ORIGINAL ARTICLE

Decline in primary care providers' prescribing of Schedule II opioids following the implementation of federal and state guidelines

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ABSTRACT

Objective: *Prescription opioid misuse represents a social and economic dilemma in the United States. The authors evaluated primary care providers' (PCPs) prescribing of Schedule II opioids at our institution in Kentucky.*

Design: *Prospective evaluation of PCPs' prescribing practices over a 3-year period (October 1, 2014 to September 30, 2017) in an outpatient setting.*

Methods: *An analysis of Schedule II opioid prescribing following the implementation of federal and state guidelines and evidence-based standards. Special attention focused on Schedule II opioid prescriptions with a quantity > 90, Opana/Oxycontin, and morphine equivalent daily dosage.*

Results: *A statistically significant increase in the total number of PCPs and PCPs who prescribed Schedule II opioids was observed, while there was a concurrent significant decrease in the average number of Schedule II opioid pills prescribed per PCP, Schedule II opioid prescriptions per PCP, Schedule II opioid pills prescribed per patient by PCPs, Schedule II opioid prescriptions with a quantity > 90 per PCP, and Opana/Oxycontin prescriptions per PCP. A statistically significant decline in the average morphine equivalent daily dosage of Schedule II opioids per PCP was noted.*

Conclusions: *This study reports the benefit of incorporating federal and state regulations and institutional evidence-based guidelines into primary care practice to decrease the number of Schedule II opioids prescribed. Further preventive measures include selecting alternative treatments to opioids and reducing the rates of opioid nonmedical use and overdose while maintaining access to prescription opioids when indicated.*

INTRODUCTION

Of the 52,404 drug overdose deaths in the United States in 2015, a total of 63.1 percent involved an opioid.[1] Furthermore, a prescription opioid was involved in approximately 15,000 (50 percent) of the opioid-related deaths. Opioid use disorder (addiction) is a chronic, relapsing disease with significant economic, personal, and public health repercussions.[2,3] In 2015, an estimated two million individuals in the United States were afflicted with opioid use disorder associated with prescription opioids.[4] According to the Centers for Disease Control and Prevention (CDC), the economic burden of prescription opioid misuse in the United States is $78.5 billion annually, including healthcare costs, lost productivity, addiction treatment, and criminal justice involvement.[2,5] Between 2000 and 2014, the rates of death from prescription-opioid overdose nearly quadrupled from 1.5 to 5.9 deaths

per 100,000 persons.[6] The morphine equivalent daily dose (MEDD) was established to determine a patient's cumulate intake of any opioid drugs over 24 hours. The Morphine Milligram Equivalent is a numerical value assigned to opioids to reflect their relative potencies.

The prescribing practices of opioids has transitioned from prescribing opioids solely for acute and postsurgical pain and end-of-life care to treating chronic noncancer pain. The burden of prescribing opioids often falls to primary care providers (PCPs) who manage their patients' chronic pain. In 1999, Kentucky implemented its prescription drug monitoring program (PDMP), Kentucky All Schedule Prescription Electronic Reporting System (KASPER), which tracks all controlled substance prescriptions dispensed within the state.[7] In response to the crisis of prescription drug misuse and diversion, House Bill 1 (HB1) passed in 2012 in Kentucky that primarily focused on the prescribing and monitoring of controlled prescription drugs and regulating pain clinics in Kentucky.[8] This bill requires that all providers and dispensers register with and utilize KASPER.

We previously reported a pilot study (January 1, 2015 to December 31, 2015) of PCPs' prescribing practices of Schedule II opioids at our institution in Kentucky, with a focus on the top 10 PCP prescribers compared to the total 149 PCP prescribers.[9] The top 10 PCP prescribers accounted for 38.4 percent of the Schedule II controlled substances and 47.8 percent of the Schedule II opioids with > 90 pills dispensed. The top 10 PCP prescribers had a considerably higher number of patients with back pain and degenerative disc disease which may have compelled them to prescribe a greater amount of Schedule II opioids compared to all 149 PCP prescribers.

