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50 Shades of Data Sharing: How a Uniform Fifty-State Prescription Drug Monitoring Program Can Restore Discretion to Opioid Prescribers and Autonomy to Chronic Pain Patients

Allyson Cady

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50 SHADES OF DATA SHARING: HOW
A UNIFORM FIFTY-STATE
PRESCRIPTION DRUG MONITORING
PROGRAM CAN RESTORE DISCRETION
TO OPIOID PRESCRIBERS AND
AUTONOMY TO CHRONIC PAIN
PATIENTS

Allyson Cady[†]

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[†] J.D. Candidate 2019, Case Western Reserve University School of Law. I would like to extend gratitude to all of the following who made this note possible: Professor Sharona Hoffman, whose constructive criticism, pointed questions, and keen eye for detail led to the production of a note that means more to me on a personal level than any piece I have ever written; Judy Craday, my grandmother, for allowing me to tell her story and being the inspiration behind this note; Lexie Florczak for encouraging me to submit this note for publication and creating the perfect title from my own personal public speaking blunder; the past and present members of Health Matrix for choosing my note for publication and making the last two years of law school memorable; and my family and friends for their support, encouragement, and feedback.

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INTRODUCTION

“When you become a person of pain, you will start on a journey that you will never forget and one of permanent change. The change that is thrust upon you will be unwanted, unpredictable, filled with uncertainty, and one that will be very destructive to your life if you do not take steps [to] control what will quickly become [an] out of control situation.”¹

Beginning in the late 1990s, the United States began to feel the effects of what has recently been declared a “public emergency” by the Department of Health and Human Services – the opioid epidemic.² The Government believed that the increase in opioid misuse, abuse, and

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1. *Testimonials*, CHRONIC PAIN, <http://www.thechronicpain.com/testimonials-1> (last visited Nov. 11, 2017) (citing a testimonial by Thomas Porter).
 2. *What is the U.S. Opioid Epidemic?*, U.S. DEP’T HEALTH & HUM. SERVS., <https://www.hhs.gov/opioids/about-the-epidemic/index.html> (last visited Feb. 17, 2019).

overdose was directly related to the number of opioid prescriptions written by doctors.³ State legislatures then responded by passing laws that imposed strict prescribing limitations and harsh punishment for those doctors that broke the law and disregarded the newly set limitations.⁴ As a result, doctors became fearful of creating addicts and breaking the law. Thus began the decline in the practice of prescribing opioids, even for those who suffered from chronic pain.⁵

Meet Judy – a seventy-three-year-old, two-time cancer survivor.⁶ In 2008, Judy was diagnosed with esophageal cancer. To combat the advanced-stage cancer, she underwent surgery to remove the cancerous portion of her esophagus. She then held tough through rounds upon rounds of chemotherapy. As a result, Judy suffered from severe chronic pain. To help, Judy's oncologist prescribed OxyContin, a narcotic pain reliever that is used to treat moderate to severe pain.⁷ Though she took it as prescribed, as time went on, she needed to take more pills to achieve the same amount of pain relief. Then, it happened again. Two years later, after beating esophageal cancer, Judy was diagnosed with liver cancer. She, again, endured multiple rounds of chemotherapy. As a result of the pain she suffered, Judy's oncologist prescribed more OxyContin. She continued to take the drug as directed, but continually required a higher dose to achieve adequate pain relief. Thankfully, Judy has been in remission since 2011. However, one effect of the cancers has

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3. Evan D. Anderson & Corey S. Davis, *Breaking the Cycle of Preventable Suffering*, 24 TEMP. INT'L & COMP. L.J. 329, 359-60 (2010).
 4. See e.g., ALASKA STAT. § 08.36.355 (2018) (enacted 2017); ALASKA STAT. § 08.36.315 (2018) (enacted 2017); H.B. 333, 2017 Gen. Assemb., Reg. Sess. (Ky. 2017); N.J. ADMIN CODE § 13:45H-7.5 (2019) (enacted 2012); N.J. ADMIN CODE § 13:45H-7.20 (2019) (enacted 2013); Act 122, 2016 Gen. Assemb., Reg. Sess. (Pa. 2016); Act 125, 2016 Gen. Assemb., Reg. Sess. (Pa. 2016); Amy J. Dilcher, *Damned If They Do, Damned If They Don't: The Need for a Comprehensive Public Policy to Address the Inadequate Management of Pain*, 13 ANNALS HEALTH L. 81, 104-05 (2004); Ashley Bruce Trehan, *Fear of Prescribing: How the DEA is Infringing on Patients' Right Palliative Care*, 61 U. MIAMI L. REV. 961, 976 (2007).
 5. See Dilcher, *supra* note 4, at 85; Rima J. Oken, *Curing Healthcare Providers' Failure to Administer Opioids in the Treatment of Severe Pain*, 23 CARDOZO L. REV. 1917, 1923 (2002).
 6. The information included in this paragraph comes from an interview conducted with my maternal grandmother. She does not wish for any other identifying information to be included in the article.
 7. *OxyContin*, DRUGS, <https://www.drugs.com/oxycontin.html> (last visited Mar. 19, 2018).

not subsided – the pain. To this day, Judy suffers from chronic pain and continually needs OxyContin.⁸

Recently, the Pennsylvania legislature has taken steps to restrict opioid prescribing practices. In particular, Pennsylvania issued prescribing guidelines that recommended 100 mg per day as the maximum dose.⁹ Judy's doctor, in response to the guideline publication and fear of scrutiny, informed Judy that he would have to decrease the amount of OxyContin she receives. For Judy, this was frightening because 100 mg was not enough and Judy now struggles to find a way to adequately treat her chronic pain.

Unfortunately, Judy is not alone; approximately fifty million Americans suffer from chronic pain.¹⁰ If access to opioid pain medication is continually restricted or eliminated as a result of attempts to combat the opioid epidemic, there can be devastating consequences for chronic pain patients.¹¹ It is time that the government reexamine its views on the opioid epidemic and how to end it. Chronic pain patients are unintentionally bearing the burden of new restrictive legislation. Therefore, there is a heightened need for a centrally coherent and comprehensive public health solution that addresses substance abuse, while at the same time providing chronic pain patients with the relief they need.¹² Until a comprehensive strategy is implemented that reduces harm while allowing providers to care for patients without undue interference, chronic pain patients, rather than opioid abusers, will be

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8. Author's interview with Judy Craday, in Corry, Pennsylvania (January 2018).
 9. OPIOID DISPENSING GUIDELINES, COMMONWEALTH OF PA. & THE PA. PHARMACISTS ASS'N (2016), *available at* <http://www.health.pa.gov/My%20Health/Diseases%20and%20Conditions/AD/Documents/PA%20Guidelines,%20on%20the%20Dispensing%20of%20Opioids.pdf>.
 10. Chuck Weber, *NIH Study Shows Prevalence of Chronic or Severe Pain in U.S. Adults*, AM. PAIN SOC'Y (Aug. 18, 2015), <http://americanpainsociety.org/about-us/press-room/nih-study-shows-prevalence-of-chronic-or-severe-pain-in-u-s-adults>.
 11. Kent Durning, *No Pain No Gain?! Who Will Make the Greatest Sacrifices in Curbing Opioid Analgesic Diversion and Abuse?*, 93 KY. L.J. 199, 239 (2004-05).
 12. See Tessa Cheng & Kora DeBeck, *Between a Rock and a Hard Place: Prescription Opioid Restrictions in the Time of Fentanyl and Other Street Drug Adulterants*, 108 CAN. J. PUB. HEALTH 325, 326 (2017).

the ones most affected by the government's attempt to combat the opioid epidemic.¹³

This Note will focus on restoring physician discretion and patient autonomy by proposing a uniform Prescription Drug Monitoring Program ("PDMP") that may be adopted by state governments. If adopted, a uniform PDMP will allow doctors to use their best judgment when treating chronic pain patients while combatting the opioid epidemic.

Part I of this Note will discuss the timeline and relevant statistics surrounding the opioid epidemic that has overwhelmed the United States in recent decades and the negative effects that the epidemic has had on the treatment of chronic pain patients. Part II will discuss the components of a PDMP and argue that a PDMP is the best approach to combat the opioid epidemic while restoring physician discretion and patient autonomy. Part III will discuss the current issues surrounding state PDMPs, including: (1) failure to collect sufficient data; (2) failure to effectively use collected data; (3) failure to distribute data across state lines; and (4) consequences of improperly structured PDMPs. Part III will also propose a uniform PDMP which incorporates the solutions to the outlined problems.

I. THE OPIOID EPIDEMIC AND ITS EFFECT ON CHRONIC PAIN PATIENTS

A. *The Driving Force of Stringent Government Regulations – Opioids and The Opioid Epidemic*

Opioids are a class of drugs that includes synthetic opioids¹⁴ such as heroin and oxycodone that are legally obtainable via prescription.¹⁵ Opioids work by chemically interacting with opioid receptors in the body and brain, thus producing euphoria in addition to pain relief.

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13. Sarah Ruiz-Grossman, *America's Drug Overdose Death Rate Keeps Getting Worse: CDC*, HUFFINGTON POST (Nov. 7, 2017, 6:57 PM), https://www.huffpost.com/entry/drug-overdose-death-rate-rise-2016-cdc_n_5a0211d3e4b06ff32c940276; Robert J. Gatchel, *Is Fear of Prescription Drug Abuse Resulting in Sufferers of Chronic Pain Being Undertreated*, 10 EXPERT REV. NEUROPATHICS 637 (2014).
 14. Synthetic opioids are narcotic analgesic drugs that are manufactured in chemical laboratories with a similar chemical structure to natural opiate drugs. Natural opiates are harvested from poppies, and contain alkaloids which have an analgesic effect. Synthetic opioids are manufactured using chemicals other than opium-related alkaloids. *Synthetic Opioids*, WORKPLACE TESTING, <https://www.workplacetesting.com/definition/3734/synthetic-opioids> (last visited Mar. 15, 2018).
 15. Opioids, NAT'L INST. DRUG ABUSE, <https://www.drugabuse.gov/drugs-abuse/opioids>. (last visited Nov. 15, 2017).

