doctor shopping. Societal benefits also include reduced expenditures associated with prescription drug misuse, as well as more intangible but potentially substantial benefits

[307] *Id*.

[308] Two tools may be useful to policymakers in comparing costs to benefits. Cost benefit analysis quantifies the costs and benefits of a course of action, comparing them using the same metric (often monetary value). Trying to quantify the benefits of a course of action can be challenging and controversial. Thus, in health interventions, cost-effectiveness analysis is often favored. Cost-effectiveness analysis divides the impact of a program (e.g., percent reduction in new cases of opioid addiction) by the cost of the program, generating a statistic termed the cost-effectiveness ratio (CER). CERs can be compared as between different policy interventions or programs. Abdul Latif Jameel Poverty Action Lab, Cost-Benefit/Effectiveness/Comparison Analyses, http://www.povertyactionlab.org/methodology/what-evaluation/cost-benefiteffectivenesscomparison-analyses (last visited Jul. 30, 2015). For further discussion of concepts and benefits of cost-effectiveness analyses for use by policymakers, *see* WORLD HEALTH ORGANIZATION, MAKING CHOICES IN HEALTH: WHO GUIDE TO COST-EFFECTIVENESS ANALYSIS, (ed. Tessa T. Edejer, Rob Baltussen, Taghreed Adam, World Health Organization: Geneva, 2003), http://www.who.int/choice/publications/p_2003_generalised_cea.pdf.

[309] Individual burdens are the focus of James Childress et al.'s discussion of the proportionality principle. *See* Childress et al., *supra* note 296, at 173-76.

associated with reduced unemployment, absenteeism, and family disruption. Illicit drug use (a large percentage of which involves opioids) costs our nation $11 billion in health care costs and $193 billion overall annually[310]—some of which expenditure could be saved if PDMPs work to curb this practice.

Societal burdens considered should include government costs of implementation and enforcement, as well as the opportunity costs of expending government and private resources (including political capital), instead of pursuing other policies to achieve the same ends. PDMPs are expensive to implement and finding the money to implement these systems has proven a challenge. Programs are funded by a combination of federal funds, private funds, and state-raised revenues, but often operate at impaired capacity when money issues arise.[311] The programs are complex to operate—from the technical components (software is usually proprietary and owned by contracted software vendors), to ensuring confidentiality of information, to checking the accuracy of data inputted by dispensers, to promoting or enforcing use by prescribers, to facilitating optimal law enforcement use of the data. Substantial resources are required to facilitate these tasks. In the current environment, PDMPs constitute the dominant state approach to addressing prescription drug misuse, perhaps at the opportunity cost of investing money and political capital into other opioid misuse prevention efforts. In order to justify these societal costs, the health benefits and cost savings will need to be explicitly proven.

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[310] National Institute on Drug Abuse, Trends and Statistics (2015), http://www.drugabuse.gov/related-topics/trends-statistics.

[311] PRESCRIPTION DRUG MONITORING PROGRAM TRAINING AND TECHNICAL ASSISTANCE CENTER, FUNDING OPTIONS FOR PRESCRIPTION DRUG MONITORING PROGRAMS, TECHNICAL ASSISTANCE GUIDE NO. 04-13 (July 2013), http://www.pdmpassist.org/pdf/PDMP_Funding_Options_TAG.pdf; Rick Jurgens, *Systems to Track Prescription Medicines Said to Need Improvement*, VALLEY NEWS, Dec. 28, 2014.

Moreover, unintended effects—both negative and positive—of regulation on population health outcomes or on non-health outcomes should be included in the calculus. There may be substantial negative unintended effects of PDMPs on populations, the extent of which are currently unknown. Although a few studies have suggested that electronic PDMPs will not have a "chilling" effect on appropriate prescribing,[312] whether PDMPs lead some prescribers to cut back on or discontinue appropriate controlled substance prescribing, thereby exacerbating the under-treatment of pain epidemic or other maladies, remains to be seen. Studies of older paper PDMPs found that prescribers did, indeed, cut back on appropriate benzodiazepine prescribing, particularly among racial minorities[313]—albeit this was a somewhat different, more forceful intervention than most electronic PDMPs. Some studies of early electronic PDMPs detected substitution from monitored (Schedule II) to non-monitored (Schedule III) opioids,[314] which lends support to the possibility that PDMPs could change pain management treatment and possibly compromise clinical care. Differentiating between appropriate and inappropriate opioid prescribing, as well as how to best use PDMPs to identify doctor shoppers and diverters, places a substantial onus on prescribers (and pharmacists) in an area where clinical disagreements abound. Also, if opioid addicts are denied pills because prescribers check PDMPs, then they may turn in increasing numbers to heroin—a perverse, negative public health

[312] *See* Baehren et al., supra note 287; Ringwalt et al., *supra* note 287.
[313] Dennis Ross-Degnan et al., *A Controlled Study of the Effects of State Surveillance on Indicators of Problematic and Nonproblematic Benzodiazepine Use in a Medicaid Population*, 34 INT. J. PSYCHIATRY MED. 103 (2004); Sally Pearson et al., *Racial Disparities in Access after Regulatory Surveillance of Benzodiazepines*, 166 ARCH . INTERNAL MED. 572 (2006).
[314] *See* Paulozzi, supra note 290; Simoni-Wastila & Qian, *supra* note 288.

ramification.[315] Many of these potential PDMP unintended consequences are substantial: research should investigate whether they occur and safety mechanisms should be instituted to prevent their matriculation. For instance, if opioid addicts are denied prescription drugs, addiction treatment options should be recommended and made available so that they are less likely to turn to heroin.

2.4.3.2 Minimal Infringement

As a corollary to the proportionality requirement, policymakers should seek to minimally infringe upon private interests and adopt the least restrictive means available. This ethical requirement can be viewed as complementary to the legal standards described in Part 2.4.1.1 (and in most cases, of a higher threshold). This condition recognizes that there may be a number of means to achieving a public health end, and the least restrictive one should be favored—particularly when using powerful police powers that are presumptively coercive, the unintended consequences of which may be ill understood.[316] Individual burdens or harms typically will fall into three categories: risks to privacy and confidentiality; risks to liberty and self-determination; and risks to justice (which will be further addressed as a fairness consideration below).[317] Even where a public health law may appear to restrict an individual's liberty, its potential to enhance the liberty of other individuals warrants consideration, as positive externalities of public health laws abound.[318]

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[315] *See* Leo Beletsky, *As Heroin Deaths Skyrocket, Prescription Monitoring Programs May Do More Harm*, HUFFINGTON POST, Mar. 18, 2015, http://www.huffingtonpost.com/leo-beletsky/as-heroin-deaths-skyrocket-prescription-monitoring-programs-may-do-more-harm_b_6883944.html.
[316] Upshur, *supra* note 296, at 102.
[317] Kass, *supra* note 231, at 1779 (discussing the burdens more or less likely to arise from different public health activities. Regulations and legislation rank among the most intrusive approaches to public health—they are coercive because they typically impose penalties for noncompliance.).
[318] Parmet, *supra* note 112, at 405.

PDMPs impose serious individual burdens on prescribers and patients. PDMP infringements on prescribers in their clinical practice are not insignificant, and prescribers have shown resistance to using PDMPs. Commonly cited prescriber objections to use include concerns about compromised patient satisfaction ratings (if checking a PDMP results in delays or denial of controlled substance prescriptions), unreimbursed time associated with using the program, burdensome enrollment procedures, cumbersome systems, and the information being viewed as unnecessary, incomplete, inaccurate, and/or untimely.[319] To minimally infringe upon prescribers and the physician-patient relationship,[320] these barriers should be reasonably addressed, for example, by automatically enrolling prescribers,[321] improving integration into clinical workflow and making data complete through frequent updates and interstate sharing (at least among neighboring states). Physicians should not be required to log into multiple, cumbersome systems, particularly absent reimbursement for their time.[322]

Use mandates adopted in twenty-two states raise a particularly interesting quandary: they infringe substantially on physicians, but they seem to increase PDMP queries and possibly reduce opioid prescribing volume and misuse. Robust evidence, therefore, should be generated from within states that have enacted strong mandates (e.g., New York and Tennessee) to justify this policy lever before it is more universally adopted given significant prescriber objections.[323]

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[319] Deyo et al., *supra* note 80;
[320] *See* Steven E. Weinberger et al., *Legislative Interference with the Patient-Physician Relationship*, 367 NEW ENG. J. MED. 1557 (2012) (citing other examples of doctor-patient interferences, such as restrictions on discussions about gun safety imposed in some states).
[321] Twenty-one states currently require prescribers and dispensers to register with the PDMP. NAMSDL Review, *supra* note 71, at 39.
[322] *See* Haffajee, et al., *supra* note 94.
[323] *Id*.

At the same time, PDMP features that serve to dis-incentivize prescribers from checking the systems, such as laws that explicitly provide prescriber immunity from liability for failure to check[324] or exemption from any obligation to query the systems,[325] should be abandoned to send the message that PDMPs ought to be checked frequently when prescribing monitored substance.

Infringements on prescribers and patients also can be substantial if their private prescription data are disclosed and/or used for law enforcement or regulatory purposes. As discussed in Part 2.4.1.4, allowing law enforcement and licensing boards unfettered access to PDMP data—namely, to identify high-volume prescribers, doctor shoppers, or diverters absent a court-issued warrant or subpoena—toes the line, legally speaking. As an ethical matter, even if the law allows wide access in certain jurisdictions, patients and prescribers arguably should be afforded heightened privacy protections to allow uninhibited doctor-patient decision-making to occur. Also, strict data security protections, particularly when information flows across states, are necessary to minimize confidentiality concerns felt by opioid prescribers and patients. These include robust technological protections[326] and penalties for disclosure by PDMP authorized users.

Effective PDMPs are likely to benefit third parties, despite other liberty infringements. Preventing addiction facilitates the enjoyment of certain liberties by others, such as avoiding being burdened by exposure to prescription opioids (which increases the likelihood of using and

[324] Twenty-five state provide such immunity. NAMSDL Review, *supra* note 71, at 38.
[325] Sixteen states absolve prescribers from any obligation to check PDMPs. NAMSDL Review, *supra* note 71, at 37.
[326] See infra Part 2.4.1.4 for PDMP security recommendations.

abusing drugs); avoiding having to care for, watch suffer, or lose a family member or friend; avoiding exposure to HIV or other diseases spread by sharing infected needles;[327] and avoiding increases in health insurance premiums (or taxes for public programs) generated by the costs of opioid-related hospitalizations or outpatient visits.[328] These benefits suggest that a balance must be struck between making PDMPs minimally intrusive on individual liberties and making them effective—as mentioned in the mandate discussion above.

2.4.3.3 Fairness

A public health law should satisfy a basic requirement of fairness.[329] Although fairness can be articulated using a number of different ethical frameworks,[330] this discussion centers on the distributive justice theory originally conceived by John Rawls,[331] which calls for the equitable distribution of benefits and costs among populations and communities. Kass and Gostin both ground fairness in distributive justice.[332] According to Kass's framework, distributive justice in public health obligates the government to ensure that interventions address the health of the least advantaged; Gostin goes a step further to assert that the

[327] *See* Abby Goodnough, *Rural Indiana Struggles to Contend with H.I.V. Outbreak*, THE NEW YORK TIMES, May 5, 2015, *available at* http://www.nytimes.com/2015/05/06/us/rural-indiana-struggles-to-contend-with-hiv-outbreak.html?_r=0.

[328] *See, e.g.,* Dr. Holm, *Harm from Drug Use Extends Beyond Illicit User*, RAPID CITY JOURNAL, Aug. 3, 2015, *available at* http://rapidcityjournal.com/harm-from-drug-abuse-extends-beyond-the-illicit-user/article_95a5e18c-fc7c-5386-a946-e74b078b82be.html (suggesting that harms extending beyond the user include "increased crime and violence, child and spouse abuse, motor vehicle accidents, sexually spread diseases, fetal malformations in children, and deaths due to accidental and intentional overdose.").

[329] Some of the fairness concepts presented in this Part resemble those of equal protection required under the Constitution, briefly discussed *supra* Part 2.4.1.3, which aims to protect those groups subjected to historical discrimination. This ethical inquiry is somewhat broader, however, and does not identify particular classes of persons particularly deserving of protection.

[330] For example, prioritarian or utilitarian frameworks can also be adopted, depending on societal conceptions of fairness.

[331] *See* JOHN RAWLS, A THEORY OF JUSTICE, Cambridge, Ma: The Belknap Press of Harvard University (1971).

[332] Kass, *supra* note 231, at 1780-81 (noting that this requirement is particularly important if an intervention is restrictive).

negative consequences of interventions do not fall disproportionately on the least advantaged.[333] Because the least advantaged are more vulnerable to public health threats as well as least likely to enjoy other social determinants to health, they arguably deserve special attention.[334]

In the case of prescription opioid misuse, the least advantaged in society (as measured by socioeconomic status, for example) are more likely to lack robust education about the science and risks of addiction; switch to cheaper and more easily accessed heroin when prescription pills are no longer available; have limited treatment options for addiction and overdose (e.g., naloxone access; substance abuse treatment); and lack access to social and other support services to address addiction and its consequences (e.g., access to clean needles). These considerations mean that PDMPs may be necessary to reduce inequalities, but also that any unintended negative consequences should not disproportionately fall upon the less advantaged. The paper triplicate form of prescription monitoring that preceded electronic PDMPs reduced problematic, as well as *non*-problematic, benzodiazepine use,[335] and had disproportionate under-prescribing impacts in minority communities.[336] The potential for these unintended consequences with electronic PDMPs should be closely monitored, to see if, for example, certain demographic groups are targeted as potential "doctor shoppers" and prescribed to less often as a result of these programs. Education and guidelines should

[333] Gostin, *supra* note 104, at 11.
[334] *Id*.
[335] Ross-Degnan et al., *supra* note 313.
[336] Pearson et al., *supra* note 313.

accompany prescriber use of the systems, to promote standardized and conscientious use of the data in a way that promotes good health and does not exacerbate social inequalities.

2.4.3.4 Public Accountability

Finally, the government should strive to be accountable to the public when implementing health laws on their behalf. Most public health laws will infringe on some private interests and impose some social cost, and thus should be explained and justified to parties impacted. Policymaking transparency respects stakeholders as moral equals who deserve to be involved in the decision-making process.[337] It also is essential to creating and maintaining public trust, an element so crucial to the acceptability and ultimate effectiveness of public health laws as well as the general legitimacy of future policymaking.[338] Public health policies may be particularly susceptible to backlash—in the form of lack of public support, legal challenges, noncompliance, or opposition to future laws—if they are coercive.[339] Policymakers should appreciate that different social groups may view public health laws from different perspectives and endeavor to gain diverse support.[340] In pluralistic societies, where there is reasonable disagreement about principles that ought to guide priority setting in meeting population health needs given limited resources, different viewpoints should be understood and respected and decision-making made as clear and accountable as possible.[341]

[337] Upshur, *supra* note 296, at 102; Childress et al., *supra* note 296, at 173.
[338] Childress et al., *supra* note 296, at 173; Parmet, *supra* note 112, at 410.
[339] Parmet, *supra* note 112, at 410.
[340] Parmet et al., *supra* note 133, at 654.
[341] *Id.*; Upshur, *supra* note 296, at 102; Norman Daniels, *Accountability for Reasonableness*, 321 BRITISH MED. J. 1300, 1300 (2000) (outlining key elements of a "fair process" for guiding public health decisions, including: transparency about the basis of a decision, appeals to common rationales that fair minded people can accept as relevant to meeting health needs fairly; and procedures for appealing/revising decisions).

PDMP implementation and policies should thus be transparent to the public. Consideration of various features and program amendments should be made with the involvement of relevant stakeholders. The process of effectuating changes to the Massachusetts PDMP provides an example of excellent public accountability in public health lawmaking. In August 2012, Massachusetts enacted a law to automatically enroll practitioners in its existing PDMP and require that they consult the database when prescribing controlled substances to new patients. The Commonwealth solicited extensive feedback and held hearings concerning these changes. Through this process, prescriber objections to the breadth of circumstances for PDMP checks surfaced and were incorporated into the final implementation rules in the form of mandate exemptions.[342] As a result, the cooperation and mutual respect between public health officials and Massachusetts providers was likely strengthened, which will facilitate future prescription drug misuse prevention endeavors. Prescribers also will be more willing to accept and comply with the PDMP mandate now in effect.

2.5 CONCLUSIONS

This Chapter seeks to simplify and systematize the inquiries critical for state policymakers when considering public health laws like PDMPs for implementation. Although various scholars have outlined factors that should guide policymaking, for instance in the public health ethics and PHLR literature, this Chapter is the first to synthesize the factors under three

[342] Commonwealth of Massachusetts Department of Public Health, Prescription Monitoring Program, Jul. 2014, http://www.mass.gov/eohhs/gov/laws-regs/dph/proposed-regulations/prescription-monitoring-program.html. For example, the final rule limited mandate coverage to new patient prescriptions for Schedule II/III drugs or benzodiazepines and included myriad exceptions (e.g., prescriptions to hospice patients, inpatients, children, or in emergency situations; emergency department practitioners who do not anticipate writing a Schedule II-V prescription or who prescribe a 5-day supply or less; and prescribers who face circumstances that render PDMP use impossible). *Id*.

key criteria relevant to *state* regulation, suggest the policymaking junctures at which they should be applied, and apply them to PDMPs. PDMPs constitute the dominant policy adopted by states to address prescription opioid misuse—a profound public health challenge that is as complex in etiology as in the policy interventions available to combat it. PDMPs exemplify unstructured policymaking uninformed by evidence or systematic guiding principles, and thus would stand to benefit from a more deliberate and organized path to success. The framework articulated herein guides PDMP recommendations, but is also generalizable to public health threats that exhibit characteristics similar to prescription drug misuse—namely significant public health problems that can be addressed with a panoply of policy options.

To satisfy legality, effectiveness, and ethical criteria—markers of successful public health policymaking—PDMPs should follow certain guidelines. First, they should include strong confidentiality protections and be searchable by authorized health care practitioners (prescribers and dispensers) only, to comport with legal and ethical privacy requirements. Strong penalties for disclosure of information by authorized users, such as medical license suspensions for prescribers, are important to provide further confidentiality incentives. Law enforcement officials, licensing boards, and researchers[343] should be provided with the data on a de-identified basis or pursuant to a court-issued warrant or subpoena.[344] Second, PDMPs should be designed to infringe minimally on and assist maximally clinical practice. To this end, the data should be as close to real-time as possible, shared across neighboring states, and accurate. The databases should be easily searchable and, as soon as practicable, integrated into

[343] Researchers receive data on a de-identified basis in 32 states at present. NAMSDL Review, *supra* note 71, at 22.
[344] *See* Unger, supra note 218.

electronic medical records. Third, the programs ought to strongly incentivize prescriber participation, first by requiring registration and abandoning laws that provide immunity for failure to check or no obligation to query. Prescriber use mandates with appropriate exceptions should be considered once further evidence of existing mandate efficacy (and possible unintended consequences) becomes available.[345] Fourth, PDMPs should include user guidelines and education about how to use the data effectively.[346] This would help to somewhat standardize opioid treatments across providers and prevent unintended consequences, such as under-prescribing for pain and burdening certain populations based on doctor shopping or diverter stereotypes. Finally, the existence and features of programs should be publicized to stakeholders, and any changes to their features going forward should incorporate diverse perspectives.

PDMPs undoubtedly show promise and should be pursued by the states, but they are still imperfect laws in need of adjustment and continued study. Effectiveness research should focus on evaluating newer, strong PDMP features (e.g., mandates) using long-term, multi-state designs (when possible) that incorporate comparison groups or outcomes. Increased evidence linking PDMPs to improved prescribing, reduced diversion and doctor shopping, and reduced overdoses, in particular, is needed. Study of the interactive effects of PDMPs and other prescription drug misuse interventions is also desirable, as these interventions are often enacted together. Such evidence will further illuminate PDMP features appropriate for

[345] *See* Haffajee*, supra* note 94.

[346] The Centers for Disease Control and Prevention has convened an expert panel to develop guidelines on opioid prescribing that will be available in 2016. These guidelines should help to develop additional clinical agreement in the clinical field and may be used to inform PDMP use, once available.

retention and replication. Incorporation of the recommendations articulated herein and ongoing re-evaluation of programs are critical in order for PDMPs to fulfill their potential to curb the opioid misuse and overdose epidemic in the United States.

3

EFFECTS OF ROBUST STATE PRESCRIPTION DRUG MONITORING PROGRAMS ON OPIOID PRESCRIBING AND USE

3.1 Abstract

Importance: Prescription drug monitoring programs (PDMPs) are a popular state-level intervention designed to reduce prescription opioid misuse by providing prescribers with comprehensive information about patient opioid prescription fill histories. Limited evidence exists regarding the effects of recently implemented "robust PDMP" features, such as those that require prescribers to query their state's PDMP before initially prescribing opioids and regularly thereafter in the case of longer-term treatments ("use mandates").

Objective: To quantify the effect of robust PDMPs on opioid prescribing and use.

Design, Setting, and Participants: We compared five states that implemented robust PDMP features from 2011 through 2013 (intervention states: Ohio, Kentucky, New Mexico, Tennessee, and New York) to neighboring states without robust PDMPs (respective control states: Pennsylvania, Missouri, Texas, Georgia, and New Jersey). We applied comparative interrupted time-series analyses to an open cohort of adults enrolled in health plans offered by a national commercial insurer and residing in these ten states of study. Patients were observed from 2010 through 2014 to assess opioid prescribing and use before and after implementation of robust PDMPs. We conducted a sensitivity analysis on a continuously enrolled cohort in the same intervention and control state sets.

Main Outcomes and Measures: Percent of enrollees filling opioid prescriptions, mean morphine equivalent dosage (MED) dispensed per enrollee. Secondary outcomes were mean number of prescribers and pharmacies used per 100 enrollees for opioid prescription fills.

Results: The percent of enrollees filling opioid prescriptions declined following implementation of robust PDMPs in four of the five intervention states (Kentucky, Ohio, Tennessee, and New York) relative to comparison states, although these decreases were not sustained through the end of the follow-up period in Tennessee and New York. Mean MED dispensed per enrollee declined in level in three of the five intervention states (Kentucky, Tennessee and New York) and in slope in two of the five intervention states (Kentucky and New Mexico) relative to comparison states in the postimplementation period. Analysis of secondary outcomes and sensitivity analyses reveal consistent results.

Conclusions and Relevance: Kentucky's robust PDMP policy is associated with substantial decreases in the proportion of enrollees filling opioid prescription, pharmacies ad prescribers

used to fill opioid prescriptions, and MED dispensed. Robust PDMPs in Tennessee and New Mexico are also associated with more modest reductions in most of these outcomes. Changes associated with Ohio and New York's robust PDMPs were either more modest or not maintained through the end of the study period. Kentucky's particularly robust PDMP features, which included a use mandate paired with a registration mandate and careful implementation supervision, are distinguishable from features implemented in states exhibiting smaller effects and thus Kentucky's policy may serve as a model for other jurisdictions seeking to curb high levels of opioid prescribing and use.

3.2 Introduction

Opioid misuse and overdoses have grown to epidemic proportions in recent years. In 2014, opioids—and most commonly, prescription hydrocodone and oxycodone—were involved in 28,647 deaths, which accounted for 61% of all drug overdose deaths.[1] The overall rate of opioid overdose deaths has tripled since 2000.[1] Rates of emergency department visits and substance abuse treatment admissions citing opioid misuse have followed a parallel trajectory during the same period.[2] The precipitous rise in adverse opioid outcomes is closely correlated with the increasing supply and prescribing of opioids. While the U.S. only accounts for five percent of the world's population, Americans consume over 80% of opioid supplies globally.[3] From 1999 to 2010, sales of opioid analgesics quadrupled in the U.S.[4] Prescribers issued 259 million opioid prescriptions in 2012 alone—enough for every American adult to have their own bottle of pills.[5] And non-medical opioid users (or "misusers") report that they obtain their opiates directly or indirectly from prescribers the vast majority of the time.[6] In short, physicians and prescribing norms play a significant role in the current opioid epidemic.

State prescription drug monitoring programs (PDMPs) are a prominent tool designed to address the prescription opioid epidemic. These programs facilitate prescription monitoring, one of the 2011 Office of National Drug Control Policy's highlighted prevention measures to curb prescription drug misuse, in light of the extremely high and variable levels of opioids prescribed in states across the country.[2] PDMPs digitally store in a statewide database dispensing information for prescription opioids and certain other drugs included in the federal Drug Enforcement Agency's Scheduled II through V controlled substances.[6] When a prescriber queries a patient's name in a PDMP, she can see the dose, supply, and prescriber of drugs with abuse potential the patient has recently filled. Knowing this information, prescribers are better equipped to identify whether a patient is at risk for overdose or other adverse consequences if they are prescribed opioids.[7] Because they offer a wealth of clinical prescription information, PDMPs are described by the Centers for Disease Control and Prevention (CDC) as "among the most promising state-level interventions to improve painkiller prescribing, inform clinical practice, and protect patients at risk."[8] Regular queries to state PDMPs were recently included as a recommendation in the CDC guidelines for prescribing opioids for chronic pain.[9]

PDMP implementation has proliferated since 1990, and today all states except Missouri have an operational program. Early programs[11,12] were often viewed as weak due to problems such as lack of ease in using of the system, infrequently updated data, and non-sharing of prescription fill information across state lines.[12,13] The evidence assessing the effectiveness of these early programs, when usership was particularly low,[14] is mixed. States with PDMPs experienced no significant change in opioid-related overdose deaths,[15] but did exhibit fewer opioid-related treatment admissions and poisonings—including in states with "superior" PDMP

features for the time (e.g., in effect for a long time, sending unsolicited reports, and monitoring comprehensive drug schedules).[16,17] However, studies are conflicting regarding whether early state PDMPs reduce opioid supply or affect prescribing behavior.[15,17-22]

Because PDMP prescriber use has historically been low, states are experimenting with new mechanisms to increase queries and, in theory, improve the utility of PDMP data for clinical care. PDMP prescriber-relevant features are documented through the end of 2014 in Table C.1, to differentiate between programs with stronger and weaker designs, and newer robust features are discussed in detail in the Appendix C.1.1. Recent features particularly gaining in popularity are mandates that clinicians query the database for information regarding a patient prior to prescribing opioids ("use mandates") and mandates that prescribers register with the systems (Table C.1).[23] A handful of states (i.e., Ohio, Kentucky, Tennessee, and New York) with robust use mandates that require checks under a comprehensive set of circumstances—for instance before initially prescribing opioids and regularly thereafter in the case of longer-term treatments—document that PDMP queries increased while opioid prescribing and doctor shopping decreased after implementation of this feature (Table C.2).[23,24] However, little rigorous evidence is available that assesses the effectiveness of use mandates coupled with generally stronger PDMP designs. One study has investigated New York's PDMP use mandate, finding that the odds of a dental patient receiving opioids was significantly reduced by 58-72% post-mandate compared to pre-mandate, but further evidence is needed.[25]

Using a rigorous longitudinal design, this study seeks to compare robust PDMPs that include comprehensive use mandates to weak PDMPs lacking such mandates and other prescriber-relevant features. We hypothesize that states with robust PDMPs experience

reductions in the proportion of patients filling opioid prescriptions, the opioid volume prescribed per patient, and the mean number of prescribers and pharmacies used by patients when filling opioid prescriptions. We also hypothesize that effects observed will be smaller in magnitude for a continuously enrolled cohort, as compared to a non-continuously enrolled one, because those using opioids at high rates that may be affected by robust PDMPs are less likely to maintain stability in private health insurance coverage and employment.

3.3 Methods

We used an interrupted time series with comparison series design to assess the effects of robust PDMPs in an open cohort of commercially-insured patients residing in ten states of study: five intervention state and five control states. We examined the percent of patients filling opioid prescriptions and the opioid volume dispensed per patient before and after implementation of robust PDMP features, from January 1, 2010 through December 31, 2014. This design allowed estimation of robust PDMP effects independent of other changes to opioid prescribing and use.

We devised a novel coding scheme to identify five states with robust PDMP policies as of the end of 2013 (to allow for sufficient follow-up observations after the policy) based on key law characteristics and with sufficient sample size and appropriate comparison states for study (Appendix C.1.1; Table C.1). Robust PDMPs were characterized as those that included seven or more of the following nine features empirically shown[15,23-25] or theoretically established as important to increasing use and utility of the data for prescribers: (1) prescriber access to the PDMP (*required feature*); (2) a use mandate, or a requirement that prescribers query the database under certain circumstances (*required feature*); (3) a robust use mandate, or a

requirement that prescribers check the PDMP before issuing initial opioid prescriptions and regularly thereafter in the case of longer-term treatments, with limited exceptions (Table C.2) (*required feature*); (4) a registration mandate, or a requirement that prescribers obtain or automatically receive a log-in to the PDMP; (5) proactive reporting that is required or permitted of the PDMP, to notify prescribers of their high prescribing patterns or their patients with outlier use patterns; (6) no prescriber immunity from liability for failure to check or effectively use the PDMP; (7) PDMP dispensing data that are updated at least weekly; (8) monitoring of at least federal Schedule II through IV controlled substances (i.e., opioids, benzodiazepines, hypnotics, and stimulants); and (9) data housed within a health agency, rather than a law enforcement entity. Further detail about these features and the rationale for including them as measures of PDMP robustness can be found in Appendix C.1.1. Based on these features, the following states were identified as potential "intervention states": Ohio, Kentucky, New Mexico, Tennessee, New York, Vermont, and West Virginia. Vermont and West Virginia were excluded from the study due to inadequate sample sizes for estimation purposes, which left five intervention states of study.

We selected as control states neighboring states without robust PDMPs that had comparable main outcomes rates during the preimplementation period. Specifically, control states had no more than four of the nine robust PDMP features identified above throughout the period of study. Control states also exhibited parallel trends with their respective intervention states for at least one of the main outcomes studied during the preimplementation period and levels for all outcomes that were no greater than twice or less than half the magnitude of the respective intervention state's levels at the beginning of the

study period (i.e. Q1/2010). Using these criteria, the following control states were selected for study (relative to each intervention state): Pennsylvania (for Ohio), Missouri (for Kentucky), Texas (for New Mexico), Georgia (for Tennessee), and New Jersey (for New York) (Table C.1; Figure C.1).

This research was approved by the institutional review boards at Harvard Pilgrim Health Care Institute and Harvard University. Informed consent was not required because the analyses are based on de-identified private insurance claims.

3.3.1 Study Population

Our data were from OptumInsight (Eden Prairie, MN), which includes inpatient, outpatient, and pharmacy claims from a large national health insurer with membership in all 50 states. While prescription data across all payers in the states of study were not available, OptumInsight data are representative of commercial claims in the United States and have been used to document trends in opioid dispensing and overdose events.[26,27] Dispensing data were used both as a proxy for prescribing and also as a measure of actual opioids obtained by patients. Available demographic information included enrollees' gender, year of birth, state of residence, race/ethnicity, education level, and household level income.