There are no national standards to monitor PCPs' prescribing practices of opioids. The present study expands upon our previous work by presenting a 3-year analysis of PCPs' prescribing practices of Schedule II opioids. Particular attention is dedicated to Schedule II opioid prescriptions with a quantity > 90, Opana/Oxycontin prescriptions, and morphine equivalent daily dosage. We discuss the federal and state guidelines pertaining to opioid prescribing that have been implemented into routine primary care practice.

METHODS

Under an institutional review board-approved protocol, this 3-year prospective study (October 1, 2014 to September 30, 2017) investigated the PCPs' prescribing practices of Schedule II opioids at our institution following the implementation of HB1 in Kentucky. Our institution is a community-based hospital system, and the PCPs treated patients in an adult outpatient setting. All other controlled substances besides Schedule II opioids were excluded from the data.

After HB1 was passed in Kentucky, our institution instituted evidence-based guidelines to ensure compatibility with HB1. All PCPs were educated about Schedule II opioids, and their prescribing behaviors were monitored and audited. The prescribing data was stratified, and the top 10 percent of PCPs who prescribed the most Schedule II opioids were identified. These physicians received intensive education and personalized feedback about their prescribing behaviors of Schedule II opioids in relation to their peers. Repeat auditing of the outlier PCPs was conducted.

Our institution developed a Controlled Substance Task Force in 2016 comprised of PCPs, a pain medicine provider, a pharmacist, a quality outcomes analyst, director of the poison control center, and the director for quality, safety, and compliance. The goals of this committee include ensuring (1) appropriate, responsible, and judicious prescribing of controlled substances, (2) patient safety, and (3) compliance with state and federal regulations regarding the prescribing of controlled substances.

Statistical analysis

The methodology utilized for the statistical analysis consisted of the Mann-Kendall test for trend in time series data, with the Holm correction for multiple comparisons. The analysis was performed for each month over the 3-year period, reflecting a 36-month test for trend in time. $p < 0.05$ indicated statistical significance.

For the majority of the metrics, the first 3 months were exceedingly large relative to the other months. When this was the case, trends generally looked artificially negative as it seemed that the numbers were decreasing solely because the first 3 months exhibited such large values. To avoid skewing the linear trend analysis, the first 3 months were removed and all of the statistical analyses were replicated. The decreasing trends were still statistically significant, with all adjusted p-values < 0.03.

RESULTS

PCPs and Schedule II opioids

There was an increase in the total number of PCPs (n = 174 to 273), PCPs who prescribed Schedule II opioids (n = 137 to 161), all prescriptions written by PCPs (n = 115,402 to 143,886), and patient-PCP encounters (n = 307,143 to 375,603) at our institution over the 3-year period (all < 0.000001; Table 1). The total number of patients prescribed Schedule II opioids (n = 5,901 to 4,288) and Schedule II opioid prescriptions (n = 8,910 to 5,673) decreased (<0.001 and 0.002, respectively; Table 1). Furthermore, the average number of Schedule II opioid pills prescribed per PCP (n = 5,117 to 1,910), Schedule II opioid prescriptions per PCP (n = 51 to 21), and Schedule II opioid pills prescribed per patient by PCPs (n = 151 to 122) all decreased (<0.001, < 0.001, and 0.002, respectively; Table 1 and Figure 1). A decline was noted in the percentage of PCPs who prescribed Schedule II opioids (n = 78.8 to 58.9 percent), total number of prescriptions prescribed by PCPs that are Schedule II opioids (n = 7.7 to 3.9 percent), and patients seen by PCPs who were prescribed Schedule II opioids (n = 1.9 to 1.1 percent) (all < 0.001; Table 1).

Schedule II opioids with a quantity > 90

The total number of Schedule II opioid prescriptions with a quantity > 90 (n = 4,321 to 2,222), and the average number of Schedule II opioid prescriptions with a quantity > 90 per PCP (n = 25 to 8) decreased during our 3-year study (both < 0.001; Table 2 and Figure 1). Additionally, the percentage of Schedule II opioid prescriptions >90 out of all Schedule II prescriptions written by PCPs declined (n = 48 to 39 percent) (<0.001; Table 2).

