Incremental Effect of the Addition of Prescriber Restrictions on a State Medicaid's Pharmacy-Only Patient Review and Restriction Program

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ABSTRACT

BACKGROUND: Patient review and restriction programs (PRRPs), used by state Medicaid programs to limit potential abuse and misuse of opioids and related controlled medications, often restrict members to a single pharmacy for controlled medications. While most states use a restricted pharmacy access model, not all states include restricted prescriber access. Oklahoma Medicaid (MOK) added a restricted prescriber access feature to its PRRP in July 2014.

OBJECTIVE: To evaluate the incremental effect that the addition of a prescriber restriction to MOK's pharmacy-only PRRP had on the pharmacy and resource utilization of the enrolled members.

METHODS: MOK members with at least 6 months of enrollment in the pharmacy-only PRRP were restricted to a maximum of 3 prescribers for controlled substances in July 2014 and were identified as "cases." Using a propensity score method, cases were matched to controls from the MOK non-PRRP enrolled population based on demographics and baseline health care utilization. Data from January 1, 2014, through December 31, 2014, were evaluated. Each member's monthly health care resource utilization, defined in terms of medical and pharmacy costs, prescription counts, and opioid use per member per month (PMPM), was analyzed. A difference-in-differences (DID) regression estimated the change in resource utilization following the July 2014 policy change.

RESULTS: This study included 378 controls and 126 cases after propensity matching. No differences were noted for daily morphine equivalents, benzodiazepine prescriptions, or maintenance prescriptions. There were decreases in mean PMPM use for both groups for short-acting opioid (SAO) claims ($P < 0.001$), overall opioid claims ($P = 0.007$ for controls and $P < 0.001$ for cases), prescribers ($P = 0.01$ for controls and $P < 0.001$ for cases), and number of pharmacies for cases ($P < 0.001$). DID analyses indicated that cases had a larger decrease in mean SAO claims (difference: -0.15 , 95% CI: -0.25 to -0.04 , $P = 0.008$); prescribers (difference: -0.25 , 95% CI: -0.36 to -0.15 , $P < 0.001$); and pharmacies (difference: -0.20 , 95% CI: -0.28 to -0.13 , $P < 0.001$) relative to controls. The difference for overall opioid claims was greater for cases than controls but did not reach statistical significance (difference: -0.12 , 95% CI: -0.25 to 0.00 , $P = 0.050$).

CONCLUSIONS: Although there was no evidence that overall opioid claims were affected, the addition of prescriber restrictions may have resulted in an incremental change to SAO, prescriber, and pharmacy use in the PRRP population. Use of PRRPs may be an effective tool in reducing inappropriate use of prescription opioids within payer systems. The question remains whether these changes result in long-term changes to behavior outside the payer system. Future research into the effects of PRRPs on patient behavior beyond the payer system is needed.

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What is already known about this subject

- Patient review and restriction programs (PRRPs) are used in Medicaid programs and other payer systems to reduce waste, misuse, and fraud related to opioid prescription use.
- The most common restriction is limiting access to pharmacies that may bill the payer for opioid prescriptions.
- Limited research has been performed to determine if these programs are successful.

What this study adds

- This study directly examined outcomes from a state PRRP, which have not widely been investigated in the literature.
- Adding prescriber restrictions to a pharmacy-only program may further reduce short-acting prescription opioid use, number of prescribers, and number of pharmacies.
- These restrictions may reduce overuse of short-acting opioids but may not reduce daily morphine equivalents over the short term.

Prescription drug abuse has become a significant economic and clinical problem in U.S. health care.¹ In 2014, the National Survey on Drug Use and Health reported that an estimated 4.3 million people used pain relievers non-medically for the first time in the previous 12 months.² In January 2012, the Centers for Medicare & Medicaid Services issued a report on drug diversion in Medicaid programs.³ This report emphasized the need for federal and state partnerships to combat the problem of drug diversion and proposed possible practices that states could enact. A key recommendation included the establishment or augmentation of patient review and restriction programs (PRRPs), colloquially known as "lock-in" programs.³ These programs allow the state to restrict patients with patterns potentially related to misuse and abuse to a single servicing pharmacy or prescriber or both.⁴

Evaluation of PRRPs in state Medicaid programs has been minimal, and programs vary from state to state.⁵⁻¹⁰ More reviews of these programs are needed to properly assess the incremental effect of different program restrictions on payers and patients.⁴ Interventions must be explored and implemented in order to decrease the drug abuse burden on the U.S. health care system.