Opioids are, generally thought of as highly addictive.¹⁶ But, opioid pain relievers such as oxycodone, hydrocodone, codeine, and morphine, are usually safe when taken as prescribed.¹⁷ However, opioids have been misused, abused, and causing death for decades. The United States is, and has been since the late 1990s, in the midst of an opioid crisis.¹⁸ In fact, over the last decade, deaths attributable to synthetic opioid overdoses have risen from approximately 3500 to 28,400.¹⁹ As a result, the Center for Disease Control has declared the opioid crisis an “epidemic.”²⁰

In response, the Government began implementing legislation to limit the number of opioids prescribed to patients across the country. Though cracking down on prescribing practices of well-intentioned physicians is not the *best* method to combat the opioid epidemic, the government’s approach is not illogical. Beginning in 1991, the United States saw a sharp increase in the number of opioid prescriptions written by prescribers²¹ That year, “doctors wrote 76 million prescriptions” for opioid painkillers, and “[b]y 2011, that number had nearly tripled, to 219 million.”²² These figures troubled lawmakers because during that time, the population of the United States increased by sixteen percent and the amount of prescriptions written for some opioids increased by over 1000%.²³ In 2012, the doctors in twelve states wrote more opioid prescriptions than the total number of patients

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16. Nancy R. Steer & Mollie A. Gass, *Monitoring Controlled Substances: Prescription Monitoring Programs as a Tool for Monitoring the Prescription Drug Epidemic*, 5 IN-HOUSE DEF. Q. 5, 6 (2016).
 17. COMMONWEALTH OF PA & THE PA PHARMACISTS ASS’N, *supra* note 9.
 18. *CDC Fifty-State Survey of Doctor Shopping Laws and Patient Prescription Abuse*, MED. RISK L. (Nov. 16, 2017), http://medicallawperspectives.com/Content_Weekly/CDC-Fifty-State-Survey-of-Doctor-Shopping-Laws-and-Patient-Prescription-Abuse.aspx [hereinafter *CDC Fifty-State Survey*]; Dan Nolan & Chris Amico, *How Bad is the Opioid Epidemic?*, PBS (Feb. 23, 2016), <https://www.pbs.org/wgbh/frontline/article/how-bad-is-the-opioid-epidemic/>.
 19. *Overdose Death Rates*, NAT’L INST. DRUG ABUSE (Sept. 2017), <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates>.
 20. Nolan & Amico, *supra* note 18.
 21. *Id.*
 22. *Id.*
 23. The statistics included in the article were from 1997 to 2011. The statistics pertained to oxycodone sold by retail pharmacies. Nancy A. Melville, *Millions of Opioid Prescriptions Go to ‘Doctor Shoppers’*, MEDSCAPE (July 23, 2013), <https://www.medscape.com/viewarticle/808266>.

treated; averaging more than one prescription per patient.²⁴ Most recently, in 2015, approximately 250 million prescriptions were written for opioid painkillers which: (1) were enough for every American to be medicated twenty-four hours a day for three weeks; and (2) further solidified the United States' position as the top consumer of opioids by exceeding the per capita rate of other countries.²⁵

Because opioids are regularly prescribed in the United States, the rise in prescription painkiller misuse is often attributed to the increasing supply and availability.²⁶ Recent statistics show that there has been an increase in the number of non-medical uses of opioid pain relievers. Specifically, in 2010 study conducted by the National Household Survey on Drug Abuse, about seven million people aged twelve and older reported recreational use of prescription opioid pain relievers and that number increased to 16.7 million in 2012.²⁷

The sharp increase in opioid prescription painkiller misuse and abuse is frightening because these practices often lead to drug overdoses

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24. The calculations looked at how many prescription opioids were prescribed per 100 people. The following twelve states prescribed more than 100 prescriptions per 100 people (in order of severity): Alabama, Tennessee, West Virginia, Kentucky, Oklahoma, Mississippi, Louisiana, Arkansas, Indiana, Michigan, South Carolina, and Ohio. Nolan & Amico, *supra* note 18.
25. The United States regularly consumes about 80% of the world's opioids which renders it the top opioid consumer in the world. See Elaine Cox, *The Hidden Victims of Opioid Epidemic*, U.S. NEWS (June 22, 2017), <https://health.usnews.com/health-care/for-better/articles/2017-06-22/the-hidden-victims-of-the-opioid-epidemic>; White House Comm'n on Combatting Drug Addiction and the Opioid Crisis, Draft Comm'n Interim Report (2017), available at <https://www.whitehouse.gov/sites/whitehouse.gov/files/ondcp/commission-interim-report.pdf> [hereinafter White House Comm'n]; *Opioid Crisis: Five Ways to Tackle the U.S. Drug Epidemic*, BBC NEWS (Aug. 6, 2017), <http://www.bbc.com/news/world-us-canada-40479686>.
26. Steer & Gass, *supra* note 16; *Increased Drug Availability is Associated with Increased Use and Overdose*, NAT'L INST. DRUG ABUSE, <https://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-abuse-heroin-use/increased-drug-availability-associated-increased-use-overdose> (last updated Jan. 2018).
27. RESULTS FROM THE 2010 NATIONAL SURVEY ON DRUG USE AND HEALTH: SUMMARY OF NATIONAL FINDINGS, U.S. DEP'T OF HEALTH & HUM. SERVICES (Sept. 2011), available at <https://www.samhsa.gov/data/sites/default/files/NSDUHNationalFindingsResults2010-web/2k10ResultsRev/NSDUHresultsRev2010.pdf>.

and quite possibly death.²⁸ In recent years, *prescription* opioids have been a driving-force in the fifteen-year increase in opioid overdose deaths.²⁹ Currently, forty-six people in the United States die every day as a result of prescription opioid overdoses; those deaths constitute about thirty-five percent of all overdose deaths annually.³⁰ The relationship between the increase in supply, misuse, and overdose deaths seems to point to prescribers as the culprits, and at first glance it seems sensible to restrict prescribers' decision-making power. But, what the government may not have considered when passing new restrictive legislation was the effect it would have on those who need access – chronic pain patients.

B. (Under)Treatment of Chronic Pain Patients and How the Opioid Epidemic Has Affected Their Treatment

1. Undertreatment of Chronic Pain Patients Unrelated to the Effects of the Opioid Epidemic

Chronic pain is the “most common and debilitating disorder” in the United States.³¹ It affects one-third of Americans at some point in their lives and is the most common cause of long-term disability.³² Chronic

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28. David Blumenthal & Shanoor Seervai, *To Combat the Opioid Epidemic, We Must Be Honest About Its Causes*, HARV. BUS. REV. (Oct. 26, 2017), <https://hbr.org/2017/10/to-combat-the-opioid-epidemic-we-must-be-honest-about-all-its-causes>.
29. See Kristin Finklea et al., *Prescription Drug Monitoring Programs*, CONG. RESEARCH SERV. (May 24, 2014), <https://fas.org/sgp/crs/misc/R42593.pdf> (“Nearly three out of four prescription drug overdoses are caused by prescription painkillers or opioids”); Prescription opioid overdoses are now twice as common as heroin and cocaine deaths combined. See Melville, *supra* note 23. In 2011, 16,917 deaths were caused by overdoses involving prescription opioids. The number of overdose deaths jumped to 33,000 in 2015 with prescription opioid overdoses contributing to more than half the total. The death total then increased again in 2016 to anywhere between 59,000-65,000 with prescription opioids accounting for 40-50% of the death total. *CDC Fifty-State Survey*, *supra* note 18; *Understanding the Epidemic*, CTR. DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/drugoverdose/epidemic/index.html> (last updated Dec. 19, 2018).
30. *Prescription Opioid Data*, CTR. DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/drugoverdose/data/prescribing.html> (last updated Dec. 19, 2018); *Understanding the Epidemic*, *supra* note 29.
31. Bhavani S. Reddy, *The Epidemic of Unrelieved Chronic Pain: The Ethical, Societal, and Regulatory Barriers Facing Opioid Prescribing Physicians*, 27 J. LEGAL MED. 427, 430 (2006).
32. *Section 1: Background and Significance*, AM. PAIN SOC'Y, http://americanpainsociety.org/uploads/education/section_1.pdf (last visited Feb. 16, 2019).

pain is defined as pain that continues beyond what was originally thought to be the “expected healing time of an injury or illness.”³³ Traditionally, severe pain that lasts for more than six months has been categorized as “chronic.” Medical professionals have, however, determined that a chronic pain diagnosis may be handed down as early as two to four weeks from the initial onset of pain.³⁴ An individual coping with chronic pain may suffer from such severe and debilitating pain that it takes a toll on the patient’s relationships and day-to-day activities.³⁵ If pain is left untreated, the individual may experience depression, or loss of employment, spouse, family, and even a loss of life if the patient commits suicide as a result of the chronic pain.³⁶ In contrast, when a patient’s pain is appropriately controlled and treated, he or she is expected to experience an enhanced quality of life, increased physical functionality, and an improvement in general overall health.³⁷ Unfortunately, chronic pain is often undiagnosed and even when diagnosed, it is generally undertreated.³⁸

It is estimated that between forty-eight and fifty million Americans suffer from chronic pain and that those individuals visit physicians’ offices approximately ninety million times a year seeking medical care for their pain.³⁹ As the population rises, the number of people who will need treatment for chronic pain is expected to rise.⁴⁰ Unfortunately for those seeking palliative care,⁴¹ there is a significant public health problem surrounding the undertreatment of pain.⁴² Despite the fact that

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33. Reddy, *supra* note 31, at 427.
34. *Id.*; Gregory Minnis, *What Is Back Pain?*, HEALTHLINE (Jan. 16, 2019), <https://www.healthline.com/health/back-pain>.
35. Reddy, *supra* note 31, at 431.
36. *Id.* at 432.
37. *Id.*
38. PAIN: CURRENT UNDERSTANDING OF ASSESSMENT, MANAGEMENT, AND TREATMENTS, NATIONAL PHARMACEUTICAL COUNCIL at 3 (Dec. 2001), available at http://americanpainsociety.org/uploads/education/section_1.pdf.
39. The number of chronic pain patients is expected to double by the year 2030 because people are expected to live longer. See Reddy, *supra* note 31, at 430; Beth Packman Weinman, *Freedom from Pain, Establishing a Constitutional Right to Pain Relief*, 24 J. LEGAL MED. 495, 503 (2003).
40. AM. PAIN SOC’Y, *supra* note 32, at 3.
41. Palliative care is different than curative treatment. It is primarily aimed at treating symptoms. See *What are Palliative Care and Hospice Care?*, NAT’L INST. AGING, <https://www.nia.nih.gov/health/what-are-palliative-care-and-hospice-care> (last updated May 17, 2017).
42. Oken, *supra* note 5, at 1931; Durning, *supra* note 11, at 215-19.

physicians have the requisite knowledge and resources to manage pain in an estimated ninety percent of individuals suffering from chronic pain,⁴³ it is estimated that more than forty to fifty percent of chronic pain patients in routine practice settings fail to receive adequate pain relief for their condition.⁴⁴

The staggering numbers of undertreated patients may be attributed to the failure to incorporate prescription opioids into chronic pain treatment programs. In a recent survey, thirty-four percent of physicians believe that moving away from powerful painkillers such as opioids may be prolonging patients' misery and harming those with chronic pain issues.⁴⁵ Despite the negative implications raised by the opioid crisis, opioids and other pain-reducing medications still play an important role in managing patient's chronic pain.⁴⁶ Prescribers often view opioids as "the most effective, and often the only, treatment that provides significant relief for most patients suffering from chronic pain."⁴⁷ But, even though opioids have been essential for pain treatment for thousands of years, and many medical professionals view prescription opioids as a preferable, acceptable, and standard form of treatment for chronic pain patients, opioids have proven to be grossly underutilized in chronic pain management.⁴⁸

Failure to manage a patient's pain creates harmful consequences and causes significant suffering.⁴⁹ Individuals with untreated pain may suffer from serious mental complications, such as "anxiety, fear, anger, [and] depression;" "impair[ed] recovery from injury or procedures;"⁵⁰ and decreased quality of life, functionality, activity, appetite, and productivity.⁵¹ Take the story of fifty-three-year-old Doug Hale, for

43. AM. PAIN SOC'Y, *supra* note 32, at 3.

44. Christine E Whitten et al., *Treating Chronic Pain: New Knowledge, More Choices*, 9 PERMANENTE J. 9 (2005); Myra Glajchen, *Chronic Pain: Treatment Barriers and Strategies for Clinical Practice*, 14 J. AM. BOARD FAM. PRACTICE 211, 211 (2001).