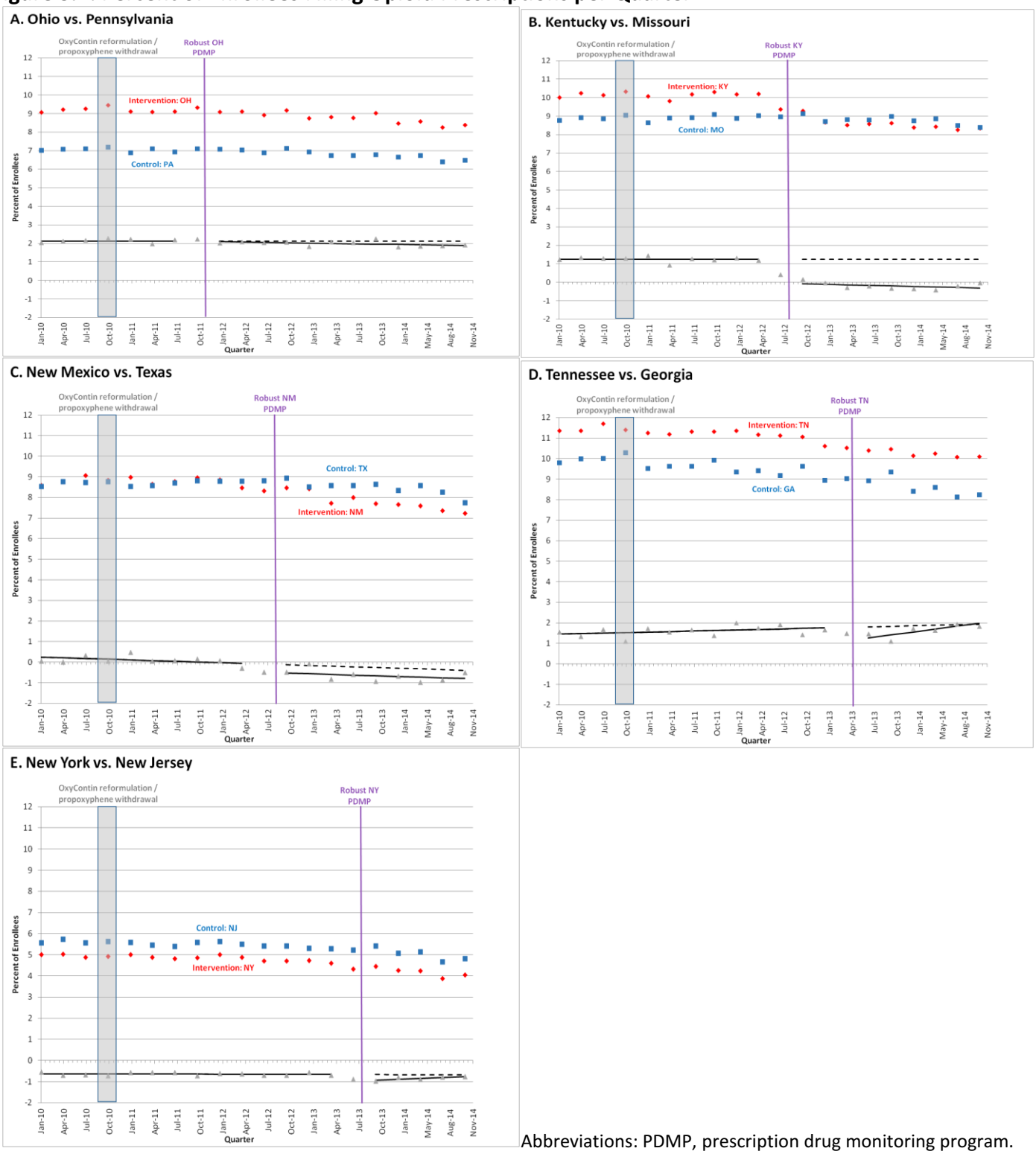
We assessed reimbursed dispensing for opiate agonists and limited opioid partial agonists among adults aged 18 to 64 years enrolled in a commercial health plan between January 1, 2011 and December 31, 2014 who resided in one of the ten states of study. We excluded children because their opioid use patterns differ from those of adults, and enrollees over age 64 because we lacked access to their Medicare claims.

We used First Databank (San Francisco, California) drug summary tables to identify National Drug Codes for opiate agonists and opioid partial agonists with American Hospital Formulary Service Classifications 28080800 and 28081200, respectively. We included the following opioids with the potential for addiction: codeine, dihydrocodeine, meperidine, morphine, oxycodone, hydrocodone, hydromorphone, fentanyl, oxymorphone, propoxyphene, methadone, tramadol, levorphanol, and buprenorphine transdermal. We excluded approximately 2.1% of opioid claims with erroneous or missing data (e.g., negative quantities or days supply of opioids dispensed).

We set the start date for study as January 1, 2010 because this provided at least a year of preimplementation data points to adequately evaluate seasonal variation.[28] This meant that two national interventions—the reformulation of OxyContin to a tamper-resistant extended-release form and the withdrawal of propoxyphene from the market—shown to be associated with decreases in opioid-related overdoses and prescribing of these substances occurred during our preimplementation period (Q4/2010).[26] But because rates in outcomes of interest following these interventions declined similarly between comparator states following these national interventions and well before our state PDMP implementation periods, we decided to include the 2010 data in our analysis (see Figures 3.1 and 3.2 for 2010 through 2011 trends).

We identified the date on which a robust use mandate became effective and was added to a pre-existing PDMP. Of note, the addition of this feature was always coupled with the addition of several other prescriber-relevant features, often a registration mandate, which cumulatively caused intervention states studied to meet or surpass the required threshold that they exhibit at least seven of the nine robust PDMP features in the 2011 to 2013 timeframe.

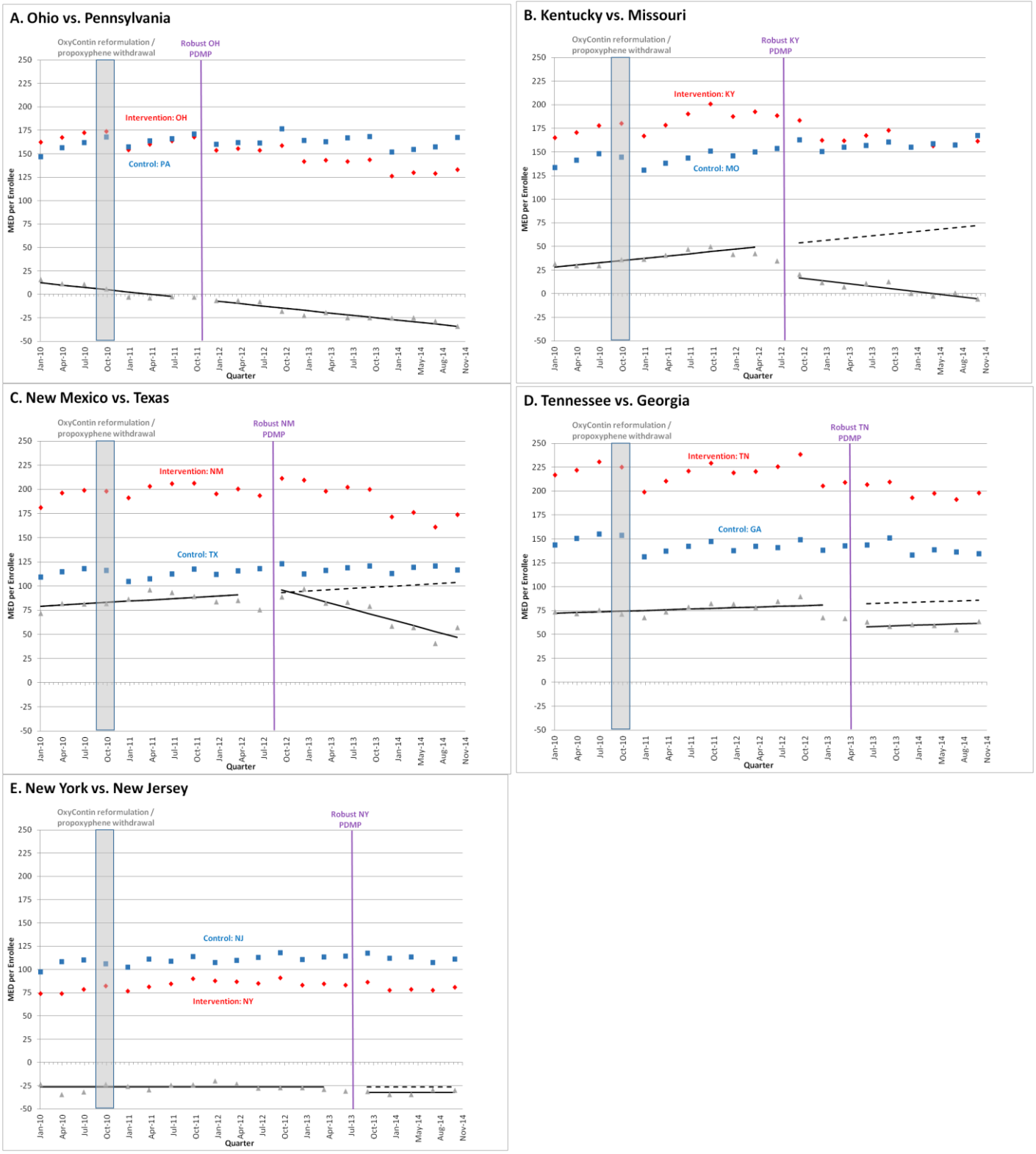
Figure 3.1: Percent of Enrollees Filling Opioid Prescriptions per Quarter



Abbreviations: PDMP, prescription drug monitoring program.

A fitted regression line shows the difference between treatment and control states in the baseline period and continues as a predicted regression line in the follow-up period, after robust PDMP implementation in the intervention state. A separate fitted regression line was calculated using population-level interrupted time series linear models for the outcome of interest (adjusted for individual age, gender, race/ethnicity, education level, and enrollment at each quarter using the STATA margins command).

Figure 3.2: Morphine Equivalent Dosage Dispensed per Enrollee per Quarter



Abbreviations: PDMP, prescription drug monitoring program; MED, morphine equivalent dosage.

A fitted regression line shows the difference between treatment and control states in the baseline period and continues as a predicted regression line in the follow-up period, after robust PDMP implementation in the intervention state. A separate fitted regression line was calculated using population-level interrupted time series linear models for the outcome of interest (adjusted for individual age, gender, race/ethnicity, education, and enrollment at each quarter using the STATA margins command).

The quarter of robust use mandate implementation was defined as the "implementation quarter" when analyzing outcomes in each intervention state versus its control state. Thus, the preimplementation and postimplementation timeframes varied by state comparator sets based on implementation quarter. Although we did not explicitly incorporate anticipation or lag effects into our models, attributing implementation to a quarter rather than the particular date of implementation allowed for some flexibility around the implementation date, which typically occurred in the middle of the quarter.

3.3.2 Outcome Measures

Our primary outcomes included percent of enrollees filling opioid prescriptions and mean morphine equivalent dosage (MED) dispensed per enrollee (i.e., total MED dispensed to each enrollee, averaged across all enrollees in a quarter), a proxy for the volume of opioids prescribed. We calculated MED using established conversion factors that take into account differences in molecules, strength, and quantity of doses dispensed.[29] As secondary outcomes, we also examined mean number of opioid prescribers and pharmacies used to fill opioid prescriptions per enrollee in that quarter, measures of opioid seeking that, when high, are associated with higher risk of opioid-related overdose deaths.[30-34]

3.3.3 Statistical Analyses

We applied segmented regression analyses to evaluate the effects of robust PDMPs in intervention states on outcomes of interest. We analyzed outcomes on a quarterly basis and excluded from analysis the robust PDMP implementation quarters, generating 19 observations for all analyses. The number of preimplementation and postimplementation observations varied by state comparator set, depending on the timing of the implementation quarter. The

minimum number of preimplementation observations was seven (in the Ohio-Pennsylvania pairing), and the minimum number of postimplementation observations was five (in the New York-New Jersey pairing).

To control for changes in cohort characteristics during the course of the study and between state comparator sets, we used marginal effects methods[35] to calculate adjusted outcome rates in each set of state comparators. We used generalized estimating equations (GEE) with a binomial distribution and a logit link function to model the proportion of enrollees filling opioid prescriptions and a negative binomial distribution and a log link function to model rates of MEDs, pharmacies, and prescribers used for opioid fills, all adjusting for enrollee age, gender, race/ethnicity, education-level, and enrollment span. We used demographic characteristics linked by Optum to identify enrollees' education-level according to five mutually-exclusive, increasing categories (below 12th grade, High School Diploma, less than a Bachelor's degree, greater than or equal to a Bachelor's degree, or unknown) and race-ethnicity according to five mutually exclusive categories (Asian, black, Hispanic, unknown, or white). White race, male gender, middle age, and low income have all been established as predictors of opioid overdoses,[36-38] while use of opioid analgesics from 1999-2012 was higher among white and black races, females, and those of older age (40 and older, as compared to 20-39).[39] Due to the missing observations in the household income variable, we excluded this from adjustments. These marginal effects methods models failed to converge when we ran state-to-state comparator models at a monthly time resolution and when we pooled intervention state versus control state models at a quarterly or monthly time resolution.

Once all quarterly outcome rates were adjusted, we used segmented regression to test for changes in each outcome after the implementation of robust PDMPs.[28] We modeled the differences in outcomes between intervention and control states for each of the five sets of state comparators separately (five models for each of the four outcomes, resulting in 20 models total). We used linear regression to quantify the robust PDMPs' effects on each outcome, because a linear trend was found to fit the data well. In the differenced models, two terms were of key interest: the change in level and the change in rate (trend) postimplementation as compared to the preimplementation period. We used a stepwise approach to test and control for autocorrelation, with an initial order of 4 (correlation within 1 year). We used regression results to estimate the absolute and relative effects, with 95% CIs, for each outcome at the end of the study period (Q4/2014) using multivariate delta methods.[40]

We performed analyses using SAS version 9.3 (SAS Institute Inc., Cary, NC) and Stata version 12 (College Station, Texas).

3.3.4 Sensitivity Analysis

To determine whether patients entering or leaving the study population biased our main analyses, we conducted a sensitivity analysis on a closed cohort of patients continuously enrolled from at least 1 year preimplementation to 1 year postimplementation of the robust PDMP in each intervention state in the respective sets of study states. For this continuously enrolled cohort, we modeled outcomes for the same five sets of intervention and comparison states using quarterly interrupted time series analyses. Members' continuous enrollment in this cohort also allowed us to apply an Adjusted Clinical Groups algorithm[41,42] to members' preimplementation year to estimate comorbidity. We adjusted for this comorbidity score in our

marginal effects regression analyses. When using GEEs to model rates of MEDs, pharmacies, and prescribers used for opioid fills, we used a poisson distribution and a log link function, instead of a negative binomial distribution because the latter failed to converge. We otherwise used the same statistical and design approaches described above in this sensitivity analysis.

3.4 Results

We compared characteristics in each state comparator set at three study time points: 12 months preimplementation, 1 month preimplementation, and 12 months postimplementation (Tables 3.1-3.5). The state with the smallest sample size, New Mexico, included approximately 36.1 thousand to 38.2 thousand enrollees over the study period, while the state with the largest sample size, Texas, included 860.0 thousand to 926.8 thousand enrollees over the study period. Although the number of enrollees at different time points varied between comparator states (e.g., New Mexico versus Texas), the enrollment over time within each state remained relatively consistent with one notable exception. Georgia experienced a significant drop-off in enrollment in the postimplementation period that was also accompanied by several demographic shifts. Apart from this change, the demographics within each state over time remained highly consistent in all other states. The average age of enrollees was approximately 40 years, 44% to 52% of enrollees were male, and the average enrollment in the insurance carrier varied from 34.3 to 52.2 months per enrollee across states and time periods. The majority of enrollees in all states were white, although in some states Hispanics (New Mexico and Texas) and blacks (Georgia) comprised greater proportions of the populations than in other states.

Table 3.1: Unadjusted Characteristics of Cohort Members: Ohio (Intervention State) vs. Pennsylvania (Control State)

	No. Thousands (%)					
	12 Mos. Pre-Robust PDMP		1 Mo. Pre-Robust PDMP		12 Mos. Post-Robust PDMP	
Characteristic	**OH**	**PA**	**OH**	**PA**	**OH**	**PA**
No. of members	411.3	125.1	402.3	115.9	388.6	114.7
Male sex	198.2(48.2)	63.3(50.6)	196.0(48.7)	59.2(51.1)	189.4(48.8)	58.4(50.9)
Age, y						
18-24	53.5(13.0)	16.0(12.8)	57.0(14.2)	15.6(13.5)	56.5(14.5)	15.5(13.5)
25-34	78.6(19.1)	28.4(22.7)	76.6(19.0)	27.0(23.3)	74.5(19.2)	27.7(24.2)
35-44	92.8(22.6)	29.5(23.6)	88.4(22.0)	26.7(23.0)	84.1(21.7)	26.4(23.0)
45-54	104.3(25.4)	31.0(24.8)	99.5(24.7)	27.8(24.0)	94.5(24.3)	27.0(23.5)
55-64	82.1(20.0)	20.2(16.1)	80.8(20.1)	18.8(16.2)	79.0(20.3)	18.2(15.9)
Race/ethnicity[†]						
Asian	9.8(2.4)	5.1(4.2)	9.7(2.4)	5.3(4.7)	10.2(2.7)	5.8(5.2)
Black	36.8(9.0)	7.5(6.2)	36.8(9.2)	7.4(6.5)	34.9(9.1)	7.7(7.0)
Hispanic	7.7(1.9)	5.1(4.2)	7.7(1.9)	5.1(4.5)	7.7(2.0)	5.1(5.0)
Unknown	16.9(4.1)	7.0(5.8)	16.2(4.1)	6.5(5.8)	15.7(4.1)	6.3(5.7)
White	337.0(82.6)	97.3(80.0)	328.8(82.4)	88.7(78.5)	316.6(82.2)	86.2(77.5)
Education level[†]						
<12th grade	0.1(0.0)	0.1(0.1)	0.1(0.0)	0.1(0.1)	0.1(0.0)	0.1(0.1)
High school diploma	149.8(36.7)	48.8(40.0)	146.0(36.6)	43.8(38.8)	143.2(37.2)	42.4(38.2)
< Bachelor degree	192.8(47.2)	49.0(40.2)	188.9(47.3)	45.5(40.3)	181.6(47.2)	44.9(40.4)
≥Bachelor degree	64.9(15.9)	24.0(20.0)	63.5(15.9)	23.4(20.7)	59.6(15.5)	23.5(21.1)
Unknown	0.6(0.1)	0.3(0.2)	0.5(0.1)	0.2(0.2)	0.6(0.2)	0.2(0.2)
Household income level[†]						
Unknown	70.2(17.2)	22.2(18.2)	67.9(17.0)	20.6(18.3)	66.0(17.1)	21.5(19.4)
<$40,000	38.3(9.4)	12.0(9.9)	37.8(9.5)	10.9(9.7)	37.2(9.7)	10.8(9.7)
$40,000-$49,000	23.7(5.8)	7.1(5.8)	23.3(5.8)	6.4(5.7)	22.6(5.9)	6.0(5.4)
$50,000-$59,000	26.3(6.5)	8.1(6.6)	26.0(6.5)	7.2(6.4)	25.3(6.6)	7.1(6.4)
$60,000-$74,000	42.2(10.3)	11.6(9.5)	41.3(10.4)	10.5(9.3)	39.8(10.3)	9.9(8.9)
$75,000-$99,000	64.3(15.8)	17.8(14.5)	63.0(15.8)	16.2(14.4)	60.6(15.7)	15.6(14.0)
≥$100,000	143.2(35.1)	43.4(35.6)	139.8(35.0)	41.1(36.4)	133.7(34.7)	40.2(36.2)
	Mean (SD)					
Age, y	41.7(13.0)	40.5(12.6)	41.5(13.2)	40.2(12.7)	41.4(13.2)	40.0(12.6)
Enrollment span, mos.	51.6(28.4)	38.9(22.8)	52.2(28.1)	41.3(22.7)	50.5(28.5)	40.6(22.7)

Abbreviations: PDMP, prescription drug monitoring program.

[†] Frequency missing: 6,189 twelve months pre-robust PDMP implementation.
6,078 one month pre-robust PDMP implementation.
7,034 twelve months post-robust PDMP implementation.

Table 3.2: Unadjusted Characteristics of Cohort Members: Kentucky (Intervention State) vs. Missouri (Control State)

	No. Thousands (%)					
	12 Mos. Pre-Robust PDMP		1 Mo. Pre-Robust PDMP		12 Mos. Post-Robust PDMP	
Characteristic	**KY**	**MO**	**KY**	**MO**	**KY**	**MO**
No. of members	67.9	243.0	67.0	247.3	69.0	234.8
Male sex	34.7(51.0)	115.3(47.5)	34.5(51.4)	117.8(47.7)	35.4(51.3)	113.5(48.4)
Age, y						
18-24	8.9(13.0)	33.4(13.8)	8.9(13.2)	34.8(14.1)	9.3(13.5)	33.1(14.1)
25-34	14.3(21.0)	49.9(20.6)	13.8(20.6)	50.9(20.6)	14.4(20.9)	49.1(20.9)
35-44	16.0(23.6)	51.6(21.2)	15.5(23.2)	52.7(21.3)	15.8(22.8)	49.3(21.0)
45-54	16.9(25.0)	59.7(24.6)	16.5(24.7)	59.2(24.0)	16.8(24.3)	55.2(23.5)
55-64	11.8(17.4)	48.3(19.9)	12.3(18.4)	49.6(20.1)	12.7(18.5)	48.1(20.5)
Race/ethnicity[†]						
Asian	1.2(1.8)	5.1(2.1)	1.3(2.0)	5.2(2.2)	1.5(2.2)	4.9(2.1)
Black	3.5(5.2)	22.5(9.4)	3.7(5.5)	22.6(9.3)	4.0(5.8)	21.5(9.3)
Hispanic	1.3(1.9)	5.1(2.1)	1.3(2.0)	5.4(2.2)	1.4(2.0)	5.4(2.3)
Unknown	1.7(2.6)	8.5(3.5)	1.7(2.6)	8.6(3.5)	1.8(2.7)	8.4(3.6)
White	59.4(88.5)	198.2(82.8)	58.3(88.0)	201.5(82.8)	59.5(87.3)	190.3(82.6)
Education level[†]						
<12th grade	0.1(0.1)	0.1(0.1)	0.1(0.1)	0.1(0.0)	0.0(0.1)	0.1(0.1)
High school diploma	31.5(46.9)	69.5(29.1)	31.2(47.1)	70.4(28.9)	31.6(46.3)	68.8(29.9)
< Bachelor degree	29.5(43.9)	132.5(55.4)	28.9(43.7)	134.3(55.2)	29.9(43.9)	125.6(54.5)
≥Bachelor degree	5.9(8.8)	37.0(15.5)	5.9(9.0)	38.3(15.7)	6.5(9.5)	35.7(15.5)
Unknown	0.2(0.2)	0.2(0.1)	0.1(0.2)	0.2(0.1)	0.1(0.2)	0.2(0.1)
Household income level[†]						
Unknown	12.7(18.9)	40.4(16.9)	12.7(19.1)	41.3(17.0)	13.6(20.0)	41.1(17.8)
<$40,000	8.9(13.3)	24.5(10.3)	8.9(13.4)	25.0(10.3)	9.0(13.2)	24.0(10.4)
$40,000-$49,000	4.2(6.2)	15.2(6.4)	4.3(6.4)	15.4(6.3)	4.3(6.3)	14.6(6.3)
$50,000-$59,000	5.0(7.5)	15.9(6.7)	4.9(7.4)	16.2(6.7)	5.0(7.3)	15.4(6.7)
$60,000-$74,000	6.7(10.0)	25.2(10.5)	6.7(10.1)	25.5(10.5)	6.7(9.8)	24.3(10.6)
$75,000-$99,000	9.4(14.0)	37.0(15.5)	9.2(13.9)	37.4(15.4)	9.2(13.6)	35.0(15.2)
≥$100,000	20.2(30.1)	81.1(33.9)	19.7(29.8)	82.5(33.9)	20.4(29.9)	76.1(33.0)
	Mean (SD)					
Age, y	41.0(12.7)	41.3(13.2)	41.1(12.8)	41.2(13.2)	41.0(12.9)	41.2(13.3)
Enrollment span, mos.	42.0(24.9)	47.1(25.5)	41.0(24.8)	45.8(25.5)	38.0(24.7)	43.4(26.0)

Abbreviations: PDMP, prescription drug monitoring program.

[†] Frequency missing: 4,458 twelve months pre-robust PDMP implementation.
4,686 one month pre-robust PDMP implementation.
5,188 twelve months post-robust PDMP implementation.

Table 3.3: Unadjusted Characteristics of Cohort Members: New Mexico (Intervention State) vs. Texas (Control State)

	No. Thousands (%)					
	12 Mos. Pre-Robust PDMP		1 Mo. Pre-Robust PDMP		12 Mos. Post-Robust PDMP	
Characteristic	**NM**	**TX**	**NM**	**TX**	**NM**	**TX**
No. of members	38.2	926.8	36.1	867.8	36.1	860.0
Male sex	18.9(50.0)	470.4(50.8)	18.1(50.1)	446.2(51.4)	18.2(50.4)	442.4(51.4)
Age, y						
18-24	5.1(13.3)	126.4(13.6)	5.0(13.8)	120.2(13.9)	5.1(14.2)	121.1(14.1)
25-34	8.6(23.2)	208.5(22.5)	8.3(23.1)	199.1(23.0)	8.4(23.3)	198.5(23.1)
35-44	8.3(21.7)	224.5(24.2)	7.9(21.9)	210.5(24.3)	7.9(21.9)	206.7(24.0)
45-54	8.8(23.0)	218.7(23.6)	8.2(22.6)	199.9(23.0)	7.9(22.0)	198.9(22.7)
55-64	7.2(18.8)	148.7(16.1)	6.7(18.6)	137.9(15.9)	6.7(18.7)	138.8(16.1)
Race/ethnicity[†]						
Asian	0.8(2.0)	40.5(4.4)	0.7(2.0)	39.4(4.6)	0.7(2.0)	40.8(4.8)
Black	0.6(1.7)	69.9(7.6)	0.6(0.1)	60.5(7.1)	0.6(1.6)	61.1(7.2)
Hispanic	15.2(40.3)	211.0(23.0)	14.1(39.7)	201.6(23.6)	14.1(39.8)	207.0(24.5)
Unknown	1.7(4.4)	27.4(3.0)	1.7(4.7)	25.6(3.0)	1.7(4.9)	25.8(3.1)
White	19.4(51.6)	567.6(61.9)	18.4(51.9)	528.4(61.8)	18.3(51.7)	510.8(60.4)
Education level[†]						
<12th grade	0.1(0.4)	18.2(2.0)	0.2(0.7)	16.0(1.9)	0.2(0.7)	16.8(2.0)
High school diploma	10.6(28.1)	235.5(25.7)	9.8(27.7)	218.6(25.6)	9.8(27.8)	216.1(25.6)
< Bachelor degree	22.6(60.1)	466.8(50.9)	21.4(60.4)	432.7(50.6)	21.4(60.5)	426.0(50.4)
≥Bachelor degree	4.2(11.1)	194.9(21.3)	3.9(11.0)	187.2(21.9)	3.8(10.7)	185.6(22.0)
Unknown	0.1(0.3)	1.1(0.1)	0.1(0.3)	1.0(0.1)	0.1(0.3)	1.0(0.1)
Household income level[†]						
Unknown	8.3(22.2)	184.7(20.2)	8.3(23.5)	176.8(20.7)	8.6(24.4)	182.7(21.6)
<$40,000	6.0(15.9)	87.6(9.6)	5.6(15.9)	82.8(9.7)	5.7(16.1)	83.3(9.9)
$40,000-$49,000	2.9(7.8)	47.5(5.2)	2.7(7.6)	44.0(5.2)	2.7(7.6)	43.3(5.1)
$50,000-$59,000	3.0(8.0)	51.9(5.7)	2.8(8.0)	48.1(5.6)	2.8(7.8)	47.4(5.6)
$60,000-$74,000	3.8(10.2)	76.0(8.3)	3.5(9.8)	70.3(8.2)	3.4(9.6)	68.3(8.1)
$75,000-$99,000	4.8(12.8)	118.8(13.0)	4.4(12.4)	109.8(12.8)	4.3(12.1)	106.1(12.6)
≥$100,000	8.6(23.1)	350.0(38.2)	8.1(22.8)	323.6(37.8)	8.0(22.5)	314.4(37.2)
	Mean (SD)					
Age, y	40.7(13.0)	40.2(12.6)	40.6(13.1)	40.1(12.6)	40.4(13.1)	40.0(12.7)
Enrollment span, mos.	48.3(26.3)	44.9(25.8)	48.5(26.3)	44.6(26.1)	45.1(27.4)	41.6(26.6)

Abbreviations: PDMP, prescription drug monitoring program.

[†] Frequency missing: 10,958 twelve months pre-robust PDMP implementation.
12,707 one month pre-robust PDMP implementation.
15,134 twelve months post-robust PDMP implementation.

Table 3.4: Unadjusted Characteristics of Cohort Members: Tennessee (Intervention State) vs. Georgia (Control State)

	No. Thousands (%)					
	12 Mos. Pre-Robust PDMP		1 Mo. Pre-Robust PDMP		12 Mos. Post-Robust PDMP	
Characteristic	**TN**	**GA**	**TN**	**GA**	**TN**	**GA**
No. of members	111.4	630.7	114.0	604.1	116.2	303.6
Male sex	55.1(49.4)	277.9(44.1)	56.2(49.3)	267.8(44.3)	57.7(49.7)	160.9(53.0)
Age, y						
18-24	14.5(13.0)	89.8(14.2)	15.2(13.4)	86.5(14.3)	15.9(13.7)	39.5(13.0)
25-34	22.9(20.6)	105.9(16.8)	23.4(20.5)	102.8(17.0)	24.9(21.5)	72.2(23.8)
35-44	25.4(22.8)	140.1(22.2)	25.7(22.5)	131.3(21.7)	25.8(22.2)	75.4(24.8)
45-54	27.2(24.4)	151.7(24.0)	27.6(24.2)	144.9(24.0)	27.7(23.9)	70.9(23.4)
55-64	21.4(19.2)	143.2(22.7)	22.1(19.4)	138.6(23.0)	21.8(18.8)	45.6(15.0)
Race/ethnicity[†]						
Asian	2.8(2.6)	18.1(2.9)	2.7(2.4)	18.7(3.1)	2.9(2.5)	21.3(7.1)
Black	16.6(15.2)	182.4(29.1)	17.4(15.6)	173.9(29.0)	19.2(16.9)	82.3(27.6)
Hispanic	3.8(3.4)	20.5(3.3)	4.1(3.7)	249.4(4.2)	4.5(3.9)	28.1(9.4)
Unknown	2.4(2.2)	13.5(2.2)	2.5(2.2)	13.1(2.2)	2.6(2.3)	7.8(2.6)
White	83.7(76.6)	391.5(62.5)	85.0(76.1)	368.1(61.5)	84.4(74.3)	158.9(53.3)
Education level[†]						
<12th grade	0.0(0.0)	0.5(0.1)	0.0(0.0)	0.3(0.1)	0.0(0.0)	0.2(0.1)
High school diploma	43.3(39.7)	252.6(40.4)	44.7(40.0)	245.4(41.0)	46.5(40.9)	125.9(42.2)
< Bachelor degree	49.8(45.6)	282.7(45.2)	50.5(45.2)	265.7(44.4)	51.2(45.1)	115.5(38.7)
≥Bachelor degree	15.9(14.6)	89.5(14.3)	16.4(14.7)	86.5(14.5)	15.7(13.8)	56.2(18.8)
Unknown	0.1(0.1)	0.8(0.1)	0.1(0.1)	0.7(0.1)	0.1(0.1)	0.5(0.2)
Household income level[†]						
Unknown	21.7(19.9)	97.0(15.5)	23.6(21.1)	109.1(18.2)	24.7(21.7)	112.7(37.8)
<$40,000	14.0(12.8)	86.8(13.9)	14.3(12.8)	77.6(13.0)	15.2(13.4)	25.7(8.6)
$40,000-$49,000	7.2(6.6)	41.6(6.7)	7.3(6.6)	37.9(6.3)	7.5(6.6)	12.9(4.3)
$50,000-$59,000	7.4(6.8)	43.8(7.0)	7.3(6.6)	40.0(6.7)	7.5(6.6)	13.5(4.5)
$60,000-$74,000	10.5(9.6)	66.2(10.6)	10.6(9.5)	60.7(10.1)	10.6(9.4)	20.4(6.8)
$75,000-$99,000	14.8(13.6)	95.3(15.2)	14.8(13.3)	88.0(14.7)	14.9(13.1)	29.9(10.0)
≥$100,000	33.6(30.7)	195.3(31.2)	33.8(30.3)	185.4(31.0)	33.1(29.2)	83.2(27.9)
	Mean (SD)					
Age, y	41.3(12.9)	42.2(13.4)	41.3(13.0)	42.2(13.5)	40.9(13.0)	40.0(12.4)
Enrollment span, mos.	43.9(23.9)	50.5(20.7)	41.1(24.4)	48.9(22.2)	34.3(25.7)	35.5(26.0)

Abbreviations: PDMP, prescription drug monitoring program.

[†] Frequency missing: 6,907 twelve months pre-robust PDMP implementation.
7,677 one month pre-robust PDMP implementation.
7,978 twelve months post-robust PDMP implementation.

