Commercial and public payer opioid analgesic prescribing policies: A case study

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Research

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Abstract

**Background:** One strategy to address the high number of U.S. opioid-related deaths is to restrict high-risk or inappropriate opioid analgesic prescribing and dispensing. Federal and state laws and regulations have implemented restrictions but less is known about commercial and public payers’ policies aside from clinician anecdotal reports that these policies are increasing. To assess the number and types of policies with temporal trends, we examined commercial and public (Medicaid) payer policies in one state, Michigan, that has high opioid-related deaths and implemented opioid analgesic prescribing laws. Between 2015 and 2018 claims paid by commercial payers dropped 30.5% and 15.2% for public payer, suggesting the impact of federal and state laws and regulations, media, advocacy groups, education, and payer policies.

**Methods:** Policies for seven large commercial payers and the public payer for 2012-2018 were reviewed and categorized by actions. Joinpoint regression was used to summarize temporal trends on number of policies for all payers and commercial and public payer subgroups.

**Results:** Across the seven years, there were 529 action policies (75.57 (95% confidence intervals (CI) 35.93, 115.22) actions per year) with a range of 36 to 103 actions by payer. Limitations on number of days for initial prescriptions being most frequently implemented policy (83 policies and implemented at least once by all eight payers). The least frequently used policy was incentives to providers which was implemented once by one payer. The temporal trend showed a decline in new policies from 2012 to 2013 but a steady increase from 2014 to 2018 (average annual percent change=29.6% (95% confidence intervals 13.2%, 48.5%). The public payer (implemented 47 policies) showed no increase in number of policies over time (AAPC=2.9% (95% CI -41.6%, 61.6%).

**Conclusions:** The eight commercial and public payers implemented many new policies to restrict opioid analgesic prescribing with a steady increase in the number of such policies implemented from 2014 to 2018. This case study documented that at least in one state with high opioid-related deaths and multiple commercial payers, new and different policies were increasingly implemented challenging clinicians providing patient care and researchers determining the impact. Key words: opioid prescribing, commercial insurance, public insurance, policies, regulations, temporal trends

Introduction

Opioid-related deaths in the United States from prescription opioid analgesics is a public health problem with increases from 3,442 deaths in 1999 to 17,029 in 2017 or a nearly 5-fold increase (1). In 2018 the number of deaths declined to 14,975 (2), the first documented decline since the current mortality coding system was implemented in 1999. Although the number of deaths declined, too many people continue to die from accidental or intentional prescription opioid analgesic ingestion.

To address the high number of prescription opioid analgesic-related deaths, multiple strategies have been implemented to reduce unsafe prescribing and dispensing of opioids. At the federal level, actions include changing hydrocodone from Schedule III to the more restrictive Schedule II controlled substance classification (3). At the state level, actions include implementing Prescription Drug Monitoring Programs (PDMP), an electronic database of prescription opioid analgesics and other controlled substance medications dispensed with related prescription-specific information and limited information on patient, prescriber and dispensing pharmacy (4-5). States varied in when they established a PDMP, type of information collected, and the requirements for use (6). Several states including Michigan have integrated their PDMP systems into electronic health records and pharmacy dispensing systems (7). States also vary in other initiatives such mandatory review by prescribers of patients receiving long-term opioid analgesic therapy (8) and type of user allowed to request and review prescription history reports under defined situations (9). In 2012, access to the PDMP was extended to pharmacy benefit managers in several states including Michigan to allow opioid prescription utilization oversight for purposes of identifying fraud or misuse (10). At the federal level, Medicare (the payer for adults ages 65 years and older and those with disabilities) has published new regulations for prescribing opioid analgesics annually since 2015; the regulations apply to all covered
lives regardless of state of residence. If the state regulations or laws are more restrictive than those of Medicare, the prescriber must comply with those of the state. Commercial and state public (i.e., Medicaid) payers have also implemented opioid prescribing policies (note: we will use the term “policy” to refer to commercial payer policies and public payer regulations). Overall, with the exception of evaluations regarding use of states’ PDMP, reviews of state laws and regulations, and payer policies have highlighted the lack of published evaluations and for those published, their low quality (11-13).