Previous research has determined that the cost within Medicaid programs are higher for those members who abuse opioid prescriptions compared with those who do not. This finding holds true in private and government insurance programs.¹¹⁻¹³ Data from a 2014 review conducted by Meyer et al. showed that annual direct health care costs for nonabusers was 8 times less than abusers, with mean annual excess health care costs for opioid abusers within Medicaid ranging from \$5,874 to \$15,183.¹

According to the Government Accountability Office (GAO), “doctor shopping” is a common means of obtaining prescriptions for medications classified as controlled substances by the Drug Enforcement Agency. This GAO report showed that approximately 1% of Medicaid beneficiaries in the states reviewed visited 6 or more doctors for prescriptions for the same type of controlled substance over a 2-year period (2006-2007).¹⁴

To limit the amount of doctor shopping in Oklahoma Medicaid's (MOK) pharmacy-only PRRP, the Oklahoma Health Care Authority (OHCA) implemented an additional restriction to the PRRP in July 2014. This restriction limited the number of unique prescribers of controlled medications for members enrolled in the PRRP. Previously, members enrolled in the PRRP were restricted to 1 pharmacy for all prescription claims. The new policy added a limit on prescribers of controlled substances and, at the same time, removed the pharmacy restriction for noncontrolled prescriptions. Most members were restricted to 1 prescriber; however, members seen by specialists, such as pain management and psychiatry, received accommodation to see more than 1 prescriber. In either case, only prescription claims from authorized prescribers were paid by OHCA.

Previous review of the MOK's pharmacy-only PRRP showed a decrease in number of opioid prescriptions for members enrolled in the PRRP.⁷ Because patients had already been subject to the pharmacy restriction, the influence of an additional restriction may be less than on a newly enrolled patient to any PRRP. In order to determine the incremental effect of adding a prescriber restriction to the existing single pharmacy condition, it was necessary to explore the outcomes within the framework of the Health Belief Model.¹⁵ Within this framework, we were able to explore the effect that the cues to action (the new restriction) had, while controlling for demographic and sociological factors.

The objective of this research was to evaluate the incremental effect that the addition of a prescriber restriction to MOK's pharmacy-only PRRP had on the pharmacy and resource utilization of the enrolled members.

Methods

Data Source

Individual-level patient claims data were extracted from the administrative claims database provided to Pharmacy Management Consultants from OHCA. This database contains

prescription, cost, enrollment, and other health care utilization data for members covered by the MOK program. The pharmacy director at OHCA and the institutional review board at the University of Oklahoma College of Pharmacy approved this research. Data were de-identified, with no other copies or crosswalks retained.

Study Population

The population for this study consisted of MOK eligible members enrolled in the PRRP from January to December 2014 and continuously eligible for Medicaid only (no Medicare) for 6 months before and after the implementation date. Since the new restriction was phased in over a 6-month period, cases were current PRRP members who had been enrolled in the pharmacy-only PRRP for at least 6 months and were newly subject to the prescriber restriction in July 2014. Since all patients were included in the new restriction, controls consisted of those members not enrolled in the PRRP who had at least 1 opioid claim during the same time period (January 1, 2014-December 31, 2014) and were matched to cases based on demographics and baseline use in order to control for systemwide events that might influence use. The control group also required 12 months of eligibility during the entire study period (Figure 1).

Design

For cases and controls, a pre/post period design was used: The preperiod was defined as 6 months before implementation of the physician restriction environment (January-June 2014), and the postperiod was defined as 6 months after implementation (July-December 2014). Baseline outcome measures, demographics, and comorbidities were collected from the preperiod, and follow-up outcome measures were collected in the postperiod.

Descriptive Variables

To determine if demographic or sociological factors were moderating the effect of the restriction on assumed behavior,¹⁶ the following variables were gathered during the baseline period: demographic measures, comorbidities related to addiction, and conditions in the Charlson Comorbidity Index. Demographic measures for members consisted of age, gender, race, and rural/micropolitan or urban location of residence. Rural/micropolitan residents lived in a population area of less than 50,000 persons. An influence on the perceived seriousness of a patient's need for change is illness level,¹⁶ and patients with opioid abuse or misuse may possess comorbidities related to addiction. Classification of these conditions occurred according to *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM) codes. The included comorbidities related to addiction were based on those found to be associated with opioid abuse and included human immunodeficiency virus infection/acquired immune deficiency

FIGURE 1 Inclusion and Exclusion Flowchart

PRRP=patient review and restriction program.

syndrome; hepatitis A, B, and C; substance abuse; skin infections; gastrointestinal bleeding; liver disease; pancreatitis; sexually transmitted diseases; burns; motor vehicle traffic accidents; poisoning; trauma; and mental disorders (see the Appendix for complete list and ICD-9-CM codes, available in online article).¹² Individuals were also designated as having a history of opioid abuse if they had any ICD-9-CM code indicating opioid dependence or abuse (304.0x, 304.7x, 305.5x, and 965.0x [excluding 965.01]).¹¹ The Charlson Comorbidity Index described severity of patient comorbidities.^{17,18}

Outcome Variables

A number of dependent health care utilization variables measured incremental effects of the addition of prescriber restrictions. The outcomes chosen were those most likely influenced by limitations on multiple prescribers. Counts of monthly totals per member were collected: all prescription claims and overall dispensed quantities, all opioid claims and dispensed opioid quantities, long-acting opioid (LAO) claims and dispensed quantities, short-acting opioid (SAO) claims and dispensed quantities, benzodiazepine claims and dispensed quantities, unique opioid prescribers, and unique number of pharmacies used. In addition, total monthly maintenance medication claims and dispensed quantities evaluated potential unintended

consequences to other therapeutic care. We performed opioid morphine equivalent conversions in order to standardize average daily morphine equivalent dose (MED) for comparisons.¹⁹⁻²² Finally, we calculated per member per month (PMPM) cost calculations for the count variables listed previously. Included in the difference-in-differences (DID) analyses were overall claims, opioid claims, LAO claims, SAO claims, daily MEDs, number of prescribers, and number of pharmacies.