Table 3.5: Unadjusted Characteristics of Cohort Members: New York (Intervention State) vs. New Jersey (Control State)

	No. Thousands(%)					
	12 Mos. Pre-Robust PDMP		1 Mo. Pre-Robust PDMP		12 Mos. Post-Robust PDMP	
Characteristic	**NY**	**NJ**	**NY**	**NJ**	**NY**	**NJ**
No. of members	258.3	149.4	258.9	149.8	244.3	148.6
Male sex	127.1(49.2)	75.6(50.6)	127.5(49.3)	75.5(50.4)	121.5(49.8)	75.3(50.7)
Age, y						
18-24	31.9(12.4))	19.7(13.2)	31.1(12.0)	20.1(13.4)	28.2(11.6)	20.0(13.5)
25-34	71.7(27.8)	36.0(24.1)	72.3(27.9)	34.9(23.3)	69.7(28.5)	35.0(23.5)
35-44	64.8(25.1)	37.9(25.4)	64.7(25.0)	37.2(24.9)	60.8(24.9)	36.1(24.3)
45-54	54.5(21.1)	35.8(23.3)	54.5(21.1)	35.6(23.8)	51.4(21.1)	35.1(23.6)
55-64	35.4(13.7)	21.0(14.1)	36.2(14.0)	21.9(14.6)	34.1(14.0)	22.5(15.2)
Race/ethnicity[†]						
Asian	22.6(8.9)	21.9(14.9)	22.7(9.0)	20.9(14.2)	23.0(10.0)	21.1(14.5)
Black	23.4(9.2)	10.1(6.8)	23.3(9.2)	9.9(6.7)	22.6(9.5)	9.9(6.8)
Hispanic	30.4(12.0)	19.1(13.0)	30.0(11.9)	19.5(13.3)	29.9(12.6)	19.7(13.5)
Unknown	15.0(5.9)	8.5(5.8)	15.4(6.1)	8.8(6.0)	15.0(6.3)	8.9(6.1)
White	162.1(64.0)	87.5(59.4)	162.1(63.9)	88.1(60.0)	147.1(61.9)	85.8(59.0)
Education level[†]						
<12th grade	0.8(0.3)	0.2(0.1)	0.7(0.3)	0.1(0.1)	0.8(0.4)	0.1(0.1)
High school diploma	49.7(19.6)	25.8(17.6)	49.4(19.5)	25.7(17.5)	48.3(20.3)	25.9(17.8)
< Bachelor degree	118.0(46.6)	64.7(44.0)	116.7(46.0)	64.6(43.9)	102.8(43.2)	63.6(43.7)
≥Bachelor degree	84.6(33.4)	56.4(38.3)	86.5(34.1)	56.7(38.5)	85.6(36.0)	55.8(38.4)
Unknown	0.3(0.1)	0.1(0.1)	0.3(0.1)	0.1(0.1)	0.2(0.1)	0.1(0.1)
Household income level[†]						
Unknown	46.7(18.4)	32.3(21.9)	48.3(19.1)	32.0(21.7)	49.7(20.9)	33.0(22.7)
<$40,000	19.5(7.7)	8.2(5.6)	19.3(7.6)	8.0(5.4)	18.6(7.9)	7.8(5.4)
$40,000-$49,000	10.8(4.3)	5.4(3.7)	10.7(4.2)	5.2(3.6)	10.2(4.3)	5.2(3.6)
$50,000-$59,000	11.9(4.7)	5.9(4.0)	11.7(4.6)	5.9(4.0)	11.0(4.6)	5.8(4.0)
$60,000-$74,000	18.4(7.3)	9.5(6.5)	18.0(7.1)	9.4(6.4)	16.4(6.9)	9.1(6.3)
$75,000-$99,000	31.2(12.3)	17.3(11.8)	31.0(12.2)	17.2(11.7)	28.2(11.9)	16.7(11.5)
≥$100,000	114.9(45.3)	68.6(46.6)	114.7(45.2)	69.6(47.3)	103.5(43.5)	67.8(46.6)
	Mean(SD)					
Age, y	39.2(12.2)	39.7(12.3)	39.3(12.2)	39.9(12.4)	39.3(12.1)	40.0(12.5)
Enrollment span, mos.	46.4(22.5)	45.8(22.6)	43.8(23.5)	42.8(23.7)	37.0(26.3)	37.0(26.1)

Abbreviations: PDMP, prescription drug monitoring program.

[†] Frequency missing: 7,247 twelve months pre-robust PDMP implementation.
7,969 one month pre-robust PDMP implementation.
9,755 twelve months post-robust PDMP implementation.

In the preimplementation period, the trends in one of our main outcomes of interest, percent of enrollees filling opioid prescriptions per quarter, were parallel for all sets of state comparators (i.e., not statistically significantly different at the $p<0.05$ level) (Table 3.6, Figure

3.1). The preimplementation trends in the other main outcome of interest, mean MED dispensed per enrollee per quarter, were parallel for all state comparator sets except for two: Ohio versus Pennsylvania and Kentucky versus Missouri (Table 3.7, Figure 3.2). Although preimplementation levels were typically statistically significantly different between comparator states (Tables 3.6 and 3.7), no state had more than double the level of its comparator state in main outcome rates during this period (Figures 3.1 and 3.2) and most levels were substantially smaller than double. Intervention states typically exhibited higher levels than control states in the preimplementation period, albeit there were several instances where the control jurisdiction exhibited higher preimplementation rates than the intervention (e.g., New York versus New Jersey). The largest difference in level exhibited in the MED dispensed per enrollee outcome was between New Mexico (preimplementation level of 181.0 MEDs per enrollee in Q1/2010) and Texas (preimplementation level of 109.1 MEDs per enrollee in Q1/2010), or a difference of 71.89 MEDs per enrollee between states.

Relative to enrollees in control states, the percent of enrollees filling opioids prescriptions per quarter statistically significantly declined in trend in one of the five intervention states (Ohio: -0.02%, p=0.007) and in level in three of the five intervention states: Kentucky (-1.30%, p<0.001), Tennessee (-0.65%, p=0.001) and New York (-0.33%, p<0.001) (Table 3.6). Declines in levels along this outcome in Tennessee and New York were not maintained, however, as the corresponding trends significantly increased in the postimplementation period relative to Georgia and New Jersey (respective changes: 0.12%, p=0.01; 0.04%, p=0.05) (Table 3.6).By the end of the study period (i.e., Q4/2014), Kentucky exhibited the largest declines in the percent of enrollees filling an opioid prescription relative to

its control, or an absolute decrease of 1.56% (-1.77%, -1.34%) and a relative decrease of 125.10% (-140.40%, -109.79%) (Table 3.6).

Table 3.6: Effect of Robust State PDMPs on Percent of Enrollees Filling Opioid Prescriptions per Quarter[1]

Comparator States	Variable	Difference Between Intervention and Control States			
		Pre-Implementation, %	Policy Effect, % (Pre- to Post-Implementation	Absolute in Q4 of 2014, % (95% CI)	Relative in Q4 of 2014, % (95% CI)
a. OH vs. PA	Level	2.12***	—	-0.24 (-0.40,-0.09)	-11.53 (-18.58, -4.48)
	Trend	—	-0.02**		
b. KY vs. MO	Level	1.24***	-1.30***	-1.56 (-1.77, -1.34)	-125.10 (-140.40, -109.79)
	Trend	—	-0.03		
c. NM vs. TX	Level	0.28*	-0.40	-0.40 (-0.85, 0.05)	101.28 (-154.25, 356.81)
	Trend	-0.03	—		
d. TN vs. GA	Level	-1.42***	-0.65**	0.05 (-0.31, 0.40)	2.48 (-16.18, 21.14)
	Trend	0.03†	0.12*		
e. NY vs. NJ	Level	-0.65***	-0.33***	-0.12 (-0.22, -0.01)	18.08 (1.83, 34.33)
	Trend	—	0.04*		

Abbreviations: PDMP, prescription drug monitoring program; Q4, fourth calendar quarter.
[1]Segmented time-series regression models adjusted for baseline trend, and changes in trend and level; we eliminated any of these predictors if they were non-significant at the p<0.2 level. Generalized estimating equations models were used to generate population outcome rates in state comparators, adjusted for age, gender, race/ethnicity, education level, and enrollment span, before implementing the segmented time-series regression models.
† p<0.1 ** p<0.01
* p<0.05 *** p<0.001

After robust PDMP implementation, the mean level of MED dispensed per enrollee per quarter decreased in three of the five intervention states relative to their controls: Kentucky (-31.60, p<0.001), Tennessee (-24.06, p<0.001) and New York (-5.57, p=0.007) (Table 3.7). The mean MED dispensed per enrollee per quarter also decreased in trend in two of the five intervention states relative to their controls: Kentucky (-5.06, p<0.001) and New Mexico (-7.43, p<0.001) (Table 3.7). By the end of the study period, Kentucky exhibited the greatest absolute and relative declines in this outcome as compared to its control, or an absolute decrease of 77.13 (-84.03, -70.23) MED dispensed per enrollee per quarter, a relative decrease of 107.20%

(-110.78, -103.61) (Table 3.7). However, the declines exhibited in New Mexico and Tennessee were also quite significant relative to their controls by the end of the study period (NM: absolute -56.84 (-81.47, -32.21), relative -54.81% (-67.89%, -41.72%); TN: absolute -24.06 (-33.69, -14.42), relative -28.06% (-36.43%, -19.69%) (Table 3.7).

Table 3.7: Effect of Robust State PDMPs on Mean Morphine Equivalent Dosage Dispensed per Enrollee per Quarter[1]

		Difference Between Intervention and Control States			
Comparator States	Variable	Pre-Implementation, MED	Policy Effect, MED (Pre- to Post-Implementation	Absolute in Q4 of 2014, MED (95% CI)	Relative in Q4 of 2014, % (95% CI)
a. OH vs. PA	Level	14.82***	—	—	—
	Trend	-2.44***	—		
b. KY vs. MO	Level	26.07***	-31.60***	-77.13	-107.20
	Trend	2.29***	-5.06***	(-84.03,-70.23)	(-110.78,-103.61)
c. NM vs. TX	Level	77.86***	10.08	-56.84	-54.81
	Trend	1.29	-7.44***	(-81.47,-32.21)	(-67.89,-41.72)
d. TN vs. GA	Level	71.52***	-24.06***	-24.06	-28.06
	Trend	0.71†	—	(-33.69,-14.42)	(-36.43,-19.69)
e. NY vs. NJ	Level	-26.53***	-5.57**	-5.57	21.00
	Trend	—	—	(-9.18,-1.96)	(6.59,35.41)

Abbreviations: PDMP, prescription drug monitoring program; Q4, fourth calendar quarter.

[1]Segmented time-series regression models adjusted for baseline trend, and changes in trend and level; we eliminated any of these predictors if they were non-significant at the p<0.2 level. Generalized estimating equations models were used to generate population outcome rates in state comparators, adjusted for age, gender, race/ethnicity, education level, and enrollment span, before implementing the segmented time-series regression models.

† p<0.1 ** p<0.01

* p<0.05 *** p<0.001

Figures 3.1 and 3.2 display the fitted trends reflected in the segmented regression estimates above. They demonstrate the general pattern of decreased levels in the percent of enrollees filling opioids and decreased levels and trends in mean MED dispensed per enrollee in the intervention states relative to the control states in the postimplementation period, with changes of the greatest magnitude occurring in Kentucky relative to Missouri.

Our basic findings were consistent with secondary outcome rates generated for mean number of prescribers and pharmacists used per 100 enrollees to fill opioid prescriptions, as well as robust to a sensitivity analysis examining all four outcomes on continuously enrolled individuals in each intervention versus its control state (Appendix C).

3.5 Discussion

Although PDMPs have been pursued widely by states to address the prescription opioid epidemic, rigorous evidence proving PDMP effectiveness in changing prescribing practices or reducing prescription opioid misuse or overdose is limited and fails to take into account more recent policy features, such as use mandates, which may make these programs more impactful. We used comparative interrupted time series analyses to evaluate changes in opioid prescribing and use associated with robust PDMP s in five states that have implemented such programs. In the majority of states studied, we found that robust PDMPs are associated with decreases in the proportion of the population filling opioids immediately following implementation and more substantial and sustained declines in the total volume of opioids prescribed (approximated by mean MED dispensed per enrollee). Robust PDMPs are also associated with reductions in characteristics correlated with higher-risk opioid use—namely a greater number of prescribers and pharmacies used by patients when filling opioid prescriptions. However, we did find variation in the magnitude and significance of effect, with Kentucky exhibiting the most dramatic and consistent decreases along all outcomes, followed by Tennessee and New Mexico (only in the MED outcome). Ohio and New York exhibited small reductions in the outcomes of study, but these changes were either not sustained through the end of the study period (in the

case of New York) or were modest in comparison to effects observed in other intervention states of study (in the case of Ohio).

Our findings are important given the persistently high magnitude of opioid misuse and overdose and the panoply of policies designed to address this public health challenge.[43] Our results are consistent with reporting from within states that have enacted robust PDMPs with use mandates, which claim that the addition of this feature improved program impacts along a number of measures, including increased PDMP queries, decreased opioid prescribing, and reduced "doctor shopping" (Table C.2).[23,24] Kentucky has undertaken perhaps the most extensive internal evaluation of the implementation of its PDMP use mandate, finding that the number of opioid prescriptions dispensed declined 7.02% in 2013 (post-mandate) as compared to 2011 (pre-mandate), a decline that occurred sharply in mid-2012 just following the robust use mandate implementation.[44] The most significant decreases occurred in the dispensing of hydrocodone and oxycodone, the most frequently prescribed opioids that were targeted by the law.[44]

Our findings also are consistent with a recent longitudinal study that found reductions in opioid prescribing and use among the highest prescribers and users at baseline in Florida following the combined implementation of a PDMP and "pill mill" law (using Georgia as a comparator state).[16] Another recent multivariate regression study of PDMPs that went online from 2001-2011 similarly found PDMP implementation to be associated with a 30% relative reduction Schedule II opioid prescribing at an ambulatory office visit (an absolute reduction of 5.5% to 3.7%)—a change that was immediate and somewhat sustained over time.[22] As compared to our study, the larger effects observed in this 2001-2011 study may be explained

by the authors' focus on Schedule II drugs (during a period when these drugs were most monitored by PDMPs), and different methods of analysis. The fact that we found differential effects, even within states with "robust" PDMPs, may explain mixed findings in other studies that failed to distinguish among PDMPs based on their characteristics and were of ecological or uncontrolled designs.[15-17,19,25]

Smaller effects observed in this study following robust PDMP implementation in Ohio and New York as compared to other intervention states may be attributable to a number of factors. Ohio was the first state to enact a PDMP use mandate applicable to a broad set of prescribers. Because Ohio's use mandate facilitated some subjective judgments on the part of the prescriber in determining whether a check was necessary (e.g., upon initial prescribing of a controlled substance *if* the prescriber has reason to believe the treatment will exceed 12 continuous weeks), the mandate itself was weaker than later iterations enacted in other intervention states of study (Table C.2). Ohio has since passed legislation effective in January 2015 that made more stringent the requirements on prescribers to use the PDMP and also coupled them with a registration mandate.[24] New York exhibited much lower preimplementation levels along the outcomes of interest than any other intervention states, so high risk opioid prescribing may have been less prevalent there – thus making a PDMP check less likely to change a prescriber's decision. Moreover, the PDMPs in Ohio and New York both included fewer robust features as compared to the other intervention jurisdictions, including the lack of a prescriber registration mandate and explicit prescriber immunity for failure to check or use the database in a particular way.

Kentucky experienced the most dramatic effects following robust PDMP implementation, and thus it's policy may serve as a model for other jurisdictions seeking to curb high levels of opioid prescribing and misuse. In addition to implementing both use *and* registration PDMP mandates simultaneously in July 2012, the Kentucky PDMP has benefited from increased administrative staffing to support its operations, more frequent (i.e., daily) updates to the dispensing data included in the PDMP, and staff have worked with prescribers to tweak aspects of the PDMP to make it more user-friendly.[24,44] From 2011 to 2014, queries to the PDMP have increased over 500 percent, and from 2012 to 2013, prescribers registered with the PDMP increased by almost 70 percent—such that by July 2013, 95% of in-state practitioners with the authority to prescribe controlled substances were registered with the Kentucky PDMP.[24,44,45]

Declines in outcomes studied in Tennessee actually appear to have begun in the first quarter of 2013, when the registration mandate was enacted just prior to the use mandate implementation in April 2013 (Table C.2). Tennessee reports that the PDMP registrants increased from 22,192 to 34,802 from 2012 to 2013 (a 56% increase), while queries to the PDMP increased from 1.86 million in 2012 to 4.50 million in 2013 (a 142% increase) (see also Table C.2).[46] Concurrent with mandate implementation, Tennessee took steps to enhance its PDMP and make it more user-friendly, such as by implementing a more robust hardware configuration that could handle increased queries to the system and by allowing delegates to check on prescribers behalfs.[46,47] Tennessee also conducted educational seminars for prescribers to disseminate information about the PDMP and solicited prescriber feedback about PDMP effectiveness to incorporate into further system enhancements.[47] Combined, the

robust features implemented in Tennessee are associated with reduced opioid prescribing and use, particularly along the MED outcome, when compared to Georgia.

MEDs per enrollee in New Mexico, relative to Texas, exhibit a more gradual decline, perhaps suggesting that it took some time for the robust PDMP requirements, including the use and registration mandates, to be adopted by prescribers. Although specific preimplementation registration and use rates are not available from New Mexico for comparison purposes, a gradual but steady monthly increase in PDMP queries after the robust feature implementation from approximately 34,000 queries in January 2013 to approximately 100,000 queries in December 2014 is consistent with our findings that MEDs steadily decreased over the study period postimplementation.[48]

Our study benefits from a careful policy analysis to differentiate PDMPs based on the robustness of their features, an analysis not previously undertaken in this level of detail or for more recent programs. We also employed a rigorous, longitudinal, controlled design and compared multiple intervention states to comparison states along several outcomes related to opioid prescribing and use. Even within the set of states with robust PDMP, we found more significant effects among states with the strongest policies (Kentucky, Tennessee, New Mexico) as compared to those that had adopted somewhat weaker features (Ohio, New York). Finally, the use of a defined cohort allowed for adjustment for changing denominator characteristics when calculating event rates, and our results were consistent in sensitivity analysis that analyzed results among a continuously enrolled cohort.

Our study includes several limitations, however. First, we used administrative data and therefore cannot observe opioid dispensing handled outside of insurance coverage (e.g., paid

for with cash), a practice commonly engaged in at "pill mills." Although the percentage of controlled substances paid for outside of insurance has not been comprehensively studied and varies by jurisdiction, approximately two-thirds of controlled substance are paid for by commercial insurance and thus our data represent a substantial share of the market.[49,50] Our cohort of study was limited to commercially insured adults aged 18 to 64 years—an age group with high opioid analgesic use—[39]and thus our results may not be generalizable beyond similar populations. We focused on opioid prescribing and use outcomes, rather than opioid-related injuries, because our data are appropriate to investigate these intermediary outcomes that are more proximal to the interventions studied. Nevertheless, opioid prescribing has been shown to be correlated with opioid overdoses and injuries.[4] Our study also does not distinguish between appropriate and inappropriate opioid prescribing, and further research is warranted here.

In terms of the interrupted time series design employed, certain threats to validity may exist. For example, New York included limited follow-up quarters for observation (five), which may limit our ability to observe effects—although the reductions immediately observed postimplementation in this state were not maintained even through the end of our study period. Some of our intervention and control states perhaps were not ideal comparators in the preimplementation period,[28] in the sense that the baseline levels were different and trends for some outcomes not parallel. However, we observed generally consistent results across outcomes and states, including in our sensitivity analysis, which suggests that these characteristics did not bias our results or conclusions significantly. Moreover, parallel trends and similar levels at baseline are not explicitly assumed or strictly required when employing a

controlled interrupted time-series design, particularly when effects observed at the time of an intervention are immediate and dramatic—such as in Kentucky. Finally, our analysis did not account for cointerventions at the state level, although we are aware of few such strong interventions that could have explained our findings. We are aware that Kentucky and Ohio, required stricter licensure standards of pill mills around the time of the robust PDMP implementation.[44,51] However, quantitative and qualitative research around the Kentucky robust PDMP implementation suggests that prescribers responded to the PDMP mandates by increasing utilization of the database and modifying their prescribing practices.[44] Moreover, we did not capture dispensing paid for outside of insurance, which is common in "pill mill" settings, so our results from Kentucky and Ohio would not as strongly reflect this law change.

3.6 Conclusions

Given the significant effects we observed after implementation of a robust PDMP in Kentucky and, to a lesser degree, in Tennessee and New Mexico, states with similar levels of baseline opioid prescribing and use might consider implementing similarly robust PDMPs as part of their regulatory strategy to address prescription opioid misuse. Unintended consequences of increased PDMP use, such as reduced prescribing when medically indicated, should be monitored closely, although it is worth noting that Kentucky did not observe adverse unintended consequences in its qualitative assessment of mandate implementation.[44] Newer features not studied here deserve further attention, including delegate ability to query a PDMP on a prescriber's behalf, automated interstate sharing of data (i.e., that does not require a separate login), and interoperability of PDMP data and medical records. Given evidence we provide suggesting it's effectiveness, a PDMP with a similar combination of features to that

employed by Kentucky may be warranted in other jurisdictions experiencing similar levels of opioid prescribing and use. Such a robust policy would house the PDMP under a health agency, update daily dispensing information for Schedules II-IV controlled substances, and proactively report outlier prescribing or patient use of substances to prescribers. Most critically, the law would require, under the threat of penalty for noncompliance,[11] registration and use of the PDMP before prescribing addictive opioid substances to any patient as well as regularly during continuous treatments.

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A

SUPPLEMENTARY MATERIALS FOR CHAPTER 1

A.1 Study Group Construction

A.1.1 State Selection

24 states without mental health parity requirements for small-group plans, either because they (a) lacked a strong state parity or minimum mandated benefits law that applied to small employers, or (b) had a parity law that specifically exempted small employers (typically defined by state laws as 50 or fewer employees, but sometimes more or less) were identified. Table A.1 details the applicable legal provisions that qualified each of the 24 states for inclusion in the study because their policies exempted small employer plans from state parity requirements prior to the Mental Health Parity and Addiction Equity Act (MHPAEA) (and throughout the study period). Small employer plan enrollees of the sizes specified in Table A.1 (see "Employer Size Included") were included in the comparison group for the study. Enrollees in self-insured plans in these same 24 states were included in the exposure group, given that they newly experienced parity by MHPAEA and were not subject to any preexisting state parity laws. In Table A.1, parity laws are designated as "strong" if they require that plans offer a minimum mental health benefit that (a) covers a comprehensive set of mental health disorders (i.e., not only severe mental illnesses) and (b) includes equivalent cost sharing and durational limits as those applied to medical/surgical benefits.

Table A.1: Small Employer Group Health Plan Exemptions from State Parity Laws

State	Law Effective Date	Summary of Applicable Law and Exemption Provision	Employer Size Included
ALABAMA	January 1, 2001	Strong parity law applies to group health plans, except employers with 50 employees or less. Code of Ala. §27-54-4.	50 or fewer
ALASKA	July 1, 2006	Parity-if-offered law that exempts small employers (50 or less employees). Alaska Stat. §21.54.151.	50 or fewer
ARIZONA	July 1, 1997	Parity-if-offered law exempts small employers of 2-50 employees. A.R.S. §20-2322.	50 or fewer
DISTRICT OF COLUMBIA	October 21, 2000	Parity for large groups, and only weak minimum mandated benefits law for small-group employers (2-50 employees). DC Code §31-3101.	50 or fewer
HAWAII	July 1, 1999	SMI parity law exempts employers with 25 or fewer employees. Haw. Rev. Stat. § 431M-5.	25 or fewer
IDAHO	July 1, 2006	Parity law covers state employees and their spouses only. Idaho Code § 67-5761A.	50 or fewer
ILLINOIS	January 1, 2002	SMI parity law applies to group plans but exempts plans with 50 or fewer employees. 215 ILCS 5/370c.	50 or fewer
INDIANA	January 1, 2000	HMO and accident sickness insurance parity-if-offered laws exempt small employers of 50 employees or less. IN ST § 27-13-7-14.8 and IN ST § 27-8-5-15.6	50 or fewer
IOWA	January 1, 2006	Parity law applies to small employers (50 employees or less) only if they offer mental illness coverage. Iowa Code 514C.22.	50 or fewer
KENTUCKY	July 14, 2000	Parity-if-offered law exempts employer plans with 51 or fewer employees. KRS § 304.17A-661; § 304.17A-669.	50 or fewer
MAINE	October 1, 2003	Parity and mandated offering laws applicable to group and HMO plans exempt employers with 20 or fewer employees. ME ST T. 24-A § 2843 and ME ST T. 24-A § 4234-A.	20 or fewer
MICHIGAN	June 29, 2000	Laws require 20 outpatients visits/year for HMO plans only; other plans must cover MH services provide coverage in state facilities. MCLS § 500.3501 and MCLS § 500.3406b	50 or fewer
MISSISSIPPI	January 1, 2002	Minimum benefits and inpatient parity laws exempt employers of 100 or fewer employees. Miss. Code Ann. § 83-9-39, 40, 41, 43. Mandated offering law applies to plans covering 100 or fewer employees. Miss. Code Ann. § 83-9-39, 40, 41, 43.	50 or fewer
NEBRASKA	January 1, 2000	Parity-if-offered law exempts small employers covering fewer than 15 employees. R.R.S. Neb. §44-791 through 795.	15 or fewer
NEW YORK	January 1, 2007	SMI parity law exempts employers with 50 employees or less. NY CLS Ins. § 3221.	50 or fewer
OKLAHOMA	January 1, 2000	SMI parity law exempts small employer plans covering 50 or fewer employees. 36 Okl. St. § 6060.10, §6060.11, §6060.12, §6060.13.	50 or fewer
PENNSYLVANIA	April 20, 1999	Minimum mandated benefit law (parity only for annual/lifetime dollar limits) for SMIs applies to groups of less than 50 employees. 40 P.S. § 764g.	50 or fewer
SOUTH CAROLINA	June 30, 2006 October 2, 2009	Parity law effective June 30, 2006 exempts small employers of no more than 50 employees. S.C. Code § 38-71-290. Parity-if-offered law effective Oct. 2, 2009 also exempts small employers. S.C. Code § 38-71-880.	50 or fewer

Table A.1: Small Employer Plan Exemptions from State Parity Laws (Continued)

State	Law Effective Date	Summary of Applicable Law and Exemption Provision	Employer Size Included
TENNESSEE	January 1, 2000	Parity and minimum mandated benefits law exempts small employers with 2-25 employees. Tenn. Code Ann. § 56-7-2360.	25 or fewer
TEXAS	April 1, 2005	SMI parity law (with outpatient/inpatient minimum benefits) exempts small employers of 50 or less. Tex. Ins. Code § 1355.001 through 1355.007.	50 or fewer
UTAH	July 1, 2001	Mandated offering of (a) minimum benefit of 50% coverage or (b) catastrophic coverage for small-group plans of 100 employees or less. Utah Code Ann. § 31A-22-625.	50 or fewer
VIRGINIA	January 1, 2000	SMI parity law exempts small employers of 25 or fewer employees. § 38.2-3412.1:01	25 or fewer
WISCONSIN	June 30, 2009	Parity-if-offered law exempts small employers of 10 employees or less. Wisc. Stat. § 632.89.	10 or fewer
WYOMING	March 7, 2008	If plan offers mental illness benefits, cannot exclude benefits for care or treatment of mental illness in a tax-supported institution of the state. §26-22-102.	50 or fewer

Abbreviations: SMI, severe mental illness.

A.1.2 Propensity Score Matching

Propensity score matching facilitated the comparison of populations with similar distributions of baseline characteristics, given that individuals were not randomly allocated into study groups. Specifically, enrollee-level 1:1 caliper matching without replacement[1] on age, sex, race/ethnicity, neighborhood poverty and education, the John Hopkins ACG® System (ACG, version 10.0.1), comorbidity score, and diagnostic qualifying month (i.e., the month an enrollee was added to the diagnostic cohort) was employed. A variable, "plan renewal month category", consisting of four plan renewal month periods (January-March; April-June; July-September; October-December), also was used in the propensity score match to evenly distribute benefit-year start dates across the groups. Study population characteristics before and after matching are presented in Table A.2.

Table A.2: Baseline Characteristics of Study Population

Characteristics	PRE-PROPENSITY SCORE MATCHING				POST-PROPENSITY SCORE MATCHING				NON-MATCHED	
	Self-Insured Plans: (n=70,558)		Small Employer Plans: (n=11,326)		Self-Insured Plans: (n=11,326)		Small Employer Plans: (n=11,326)		Self-Insured Plans: (n=59,232)	
Index mo. age, Mean (SD)	43.8	(11.4)	43.8	(11.8)	44.0	(11.4)	43.8	(11.8)	43.8	(11.3)
Female, No. (%)	42821	(60.7)	6371	(56.3)	6553	(57.9)	6371	(56.3)	36268	(61.2)
ACG score in index month, Mean (SD)	2.5	(3.3)	2.3	(3.1)	2.3	(3.1)	2.3	(3.1)	2.5	(3.4)
Diagnosis qualifying month (1-12), Mean (SD)	6.3	(3.5)	6.4	(3.4)	6.4	(3.4)	6.4	(3.4)	6.3	(3.5)
Plan renewal month (1-12), Mean (SD)	2.9	(3.1)	6.4	(3.3)	5.8	(3.5)	6.4	(3.3)	2.3	(2.6)
Race/ethnicity,[a] No. (%)										
Hispanic	7305	(10.4)	817	(7.2)	913	(8.1)	817	(7.2)	6392	(10.8)
Asian	1437	(2.0)	194	(1.7)	186	(1.7)	194	(1.7)	1251	(2.1)
White neighborhood	51709	(73.4)	8734	(77.2)	8700	(77.0)	8734	(77.2)	43009	(72.7)
Black neighborhood	812	(1.2)	96	(0.9)	96	(0.9)	96	(0.9)	716	(1.2)
Mixed neighborhood	9179	(13.0)	1471	(13.0)	1401	(12.4)	1471	(13.0)	7778	(13.2)
Neighborhood education,[b] No. (%)										
High	45481	(64.5)	7344	(64.9)	7331	(64.8)	7344	(64.9)	38150	(64.5)
High-middle	14359	(20.4)	2259	(20.0)	2269	(20.1)	2259	(20.0)	12090	(20.4)
Low-middle	7908	(11.2)	1286	(11.4)	1295	(11.5)	1286	(11.4)	6613	(11.2)
Low	2759	(3.9)	427	(3.8)	417	(3.7)	427	(3.8)	2342	(3.9)
Neighborhood poverty,[c] No. (%)										
Low	35264	(50.0)	5723	(50.6)	5727	(50.6)	5723	(50.6)	29537	(49.9)
Low-middle	17714	(25.1)	2728	(24.1)	2746	(24.3)	2728	(24.1)	14968	(25.3)
High-middle	12309	(17.5)	1983	(17.5)	1978	(17.5)	1983	(17.5)	10331	(17.5)
High	5220	(7.4)	882	(7.8)	861	(7.6)	882	(7.8)	4359	(7.4)
Qualifying diagnoses,[d] No. (%)										
Schizophrenia & other psychoses	574	(0.7)	95	(0.7)	83	(0.6)	95	(0.7)	491	(0.8)
Bipolar disorder	1710	(2.0)	286	(2.1)	249	(1.9)	286	(2.1)	1461	(2.5)
Major depression	8089	(9.6)	1142	(8.5)	1203	(9.0)	1142	(8.5)	6886	(11.6)
Anxiety disorders	20264	(23.9)	3184	(23.6)	3166	(23.4)	3184	(23.6)	17098	(28.9)
Attention deficit/ hyperactivity disorder	4012	(4.7)	871	(6.5)	692	(5.2)	871	(6.5)	3320	(5.6)
Adjustment disorders	9457	(11.2)	1347	(10.0)	1490	(11.1)	1347	(10.0)	7967	(13.5)
Other mental & substance abuse disorders	40512	(47.9)	6539	(48.6)	6539	(48.7)	6539	(48.6)	33958	(57.3)

Table A.2: Baseline Characteristics of Study Population (Continued)

	PRE-PROPENSITY SCORE MATCHING				POST-PROPENSITY SCORE MATCHING				NON- MATCHED	
Characteristics	Self-Insured Plans: (n=70,558)		Small Employer Plans: (n=11,326)		Self-Insured Plans: (n=11,326)		Small Employer Plans: (n=11,326)		Self-Insured Plans (n=59,232)	
State of residence, No. (%)										
Alabama	908	(1.3)	130	(1.2)	186	(1.6)	130	(1.2)	722	(1.0)
Alaska	51	(0.1)	13	(0.1)	6	(0.1)	13	(0.1)	45	(0.1)
Arizona	6535	(9.3)	1120	(9.9)	1710	(15.1)	1120	(9.9)	4825	(8.2)
District of Columbia	290	(0.4)	50	(0.4)	39	(0.3)	50	(0.4)	251	(0.4)
Hawaii	36	(0.1)	3	(0.0)	2	(0.0)	3	(0.0)	34	(0.1)
Idaho	624	(0.9)	7	(0.1)	61	(0.5)	7	(0.1)	563	(1.0)
Illinois	4369	(6.2)	1387	(12.3)	788	(7.0)	1387	(12.3)	3581	(6.1)
Indiana	2418	(3.4)	772	(6.8)	474	(4.2)	772	(6.8)	1944	(3.3)
Iowa	2341	(3.3)	212	(1.9)	525	(4.6)	212	(1.9)	1816	(3.1)
Kentucky	1452	(2.1)	172	(1.5)	189	(1.7)	172	(1.5)	1263	(2.1)
Maine	305	(0.4)	10	(0.1)	35	(0.3)	10	(0.1)	270	(0.5)
Michigan	1399	(2.0)	227	(2.0)	154	(1.4)	227	(2.0)	1245	(2.1)
Mississippi	653	(0.9)	251	(2.2)	127	(1.1)	251	(2.2)	526	(0.9)
Nebraska	2095	(3.0)	76	(0.7)	215	(1.9)	76	(0.7)	1880	(3.2)
New York	8228	(11.7)	323	(2.9)	901	(8.0)	323	(2.9)	7327	(12.4)
Oklahoma	1512	(2.1)	369	(3.3)	183	(1.6)	369	(3.3)	1329	(2.2)
Pennsylvania	2527	(3.6)	226	(2.0)	291	(2.6)	226	(2.0)	2236	(3.8)
South Carolina	1215	(1.7)	421	(3.7)	221	(2.0)	421	(3.7)	994	(1.7)
Tennessee	2984	(4.2)	700	(6.2)	549	(4.9)	700	(6.2)	2435	(4.1)
Texas	20450	(29.0)	3322	(29.3)	3214	(28.4)	3322	(29.3)	17236	(29.1)
Utah	1645	(2.3)	248	(2.2)	144	(1.3)	248	(2.2)	1501	(2.5)
Virginia	3063	(4.3)	403	(3.6)	507	(4.5)	403	(3.6)	2556	(4.3)
Wisconsin	5305	(7.5)	878	(7.8)	781	(6.9)	878	(7.8)	4524	(7.6)
Wyoming	153	(0.2)	6	(0.1)	24	(0.2)	6	(0.1)	129	(0.2)

[a] Race/ethnicity was derived from a combination of geocoded census-block group level race from the 2000 US Census and surname analysis to identify Asian and Hispanic individuals. Mixed neighborhoods are those that do not meet a 75% threshold for white, black or Hispanic.