For the few payer policies evaluated, there have been comparisons between states (and over time) for prior authorization by Medicaid (14) but policies of commercial payers have been mostly limited to pre and post implementation of providers’ behavior (15) or number of prescriptions (16). In Massachusetts, Blue Cross Blue Shield implemented a comprehensive policy for opioid prescribing with seven different actions or components in 2012 (16). The investigators showed a 14.7% decline in average monthly prescribing rate for all opioids during the 3 years post-implementation but it is not clear that the decline was specific to their members or independent of other interventions such as education, media attention or policies of competing commercial payers. For example, two studies showed that policies can result in members dropping coverage (17) or paying cash for prescriptions (18). Other complications include patients with more than one health plan coverage and prescribers paneled by more than one commercial payer and therefore exposed to multiple opioid prescribing policies. As stated by Comerci and colleagues (19):

> Increasingly, prescription-drug plans are instituting complicated and confusing opioid-prescribing rules. Often, limits are placed on dosage forms, quantities, or both without any evidence that such restrictions will ameliorate opioid overuse and misuse. Navigating these rules is time consuming for both clinicians and pharmacists…

Before the impact of payer policies can be evaluated, the magnitude of the “complicated and confusing” policies have to be articulated. The aim of this study is to quantify the number and type of opioid analgesic prescribing policies implemented by commercial payers and Medicaid in one state, Michigan. This approach allows us to explore the policies while holding constant state laws and regulations.

**Michigan as a case study**

Michigan makes a reasonable case study as it was affected by the opioid epidemic with drug overdose deaths increasing from age-adjusted rate of 6.1 per 100,000 in 1999 to 21.7 in 2017 (20). The age-adjusted rate then declined by 4.1% to 20.7 per 100,000 in 2018 with 78% involving at least one opioid (20). In 2018 Michigan providers wrote 62.7 opioid prescriptions per 100 residents compared to U.S. rate of 51.4 prescriptions (20).

In Michigan, the number of opioid prescriptions paid by commercial insurance accounted for 62.1% of such prescriptions in 2015 with the total number of opioid prescriptions declining in subsequent years (21). From 2015 to 2018, the number of prescriptions declined 30.5% for commercial payers, 11.4% for Medicaid, 15.2% for Medicare and 25.0% for cash (21). The number of opioid prescribers also declined during this time period from 55,180 to 53,850 similar to national analysis (22) even though opioid prescriptions and prescribers were added with the phased inclusion of Veteran’s Administration prescription data into the PDMP (23). The Veteran Administration prescribers were using Michigan’s PDMP by 2018 when prescribers and pharmacists were required to register (24).
Other changes include Michigan requiring Physician Assistants and Advanced Practice Nurses in 2017 to obtain their own Drug Enforcement Administration registration number instead of prescribing under a delegating physicians' number (25). The PDMP originally adopted in 2008 was replaced in 2017 with an updated version having electronic medical record interface and improved drug prescription history reporting capabilities. A proprietary patients’ overdose risk score was also added. In 2017, Michigan passed a law protecting pharmacists from civil liability if they refuse to dispense controlled substance prescriptions when they have a reasonable and good-faith belief that the prescription was not written by a prescriber in good faith or the prescription did not have a medical purpose (26).

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In 2017 Michigan mandated prescribers and pharmacist to register and check the PDMP prior to prescribing or dispensing opioids and other controlled substances (25). Additional laws applicable to all payers implemented during 2018 and 2019 were informed consent for opioid treatment for minors and providing patient information on opioid risks (27); requiring a bona-fide provider-patient relationship for prescribing controlled substances (28) (implemented March 31, 2018 but later extended to March 31, 2019); and limit of seven days prescribing of opioids for acute pain (29), (implemented July 1, 2018).

**Purpose**

Quantifying of number and type of payer policy is a necessary first step in describing the opioid analgesic prescribing restrictions for clinicians and pharmacists prior to evaluating their policy impact. As such, our expectations were that all payers examined would have opioid analgesic prescribing policies, and consistent with the observation by Comerci and colleagues (19), more policies would be implemented over time.

**Methods**
To quantify the number and types of polices, the investigators first collected and then categorized policies implemented by both public (i.e., Medicaid) and major commercial insurers in Michigan on opioid prescriptions from January 2012 through December 2018. This time frame included the estimated 2012 peak Michigan opioid prescribing rate and subsequent monotonic decline (30). We documented policy implementation by year to highlight trends and variability in policy activity by individual payers. Policies related to treatment of substance use disorder or naloxone access were excluded as the study focus was restrictions on opioid analgesic prescribing.

Payers

Commercial payers included in the study were Blue Cross Blue Shield of Michigan, Blue Care Network, Priority Health, Health Alliance Plan, Aetna, United Healthcare, and Cigna. All the payers are for-profit except Health Alliance Plan (nonprofit), Blue Care Network and Blue Cross Blue Shield of Michigan (became a nonprofit mutual in 2014). During the 7-year period, Blue Cross Blue Shield of Michigan was the dominant commercial insurer in the state. In 2016 and 2017, Blue Cross Blue Shield of Michigan, Priority Health and Health Alliance Plan accounted for at least 80% of the large group commercial health insurer market in Michigan (31).