45. *Happening Now: Are Doctors Harming Patients by Cutting Back on Prescription Painkillers?*, FOX NEWS, (Jan. 6, 2017), <https://www.foxnews.com/health/happening-now-are-doctors-harming-patients-by-cutting-back-on-prescription-painkillers>.

46. Gatchel, *supra* note 13.

47. Durning, *supra* note 11, at 221; Reddy, *supra* note 31, at 428.

48. Reddy, *supra* note 31, at 428.

49. AM. PAIN SOC'Y, *supra* note 32, at 3.

50. *Id.*; see Reddy, *supra* note 31, at 430.

51. See Reddy, *supra* note 31, at 431.

example.⁵² Mr. Hale suffered from interstitial cystitis, severe migraines, and a back condition.⁵³ He was prescribed methadone and oxycodone in 2001 and continued to take the medication until his untimely death.⁵⁴ During his treatment, Mr. Hale's physician eventually told Mr. Hale that he did not want to risk his medical license and, therefore, he could no longer provide Mr. Hale with his pain medication.⁵⁵ Mr. Hale suffered for six weeks while attempting to find another doctor to treat his pain – those six weeks without pain medication drove Mr. Hale to suicide.⁵⁶

Similarly, Hailey Weeks met an untimely death due to a lack of chronic pain treatment. Ms. Weeks injured her back at age thirty-five and never recovered.⁵⁷ She received opioids and sedatives to help with the pain, but when her doctor retired, she was left “with a one-month prescription and a list of doctors” to call.⁵⁸ When those doctors refused to treat her, Ms. Weeks decided to try to wean herself off the medication.⁵⁹ As a result, Ms. Weeks hastened her alcohol abuse, which led to a trip to the emergency room, and then found herself in jail, where she eventually died.⁶⁰

Lastly, consider the story of Jean Karchefsky – a sixty-three-year-old retired school bus driver.⁶¹ Ms. Karchefsky's doctor told her that he would no longer treat her longstanding chronic pain resulting from disk and bone degeneration in her neck and spine.⁶² Unable to find a new doctor willing to renew her prescription, Ms. Karchefsky has suffered for months, going through withdrawal and with pain that leaves her vulnerable to nausea, anxiety, and insomnia.⁶³

52. Stefan Kertesz & Sally Satel, *Some People Still Need Opioids*, SLATE (Aug. 17, 2017, 3:53 PM), <https://slate.com/technology/2017/08/cutting-down-on-opioids-has-made-life-miserable-for-chronic-pain-patients.html>.

53. *Id.*

54. *Id.*

55. *Id.*

56. *Id.*

57. *Id.*

58. *Id.*

59. *Id.*

60. *Id.*

61. Brie Zeltner, *Suffering and Abandoned: Chronic Pain Patients Cut Off in the Opioid Era*, CLEVELAND, https://www.cleveland.com/healthfit/index.ssf/2018/04/suffering_and_abandoned_chroni.html (last updated Oct. 19, 2018).

62. *Id.*

63. *Id.*

In addition to psychological suffering, chronic pain may also prove difficult for the patient to maintain employment and engage in what most would consider daily activities.⁶⁴ Difficulty maintaining employment is unfortunately all too common for those who suffer from unrelieved chronic pain. Chronic pain patients collectively use about fifty million sick days per year, which renders chronic pain “the second leading cause of medically related absenteeism and lost productivity in the workplace.”⁶⁵ Additionally, forty-two percent of those with chronic pain report such severe pain that they are incapable of working.⁶⁶ For example, if an individual is a laborer, the physical limitations caused by chronic pain may impair his or her ability to maintain employment.⁶⁷ Even if the individual works a sedentary job, pain may impair his or her concentration and make it difficult to complete necessary tasks.⁶⁸ Simply sitting for a long period of time or tilting one’s head to view a computer screen may become impossible due to chronic pain.⁶⁹

In addition, some sixty-three percent of chronic pain patients are unable to engage in the typical day-to-day activities that many healthy individuals take for granted.⁷⁰ The chronic pain sufferer is significantly limited in his or her ability to carry out simple tasks like bathing, dressing, eating, cooking, shopping, and doing the laundry.⁷¹ According

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64. Dennis Thompson Jr., *Managing Chronic Pain at Work*, EVERYDAY HEALTH (Mar. 4, 2010), <https://www.everydayhealth.com/pain-management/managing-chronic-pain-at-work.aspx>.
65. Reddy, *supra* note 31, at 431.
66. Weinman, *supra* note 39, at 505.
67. WILLIAM SHAW ET AL., IMPROVING PAIN MANAGEMENT AND SUPPORT FOR WORKERS WITH MUSCULOSKELETAL DISORDERS: POLICIES TO PREVENT WORK DISABILITY AND JOB LOSS 3-7 (2017).
68. *Chronic Pain Has A Major Impact In The Workplace*, C&S PATIENT EDUC. FOUND. (Apr. 10, 2006), <https://www.conquerchiari.org/articles/pain-and-depression/effects-of/chronic-pain-has-a-major-impact-in-the-workplace.html>.
69. Philip Kinghorn et al., *Developing a Capability-Based Questionnaire for Assessing Well-Being in Patients with Chronic Pain*, 120 SOC. INDICATORS RES. 897, 905, 911 (2015); see Kathleen Sutherland, *When Chronic Pain Made Me Unable to Sit*, MIGHTY (Sept. 7, 2017), <https://themighty.com/2017/09/difficulties-sitting-chronic-pain-fibromyalgia/>.
70. Weinman, *supra* note 39, at 505.
71. Paige Wyant, *16 Everyday Tasks, and What They Feel Like for a Person With Chronic Pain*, MIGHTY (Nov. 1, 2018), <https://themighty.com/2018/11/doing-basic-everyday-tasks-with-chronic-pain/#conversation>.

to studies, the inability to engage in daily living activities often leads to increased frustration and depression.⁷²

However, when a patient's chronic pain managed and treated to the fullest extent, he or she suffers less and can engage in average daily activities, thereby experiencing greater quality of life.⁷³ Unfortunately, instead of ensuring that prescription opioids are accessible for those who need them and inaccessible to those who do not, restrictive prescribing legislation has hindered access to necessary treatments.

2. Further Exacerbating Undertreatment – The Effects of the Opioid Epidemic on the Chronic Pain Population

Despite potentially disastrous consequences, legislative and judicial responses to the opioid epidemic have exacerbated the undertreatment of chronic pain. The government's "war on drugs" has instilled fear in physicians which in turn has had a detrimental impact on the care they provide to those suffering from chronic pain.⁷⁴ There are now two more barriers to accessing prescription opioids: (1) opiophobia; and (2) fear of regulatory scrutiny.

a. *Infecting Prescribers With Opiophobia*⁷⁵

The first access barrier arises out of the fear that prescribing opioids for long periods of time "creat[es] drug addicts."⁷⁶ Health care providers have been infected with opiophobia.⁷⁷ They fear that the use of narcotics

72. *Chronic Pain and Depression*, AM. CHIROPRACTIC ASS'N, <https://www.acatoday.org/Patients/Health-Wellness-Information/Chronic-Pain-and-Depression> (last visited Feb. 2, 2018); Rachel Noble Benner, *Chronic Pain Not Only Hurts, It Also Causes Isolation and Depression. But There's Hope*, WASH. POST (Jan. 12, 2015), <https://www.washingtonpost.com/national/health-science/chronic-pain-not-only-hurts-it-also-causes-isolation-and-depression-but-theres-hope/2015/01/12/db576178>.

73. Reddy, *supra* note 31, at 432.

74. *See* Oken, *supra* note 5, at 1940.

75. "Opiophobia refers to a phenomenon in which exaggerated concern about the risks associated with opioids prevent appropriate medical use of opioid analgesics. Anyone involved in the drug distribution system, as well as patients, family members, and members of the public, can have these exaggerated concerns." *Glossary – Opiophobia*, PAIN & POL'Y STUDIES GRP., <http://www.painpolicy.wisc.edu/glossary/opiophobia> (last visited Apr. 10, 2019).

76. *See* Reddy, *supra* note 31, at 428.

77. *See generally* Dilcher, *supra* note 4, at 113-15.

causes drug abuse and addiction, and are therefore reluctant to prescribe, administer, or dispense controlled substances.⁷⁸

Because chronic pain is typically treated with a long-term prescription opioid regimen, a patient may build up tolerance and physiological dependence and eventually need higher doses in order to achieve adequate pain relief.⁷⁹ Fear of “creating addicts” arises out of the misperception that physical dependence is equivalent to addiction.⁸⁰ But, it is important to realize that physiological dependence does not *always* indicate addiction. Though addiction may occur as a result of opioid pain treatment, physiological dependence and tolerance “is a wholly distinct and separate phenomenon.”⁸¹ Physiological dependence is defined as “the ability to use greatly increased amounts of a substance with diminished intoxicating effect.”⁸² On the other hand, “[a]ddiction is a behavioral disorder characterized by craving, drug use, and continued use despite personal harm.”⁸³ The behavioral patterns of an addict tend to differ from that of an individual who is physiologically dependent and the patterns of an addict can therefore be identified. Those patterns include: (1) doctor-shopping; (2) repeated emergency room visits wherein the individual requests opioid pain relievers; (3) self-medicating by increasing the number of prescription medications used; and (4) continually using a substance despite a decreased quality of life.⁸⁴

A chronic pain patient may exhibit the behavioral tendencies of an addict if the patient is driven by untreated pain to display certain drug-seeking behaviors.⁸⁵ These individuals have been dubbed “pseudoaddicts” but are actually chronic pain patients who have been mistakenly diagnosed as addicts due to their behaviors.⁸⁶ Regardless of similar behaviors, pseudoaddicts are distinguishable from addicts because they act *only* as a result of uncontrolled pain.⁸⁷ To point out the difference between the two: if an addict is given the drug that he seeks, it only exacerbates his disease; but, if a pseudoaddict is given the

78. *Id.* at 114.

79. Reddy, *supra* note 31, at 436.

80. Dilcher, *supra* note 4, at 115.

81. Reddy, *supra* note 31, at 436.

82. *Id.*

83. *Id.* at 435.

84. *Id.*

85. *Id.* at 436.

86. “Pseudoaddict” was coined in the late 1980s and carried through into the 1990s when the opioid epidemic began to take hold. *See id.* at 435-36.