[b] Neighborhood education based on geocoded census-block group level data from the 2000 US Census. High denotes neighborhoods with <15% of the population with less than a high school education, high-middle 15%-24.9%, low-middle 25%-39.9%, and low ≥40%.

[c] Neighborhood poverty based on geocoded census-block group level data from 2000 US Census. Low denotes neighborhoods with <5% living below poverty level, high-middle 5%-9.9%, low-middle 10%-19.9%, and high ≥20%.

[d] The sum of the qualifying diagnoses in each group adds up to more than the total enrollees in the group because an individual could be identified as being in more than one mental health disorder diagnosis category, but s/he was included in the cohort only once.

Propensity score matching improved balance between enrollees in the self-funded plan enrollees (n=11,326) and small employer plan enrollees (n=11,326) in distributions of gender, comorbidity score, diagnosis qualifying month, plan renewal month, race/ethnicity, and neighborhood education and poverty levels. In both the matched and unmatched samples,

members in each group were drawn from 24 states of diverse geographic regions, and no one state dominated either group's membership. The distribution of mental health diagnoses was roughly comparable across groups both before and after the match. Characteristics of the unmatched self-insured plan enrollees (n=59,232) are also presented in Table A.2. As compared to the matched self-insured plan enrollees, these unmatched enrollees had earlier plan renewal months (in the calendar year) and were sicker and more often female.

A.1.3 Outcome Measures

Procedure and diagnostic codes used to classify outpatient mental health visits (along with mental health provider codes specific to the Optum data) are listed in Table A.3. The number of visits per enrollee was calculated over the study period, and out-of-pocket spending on these visits was summed to calculate mean out-of-pocket spending per visit.

Table A.3: Procedure and Diagnostic Codes for Outpatient Mental Health Visits

Code	Code Description	Code Source	Treatment Type
9381	Recreational therapy	ICD-9	Psychosocial rehab
9382	Educational therapy	ICD-9	Psychosocial rehab
9383	Occupational therapy	ICD-9	Psychosocial rehab
9384	Music therapy	ICD-9	Psychosocial rehab
9385	Vocational rehabilitation	ICD-9	Psychosocial rehab
9389	Rehabilitation not elsewhere classified	ICD-9	Psychosocial rehab
9409	Psychologic mental status determination not o/w specified	ICD-9	Initial evaluations, mental status exam
9411	Psychiatric mental status determination	ICD-9	Initial evaluations, mental status exam
9412	Routine psychiatric visit not otherwise specified	ICD-9	Miscellaneous visit
9419	Other psychiatric interview and evaluation	ICD-9	Initial evaluations, mental status exam
9421	Narcoanalysis Narcosynthesis Psychoanalysis	ICD-9	Individual therapy
9422	Lithium therapy	ICD-9	Miscellaneous visit
9423	Neuroleptic therapy	ICD-9	Miscellaneous visit
9425	Other psychiatric drug therapy	ICD-9	Miscellaneous visit
9429	Other psychiatric somatotherapy	ICD-9	Miscellaneous visit
9431	Individual psychotherapy/Psychoanalysis	ICD-9	Individual therapy
9432	Hypnotherapy/ Hypnodrome/ Hypnosis	ICD-9	Individual therapy
9433	Behavior therapy/ Aversion desensitization	ICD-9	Individual therapy
9434	Individual therapy for psychosexual dysfunction	ICD-9	Individual therapy
9436	Play psychotherapy	ICD-9	Individual therapy

Table A.3: Procedure and Diagnostic Codes for Outpatient Mental Health Visits (Continued)

Code	Code Description	Code Source	Treatment Type
9437	Exploratory verbal psychotherapy	ICD-9	Individual therapy
9438	Supportive verbal psychotherapy	ICD-9	Individual therapy
9439	Other individual psychotherapy biofeedback	ICD-9	Individual therapy
9441	Group therapy for psychosexual dysfunction	ICD-9	Group therapy
9442	Family therapy	ICD-9	Family therapy
9443	Psychodrama	ICD-9	Group therapy
9444	Other group psychotherapy	ICD-9	Group therapy
9449	Other counseling	ICD-9	Individual therapy
90801	Psychiatric diagnostic interview examination	CPT-4	Initial evaluations, mental status exam
90802	Interactive psychiatric interview examination	CPT-4	Initial evaluations, mental status exam
90804	Individual therapy outpatient 20-30 min.	CPT-4	Individual therapy
90805	Individual therapy outpatient with evaluation and management 20-30 min.	CPT-4	Individual therapy
90806	Individual therapy outpatient 45-50 min.	CPT-4	Individual therapy
90807	Individual therapy outpatient with evaluation and management 45-50min.	CPT-4	Individual therapy
90808	Individual therapy outpatient 75-80 min.	CPT-4	Individual therapy
90809	Individual therapy outpatient with evaluation and management 75-80 min.	CPT-4	Individual therapy
90810	Interactive individual therapy outpatient 20-30m	CPT-4	Individual therapy
90811	Interactive individual therapy outpatient with evaluation and management 20-30m	CPT-4	Individual therapy
90812	Interactive individual therapy outpatient 45-50m	CPT-4	Individual therapy
90813	Interactive individual therapy outpatient with evaluation and management 45-50m	CPT-4	Individual therapy
90814	Interactive individual therapy outpatient 75-80m	CPT-4	Individual therapy
90815	Interactive individual therapy outpatient with evaluation and management 75-80m	CPT-4	Individual therapy
90820	Interactive psychiatric interview examination	CPT-4	Initial evaluations, mental status exam
90831	Tel call complex or lengthy	CPT-4	Telephone calls
90842	Individual therapy outpatient 75-80m (deleted code use 90808)	CPT-4	Individual therapy
90843	Individual therapy outpatient 20-30m (deleted code use 90804)	CPT-4	Individual therapy
90844	Individual therapy outpatient 45-50m (deleted code use 90806)	CPT-4	Individual therapy
90845	Psychoanalysis	CPT-4	Individual therapy
90847	Family psychotherapy with patient present	CPT-4	Family therapy
90848	Family psychotherapy with patient present	CPT-4	Family therapy
90849	Multiple family group psychotherapy	CPT-4	Family therapy
90853	Group psychotherapy	CPT-4	Group therapy
90855	Interactive Individual therapy outpatient 20-30min. (deleted code use 90810)	CPT-4	Individual therapy
90857	Interactive group psychotherapy	CPT-4	Group therapy
90862	Pharmacologic management	CPT-4	Initial evaluations, mental status exam

Table A.3: Procedure and Diagnostic Codes for Outpatient Mental Health Visits (Continued)

Code	Code Description	Code Source	Treatment Type
90865	Narcosynthesis for psychiatric diagnosis and therapeutic purposes	CPT-4	Miscellaneous visit
90875	Individual therapy outpatient biofeedback and psychotherapy 20-30 min.	CPT-4	Individual therapy
90876	Individual therapy outpatient biofeedback and psychotherapy 45-50 min.	CPT-4	Individual therapy
90880	Hypnotherapy	CPT-4	Individual therapy
90900	Biofeedback training by any modality	CPT-4	Biofeedback
90901	Biofeedback training by any modality	CPT-4	Biofeedback
90902	Biofeedback training by any modality	CPT-4	Biofeedback
90904	Biofeedback training by any modality	CPT-4	Biofeedback
90906	Biofeedback training by any modality	CPT-4	Biofeedback
90908	Biofeedback training by any modality	CPT-4	Biofeedback
90910	Biofeedback training by any modality	CPT-4	Biofeedback
97003	Occupational therapy evaluation	CPT-4	Psychosocial rehab
97004	Occupational therapy re-evaluation	CPT-4	Psychosocial rehab
99058	Office services provided on emergency basis	CPT-4	Miscellaneous visit
99201	New patient outpatient moderate problem 10 min.	CPT-4	Initial evaluations, mental status exam
99202	New patient outpatient with moderate complexity 20 min.	CPT-4	Initial evaluations, mental status exam
99203	New patient outpatient moderate severity 30 min.	CPT-4	Initial evaluations, mental status exam
99204	New patient outpatient moderate to high severity 45 min.	CPT-4	Initial evaluations, mental status exam
99205	New patient outpatient moderate to high severity 60 min.	CPT-4	Initial evaluations, mental status exam
99211	Established patient outpatient moderate severity 5 min.	CPT-4	Initial evaluations, mental status exam
99212	Established patient outpatient moderate severity 10 min.	CPT-4	Initial evaluations, mental status exam
99213	Established patient outpatient low to moderate severity	CPT-4	Initial evaluations, mental status exam
99214	Established patient outpatient moderate to high severity 25 min.	CPT-4	Initial evaluations, mental status exam
99215	Established patient outpatient moderate to high severity 40 min.	CPT-4	Initial evaluations, mental status exam
99241	Consultation outpatient moderate severity 15min.	CPT-4	Initial evaluations, mental status exam
99242	Consultation outpatient low severity 30 min.	CPT-4	Initial evaluations, mental status exam
99243	Consultation outpatient moderate severity 40 min.	CPT-4	Initial evaluations, mental status exam
99244	Consultation outpatient moderate to high severity 60 min.	CPT-4	Initial evaluations, mental status exam
99245	Consultation outpatient moderate to high severity 80 min.	CPT-4	Initial evaluations, mental status exam
99371	Telephone call simple or brief	CPT-4	Telephone calls
99372	Telephone call intermediate	CPT-4	Telephone calls
99373	Telephone call complex or lengthy	CPT-4	Telephone calls

Abbreviations: CPT-4, Current Procedural Terminology, 4th Edition; ICD-9, International Classification of Diseases, 9th Revision

Total out-of-pocket spending on mental health outpatient visits (copayment, coinsurance and deductible spending combined) per enrollee was also calculated over the study period. We included only visits made by the patient to his or her health care clinician, not visits

made by family members or others on behalf of the patient. ED visits and hospitalizations per enrollee were not necessarily specific to mental health.

A.1.4 Covariates

The ACG algorithm[2,3] was applied to enrollees' baseline period to estimate comorbidity. Previously validated categorical variables of Census block group poverty level (below-poverty-levels of <5%, 5-9.9%, 10-19.9%, and ≥20%) and education level (below-high-school education levels of <15%, 15-24.9%, 25-39.9%. and ≥40%) derived from 2000 US Census reports were used to generate proxy measures of socioeconomic status.[4-6] A combination of 2000 US Census[4] neighborhood characteristics and surname analysis characterized enrollees as white, black, Hispanic, Asian, or of mixed race/ethnicity, a validated approach with high positive predictive value.[7] Enrollees were classified as residing in white, black, or Hispanic neighborhoods based on living in neighborhoods with 75% of more persons of the given race/ethnicity, and we assigned Census blocks with 75% or more persons of both Hispanic ethnicity and black race to the Hispanic category. Individuals from Census black groups that did not fall into one of the three race/ethnicity categories were classified as living in mixed race/ethnicity neighborhoods. Surname analysis was used to identify Hispanic and Asian individuals; this superseded the neighborhood-based measure. Enrollees were classified as Hispanic if they lived in a predominantly Hispanic neighborhood or had a Hispanic surname.

A.1.5 Statistical Analyses

The study used a difference-in-differences approach to analyze our before-after with a comparison group design. We indexed time for all enrollees from their respective plan renewal months and used generalized estimating equations with a negative binomial distribution with a

log link function to model rates of outpatient mental health visits, ED visits, hospitalizations, and out-of-pocket spending on outpatient mental health visits, adjusting for age, gender, race/ethnicity, education-level, poverty-level, comorbidity score, state of residence, follow-up time, and plan renewal month. Mean out-of-pocket spending per outpatient mental health visit was calculated using the same model. The generalized estimating equation difference-in-differences models took the following form:

$$Y_{it} = \beta_0 + \beta_1 * T_i + \beta_2 * post_t + \beta_3 * T_i * post_t + \beta_4 X_i + e_{it}$$

Where:

i =individual identifier

t = year identifier

Y_{it} = dependent variable for individual at time t (e.g., ED visits/enrollee)

T_i = indicator variable for plan type (self-insured vs. small group)

$post_t$ = indicator variable for pre- or post-MHPAEA exposure

X_i= a vector of individual characteristics

The term of interest in the generalized estimating equation model was a coefficient (β_3) of the interaction between the indicators of self-insured versus small-group plan type (T_i) and the pre- or post-MHPAEA implementation period ($post_t$). Marginal effects methods[8] were used to calculate adjusted visit rates and spending, and absolute and relative difference-in-differences before and after MHPAEA.

To create the interrupted time series display, differenced outcome rates for monthly time series plots were generated by subtracting mean exposure group outcomes from mean comparison group outcomes in each month. Interrupted time series regression was used with a

linear trend term to model the differenced series, adjusting standard errors for autocorrelation. Separate models were fit for each year after MHPAEA implementation to account for plan-year declining trends in out-of-pocket spending (attributable to individuals hitting limits on deductibles). The model for a given year (e.g., year 1) after MHPAEA implementation is:

$$Y_t = \beta_0 + \beta_1 * \text{time}_t + \beta_2 * \text{exposure}_t + \beta_3 * \text{time\_after\_int}_t + e_t$$

Where:

t = month identifier

Y_t = difference in means of dependent variable for exposure group minus comparison group

time_t = continuous variable indicating time in months at time t from MHPAEA

exposure_t = indicator variable for time t occurring before (exposure=0) or after (exposure=1) MHPAEA

time_after_int_t = continuous variable counting number of months after MHPAEA at time t, coded 0 pre-MHPAEA and (t – months since MHPAEA) post-MHPAEA

A.2 Sensitivity Analyses

A.2.1 Sensitivity Propensity Matched Cohort Analysis

A sensitivity analysis was conducted in order to (a) rule out the possibility that the effects detected were due to different price sensitivity between the exposure and control groups, (b) improve the comparability of baseline trends in our key measure, and (c) better match on the cost-sharing requirements between the study groups. This involved matching exposure and comparison groups on plan renewal month category as well as monthly outpatient mental health visits and spending (specifically, deductibles, coinsurance, and copays)

in the enrollment (pre-baseline) and baseline years. Enrollee-level 1:1 caliper matching without replacement[1] on these variables was used to compare outcomes in groups with similar baseline price sensitivities (i.e., similar visit rates and out-of-pocket spending). Matching at baseline on the trend of the outcome measure(s)—outpatient mental health visits and spending in this case—has been shown to closely approximate randomized controlled trial results.[9] This propensity score matching method improved balance among enrollees in the groups in terms of comorbidity score, diagnosis qualifying month, and plan renewal month, but slightly worsened comparability along gender, race/ethnicity, and neighborhood education and poverty dimensions (Table A.4). However, when we tried to match on the same fixed covariates as for our primary analysis in addition to monthly outpatient mental visits and spending, trends in the baseline outcome variables were less similar; thus, we omitted most fixed covariates from this matched sensitivity analysis. The baseline characteristics of this matched population, as compared to the unmatched sample, are presented in Table A.4.

After matching, in both groups the mean age of enrollees in the index month was 44 and the ACG comorbidity score was 2.3. Sixty percent of the exposure group and 56% of the comparison group were female. The majority of enrollees in the exposure and comparison groups were from high-education (63% and 65%, respectively) and low-poverty neighborhoods (49% and 51%, respectively). Members in both groups were from predominantly white neighborhoods (73% and 77%, respectively). A greater proportion of members of the exposure group than the comparison group were from Hispanic neighborhoods (11% as opposed to 7%); members of other races and ethnicities comprised comparable percentages in each group. Members in each group were drawn from 24 states of diverse geographic regions, and the

distribution of mental health diagnoses was roughly comparable across groups both before and after the match.

Table A.4: Baseline Characteristics of Study Population in the Sensitivity Propensity Matched Cohort[a]

	PRE-PROPENSITY SCORE MATCHING				POST-PROPENSITY SCORE MATCHING			
Characteristics	**Self-Insured Plans: (n=70,558)**		**Small Employer Plans: (n=11,326)**		**Self-Insured Plans: (n=10,363)**		**Small Employer Plans: (n=10,363)**	
Index mo. age, Mean (SD)	43.8	(11.4)	43.8	(11.8)	44.0	(11.3)	44.2	(11.8)
Female, No. (%)	42821	(60.7)	6371	(56.3)	6312	(60.9)	5777	(55.8)
ACG score in index month, Mean (SD)	2.5	(3.3)	2.3	(3.1)	2.3	(3.1)	2.3	(3.1)
Diagnosis qualifying month (1-12), Mean (SD)	6.3	(3.5)	6.4	(3.4)	6.4	(3.5)	6.4	(3.4)
Plan renewal month (1-12), Mean (SD)	2.9	(3.1)	6.4	(3.3)	5.7	(3.7)	6.3	(3.3)
Race/ethnicity,[b] No. (%)								
Hispanic	7305	(10.4)	817	(7.2)	1160	(11.2)	730	(7.1)
Asian	1437	(2.0)	194	(1.7)	193	(1.9)	169	(1.6)
White neighborhood	51709	(73.4)	8734	(77.2)	7483	(72.4)	8007	(77.4)
Black neighborhood	812	(1.2)	96	(0.9)	121	(1.2)	88	(0.9)
Mixed neighborhood	9179	(13.0)	1471	(13.0)	1382	(13.4)	1355	(13.1)
Neighborhood education,[c] No. (%)								
High	45481	(64.5)	7344	(64.9)	6508	(62.8)	6703	(64.7)
High-middle	14359	(20.4)	2259	(20.0)	2155	(20.8)	2078	(20.1)
Low-middle	7908	(11.2)	1286	(11.4)	1271	(12.3)	1179	(11.4)
Low	2759	(3.9)	427	(3.8)	418	(4.0)	393	(3.8)
Neighborhood poverty,[d] No. (%)								
Low	35264	(50.0)	5723	(50.6)	5043	(48.7)	5228	(50.5)
Low-middle	17714	(25.1)	2728	(24.1)	2544	(24.6)	2505	(24.2)
High-middle	12309	(17.5)	1983	(17.5)	1976	(19.1)	1803	(17.4)
High	5220	(7.4)	882	(7.8)	789	(7.6)	817	(7.9)
Qualifying diagnoses,[e] No. (%)								
Schizophrenia and other psychoses	574	(0.7)	95	(0.7)	75	(0.6)	88	(0.7)
Bipolar disorder	1710	(2.0)	286	(2.1)	243	(2.0)	262	(2.1)
Major depression	8089	(9.6)	1142	(8.5)	1054	(8.6)	1014	(8.3)
Anxiety disorders	20264	(23.9)	3184	(23.6)	2887	(23.7)	2897	(23.6)
Attention deficit/hyperactivity disorder	4012	(4.7)	871	(6.5)	582	(4.8)	769	(6.3)
Adjustment disorders	9457	(11.2)	1347	(10.0)	1314	(10.8)	1207	(9.8)
Other mental & substance abuse disorders	40512	(47.9)	6539	(48.6)	6048	(49.6)	6035	(49.2)

Table A.4: Baseline Characteristics of Study Population in the Sensitivity Propensity Matched Cohort[a] (Continued)

	PRE-PROPENSITY SCORE MATCHING				POST-PROPENSITY SCORE MATCHING			
Characteristics	Self-Insured Plans: (n=70,558)		Small Employer Plans: (n=11,326)		Self-Insured Plans: (n=10,363)		Small Employer Plans: (n=10,363)	
State of residence, No. (%)								
Alabama	908	(1.3)	130	(1.2)	151	(1.5)	121	(1.2)
Alaska	51	(0.1)	13	(0.1)	5	(0.1)	10	(0.1)
Arizona	6535	(9.3)	1120	(9.9)	1612	(15.6)	1020	(9.8)
District of Columbia	290	(0.4)	50	(0.4)	31	(0.3)	43	(0.4)
Hawaii	36	(0.1)	3	(0.0)	4	(0.0)	3	(0.0)
Idaho	624	(0.9)	7	(0.1)	63	(0.6)	7	(0.1)
Illinois	4369	(6.2)	1387	(12.3)	649	(6.3)	1292	(12.5)
Indiana	2418	(3.4)	772	(6.8)	407	(4.0)	714	(6.9)
Iowa	2341	(3.3)	212	(1.9)	361	(3.5)	193	(1.9)
Kentucky	1452	(2.1)	172	(1.5)	177	(1.7)	158	(1.5)
Maine	305	(0.4)	10	(0.1)	37	(0.4)	9	(0.1)
Michigan	1399	(2.0)	227	(2.0)	151	(1.5)	215	(2.1)
Mississippi	653	(0.9)	251	(2.2)	127	(1.2)	226	(2.2)
Nebraska	2095	(3.0)	76	(0.7)	241	(2.3)	67	(0.7)
New York	8228	(11.7)	323	(2.9)	718	(6.9)	309	(3.0)
Oklahoma	1512	(2.1)	369	(3.3)	170	(1.6)	345	(3.3)
Pennsylvania	2527	(3.6)	226	(2.0)	266	(2.6)	204	(2.0)
South Carolina	1215	(1.7)	421	(3.7)	185	(1.8)	389	(3.8)
Tennessee	2984	(4.2)	700	(6.2)	494	(4.8)	649	(6.3)
Texas	20450	(29.0)	3322	(29.3)	3290	(31.8)	2987	(28.8)
Utah	1645	(2.3)	248	(2.2)	175	(1.7)	233	(2.3)
Virginia	3063	(4.3)	403	(3.6)	389	(3.8)	362	(3.5)
Wisconsin	5305	(7.5)	878	(7.8)	635	(6.1)	801	(7.7)
Wyoming	153	(0.2)	6	(0.1)	25	(0.2)	6	(0.1)

[a]For this sensitivity analysis, exposure and comparison groups were enrollee-level 1:1 caliper matched in the pre-baseline and baseline years (i.e., the two years before MHPAEA) on monthly outpatient mental health visits and spending (specifically, deductibles, coinsurance, and copays), as well as on plan renewal month category. The matching employed in this sensitivity analysis differs from that employed in the main analysis, where enrollees were matched based on fixed characteristics (i.e., age, sex, race/ethnicity, neighborhood poverty and education, ACG comorbidity score, diagnostic qualifying month, and plan renewal month category).

[b] Race/ethnicity was derived from a combination of geocoded census-block group level race from the 2000 US Census and surname analysis to identify Asian and Hispanic individuals. Mixed neighborhoods are those that do not meet a 75% threshold for white, black or Hispanic.

[c] Neighborhood education based on geocoded census-block group level data from the 2000 US Census. High denotes neighborhoods with <15% of the population with less than a high school education, high-middle 15%-24.9%, low-middle 25%-39.9%, and low ≥40 .

[d] Neighborhood poverty based on geocoded census-block group level data from 2000 US Census. Low denotes neighborhoods with <5% living below poverty level, high-middle 5%-9.9%, low-middle 10%-19.9%, and high ≥20%.

[e] The sum of the qualifying diagnoses in each group adds up to more than the total enrollees in the group because an individual could be identified as being in more than one mental health disorder diagnosis category, but s/he was included in the cohort only once.

Table A.5 and Table A.6 show the difference-in-differences estimates for spending and use outcomes of interest. Baseline year mean out-of-pocket spending per outpatient mental health visit in the exposure and comparison cohorts were $35.38 and $36.51; and mean total out-of-pocket spending on outpatient mental health visits was $232.81 and $229.40, respectively (Table A.5). Relative to enrollees in the comparison group, enrollees in the exposure group experienced statistically significant declines in mean out-of-pocket spending per visit of $2.76 (3.46, 2.06) in year 1 and $4.23 (5.48, 2.99) in year 2 after MHPAEA—relative changes of 6.81% and 9.77%, respectively. These changes are in the same direction as, albeit greater in magnitude in each year after MHPAEA, than those reported in the main analysis. Unlike in the main analysis, a significant decline in mean total out-of-pocket spending on mental health outpatient visits in the exposure group relative to the comparison group of $17.64 (26.38, 8.90) in year 1 after MHPAEA was detected.

The cohorts had similar baseline use of outpatient mental health services (6.57 and 6.49 visits per enrollee), ED visits (0.26 and 0.27 visits per enrollee) and inpatient admission rates (0.08 and 0.07 per enrollee) (Table A.6). Enrollees in the exposure group experienced statistically significant increases, relative to enrollees in the comparison group, in outpatient mental health visits of 0.46 visits (0.27, 0.66) in year 1 and 0.73 visits (0.49, 0.96) in year 2 after MHPAEA— relative changes of 7.09% (3.95, 10.23) and 11.28% (7.48, 15.09), respectively. These increases are of a greater magnitude than those found in the main analysis. Similar to the main analysis, no significant difference between groups in ED visits or inpatient admissions per enrollee was detected that can be attributed to MHPAEA.

Table A.5: Out-of-Pocket Spending on Outpatient Mental Health Visits among Self-Insured Enrollees (Exposure Group) and Small Employer Enrollees (Comparison Group) in the Sensitivity Propensity Matched Cohort[a,b]

	Mean Spending ($)						Mean Change From Baseline to Follow-Up, Exposure Group vs Comparison Group	
	Exposure Group (n=10,363)			Comparison Group (n=10,363)			Absolute Spending ($)	Relative, %
	Pre	Post	Change	Pre	Post	Change	Estimate (95% CI)	Estimate (95% CI)
MHPAEA, Year 1								
OOP Spending per Visit	35.38	36.23	0.85	36.51	40.12	3.64	-2.76 (-3.46,-2.06)**	-6.81 (-8.57,-5.05)**
Total OOP Spending per Enrollee	232.81	255.76	5.31	229.40	234.71	22.95	-17.64 (-26.38,-8.90)**	-6.87 (-10.25,-3.48)**
MHPAEA, Year 2								
OOP Spending per Visit	35.38	37.34	1.96	36.51	42.70	6.19	-4.23 (-5.48,-2.99)**	-9.77 (-12.55,-6.99)**
Total OOP Spending per Enrollee	232.81	257.58	15.32	229.40	244.71	24.77	-9.45 (-19.08,0.18)	-3.58 (-7.42,0.25)

Abbreviations: MHPAEA, Mental Health Parity and Addiction Equity Act; OOP, out-of-pocket.

[a]For this sensitivity analysis, exposure and comparison groups were enrollee-level 1:1 caliper matched in the pre-baseline and baseline years (i.e., the two years before MHPAEA) on monthly outpatient mental health visits and spending (specifically, deductibles, coinsurance, and copays), as well as on plan renewal month category. The matching employed in this sensitivity analysis differs from that employed in the main analysis, where enrollees were matched based on fixed characteristics (i.e., age, sex, race/ethnicity, neighborhood poverty and education, ACG comorbidity score, diagnostic qualifying month, and plan renewal month category).

[b]All rates and changes estimated using the Stata margins and/or nlcom commands and adjusted for age, gender, race/ethnicity, education level, poverty level, ACG score, state of residence, and plan renewal month.

† $p<0.05$

* $p<0.01$

** $p<0.001$

Table A.6: Health Care Utilization Among Self-Insured Enrollees (Exposure Group) and Small Employer Enrollees (Comparison Group) in the Sensitivity Propensity Matched Cohort[a,b]

	Mean Visits per Enrollee						Mean Change From Baseline to Follow-Up, Exposure Group vs Comparison Group	
	Exposure Group (n=10,363)			Comparison Group (n=10,363)			Absolute, per Enrollee	Relative, %
	Pre	Post	Change	Pre	Post	Change	Estimate (95% CI)	Estimate (95% CI)
MHPAEA, Year 1								
Outpatient Mental Health	6.57	7.01	0.44	6.49	6.47	-0.02	0.46 (0.27,0.66)**	7.09 (3.95,10.23)**
Emergency Department	0.26	0.28	0.02	0.27	0.29	0.03	-0.00 (-0.03,0.02)	-0.34 (-9.78,9.11)
Inpatient	0.08	0.09	0.01	0.07	0.08	0.01	0.00 (-0.01,0.01)	1.87 (-13.71,17.44)
MHPAEA, Year 2								
Outpatient Mental Health	6.57	7.18	0.61	6.49	6.37	-0.12	0.73 (0.49,0.96)**	11.28 (7.48,15.09)**
Emergency Department	0.26	0.32	0.06	0.27	0.30	0.03	0.02 (-0.01,0.05)	7.86 (-2.74,18.64)
Inpatient	0.08	0.09	0.02	0.07	0.09	0.01	0.01 (-0.01,0.02)	5.54 (-10.98,22.06)

Abbreviations: MHPAEA, Mental Health Parity and Addiction Equity Act.

[a]For this sensitivity analysis, exposure and comparison groups were enrollee-level 1:1 caliper matched in the pre-baseline and baseline years (i.e., the two years before MHPAEA) on monthly outpatient mental health visits and spending (specifically, deductibles, coinsurance, and copays), as well as on plan renewal month category. The matching employed in this sensitivity analysis differs from that employed in the main analysis, where enrollees were matched based on fixed characteristics (i.e., age, sex, race/ethnicity, neighborhood poverty and education, ACG comorbidity score, diagnostic qualifying month, and plan renewal month category).

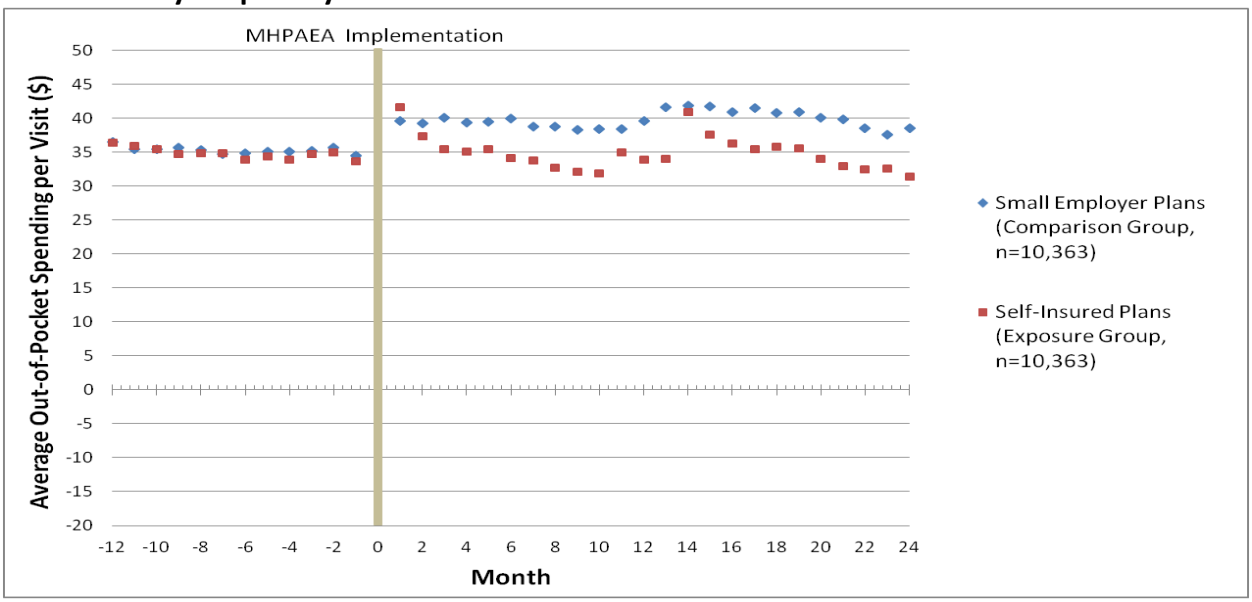
[b]All rates and changes estimated using the Stata margins and/or nlcom commands and adjusted for age, gender, race/ethnicity, education level, poverty level, ACG score, state of residence, and plan renewal month.