Statistical Analyses

Descriptive statistics summarized the measures of interest: the average PMPM use and patient demographics for members in the pre- and postperiods. T-tests for continuous measures, chi-square tests for proportions, and Fisher's exact test for cells with expected counts <5 were used to assess differences between cases and controls for descriptive characteristics. Dependent means were compared using paired t-tests for paired data and compared outcome measures for cases and controls in the pre- and postperiods.

A propensity score-matching method combined with a DID regression encompassed the main analysis for this study. The propensity score allows an observational research design that mimics randomized controlled trials and reduces effects of confounding.²³ Propensity scores were generated through

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TABLE 1 Descriptive Characteristics of PRRP Population, 2014

	Controls (n = 378)		Cases (n = 126)		P Value for Difference ^a
Age, mean (±SD)	41.2	(±13.2)	40.4	(±10.8)	0.483
Female, n (%)	264	(69.8)	98	(77.8)	0.086
Race, n (%)					
White	271	(71.7)	90	(71.4)	0.541
Black/African-American	45	(11.9)	15	(11.9)	
American Indian/Alaska Native	33	(8.7)	15	(11.9)	
Other	29	(7.7)	6	(4.8)	
Rural or micropolitan residence, n (%)	129	(34.1)	29	(23.0)	0.006 ^b
Charlson Comorbidity Index, mean (±SD)	1.4	(±1.8)	1.6	(±2.2)	0.467
Comorbidities, n (%)					
Myocardial infarction	18	(4.8)	12	(9.5)	0.050
Congestive heart failure	27	(7.14)	17	(13.5)	0.029 ^b
Peripheral vascular disease	15	(4.0)	4	(3.2)	0.794
Cerebrovascular disease	29	(7.7)	9	(7.1)	0.846
Dementia	1	(0.3)	0	(0.0)	1.000
Chronic pulmonary disease	143	(37.8)	56	(44.4)	0.188
Rheumatic disease	19	(5.0)	14	(11.1)	0.017 ^b
Peptic ulcer disease	17	(4.5)	5	(4.0)	0.801
Mild liver disease	10	(2.7)	5	(4.0)	0.544
Moderate or severe liver disease	6	(1.6)	0	(0.0)	0.345
Diabetes without chronic complication	70	(18.5)	26	(20.6)	0.600
Diabetes with chronic complication	29	(7.7)	8	(6.4)	0.622
Hemiplegia or paraplegia	7	(1.9)	3	(2.4)	0.716
Renal disease	17	(4.5)	5	(4.0)	0.801
Any malignancy, including lymphoma and leukemia, except malignant neoplasm of skin	16	(4.2)	2	(1.6)	0.266
Metastatic solid tumor	2	(0.5)	1	(0.8)	1.000
HIV/AIDS	2	(0.5)	1	(0.8)	1.000
Comorbidities related to addiction, n (%)					
Substance abuse (nonopioid)	315	(83.3)	99	(78.6)	0.227
Opioid dependence	136	(36.0)	46	(36.5)	0.915
Mental health	331	(87.6)	111	(88.1)	0.876
HIV/AIDS	2	(0.5)	1	(0.8)	1.000
Skin infections	70	(18.5)	43	(34.1)	<0.001 ^b
Gastrointestinal bleeding	112	(29.6)	42	(33.3)	0.434
Cirrhosis	34	(9.0)	15	(11.9)	0.340
Hepatitis A, B, or C	36	(9.5)	12	(9.5)	1.000
Pancreatitis	11	(2.9)	6	(4.8)	0.319
Sexually transmitted disease	52	(13.8)	17	(13.5)	0.940
Burns	11	(2.9)	3	(2.4)	1.000
Trauma	238	(63.0)	97	(77.0)	0.004 ^b
Motor vehicle accident	3	(0.8)	9	(7.1)	<0.001 ^b
Poisonings	32	(8.5)	22	(17.5)	0.005 ^b

^aDifferences between cases and controls evaluated with t-tests for continuous measures, chi-square test for proportions, and Fisher's exact test for cells with expected counts less than 5.

^bSignificant at $P < 0.05$.

HIV/AIDS = human immunodeficiency virus/acquired immune deficiency syndrome; PRRP = patient review and restriction program; SD = standard deviation.

a logistic regression with an indicator for being under the prescriber restriction as an outcome variable and age, with sex; race; select diagnoses (mental health disorders, substance abuse disorders, and opioid dependence); and baseline PMPM pharmacy utilization measures (i.e., LAO claims, SAO claims, daily

MEDs, benzodiazepine claims, number of prescribers, and pharmacies visited) serving as independent variables. Using a greedy matching algorithm, non-PRRP members who had at least 1 claim for an opioid (controls) were then matched 3:1 without replacement to cases based on similar propensity scores.