87. *See id.* at 437.

medication he seeks, his physical functioning improves, he stabilizes, and the behaviors that lead to him being categorized as a “pseudoaddict” subside.⁸⁸

Because referring to those with physiological dependence as addicts stigmatizes patients, fuels opiophobia, and results in continued undertreatment of chronic pain patients, it is important that when passing future legislation, legislators are careful to differentiate between the two in order to reduce the fear felt by providers.

b. To Prescribe or Not to Prescribe – Intimidating Physicians Through Threats of Regulatory Scrutiny

The second barrier to access is a direct result of restrictive drug policies set forth by the legislatures: prescribers’ fear of regulatory scrutiny.⁸⁹ Physicians are faced with uncertainty about what constitutes legitimate opioid prescribing practices and are further intimidated by a regulatory system riddled with the threat of sanctions.⁹⁰ The risk of sanctions looms over physicians when deciding whether or not to write an opioid prescription. Prescribers may face criminal prosecution, loss of hospital privileges, and disciplinary action by medical licensing boards.⁹¹ So, a prescriber, when asked why he or she is reluctant to prescribe opioids to chronic pain patients, will likely respond that he or she fears discipline for doing so.⁹² In fact, forty percent of the physician members of the American Pain Society said just that when asked why they avoided prescribing opioids for chronic pain. They stated “that concerns about regulatory scrutiny, rather than medical considerations” influenced their decision.⁹³ In response to the increase in arrests, prosecutions, and sanctions, doctors are changing their prescribing practices to avoid attracting the unwarranted attention of state medical boards.⁹⁴ Physicians are now reducing the number of opioids prescribed and the dosage provided, the number of refills available to patients, and choosing drugs with a decreased potential for abuse.⁹⁵ For example, a 2003 study concluded that the fear of addiction and side effects limited

88. *See id.*

89. *See Weinman, supra note 39, at 532.*

90. Kelly K. Dineen & James M. DuBois, *Between a Rock and a Hard Place: Can Physicians Prescribe Opioids to Treat Pain Adequately While Avoiding Legal Sanction?* 42 AM. J.L. & MED. 7, 8 (2016); Durning, *supra* note 11, at 215-16.

91. Dineen & DuBois, *supra* note 90 at 7, 8.

92. Weinman, *supra* note 39, at 532.

93. Dilcher, *supra* note 4, at 85.

94. Reddy, *supra* note 31, at 439.

95. *Id.*

prescribers' usage of opioids to treat chronic pain. Specifically, the study found that around half of the subjects had changed physicians at least once because their doctor was unwilling to treat their chronic pain with opioids.⁹⁶ These self-protective measures may continue to further negatively impact the treatment of chronic pain patients.⁹⁷

Due to the already limited number of physicians willing to treat the chronic pain population, increases in the arrests and prosecutions of doctors have made it extremely difficult or nearly impossible for these patients to seek care.⁹⁸ The strict legislative approach taken in recent years has instilled fear in prescribers who have since changed their prescribing practices and reduced and/or eliminated the benefits that chronic pain patients receive from opioid therapy.⁹⁹ Reducing the benefits provided to chronic pain patients by opioid medications is an unsound approach to guarding against the conduct of those who wish to use the medications illegally.¹⁰⁰ Though the government needed to act to combat the opioid epidemic, its solution was not as effective as it could have been. It is time that the legislators focus on providing access to those who are in need and restricting access to those who are not. To narrow that focus and create tailored legislation, it is important that legislators inform themselves about the basic building blocks of medical decision-making: physician discretion and patient autonomy.

*C. Rights to Be Restored – Physician Discretion and Patient
Autonomy*

The basis of medical decision-making rests in the patient-physician relationship. That relationship is “one of mutual obligation,” which means that a patient’s “autonomy must be balanced with respect for

96. The study was conducted by the American Pain Society, the American Academy of Pain, and Janssen Pharmaceutical. The study was conducted by Roper Starch Worldwide. The sample was made up of 500,000 households which were representative of all households in the U.S., a total of 35,000 screening questionnaires were sent to a random cross-section of 705 individuals. See Alexander DeLuca, *The War on Drugs, the War on Doctors, and the Pain Crisis in America – Eight Years of Naked Emperors*, DR. DELUCA (June 14, 2011), <http://doctordeluca.com/Library/WOD/WOD-PCA060404cWeb.htm>.

97. Dilcher, *supra* note 4, at 85; see Durning, *supra* note 11, at 217.

98. Diane E. Hoffmann, *Physicians Who Break the Law*, 53 ST. LOUIS U. L.J. 1049, 1077 (2009).

99. Durning, *supra* note 11, at 216-17.

100. *Id.* at 203-04.

the physician's autonomy."¹⁰¹ Physician discretion is the right to "discretionary latitude in clinical decisions."¹⁰² Because society demands that the physician make his knowledge available, society provides the physician with sufficient discretionary latitude that allows him to capably and safely apply that knowledge.¹⁰³ Without this freedom, the physician could not personalize individual care nor could he fulfill his obligation to use his knowledge to benefit the patient.¹⁰⁴

Despite the need for balance, patient autonomy dominates medical decision-making in the United States.¹⁰⁵ Patients have the right and ability to make their own choices and decisions about medical care and treatment they receive, however this right is not unrestricted. Once a doctor provides a patient with a litany of treatment options, the patient is free to make decisions about the treatment plan he or she would like to pursue.¹⁰⁶

Though there is widespread recognition for patient autonomy alone, the patient-physician relationship cannot function without a healthy respect for *both* patient autonomy and physician discretion.¹⁰⁷ Unfortunately, laws surrounding opioid prescribing practices have diminished physician discretion and patient autonomy by dictating both the number of and how often opioids can be prescribed to a certain individual and by imposing ever harsher sanctions on physicians who break these new laws thereby causing them to fear prescribing opioids at all. Though it is recognized that opioid prescribing practices need to be regulated for safety purposes, a proper balance must be struck so as to restore physician discretion and patient autonomy.¹⁰⁸

II. THE WHAT AND WHY OF PRESCRIPTION DRUG MONITORING PROGRAMS

Legislative campaigns from the past twenty years have aimed at combatting the opioid epidemic have been geared towards a closed-

101. Edmund D. Pellegrino, *Patient and Physician Autonomy: Conflicting Rights and Obligations in the Physician-Patient Relationship*, 10 J. CONTEMP. HEALTH L. & POL'Y 47, 51 (1994).

102. *Id.* at 61.

103. *Id.* at 52-53.

104. *Id.* at 61.

105. *Right to Autonomy and Self Determination*, USLEGAL, <https://healthcare.uslegal.com/patient-rights/right-to-autonomy-and-self-determination/> (last visited Mar. 8, 2019).

106. *Id.*

107. Pellegrino, *supra* note 101, at 57.

108. *See* Oken, *supra* note 5, at 1943.

regulation system with a “‘zero-tolerance’ approach.”¹⁰⁹ These new laws are jam-packed with burdensome administrative processes, ever-harsher penalties, and more militant and expensive enforcement tactics.¹¹⁰ The rigid nature of recent legislative enactments has placed a heavy burden on both patients and prescribers.¹¹¹ For example, strict limits on the number of pills that can be dispensed at one time and limits on the amount of time a patient is permitted to receive a specific medication creates substantial obstacles for patients in remote areas or those who have a disabling condition and cannot travel to collect their prescriptions.¹¹² Furthermore, due to recent legislation, physicians are more reluctant than ever to prescribe opioids, not only because they dread the trek through the newly created administrative maze, but also because they fear prosecution for making a good faith mistake.¹¹³ The new system will continue to limit patient access to prescription opioids unless physicians feel comfortable prescribing and access is permitted, encouraged, and facilitated by the government.¹¹⁴ It is clear that there needs to be a balance between: (1) the freedom of physicians to use their judgment in prescribing; (2) efficient processes by which individuals in need of medication can receive it; and (3) legitimate law enforcement efforts.¹¹⁵ Though the balance has yet to be struck, many state governments took a step in the right direction by creating and implementing prescription drug monitoring programs.

A. *What is a Prescription Drug Monitoring Program?*

PDMPs are defined and function as “statewide electronic database[s] which collect[] designated data on substances dispensed in

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109. See Anderson & Davis, *supra* note 3, at 341; see also Oken, *supra* note 5, at 1942.
110. Oken, *supra* note 5, at 1942; see also Anderson & Davis, *supra* note 3, at 340-41.
111. Oken, *supra* note 5, at 1942-43; see e.g., Anderson & Davis, *supra* note 3, at 340-41.
112. See e.g., ALASKA STAT. § 08.36.355 (2019); H.B. 333, 2017 Gen. Assemb., Reg. Sess. (Ky. 2017); N.J. ADMIN. CODE § 13:45H-7.5-7.20 (2019); Act 122, 2016 Gen. Assemb., Reg. Sess. (Pa. 2016); Act 125, 2016 Gen. Assemb., Reg. Sess. (Pa. 2016); Anderson & Davis, *supra* note 3, at 358.
113. Anderson & Davis, *supra* note 3, at 359.
114. *Id.*
115. See generally Oken, *supra* note 5, at 1942-43; see also Jeffrey A. Singer, *In the Opioid Crisis, Keep Your Eyes On Heroin and Fentanyl*, CATO INST., (Oct. 25, 2017), <https://www.cato.org/publications/commentary/opioid-crisis-keep-eyes-heroin-fentanyl>.

the state.”¹¹⁶ These programs contain and compile information on controlled substance prescriptions written by prescribers and dispensed by pharmacies.¹¹⁷ PDMPs collect data via prescribers and pharmacists entering controlled substance prescriptions into the centralized database thereby making the information available to authorized users.¹¹⁸ Authorized users typically include prescribers and pharmacists, as well as licensure boards, law enforcement, medical examiners, drug courts, criminal diversion programs, addiction treatment programs, insurance companies, and other public health and safety agencies.¹¹⁹ The extent of access varies among users, but it is clear that *only* authorized users can access the data and those users can *only* access the data with login credentials provided by registering with the requisite state prescription drug monitoring program.¹²⁰ Once authorized, users can see data including the name of the patient, prescriber, pharmacy, prescription, dose, and form of payment.¹²¹

Armed with the information contained in the PDMP interface, authorized users can use PDMP data to improve patient safety by allowing prescribers to: (1) identify patients who are obtaining opioids from multiple providers; (2) calculate the total amount of opioids prescribed per patient per day; and (3) identify patients who are prescribed substances that may increase the risk of abuse.¹²² Moreover, the information collected by PDMPs may also be used to facilitate access to prescription opioids for those in need; identify and prevent drug abuse and diversion; and aid in identifying drug-addicted individuals, thereby enabling intervention and treatment.¹²³

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116. *State Prescription Drug Monitoring Programs – Questions and Answers*, U.S. DEP’T OF JUSTICE & DRUG ENF’T AGENCY, https://www.deadiversion.usdoj.gov/faq/rx_monitor.htm#4 (last updated June 2016).
117. Finklea et al., *supra* note 29; *What States Need to Know About PDMPs*, CTR. DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/drugoverdose/pdmp/states.html> (last visited Nov. 11, 2017).
118. *See CDC Fifty-State Survey*, *supra* note 18.
119. Steer & Gass, *supra* note 16, at 7.
120. Rebecca L. Haffajee, *Preventing Opioid Misuse with Prescription Drug Monitoring Programs: A Framework for Evaluating the Success of State Public Health Laws*, 67 HASTINGS L.J. 1621, 1634 (2016).
121. Steer & Gass, *supra* note 16, at 6-8.
122. *See* LISA N. SACCO ET AL., PRESCRIPTION DRUG MONITORING PROGRAMS, CONGRESSIONAL RES. SERV. 4 (2018); Austin Frakt, *A Helpful Tool to Combat the Opioid Crisis*, N.Y. TIMES (Sept. 11, 2017), <https://www.nytimes.com/2017/09/11/upshot/a-helpful-tool-to-combat-the-opioid-crisis.html>; Haffajee, *supra* note 120, at 1634-35.
123. SACCO ET AL., *supra* note 122, at 3.