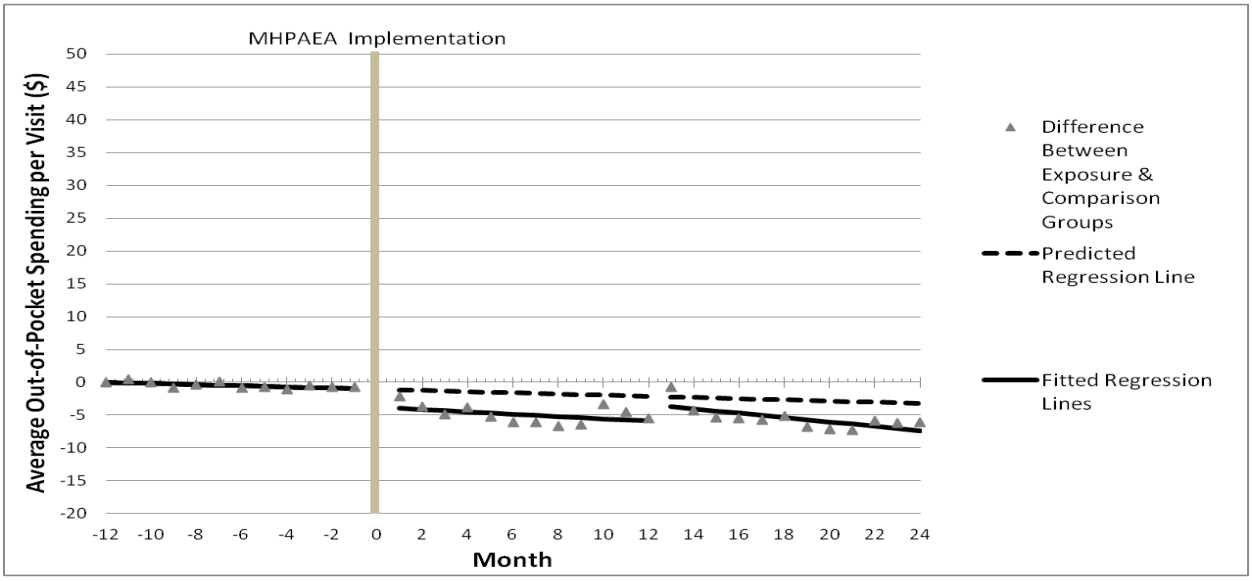
† $p<0.05$

* $p<0.01$

** $p<0.001$

Figure A.1: Unadjusted Out-of-Pocket Spending per Mental Health Outpatient Visit among Self-Insured Enrollees (Exposure Group) and Small Employer Enrollees (Comparison Group) in the Sensitivity Propensity Matched Cohort[a]



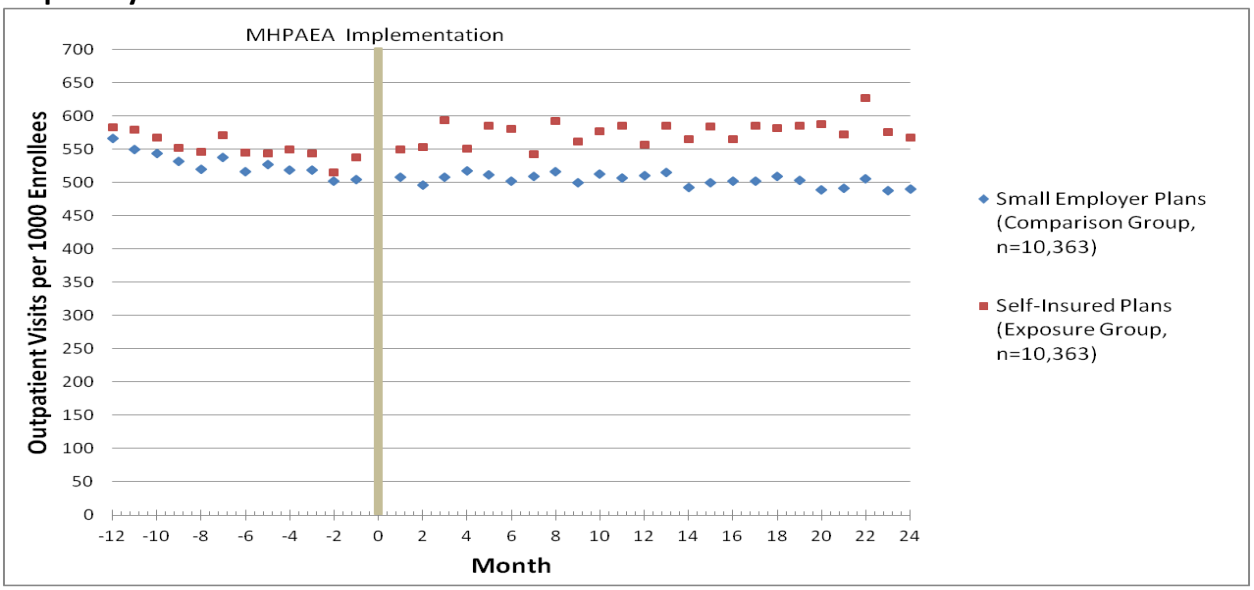


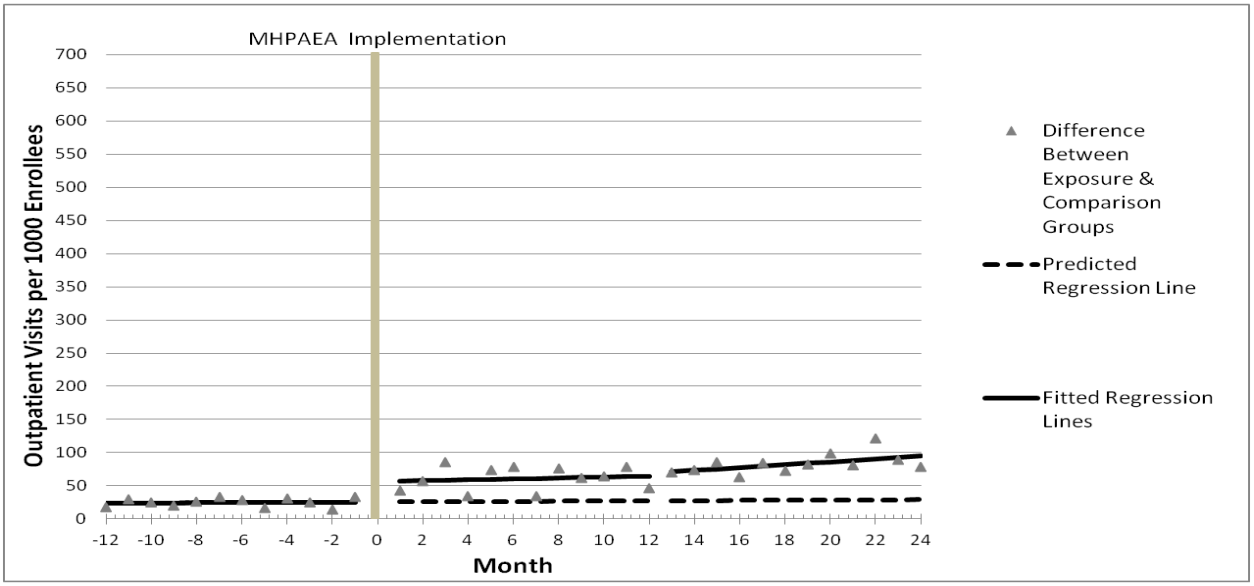
Abbreviations: MHPAEA, Mental Health Parity and Addiction Equity Act.

[a]For this sensitivity analysis, exposure and comparison groups were enrollee-level 1:1 caliper matched in the pre-baseline and baseline years (i.e., the two years before MHPAEA) on monthly outpatient mental health visits and spending (specifically, deductibles, coinsurance, and copays), as well as on plan renewal month category. The matching employed in this sensitivity analysis differs from that employed in the main analysis, where enrollees were matched based on fixed demographic characteristics (i.e., age, sex, race/ethnicity, neighborhood poverty and education, ACG comorbidity score, diagnostic qualifying month, and plan renewal month category.

A fitted regression line shows the difference between exposure and comparison groups in the baseline period and continues as a predicted regression line in the follow-up period. Separate regression lines were fitted for years 1 and 2 of the follow-up period. Regression lines were calculated using unadjusted population-level interrupted time series linear models for the outcomes of interest.

Figure A.2: Unadjusted Mental Health Outpatient Visit Rates among Self-Insured Enrollees (Exposure Group) and Small Employer Enrollees (Comparison Group) in the Sensitivity Propensity Matched Cohort[a]





Abbreviations: MHPAEA, Mental Health Parity and Addiction Equity Act.

[a]For this sensitivity analysis, exposure and comparison groups were enrollee-level 1:1 caliper matched in the pre-baseline and baseline years (i.e., the two years before MHPAEA) on monthly outpatient mental health visits and spending (specifically, deductibles, coinsurance, and copays), as well as on plan renewal month category. The matching employed in this sensitivity analysis differs from that employed in the main analysis, where enrollees were matched based on fixed demographic characteristics (i.e., age, sex, race/ethnicity, neighborhood poverty and education, ACG comorbidity score, diagnostic qualifying month, and plan renewal month category.

A fitted regression line shows the difference between exposure and comparison groups in the baseline period and continues as a predicted regression line in the follow-up period. Separate regression lines were fitted for years 1 and 2 of the follow-up period. Regression lines were calculated using unadjusted population-level interrupted time series linear models for the outcomes of interest.

Figure A.1 and Figure A.2 display monthly interrupted time series plots of the before and after MHPAEA exposure and comparison groups for the mean out-of-pocket expenditures per outpatient mental health visit and visit rate (per 1000 enrollees) outcomes for the sensitivity analysis matched groups. These figures demonstrate very comparable baseline trends across groups in the outcomes of interest. In Figure A.1, the follow-up period trends are at lower levels than the trend predicted under the model fitted to the pre-exposure data, suggesting that the exposure group experienced reduced mean out-of-pocket spending per outpatient mental health visit relative to the comparison group after MHPAEA implementation. In Figure A.2, the follow-up period trends are higher (and steeper in year 2) than the predicted trend, indicating that the exposure group experienced increased visits (per 1,000 enrollees) after the policy relative to the comparison group. Both of these results are of a similar nature, but a greater magnitude, than those displayed in the main analyses.

These sensitivity results support the main analysis results. The magnitude of decreases in mean out-of-pocket spending per outpatient mental health visit and increases in such visits per enrollee is likely greater in the sensitivity analysis because we effectively selected individuals from the exposure group with less generous than average benefit designs (i.e., higher mean out-of-pocket spending per visit) and lower than average visits per enrollee at baseline than in the overall unmatched self-funded plan group. We therefore might have selected self-funded group enrollees with plans that were less likely to offer comparable mental and physical health benefits absent a parity requirement and thus were more likely to respond to MHPAEA by changing benefit designs and practices. Some self-insured plans may have offered generous mental health benefits prior to MHPAEA, given the size of such plans and the

opportunity for risk pooling. Enrollees insured through these employers therefore would already have "parity" even before MHPAEA, despite the fact that their self-insured employers were not subject to any mental health parity legislation. Our main results may, therefore, underestimate the effects of MHPAEA on those for whom the law made a difference to their mental health coverage, given the potential inclusion in the matched exposure group of enrollees in already parity-compliant self-insured plans.

A.2.2 Sensitivity Analysis: Look-Back Falsification Analysis

By matching on spending and use baseline measures in the sensitivity propensity matched cohort analysis, we may have introduced regression to the mean in these outcomes after MHPAEA, and thus overstated effects in this sensitivity analysis. Regression to the mean refers to the tendency of an estimated population rate that is selected to be closer to one extreme on its first measurement(s) to naturally return towards the population's underlying mean rate over time; for example, the 10% of patients with the highest spending in a given year will not all be such high spenders in the following year. By matching on individual use and spending on outpatient mental health visits at baseline, we might have selected a population with extreme values along these dimensions for the baseline and diagnostic periods (self-insured plan cases with acutely high spending, and small-group cases with low spending) that then regressed back to the respective population means in the years following MHPAEA implementation, thereby creating an artifactual effect unrelated to the policy change.

To test for this possibility, a 2-year "look-back" sensitivity analysis was conducted in the pre-MHPAEA timeframe—essentially by shifting all analyses back by 2 years and similarly matching in the baseline and pre-baseline years to assess trends in the follow-up 2 years. Since

in that period there was no general policy change affecting mental health coverage for either group, any effects detected after a "mock" interruption in this analysis might be attributable to regression to the mean or some other confounding mechanism. Although secular trends in outpatient mental health visits in the shifted timeframe differed from those in our main analysis study period, this look-back sensitivity analysis did not suggest that regression to the mean was a concern in this outcome. Specifically, the self-insured and small employer plan enrollees had similar baseline use of outpatient mental health services (2.35 and 2.24 visits per enrollee) (Table A.7). Enrollees in the self-funded group experienced no statistically significant increases, relative to enrollees in the comparison group, in outpatient mental health visits in year 1 or year 2 after the "mock" interruption. Similarly, the self-funded group experienced no significant change in total out-of-pocket spending on these visits relative to the small-group plan group. The mean spending per outpatient mental health visit did decline—albeit more modestly in year 1 and particularly year 2 than in the sensitivity analysis—after the "mock" interruption by $2.19 (3.31, 1.07) in year 1 and $1.69 (3.00, 0.38) in year 2 (Table A.8). These results are consistent with our finding that the mean out-of-pocket spending declines detected in both the main and sensitivity analysis, though statistically significant, were quite small.

The decrease in mean out-of-pocket spending per visit detected in both the main and sensitivity analyses was small, particularly in the first year after implementation. The constituent components of out-of-pocket spending—deductibles, copayments, and coinsurance—may be affected by parity (or other changes introduced at the same time) in different ways, resulting in a modest change in the mean out-of-pocket spending. For example, disaggregating spending into its component parts revealed a significant increase in deductible

spending among the exposure group as compared to the comparison group after MHPAEA. This could be attributable to an increase in the number of self-insured plans that switched to high-deductible plans around the time of MHPAEA.[10] Such switching could actually help satisfy parity requirements by combining mental and physical health deductibles, as is required under MHPAEA,[11] although it does not appear to offer added financial protection to patients and may have biased our spending results to the null. We have no way of confirming the reason for this increase in deductible spending among the exposure group in order to better understand its relationship to MHPAEA.

Table A.7: Health Care Utilization Among Self-Insured Enrollees (Exposure Group) and Small Employer Enrollees (Comparison Group) in the Sensitivity Look-Back Analysis[a,b]

	Mean Visits per Enrollee						Mean Change From Baseline to Follow-Up, Exposure Group vs Comparison Group	
	Exposure Group (n=10,363)			Comparison Group (n=10,363)			Absolute, per Enrollee	Relative, %
	Pre	Post	Change	Pre	Post	Change	Estimate (95% CI)	Estimate (95% CI)
"Mock" Interruption, Year 1								
Outpatient Mental Health	2.35	2.43	0.08	2.24	2.24	0.01	0.08 (-0.06,0.22)	3.19 (-3.04,9.42)
"Mock" Interruption, Year 2								
Outpatient Mental Health	2.35	2.41	0.06	2.24	2.14	-0.10	0.16 (-0.03,0.35)	7.19 (-1.77,1.61)

[a] For this sensitivity look-back analysis, all methods adopted in the sensitivity propensity matched cohort analysis (i.e., matching the exposure and comparison groups in the pre-baseline and baseline years on monthly outpatient mental health visits and spending, as well as on plan renewal month category) were replicated, but shifted back by 2-years—during which period there was no general policy change affecting mental health coverage for the study groups across the states of study. The "mock" interruption during this pre-MHPAEA, look-back analysis timeframe is analogous to MHPAEA during the actual study period.

[b] All rates and changes estimated using the Stata margins and/or nlcom commands and adjusted for age, gender, race/ethnicity, education level, poverty level, ACG score, state of residence, and plan renewal month.

† $p<0.05$

* $p<0.01$

** $p<0.001$

Table A.8: Out-of-Pocket Spending on Outpatient Mental Health Visits among Self-Insured Enrollees (Exposure Group) and Small Employer Enrollees (Comparison Group) in the Sensitivity Look-Back Analysis[a,b]

	Mean Spending ($)						Mean Change From Baseline to Follow-Up, Exposure Group vs Comparison Group	
	Exposure Group (n=12,750)			Comparison Group (n=12,750)			Absolute Spending ($)	Relative, %
	Pre	Post	Change	Pre	Post	Change	Estimate (95% CI)	Estimate (95% CI)
"Mock" Interruption, Year 1								
OOP Spending per Visit	32.32	34.44	2.12	36.82	41.13	4.31	-2.19 (-3.31,-1.07)**	-4.62 (-7.59,-1.64)*
Total OOP Spending per Enrollee	72.94	79.35	6.41	82.06	91.42	9.36	-2.95 (-9.81,3.91)	-2.35 (-10.39,5.69)
"Mock" Interruption, Year 2								
OOP Spending per Visit	32.32	35.67)	3.35	36.82	41.86	5.04	-1.69 (-3.00,-0.38)†	-2.92 (-6.34,0.53)
Total OOP Spending per Enrollee	72.94	81.28	8.34	82.06	89.00	6.94	1.40 (-8.35,10.15)	2.75 (-7.99,13.48)

Abbreviations: OOP, out-of-pocket.

[a]For this sensitivity look-back analysis, all methods adopted in the sensitivity propensity matched cohort analysis (i.e., matching the exposure and comparison groups in the pre-baseline and baseline years on monthly outpatient mental health visits and spending, as well as on plan renewal month category) were replicated, but shifted back by 2-years—during which period there was no general policy change affecting mental health coverage for the study groups across the states of study. The "mock" interruption during this pre-MHPAEA, look-back analysis timeframe is analogous to MHPAEA during the actual study period.

[b]All rates and changes estimated using the Stata margins and/or nlcom commands and adjusted for age, gender, race/ethnicity, education level, poverty level, ACG score, state of residence, and plan renewal month.

† $p<0.05$

* $p<0.01$

** $p<0.001$

A.2.3 Sensitivity Analysis: Non-Substance Use Disorder Cohort

We conducted a sensitivity analysis to exclude those enrollees who met the cohort inclusion criteria for a substance use disorder diagnosis, which corresponds to the ICD-9 diagnostic codes 291, 292, or 303-305 within the "other mental health and substance use disorders" category (Table A.9).

Table A.9: Psychiatric Diagnostic Groups for Adults by Corresponding ICD-9 Codes

	Psychiatric Disorder	ICD-9 Diagnostic Codes Identified
1.	Schizophrenia and other psychoses	295, 297-298
2.	Bipolar disorder	296.0, 296.1, 296.4-296.7
3.	Major Depression	296.2, 296.3
4.	Anxiety disorders	300.0, 300.2, 300.3, 309.81
5.	Attention deficit/hyperactivity disorder (ADHD)	314
6.	Adjustment disorders	308, 309.0-309.4, 309.82, 309.83, 309.89, 309.9
7.	Other mental health and substance use disorders	290-314 (includes only the codes not listed above)

Abbreviations: ICD-9, International Classification of Diseases, 9th Revision.

Because our outpatient mental health visit and spending outcomes focus on mental health care and are identified by mental health-specific diagnostic and procedure codes (Table A.3), the inclusion of substance use disorder-specific diagnoses in the denominator cohort has the potential to bias our estimates to the null. Therefore, we excluded from the cohort those enrollees that had, in the year prior to the baseline period, either (1) ≥2 outpatient or ED claims (on separate dates) within a "substance use disorder diagnosis category" (i.e., ICD-9 codes 291,292, 303-305); (2) ≥1 inpatient claims within a substance use disorder diagnosis category; or (3) ≥1 outpatient or ED claims within a substance use disorder diagnosis category if there was no more than one other claim on a separate date within a different diagnosis category—provided that such enrollees did not separately meet the inclusion criteria by virtue of being diagnosed with a non-substance use disorder diagnosis (i.e., in the psychiatric diagnosis categories of schizophrenia and other psychoses, bipolar disorder, major depression, anxiety

disorders, attention deficit/hyperactivity disorder (ADHD), adjustment disorders, or other mental health disorders not including substance use disorders).

After excluding these substance use disorder-diagnosed individuals from eligibility for our study sample, the exposure and comparison groups were propensity-score matched as in the main analysis based on fixed characteristics (i.e., age sex, race/ethnicity, neighborhood poverty and education, ACG comorbidity score, diagnostic qualifying month, and plan renewal month category). The sample size in these matched cohorts was reduced by approximately 20-percent (n=8,923 in each the exposure and comparison groups, as compared to n=11,326 in each group in the main analysis). Outpatient mental health visit and spending estimates were calculated for this non-substance use disorder cohort, and results were consistent with those generated in the main analysis. The baseline year average out-of-pocket spending per mental health outpatient visit, or $30.68 and $37.34 for the exposure and comparison groups, respectively (Table A.10), were very similar in magnitude to those estimated in the main analysis (Table 1.3). The total annual out-of-pocket costs for these visits per enrollee were $226.92 and $267.97, respectively (Table A.10), which were slightly higher than estimates generated in the main analysis (Table 1.3). The mean spending per outpatient mental health visit declined in this sensitivity analysis—albeit more modestly than in the main analysis—by $0.58 (-1.29, 0.14) in year 1 and $1.47 (-2.28, -0.67) in year 2 after MHPAEA (Table A.10). As in the main analysis, the self-funded group experienced no significant change in total out-of-pocket spending on these visits relative to the small-employer group. These results are consistent with our finding that the mean out-of-pocket spending declines detected in the main analysis, though statistically significant, were quite small.

Table A.10: Out-of-Pocket Spending on Outpatient Mental Health Visits among Self-Insured Enrollees (Exposure Group) and Small Employer Enrollees (Comparison Group) in the Sensitivity Non-Substance Use Disorder Cohort[a,b]

	Mean Spending ($)						Mean Change From Baseline to Follow-Up, Exposure Group vs Comparison Group	
	Exposure Group (n=8,923)			Comparison Group (n=8,923)			Absolute Spending ($)	Relative, %
	Pre	Post	Change	Pre	Post	Change	Estimate (95% CI)	Estimate (95% CI)
MHPAEA, Year 1								
OOP Spending per Visit	30.68	33.40	2.72	37.34	40.64	3.30	0.58 (-1.29,0.14)	0.04 (-1.97, 2.06)
Total OOP Spending per Enrollee	226.92	245.66	18.74	267.97	285.28	17.30	1.44 (-8.55,11.43)	1.69 (-2.22,5.61)
MHPAEA, Year 2								
OOP Spending per Visit	30.68	34.36	3.69	37.34	42.49	5.15	-1.47 (-2.28,-0.67)**	-1.57 (-3.77,-0.63)
Total OOP Spending per Enrollee	226.92	245.65	18.72	267.97	279.97	12.00	6.73 (-3.86,17.32)	3.62 (-0.67,7.90)

Abbreviations: MHPAEA, Mental Health Parity and Addiction Equity Act; OOP, out-of-pocket.

[a]For this sensitivity non-substance use disorder cohort analysis, the cohort was restricted to exclude those enrollees who met the criteria for inclusion by virtue of being diagnosed with a substance use disorder. The exposure and comparison groups were then propensity score matched as in the main analysis on fixed characteristics (i.e., age, sex, race/ethnicity, neighborhood poverty and education, ACG comorbidity score, diagnostic qualifying month, and plan renewal month category).

[b]All rates and changes estimated using the Stata margins and/or nlcom commands and adjusted for age, gender, race/ethnicity, education level, poverty level, ACG score, state of residence, and plan renewal month.

† $p<0.05$

* $p<0.01$

** $p<0.001$

In this non-substance use disorder cohort, the self-insured and small employer plan enrollees had slightly higher baseline use of outpatient mental health services (7.85 versus 7.24 visits per enrollee, Table A.11) as compared to in the main analysis (7.24 versus 6.79 visits per enrollee, Table 1.4). Enrollees in the exposure group experienced statistically significant increases, relative to comparison group enrollees, in outpatient mental health utilization of 0.35 visit (0.13, 0.58; relative 4.75%) in year 1 or and 0.56 visits (0.31, 0.82; relative 7.9%) in

year 2 after MHPAEA (Table A.11)—changes that were slightly greater in magnitude than those detected in the main analysis (Table 1.4). These results are consistent with our findings in that mental health outpatient visit utilization increased after MHPAEA. Because our mental health outpatient spending and utilization findings were largely unchanged after excluding members with a substance use disorder diagnosis from the cohort, because substance use disorder and mental health diagnoses are commonly comorbid, and because of the potential for imprecise diagnoses in administrative claims data, we retain the cumulative "other mental health and substance use disorders" diagnostic category for our main analysis.

Table A.11: Health Care Utilization Among Self-Insured Enrollees (Exposure Group) and Small Employer Enrollees (Comparison Group) in the Sensitivity Non-Substance Use Disorder Cohort[a,b]

	Mean Visits per Enrollee						Mean Change From Baseline to Follow-Up, Exposure Group vs Comparison Group	
	Exposure Group (n=8,923)			Comparison Group (n=8,923)			Absolute, per Enrollee	Relative, %
	Pre	Post	Change	Pre	Post	Change	Estimate (95% CI)	Estimate (95% CI)
MHPAEA, Year 1								
Outpatient Mental Health	7.85	8.06	0.21	7.24	7.10	-0.14	0.35 (0.13,0.58)*	4.75 (1.62,7.88)*
MHPAEA, Year 2								
Outpatient Mental Health	7.85	8.07	0.23	7.24)	6.91	-0.34	0.56 (0.31,0.82)**	7.90 (4.25,11.55)

Abbreviations: MHPAEA, Mental Health Parity and Addiction Equity Act.

[a]For this sensitivity non-substance use disorder cohort analysis, the cohort was restricted to exclude those enrollees who met the criteria for inclusion by virtue of being diagnosed with a substance use disorder. The exposure and comparison groups were then propensity score matched as in the main analysis on fixed characteristics (i.e., age, sex, race/ethnicity, neighborhood poverty and education, ACG comorbidity score, diagnostic qualifying month, and plan renewal month category).

[b]All rates and changes estimated using the Stata margins and/or nlcom commands and adjusted for age, gender, race/ethnicity, education level, poverty level, ACG score, state of residence, and plan renewal month.

† $p<0.05$

* $p<0.01$

** $p<0.001$

A.3 Stratified Analyses

We conducted several stratified analysis to identify variation in the strength of MHPAEA associations with mental health outpatient outcomes by subgroup. In the main analysis, we stratified the exposure and control groups (n=11,326 for each group after the propensity score match) by quartile in terms of (1) baseline year mental health outpatient visits for this visit outcome, and (2) baseline year out-of-pocket spending on mental health outpatient visits for the spending outcomes.

We also stratified the propensity-score-matched exposure and comparison groups from the main analysis by mental health diagnosis category. For this analysis, we applied the diagnostic algorithm outlined in the main text hierarchically, in the order of diagnostic category set forth in Table A.9. Specifically, we first identified enrollees that met the diagnostic inclusion criteria for schizophrenia and other psychoses; those who did not meet the criteria for schizophrenia were eligible and tested for satisfaction of the diagnostic inclusion criteria for bipolar disorder; those who did not meet the criteria for inclusion in the schizophrenia or bipolar disorder categories were eligible and tested for satisfaction of the diagnostic inclusion criteria for major depression, etc. Thus for this sub-analysis, an individual was categorized within only one psychiatric diagnostic group.

Mental health outpatient spending and utilization outcomes by diagnosis category are presented in Table A.12 and Table A.13, respectively. Because the sample sizes for the schizophrenia (n=178) and bipolar disorder categories (n=509) were very small, we did not report the results for these categories. We also did not report the results for “other mental health and substance use disorders” given that this is a catch-all, non-specific diagnosis

category. Thus, we reported the results for major depression, anxiety disorders, ADHD, and adjustment disorders.

Effect estimates were not statistically significant in any diagnosis category other than depression, likely in part because the sample sizes in these groups were significantly smaller than in the main analysis. For the depression cohort (n=2,260 total), the results were consistent with those detected in the main analysis. The baseline mean spending per mental health outpatient visit ($31.94 and $38.50 in the exposure and comparison groups, respectively) and total spending on these visits per enrollee ($323.26 and 388.14, respectively) (Table A.12) were higher than in the main analysis (Table 1.3). The mean spending per outpatient mental health visit declined more significantly among the exposure group (as compared to the comparison group) in this depression cohort, or by $2.42 per visit (4.41, 0.43; relative 4.92%) in year 1 and by $3.19 (5.38, 1.00; relative 6.33%) in year 2 after MHPAEA, than in the main analysis (Table 2). The baseline year outpatient mental health care utilization was higher in this depression cohort (or 10.90 visits in the exposure and 10.04 visits in the comparison group) (Table A.12) than in the main analysis (Table 1.4). As in the main analysis, self-insured enrollees in this depression cohort experienced a statistically significant increase in mental health outpatient visits in year 2 after MHPAEA as compared to small-group enrollees, of 1.07 visits (0.15, 1.98; relative: 13.31%). These depression cohort results are consistent with our main findings, including those that the magnitude of increases in visits is greater among higher utilizers at baseline (which those diagnosed with major depression are).

Table A.12: Out-of-Pocket Spending on Outpatient Mental Health Visits among Self-Insured Enrollees (Exposure Group) and Small Employer Enrollees (Comparison Group) by Mental Health Disorder Category in the Propensity Matched Cohort[a,b]

	Mean Spending						Mean Change From Baseline to Follow-Up, Exposure Group vs Comparison Group	
	Exposure Group (n=11,326)			Comparison Group (n=11,326)			Absolute Spending ($)	Relative, %
	Pre	Post	Change	Pre	Post	Change	Estimate (95% CI)	Estimate (95% CI)
Major Depression (n=2,260)								
MHPAEA, Year 1								
OOP Spending per Visit	31.94	33.55	1.61	38.50	42.53	4.03	-2.42 (-4.41,-0.43) †	-4.92 (-10.17,0.00)
Total OOP Spending per Enrollee	323.26	327.38	4.02	388.14	389.31	1.77	2.84 (-33.59,39.27)	0.94 (-9.35,11.22)
MHPAEA, Year 2								
OOP Spending per Visit	31.94	33.97	2.03	38.50	43.72	5.22	-3.19 (-5.38,-1.00)*	-6.33 (-11.95,-0.73) †
Total OOP Spending per Enrollee	323.26	309.76	-13.60	388.14	346.65	-41.49	27.88 (-11.14,66.91)	7.26 (-5.06,19.58)
Anxiety Disorders (n=5,775)								
MHPAEA, Year 1								
OOP Spending per Visit	30.44	33.17	2.73	36.47	39.27	2.81	-0.08 (-1.30,1.14)	1.17 (-2.42,4.76)
Total OOP Spending per Enrollee	219.40	236.77	17.38	247.03)	272.78	25.74	-8.37 (-24.49,7.75)	-2.27 (-8.60,4.06)
MHPAEA, Year 2								
OOP Spending per Visit	30.44	33.93	3.49	323.26	42.08	5.61	-2.13 (-3.52,-0.74)*	-3.42 (-7.15,0.31)
Total OOP Spending per Enrollee	219.40	239.77	20.37	247.03	272.20	25.17	-4.80 (-22.01,12.42)	-0.82 (-7.75,6.11)
Attention Deficit/Hyperactivity Disorder (n=1,241)								
MHPAEA, Year 1								
OOP Spending per Visit	28.58	32.37	3.79	37.50	39.87	2.37	1.42 (-1.15,4.00)	6.54 (-1.50,14.58)
Total OOP Spending per Enrollee	176.01	191.32	15.31	221.75	230.33	8.58	6.72 (-22.88,36.33)	4.65 (-10.53,19.82)
MHPAEA, Year 2								
OOP Spending per Visit	28.58	33.17	4.60	37.50	42.55	5.05	-0.45 (-3.43,2.52)	2.31 (-6.34,10.96)
Total OOP Spending per Enrollee	176.01	208.76	32.75	221.75	240.85	19.10	13.64 (-20.00,47.28)	9.20 (-7.94,26.33)

Table A.12: Out-of-Pocket Spending on Outpatient Mental Health Visits among Self-Insured Enrollees (Exposure Group) and Small Employer Enrollees (Comparison Group) by Mental Health Disorder Category in the Propensity Matched Cohort[a,b] (Continued)

	Mean Spending						Mean Change From Baseline to Follow-Up, Exposure Group vs Comparison Group	
	Exposure Group (n=11,326)			Comparison Group (n=11,326)			Absolute Spending ($)	Relative, %
	Pre	Post	Change	Pre	Post	Change	Estimate (95% CI)	Estimate (95% CI)
Adjustment Disorders (n=2,353)								
MHPAEA, Year 1								
OOP Spending per Visit	32.21	34.41	2.21	39.49	41.37	1.88	0.32 (-1.85,2.49)	1.98 (-3.97,7.94)
Total OOP Spending per Enrollee	266.71	233.25	-33.46	292.34	262.33	-30.01	-3.45 (-33.33,26.42)	-2.54 (-13.42,8.33)
MHPAEA, Year 2								
OOP Spending per Visit	32.21	35.47	3.27	39.49	42.74	3.24	0.02 (-2.34,2.83)	1.78 (-4.58,8.13)
Total OOP Spending per Enrollee	266.71	230.76	-35.95	292.34	253.76	-38.58	2.63 (-29.80,35.06)	-0.32 (-12.56,11.91)

Abbreviations: MHPAEA, Mental Health Parity and Addiction Equity Act; OOP, out-of-pocket.