Opana/Oxycontin

A reduction in the total number of Opana/Oxycontin prescriptions (n = 148 to 120) and average number of Opana/Oxycontin prescriptions per PCP (n = 0.8 to 0.44) was observed (0.002 and 0.03, respectively; Table 2).

Morphine equivalent daily dosage

Both the total MEDD of Schedule II opioids ordered by PCPs (n = 343,155 to 258,270) and average MEDD of Schedule II opioids per PCP (n = 47.57 to 45.63) decreased during the 3 years (both 0.0006; Table 2).

Table 1. PCPs' prescribing of Schedule II opioids at our institution (October 1, 2014-September 30, 2017)

Metric	October 2014	September 2017	p-Value
Total number of PCPs	174	273	<0.000001
Total number of PCPs who prescribed Schedule II opioids	137	161	<0.000001
Total number of all prescriptions written by PCPs	115,402	143,886	<0.000001
Total number of patient-PCP encounters	307,143	375,603	<0.000001
Total number of patients prescribed Schedule II opioids	5,901	4,288	<0.001
Total number of Schedule II opioid prescriptions	8,910	5,673	0.002
Average number of Schedule II opioid pills prescribed per PCP	5,117	1,910	<0.001
Average number of Schedule II opioid prescriptions per PCP	51	21	<0.001
Average number of Schedule II opioid pills prescribed per patient by PCPs	151	122	0.002
Percentage of PCPs who prescribe Schedule II opioids	78.7 percent	58.9 percent	<0.001
Percentage of total number of prescriptions prescribed by PCPs that are Schedule II opioids	7.7 percent	3.9 percent	<0.001
Percentage of patients seen by PCPs who were prescribed Schedule II opioids	1.9 percent	1.1 percent	<0.001

Abbreviation: PCP, primary care physician.