A majority of states have operational PDMPs.¹²⁴ As of recently, legislation authorizing the collection of data is in place in every state except Missouri.¹²⁵ Despite the widespread creation and implementation of PDMPs, each program varies in several important ways. First, state PDMPs tend to differ with respect to the agency responsible for housing and maintaining them.¹²⁶ The agency charged with managing the PDMP may be located in either the state's Board of Pharmacy, Department of Health and Human Services, or a law enforcement agency.¹²⁷ Second, states tend to take different stances on which conditions need to be met in order for a user to be authorized to request and receive PDMP reports.¹²⁸ Lastly, though some states merely suggest the use of PDMPs, other states mandate their use. For example, a state may require prescribers to check the PDMP before writing a prescription for an opioid.¹²⁹ Overall, even though PDMPs vary widely across the forty-nine states that have them, the principal goal of effectively regulating controlled substances is generally accepted and championed by each one.¹³⁰

124. *See Steer & Gass, supra* note 16, at 5.

125. *Id.* at 7; Missouri does not have a functioning PDMP due to consistent filibustering when legislation is introduced. Senator Rob Schaff consistently leads filibusters against any PDMP brought in front of the Missouri legislature. Megan Thielking, *Missouri is the Only State Not Monitoring Prescription Drug Use. Will It Finally Create a Database?*, STAT NEWS (Mar. 7, 2017), <https://www.statnews.com/2017/03/07/missouri-prescription-drug-database>.

126. Blumenthal & Seervai, *supra* note 28; Steer & Gass, *supra* note 16, at 7.

127. SACCO ET AL., *supra* note 122, at 4.

128. *Id.*; *see also Prescription-Drug Monitoring Cuts Doctor-Shopping for Painkillers*, FOX NEWS (Feb. 17, 2017), <http://www.foxnews.com/health/2017/02/17/prescription-drug-monitoring-cuts-doctor-shopping-for-painkillers.html>.

129. *See FOX NEWS, supra* note 130. Kentucky, New York, and Ohio are potential models for states looking to mandate prescriber use. *See also Mandated Use of State Prescription Drug Monitoring Programs (PMPs) – Highlights of Key State Requirements*, NAT'L ALLIANCE FOR MODEL STATE DRUG L. (June 30, 2017), [http://namsdl.dynamicwebware.com/News%20Tab/Highlighted%20Issues/Mandated%20Use%20of%20State%20Prescription%20Drug%20Monitoring%20Programs%20\(PMPs\)%20-%20Highlights%20of%20Key%20State%20Requirements%20\(June%2030%2C%202017\).pdf](http://namsdl.dynamicwebware.com/News%20Tab/Highlighted%20Issues/Mandated%20Use%20of%20State%20Prescription%20Drug%20Monitoring%20Programs%20(PMPs)%20-%20Highlights%20of%20Key%20State%20Requirements%20(June%2030%2C%202017).pdf).

130. *See Steer & Gass, supra* note 16, at 8.

B. Why a Prescription Drug Monitoring Program?

The risks presented by prescription opioids make it clear that their use needs to be monitored.¹³¹ But, combatting prescription opioid diversion and abuse is no easy feat. An effective monitoring regime requires the coordinated effort of various state regulatory, judicial, and law enforcement bodies.¹³² To be clear, this Note recognizes that PDMPs serve to supplement other state drug enforcement laws. But, this Note focuses on the argument that, with a few changes, PDMPs will address the issues surrounding prescription opioids. Notwithstanding the need for other state laws, a top priority should be that the program and accompanying guidelines enable health care providers to rely on their judgment and confidently provide pain treatments to those in need without fear of prosecution and criminal discipline.¹³³

C. Current Regulatory and Legislative Problems

Aside from the laws that create PDMPs, other current state policies restrict prescriber autonomy in three major ways.¹³⁴ First, various state policies place limitations on the ability to prescribe opioid pain medications by preventing prescribing to patients with certain characteristics. These policies focus on characteristics like age, diagnosis, or prognosis.¹³⁵ These restrictions tend to diminish a prescriber's ability to provide treatment to those in need and hinder patient access to much needed pain treatment.¹³⁶ For example, if a physician treats a patient who under state law cannot receive an opioid prescription for their pain, that physician is forced to seek out another potentially less effective treatment method. Second, certain states require prescribers to consult with at least one other provider before writing a prescription for an opioid.¹³⁷ Requiring a physician to present his or her recommendations to another in order to write a prescription deprives the doctor of his discretion and makes it more difficult for

131. Prescription opioids tend to be safe when taken as directed, but because the drug interacts with pain receptors in the brain and nervous system and produces a sense of euphoria in addition to pain relief, they can be misused and abused. *See generally* COMMONWEALTH OF PA. & THE PA. PHARMACISTS ASS'N, *supra* note 9; *see also* Steer & Gass, *supra* note 16.

132. Durning, *supra* note 11, at 241.

133. *Id.* at 215-16.

134. Dilcher, *supra* note 4, at 101-02.

135. *Id.* at 103.

136. *Id.*; *see also* Oken, *supra* note 5, at 1938-39; Trehan, *supra* note 4, at 962.

137. *See* Dilcher, *supra* note 4, at 103-04.

chronic pain patients to receive the opioid pain medications they need.¹³⁸ Last, but most importantly, though federal law does not limit the quantity of drugs that a prescriber can dispense, states are beginning to limit the amount of opioid painkillers that can be dispensed or prescribed at one time.¹³⁹ States claim they are trying to control the availability of prescription opioids that present a potential for abuse and diversion, but state lawmakers need to understand the real-life implications of their policies – hindering patient access to needed pain relief treatment.¹⁴⁰ For a chronic pain patient with a disabling medical condition that renders it difficult for him to return to the doctor multiple times to receive a new prescription and to travel to a pharmacy to fill that prescription, may have to go days without necessary medication.¹⁴¹ Patients without reliable transportation or those who live in rural areas and have to travel long distances may suffer the same fate.¹⁴²

Opioids are safe and effective in the treatment and management of pain but for them to be effective, they must be accessible.¹⁴³ There needs to be a substantially greater focus on palliative care when creating a balanced policy approach relating to prescription opioids.¹⁴⁴ Policies and programs aimed at monitoring prescription opioids should crackdown on unintended third parties and not on the intended recipients of prescription opioids. Any response to the prescription opioid epidemic that prevents patient access to medication and restricts prescribers' abilities to manage pain could inappropriately further contribute to the already rampant public health crisis of pain undertreatment.¹⁴⁵ PDMPs do the opposite; they assist prescribers and pharmacists in identifying illicit behavior while also ensuring that patients have access to the medications they need.

D. The Benefits of PDMPs

Overall, PDMPs are taking promising steps to mitigate the opioid epidemic.¹⁴⁶ These data-collection programs continue to be among the

138. *See id.*

139. *See id.* at 100.

140. *See* Weinman, *supra* note 39, at 539; Dilcher, *supra* note 4, at 104-05.

141. Dilcher, *supra* note 4, at 105.

142. *Id.* at 104-05.

143. *Id.* at 82.

144. *Id.* at 109; Durning, *supra* note 11, at 239-40.

145. *See* Durning, *supra* note 11, at 241; *see also* Weinman, *supra* note 39, at 539.

146. *See, e.g.*, Frakt, *supra* note 122, SACCO ET AL., *supra* note 122.

most promising interventions aimed at combatting drug abuse and diversion while ensuring that those in need of prescription opioid painkillers have access.¹⁴⁷ PDMPs allow prescribers and pharmacists to identify, prevent, and deter drug abuse and diversion practices.¹⁴⁸ When a physician or other authorized user checks the database and sees an unusual pattern of opioid distribution, they can deny or change a prescription, screen for an opioid/substance abuse disorder, or even counsel the patient and suggest seeking other forms of pain management or addiction treatment if necessary.¹⁴⁹

In 2012, a review article concluded that PDMPs, in general, are responsible for reducing doctor-shopping¹⁵⁰ and prescription drug abuse.¹⁵¹ Statistics specifically show that in states with active PDMPs, when investigating cases of doctor shopping, law enforcement officers were able to solve cases significantly faster than in states without; and while opioid abuse rates were increasing, the increase was slower in states with PDMPs.¹⁵² Recent research funded by the National Institute on Drug Abuse arrived at the same conclusion – PDMPs are effective in reducing drug abuse, misuse, and curbing overdose deaths.¹⁵³ After reviewing the relevant statistics, researchers concluded that state

147. See, e.g., Frakt, *supra* note 122, SACCO ET AL., *supra* note 122; *State Successes*, CTR. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/drugoverdose/policy/successes.html> (last visited Nov. 11, 2017).

148. SACCO ET AL., *supra* note 122.

149. Frakt, *supra* note 122.

150. Doctor shopping occurs when a patient visits multiple providers to get multiple prescriptions from each of them without the providers knowing about the other prescriptions. *Doctor Shopping Laws*, CTR. FOR DISEASE CONTROL & PREVENTION (2012), <https://www.cdc.gov/phlp/docs/menu-shoppinglaws.pdf>.

151. SACCO ET AL., *supra* note 122.

152. *Id.*

153. Overall, if a state implements a PDMP, there is likely to be a decrease of 1.12 opioid-related overdose deaths per 100,000 people annually. See *Prescription Drug Monitoring Programs Linked to Reductions in Opioid Overdose Deaths*, NAT'L INST. ON DRUG ABUSE (June 22, 2016), <https://www.drugabuse.gov/news-events/news-releases/2016/06/prescription-drug-monitoring-programs-linked-to-reductions-in-opioid-overdose-deaths>.

implementation of PDMPs was associated with an overall reduction in opioid-related overdose deaths.¹⁵⁴

By providing physicians with a medium through which they can efficiently monitor a patient's opioid use, while also paving the way for physicians to safely continue to prescribe opioids, PDMPs have worked to not only restore decisional autonomy to prescribers and ensure efficacious access to prescription opioids for chronic pain patients, but they have also taken steps that have proven successful in combatting the opioid epidemic. PDMPs have finally struck the policy balance that prescribers, patients, and lawmakers have been waiting for. Unfortunately, despite the overarching success of PDMPs, the lack of uniformity amongst the programs has led to problems that can only be fixed by instating a uniform fifty-state PDMP. The uniform PDMP will combat the challenges facing existing PDMPs by implementing new strategies that result in greater collection and effective utilization of data; greater interstate data sharing; and fewer unintended consequences impacting access.

III. PROBLEMS WITHIN PRESCRIPTION DRUG MONITORING PROGRAMS AND THEIR SOLUTIONS

A. *Problems with Current PDMPs*

The significant differences among state PDMPs demonstrate the lack of interstate communication and organization that unfortunately surrounds many of the attempts to combat the opioid epidemic.¹⁵⁵ Despite the fact that all forty-nine states with operational PDMPs share many of the same goals, *all* forty-nine programs vary.¹⁵⁶ The

154. The NIDA-funded research study found that state implemented PDMPs that monitored greater numbers of drugs with high potential for abuse and took care to more frequently update data had a larger decrease in opioid-related overdose deaths than PDMPs that did not. Specifically, states “that monitored four or more drug schedules and updated their information at least weekly” had “1.55 fewer opioid-related overdose deaths per 100,000” annually than other programs. *See id.*

155. *See* Haffajee, *supra* note 120, at 1625.