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TABLE 2 Bivariate Comparison of Utilization Outcomes by Cases and Controls

Variable	Control January-June 2014 (n = 378)	Case January-June 2014 (n = 126)	P Value for Difference Between Cases and Controls ^a	Control July-December 2014 (n = 378)	Case July-December 2014 (n = 126)	P Value for Difference Between Cases and Controls ^a
Overall claims	4.08	3.97	0.631	3.79	3.63	0.600
Overall quantity	302.60	254.00	0.337	242.50	220.20	0.441
Overall cost, \$	397.50	328.00	0.660	298.60	222.90	0.323
Opioid claims	0.95	1.01	0.497	0.82	0.72	0.215
Opioid quantity	74.61	79.79	0.529	68.78	62.28	0.400
Opioid cost	62.32	69.83	0.633	62.83	52.44	0.454
Morphine equivalent daily dose (mg)	40.61	49.67	0.615	40.56	45.26	0.780
LAO claims	0.14	0.14	0.916	0.14	0.17	0.490
LAO quantity	8.63	8.08	0.848	8.23	9.12	0.760
LAO cost, \$	34.94	28.35	0.575	34.65	23.32	0.256
SAO claims	0.81	0.87	0.378	0.68	0.56	0.026 ^b
SAO quantity	65.98	71.71	0.417	60.54	53.16	0.248
SAO cost, \$	27.38	41.48	0.117	28.18	29.11	0.906
Benzodiazepine claims	0.35	0.39	0.515	0.34	0.32	0.710
Benzodiazepine quantity	21.12	23.49	0.479	20.88	19.96	0.785
Benzodiazepine costs, \$	6.80	3.67	0.412	2.74	2.02	0.330
Maintenance claims	1.62	1.49	0.407	1.55	1.50	0.771
Maintenance quantity	90.89	76.81	0.152	85.17	78.70	0.653
Maintenance cost, \$	131.40	87.84	0.043 ^b	118.60	87.86	0.156
Prescribers seen	0.90	0.95	0.462	0.82	0.58	<0.001 ^b
Pharmacies visited	0.74	0.75	0.675	0.72	0.52	<0.001 ^b

Note: All measures defined as mean PMPM.

^aMonthly means compared with t-tests for continuous measures.

^bSignificant at $\alpha < 0.05$.

LAO = long-acting opioid; PMPM = per member per month; SAO = short-acting opioid.

The DID regression compared the changes in use from before to after the implementation of the prescriber restriction policy between cases and controls. This method has been used in many studies to examine causal effects of policy changes.²⁴ Utilization calculations performed for each outcome included (Q1) estimated PMPM use before the implementation of the prescriber restriction policy in the control group; (Q2) estimated PMPM use before implementation of the prescriber restriction policy in the case group; (Q3) estimated PMPM use following implementation of the prescriber restriction policy in the control group; and (Q4) estimated PMPM use following implementation of the prescriber restriction policy in the case group. The DID estimate was the mean of (Q4-Q2) - (Q3-Q1) and used to determine if there were statistically significant differences in changes between cases and controls. We performed generalized linear models for all outcomes, with a Poisson distribution specified for overall claims, opioid claims, LAO claims, SAO claims, prescribers seen, and pharmacies visited. We assumed a negative binomial distribution for average MED. All models also assumed an autoregressive (1) covariance matrix to account for multiple observations per member. The independent variables were prescriber restriction status (0 for

controls and 1 for cases), time (0 before implementation and 1 after implementation), and an interaction term between time and prescriber restriction status. The data analysis was conducted using SAS software version 9.3 of the SAS System for Windows (SAS Institute, Cary, NC).²⁵

Results

Of the existing MOK members previously enrolled in the PRRP for a minimum of 6 months, 167 were added to the prescriber portion of the PRRP program in July 2014, and the remaining members were enrolled in subsequent months. Of these members, 128 met the inclusion criteria. In 2014, 140,857 MOK members had at least 1 opioid claim. After applying inclusion criteria, 83,942 were eligible. After propensity score matching, 378 controls and 126 cases remained in the study (Figure 1). Table 1 lists the descriptive characteristics for the study members. The average age was 41.2 years for controls and 40.4 years for cases ($P = 0.483$). Females made up 77.8% of the cases and 69.8% of the controls ($P = 0.086$), and a majority of the patients self-reported white for race (71.7% for controls and 71.4% for cases, $P = 0.541$). There was also a difference in those living in rural or micropolitan areas, with 34.1% of controls living in

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TABLE 3 Mean Change in Monthly Utilization Per Member from Before to After Implementation of Prescriber Restriction Policy, 2014