To obtain information on specific payer opioid policies, one investigator (VTL) conducted reviews of the Michigan Department of Health and Human Services preferred drug list and commercial plan formulary updates, and the Michigan legislative activity regarding opioid prescribing. Other sources reviewed included pharmacy association websites, Michigan Department of Health and Human Services Pharmacy and Therapeutic committee and Drug Utilization Review meeting minutes, commercial payer press releases, policy documents and formulary files. Formularies were reviewed for “CNS medications-opioid analgesics”, “narcotic analgesics”, “opioid analgesics”, and “pain relievers-narcotics (or opioids)”. Formulary information regarding a specific opioid agent or dosage form (long acting opioids), transmucosal fentanyl products, as well as medication additions or deletions, restrictions to use, prior authorizations, quantity limits, pharmacy safety reviews (or step edits) were documented. In cases of ambiguities, there were personal follow-up with responsible individuals from the payer plans. From this examination, a chronological list of policies for each payer across the 7-year study period was compiled.

Categorizing policies

To categorize the policy activities the investigators used common formulary management strategies used by payers to promote safe and appropriate opioid prescribing. These strategies were then discussed with five experienced pharmacists practicing formulary management, community, hospital, long-term care and home infusion. The discussions lead to the 12 different action categories, including formulary limitations, limitations on the number of days for an initial opioid prescription, limitations on number of refills, limitations on dosages within the formulary, and prior authorization for initial prescriptions and/or refills.

During the initial review of payer actions, it became apparent that another action category of “pharmacy safety review” or “step-edits” was required, resulting in 13 separate categories of activity (Table 1). The action of safety reviews indicates that the pharmacist must review and document approval to dispense medication. Information required for the pharmacy review can include patient must have first tried and failed other (often first-line and less expensive) therapies, demonstrated an intolerance/allergy/adverse reaction to first-line therapies, or require prescribing by a specialist provider. It also specifies criteria and actions for pharmacists to ensure that a medication is appropriate for an individual patient with respect to dosage, concurrent medications or other factors.

An individual policy can result in more than one activity. An example would be “lock-in program” initiated by a payer to restrict members’ access to opioid analgesics (18). Lock-in programs identify members with pre-defined criteria and restrict their access to one prescriber and pharmacy for opioid prescription claims reimbursement (18). We coded lock-in programs as 1) creating a patient registry, 2) limitation on providers, and 3) limitations on pharmacies. This coding system allows maximum flexibility for other policies with overlapping actions.
Policies were categorized by one investigator (VTL) during documentation for the individual payers. To minimize subjectivity and bias, policy actions were categorized whenever possible using the original titles or formulary classifications (e.g. prior authorization for initial prescription) or intentions (e.g. feedback to providers regarding prescriptions). The action may involve one opioid medication (e.g. deletion of OxyContin from formulary) or a group of medications (e.g. short acting opioids quantity limits). Another investigator (CLA) reviewed the category action assignment for consistency in coding decisions. The investigators discussed category assignment of specific policies to obtain mutual agreement for policies that fit more than one category or were complex in nature.

**Analysis**

The number of actions taken by different payers and years were summarized with descriptive statistics. To examine temporal trends, Joinpoint Regression (version 4.8.0.1) (32) was used with mean number of actions by year across all eight payers as well as subgroups of top three payers, all commercial payers and Medicaid. Joinpoint Regression identifies the model with the best-fitting set of inflection points in the regression model using permutation tests (33) and calculates the annual percent change (APC) to characterize trends over time per segment. Significance tests, 95% confidence intervals (95% CI) for annual percent change and average annual percent change (AAPC) for the entire time period (if there are no inflection points identified) were also computed.

The Wayne State University Institutional Review Board concurred that the project was exempt from human subject research review.

**Results**

For the eight different payers included in the analysis, there were 529 separate opioid analgesic prescription policy actions implemented across seven years (Table 1), for a mean of 75.57 actions (95% CI 35.93, 115.22) per year. Every year had at least one policy implemented with the most actions in 2018 (n=154) and the fewest in 2013 (n=39). Of the payers analyzed, the range in number of actions implemented was wide: 36 to 103. The top three commercial payers by market share had 58, 70 and 72 total number of actions implemented while the public payer had 47 actions implemented. Not all payers implemented new opioid analgesic prescribing actions every year. There were no actions implemented by two payers in 2013, two payers in 2014 and one payer in 2015.