156. Prescription drug monitoring programs vary widely in ways such as: who can see the data; whether unsolicited reports are sent to users; whether prescribers/dispensers can delegate access to a certain person; whether a patient has to be notified when and if their data is accessed; if data is shared with other states; how frequently data is updated; and whether training is required in order to become an authorized user. *See* Haffajee, *supra* note 120, at 1636; SACCO ET AL., *supra* note 122; *Prescription Drug Monitoring Frequently Asked Questions (FAQ)*, PDMP ASSIST, <http://www.pdmpassist.org/content/prescription-drug-monitoring-frequently-asked-questions-faq> (last visited Apr. 9, 2019).

variations amongst the programs have led to four key issues that must be addressed in order for PDMPs to continually succeed.¹⁵⁷ These issues are: (1) failure to collect sufficient data; (2) failure to effectively use collected data; (3) failure to distribute data across state lines; and (4) consequences of improperly structured PDMPs.

1. Failure to Collect Sufficient Data

First, PDMPs, unfortunately, fail to collect enough data successfully combat the opioid epidemic. Many state PDMPs do not require prescribers or pharmacists to report vital information that could assist in tracking down doctor-shoppers or those who engage in prescription opioid diversion. For example, to evade detection, drug abusers, doctor-shoppers, and prescription opioid diverters often pay for prescription pain killers in cash rather than using their insurance plan.¹⁵⁸ It is important for states to track the method of payment used by an individual picking up a prescription. Though there is an inherent risk in failing to track cash transactions,¹⁵⁹ a large percentage of states do not require pharmacists to record the payment method that the patient uses when picking up a prescription opioid.¹⁶⁰ Most state PDMPs also do not require pharmacists to record the name or identity of the individual picking up the prescription opioid.¹⁶¹ In failing to record the identity of the individual, these policies create a risk for diversion. Lastly, as of 2014, state PDMPs failed to collect all relevant prescriber data.¹⁶² State PDMPs fail to collect data relating to the disciplinary history or whether a prescriber is even alive.¹⁶³ The lack of data collection could allow a drug-seeking individual to fill an opioid prescription: (1) written by a prescriber who is no longer permitted to write prescriptions; or (2) written by an individual other than the deceased prescriber on a deceased prescriber's prescription pad. Fixing this data gap would enable PDMPs to continue to allow access to those in need of opioids while better serving the goal to prevent unintended access.

157. See Hafaajee, *supra* note 120, at 1637, 1676.

158. Joanna Shepherd, *Combating the Prescription Painkiller Epidemic: A National Prescription Drug Reporting Program*, 40 AM. J.L. & MED. 85, 86 (2014).

159. To evade detection, drug abusers, doctor-shoppers, and prescription opioid diverters often pay for prescription pain killers in cash rather than using their insurance plan. *Id.*

160. *Id.* at 105.

161. *Id.*

162. *Id.* at 106.

163. *Id.*

2. Failure to Effectively Use the Data that is Collected

Authorized users with access to state PDMPs fail to properly enter or use data that is collected. Specifically, many prescribers worry that entering data into or checking the PDMP will prove to be burdensome and become another task to complete in order to meet the requisite “duty of care.” Prescribers fear that if this newly enhanced duty were to be unmet, they would be subjected to sanctions and lawsuits.¹⁶⁴ Though some states have tried to scare prescribers into using prescription drug monitoring programs by threatening disciplinary action for non-use, there is no universal “carrot and stick” approach that has successfully raised the prescriber participation rate.¹⁶⁵

As a result, at least eleven states are now requiring that prescribers check PDMPs when writing a prescription for opioids for certain patients and under particular circumstances.¹⁶⁶ For example, a newly enacted Pennsylvania law requires a prescriber to query the PDMP system each time a patient is prescribed an opioid but does not require a query if a patient is admitted to a licensed healthcare facility. Yet, most states do not require prescribers and pharmacists to consult PDMP data at all.¹⁶⁷ However, suppose that a prescriber, regardless of whether he is required to do so, does consult a PDMP. Often a new issue arises – a failure to report timely data.¹⁶⁸ Because prescribers and pharmacists may only input data once every week or two, other authorized users cannot see the most up-to-date or timely data. If a prescriber or pharmacist does not have access to the most recent data, they may be unaware of new information that indicates potential drug abuse or doctor-shopping.¹⁶⁹

3. Failure to Distribute the Data Collected Across State Lines

Third, although a significant number of PDMPs are making efforts to share data with other states, there are gaps in the uniformity, efficacy, and real-time sharing of data across state lines.¹⁷⁰

164. *See id.*

165. *See id.* at 86.

166. Haffajee, *supra* note 120, at 1636 n.86.

167. Kelly K. Dineen, *Addressing Prescription Opioid Abuse Concerns in Context: Synchronizing Policy Solutions to Multiple Complex Public Health Problems*, 40 L. & PSYCHOL. REV. 1, 61 (2016).

168. *Id.* at 62.

169. *See What States Need to Know About PDMPs*, CTR. FOR DISEASE CONTROL & PREVENTION (Oct. 3, 2017), <https://www.cdc.gov/drugoverdose/pdmp/states.html>.

170. Shepherd, *supra* note 158, at 107.

Implementing full interstate data-sharing measures will involve making extensive changes to existing programs and require coordination among many regulatory and legislative bodies, which is a major challenge for new data-sharing initiatives.¹⁷¹ Unfortunately, some states have not enacted legislation that provides the authority to share this type of data.¹⁷² The federal government tried to jumpstart interstate data sharing by creating the Prescription Monitoring Information Exchange (“PMIX”). PMIX is a system intended to promote and enable interoperability between state PDMPs.¹⁷³ The system provides information on an individual’s prescription drug history by establishing RxCheck Hubs.¹⁷⁴ Hubs can exist at either the national or state level and information can be shared amongst all hubs.¹⁷⁵ For privacy purposes, patient data is encrypted as it passes through the hubs and no data is actually stored on the hub.¹⁷⁶ But instead of joining PMIX, forty-one states became members of PMP InterConnect which facilitates the transfer of PDMP data between participating states.¹⁷⁷ Though this is a step in the right direction, eight states still fail to share their data with the rest of the country which may provide an incentive for drug abusers and diverters to cross state lines to obtain prescription opioids.

4. The Consequence of Improperly Structured PDMPs

Lastly, if improperly tailored or structured, PDMPs may have an unintended consequence.¹⁷⁸ Though PDMPs typically strike the proper balance between physician discretion, patient access, and efforts to combat the opioid epidemic, prescribers may still refuse or hesitate to prescribe opioids that are monitored by the PDMP due to the extra

171. *Id.*

172. *Id.*

173. *Prescription Monitoring Information Exchange (PMIX) Architecture*, PRESCRIPTION DRUG MONITORING PROGRAM TRAINING & TECHNICAL ASSISTANCE CTR., <http://pdmpassist.org/content/prescription-drug-monitoring-information-architecture-pmix> (last visited Mar. 16, 2018).

174. *Id.*

175. *Id.*

176. *PMIX National Architecture Overview*, PRESCRIPTION DRUG MONITORING PROGRAM TRAINING & TECHNICAL ASSISTANCE CTR., <https://www.pdmpassist.org/pdf/PMIX%20National%20Architecture%20Overview.pdf> (last visited Feb. 17, 2019).

177. *NABP PMP InterConnect: The Only National Network of State-Based PMPs*, NAT’L ASS’N BOARDS PHARMACY, <https://nabp.pharmacy/initiatives/pmp-interconnect/> (last visited Jan. 9, 2019).

178. SACCO ET AL., *supra* note 122.

scrutiny by law enforcement.¹⁷⁹ These increasing concerns may further contribute to the crisis of undertreatment that PDMPs were designed to alleviate. In addition, some *patients* may also fear scrutiny from law enforcement authorities for using prescription opioids monitored by the PDMP, even if they have a legitimate medical reason for doing so.¹⁸⁰

*B. How a Uniform Approach Can Fix the Problems that Exist Within
Current State PDMPs*

Many of the problems that relate to PDMPs arise out of a lack of regulatory and legislative uniformity. The best way to address contemporary challenges is to give states the option to adopt a new, comprehensive, and uniform PDMP laws that quell patient and prescriber concerns by restoring autonomy to both parties while also bringing down the “legislative hammer” on those who contribute to the opioid epidemic.

1. State Licensing Boards, New Reporting Requirements, and the
Solution to Inadequate Data Collection

To improve data collection, the uniform PDMP will require that prescribers and pharmacists include more information in the reports they submit. Though entering more information into the PDMP interface may place a burden on prescribers and pharmacists, increasing the amount of available information will assist them in identifying doctor-shoppers and individuals who divert prescription opioids.¹⁸¹

As it pertains to prescribers, the uniform PDMP will adopt the information reporting requirements of Indiana’s PDMP, INSPECT.¹⁸² The uniform PDMP, like INSPECT, will require that, whenever a controlled substance is prescribed, the prescriber reports: (1) the recipient’s name and date of birth; (2) the national drug code number;¹⁸³ (3) the date the prescription was written; (4) the quantity and number of days of supply of the opioid given; (5) the prescriber’s Drug Enforcement Administration (DEA) registration number; and (6) whether the prescriber transmitted the prescription to the pharmacy orally or in writing.¹⁸⁴

179. *Id.*

180. *Id.*

181. *See* Shepherd, *supra* note 158, at 106, 108.

182. *See generally* IND. CODE § 35-48-7 (2017) (repealed and amended by 2010 Ind. Leg. Serv. 84 (West)).

183. *National Drug Code Directory*, FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/informationondrugs/ucm142438.htm> (last visited Feb. 9, 2019).

184. IND. CODE § 35-48-7-8.1 (2018).

As it pertains to pharmacists, the uniform PDMP will adopt the reporting requirements currently used by the Washington and Alabama PDMPs.¹⁸⁵ Before an opioid is dispensed, the uniform PDMP will require pharmacists to report: (1) patient identifiers including their name, social security number, and date of birth; (2) the name of the drug dispensed; (3) the date the drug is dispensed; (4) the quantity of the drug dispensed; (5) the prescriber's name; (6) the dispenser's name and location;¹⁸⁶ and (7) the method of payment used.¹⁸⁷ Adopting these reporting requirements resolves an issue that surrounds current PDMPs – specifically, the failure to record the identity and method of payment used by the individual picking up the prescription. Requiring the pharmacist to record a patient identifier and the method of payment will decrease possible opportunities for diversion and assist in identifying individuals who engage in those practices.

Adopting elements from existing PDMPs is a step in the right direction, but it does not completely solve the problem of inadequate data collection. That is why the uniform PDMP must enter uncharted territory and begin collecting data relating to the disciplinary or life/death status of prescribers.¹⁸⁸ To facilitate this data collection, the uniform PDMP will be maintained by state professional licensing agencies. The state licensing agency in charge of the uniform PDMP will designate a group of people to form a board (“the Board”). State licensing agencies should have discretion to decide the specific duties that will be assigned to the Board and the qualifications Board members should have. However, it is recommended that the Board be charged with not only maintaining the PDMP, but also keeping prescriber data up to date. Much like the data-entry timelines that apply to pharmacists and prescribers, the Board should routinely update prescriber statuses within the database.¹⁸⁹ However, because prescriber statuses are not likely to change as frequently as an individual's prescription, the board should be required to check and update prescriber status once a month. By continually updating prescriber information within the database, the uniform PDMP will take significant steps toward preventing individuals from filling prescriptions for opioids that are invalid because they are written by a prescriber

185. *See generally* WASH. REV. CODE § 70.225 (2018); *see also* H.B. 150, 2013 Gen. Assemb., Reg. Sess. (Ala. 2013).