Utilization Measures (95% CI)	Controls (n = 378)	P Value for Change ^a	Cases (n = 126)	P Value for Change ^a	Difference-in-Difference	P Value for Difference-in-Difference ^b
Overall claims	-0.17 (-0.33 to 0.01)	0.065	-0.38 (-0.65 to -0.10)	0.008 ^c	-0.21 (-0.54 to 0.11)	0.199
Opioid claims	-0.09 (-0.15 to -0.02)	0.007 ^c	-0.21 (-0.31 to -0.10)	<0.001 ^c	-0.12 (-0.25 to 0.00)	0.050
LAO claims	-0.02 (-0.01 to 0.04)	0.196	0.01 (-0.02 to 0.06)	0.335	0.004 (-0.04 to 0.05)	0.851
SAO claims	-0.10 (-0.16 to -0.05)	<0.001 ^c	-0.25 (-0.34 to -0.16)	<0.001 ^c	-0.15 (-0.25 to -0.04)	0.008 ^c
Daily morphine milligram equivalents	-2.55 (-10.82 to 5.71)	0.546	-3.48 (-20.58 to 13.61)	0.676	-0.93 (-19.91 to 18.06)	0.924
Prescribers seen	-0.07 (-0.12 to -0.02)	0.010 ^c	-0.32 (-0.41 to -0.23)	<0.001 ^c	-0.25 (-0.36 to -0.15)	<0.001 ^c
Pharmacies visited	0.002 (-0.04 to 0.04)	0.936	-0.20 (-0.27 to -0.13)	<0.001 ^c	-0.20 (-0.28 to -0.13)	<0.001 ^c

^aPre- to postrestriction means evaluated with paired *t*-tests.

^bP values generated from difference-in-difference regression.

^cSignificant at *P* < 0.05.

CI = confidence interval; LAO = long-acting opioid; SAO = short-acting opioid.

nonurban areas but only 23.0% of cases living in nonurban areas (*P* = 0.006; Table 1).

The most commonly occurring diagnosis included in the Charlson Comorbidity Index was chronic pulmonary disease (cases = 44.4%, controls = 37.8%, *P* = 0.188) followed by diabetes without complications (cases = 20.06%, controls = 18.5%, *P* = 0.600). There was a difference between the proportion of cases and controls who had congestive heart failure (cases = 13.5%, controls = 7.1%, *P* = 0.029) and rheumatic disease (cases = 11.1%, controls = 5.0%, *P* = 0.017; Table 1). Review of comorbidities related to addiction revealed differences between the 2 groups for skin infections (cases = 34.1%, controls = 18.5%, *P* < 0.001), motor vehicle accidents (cases = 7.1%, controls = 0.80%, *P* < 0.001), and poisonings (cases = 17.5%, controls = 8.5%, *P* = 0.005; Table 1).

Table 2 displays results of the bivariate analyses of utilization outcomes. There were no differences found in overall mean PMPM prescription claims between cases and controls in either the pre- or postperiods. Likewise, no differences were found for overall prescription cost or opioid prescription claims. There was a difference found in the postperiod for SAO claims between groups, with cases having 0.56 PMPM claims and controls 0.68 PMPM claims (*P* = 0.026; Table 2). Both cases and controls experienced decreases in SAO claims, which may have been related to the change of hydrocodone to a higher control level (Schedule II). No differences were found for MED, benzodiazepine prescriptions PMPM, or maintenance prescriptions PMPM. There were differences found in the postperiod between cases and controls for the number of prescribers listed on opioid prescriptions and the number of pharmacies visited for controlled substances (prescribers: cases = 0.58, controls = 0.82, *P* < 0.001; pharmacies: cases = 0.52, controls = 0.72, *P* < 0.001; Table 1).

The differences between the pre- and postperiods for cases and controls and DID analyses for key utilization outcomes are

shown in Table 3. Cases had a significant decrease in mean PMPM for overall prescription claims (*P* = 0.008), and cases and controls had a decreased mean PMPM for overall opioid claims (cases *P* < 0.001; controls *P* = 0.007) from before to after implementation of the policy. Both groups also had significant decreases in mean PMPM for SAO claims (*P* < 0.001 for both) and number of prescribers (*P* = 0.010 for controls and *P* < 0.001 for cases), and cases had a significant decrease in number of pharmacies (*P* < 0.001 for cases). No significant change occurred with mean PMPM for LAO claims and daily MEDs for cases and controls. The difference in decreases between the 2 groups was not statistically significant for overall prescription claims (*P* = 0.199) and overall opioid claims (difference: -0.12, *P* = 0.050). Cases experienced a significantly larger decrease in SAOs (difference: -0.15, 95% confidence interval [CI]: -0.25 to -0.04, *P* = 0.008), number of prescribers (difference: -0.25, 95% CI: -0.36 to -0.15, *P* < 0.001), and number of pharmacies (difference: -0.20, 95% CI: -0.28 to -0.13, *P* < 0.001) relative to controls.

Figure 2 shows the results of these analyses for overall opioid claims, LAO claims, SAO claims, prescribers seen, and pharmacies visited in graph format. Figures 2C, 2D, and 2E best demonstrate the change in SAO, prescribers, and pharmacies that was greater than the change to the control group.

Discussion

The results of this research suggest that the addition of prescriber restrictions to the pharmacy-only PRRP produced an incremental change in SAO use, number of prescribers, and number of pharmacies for members already enrolled in the program. Use of PRRP in Medicaid programs are a long-standing tool for monitoring and controlling misuse and abuse of prescription opioids and other controlled substances within their programs.^{5-10,26} Differences exist in these programs, such as the level of restriction (pharmacy or prescriber or both) and requirements for inclusion in the programs. Because the

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FIGURE 2 Mean PMPM Health Care Utilization Measures for Cases and Controls, 2014

CI=confidence interval; LAO=long-acting opioid; LS=least squares; PMPM=per member per month; SAO=short-acting opioid.

opioid abuse epidemic has become a focus of national attention, review of the incremental changes when adding additional restriction levels is important and necessary. Roberts and Skinner (2014), in their assessment of the current Medicaid programs, found that PRRPs play a meaningful role in reducing misuse and abuse of opioids, but they stress the need for further research, greater collaboration between academic and policy centers, and coordination of policies (including the prescription drug monitoring programs).⁴ Our research provides supporting information regarding the

benefits of pharmacy and prescriber restrictions as part of the PRRP in a state Medicaid program.