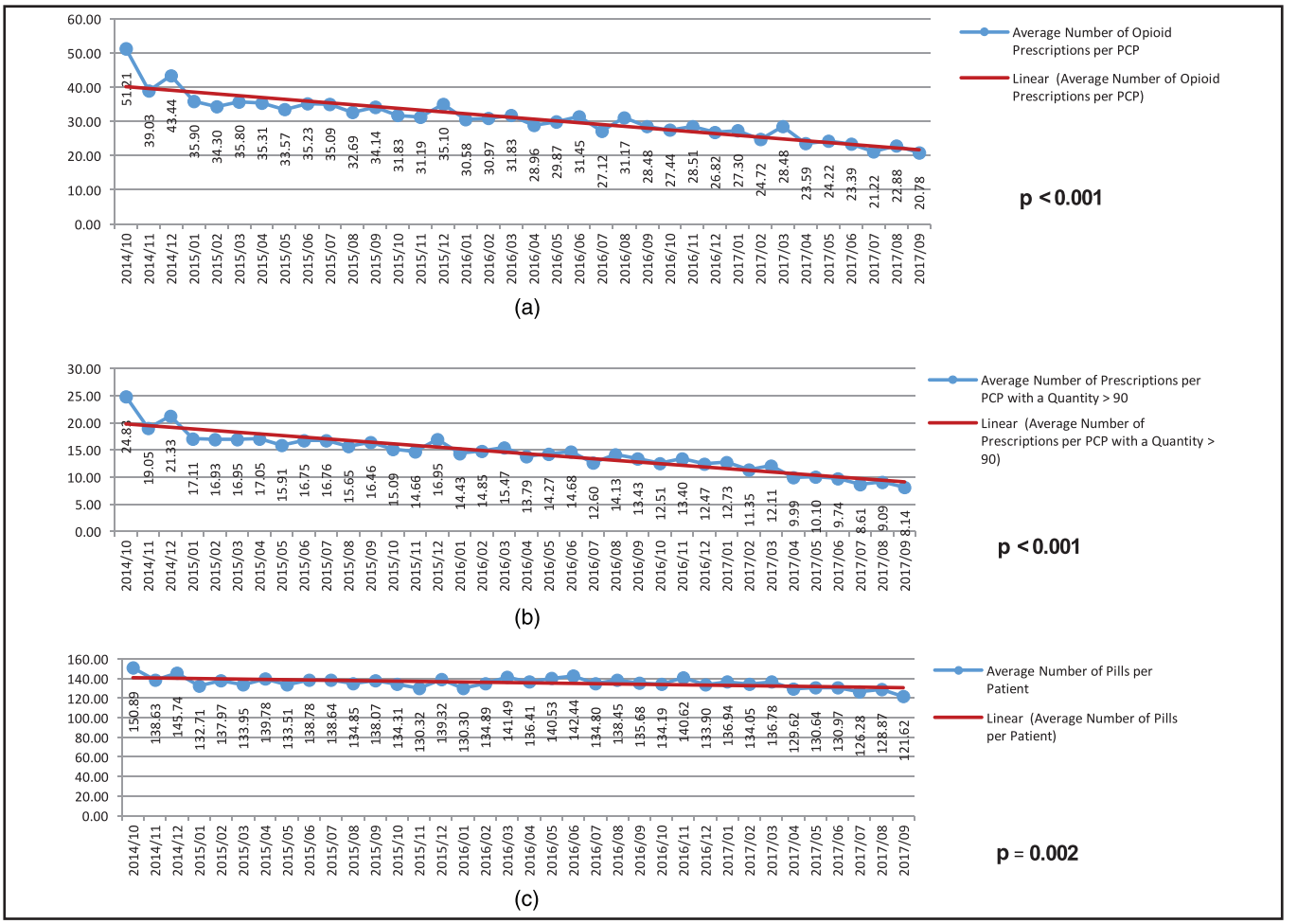

Figure 1. Trend curves demonstrating the average number of (A) Schedule II opioid prescriptions per PCP at our institution, (B) Schedule II opioid prescriptions with a quantity > 90 per PCP at our institution, and (C) Schedule II opioid prescriptions per patient by PCPs at our institution.

DISCUSSION

PCPs' prescribing of Schedule II opioids represents a fine line between alleviating patients' pain with the lowest opioid dose possible without burgeoning an addiction. In this study, we present a model of incorporating federal and state regulations and institutional evidence-based guidelines into the prescribing practices of PCPs. Although there was a statistically significant increase in the total number of PCPs and PCPs who prescribed Schedule II opioids, we observed a statistically significant decrease in the average number of Schedule II opioid pills prescribed per PCP, Schedule II opioid prescriptions per PCP, Schedule II opioid pills prescribed per patient by PCPs, Schedule II opioid prescriptions with a quantity > 90 per PCP, and Opana/Oxycontin prescriptions per PCP. Additionally, a statistically significant decline in the average MEDD of Schedule II opioids per PCP was noted.

Opioid misuse has escalated to a significant crisis in the United States and particularly in the state of Kentucky.[9-11] Prescription opioid-related overdose deaths increased sharply in the United States between 1999 and 2010 concurrently with an increase in opioid prescribing.[2] The amount of opioids prescribed in 2015 was approximately three times as high as in 1999.[2] Long-term opioid use to treat noncancer pain has been increasingly encountered in the primary care setting with the accompanying risks of addiction, diversion, and overdose.[12-19] Several studies have addressed implementing opioid prescribing guidelines in primary care.[12,15,20] Following a multidisciplinary group intervention, Chen and colleagues reported that noncancer patients receiving any opioid prescriptions decreased from 3.9 to 3.4 percent

Table 2. PCPs' prescribing of Schedule II opioids with a quantity > 90, Opana/Oxycontin, and morphine equivalents at our institution (October 1, 2014-September 30, 2017)			
Metric	**October 2014**	**September 2017**	**p-Value**
Total number of Schedule II opioid prescriptions with a quantity > 90	4,321	2,222	<0.001
Average number of Schedule II opioid prescriptions with a quantity > 90 per PCP	25	8	<0.001
Percentage of Schedule II opioid prescriptions > 90 out of all Schedule II prescriptions written by PCPs	48 percent	39 percent	<0.001
Total number of Opana/Oxycontin prescriptions	148	120	0.002
Average number of Opana/Oxycontin prescriptions per PCP	0.8	0.44	0.03
Total MEDD of Schedule II opioids ordered by PCPs	343,155	258,270	0.0006
Average MEDD of Schedule II opioids per PCP	47.57	45.63	0.0006
Abbreviations: PCP, primary care provider; MEDD, morphine equivalent daily dosage.			