186. Prescription Monitoring Program, WASH. REV. CODE § 70.225.020(2) (2018).

187. H.B. 150, 2013 Gen. Assemb., Reg. Sess. (Ala. 2013).

188. *See* Shepherd, *supra* note 158, at 106, 111.

189. *See* 14-118-11 ME. CODE. R. § 5(C)(1) (LexisNexis 2017); OR. ADMIN. R. 410-121-4010(1) (2019).

who is no longer licensed or by an individual using a deceased prescriber's prescription pad.¹⁹⁰

2. Curing the Ineffective Utilization of PDMP Data by Facilitating Access, Enrollment, and Consultation

Addressing the ineffective utilization of PDMP data is more difficult than addressing the issue of data collection, but it can be done by: (1) providing simple online access and increasing prescriber and pharmacist participation by increasing the availability of educational and promotional campaigns; (2) mandating prescriber use; (3) allowing prescribers to designate someone on staff to access the PDMP on their behalf; and (4) issuing automated reports.¹⁹¹

a. *Expediting Enrollment and Mandating Agency-Sponsored Training Programs*

First, many prescribers and pharmacists attribute their lack of PDMP consultation to burdensome enrollment and difficulties associated with use.¹⁹² For example: in some states individuals that register for the PDMP must also look through an extensive list of practices and register individually for each practice applicable to them.¹⁹³ This process could take hours and may dissuade prescribers and pharmacists from registering with the PDMP. Moreover, after gaining access, many physicians argue that it takes a considerable amount of time to navigate the online portal and therefore do not use it.¹⁹⁴

To facilitate prescriber use, the uniform PDMP will first provide a streamlined enrollment process that will institute automatic PDMP registration. This automatic registration will be triggered by DEA controlled substance registration.¹⁹⁵ Massachusetts has the MassPAT system, which automatically enrolls DEA registrants.¹⁹⁶ Following this program, the uniform PDMP will issue registration to any physician, dentist, or podiatrist, who is duly authorized to practice in the state and is registered with the DEA to prescribe or dispense prescription

190. See Shepherd, *supra* note 158, at 111.

191. SACCO ET AL., *supra* note 122; see also *State Prescription Drug Monitoring Programs— Questions and Answers*, *supra* note 116.

192. See Marilyn Bulloch, *The Evolution of the PDMP*, PHARMACY TIMES (July 25, 2018), <https://www.pharmacytimes.com/contributor/marilyn-bulloch-pharmd-bcps/2018/07/the-evolution-of-the-pdmp>.

193. See generally 105 MASS. CODE REGS. § 700.004 (2019).

194. SACCO ET AL., *supra* note 122.

195. See 105 MASS. CODE REGS. § 700.004(D) (2019).

196. *Id.*

opioids.¹⁹⁷ By automatically enrolling DEA registrants, the uniform PDMP will shift the burden of enrollment to the state licensing agency that manages the uniform PDMP.

The uniform PDMP will also require the Board to provide training on how to access and use PDMP data.¹⁹⁸ First, the Board should contract with the vendor who provides the interface in order to obtain and design an online technical assistance program.¹⁹⁹ At a minimum, the program should include tutorials on: how to access prescription monitoring information; rights of persons whose information the user is viewing; responsibilities of persons who access PDMP information; permitted uses of PDMP information; and possible penalties for failure to use or improper use by authorized users.²⁰⁰ The online system will then be offered to registered PDMP users.²⁰¹ Authorized users must successfully complete the training program before having access to the system.²⁰² The Board should also be responsible for engaging with the vendor on a regular basis to provide new tutorials as needed; keeping the online technical assistance program up-to-date and informing authorized users of the new tutorials. For example, if a new feature was added to the uniform PDMP, the Board should be responsible for contacting the vendor, specifying the new tutorial that is needed, and informing all of the authorized users in the state about that new tutorial. Once an authorized user is informed of a new tutorial, that user must successfully complete the tutorial within six months.²⁰³

By expediting the enrollment process through automatic registration and mandated agency-sponsored training programs, prescribers and pharmacists will be more likely to competently comply with the requirements of the uniform PDMP.

b. Mandating PDMP Consultation

Taking steps to facilitate enrollment and use are not enough. The best way to ensure that prescribers and pharmacists consult the PDMP

197. *See id.*

198. *See e.g.*, 105 MASS. CODE REGS. § 700.004(F)(2) (2019); N.J. STAT. ANN. § 45:1-46(26)(k) (West 2018); MINN. STAT. § 152.126(2)(b) (2019).

199. MINN. STAT. § 152.126(2)(b) (2019).

200. *See* N.J. STAT. ANN. § 45:1-46(26)(k) (West 2019).

201. *See id.*

202. *See* 105 MASS. CODE REGS. § 700.004(F)(2) (2019).

203. Based off the idea adopted by Massachusetts lawmakers that authorized users must successfully complete a training program that meets the specifications sets by the agency that maintains the PDMP every two years. *See e.g.*, 105 MASS. CODE REGS. § 700.004(F)(2)(e) (2019).

is to mandate it.²⁰⁴ Therefore the uniform PDMP, will require that authorized users who dispense or prescribe opioids check the PDMP before doing so. The uniform PDMP will require that dispensers, health facilities, or individuals with DEA registration numbers both check the system before prescribing and enter all prescribed or dispensed opioids into the system. By issuing a comprehensive consultation mandate, the uniform PDMP will ensure that most, if not all, pharmacies, drug wholesalers, pharmacists, prescribers, and the like will check the system, thereby cutting down illicit drug practices.²⁰⁵

c. Reducing the Clinical Workflow Through Delegation

Because it is important that prescribers and pharmacists spend more time with their patients or customers and less time consulting the PDMP, in lieu of the mandate, the uniform PDMP will allow authorized users to delegate the responsibility of checking the uniform PDMP to other individuals such as RNs, LPNs, CRNAs, and pharmacy technicians.²⁰⁶ However, there will be restrictions on whether or not an individual can be a delegate. For example, an individual who is eligible in his or her own right to become an authorized user may not serve as a delegate under another authorized user.²⁰⁷ Furthermore, the authorized user must submit a request to the Board asking it to create a separate “delegate sub-account” for the authorized users.²⁰⁸ The Board will have discretion to deny the authorized user’s request and may thereby refuse to create a delegate sub-account.

If the Board grants access, delegates are considered “permissible users” and are permitted to access the same data as authorized PDMP users.²⁰⁹ To avoid improprieties and protect patient privacy concerns, the uniform PDMP will set forth specific purposes for which authorized users and their delegates may access PDMP data. To avoid penalties, authorized and permissible users may only access PDMP data to the extent that the information relates specifically to a current patient to whom the prescriber is: (1) prescribing or considering prescribing a controlled substance; (2) providing emergency medical treatment; (3)

204. White House Comm’n, *supra* note 25.

205. Studies show that the rate of doctor-shopping drops in states that require pharmacists and prescribers to consult the PDMP prior to do dispensing or prescribing opioids. *See* Frakt, *supra* note 122.

206. *See e.g.*, H.B. 150, 2013 Gen. Assemb., Reg. Sess. (Ala. 2013); MINN. STAT. § 152.126 (2019); *see* 14-118-11 ME. CODE R. § 7 (LexisNexis 2017); 105 MASS. CODE REGS. § 700.004(I)(1) (2019).

207. *See* 105 MASS. CODE REGS. § 700.004(I)(1) (2019).

208. *See generally* 105 MASS. CODE REGS. § 700.004(I)(2) (2019).

209. *See* MINN. STAT. § 152.126(5) (2019).

providing care to someone reasonably believed to have a substance abuse problem; or (4) there is a clinically valid reason for checking the system.²¹⁰

Delegation will make it easier for authorized users to work PDMP consultation into their everyday clinical duties. Prescribers will be able to spend more time with patients and will be less likely to argue that mandated PDMP consultation constitutes a significant burden.

d. Board Issued Reports

To further ensure that PDMP data is utilized in the most effective way the Board will determine whether or not to issue a report indicating that there are concerns regarding a patient seeking or receiving opioids.²¹¹ The Board shall have discretion to determine the way by which patients are flagged in the system, thereby indicating that a report may need to be issued. For example, the Board may hire individuals to review entries, or more efficiently, invest in software that reviews each entry and alerts the Board when there is an issue. Once disseminated to providers and pharmacies, the report will instruct authorized users to log into their accounts to view the patient's prescription history.²¹² When viewing the report, the authorized user will see: the names of the providers and pharmacies that prescribed or dispensed opioids to the patient; the name and quantity of the drug prescribed or dispensed; and other prescriptions that the patient was prescribed in the last three months.²¹³ Though it may strike some as a violation of the patient's privacy, the report is *only* available to authorized users, and *not* law enforcement. The report is issued to encourage authorized users to talk to their patients about possible treatment for abuse and misuse while also taking proactive steps toward preventing further illicit behavior.

When considering whether to disseminate a report, the Board should consider whether the behavior exhibited by the patient is indicative of: (1) abuse, misuse, or diversion of a controlled substance; or (2) doctor-shopping.²¹⁴ If the Board notices that an individual receives an excessive amount of prescriptions containing opioids,

210. See 105 MASS. CODE REGS. § 700.004(C)(2) (2019).

211. See e.g., N.J. STAT. ANN. § 45:1-46(26) (West 2019); see also *Guidance on PDMP Best Practices: Options for Unsolicited Reporting*, PDMP CTR. EXCELLENCE BRANDEIS UNIV. (May 2016), http://www.pdmpassist.org/pdf/COE_documents/Add_to_TTAC/Update%20to%20Brandeis%20COE%20Guidance%20on%20Unsolicited%20Reporting%20final.pdf [hereinafter *Options for Unsolicited Reporting*].

212. *Options for Unsolicited Reporting*, supra note 211.

213. See *id.*

214. N.J. STAT. ANN. § 45:1-46(26) (West 2019).

receives prescriptions from a variety of prescribers, or visits a large number of pharmacies in a certain period, it may issue a report.²¹⁵

By facilitating enrollment and use through automated registration and educational programs, mandating PDMP use while also helping to balance clinical workflow by allowing users to delegate PDMP consultation, and sending automated reports, the uniform PDMP will ensure that prescribers and pharmacists alike are effectively utilizing this data resource.

3. Conforming to the National Prescription Monitoring Information Exchange Architecture

As of September 2017, forty-three states permitted PDMP interstate data-sharing on some level.²¹⁶ But, due to a lack of uniformity, there is still insufficient access to all available PDMP data.²¹⁷ To improve existing PDMPs, the uniform PDMP will require states to conform with PMIX to increase data sharing among states.²¹⁸ In order to participate in PMIX, states must: (1) have legislation allowing them to share patient information with authorized users in other states in real time; (2) identify at least one other state with which it desires to partner to exchange data; and (3) either establish a memorandum of understanding with its identified partner(s) or ratify the prescription monitoring interstate compact (“PMIC”).²¹⁹ PMIC is an “agreement between two or more states for cooperative effort, mutual assistance, management, and regulation of [prescription opioid prescriptions] by the states, which transcend the boundaries of one state.”²²⁰ Moreover, any provisions within PMIC take precedence over conflicting and inconsistent laws of states.²²¹

If a state adopts the uniform PDMP, that state will have to adopt legislation that allows patient information to be shared with authorized users in other states in real time. The uniform PDMP will require states to share patient information with all other states who adopt the uniform PDMP by requiring states to join PMP InterConnect if they have not

215. *Options for Unsolicited Reporting*, *supra* note 211.

