

# Impact of State Regulations on Initial Opioid Prescribing Behavior in Rhode Island

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## ABSTRACT

The opioid epidemic presents an urgent public health problem. Rhode Island has enacted comprehensive rules to address primary prevention of opioid overdose. This study evaluates the efficacy of those regulations in altering prescribing behavior, specifically regarding the initial prescription. Using data extracted from the Rhode Island Prescription Drug Monitoring Program (PDMP), before and after the publication of updated acute pain management regulations, we studied the rate of opioid prescribing using statistical process control (SPC) charts and found that the rate of prescribing unsafe doses of opioids, more than 30 morphine milligram equivalents (MMEs) per day or more than 20 doses to opioid naïve patients, decreased significantly.

**KEYWORDS:** Opioids; Primary Prevention; Regulations; Acute Pain Management; Prescription Drug Monitoring Program

## BACKGROUND AND PURPOSE

Since 2000, the opioid overdose death rate for the US has increased from 1.4 per 100,000 to 10.2 per 100,000 in 2016.<sup>1</sup> Similarly, over the same time period, Rhode Island's rate has increased from 5.4 per 100,000 to 26.7 per 100,000.<sup>2</sup> It has also adversely affected the lives of 1 in 10 people who have chronic pain who suffer from opioid addiction<sup>3</sup>. Efforts to combat the public health impact of opioid overdose deaths have ranged from tertiary prevention (i.e., increasing the availability of naloxone to first responders); secondary prevention (i.e., increasing the prescribing of Medication Assisted Treatment (MAT) to at-risk opioid users), and primary prevention (i.e., reducing the use of opioids in opioid naïve patients).

In an effort to reduce overdose deaths, State regulatory bodies, pharmacies, and insurers have largely focused on the duration of the initial prescription, based on evidence that this may be a dominant factor in eventual dependence. However, this focus on duration of the initial prescription neglects that prescriptions with higher MMEs or more doses can be spread over longer durations than intended, and that these factors are also independent predictors of dependence.<sup>4-7</sup> Additionally, few studies have evaluated the

efficacy of such prescribing policies promulgated as regulations, and no prior studies have evaluated an all-inclusive set of policies promulgated as regulations such as those in Rhode Island.

This study aims to evaluate the rates of unsafe opioid prescribing before and after the publication of Rhode Island's updated acute pain management regulations, along with the implementation strategies that followed.

## SETTING

Rhode Island promulgated regulations regarding controlled substance prescribing in March 2015.<sup>8</sup> Regulations differ from guidelines as they have the force of law and represent a minimum standard for prescribers. The acute pain management regulations, updated in March 2017, reflected a statutory change that required that initial prescriptions for a patient new to the prescription of opioids (no prior opioid in the preceding 30 days) not exceed 20 doses and 30 MME/day. These regulations were based on research showing that regardless of the indication, initial opioid prescription dose and duration increased the risk for patients to experience long-term dependence and overdose.<sup>4-7</sup>

Patients who are new to the prescription of opioids, (i.e., have not taken an opioid in the most recent 30 days) are referred to as "initiates." These patients represent a vulnerable group relevant to persistent opioid use and overdose since they do not have prior exposure or tolerance to opioids. The 2017 updated pain management regulations align with RIDOH's public health priorities which aim to decrease the number of opioid-naïve individuals exposed to an opioid, decrease the number of persistent opioid users, and decrease the number of individuals who have experienced an opioid overdose.

## INTERVENTIONS

RIDOH developed two primary interventions to enforce these updated acute pain management regulations. Intervention 1 was a strategic communications plan of the acute pain regulations to prescribers of controlled substances in April of 2017.

Intervention 2 launched in July 2017 as a cooperative effort by RIDOH and the largest third-party payers in the State of Rhode Island by activating a pharmacy system alert

(prior authorization) for any opioid prescription to a patient that was new to the prescription of opioids and exceeded 20 doses and 30 MME/day. This prior authorization occurred prior to dispensing and allowed the pharmacists to contact the prescriber for a change in the prescribed amount, or alternatively, override the prior authorization, if there was an appropriate exception to the regulation (e.g., a diagnosis of chronic pain).

## IMPLEMENTATION

This communications plan consisted of letters to prescribers from relevant State regulators of controlled substances prescribing and dispensing. The content of the letter informed prescribers of the regulation and emphasized the importance of complying with this regulation, as well as announcing an eight-hour Continuing Medical Education (CME) opportunity being offered by a local university relevant to the interdisciplinary treatment of pain. This messaging was delivered from five separate regulatory leaders to their respective members, including letters from the Director of Health, Chief Administrative Officer of the Board of Medical Licensure and Discipline, Chief Administrative Officer of the Board of Dental Examiners, State Director of Nursing, and Chief Administrative Officer of the Board of Pharmacy. In addition, Rhode Island's top 2,000 opioid prescribers were identified by gathering data from the Rhode Island PDMP. These top prescribers received letters via the US Postal Service that were written and signed by RIDOH Director of Health. RIDOH also leveraged partnerships with the State's third-party payers and medical associations to promote this regulatory messaging.