(p = 0.02) and chronic opioid prescriptions dropped from 2.0 to 1.6 percent (p = 0.03).[12] The rate of urine drug screening increased from 9.2 to 17.3 percent (p = 0.005) among noncancer chronic opioid patients.[12] Interestingly, the majority (60.8 percent) of PCPs do not feel confident managing chronic pain as discerned in the Opioid Therapy Provider Survey.[21] Provider confidence in managing chronic pain was positively associated with an opioid therapy protocol (p = 0.001), a consistent practice-based approach (p < 0.001), and identifying patients at risk for opioid misuse (p = 0.006).[21] These findings reflect the importance of establishing standardized guidelines to prescribe opioids and recognizing and monitoring patients who may be at risk of opioid misuse.

Several organizations have strived to combat the rampant opioid epidemic. In 2015, the American Society of Addiction Medicine proposed national practice guidelines for evaluating and treating individuals with opioid use disorder.[3] In 2016, the CDC updated the guidelines for prescribing opioids for chronic pain with the primary goals of (1) enhancing communication about the benefits and risks of opioids for chronic pain, with non-opioids as the preferable therapy; (2) improving safety and effectiveness of pain treatment; and (3) decreasing risks associated with long-term opioid therapy.[22] These guidelines were intended for PCPs who treat patients with chronic pain (>3 months and excluding active cancer treatment, palliative care, and end-of-life care) in an outpatient setting.[22]

In addition to Kentucky's HB1, Kentucky's House Bill 333 passed on June 29, 2017 and modified the Kentucky Board of Medical Licensure (KBML) with respect to prescribing Schedule II medications (Table 3).[23] Kentucky physicians are required to know and adhere to the KBML requirements and meet the documentation obligations. A myriad of methods has also been suggested to reduce prescription opioid misuse, including patient contracts, urine drug testing, requiring prescribers to check a centralized database prior to prescribing opioids, and imposing tighter restriction on the marketing and promotion of opioids.[14,18]

In addition to the surge in opioid prescriptions, a total of 10.3 million individuals consumed prescription opioids nonmedically in the United States in 2014.[6] The valiant efforts aimed to reduce both medical and nonmedical prescription opioid use has simultaneously drastically increased the rates of heroin use and deaths from heroin overdose.[24] A total of 914,000 individuals reported heroin use in the United States in 2014 representing a 145 percent increase since 2007, and mortality due to heroin overdose more than quintupled, from 1,842 deaths in 2000 to 10,574 deaths in 2014.[6] While it has been suggested that the decreased availability of prescription opioids due to tightened restrictions has spurred the heroin epidemic,[25] increased accessibility, reduced price, and high purity of heroin may seem more likely triggers.[26] Fentanyl- and heroin-related overdose death rates increased across

Table 3. Kentucky's House Bills 1 and 333

House Bill 1

- Practitioner or pharmacist must register with the Cabinet to use KASPER
- Before initial prescribing or dispensing of Schedule II controlled substance:
  - Obtain complete history and physical
  - Query KASPER every 3 months on patient's personal data
  - Educate patients about specific drug
  - Develop written treatment plan
  - Discuss and obtain written informed consent
- Prescribing over 90 days requires:
  - Random urine drug screen and pill counts
  - Consider referring to a specialist

House Bill 333

- A 3-day limit on prescribing for acute conditions unless a physician documents:
  - Description of the acute condition
  - Assessment that more than 3 days is necessary
  - Alternative treatments are inadequate
- If patients are noncompliant: physicians must taper medications, stop prescribing, or refer the patient to an addiction and/or pain management specialist
- Tapering in a slow manner to minimize signs and symptoms of opioid withdrawal
- Refer patients to addiction treatment if they have not attained improvement of their medical complaint, have experienced significant adverse effects including an overdose, exhibit drug-seeking behavior or diversion, or consuming high-risk medications concurrently