216. SACCO ET AL., *supra* note 122.

217. PDMPs AND THIRD PARTY PLAYERS MEETING, REPORT OF PROCEEDINGS, BUREAU OF JUSTICE ASSISTANCE U.S. DEP’T JUSTICE (Apr. 2014).

218. *See* SACCO ET AL., *supra* note 122; Frakt, *supra* note 122.

219. *Id.*

220. R. Crady deGolian, *Prescription Monitoring Program Compact*, NAT’L CTR. STATE GOVERNMENTS, <http://www.csg.org/programs/policyprograms/NCIC/documents/PMPBackgrounder.pdf> (last visited Mar. 16, 2018).

221. *Id.*

already. By taking these steps, states will take significant steps toward successful interstate data-sharing.

4. Counteracting Unintended Consequences

Another issue facing the uniform PDMP is whether and how to allow law enforcement access. A majority of states, for obvious reasons, allow pharmacists and prescribers to access PDMP information related to their patients.²²² But some states also allow other entities such as law enforcement to access the information.²²³ Prescribers typically object to PDMPs that permit this type of access because they see these programs as placing law enforcement above healthcare and patient treatment.²²⁴ Their fear is not unwarranted. If law enforcement and licensing agencies have access to PDMP files without presenting probable cause or overcoming reasonable restrictions, PDMPs could turn into instruments used to sniff out criminal conduct and not be embraced by the medical community.²²⁵

To ensure that prescribers are entitled to use their best judgment in creating treatment plans for patients in need, the uniform PDMP will adopt an approach similar to that of the Oregon PDMP.²²⁶ The uniform PDMP will require that any federal, state, or local law enforcement agency that wishes to have access to PDMP data be engaged in an authorized drug-related investigation of a specific individual.²²⁷ The uniform PDMP will require that the law enforcement agency submit a request form that specifies the information requested and a copy of a valid court order based on probable cause.²²⁸ Once the agency submits the form, it is up to the Board to review the request and determine whether or not to provide the agency with the requisite information.²²⁹

Allowing the Board to review law enforcement requests will strike the proper balance between facilitating drug investigations and

222. Haffejee, *supra* note 120, at 1634; NAT'L ALL. FOR MODEL STATE DRUG LAWS, STATES THAT ALLOW PRESCRIBERS AND/OR DISPENSERS TO APPOINT A DELEGATE TO ACCESS TO PMP (2014).

223. Haffejee, *supra* note 120, at 1634.

224. See Andis Robeznieks, *PDMP Case Pits Patient Privacy Against Law-Enforcement Intrusion*, AM. MED. ASS'N (Aug. 16, 2017), <https://www.ama-assn.org/delivering-care/patient-support-advocacy/pdmp-case-pits-patient-privacy-against-law-enforcement>.

225. Haffejee, *supra* note 120, at 1657.

226. See generally OR. ADMIN. R. 410-121-4020(35) (2019).

227. *Id.*

228. OR. ADMIN. R. 410-121-4020(36) (2019).

229. *Id.*

protecting doctor/patient autonomy and permit PDMP goals to remain intact.²³⁰

5. Additional Measures to Bolster the Effectiveness of the Uniform
PDMP

Aside from the issues that commonly plague PDMPs, there are additional improvements that can be made. In addition to the previously mentioned policy changes, the uniform PDMP will expand the number of drug schedules monitored by the program.²³¹ Drugs and the substances or other chemicals used to make them are placed into one of five schedules. The drug, substance, or chemical is classified into a certain schedule after the drug's acceptable medical uses, and potential for abuse or dependency are analyzed.²³² Lower numbered schedules are associated with a higher risk drug, for example, schedule one drugs are illegal and have no accepted medical uses.²³³ Opioids tend to fall within schedules two and four,²³⁴ therefore because studies show that the more schedules monitored by a state PDMP, the lower the rate of opioid-related overdose deaths, the uniform PDMP will require that states also monitor drugs that fall within schedules two through five. This means that the uniform PDMP will monitor all drugs with accepted medical uses that are subject to potential abuse.²³⁵

The uniform PDMP will also require authorized users, primarily prescribers and pharmacists, to input data more frequently. But, to minimize any potential burden, prescribers and pharmacists will be required to upload information into the database at set, daily intervals.²³⁶ It is important that these users upload data no later than

230. See Haffajee, *supra* note 120, at 1662.

231. See *Prescription Drug Monitoring Programs Linked to Reductions in Opioid Overdose Deaths*, *supra* note 153; see also, 105 MASS. CODE REGS. § 700.004(G)(1) (2018).

232. *Drug Schedules*, U.S. DRUG ENF'T ADMIN., <https://www.dea.gov/drug-scheduling> (last visited Mar. 16, 2018).

233. *Id.*

234. *Id.*

235. *Prescription Drug Monitoring Programs*, CONG. RESEARCH SERV. (May 24, 2018), <https://www.everycrsreport.com/reports/R42593.html>; see e.g., H.B. 150, 2013 Gen. Assemb., Reg. Sess. (Ala. 2013); 105 MASS. CODE REGS. § 700.004(G)(1) (2018); see USING THE PDMP TO OPTIMIZE PAIN MANAGEMENT, PA. PRESCRIPTION DRUG MONITORING PROGRAM SYSTEM USER AND STAKEHOLDER TRAINING (2017), available at https://www.health.pa.gov/topics/Documents/Programs/PDMP/3-PDMP_UsingPMDP-Guide_F.pdf.

236. See e.g., 902 KY. ADMIN. REGS. 55:110 § 2 (2019); See also 14-118-11 ME. CODE. R. § 5(C)(1) (LexisNexis 2017).

midnight on the day on which the prescription was written and the day it was filled, because these users are responsible for supplying the uniform PDMP with essential data. However, these users may file for an extension if needed. Users responsible for inputting data may file for an extension within twenty-four hours after discovering either: (1) a mechanical or electrical failure; or (2) a reason beyond the user's control that prevents the user from inputting data on time.²³⁷ The user must submit the extension request to the Board who should then issue a response within twenty-four hours. If the request falls within either of the above stated categories, the Board should grant the extension and the user will be free from penalties. But, if the Board denies the extension, absent the user self-reporting the necessary data, the user will be subject to penalties for failing to upload PDMP data in a timely manner.²³⁸

By making additional modifications, the uniform PDMP will protect the autonomy of chronic pain patients, the discretion of doctors, and may even save the lives of opioid abusers. However, the improvement should not end here. The uniform PDMP should operate with as much flexibility as possible – allowing it to change as required to serve its purpose in combatting the opioid epidemic as well as the chronic pain population. The Board should remain vigilant in monitoring opioid-related statistics and make changes to the program as needed to ensure that the system achieves its overall goals.

6. How Does This Fix the Problem?

There are numerous issues that contribute to the undertreatment of pain in the United States, however two of the most serious obstacles to proper pain management are legal and societal.²³⁹ Restrictive laws, regulations, and guidelines surrounding prescription opioids have led to confusion about the appropriate role of opioids in pain management and put pressure on physicians to constrain prescribing.²⁴⁰ As a result, many physicians, out of fear of fueling the ever-worsening epidemic, began asking chronic pain patients who receive opioids to sign “pain contracts.”²⁴¹ If a patient signs this contract, he is agreeing to only obtain medication from one doctor, submit to random drug screens and pill counts, and not to engage in any criminal activity which may include, but is not limited to using heroin or selling prescription

237. See 902 KY. ADMIN. REGS. 55:110 § 2(4)(a) (2019).

238. Penalties for failure to comply with reporting and monitoring requirements are to be left to the Board's discretion.

239. AM. PAIN SOC'Y, *supra* note 32, at 17.

240. *Id.* at 17.

241. Zeltner, *supra* note 61.

drugs.²⁴² There is little evidence that the contracts work to deter prescription drug diversion, however they do work to further restrict legitimate access. However, the uniform PDMP provides a method by which to reduce these issues. The PDMP can be used to solve the continuing undertreatment problem by reducing the need for burdensome and restrictive government action while ensuring that those who need prescription opioids actually receive them.²⁴³

The uniform PDMP will first reassure physicians that opioids have a legitimate place in the realm of pain management. The uniform PDMP will provide an efficient method by which physicians can effectively manage, improve, and change pain management strategies. In doing so, the uniform PDMP will guarantee that chronic pain patients are receiving the medications they need while also facilitating discussions about alternative pain management. The uniform PDMP can also assist physicians in developing a patient's medical history which in turn supports patient safety.²⁴⁴ Because the PDMP will serve as an interface for opioid prescription data, a physician will have access to a patient's previous prescriptions and be able to determine whether the patient needs an increased or decreased dosage, or whether the patient may need to seek help if they are exhibiting dangerous or addictive tendencies. Similarly, because the PDMP serves as a monitorable interface, physicians will be able to readily identify drug-seeking behavior and thereby reduce doctor-shopping, diversion of controlled substances, and assist in other elements used to curb the abuse of prescription opioids, thereby eliminating the need for restrictive legislation, regulation, and guidelines that serve to harm the chronic pain population.

IV. CONCLUSION

Beginning in the 1990s, the United States has fallen victim to the opioid epidemic. Since then, state legislatures have searched for a comprehensive solution.²⁴⁵ However, state actions have failed to strike the necessary balance. Recent judicial, regulatory, and legislative steps created an overtly restrictive regime that impeded physician discretion and patient autonomy.²⁴⁶ It seems as though legislators failed to consider the importance of medical decision-making when trying to create a comprehensive approach to battling the opioid epidemic.

242. *Id.*

243. *Id.*

244. *Id.*

245. Reddy, *supra* note 31, at 439.

246. *See* Weinman, *supra* note 39, at 531-533.

Moreover, recent legislative approaches have prevented chronic pain patients accessing much needed opioid prescriptions.²⁴⁷ In addition to already existing public health crisis related to the undertreatment of pain, restrictive state approaches added additional hurdles for these patients to access prescription opioids.

However, many states took a step in the right direction by implementing PDMPs. In doing so, states provided prescribers and pharmacists with useful tools to detect abuse, misuse, drug diversion, and other illicit drug practices. However, these programs lacked uniformity and were riddled with issues such as inadequate data collection, ineffective utilization of data, insufficient interstate data-sharing, and other unintended consequences. Therefore, despite taking an initial step in the right direction, state action has halted until a solution is implemented.

Fortunately, a solution can be found by means of a uniform PDMP. The uniform PDMP will build upon current state PDMPs by using promising practices. The new system will ensure that data is used effectively and efficiently by prescribers and pharmacists while quelling physicians' sanction-related fears. If states adopt the uniform PDMP and use it in conjunction with other less-restrictive measures adopted to combat the epidemic, the entire regime will equate to a promising step toward combating, and possibly ending, the opioid epidemic entirely. Lastly, and most importantly, if states adopt the uniform PDMP, physicians' discretion and patient autonomy will be restored to pre-epidemic levels that conform to the rights owed to both parties. Overall, by adopting the uniform PDMP in its entirety, states have the ability to strike a required, and much needed, balance between medical decision-making, patient access, and combatting the opioid epidemic.

247. Durning, *supra* note 11, at 239.