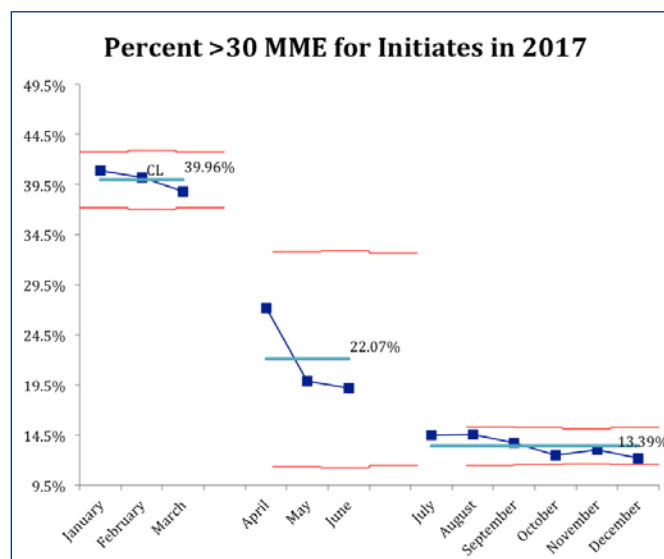
## EVALUATION

Opioid prescription data were abstracted from the Rhode Island PDMP from 2017, and were categorized according to duration (<3, 3-30, 30-90, and >90 days); number of doses (<5, 5-21, 21-90, and >90 doses); and, daily MME (<30, 30-90, and >90 MME) prescribed. The categories chosen were informed by the regulations in order to determine the proportion of prescriptions by month above safe prescribing limits as defined by the updated acute pain management regulations.

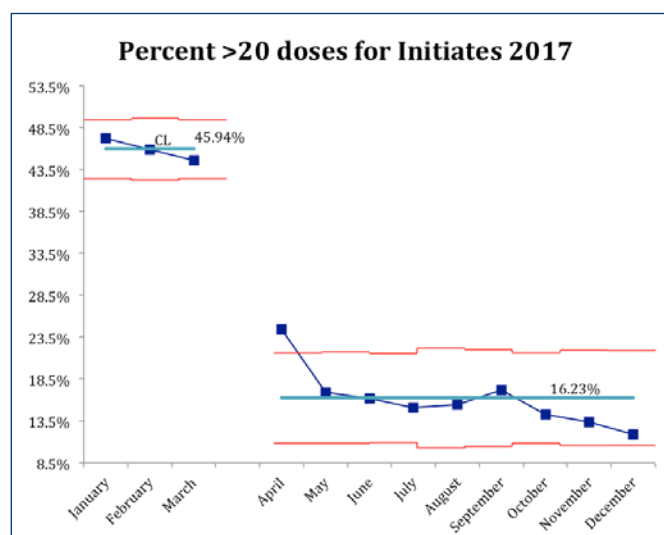
For initiates, we evaluated the proportion of unsafe prescriptions (i.e., not adhering to the updated acute pain regulations: >30 MME/day or >20 doses) out of the total monthly initiate prescriptions using statistical process control charts. Using P' charts, with Laney's approach<sup>9,10</sup> we identified special cause variation when points fell outside of the control limits (i.e., at three standard deviations).

**Figure 1** shows the percent of prescriptions greater than 30 MME, and demonstrates non-random and sustained decreases from 40% to 22%, in April 2017, and from 22% to 13% in July 2017. Chi squared test of proportions found these

**Figure 1.** p-chart with monthly initiate prescriptions >30 MME out of total initiate prescriptions. Significant downward shifts are noted in April and July. The center line has been segmented at those points to show the mean over those periods. Control limits are shown in red, and define 3 standard deviations above and below the mean.



**Figure 2.** p-chart with monthly initiate prescriptions >20 doses out of total initiate prescriptions. A significant downward shift is noted in April. The center line has been segmented to show the mean over those periods. Control limits are shown in red, and define 3 standard deviations above and below the mean.



decreases to statistical significance with p values <0.0001 for these changes in April and July. A related increase was seen in the number of patients receiving less than 30MME.

**Figure 2** shows the percent of prescriptions greater than 20 doses, and demonstrates a non-random and sustained decrease in April 2017. Chi squared test of proportions showed a decrease from 46% to 16% (p<0.0001).

## SUSTAINABILITY

The decrease demonstrated in the process control charts appear to be sustained over the months observed, though 2 more months of data are required to establish a process in statistical control. The updated acute pain management regulations are sustained by state law and are enforced by the RIDOH. The additional prior authorizations are sustained by the cooperative agreement between the RIDOH and third-party payers. Although our current analysis is limited to the end of 2017, other RIDOH published data<sup>11</sup> demonstrate a 29% decrease in the number of people who are receiving a new opioid prescription since January of 2017. Additionally, there is a 13% decreased in average MME per prescription since January of 2017. This suggests a long-term adoption of this regulation by prescribers and pharmacists and an effective, sustainable public health intervention.

## PUBLIC HEALTH SIGNIFICANCE

State regulation as a means of enforcing safe opioid prescribing represents an important step towards primary prevention of opioid dependence and overdose. Rhode Island's updated acute pain management regulations successfully decreased the number of unsafe prescriptions to opioid naïve patients. Our results suggest that this regulation, which limits dose and potency of the initial prescription, has been successful in changing prescribing behavior towards known safe standards.

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