[a]For this stratified analysis, enrollees in the propensity score matched exposure and comparison groups from the main analysis (i.e., matched on age, sex, race/ethnicity, neighborhood poverty and education, ACG comorbidity score, diagnostic qualifying month, and plan renewal month category), were categorized to mutually exclusive mental health diagnostic category.

[b]All rates and changes estimated using the Stata margins and/or nlcom commands and adjusted for age, gender, race/ethnicity, education level, poverty level, ACG score, state of residence, and plan renewal month.

† $p<0.05$

* $p<0.01$

** $p<0.001$

Table A.13: Health Care Utilization Among Self-Insured Enrollees (Exposure Group) and Small Employer Enrollees (Comparison Group) by Mental Health Disorder Category in the Propensity Matched Cohort[a,b]

	Mean Visits per Enrollee						Mean Change From Baseline to Follow-Up, Exposure Group vs Comparison Group	
	Exposure Group (n=11,326)			Comparison Group (n=11,326)			Absolute, per Enrollee	Relative, %
	Pre	Post	Change	Pre	Post	Change	Estimate (95% CI)	Estimate (95% CI)
Major Depression (n=2,260)								
MHPAEA, Year 1								
Outpatient Mental Health	10.90	10.90	0.00	10.04	9.28	-0.76	0.76 (-0.07,1.59)	8.18 (-0.46,16.82)
MHPAEA, Year 2								
Outpatient Mental Health	10.90	10.29	-0.61	10.04	8.37	-1.67	1.07 (0.15,1.98)*	13.31 (2.87,2.38)†
Anxiety Disorders (n=5,775)								
MHPAEA, Year 1								
Outpatient Mental Health	7.67	7.79	0.12	6.87	7.00	0.14	-0.15 (-0.39,0.36)	-0.39 (-5.42, 4.63)
MHPAEA, Year 2								
Outpatient Mental Health	7.67	7.89	0.23	6.87	6.83	-0.04	0.26 (-0.15,0.68)	3.52 (-2.37,9.42)
Attention Deficit/Hyperactivity Disorder (n=1,241)								
MHPAEA, Year 1								
Outpatient Mental Health	6.07	6.20	0.12	5.92	5.68	-0.24	0.36 (-0.31,1.03)	6.30 (-5.58,18.19)
MHPAEA, Year 2								
Outpatient Mental Health	6.07	6.47	0.40	5.92)	5.74	-0.18	0.58 (-0.19,1.35)	9.88 (-4.08,0.24)
Adjustment Disorders (n=2,353)								
MHPAEA, Year 1								
Outpatient Mental Health	8.40	7.42	-0.98	7.54	6.46	-1.08	0.11 (-0.56,0.77)	3.22 (-6.08,12.52)
MHPAEA, Year 2								
Outpatient Mental Health	8.40	7.34	-1.05	7.54)	6.25	-1.29	0.23 (-0.48,0.95)	5.48 (-4.82,15.79)

Abbreviations: MHPAEA, Mental Health Parity and Addiction Equity Act.

[a]For this stratified analysis, enrollees in the propensity score matched exposure and comparison groups from the main analysis (i.e., matched on age, sex, race/ethnicity, neighborhood poverty and education, ACG comorbidity score, diagnostic qualifying month, and plan renewal month category), were categorized to mutually exclusive mental health diagnostic category.

[b]All rates and changes estimated using the Stata margins and/or nlcom commands and adjusted for age, gender, race/ethnicity, education level, poverty level, ACG score, state of residence, and plan renewal month.

† $p<0.05$

* $p<0.01$

** $p<0.001$

A.4 Appendix A References

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B

SUPPLEMENTARY MATERIALS FOR CHAPTER 2

Table B.1. Literature Review: Published Studies of PDMP Effectiveness in Addressing Opioid Misuse, 1990-2015

Citation	Design	Data Source	PDMP Measures	Findings	Methodological Comments
PRIMARY OUTCOMES					
Opioid-Related Overdoses					
Chris Delcher et al., *Abrupt Decline in Oxycodone-Caused Mortality After Implementation of Florida's Prescription Drug Monitoring Program*, 150 DRUG & ALC. DEPENDENCE 63 (2015).	Interrupted time series with comparison groups	Florida Medical Examiners Commission drug-related death data (2003-2012).	Two measures of Florida PDMP (1) binary indicator for pre- and post-PDMP; (2) continuous variable for number of health provider PDMP queries.	**Significant**. Oxycodone-caused mortality declined 25% in the month after PDMP.	*Strengths*: Control for three concurrent Florida prescription drug misuse interventions. co-interventions. Incorporate actual provider use of PDMP into intervention measure. *Limitations*: Effect observed is dramatic, particularly given that PDMP was not mandatory and use gradually increased after implementation. Ability to control for co-interventions using model chosen is unclear. Limited generalizability to other states.
Leonard J. Paulozzi et al., *Prescription Drug Monitoring Programs and Death Rates from Drug Overdose*, 12 PAIN MED. 747 (2011).	Multiple parallel time series, comparing groups without interruption	Automation of Reports and Consolidated Orders System (ARCOS) data for drug distribution (1997-2005). National Center for Health Statistics & CDC drug overdose mortality data (1999-2005).	National sample that characterized states based on the presence at some time during the study period (19) or total absence (31) of a PDMP.	**Not significant**. PDMPs not associated with lower rates of opioid overdose mortality or lower rates of opioid consumption.	*Strengths*: Only national study to assess relationship between PDMPs and mortality, using supply as an intermediary mechanism. *Limitations*: Older study, conducted when PDMPs were not very strong. Combined all states that had PDMP at any time during study period into treatment group. Lacks before-after comparisons within states.

Table B.1. Literature Review: Published Studies of PDMP Effectiveness in Addressing Opioid Misuse, 1990-2015 (Continued)

Citation	Design	Data Source	PDMP Measures	Findings	Methodological Comments
Opioid-Related Treatment Admissions & Poisonings					
Lisa M. Reifler et al., *Do Prescription Monitoring Programs Impact State Trends in Opioid Abuse/Misuse?*, 13 PAIN MED. 434 (2012).	Controlled pre-post	Research Abuse Diversion & Addiction-Related Surveillance (RADARS) Poison Center (2003-2009). Opioid treatment surveillance data (2003-2009).	National sample that characterized states based on the presence or absence of a PDMP, by quarter.	**Significant.** PDMPs were associated with lower poison center intentional exposures and lower substance abuse treatment admissions.	*Strengths*: Conducted sub-analyses of superior PDMP features (i.e., in effect for a long time, unsolicited reports, monitor drugs through Schedule IV) with consistent results. *Limitations*: RADARS data are self-reported.
Richard M. Reisman et al., *Prescription Opioid Usage and Abuse Relationships: An Evaluation of State Prescription Drug Monitoring Program Efficacy*, 3 SUBSTANCE ABUSE 41 (2009).	Multiple parallel time series display with controlled pre-post regression analysis	ARCOS data for opioid shipments (1997-2003) Treatment Episode Data Set (TEDS) data for opioid abuse admissions (1997-2003).	National sample that characterized states based on the presence (14) or absence (36) of a PDMP.	**Significant**. PDMPs were associated with fewer Schedule II opioid shipments and fewer opioid abuse treatment admissions.	*Strengths*: national sample with measures of both mechanisms (supply) and health (treatment admissions). *Limitations*: Outdated. Imprecise measures of PDMP laws, which were generally weak during this study period.
SECONDARY OUTCOMES					
Opioid Supply					
Jane E. Brady et al., *Prescription Drug Monitoring and Dispensing of Prescription Opioids*, 129 PUB. HEALTH REPORTS 139 (2014).	Controlled pre-post	ARCOS data on opioid shipments (1999-2008, quarterly).	National sample that characterized states based on presence or absence of a PDMP by quarter.	**Not significant**. State PDMPs not associated with changes in per-capita opioids dispensed.	*Strengths*: national sample with data over a long time period. Multivariable linear models adjust for demographics and geographic region. *Limitations*: Effect of PDMP varied hugely between states (66% decrease in Colorado, 61% increase in Connecticut), suggesting that measurement was imprecise.

Table B.1. Literature Review: Published Studies of PDMP Effectiveness in Addressing Opioid Misuse, 1990-2015 (Continued)

Citation	Design	Data Source	PDMP Measures	Findings	Methodological Comments
Leonard J. Paulozzi et al. (see above)	(see above)	(see above)	(see above)	**Not significant**. PDMPs not associated with lower rates of opioid consumption. States with PDMPs consumed more hydrocodone (Schedule III, less frequently monitored), suggesting substitution.	(see above)
Richard M. Reisman et al. (see above)	(see above)	(see above)	(see above)	**Significant**. PDMPs associated with fewer Schedule II opioid shipments.	(see above)
Lainie Rutkow et al., *Effect of Florida's Prescription Drug Monitoring Program and Pill Mill Laws on Opioid Prescribing and Use*, JAMA INTERNAL MED. (Aug. 17, 2015), available at doi:10.1001/jamainternmed.2015.3931.	Interrupted time series with comparison group	IMS Health LifeLink LRx prescription claims data (July 2010-Sept. 2012)	Florida PDMP and pill mill law concurrent implementation	**Significant**. Florida PDMP and pill mill laws were associated with modest decreases in total opioid volume among highest baseline users.	*Strengths*: Excellent data source and robust methods used to detect multiple effects among high prescribers and users. *Limitations*: Comparison group, Georgia, had different levels of opioid use and prescribing at baseline. Difficult to assess whether effects are largely attributable to PDMPs or pill mill laws (or the combination). Results not very generalizable to other states.

Table B.1. Literature Review: Published Studies of PDMP Effectiveness in Addressing Opioid Misuse, 1990-2015 (Continued)

Citation	Design	Data Source	PDMP Measures	Findings	Methodological Comments
Prescribing Behavior					
David F. Baehren et al., *A Statewide Prescription Monitoring Program Affects Emergency Department Prescribing Behaviors*, 56 ANNALS EMERGENCY MED. 19 (2010).	Un-controlled pre-post	Survey of University of Toledo Medical Center Emergency Department Physicians ED, (Jun.-Jul. 2008)	Ohio PDMP ("OARRS") consultation	**Significant**. Prescribing was altered in 41% of cases: 60% of these cases resulted in fewer or no prescription painkiller being prescribed due to the patient's number of previous fills; in 39% of these cases, physicians prescribed painkillers when they wouldn't have otherwise.	*Strengths*: Detailed analysis demonstrates impact of PDMP information on a physician. *Limitations*: Small sample (n=179), limited to Ohio PDMP so not very generalizable. Results subject to response bias. No comparison group.
Matthew W. McAllister et al., *Impact of Prescription Drug-Monitoring Program on Controlled Substance Prescribing in the ED*, 33 AM. J. EMERGENCY MED. 781 (2015).	Un-controlled pre-post	PDMP prescribing data of Emergency Department physicians of a tertiary care, urban university teaching hospital (2-week period in Feb. 2014 vs. 2-week period in Dec. 2013)	Florida PDMP ("EFORCSE") consultation	**Not significant**. PDMP data was not associated with any change in average number of controlled substances prescribed per patient.	*Strengths*: Conducted additional survey of physician impressions of PDMP data, which suggested that they felt it altered their prescribing. *Limitations*: Small sample (n=710 patients), limited to Florida so not very generalizable. "Historical control" not true comparison group.

Table B.1. Literature Review: Published Studies of PDMP Effectiveness in Addressing Opioid Misuse, 1990-2015 (Continued)

Citation	Design	Data Source	PDMP Measures	Findings	Methodological Comments
Linda Rasubala, et al., Impact of Mandatory Prescription Drug Monitoring Program on Prescription of Opioid Analgesics by Dentists, 10 PLoS ONE e0135957 (2015).	Un-controlled pre-post	Dental urgent care center electronic medical records (Three periods: Pre-PDMP: Dec. 2012-Feb. 2013; Post-PDMP-1: Dec. 2013-Feb. 2014; Post-PDMP-2: Mar.-May 2014)	New York PDMP ("I-STOP") mandatory query implementation (applied to Dentists as well as other prescribers)	**Significant**. The odds for a patient to receive opioids was reduced by 58% in Post-PDMP-1and 72% in Post-PDMP-2 as compared to the Pre-PDMP period (when adjusting for differences in surgical volume across periods).	*Strengths*: First study to investigate mandates. Data consisted of close chart reviews and allowed sufficient time post-implementation to detect effects. *Limitations*: No comparison group. More sophisticated analytical methods preferred.
Chris Ringwalt et al., *The Effects of North Carolina's Prescription Drug Monitoring Program on the Prescribing Behaviors of the State's Providers*, 36 J. PRIMARY PREVENTION 131 (2015).	Un-controlled post only	North Carolina PDMP data (2009-2011, divided into 6-month blocks)	Two measures of use of North Carolina's PDMP: (1) number of providers who queried the PDMP, and (2) mean number of days on which providers queried.	**(Slightly) significant**. Slightly positive association between increased use of PDMP and number of opioid prescriptions filled, suggesting that the PDMP had no "chilling effect" on prescribing.	*Strengths*: Incorporated measures of PDMP use into intervention measures. Displays time trends *Limitations*: Post-only study, after PDMP implementation (2005). No comparison group. Registration rates low (27%), so unlikely PDMP use explains overall prescribing trends.

Table B.1. Literature Review: Published Studies of PDMP Effectiveness in Addressing Opioid Misuse, 1990-2015 (Continued)

Citation	Design	Data Source	PDMP Measures	Findings	Methodological Comments
Lainie Rutkow et al., (see above)	(see above)	(see above)	(see above)	**Significant**. Florida PDMP and pill mill laws associated with modest decreases in MME per transaction and opioid prescriptions (1 year post), but not changes in mean days' supply per transaction. Reductions limited to highest baseline prescribers.	(see above)
Scott G. Weiner et al., *Clinician Impression Versus Prescription Drug Monitoring Program Criteria in the Assessment of Drug-Seeking Behavior in the Emergency Department,* 62 ANNALS EMERGENCY MED. 281 (2013).	Un-controlled pre-post	Emergency department physicians of patients presenting in two academic medical centers with chief complaint of back pain, dental pain, or headache. (Jun. 2011-Jan. 2013)	Massachusetts PDMP consultation	**Significant**. After PDMP exposure, emergency department physicians changed plans to prescribe opioids in 9.5% cases: 6.5% patients received opioid that were not previously planned, while 3% no longer received opioids.	*Strengths*: Careful survey of physician prescribing plans before and after consulting PDMP. *Limitations*: Small sample (n=38) of physicians, limited to Massachusetts PDMP so not very generalizable. Responses subject to response bias. No comparison group.

Table B.1. Literature Review: Published Studies of PDMP Effectiveness in Addressing Opioid Misuse, 1990-2015 (Continued)

Citation	Design	Data Source	PDMP Measures	Findings	Methodological Comments
Patient Behavior					
Linda Simoni-Wastila & Jingjing Qian, *Influence of Prescription Monitoring Programs on Analgesic Utilization by an Insured Retiree Population*, 21 PHARMACOEPIDEMIOLOGY & DRUG SAFETY 1261 (2012).	Cross-sectional	Coordination of Benefits MarketScan claims data of Medicare eligible and their dependents (2007)	National sample that characterized patient exposure to PDMP or not in 2007.	**Significant**. PDMPs were associated with decreased utilization of Schedule II opioids but an increase in Schedule III opioids, which were less frequently monitored, suggesting a substitution effect.	*Strengths*: Multi-variable regression analysis using large sample. *Limitations*: Medicare population results not generalizable to other age groups. PDMPs not characterized by the strength of features. Cross-sectional design shows association only.
Hillary L. Surratt et al., *Reductions in Prescription Opioid Diversion Following Recent Legislative Interventions in Florida*, 23 PHARMACOEPIDEMIOLOGY & DRUG SAFETY 314 (2014).	Un controlled pre-post	RADARS System (Jan. 2009-Sept. 2012, quarterly)	Florida PDMP and closely implemented prescribing laws in 2010-2011 (pill mill regulations, limitations on cash payments)	**Significant**. Decreases in diversion observed for three Schedule II opioid substances (methadone, morphine, and oxycodone), but did not significantly decline for a fourth Schedule II opioid (hydrocodone).	*Strengths*: Sophisticated multi-level models adopted. *Limitations*: Diversion reports could have exhibited reporting bias. Difficult to disentangle PDMP from other related laws. No comparison group.

The strongest studies are cited in bold print.

C

SUPPLEMENTARY MATERIALS FOR CHAPTER 3

C.1 Study Group Construction

C.1.1 State Selection

State PDMP laws were reviewed and analyzed in significant detail. We built upon a preexisting dataset of PDMP laws from January 1, 1998 through December 31, 2011 compiled by the Robert Wood Johnson Foundation's Public Health Law Research Program.[1] We updated the dataset to include laws from January 1, 2012 through December 2014, and to characterize certain prescriber-level features important to our analysis. Based on a comprehensive review of the laws, a binary coding scheme was developed to include the following, nine law features important to strength of state PDMP policies for use as a clinical tool–most critically, a robust requirement that prescribers query the systems (i.e., a robust use mandate), as shown in Table C.1 (*indicates a required feature for intervention states):

1. **PDMP for Prescribers*: Although the vast majority of operational PDMPs can be accessed by prescribers, some were originally only accessible by law enforcement officials and a handful have maintained such status through the study period.
2. **Use Mandate*: A requirement that prescribers access the PDMP under certain circumstances.
3. **Robust Use Mandate:* Use mandate that specifies objective criteria for checking the

PDMP (rather than based on a prescriber's subjective beliefs), covers at least Schedule II-III drugs, covers a broad array of prescribing contexts (not just methadone clinics or opioid treatment facilities), and requires the PDMP be checked at prior to initial prescribing of addictive substances. These robust use mandates can be for chronic course and at least annually after the initial prescribing context, and can include reasonable exemptions (e.g., hospice, five-to-seven day supply or less, emergency situations). Details of the five robust use mandates of study, along with their effective dates, can be found in Table C.2.

4. *No Prescriber Immunity for Failure to Check/Use PDMP*: Many PDMP laws have broad immunity grants, which protect prescribers from civil and/or criminal liability if they fail to check or use information in the PDMP. These grants, particularly when combined with a use mandate, may relax the impetus prescribers feel to check the database if there is no penalty associated with failure to do so.
5. *Registration Mandate*: Requirement that prescribers enroll in (i.e., obtain a login to) the PDMP, or PDMPs that automatically prescriber enrollment.
6. *Proactive Reporting Required or Permitted*: Indicates that the PDMP is permitted or required to proactively identify suspicious prescribing, dispensing, or purchasing and report findings to professional licensing body, prescribers, dispensers, and/or law enforcement officials. (Note: specific trigger requirements are typically left to PDMP discretion rather than proscribed by law. It is thus difficult to differentiate between required and permitted reporting in the laws, so they were collapsed into one category.)
7. *Housed in a Health Agency*: Indicates that the PDMP is housed in a Department of

Health, Board of Pharmacy, or Professional Licensing Body and thus is designed as a user-friendly clinical tool for prescribers, as opposed to within a law enforcement or public safety entity, which is more likely to design the tool to track illegal activity.

8. *Data Frequency at Least Weekly*: PDMP is updated with dispensing information at least weekly, to ensure timely provision of information to prescribers checking the system.
9. *Monitors at Least Schedules II-IV*: Indicates that the PDMP monitors at least controlled substances included in the federal Schedules II-IV (i.e., opioids, benzodiazepines, hypnotics, and stimulants with high to low potential for abuse).

Other features that were considered for inclusion in our robustness metrics but ultimately excluded because they lacked heterogeneity across states or were of limited or uncertain impact or documentation included:

1. *Interoperability of PDMPs and Medical Records*: Inter-operability between PDMPs and electronic medical records is a goal among advocates of these programs, to increase the ease of use and use of information among clinicians. However, the technology to support these initiatives is still in its infancy and it's implementation faces privacy hurdles. Moreover, information about actual interoperability (as opposed to permission to make systems interoperable) is unreliable.
2. *Inter-state sharing of data*: Many PDMPs authorize inter-state sharing of data – either by prescribers obtaining separate logins for other states, or linking of databases (similar to interoperability above). The operationalization of this feature is not yet reliably reported in a centralized way, however.
3. *Prescriber Education to Access PDMP*: Most PDMP laws do not include a provision that

either requires prescribers to be educated on using the PDMP or on controlled substance prescribing in order to access PDMP data. Thus this feature was not included in the analysis.

Table C.1: Prescription Drug Monitoring Policy Features and Robustness Determinations

State	PDMP for Prescribers (eff. date)	Use Mandate (eff. date)	Robust Use Mandate (eff. date)	Registration Mandate (eff. date)	Proactive Reporting (eff.date)	No Prescriber Immunity (eff. date)	Data Updates at Least Weekly (eff. date)	Housed in Health Agency (eff. date)	Monitors Schedule II-IV (eff. date)	Total
States of Study										
Intervention States										
OH	1 (5/18/05)	1 (11/30/11)	1 (11/30/11)	0 (1/1/15)	1 (5/20/11)	0 (5/20/11)	1 (10/27/11)	1 (5/18/05)	1 (8/19/05)	7
KY	1 (7/15/98)	1 (7/20/12)	1 (7/20/12)	1 (7/20/12)	1 (7/13/04)	1	1 (7/31/09)	1 (7/15/98)	1 (7/15/98)	9
NM	1 (7/15/04)	1 (9/28/12)	1 (9/28/12)	1 (8/31/12)	1 (7/15/04)	0	1 (6/11/11)	1 (7/15/04)	1 (7/15/04)	8
TN	1 (1/1/03)	1 (3/26/12)	1 (4/1/13)	1 (1/1/13)	1 (7/1/11)	0 (1/1/03)	1 (1/1/13)	1 (1/1/03)	1 (1/1/03)	9
NY	1 (5/1/01)	1 (8/27/13)	1 (8/27/13)	0	1 (8/27/13)	0 (8/27/13)	1 (8/21/13)	1 (5/1/01)	1 (5/1/01)	7
Control States										
PA	0	0	0	0	0	0	0	0	0	0
MO	0	0	0	0	0	0	0	0	0	0
TX	1 (9/1/81)	0	0	0	0	1	1 (9/1/11)	0	1 (9/1/08)	4
GA	1 (7/1/11)	0	0	0	0	0 (7/11/11)	1 (7/11/11)	0	1 (7/11/11)	3
NJ	1 (8/1/09)	0	0	0	1 (8/1/09)	1	0	0	1 (8/1/09)	4
States Not Included in Study										
AK	1 (9/7/08)	0	0	0	1 (9/7/08)	0 (9/7/08)	0	1 (9/7/08)	1 (9/7/08)	4
AL	1 (8/1/04)	0	0	0	0	1	1 (3/24/06)	1 (8/1/04)	1 (8/1/04)	5
AR	1 (3/1/13)	0	0	0	1 (3/1/13)	1	1 (3/1/13)	1 (3/1/13)	1 (3/1/13)	6
AZ	1 (9/19/07)	0	0	0	1 (9/19/07)	0 (9/19/07)	1 (9/19/07)	1 (9/19/07)	1 (9/19/07)	5

Table C.1: Prescription Drug Monitoring Policy Features and Robustness Determinations (Continued)

State	PDMP for Prescribers (eff. date)	Use Mandate (eff. date)	Robust Use Mandate (eff. date)	Registration Mandate (eff. date)	Proactive Reporting (eff.date)	No Prescriber Immunity (eff. date)	Data Updates at Least Weekly (eff. date)	Housed in Health Agency (eff. date)	Monitors Schedule II-IV (eff. date)	Total
CA	1 (1/1/03)	0	0	1 (1/1/03)	1 (1/1/04)	1	1 (1/1/07)	0	1 (1/1/07)	6
CO	1 (6/3/05)	0	0	0	1 (7/1/12)	1	1 (7/1/12)	1	1 (6/3/05)	6
CT	1 (10/1/06)	0	0	1 (6/21/13)	1 (8/1/07)	1	1 (6/21/13)	0	1 (10/1/06)	6
DE	1 (3/1/12)	1 (3/1/12)	0	1 (1/1/14)	1 (3/1/12)	0 (3/1/12)	1 (3/1/12)	0	1 (3/1/12)	6
FL	1 (7/1/09)	0	0	0	1 (10/1/10)	0 (7/1/09)	1 (7/6/11)	1 (7/1/09)	1 (7/1/09)	5
HI	1 (1/1/98)	0	0	0	1 (1/1/98)	1	1 (1/1/98)	0	0	4
IA	1 (5/31/06)	0	0	0	0	0 (5/31/06)	1 (8/5/09)	1 (5/31/06)	1 (5/31/06)	4
ID	1 (4/4/00)	0	0	0	1 (4/4/20)	0	1 (4/7/11)	1 (4/4/00)	1 (4/4/00)	5
IL	1 (4/1/00)	0	0	0	0	0 (12/9/09)	1 (1/1/08)	1 (4/1/00)	1 (12/9/09)	4
IN	1 (7/1/07)	1 (7/1/14)	0	0	1 (7/1/07)	1 (7/1/07)	1 (7/1/07)	1 (1/1/98)	1 (3/15/00)	7
KS	1 (7/1/08)	0	0	0	0	0 (7/1/08)	1 (10/15/10)	1 (7/1/08)	1 (7/1/08)	4
LA	1 (7/1/06)	1 (6/22/10)	0	0	1 (7/1/06)	0 (8/15/09)	1 (6/22/10)	1 (7/1/06)	1 (7/1/06)	6
ME	1 (9/13/03)	0	0	1 (1/1/14)	1 (9/13/03)	1	1 (6/9/10)	1 (9/13/03)	1 (9/13/03)	7
MD	1 (10/1/11)	0	0	0	1 (1/7/13)	0 (1/7/13)	1 (1/7/13)	1 (10/1/11)	1 (10/1/11)	5
MA	1 (1/1/98)	1 (12/5/14)	1 (12/5/24)	1 (1/1/13)	1 (9/3/10)	1	1 (9/3/10)	1 (1/1/98)	1 (9/3/10)	9
MI	1 (1/3/02)	0	0	0	0	1	1 (12/12/13)	1 (7/20/11)	1 (1/3/02)	5
MN	1 (7/1/07)	1 (8/1/13)	0	0	1 (8/1/13)	0 (7/1/07)	1 (8/1/13)	1 (7/1/07)	1 (7/1/07)	7
MS	1 (6/30/06)	1 (8/16/12)	0	1 (8/16/12)	1 (6/3/12)	1	1 (6/3/12)	1 (6/30/06)	1 (6/30/06)	8
MT	0	0	0	0	1 (7/1/11)	0 (7/1/11)	1 (3/9/12)	1 (7/1/11)	1 (7/1/11)	5

Table C.1: Prescription Drug Monitoring Policy Features and Robustness Determinations (Continued)

State	PDMP for Prescribers (eff. date)	Use Mandate (eff. date)	Robust Use Mandate (eff. date)	Registration Mandate (eff. date)	Proactive Reporting (eff.date)	No Prescriber Immunity (eff. date)	Data Updates at Least Weekly (eff. date)	Housed in Health Agency (eff. date)	Monitors Schedule II-IV (eff. date)	Total
NE	1 (8/27/11)	0	0	0	0	0	1 (8/27/11)	1 (8/27/11)	1 (8/27/11)	4
NV	1 (1/1/98)	1 (10/1/07)	0	0	1 (1/1/98)	0 (10/1/11)	1 (10/31/07)	1 (1/1/98)	1 (1/1/98)	6
NH	1 (6/12/12)	0	0	1 (6/30/15)	1 (6/12/12)	0 (6/12/12)	1 (6/12/12)	1 (6/12/12)	1 (6/12/12)	6
NC	1 (1/1/06)	0	0	0	1 (1/1/06)	0 (6/19/13)	1 (1/2/10)	1 (1/1/06)	1 (1/1/06)	5
ND	1 (4/5/07)	1 (4/1/14)	0	0	1 (4/5/07)	0 (4/5/07)	1 (4/5/07)	1 (4/5/07)	1 (4/5/07)	6
OK	1 (5/15/90)	1 (11/1/10)	0	0	1 (11/1/13)	0 (7/1/09)	1 (7/1/09)	0	1 (5/12/04)	5
OR	1 (7/23/09)	0	0	0	0	0 (7/1/10)	1 (7/1/10)	1 (7/23/09)	1 (7/23/09)	4
RI	1 (5/9/10)	1 (5/9/10)	0	1 (5/27/14)	1 (1/1/98)	1	1 (7/17/14)	1 (1/1/98)	1 (6/24/13)	8
SC	1 (6/14/06)	0	0	0	1 (6/14/06)	0 (6/14/06)	1 (6/6/14)	1 (6/14/06)	1 (6/14/06)	5
SD	1 (7/1/10)	0	0	0	1 (7/1/10)	0 (7/1/10)	1 (7/1/10)	1 (7/1/10)	1 (7/1/10)	5
UT	1 (1/1/95)	0	0	1 (9/30/10)	0	0	1 (5/12/09)	1 (1/1/98)	1 (1/1/98)	5
VT	1 (7/1/06)	1 (5/8/12)	1 (10/1/13)	1 (11/15/13)	1 (7/1/06)	0 (7/1/06)	1 (7/1/08)	1 (7/1/06)	1 (7/1/06)	8
VA	1 (4/1/03)	1 (12/7/11)	0	1 (7/1/15)	1 (7/1/05)	0 (4/1/03)	1 (10/1/10)	1 (4/1/03)	1 (7/1/05)	7
WA	1 (7/22/07)	1 (7/1/13)	0	0	0	0 (7/22/07)	1 (8/27/11)	1 (7/22/07)	1 (7/22/07)	5
WV	1 (9/1/02)	1 (5/16/13)	1 (5/16/13)	1 (5/16/13)	1 (6/8/12)	0 (1/1/98)	1 (9/1/02)	1 (1/1/98)	1 (9/1/02)	8
WI	1 (4/1/13)	0	0	0	1 (4/1/13)	0 (4/1/13)	1 (4/1/13)	1 (4/1/13)	1 (4/1/13)	5
WY	1 (7/1/03)	0	0	0	1 (7/1/03)	0 (7/1/03)	1 (7/1/09)	1 (7/1/03)	1 (7/1/03)	5

Table C.2: Illustrative PDMP Prescriber Use Mandates and Their Reported Potential Effects[1-7]

State (Date Use Mandate Implem-ented)	Circumstances that Require a PDMP Check	Penalties for Failure to Check	Reported Effect
Ohio[††] (Nov. 31, 2011**)**	• Upon initial prescribing of Schedule II-V substances if prescriber has reason to believe treatment will exceed 12 continuous weeks • Annually after the initial prescription for courses of treatment that last beyond 1 year for that patient • If physician believes patient may be abusing or diverting drugs based on enumerated signs, e.g., frequently asking for early refills of reported drugs *Prescribing exceptions*: • Hospice patients	Disciplinary sanctions by licensing board	• Number of PDMP queries rose from 911,000 in 2010 to 1.8 million in 2011, 5.4 million in 2012, 7.4 million in 2013, 10.8 million in 2014, and 16.5 million in 2015 • From 2012 to 2013, number of hydrocodone prescriptions and doses dropped by 11.1%, and 3.5% respectively, and number of oxycodone prescriptions and doses dropped by 8.7% and 1.7%, respectively • Morphine equivalent dose per opioid prescription fell 8% from 2010 (55.5) to 2013 (51) (post-mandate) • Number of individuals prescribed to by ≥ 5 prescribers and filling at ≥ 5 pharmacies in a 3-month period fell from 25 per 100,000 residents in the first quarter of 2010 to ~10 per 100,000 in the last quarter of 2013 (post-mandate)
Kentucky[†] (Jun. 20, 2012)	• Upon initial prescribing or dispensing of any Schedule II substance or Schedule III substance containing hydrocodone • Every 3 months after the initial prescription for courses of treatment that last beyond 3 months for that patient • Before prescribing refills or any additional Schedule II substances or Schedule III substances containing hydrocodone to that patient *Prescribing exceptions*: • issued during an emergency or following surgery • patients in hospitals or long-term care facilities • cancer and end-of-life treatments • single dose treatments to relieve symptoms from a procedure	Disciplinary sanctions by licensing board	• Number of PDMP queries rose as follows: o Pre-mandate: 802,131 in 2011 and ~2.67 million in 2012 o Post-mandate: ~4.55 million in 2013, ~5.00 million in 2014, and ~5.50 million in 2015. • Overall controlled substance dispensing declined from ~7.4 million doses in the year before to ~6.8 million in the year after the mandate