For the separate actions (Table 1), limitations on number of days for initial prescription (n=83) was the most common action followed by prior authorizations for initial prescription (n=77). The least common action implemented was incentives to providers which was implemented once by one payer. The public payer implemented the fewest different actions (9 of 13). Not all payers implemented every action (Table 1).

The payers differed in which actions were most commonly implemented. Three payers most frequently implemented limitations on the number of days for initial prescription, and two payers most frequently implemented prior authorizations for initial prescription, one payer most frequently implemented both limitations on the number of days for initial prescription and prior authorizations for initial prescription. One payer most frequently implemented step-edits and one payer most frequently implement limitations on number of refills and registries.

**Examples of payers having different policies addressing similar opioid prescribing challenges**

To illustrate that the payers implemented separate policies, we examined their response to federal guidelines recommending opioid analgesic prescribing daily limit of $\leq 50$ MME (morphine milligram equivalents) (34). The public payer implemented a 45 MME daily limit on opioid analgesic prescriptions March 2016. One commercial payer implemented a 50 MME daily limit August 2016, one commercial payer implemented a 50 MME daily limit for short acting opioids December 2017, and one commercial payer implemented a 50 MME daily limit July 2018. The remaining four payers had limits of 90 MME or higher as of December 2018.
Another example is the response to the 2016 safety warning on combined use of opioid and benzodiazepine medications (35). Two commercial payers implemented pharmacist safety reviews January 2017, two commercial payers implemented feedback to prescribers of opioid analgesics >100 MME per day in combination with benzodiazepines March 2016 and June 2016, and a commercial payer implemented a registry of patients filling prescriptions for these medications June 2016. Three payers did not implement policy as of December 2018.

**Policies superseded by state law**

We also documented that some policies were made moot by later state regulations. For example, three payers implemented limitations on the number of days of opioid analgesics for acute pain prior to the state implementing the same limitation by law. However, policies superseded by state law were in the minority.

**Temporal trends**

The temporal trends of implementing new opioid analgesic policy actions across all eight payers identified one inflection point occurring in 2014 (Figure 1). The APC was 19.8% for 2012-2014 (not significantly different from 0) and 42.3% for 2014-2018 (significantly different from 0, p<.001). Across the time period, the AAPC was 29.6% (13.2%, 48.5%) for the seven commercial payers, 2.9% (-41.6%, 61.6%) for the public payer, and 23.2% (13.4%, 33.9%) for the top three commercial payers in market share. No subgroup analysis found an inflection point.

**Discussion**

In this review we found commercial and public payers in Michigan implemented multiple opioid analgesic prescription policies during the examined period: 2012 through 2018. Each payer implemented a range of policy actions during almost every year reviewed and the actions differed across payers. Importantly the number of actions for the group of payers showed a steady increase over time that was not restricted to Medicaid, commercial or subsets of the commercial payers. These opioid analgesic prescribing policies were implemented even though there were federal and state laws and regulations, suggesting that payers in other states may act similarly. Furthermore, the policies may predate state law but they were in the minority. Payers may implement these policies in response to growing medical evidence of over-use of opioids, demands of advocacy groups, media attention, corporate concern and/or costs of medications and adverse outcomes. Payers have a financial incentive to minimize inappropriate opioid use to avoid the costs of treating opioid use disorder, overdoses, and other outcomes.

Finding these policies is challenging. They do not reside in one location. Multiple locations were searched including searches of formularies over time by payer name and reviews of comprehensive payer websites such as the Michigan Department of Health and Human Services Pharmacy Preferred Drug List for the public payer. This latter source was the most productive source for the public payer.

What is the impact of these policies? Our purpose was to first document that the policies existed, the type of policies, and the increasing number of them (at least through 2018). After showing that there are numerous and increasing policies, the next step is to determine their impact on providers and patients. The policies may improve appropriate prescribing or they may increase discontinuations of opioid analgesics and withholding needed medication from eligible patients. The variety of policies by the different payers offers natural experiments to evaluate them. However, the sheer number of policies and the right of patients to change payers or to pay cash complicates any such analysis. Investigators should also examine the decline in the number of prescribers, observed both in Michigan and nationally (22), and if that is related to the number of policies.