Abbreviations: KASPER, Kentucky All Schedule Prescription Electronic Reporting; MME, morphine milligram equivalents.

all age groups in Kentucky from years 2011 to 2015 with the highest rates consistently among 25-34 year olds.[11] Interestingly, the majority of the heroin and fentanyl overdose decedents had a history of significant exposure to legally acquired prescription opioids. For example, a total of 91 percent of heroin decedents had PDMP records for opioid analgesics excluding buprenorphine during the 5 years prior to death, and 77 percent had opioid prescriptions filled within 2 years before death.[11]

KASPER represents the "gold standard" for PDMPs. KASPER serves many valuable roles, such as (1) assisting prescribers with their treatment decisions, (2) identifying patients who would benefit from substance misuse treatment, (3) recognizing doctor shoppers, and (4) serving as an investigative tool for law enforcement and regulatory agencies.[7] Kentucky's ranking among states with the highest nonmedical use of prescription opioids in Kentucky plunged from second to thirty-first place.[27] Kentucky physicians' prescribing practices have strengthened by their use of KASPER, as reflected by a survey indicating that 90 percent of physicians have "refused to prescribe or dispense a controlled substance based on the information contained in a KASPER report."[27] The number of KASPER report requests substantially increased between 2009 and 2017, including an escalation in PDMP data sharing (Figure 2). Of note, the percent change of Schedule II opioids hydrocodone and oxymorphone (brand names Opana and Opana ER) substantially decreased between July 2011 and June 2012 (prior to the passage of HB1) and July 2015 and June 2016 as reported to KASPER, specifically, 21.6 and 19.7 percent (Figure 3). This data indicate the intended goal of HB1 to decrease the prescribing of Schedule II opioids.

Concurrent with an increase in public awareness of opioids and fear of addiction is PCPs' concern about being audited and losing their license due to inappropriate prescribing of Schedule II opioids. Our 3-year study identifying the trends of PCPs' prescribing of Schedule II opioids and incorporating federal and state prescribing guidelines into daily practice demonstrated a statistically significant decline in the number of Schedule II opioids prescribed per patient by PCPs despite an increase in number of prescribing PCPs. In addition to the multidisciplinary Controlled Substance Task Force established at our institution in 2016, we also received a $50,000 grant in 2017 intended to serve as an education initiative with a recognition of responsibility for both PCPs and patients. PCPs are encouraged to be more transparent and judicious with patients, prescribe fewer Schedule II opioid substances and discontinue these medications sooner, and lower each patient's daily MED. Patients should be informed about the risk of opioid addiction, how to store their opioid medications properly, be offered alternatives to opioids such as nonsteroidal anti-inflammatory drugs, massage, and acupuncture, and be educated about disposing of opioid medications without resorting to drug diversion. These tools offer an effective means of positively impacting the opioid epidemic while keeping PCPs safe from an auditing standpoint and ensuring the highest quality care to patients.

The limitation of our study is that it focused solely on PCPs' prescribing practices of Schedule II opioids. We intend to expand our efforts to include stimulant and sedative medications as well as specialists' prescribing of controlled substances.