While propensity score matching accounted for differences in patient characteristics, including age, sex, and race, some differences in comorbidities still existed within the case and control groups included in our research. Differences in health status may be important when considering these results. For instance, a higher proportion of patients with rheumatic disease was found in the case group (11.1%) compared with the control group (5.03%; $P<0.017$) and may account for a higher level of opioid use for these patients whether or not

they are enrolled in a PRRP. Review of the comorbidities related to addiction between groups also reveals some interesting differences. Motor vehicle accidents and poisonings were higher in the case group than in the control group (7.1% and 0.80% vs. 17.5% and 8.5%, respectively; Table 1). This difference may indicate that, although they were already part of the program, cases may have still been misusing opioids and other substances at a higher rate than controls. However, it is unknown if the reported incidences in the preperiod continued throughout the study period, since this was not part of the data collection process. Further research may be necessary to determine if any changes in incidence may have occurred after implementation.

Review of the mean PMPM for overall opioid claims indicates that both groups experienced decreases after implementation and, although not statistically different, requires further analyses for an extended period to determine if a difference may exist between the groups over time. One of the most interesting findings was the change to LAO and SAO PMPM in the cases after implementation. After implementation, LAO remained relatively stable for the control group but increased (not statistically significant) for the cases (Figure 2B).

For the SAO PMPM, although there is some decrease in both groups, a larger decrease occurs for the cases (controls vs. cases: -0.15 , $P=0.008$; Figure 2C). This pattern is similar to previous findings in this program, which reviewed the effect of initial enrollment in the PRRP and found that after enrollment, use of LAOs increased while SAO use decreased.⁷ It is unknown whether this effect has occurred in other Medicaid populations or if it is specific to this program. Further review of other programs is required to determine the frequency of occurrence of this effect.

In addition, the relative stability of MED across the study period for both groups, regardless of the change in LAO and SAO prescription claims, may indicate a change in type of opioid used but not an initial change in dosing. Also, the short time frame of 6 months may not fully allow for titrations of overall dose, which may have been initiated by prescribers after patient enrollment. Daily MED was reduced for cases by approximately 3.5 MED but not found to be statistically significant.

Finally, Figures 2D and 2E clearly demonstrate the change in number of prescribers and pharmacies. In both cases, there is a decrease at the point of implementation and a decrease in trend during the postperiod, indicating that the program was successful at further limiting the use of multiple pharmacies and prescribers for opioid claims reimbursed by the Medicaid system.

Research in other programs found similar results, generally decreases in use of resources and number of pharmacies.^{5,6,9,10} In a study that reviewed prescriber and pharmacy PRRPs compared with pharmacy-only PRRPs, the pharmacy-only group experienced statistically significant changes in opioids, but the prescriber group did not.⁵ The prescriber group,

however, experienced reductions in maintenance medications and pharmacy costs.⁵ Differences may be due to the study design (quasi-experimental without a control group) or the small subsample ($n=227$) in the prescriber arm of the study. In our research, the addition of prescriber restrictions did not affect maintenance medications but did decrease use of opioids, particularly SAOs.

Limitations

This study has several limitations to consider when reviewing the results of the analysis. The first limitation is the use of administrative claims data gathered for purposes of payment to health care providers for products or services. This secondary data may contain errors in billing or coding; however, these errors are considered to be equally distributed throughout the collected data and so do not represent a systematic bias.

Second, a key limitation related to the data source is the inability of this research to account for use occurring outside of the payment system. In other words, if patients received opioids, but Medicaid did not pay for them, then we did not account for these in this research. Therefore, all changes in use found in this study reflect services and prescriptions purchased by the payer and not necessarily everything received by the patient.

Third, there were limitations in the analytical approach. Propensity scores can only reduce bias in measured characteristics that were specified in the multivariable logistic regression model. An unmeasured variable may exist that could confound results. For DID regression, the choice of control group was important, since we were investigating what might have happened if there was no policy change. Differences in patient characteristics may have caused results to skew either positively or negatively, but we attempted to mitigate this through the propensity score-matching method. Policymakers should weigh the effect of these differences when considering results. Finally, the short review time frame may have prevented all changes from fully occurring.

Conclusions

After the addition of a single prescriber restriction to a PRRP program in a Medicaid population, incremental changes were observed in the number of SAO prescriptions, pharmacies, and prescribers use. The addition of prescriber restrictions may have been a useful tool in decreasing prescription SAO use within a state Medicaid payer system. Whether these additions result in long-term changes to behavior or utilization patterns outside the payer system are unknown, but this question deserves further consideration and review. Future research into PRRPs should determine if these effects are long term and if behaviors outside of the payer system are affected.

