Kentucky House Bill 1 Impact Evaluation: Executive Summary

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Background

In 2012, the Kentucky General Assembly passed comprehensive legislation aimed at addressing the continuing problem of prescription drug abuse and diversion. House Bill 1 (HB1), effective July 20, 2012 and outlined in Kentucky Revised Statutes (KRS) 218A.172, made sweeping changes relative to the prescribing and monitoring of controlled prescription drugs in an effort to address the prescription drug abuse problem in Kentucky. HB1 regulated pain clinics and placed new expectations on prescribers and dispensers of controlled substances (CS), including mandatory registration with the Kentucky All Schedule Prescription Electronic Reporting (KASPER) system and the requirement to query the KASPER system under particular circumstances. Additionally, HB1 required dispensers of CS to report dispensing records to KASPER within one day of dispensing.

The requirements for mandatory registration and utilization of KASPER were included to assist prescribers in making appropriate treatment decisions, to identify patients potentially in need of substance abuse treatment interventions and to identify possible doctor shoppers. However, as with any policy change, there was concern over unintended consequences that impacted patients and providers due to implementation of the law. To maximize the effectiveness of HB1 and minimize unintended consequences, a comprehensive assessment of HB1's impact on patients, prescribers, and citizens in Kentucky was needed. The goals of the HB1 Impact Evaluation were to: 1) evaluate the impact of HB1 on reducing prescription drug abuse and diversion in Kentucky; 2) identify unintended consequences associated with implementation of HB1; and 3) develop recommendations to improve effectiveness of HB1 and mitigate unintended consequences.

To achieve these goals three distinct projects were conducted with the following aims. Project 1 was conducted to study changes in KASPER utilization and CS prescribing. Project 2 was a qualitative study designed to collect user perceptions of the effectiveness of KASPER and to identify potential unintended consequences of HB1. Project 3 was conducted to study changes in patient and prescriber behavior and outcomes.

Key Findings

General Impact of HB1

As expected, the total number of CS prescriptions dispensed in Kentucky decreased for the first time since the inception of KASPER in the post-HB1 period, with the numbers of prescriptions dispensed for all Schedules of CS (CII

– CV) decreasing by 4 to 8% in the post-HB1 period. While both opioid and benzodiazepine prescribing decreased, stimulant prescribing continued to increase at its previous rate. As HB1 was originally crafted by the legislature to specifically address the abuse and diversion of Schedule II opioid and Schedule III hydrocodone products, this was the desired outcome. The continued increase in stimulant prescribing is evidence that stimulant prescribing was not the focus of the legislation and argues against a blanket chilling effect of HB1 on CS prescribing.

In interviews and surveys of prescribers, pharmacists and law enforcement when asked about their experience with HB1 and its implementation stated that although there was initial confusion and disruptions to workflow in their professions those have largely been resolved and, for the most part, have not negatively impacted health care professional practices. It should be noted however, that a minority of prescribers indicated they no longer prescribe CS, or prescribe fewer CS, as a result of the HB1 mandate and its burden on their practices.

In the quantitative evaluation, it was found that HB1 had a significant impact on KASPER registration and utilization in these professionals' workplace. As a result of the HB1 mandate, prescriber registrants increased by 262% and the mean number of queries made annually by prescribers increased by 650%. Similarly, pharmacist registrants increased by 322% and mean number of pharmacist queries increased by 124%. The preferential impact on prescriber queries compared to pharmacists was expected, as HB1 did not mandate pharmacists to query KASPER prior to dispensing.

Concurrently, in the interviews and stakeholder surveys, prescribers and pharmacists indicated utilizing more KASPER reports in their practice and discussing KASPER reports with patients and other health care providers more frequently. This observation may be a direct result of the statutory changes in HB1 that authorized providers to provide copies of reports to patients and allowed them to be shared with other health care providers and placed in medical charts. Additionally, the majority of prescriber and pharmacist respondents reported little change in prescribing and dispensing habits since implementation of HB1, although they perceived their prescribing and dispensing behaviors to be monitored more closely.

Impact on Prescriber Behavior

In the post-HB1 period, the number of unique prescribers and unique patients in the KASPER dataset decreased by 14% and 7%, respectively. At any given time

throughout the study period, almost two-thirds of the over 55,000 unique prescribers in the KASPER dataset were identified as out-of-state prescribers who, on average, issued only about 10% of all the CS prescriptions reported to KASPER. In contrast, the approximately 14,000 unique Kentucky prescribers identified in the dataset each fiscal year studied, issued over 10 million CS prescriptions or about 90% of the total CS prescriptions reported to KASPER. Interestingly, the number of unique Kentucky prescribers increased each fiscal year studied. Although individual prescribers may have opted out of prescribing CS post-HB1 as suggested from the surveys, overall, the number of unique Kentucky prescribers issuing CS did not decline. Nurse practitioners (APRNs) as a group represent a small proportion of the overall number of CS prescribers and issue relatively few (<10%) of the CS prescriptions dispensed. However, across the study period, the number of Kentucky APRNs issuing CS prescriptions grew considerably, as did the total and mean number of CS prescriptions dispensed by this group of prescribers. This suggests that this group of CS prescribers may play a role in ensuring access to legitimate CS therapy.