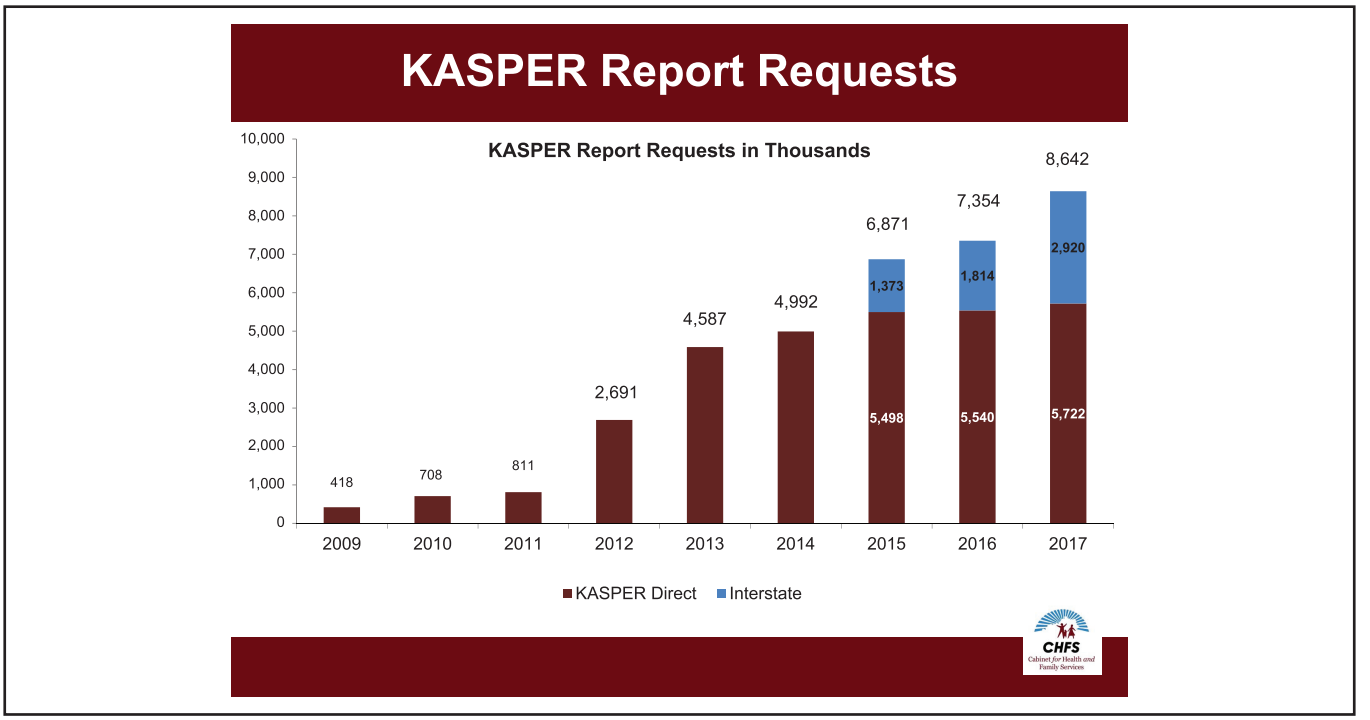

Figure 2. Number of KASPER reports requested between 2009 and 2017. The maroon represents requests from authorized KASPER users logged into their own KASPER account. The blue reflects authorized users of other state prescription drug monitoring programs (PDMP) logged into their home state PDMP who requested Kentucky data on their patients via Kentucky's interstate data sharing capability. (KASPER data provided by the Cabinet for Health and Family Services, Frankfort, KY).

Controlled Substance Dispensing Comparison

Drug	July 2011 - June 2012	July 2015 - June 2016	Percent Change
Hydrocodone	3,303,453	2,590,661	– 21.6 percent
Oxycodone	977,256	1,058,655	+ 8.3 percent
Oxymorphone	24,485	19,655	– 19.7 percent
Tramadol	431,455	594,309	+ 37.7 percent
Alprazolam	947,672	786,267	– 17.0 percent
Diazepam	413,983	360,905	– 12.8 percent
C-II Stimulants	838,170	1,021,748	+ 21.9 percent
Buprenorphine/ Naloxone	269,488	647,029	+ 240.1 percent
All Controlled Substances	10,943,722	10,681,811	– 2.4 percent

Number of prescriptions dispensed as reported to KASPER

CHFS Cabinet for Health and Family Services

Figure 3. Schedule II controlled substances dispensed statewide prior to and following the implementation of House Bill 1 in Kentucky (KASPER data provided by the Cabinet for Health and Family Services, Frankfort, KY).

CONCLUSION

The number of Schedule II opioids decreased both statewide and at our institution prescribed by PCPs following the implementation of HB1 in Kentucky in 2012. Additionally, the number of KASPER reports requested increased statewide. Further efforts to curtail the opioid epidemic include continued monitoring of the impact of HB1 at our institution, investigating the prescribing habits of PCPs with a focus on outliers, and educating physicians and patients about the negative consequences of Schedule II opioids such as misuse, addiction, diversion, and a potential fatality.

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