Table C.2: Illustrative PDMP Prescriber Use Mandates and Their Reported Potential Effects[1-7] (Continued)

State (Date Use Mandate Implem-ented)	Circumstances that Require a PDMP Check	Penalties for Failure to Check	Reported Effect
New Mexico[†††] (Sept. 28, 2012)	• Upon initial prescribing or administering any Schedule II-IV for new patients • Every 6 months after the initial prescription during continuous use of opioids for an established patient.	None	• Number of PDMP queries post-mandate increased from ~34,000/month in Jan. 2013 to 60,000 per month in Jan 2014 to 110,000/month in Jan. 2015. (Pre-mandate figures not available.)
Tennessee[†] (Apr. 1, 2013)	• Upon initial prescribing of opioids and benzodiazepines for more than 7 days • Every 12 months after the initial prescription when prescribed controlled substance remains part of the treatment for that patient *Prescribing exceptions*: • hospice patients • issued following surgery (non-refillable) • 7-day supply or less • patients in inpatient or residential settings	Disciplinary sanctions by licensing board	• Number of PDMP queries rose from 124,000/month in 2011 and 155,000/month in 2012 (pre-mandate) to 415,000/month in 2013 (post-mandate) • Number of opioid prescriptions fell from 1.6 million to 1.5 million and morphine milligram equivalents dispensed dropped 6% from August 2012 to July 2013 • Number of individuals prescribed to by ≥ 5 prescribers and filling at ≥ 5 pharmacies in a 3-month period fell 36% from August–October 2012 to May–July 2013
New York (Aug. 27, 2013)	• Prior to prescribing or dispensing any Schedule II-IV substance *Prescribing exceptions*: • practitioner-administered controlled substances • issued in emergency department (5-day supply or less) • hospice patients • when it is not reasonably practicable to access the registry in a timely manner or registry consultation would adversely impact a patient's medical condition	Fine up to $2,000, up to 1 year in jail, and/or professional misconduct charges that can result in permanent revocation of license	• Number of PDMP queries rose from 11,000/*month* in the 3.5 years pre-mandate to 42,300/*day* in the 6 months post-mandate • Number of individuals prescribed to by ≥ 5 prescribers and filling at ≥ 5 pharmacies in a 3-month period fell by 75%, and number of opioid prescriptions and individuals with opioid prescriptions fell by 9.5% from the fourth quarter 2012 to the fourth quarter 2013 (post-mandate)

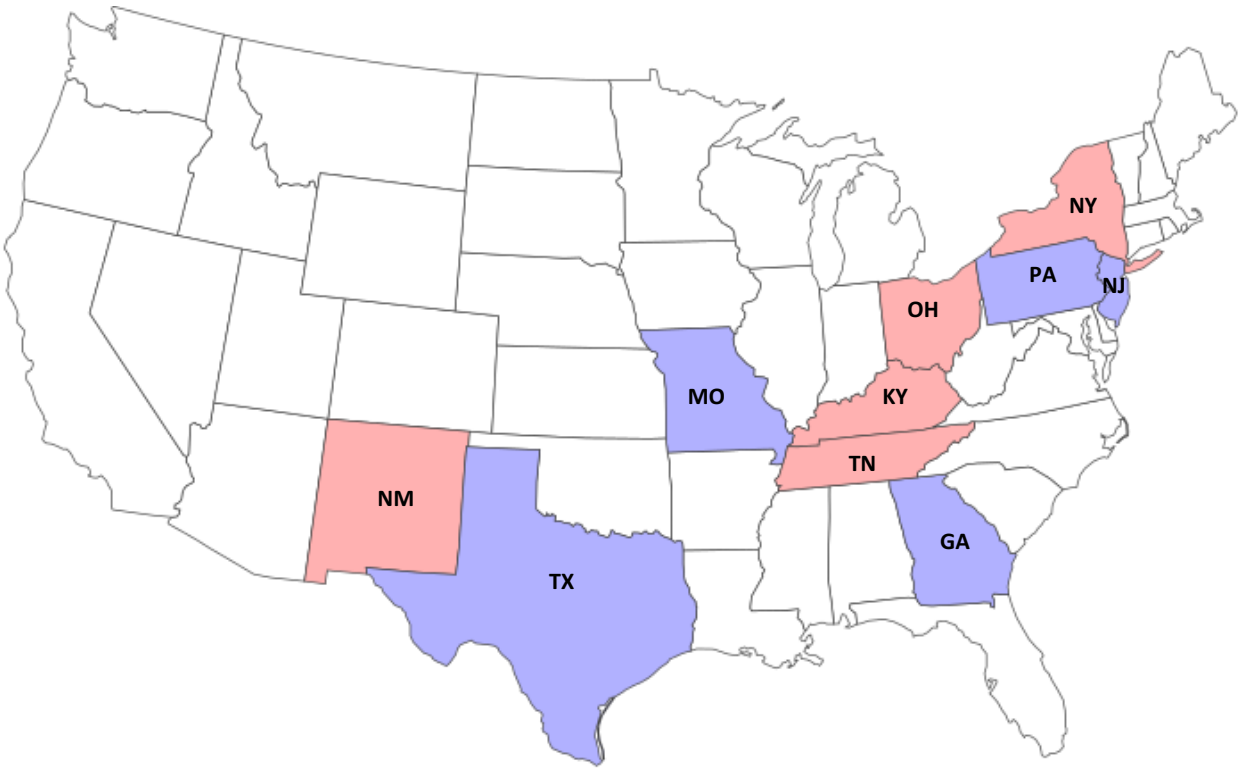
[†] Kentucky and Tennessee also implemented, in the same timeframe, PDMP enrollment mandates, to which they ascribe significant increases in registered users. Kentucky's enrollment mandate took effect the same date as the use mandate on Jun. 7, 2012. Tennessee's enrollment mandate took effect on Jan. 1, 2013.

[††] In June 2014, Ohio passed additional, more objective PDMP use mandate requirements in addition to a registration mandate, effective April 1, 2015.

[†††]New Mexico also requires that prescribers undergo training on how to use the PDMP as of Aug. 31, 2012.

We selected as comparison jurisdictions neighboring states with four or less of the nine robust PDMP features that had comparable trends (i.e., no more than twice or ½ the magnitude of the intervention states) and parallel levels in at least one of the main outcomes of interest during the preimplementation period: Pennsylvania (for Ohio), Missouri (for Kentucky), Texas (for New Mexico), Georgia (for Tennessee), and New Jersey (for New York) (Table C.1). A map of the sets of intervention and comparator states is shown in Figure C.1.

Figure C.1: Map of Intervention States (Pink) and Comparison States (Blue)



C.1.2 Statistical Adjustment Methods

Before implementing the segmented regression models to generate our policy effect estimates, we used marginal effects methods to calculate adjusted outcome rates in each set of state comparators in order to control for differences in individual characteristics during the course of the study and between state comparator sets. We used generalized estimating

equations with a binomial distribution and a logit link function to model whether individuals filled opioid prescriptions (and later multiplied these adjusted outcome rates by 100 to analyze the percent of enrollees filling opioid prescriptions), adjusting for age, gender, race/ethnicity, education-level, and enrollment span. Mean morphine equivalent dosages dispensed per enrollee per quarter and mean prescribers and pharmacies used to fill opioid prescriptions were adjusted using the same model, except we used GEEs with a negative binomial distribution and a log link function for these outcomes. We used exchangeable correlation structures for all adjustment models to account for potential autocorrelation between observations within individuals. The generalized estimating equation took the following form:

$$Y_i = \beta_0 + \beta_1 * time_i + \beta_2 * T_i + \beta_3 * T_i * time_i + \beta_4 X_i + e_i$$

Where:

i =individual identifier

Y_{it} = dependent variable for individual at time t (e.g., MED dispensed/enrollee)

T_i = indicator variable for treatment (intervention vs. control state)

$time_i$ = count variable for time (in quarters)

X_i= a vector of individual characteristics

We present the coefficients for the individual characteristics only for the main outcome models in Tables C.3 and C.4. These results reveal that for most models, individual characteristics were significantly predictive of whether an individual filled opioid prescriptions and of the mean MED dispensed, and therefore appropriate to adjust for to generate population-level outcome estimates prior to implementing our population-level segmented regression results. Consistent with the literature, we found white race, female gender, and

older age to be associated with higher rates in our main outcomes of mean MED dispensed per enrollee and whether an enrollee was filling opioid prescriptions (Tables C.3 and C.4). We also found that education above a 12 grade level to be associated with higher rates in these outcomes, however this may be reflective of the fact that we were studying an adult population (Tables C.3 and C.4).

Table C.3: Coefficients from Generalized Estimating Equations Models for Percent of Enrollees Filling Per Quarter[1]

Covariate	OH vs. PA		KY vs. MO		NM vs. TX		TN vs. GA		NY vs. NJ	
	Coeff.	*p-value*	*Coeff.*	*p-value*	*Coeff.*	*p-value*	*Coeff.*	*p-value*	*Coeff.*	*p-value*
Intercept	-4.48	0.00	-4.10	0.00	-3.75	0.00	-3.96	0.00	-4.79	0.00
Female	0.28	0.00	0.30	0.00	0.38	0.00	0.30	0.00	0.19	0.00
Age	0.02	0.00	0.02	0.00	0.02	0.00	0.02	0.00	0.02	0.00
Race/ethnicity										
White (ref)	—	—	—	—		—	—	—	—	—
Black	0.03	0.00	-0.04	0.00	-0.07	0.00	-0.12	0.00	-0.21	0.00
Asian	-0.58	0.00	-0.52	0.00	-0.77	0.00	-0.84	0.00	-0.80	0.00
Hispanic	-0.10	0.00	-0.13	0.00	-0.33	0.00	-0.59	0.00	-0.17	0.00
Education										
<12 grade(ref)		—	—	—		—	—	—	—	—
High School	0.93	0.00	0.85	0.00	0.51	0.00	0.73	0.00	1.20	0.00
<Bachelor's	0.70	0.00	0.66	0.00	0.42	0.00	0.59	0.00	1.12	0.00
≥Bachelor	0.38	0.00	0.33	0.00	0.15	0.00	0.29	0.00	0.87	0.00
Enrollment span	0.00	0.00	0.00	0.88	0.00	0.00	0.00	0.00	0.00	0.00
Quarter										
1 (ref)			—	—	—	—	—	—	—	—
2	0.01	0.48	0.02	0.04	0.03	0.00	0.02	0.00	0.03	0.03
3	0.01	0.36	0.01	0.21	0.03	0.00	0.02	0.00	0.00	0.98
4	0.03	0.05	0.03	0.00	0.03	0.00	0.05	0.00	0.01	0.32
5	-0.02	0.13	-0.02	0.06	0.00	0.75	-0.03	0.00	0.00	0.78
6	0.01	0.35	0.01	0.10	0.01	0.17	-0.02	0.00	-0.02	0.18
7	-0.02	0.27	0.02	0.05	0.02	0.00	-0.02	0.00	-0.03	0.03
8	0.01	0.37	0.04	0.00	0.03	0.00	0.01	0.01	0.01	0.70
9	0.01	0.58	0.01	0.13	0.03	0.00	-0.05	0.00	0.01	0.48
10	0.00	0.91	0.03	0.00	0.03	0.00	-0.04	0.00	-0.01	0.48
11	-0.02	0.15	0.02	0.01	0.03	0.00	-0.07	0.00	-0.03	0.06
12	0.02	0.29	0.04	0.00	0.05	0.00	-0.02	0.00	-0.03	0.06
13	-0.01	0.34	-0.01	0.34	0.00	0.43	-0.10	0.00	-0.05	0.00
14	-0.05	0.00	0.00	0.65	0.00	0.36	-0.09	0.00	-0.05	0.00
15	-0.04	0.00	0.00	0.76	0.01	0.23	-0.11	0.00	-0.07	0.00
16	-0.04	0.01	0.02	0.01	0.01	0.01	-0.05	0.00	-0.03	0.05
17	-0.06	0.00	0.00	0.66	-0.03	0.00	-0.17	0.00	-0.10	0.00
18	-0.04	0.00	0.01	0.32	0.00	0.39	-0.15	0.00	-0.08	0.00
19	-0.10	0.00	-0.04	0.00	-0.04	0.00	-0.21	0.00	-0.19	0.00
20	-0.09	0.00	-0.05	0.00	-0.11	0.00	-0.19	0.00	-0.15	0.00

Table C.3: Coefficients from Generalized Estimating Equations Models for Percent of Enrollees Filling Per Quarter[1] (continued)

Covariate	OH vs. PA		KY vs. MO		NM vs. TX		TN vs. GA		NY vs. NJ	
	Coeff.	*p-value*	*Coeff.*	*p-value*	*Coeff.*	*p-value*	*Coeff.*	*p-value*	*Coeff.*	*p-value*
Intervention state	0.28	0.00	0.15	0.00	0.01	0.00	0.17	0.00	-0.11	0.00
Quarter										
1 (ref)	—	—	—	—	—	—	—	—	—	—
2	0.01	0.54	0.01	0.57	0.00	0.83	-0.02	0.06	-0.03	0.11
3	0.01	0.44	0.00	0.80	0.04	0.11	0.01	0.40	-0.03	0.11
4	0.02	0.15	0.00	0.84	0.00	0.97	-0.05	0.00	-0.03	0.06
5	0.03	0.07	0.02	0.18	0.05	0.02	0.02	0.08	-0.01	0.77
6	-0.01	0.48	-0.04	0.05	0.00	0.95	0.00	0.85	-0.01	0.70
7	0.02	0.16	0.00	0.89	0.00	0.88	0.01	0.28	-0.01	0.65
8	0.02	0.18	-0.01	0.73	0.01	0.56	-0.02	0.13	-0.04	0.05
9	-0.01	0.71	0.01	0.68	0.00	0.92	0.05	0.00	-0.01	0.48
10	0.00	0.80	-0.01	0.67	-0.04	0.05	0.03	0.04	-0.02	0.30
11	0.00	0.84	-0.10	0.00	-0.07	0.00	0.05	0.00	-0.04	0.04
12	0.00	0.89	-0.13	0.00	-0.07	0.00	-0.01	0.45	-0.04	0.04
13	-0.03	0.11	-0.15	0.00	-0.02	0.48	0.02	0.06	-0.01	0.50
14	0.02	0.33	-0.18	0.00	-0.12	0.00	0.00	0.74	-0.04	0.04
15	0.01	0.65	-0.17	0.00	-0.08	0.00	0.00	0.73	-0.09	0.00
16	0.04	0.03	-0.19	0.00	-0.13	0.00	-0.04	0.00	-0.10	0.00
17	-0.02	0.25	-0.19	0.00	-0.10	0.00	0.04	0.00	-0.08	0.00
18	-0.02	0.28	-0.20	0.00	-0.14	0.00	0.03	0.03	-0.09	0.00
19	0.00	0.98	-0.18	0.00	-0.13	0.00	0.07	0.00	-0.09	0.00
20	0.00	0.93	-0.15	0.00	-0.08	0.00	0.06	0.00	-0.07	0.00

[1]Generalized estimating equations models were adjusted for age, gender, race/ethnicity, education level, and enrollment span.

Table C.4: Coefficients from Generalized Estimating Equations Models for Mean Morphine Equivalent Dosage (MED) Dispensed Per Enrollee Per Quarter[1]

Covariate	OH vs. PA		KY vs. MO		NM vs. TX		TN vs. GA		NY vs. NJ	
	Coeff.	*p-value*	*Coeff.*	*p-value*	*Coeff.*	*p-value*	*Coeff.*	*p-value*	*Coeff.*	*p-value*
Intercept	1.47	0.00	1.27	0.00	1.25	0.00	1.61	0.00	0.96	0.00
Female	0.06	0.00	0.16	0.00	0.31	0.00	-0.02	0.00	-0.18	0.00
Age	0.06	0.00	0.06	0.00	0.06	0.00	0.06	0.00	0.06	0.00
Race/ethnicity										
White (ref)	—	—	—	—	—	—	—	—	—	—
Black	-0.16	0.00	-0.35	0.00	-0.41	0.00	-0.49	0.00	-0.58	0.00
Asian	-1.24	0.00	-1.15	0.00	-1.45	0.00	-1.29	0.00	-1.59	0.00
Hispanic	-0.34	0.00	-0.23	0.00	-0.73	0.00	-0.94	0.00	-0.42	0.00
Education										
<12 grade(ref)	—	—	—	—	—	—	—	—	—	—
High School	0.69	0.00	0.74	0.00	0.65	0.00	0.60	0.00	1.46	0.00
<Bachelor's	0.35	0.00	0.50	0.00	0.64	0.00	0.46	0.00	1.42	0.00
≥Bachelor	-0.18	0.00	0.01	0.07	0.22	0.00	-0.10	0.00	0.72	0.00
Enrollment span	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Quarter										
1 (ref)	—	—	—	—	—	—	—	—	—	—
2	0.07	0.00	0.05	0.00	0.05	0.00	0.05	0.00	0.11	0.00
3	0.10	0.00	0.10	0.00	0.08	0.00	0.08	0.00	0.12	0.00
4	0.14	0.00	0.08	0.00	0.06	0.00	0.07	0.00	0.08	0.00
5	0.07	0.00	-0.02	0.00	-0.04	0.00	-0.09	0.00	0.05	0.00
6	0.11	0.00	0.03	0.00	-0.02	0.00	-0.05	0.00	0.13	0.00
7	0.13	0.00	0.07	0.00	0.03	0.00	-0.01	0.00	0.11	0.00
8	0.15	0.00	0.12	0.00	0.07	0.00	0.03	0.00	0.16	0.00
9	0.09	0.00	0.09	0.00	0.03	0.00	-0.04	0.00	0.10	0.00
10	0.10	0.00	0.12	0.00	0.06	0.00	-0.01	0.00	0.12	0.00
11	0.10	0.00	0.14	0.00	0.08	0.00	-0.02	0.00	0.15	0.00
12	0.19	0.00	0.20	0.00	0.12	0.00	0.04	0.00	0.19	0.00
13	0.11	0.00	0.12	0.00	0.03	0.00	-0.04	0.00	0.13	0.00
14	0.10	0.00	0.15	0.00	0.06	0.00	-0.01	0.00	0.15	0.00
15	0.13	0.00	0.16	0.00	0.09	0.00	0.00	0.07	0.16	0.00
16	0.14	0.00	0.18	0.00	0.10	0.00	0.05	0.00	0.19	0.00
17	0.04	0.00	0.15	0.00	0.04	0.00	-0.08	0.00	0.14	0.00
18	0.05	0.00	0.17	0.00	0.09	0.00	-0.04	0.00	0.15	0.00
19	0.07	0.00	0.16	0.00	0.10	0.00	-0.05	0.00	0.10	0.00
20	0.13	0.00	0.23	0.00	0.07	0.00	-0.07	0.00	0.13	0.00

Table C.4: Coefficients from Generalized Estimating Equations Models for Mean Morphine Equivalent Dosage (MED) Dispensed Per Enrollee Per Quarter[1] (continued)

Covariate	OH vs. PA		KY vs. MO		NM vs. TX		TN vs. GA		NY vs. NJ	
	Coeff.	*p-value*	*Coeff.*	*p-value*	*Coeff.*	*p-value*	*Coeff.*	*p-value*	*Coeff.*	*p-value*
Intervention state	0.10	0.00	0.21	0.00	0.51	0.00	0.41	0.00	-0.28	0.00
Quarter										
1 (ref)	—	—	—	—	—	—	—	—	—	—
2	-0.03	0.00	-0.02	0.00	0.03	0.00	-0.02	0.00	-0.10	0.00
3	-0.04	0.00	-0.03	0.00	0.02	0.00	-0.02	0.00	-0.06	0.00
4	-0.07	0.00	0.01	0.00	0.03	0.00	-0.03	0.00	0.02	0.00
5	-0.12	0.00	0.04	0.00	0.10	0.00	0.00	0.61	-0.01	0.00
6	-0.13	0.00	0.05	0.00	0.13	0.00	0.02	0.00	-0.03	0.00
7	-0.12	0.00	0.07	0.00	0.10	0.00	0.03	0.00	0.02	0.00
8	-0.12	0.00	0.07	0.00	0.06	0.00	0.03	0.00	0.04	0.00
9	-0.14	0.00	0.04	0.00	0.05	0.00	0.05	0.00	0.07	0.00
10	-0.14	0.00	0.04	0.00	0.05	0.00	0.02	0.00	0.04	0.00
11	-0.15	0.00	-0.01	0.04	-0.01	0.02	0.06	0.00	0.00	0.09
12	-0.21	0.00	-0.09	0.00	0.04	0.00	0.06	0.00	0.02	0.00
13	-0.25	0.00	-0.14	0.00	0.11	0.00	-0.01	0.00	-0.01	0.02
14	-0.23	0.00	-0.17	0.00	0.03	0.00	-0.03	0.00	-0.02	0.00
15	-0.26	0.00	-0.14	0.00	0.02	0.00	-0.05	0.00	-0.04	0.00
16	-0.26	0.00	-0.14	0.00	0.00	0.78	-0.08	0.00	-0.03	0.00
17	-0.29	0.00	-0.21	0.00	-0.09	0.00	-0.04	0.00	-0.09	0.00
18	-0.28	0.00	-0.23	0.00	-0.12	0.00	-0.06	0.00	-0.09	0.00
19	-0.30	0.00	-0.21	0.00	-0.22	0.00	-0.07	0.00	-0.05	0.00
20	-0.33	0.00	-0.25	0.00	-0.11	0.00	-0.03	0.00	-0.04	0.00

[1]Generalized estimating equations models were adjusted for age, gender, race/ethnicity, education level, and enrollment span.

C.2 Secondary Outcomes

In the preimplementation period, the trends in at least one of our secondary outcomes of interest, mean number of pharmacies and prescribers used to fill opioid prescriptions per 100 enrollees per quarter, were parallel for all sets of state comparators (i.e., not statistically significantly different at the $p<0.05$ level), except for Tennessee versus Georgia (Tables C.5 and C.6, Figures C.2 and C.3). Although preimplementation levels were typically statistically significantly different between comparator states (Tables C.5 and C.6), no state had more than double the level of its comparator state in these outcome rates—and most level differences were quite small relative to the magnitude of the smaller of these state levels (i.e., 30% or less)

(Figures C.2 and C.3). Intervention states typically exhibited higher levels than control states in the preimplementation period, albeit the reverse was true for New York versus New Jersey.

Table C.5: Effect of Robust State PDMPs on Mean Number of Pharmacies Used to Fill Opioid Prescriptions Per 100 Enrollees per Quarter[1]

		Difference Between Intervention and Control States			
Comparator States	Variable	Pre-Implementation, No.	Policy Effect, No. (Pre- to Post-Implementation	Absolute in Q4 of 2014, No. (95% CI)	Relative in Q4 of 2014, % (95% CI)
a. OH vs. PA	Level	3.67***	—	-0.64(-0.86,-0.42)	-17.43(-23.23,-11.64)
	Trend	—	-0.05***		
b. KY vs. MO	Level	2.91***	-2.28***	-2.85(-3.19,-2.50)	-97.74(-108.34,-87.13)
	Trend	—	-0.06†		
c. NM vs. TX	Level	0.99***	-0.53†	-0.53(-1.11,0.05)	1258.76 (-22126.80,24644.33)
	Trend	-0.05†	—		
d. TN vs. GA	Level	3.04***	-0.73*	-0.73(-1.25,-0.22)	-17.04(-27.16,-6.93)
	Trend	0.06**	—		
e. NY vs. NJ	Level	-1.11***	-0.49***	0.02(-0.15,0.20)	-1.54(-14.31,11.24)
	Trend	-0.01*	0.10***		

Abbreviations: PDMP, prescription drug monitoring program; Q4, fourth calendar quarter.

[1]Segmented time-series regression models adjusted for baseline trend, and changes in trend and level; we eliminated any of these predictors if they were non-significant at the p<0.2 level. Generalized estimating equations models were used to generate population quarterly outcome rates, adjusted for age, gender, race/ethnicity, education level, and enrollment span, prior to implementing the segmented time-series regression models.

† p<0.1 ** p<0.01

* p<0.05 *** p<0.001

Table C.6: Effect of Robust State PDMPs on Mean Number of Prescribers Used to Fill Opioid Prescriptions Per 100 Enrollees per Quarter[1]

		Difference Between Intervention and Control States			
Comparator States	Variable	Pre-Implementation, No.	Policy Effect, No. (Pre- to Post-Implementation	Absolute in Q4 of 2014, No. (95% CI)	Relative in Q4 of 2014, % (95% CI)
a. OH vs. PA	Level	3.57***	—	-0.43(-0.64,-0.22)	-12.02(-17.73,-6.32)
	Trend	—	-0.04***		
b. KY vs. MO	Level	3.34***	-2.58***	-3.19(-3.57,-2.81)	-95.43(-105.55,-85.32)
	Trend	—	-0.07†		
c. NM vs. TX	Level	1.35***	-0.64†	-0.64(-1.28,0.01)	422.75 (-2264.55,3110.05)
	Trend	-0.07*	—		
d. TN vs. GA	Level	2.62***	-1.03**	-1.03(-1.62,-0.44)	-22.38(-32.47,-12.28)
	Trend	0.10***	—		
e. NY vs. NJ	Level	-1.41***	-0.65***	-0.19(-0.42,0.04)	15.51(-5.04,36.06)
	Trend	0.01	0.09*		

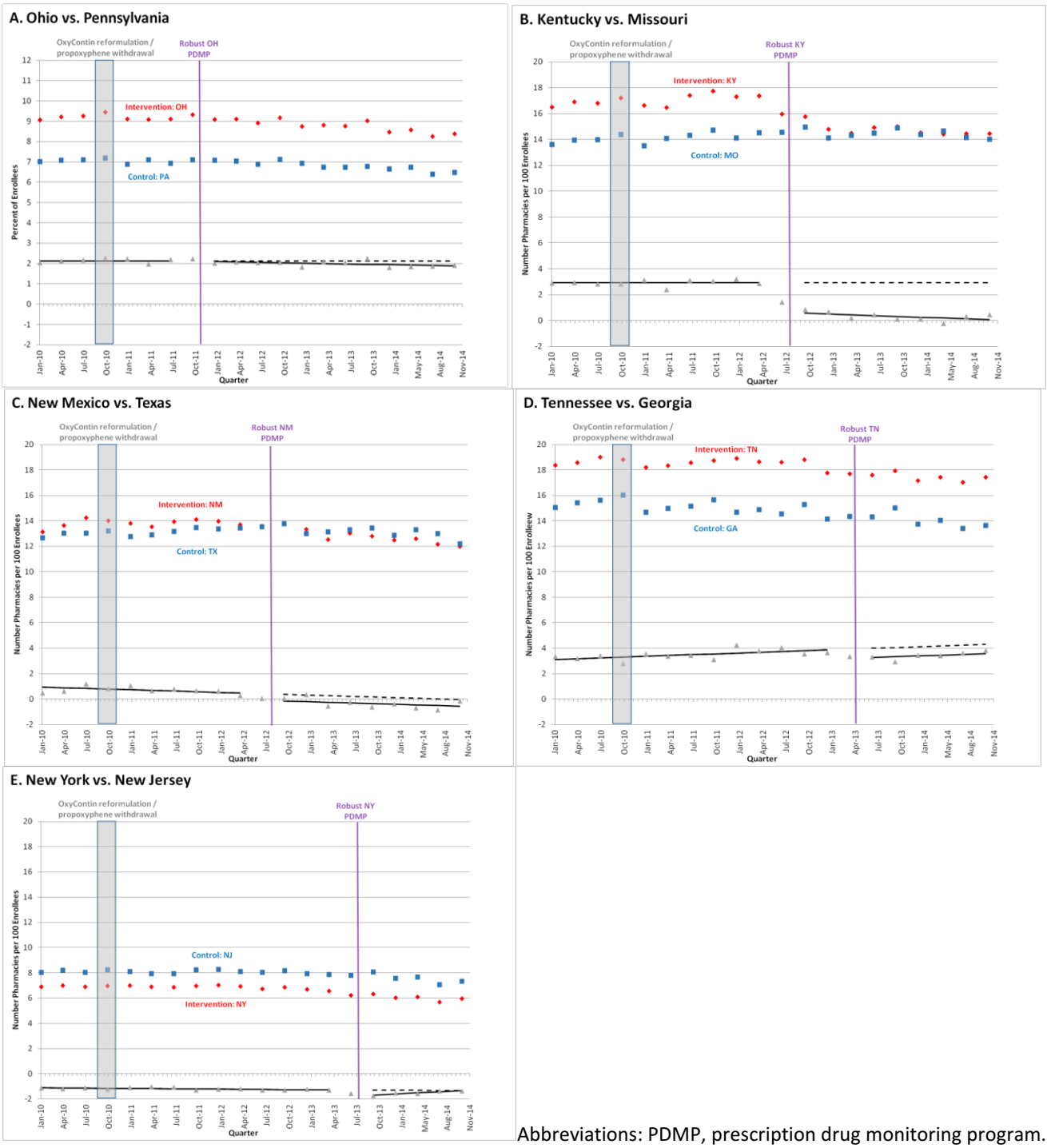
Abbreviations: PDMP, prescription drug monitoring program; Q4, fourth calendar quarter.

[1]Segmented time-series regression models adjusted for baseline trend, and changes in trend and level; we eliminated any of these predictors if they were non-significant at the p<0.2 level. Generalized estimating equations models were used to generate population quarterly outcome rates, adjusted for age, gender, race/ethnicity, education level, and enrollment span, prior to implementing the segmented time-series regression models.

† p<0.1 ** p<0.01

* p<0.05 *** p<0.001

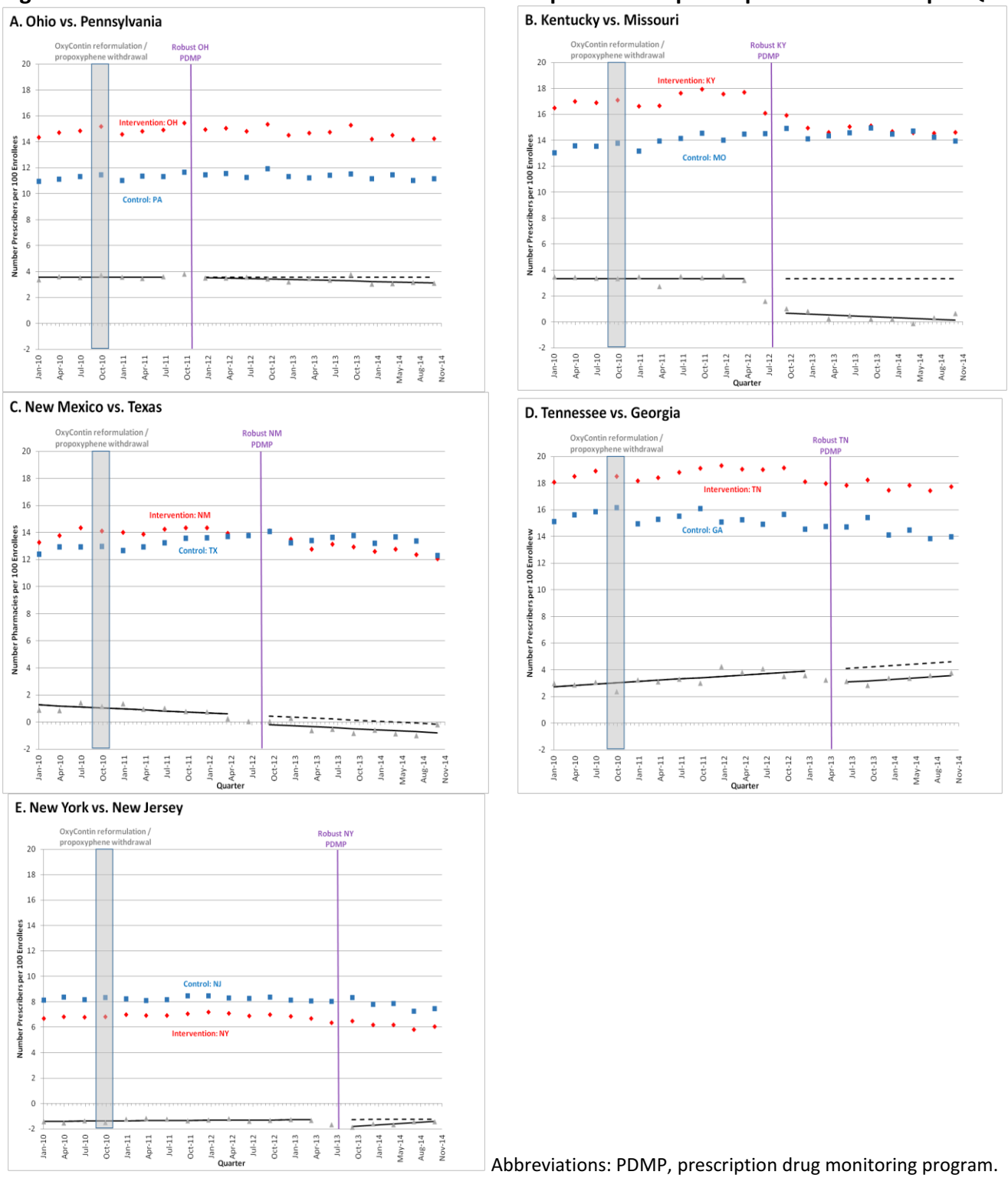
Figure C.2: Mean Number of Pharmacies Used to Fill Opioid Prescriptions per 100 Enrollees per Quarter



Abbreviations: PDMP, prescription drug monitoring program.