HB1 preferentially impacted patient-level prescribing of specific drug classes and individual drugs within a class. The mean number of prescriptions issued for oxycodone, hydrocodone and oxymorphone - three specific opioids associated with abuse and diversion in Kentucky - decreased in the post-HB1 period, while the mean number of prescriptions per patient for other opioids commonly used to treat chronic cancer pain increased, arguing against an opioid chilling effect of HB1. Similarly, in the drug class benzodiazepines the prescribing of clonazepam, often used for seizure disorders, was less impacted than the prescribing of alprazolam and diazepam, two drugs more commonly associated with abuse. The prescribing of CS in Kentucky remains highly concentrated in the post-HB1 period, with between 80 and 90% of the CS prescriptions dispensed issued by the top decile of prescribers. For opioids specifically, this high concentration may represent referral of patients to pain management specialists. HB1 had a significant impact on potentially inappropriate prescribing behavior as evidenced by decreases in high-dose oxycodone prescribing. Additionally, the number of patients receiving concurrent therapy with a drug combination known as the ‘holy trinity’ decreased by 30% in the post-HB1 period. Significant increases in prescribing of buprenorphine/naloxone by over 40% in the post-HB1 period is driven by a large increase in the number of buprenorphine/naloxone prescribers, although it is unclear what percentage of this increase is for Medication Assisted Treatment and what is off-label use for treatment of pain.

Overall, these results indicate that HB1 had a significant impact on prescribing behavior, including inappropriate prescribing, either through its strengthened pain

clinic regulations that resulted in closure of several pain clinics immediately following HB1 implementation or through changes in prescribing behavior of individual prescribers who make different treatment decisions as a result of querying the KASPER system under the HB1 mandate.

Impact on Patient Behavior (Doctor Shopping)

One of the main patient behaviors legislators hoped to decrease with the passage of HB1 was that of "doctor shopping." For the purposes of this evaluation, doctor shopping was defined as a patient receiving multiple prescriptions from four or more different prescribers and filled at four or more different pharmacies within a three-month period. There is evidence that HB1 significantly impacted doctor shopping behavior as evidenced by an over 50% decrease in the number of patients who met this criterion in the post-HB1 period. This supports qualitative evidence gleaned from the stakeholder interviews and surveys of KASPER registrants that HB1 significantly impacted doctor shopping and that KASPER is an effective tool to reduce doctor shopping.

In the surveys and stakeholder interviews, prescribers, pharmacists and law enforcement believed KASPER to be more effective at reducing doctor shopping than reducing the abuse and diversion of prescription drugs. This perception may be a direct result of the impact of mandatory registration and greater use of KASPER by these professionals.

Impact on Patient Outcomes

Analysis of the Treatment Episode Dataset (TEDs) revealed that substance abuse treatment admissions for prescription opioids decreased across the study period with a concurrent increase in treatment admissions related to heroin. When expressed as a percent of all treatment admissions, treatment admissions in Kentucky for prescription opioids decreased at a higher rate while treatment admissions related to heroin increased at a higher rate compared to surrounding states. Similarly, hospital discharges and deaths due to prescription opioid overdose in Kentucky declined post-HB1 while hospital discharges and deaths due to heroin overdose increased. These results suggest the morbidity and mortality related to opioid abuse is shifting away from prescription opioids to heroin.

In the surveys and interviews of both prescribers and pharmacists, they indicated that they referred few patients to substance treatment and HB1 has not impacted their rate of referrals. Information gleaned from the stakeholder interviews, coupled with the survey findings suggest substance abuse treatment may be an area where additional policy interventions are warranted.

Unintended Consequences

Several concerns have been raised relative to possible unintended consequences of HB1. For example, it has been suggested that HB1 exerts a chilling effect on CS prescribers such that patients with legitimate medical needs have difficulty accessing CS therapy. Although qualitative evidence from the interviews and surveys suggests that some individual prescribers have opted out of prescribing CS completely as a result of HB1, multiple analyses in this comprehensive evaluation argue against a blanket chilling effect of HB1.

A second unintended consequence often attributed to HB1 is the rise in heroin abuse. It has been hypothesized that diminished access to and increased cost of prescription opioids as a result of HB1 on doctor shoppers for prescription opioids has fueled the increase in heroin abuse. Although simple economic principles argue in favor of this hypothesis, i.e., decreased prescription opioid supply results in increased cost and lower demand, many factors likely contribute to the rise in heroin abuse indices. In this evaluation, we document changes in heroin abuse indices, including substance abuse treatment admissions, heroin-related hospitalizations and overdose deaths that occur well before implementation of HB1 and appear temporally related to the reformulation of OxyContin® that occurred in late 2010. The observations suggest that although interventions, such as the mandatory use of KASPER included in HB1, did impact prescription opioid supply, alterations in the heroin market were underway prior to HB1 and this policy change should not be characterized as the sole contributor to the rise in heroin abuse in Kentucky.

Summary and Recommendations

This evaluation shows that HB1, which mandated registration and use of KASPER, significantly and preferentially impacted the prescribing of select opioids and benzodiazepines in Kentucky, decreased potentially inappropriate prescribing behavior and decreased patient doctor-shopping behavior. Multiple analyses argue against a blanket chilling effect of HB1, although stakeholders suggest that individual prescribers have opted out of prescribing CS in Kentucky as a result of the HB1 mandate. High-volume prescribers contribute significantly to the overall prescribing of CS in Kentucky and the Cabinet for Health and Family Services should continue to identify and investigate top prescribers for appropriate prescribing practices. Continued analyses of prescribing behavior, patient behavior and outcomes in the post-HB1 period are warranted to determine if the impacts observed in the first year following implementation of HB1 are sustained.