Incremental Effect of the Addition of Prescriber Restrictions on a State Medicaid's Pharmacy-Only Patient Review and Restriction Program

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REFERENCES

1. Meyer R, Patel AM, Rattana SK, Quock TP, Mody SH. Prescription opioid abuse: a literature review of the clinical and economic burden in the United States. *Popul Health Manag*. 2014;17(6):372-87.
2. Center for Behavioral Health Statistics and Quality. Behavioral health trends in the United States: results from the 2014 National Survey on Drug Use and Health. HHS Publication No. SMA 15-4927, NSDUH Series H-50. September 2015. Available at: <https://www.samhsa.gov/data/sites/default/files/NSDUH-FRR1-2014/NSDUH-FRR1-2014.pdf>. Accessed June 1, 2017.
3. Centers for Medicare & Medicaid Services. Drug diversion in the Medicaid program: state strategies for reducing prescription drug diversion in Medicaid. January 2012. Available at: <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/MedicaidIntegrityProgram/Downloads/drugdiversion.pdf>. Accessed June 1, 2017.
4. Roberts AW, Skinner AC. Assessing the present state and potential of Medicaid controlled substance lock-in programs. *J Manag Care Spec Pharm*. 2014;20(5):439-46. Available at: <http://www.jmcp.org/doi/10.18553/jmcp.2014.20.5.439>.
5. Blake S, Felkhaus JF, Hunter TS, Rapport H, Holt G, Medon PJ. The effect of the Louisiana Medicaid lock-in on prescription drug utilization and expenditures. *Value Health*. 1998;1(1):72 [Abstract PMD2]. Available at: <http://onlinelibrary.wiley.com/doi/10.1046/j.1524-4733.1998.1100712.x/abstract>. Accessed June 13, 2017.
6. Chinn F. Medicaid recipient lock-in program—Hawaii's experience in six years. *Hawaii Med J*. 1985;44(1):9-18.
7. Keast SL, Nesser N, Farmer K. Strategies aimed at controlling misuse and abuse of opioid prescription medications in a state Medicaid program: a policymaker's perspective. *Am J Drug Alcohol Abuse*. 2015;41(1):1-6.
8. Roberts AW, Farley JF, Holmes GM, et al. Controlled substance lock-in programs: examining an unintended consequence of a prescription drug abuse policy. *Health Aff (Millwood)*. 2016;35(10):1884-92.
9. Singleton TE. Missouri's lock-in: control of recipient misutilization. *J Medicaid Manage*. 1977;1(3):10-17.
10. Werth SR, Sachdeva N, Roberts AW, et al. North Carolina Medicaid recipient management lock-in program: the pharmacist's perspective. *J Manag Care Spec Pharm*. 2014;20(11):1122-29. Available at: <http://www.jmcp.org/doi/10.18553/jmcp.2014.20.11.1122>.
11. Ghate SR, Haroutiunian S, Winslow R, McAdam-Marx C. Cost and comorbidities associated with opioid abuse in managed care and Medicaid patients in the United States: a comparison of two recently published studies. *J Pain Palliat Care Pharmacother*. 2010;24(3):251-58.
12. White AG, Birnbaum H, Mareva M, et al. Direct costs of opioid abuse in an insured population in the United States. *J Manag Care Pharm*. 2005;11(6):469-79. Available at: <http://www.jmcp.org/doi/10.18553/jmcp.2005.11.6.469>.
13. McAdam-Marx C, Roland CL, Cleveland J, Oderda GM. Costs of opioid abuse and misuse determined from a Medicaid database. *J Pain Palliat Care Pharmacother*. 2010;24(1):5-18.
14. U.S. Government Accountability Office. Medicaid: fraud and abuse related to controlled substances identified in selected states. GAO-09-1004T. September 30, 2009. Available at: <http://www.gao.gov/products/GAO-09-1004T>. Accessed June 1, 2017.
15. Janz NK, Becker MH. The Health Belief Model: a decade later. *Health Educ Q*. 1984;11(1):1-47.
16. Andersen R, Newman JF. Societal and individual determinants of medical care utilization in the United States. *Milbank Q*. 2005;83(4). Online only. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2690261/>. Accessed June 1, 2017.
17. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis*. 1987;40(5):373-83.
18. Quan H, Li B, Couris CM, et al. Updating and validating the Charlson Comorbidity Index and score for risk adjustment in hospital discharge abstracts using data from 6 countries. *Am J Epidemiol*. 2011;173(6):676-82.
19. McPherson ML. *Demystifying Opioid Conversion Calculations: A Guide for Effective Dosing*. Bethesda, MD: American Society of Health-Systems Pharmacists; 2010.
20. Palliative Meds Info. Opioid conversion chart. January 2014. Available at: <https://olh.ie/wp-content/uploads/2014/09/Opioid-Conversion-Chart.pdf>. Accessed June 1, 2017.
21. Therapeutic Research Center. Equianalgesic dosing of opioids for pain management. PL Detail-Document #280801. *Pharmacist's Letter/Prescriber's Letter*. August 2012. Available at: <https://www.nhms.org/sites/default/files/Pdfs/Opioid-Comparison-Chart-Prescriber-Letter-2012.pdf>. Accessed June 1, 2017.
22. Medical University of South Carolina, Department of Pharmacy Services and the Pain Management Service. MUSC opioid analgesic comparison chart. December 2011. Available at: <http://docplayer.net/15102741-Musc-opioid-analgesic-comparison-chart.html>. Accessed June 13, 2017.
23. D'Agostino RB Jr. Propensity score methods for bias reduction in the comparison of a treatment to a non-randomized control group. *Stat Med*. 1998;17(19):2265-81.
24. Angrist JD, Pischke JS. *Mostly Harmless Econometrics: An Empiricist's Companion*. Princeton, NJ: Princeton University Press; 2008.
25. Gonzalez AM, Kolbasovsky A. Impact of a managed controlled-opioid prescription monitoring program on care coordination. *Am J Manag Care*. 2012;18(9):516-24.
26. Centers for Disease Control and Prevention. Patient review and restriction programs: lessons learned from state Medicaid programs. CDC Expert Panel Meeting Report. August 2012. Available at: https://www.cdc.gov/drugoverdose/pdf/pdo_patient_review_meeting-a.pdf. Accessed June 13, 2017.