A fitted regression line shows the difference between treatment and control states in the baseline period and continues as a predicted regression line in the follow-up period, after robust PDMP implementation in the intervention state. A separate fitted regression line was calculated using population-level interrupted time series linear models for the outcome of interest (adjusted for individual age, gender, race/ethnicity, education level, and enrollment at each quarter using the STATA margins command).

Figure C.3: Mean Number of Prescribers Used to Fill Opioid Prescriptions per 100 Enrollees per Quarter



Abbreviations: PDMP, prescription drug monitoring program.

A fitted regression line shows the difference between treatment and control states in the baseline period and continues as a predicted regression line in the follow-up period, after robust PDMP implementation in the intervention state. A separate fitted regression line was calculated using population-level interrupted time series linear models for the outcome of interest (adjusted for individual age, gender, race/ethnicity, education level, and enrollment at each quarter using the STATA margins command).

Relative to enrollees in control states, the mean number of pharmacies used to fill opioid prescriptions per 100 enrollees per quarter modestly but statistically significantly declined in trend in one of the five states (Ohio: -0.05, p<0.001) and in level in three of the five intervention states: Kentucky (-2.28, p<0.001), Tennessee (-0.73, p=0.01) and New York (-0.49, p<0.001) (Table C.5). Declines in levels along this outcome in New York were not maintained, however, as the corresponding trends significantly increased in the postimplementation period relative to New Jersey (0.10, p<0.001) (Table C.5). By the end of the study period (i.e., fourth quarter of 2014), Kentucky exhibited the largest declines in this outcome relative to its control, or an absolute decrease of 2.85 pharmacies (-3.19, -2.50) and a relative decrease of 97.74% (-108.34%, -87.13%) (Table C.5).

Results for the mean number of pharmacies and prescribers used to fill opioid prescriptions per 100 enrollees per quarter were very similar. Relative to enrollees in control states, the mean number of prescriber used to fill opioid prescriptions per 100 enrollees per quarter modestly but statistically significantly declined in trend in one of the five states (Ohio: -0.04, p<0.001) and in level in three of the five intervention states: Kentucky (-2.58, p<0.001), Tennessee (-1.03, p=0.003) and New York (-0.65, p<0.001) (Table C.6). Declines in levels along this outcome in New York were not maintained, however, as the corresponding trends significantly increased in the postimplementation period relative to New Jersey (0.09, p=0.01) (Table C.6). By the end of the study period (i.e., fourth quarter of 2014), Kentucky exhibited the largest declines in this outcome relative to its control, or an absolute decrease of 3.19 prescribers (-3.57, -2.81) and a relative decrease of 95.43% (-105.55%, -85.32%) (Table C.6).

Figures C.2 and C.3 display the fitted trends reflected in the segmented regression estimates above. They demonstrate the general pattern of decreased levels in the number of pharmacies and prescribers used to fill opioid prescriptions per 100 enrollees per quarter in the intervention states relative to the control states in the postimplementation period, with changes of the greatest magnitude occurring in Kentucky relative to Missouri.

C.3 Sensitivity Analyses

To determine whether patients entering or leaving the study population biased our main analyses, we conducted a sensitivity analysis on a closed cohort of patients continuously enrolled from at least 1 year preimplementation to 1 year postimplementation of the robust PDMP in each intervention state in the respective sets of study states. We hypothesized that that reductions in the outcomes of interest would be smaller in magnitude for a continuously enrolled cohort, as compared to a non-continuously enrolled one studied in our main analysis, because those using opioids at high rates who may be affected by robust PDMPs are less likely to have stability in private health insurance coverage and employment.

For this continuously enrolled cohort, we modeled outcomes for the same five sets of intervention and comparison states using quarterly interrupted time series analyses. We adjusted for comorbidity, in addition to enrollee age, gender, race/ethnicity, education-level, and enrollment span in our marginal effects regression analyses. When using GEEs to model rates of MEDs, pharmacies, and prescribers used for opioid fills, we used a poisson distribution and a log link function, instead of a negative binomial distribution because the latter failed to converge. We otherwise used the same statistical and design approaches for the main analysis in this sensitivity analysis.

In the preimplementation period, the trends in our four outcomes of interest (percent of enrollees filling opioid prescriptions per quarter, mean MED dispensed per enrollee per quarter, and mean pharmacies and prescribers used to fill opioid prescriptions per 100 enrollees per quarter) were generally parallel. A handful of exception include: New York versus New Jersey for all outcomes except the mean MED outcome; Ohio versus Pennsylvania for the mean MED and mean number of prescribers outcomes; and Tennessee versus Georgia for the mean MED outcome (Tables C.7-C.10). Preimplementation levels were typically statistically significantly different between comparator states (Tables C.7-C.10), but no state had more than double the level of its comparator state in any outcome rates during this period (Figures C.4-C.7) and most levels were substantially smaller than double. Intervention states typically exhibited higher levels than control states in the preimplementation period, although there were several instances where the control jurisdiction exhibited higher preimplementation rates than the intervention (e.g., New York versus New Jersey).

As compared to the main analyses, results for this sensitivity analysis were generally consistent across all outcomes, albeit reductions were more consistent across intervention states and greater in relative magnitude in this sensitivity analysis. All five intervention states experienced reductions postimplementation of a robust PDMP in either level (Ohio) or trend (Kentucky, New York, New Mexico, and Tennessee) for the outcomes of percent of enrollees filling opioid prescriptions (relative reductions of over 150% in Kentucky and New Mexico by Q4 of 2014) and the number of pharmacies and prescribers used to fill such prescriptions (relative reductions of 132% and 110%, respectively, in Kentucky by Q4 of 2014) (Tables C.7-C.10). Reductions exhibited in New York in the number of prescribers and pharmacies used to fill

opioid prescriptions were not sustained through the end of the follow-up period. For the mean MED dispensed per enrollee per quarter, we found significant reductions in level in three states (Kentucky, Tennessee, and New York) and in the trend in three states (Ohio, Kentucky and Tennessee). This resulted in some significant absolute and relative reductions in MEDs dispensed per enrollee per quarter, such as of 33.47 MEDs (625.31% [-887.48%, -363.13%] relative reduction) in Kentucky and 31.22 MEDs (56.24% [-64.94%,-47.54%] in Tennessee.

Table C.7: Effect of Robust State PDMPs on Percent of Enrollees Filling Opioid Prescriptions per Quarter (Sensitivity Analysis)[1]

Comparator States	Variable	Difference Between Intervention and Control States			
		Pre-Implementation, %	Policy Effect, % (Pre- to Post-Implementation	Absolute in Q4 of 2014, % (95% CI)	Relative in Q4 of 2014, % (95% CI)
a. OH vs. PA	Level	2.18***	—	-0.54(-0.66,-0.42)	-24.70(-29.64,-19.76)
	Trend	—	-0.04***		
b. KY vs. MO	Level	0.78***	-1.23***	-1.23(-1.40,-1.07)	-157.39(-175.04,-139.74)
	Trend	—	—		
c. NM vs. TX	Level	0.43**	-0.67***	-0.67(-0.98,-0.36)	-154.98(-214.15,-95.81)
	Trend	—	—		
d. TN vs. GA	Level	1.04***	-0.30*	-0.30(-0.53,-0.07)	-28.59(-48.38,-8.81)
	Trend	—	—		
e. NY vs. NJ	Level	-0.56***	-0.19**	-0.01(-0.11,0.09)	1.30(-11.70,14.30)
	Trend	-0.01***	0.04†		

Abbreviations: PDMP, prescription drug monitoring program; Q4, fourth calendar quarter.

[1]Segmented time-series regression models adjusted for baseline trend, and changes in trend and level; we eliminated any of these predictors if they were non-significant at the p<0.2 level. Generalized estimating equations models were used to generate population quarterly outcome rates, adjusted for age, gender, race/ethnicity, education level, and enrollment span, prior to implementing the segmented time-series regression models.

† p<0.1 ** p<0.01

* p<0.05 *** p<0.001

Table C.8: Effect of Robust State PDMPs on Mean Morphine Equivalent Dosage Dispensed per Enrollee per Quarter (Sensitivity Analysis)[1]

Comparator States	Variable	Difference Between Intervention and Control States			
		Pre-Implementation, MED	Policy Effect, MED (Pre- to Post-Implementation	Absolute in Q4 of 2014, MED (95% CI)	Relative in Q4 of 2014, % (95% CI)
a. OH vs. PA	Level	27.18***	—	-15.06(-28.21,-1.91)	138.37(-129.73,406.47)
	Trend	-1.90***	-1.26***		
b. KY vs. MO	Level	5.35***	-19.59***	-33.47(-38.95,-28.00)	-625.31(-887.48,-363.13)
	Trend	—	-1.54***		
c. NM vs. TX	Level	76.03***	-6.88	-20.66(-28.53,-12.79)	-27.18(-37.01,-17.35)
	Trend	—	-1.53†		
d. TN vs. GA	Level	22.46***	-12.19**	-31.22(-38.28,-24.17)	-56.24(-64.94,-47.54)
	Trend	1.65***	-3.17***		
e. NY vs. NJ	Level	-14.99***	-7.04**	-7.04(-11.41,-2.67)	34.63(6.56,62.70)
	Trend	-0.27	—		

Abbreviations: PDMP, prescription drug monitoring program; Q4, fourth calendar quarter.
[1]Segmented time-series regression models adjusted for baseline trend, and changes in trend and level; we eliminated any of these predictors if they were non-significant at the p<0.2 level. Generalized estimating equations models were used to generate population quarterly outcome rates, adjusted for age, gender, race/ethnicity, education level, and enrollment span, prior to implementing the segmented time-series regression models.
† p<0.1 ** p<0.01
* p<0.05 *** p<0.001

Table C.9: Effect of Robust State PDMPs on Mean Number of Pharmacies Used to Fill Opioid Prescriptions Per 100 Enrollees per Quarter (Sensitivity Analysis)[1]

Comparator States	Variable	Difference Between Intervention and Control States			
		Pre-Implementation, No.	Policy Effect, No. (Pre- to Post-Implementation	Absolute in Q4 of 2014, No. (95% CI)	Relative in Q4 of 2014, % (95% CI)
a. OH vs. PA	Level	3.98***	—	-1.14(-1.29,-0.99)	-28.62(-31.99,-25.24)
	Trend	—	-0.09***		
b. KY vs. MO	Level	2.01***	-2.03***	-2.66(-3.13,-2.19)	-132.11(-153.08,-111.13)
	Trend	—	-0.07		
c. NM vs. TX	Level	1.86***	-1.01***	-1.01(-1.40,-0.63)	-54.57(-70.90,-38.25)
	Trend	—	—		
d. TN vs. GA	Level	2.10***	-0.31*	-0.31(-0.56,-0.06)	-14.58(-25.95,-3.20)
	Trend	—	—		
e. NY vs. NJ	Level	-0.84***	-0.24**	0.21(0.15,0.31)	-14.05(-20.36,-7.73)
	Trend	-0.03***	0.09**		

Abbreviations: PDMP, prescription drug monitoring program; Q4, fourth calendar quarter.
[1]Segmented time-series regression models adjusted for baseline trend, and changes in trend and level; we eliminated any of these predictors if they were non-significant at the p<0.2 level. Generalized estimating equations models were used to generate population outcome rates in state comparators, adjusted for age, gender, race/ethnicity, education level, and enrollment span, before implementing the segmented time-series regression models.
† p<0.1 ** p<0.01
* p<0.05 *** p<0.001

Table C.10. Effect of Robust State PDMPs on Mean Number of Prescribers Used to Fill Opioid Prescriptions Per 100 Enrollees per Quarter (Sensitivity Analysis)[1]

Comparator States	Variable	Difference Between Intervention and Control States			
		Pre-Implementation, No.	Policy Effect, No. (Pre- to Post-Implementation	Absolute in Q4 of 2014, No. (95% CI)	Relative in Q4 of 2014, % (95% CI)
a. OH vs. PA	Level	3.67***	—	-1.59(-1.89,-1.29)	-35.58(-40.21,-30.94)
	Trend	0.04***	-0.13***		
b. KY vs. MO	Level	2.37***	-2.63***	-2.63(--2.95,-2.30)	-110.90(-120.93,-100.88)
	Trend	—	—		
c. NM vs. TX	Level	1.91***	-1.35***	-1.35(-1.77,-0.93)	-70.55(-87.10,-54.00)
	Trend	—	—		
d. TN vs. GA	Level	1.72***	-0.79**	-0.79(-1.29,-0.28)	-30.89(-45.06,-16.73)
	Trend	0.04†	—		
e. NY vs. NJ	Level	-1.09***	-0.34***	0.05(-0.07,0.16)	-3.38(-11.53.4.77)
	Trend	-0.02***	0.08**		

Abbreviations: PDMP, prescription drug monitoring program; Q4, fourth calendar quarter.

[1]Segmented time-series regression models adjusted for baseline trend, and changes in trend and level; we eliminated any of these predictors if they were non-significant at the p<0.2 level. Generalized estimating equations models were used to generate population quarterly outcome rates, adjusted for age, gender, race/ethnicity, education level, and enrollment span, prior to implementing the segmented time-series regression models.

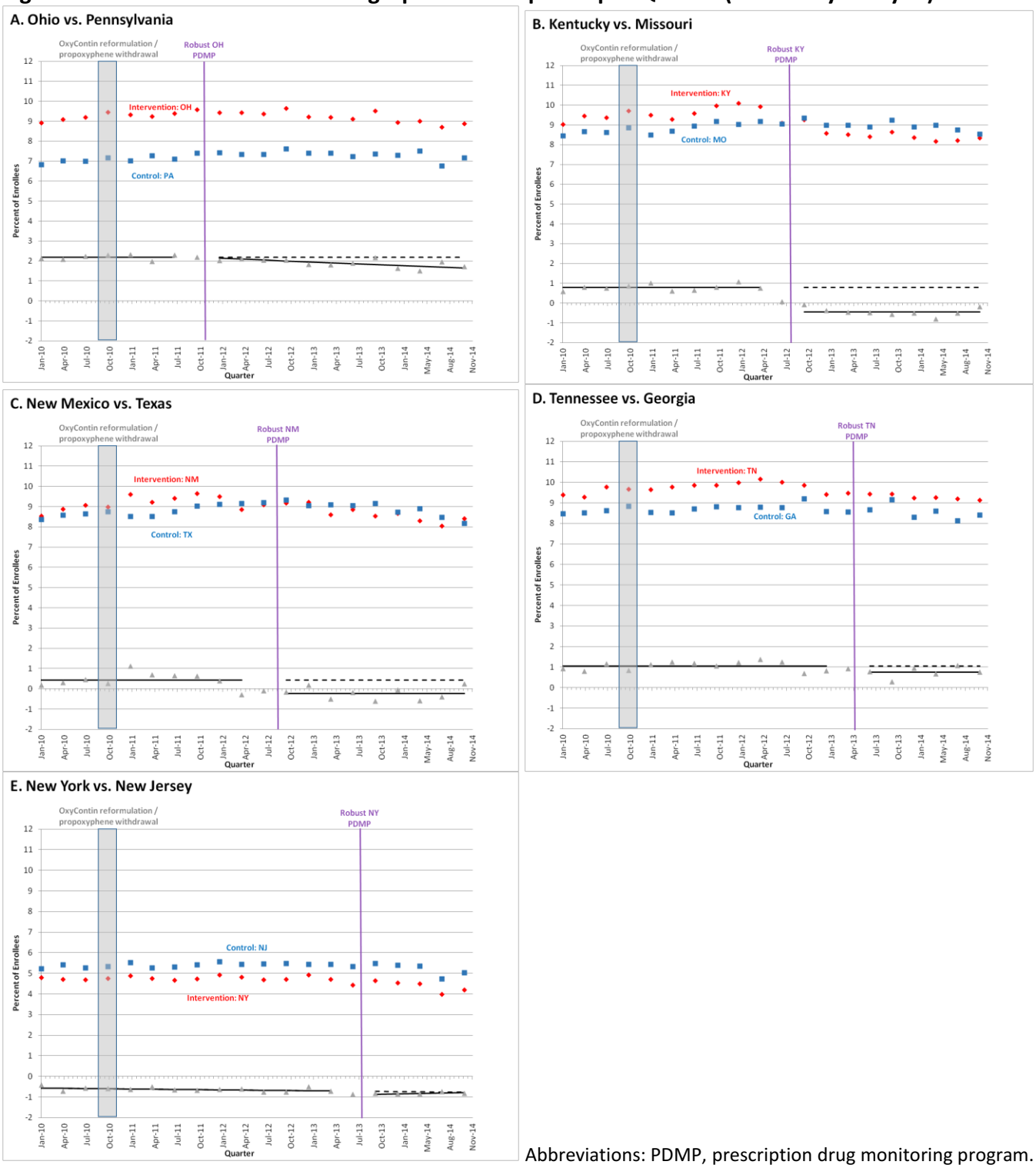
† p<0.1 ** p<0.01

* p<0.05 *** p<0.001

Figures C.4-C.7 display the fitted trends reflected in the segmented regression estimates above. They demonstrate the general pattern of decreased levels in percent of enrollees filling opioids and number of prescribers and pharmacies used to fill opioid prescriptions by enrollees, as well as decreased levels and trends of mean MEDs dispensed per enrollee in the intervention states in post-PDMP implementation, most dramatically in Kentucky relative to Missouri.

Although the changes in magnitude were smaller for this continuously enrolled cohort as compared to those non-continuously enrolled, the relative reductions were more significant. This could perhaps be explained by the fact that the levels of opioid prescribing and use were lower (thus relative changes are more pronounced). Also, this cohort included chronic opioid users that more likely maintained coverage over much of the study period, and therefore paid for their prescriptions through insurance. When these individuals experienced reductions in opioid dispensing or MEDs prescribed, we would therefore have observed these decreases.

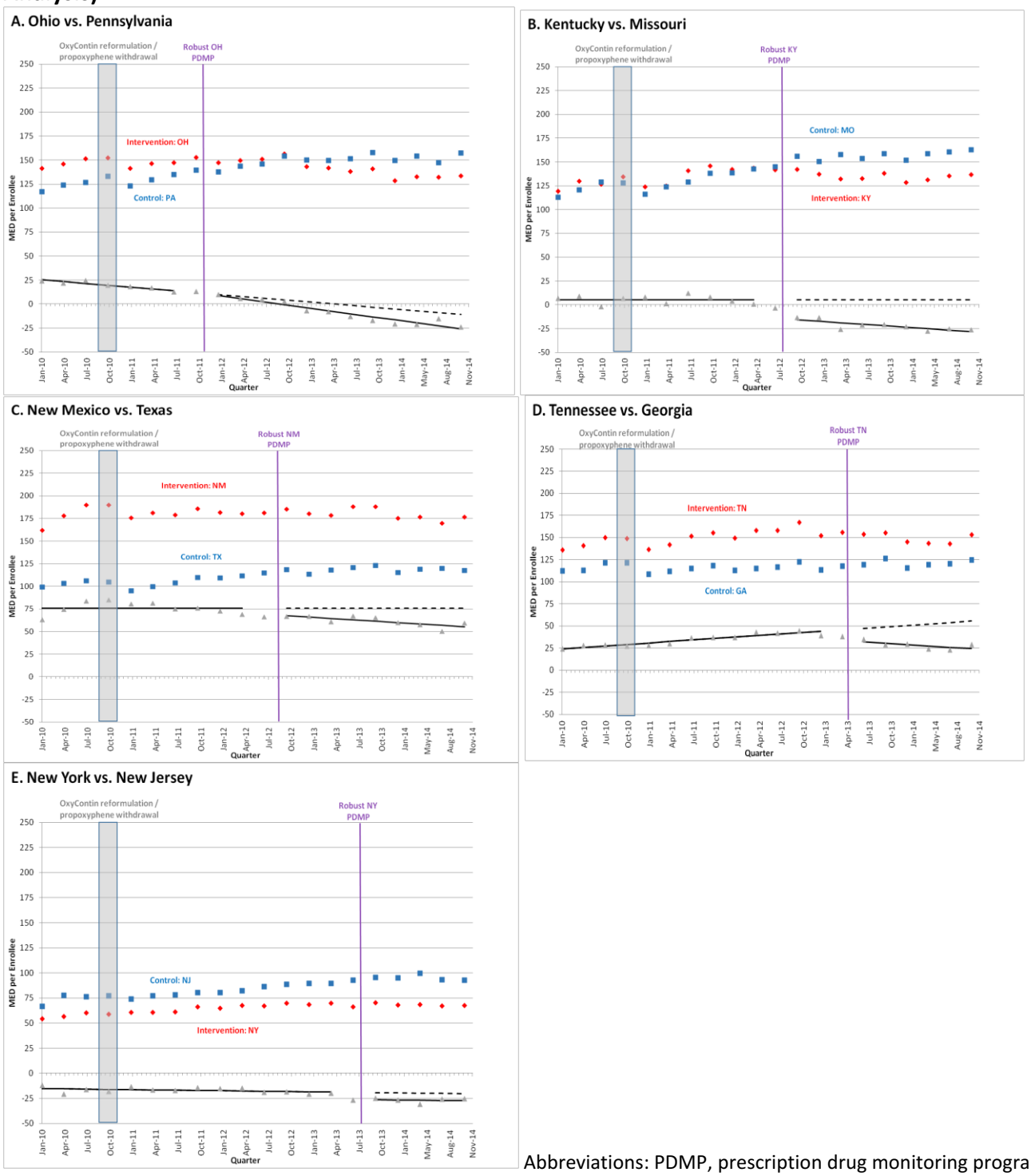
Figure C4: Percent of Enrollees Filling Opioid Prescriptions per Quarter (Sensitivity Analysis)



Abbreviations: PDMP, prescription drug monitoring program.

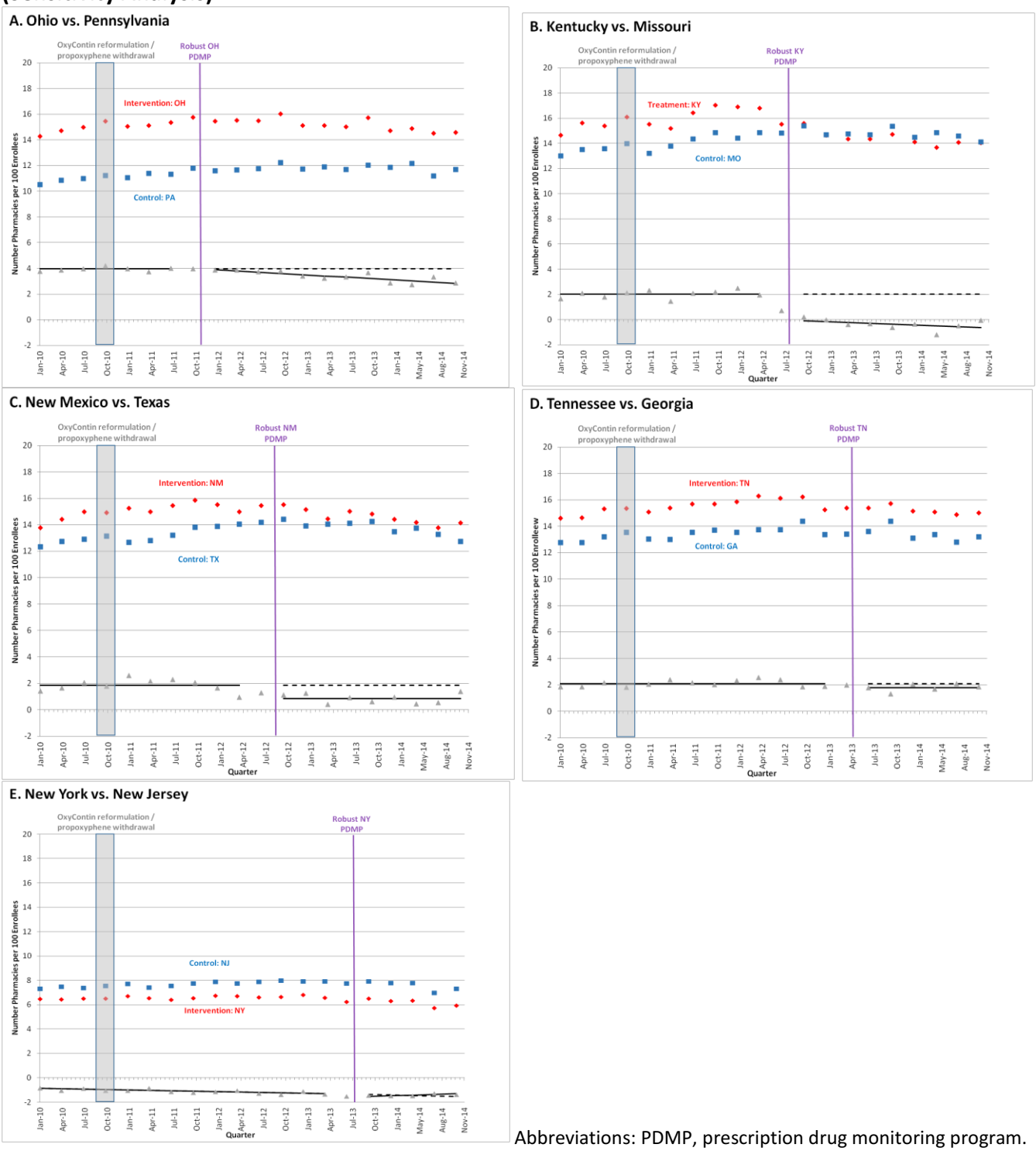
A fitted regression line shows the difference between treatment and control states in the baseline period and continues as a predicted regression line in the follow-up period, after robust PDMP implementation in the intervention state. A separate fitted regression line was calculated using population-level interrupted time series linear models for the outcome of interest (adjusted for individual age, gender, race/ethnicity, education level, and enrollment at each quarter using the STATA margins command).

Figure C.5: Mean Morphine Equivalent Dosage Dispensed per Enrollee per Quarter (Sensitivity Analysis)



Abbreviations: PDMP, prescription drug monitoring program; MED, morphine equivalent dosage. A fitted regression line shows the difference between treatment and control states in the baseline period and continues as a predicted regression line in the follow-up period, after robust PDMP implementation in the intervention state. A separate fitted regression line was calculated using population-level interrupted time series linear models for the outcome of interest (adjusted for individual age, gender, race/ethnicity, education level, and enrollment at each quarter using the STATA margins command).

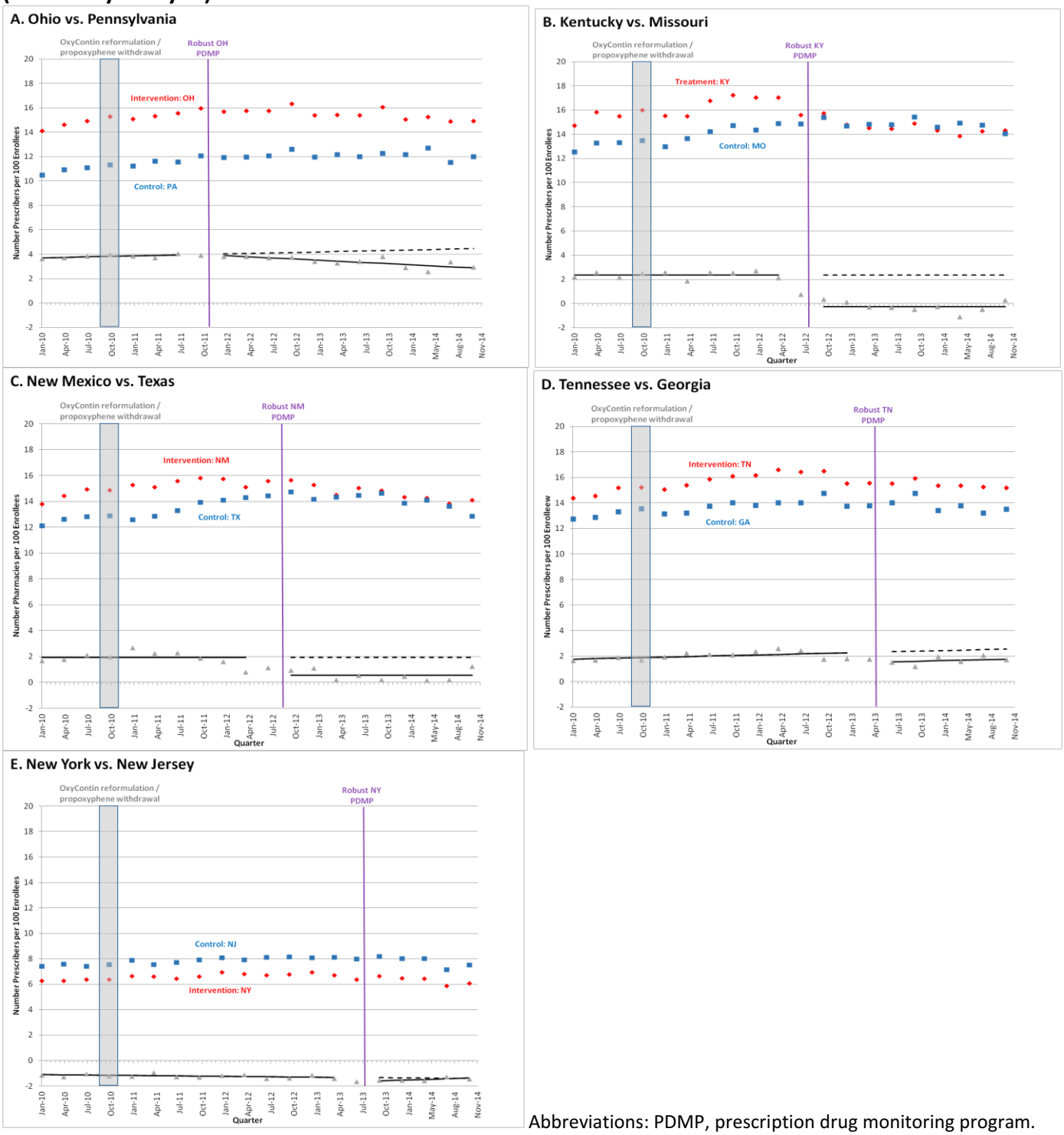
Figure C.6: Mean Number of Pharmacies Used to Fill Opioid Prescriptions per 100 Enrollees per Quarter (Sensitivity Analysis)



Abbreviations: PDMP, prescription drug monitoring program.

A fitted regression line shows the difference between treatment and control states in the baseline period and continues as a predicted regression line in the follow-up period, after robust PDMP implementation in the intervention state. A separate fitted regression line was calculated using population-level interrupted time series linear models for the outcome of interest (adjusted for individual age, gender, race/ethnicity, education level, and enrollment at each quarter using the STATA margins command).

Figure C.7: Mean Number of Prescribers Used to Fill Opioid Prescriptions per 100 Enrollees per Quarter (Sensitivity Analysis)



Abbreviations: PDMP, prescription drug monitoring program.

A fitted regression line shows the difference between treatment and control states in the baseline period and continues as a predicted regression line in the follow-up period, after robust PDMP implementation in the intervention state. A separate fitted regression line was calculated using population-level interrupted time series linear models for the outcome of interest (adjusted for individual age, gender, race/ethnicity, education level, and enrollment at each quarter using the STATA margins command).

C.4 Appendix C References

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