The study is limited by time frame and examination of only one state. We did not review all commercial payers (although we included the largest carriers in the state) or Medicare Advantage plans. We also did not include the Michigan Medicaid managed care plans. Our review focused on commercial plan drug formularies for the commercial payers and Medicaid fee-
for-service preferred drug lists. We are aware that these policies do not represent all past and present commercial payer plans. Policies may have been implemented that were missed in our retrospective review despite checking multiple sources. Other reviewers may categorize the policy actions differently. We also did not evaluate the ease of complying with policies as a prescriber, pharmacist, or patient, including the time required to obtain approval of authorization for an opioid analgesic prescription from a payer.

**Conclusion**

Commercial and public payer policies on opioid analgesic prescribing should both prioritize reducing diversion, misuse and overdoses through safe prescribing and dispensing practices while also prioritizing access to an essential medication class for pain management. The increase and proliferation of different action policies over time in one state that differ by payers challenges clinicians and patients to find a balance and achieve optimal clinical care for patients requiring pain management. In that respect, we concur with Comerci and colleagues (19) of finding “complicated and confusing” opioid analgesic prescribing policies.

**Abbreviations**

AAPC average annual percent change  
APC annual percent change  
CI confidence intervals  
MME morphine milligram equivalents  
PDMP Prescription Drug Monitoring Program

**Declarations**

**Ethics approval and consent to participate:**

The Wayne State University Investigational Review Board reviewed the study and found it to qualify for exemption under the Department of Health and Human Services Code of Federal Regulations (Concurrence of Exemption IRB # 051318MP2X).

No human participants or medical records or animals were accessed.

**Consent for publication:**

Not applicable

**Availability of data and materials:**

The dataset generated and analyzed during the current study are available from the corresponding author on reasonable request.

**Competing interests:**

The authors declare that they have no competing interests.

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**Authors' contributions:**

CLA and VTL had equally significant contributions to the conception and design of the research, collection of data, and interpretation of the results. CLA conducted the analyses. Both authors were involved in the writing of the manuscript and approved the final version.

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Table 1. Policy actions by seven commercial insurers and Medicaid-for-service for prescribing opioid analgesics by year, Michigan
### Specific Action

| Specific Action                                                                 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | Total | # payers implemented |
|--------------------------------------------------------------------------------|------|------|------|------|------|------|------|-------|---------------------|
| LIMITATIONS on number days initial prescription                              | 8    | 4    | 4    | 7    | 11   | 22   | 27   | 83    | 8                   |
| PRIOR AUTHORIZATION on initial prescription                                   | 9    | 7    | 5    | 9    | 13   | 16   | 18   | 77    | 8                   |
| Formulary limitation                                                           | 5    | 1    | 3    | 5    | 10   | 12   | 24   | 60    | 8                   |
| Registry of patients                                                           | 11   | 4    | 6    | 6    | 6    | 7    | 18   | 58    | 8                   |
| Pharmacy safety review/step edit                                              | 4    | 6    | 6    | 9    | 6    | 14   | 12   | 57    | 8                   |
| PRIOR AUTHORIZATION for long-acting/extended release opioids                  | 6    | 2    | 5    | 4    | 3    | 6    | 10   | 36    | 8                   |
| LIMITATIONS on providers                                                      | 4    | 6    | 5    | 7    | 3    | 8    | 3    | 36    | 8                   |
| LIMITATIONS on number refills                                                 | 6    | 2    | 3    | 2    | 0    | 10   | 13   | 36    | 7                   |
| LIMITATIONS on dosages within formulary                                        | 4    | 1    | 2    | 2    | 5    | 7    | 9    | 30    | 7                   |
| PRIOR AUTHORIZATIONS for refill prescription(s)                               | 1    | 3    | 2    | 1    | 1    | 1    | 8    | 9     | 25                  |
| PRIOR AUTHORIZATIONS for higher potency opioids                                | 2    | 1    | 2    | 1    | 1    | 5    | 9    | 25    | 8                   |
| Feedback to providers on opioid prescribing                                   | 2    | 2    | 0    | 3    | 0    | 1    | 1    | 9     | 3                   |
| Incentives to providers                                                       | 0    | 0    | 0    | 0    | 0    | 0    | 1    | 1     | 1                   |
| **Total**                                                                     | **62** | **39** | **43** | **56** | **59** | **116** | **154** | **529** |                     |

### Figures

**Figure 1**

![Figure 1](image-url)

*Indicates that the cox models were significant (p ≤ 0.05) compared to the baseline model with no covariates. No significant differences were found at p ≤ 0.05.*
Mean number of action policies implemented by year for seven commercial and one public payer, Michigan. The line shows the average percent change with increases from 2014 to 2018.