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APPENDIX Comorbidities Associated with Addiction^{11,12}

Grouping	Included Diagnoses	ICD-9-CM
Substance abuse (excluding opioid or sedative)	Alcohol dependence syndrome, drug dependence, nondependent abuse of drugs, cannabis, tobacco	303.xx, 304.1x-304.6x, 304.8x, 304.9x 305.0x-305.4x, 305.6x-305.9x, V11.3
HIV/AIDS	N/A	042.xx, 079.53, v08.xx, 795.71
Hepatitis, A, B, and C	N/A	070.0x, 070.1x, 070.2x, 070.3x, 070.41, 070.44, 070.51, 070.54, 070.70, 070.71, V02.61, V02.62
Skin infections	Cellulitis, due to drugs and medicines, chronic ulcer	111.8x, 111.9x, 680.xx, 681.xx, 682.xx, 684.xx, 685.xx, 686.xx, 681.xx, 693.0x, 693.8x, 693.9x, 707.9x
Mental health	Organic psychotic conditions, other psychoses, neurotic disorders, personality disorders, nonpsychotic disorders, intellectual disabilities	290.xx, 291.xx, 292.xx, 293.xx, 294.xx, 295.xx, 296.xx, 297.xx, 298.xx, 299.xx, 300.xx, 301.xx, 302.xx, 306.xx, 307.xx, 308.xx, 309.xx, 310.xx, 311.xx, 312.xx, 313.xx, 314.xx, 315.xx, 316.xx, 317.xx, 318.xx, 319.xx, V11.0x, V11.1x, V11.2x, V11.4x, V11.8x, V11.9x
Liver disease	Necrosis of liver, cirrhosis, chronic liver disease	570.xx, 571.0x, 571.2x, 571.3x, 571.4x, 571.5x, 571.6x, 571.8x, 571.9x, 572.xx, 573.xx
Pancreatitis	N/A	577.xx
Motor vehicle accidents	N/A	E810.xx, E811.xx, E812.xx, E813.xx, E814.xx, E815.xx, E816.xx, E817.xx, E818.xx, E819.xx
Gastrointestinal bleeding	Gastrointestinal hemorrhage, gastric ulcer, duodenal ulcer, peptic ulcer, gastrojejunal ulcer, esophageal varices	578.xx, 456.xx, 530.8x, 531.0x, 531.2x, 532.0x, 532.2x, 533.0x, 533.2x, 534.0x, 534.2x
Sexually transmitted diseases	Syphilis, candidiasis, chlamydia, genital warts, gonorrhea, trichomoniasis, dysplasia of cervix or vagina	090.xx, 091.xx, 092.xx, 093.xx, 094.xx, 099.xx, 112.1x, 112.2x, 483.1x, 078.19, 078.11, V02.7x, V02.8x, 647.0x, 647.1x, 647.2x, 614.xx, 615.xx, 616.xx, 131.00, 131.01, 131.02, 131.03, 131.09, 622.1x, 623.0x
Burns	N/A	940.xx, 941.xx, 942.xx, 943.xx, 944.xx, 945.xx, 946.xx, 947.xx, 948.xx, 949.xx
Trauma (excluding motor vehicle accidents)	Fractures, dislocation, open wounds, contusions, sprains and strains	800.xx-848.xx, 850.xx-854.xx, 860.xx-887.xx, 890.xx-897.xx, 900.xx-939.xx, 950.xx-959.xx
Poisonings (excluding opioid abuse)	N/A	960.xx, 961.xx, 962.xx, 963.xx, 964.xx, 965.00, 965.01, 965.03, 965.04, 965.05, 965.07, 965.08, 966.xx, 967.xx, 968.xx, 969.xx, 970.xx-979.xx, 980.xx-989.xx

HIV/AIDS = human immunodeficiency virus/acquired immune deficiency syndrome; ICD-9-CM = International Classification of Diseases, Ninth Revision, Clinical Modification; N/A = not applicable.