

# The Right Hammer for the Right Nail: Public Health Tools in the Struggle Between Pain and Addiction

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“[O]ver the course of the past two centuries, studies and interventions influenced by the population perspective have taught the world much and paved the way for collective actions that have saved millions of lives. More often than not, these interventions have relied on law.”

—Wendy E. Parmet,

*Populations, Public Health, and the Law* 22 (2009).

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## I. INTRODUCTION

The field of public health “is the science of protecting and improving health.”<sup>1</sup> It aims to create an environment in which populations have the greatest likelihood of achieving optimal health, largely through prevention activities, ranging from ensuring that water systems provide potable drinking water to providing vaccinations and responding to outbreaks of infectious diseases.<sup>2</sup> Historically, public health arose in response to communicable disease threats,<sup>3</sup> although many of the greatest public health accomplishments relate to the environment and chronic disease. For example, water fluoridation has led to dramatic decreases in oral disease in the community, with up to

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1. CDC FOUNDATION, CTNS. FOR DISEASE CONTROL & PREVENTION, *What Is Public Health?*, <https://www.cdcfoundation.org/what-public-health> (last visited Nov. 23, 2018).

2. *See generally CDC Timeline 1940's–1970's*, CTNS. FOR DISEASE CONTROL & PREVENTION (Jan. 31, 2018), <https://www.cdc.gov/museum/timeline/1940-1970.html> (providing a timeline of CDC action throughout the mid-twentieth century).

3. *See id.*

a 70% decrease in childhood tooth decay.<sup>4</sup> Motor vehicle-related deaths have decreased substantially with improvements in safety features and changes to personal behavior including seat belt use.<sup>5</sup> Although rates are still too high, infant and maternal mortality have both decreased more than 90% since 1990, with a combination of hygiene, nutrition, antibiotics and access to health care.<sup>6</sup> Responses to these and other health threats have always included invoking medical science alongside law and policy, and the deployment of legal measures has always been a necessary part of public health.

The standard text for public health students defines “public health law” as:

the study of the legal powers and duties of the state to assure the conditions for people to be healthy (to identify, prevent, and ameliorate risks to health in the population) and the limitations on the power of the state to constrain the autonomy, privacy, liberty, proprietary, or other legally protected interests of individuals for the common good. *The prime objective of public health law is to pursue the highest possible level of physical and mental health in the population, consistent with the values of social justice.*<sup>7</sup>

In public health and medicine, we use the terms “primary,” “secondary,” and “tertiary prevention” to describe actions that occur along the continuum of disease process, all of which are designed to prevent a particular poor health outcome.<sup>8</sup> First, primary prevention

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4. Ctrs. for Disease Control & Prevention, *Ten Great Public Health Achievements—United States, 1990–1999*, 48 MORBIDITY & MORTALITY WKLY. REP. 241, 241–43 (1999), <https://www.cdc.gov/mmwr/preview/mmwrhtml/00056796.htm>.

5. *Id.*

6. *Id.*

7. LAWRENCE O. GOSTIN & LINDSAY F. WILEY, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT 4 (3d ed. 2016) (emphasis added).

8. WORLD HEALTH ORG., THE CASE FOR INVESTING IN PUBLIC HEALTH: A PUBLIC HEALTH SUMMARY REPORT FOR EPHO 8, at 7 (2014), [http://www.euro.who.int/\\_\\_data/assets/pdf\\_file/0009/278073/Case-Investing-Public-Health.pdf](http://www.euro.who.int/__data/assets/pdf_file/0009/278073/Case-Investing-Public-Health.pdf).

aims to prevent disease from ever occurring.<sup>9</sup> Primary prevention initiatives might include ensuring that individuals have adequate nutrition through population-level interventions such as nutritional information on menus and prepared food products<sup>10</sup> or reducing food deserts.<sup>11</sup> Secondary prevention takes place when biological changes have begun but a disease is not yet diagnosed.<sup>12</sup> This phase in a disease process is also known as “subclinical” in that an underlying disease process is occurring but is not yet obvious.<sup>13</sup> Secondary prevention measures address individuals whose blood sugar is elevated, for example, but for whom a diagnosis of diabetes is not yet warranted; such interventions include dietary changes and an exercise regimen.<sup>14</sup> Lastly, tertiary prevention recognizes that, even when disease is present, intervention can still stave off poor outcomes, including an early death that could have been avoided by dietary management and insulin regulation.<sup>15</sup> In this Article, we will place a series of laws passed in Tennessee in relation to the opioid epidemic in the public health framework of primary, secondary and tertiary prevention. Framing the opioid epidemic and public health’s response in these

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9. *Id.*

10. See generally Sylvia Hurd Crixell et al., *Improving Children’s Menus in Community Restaurants: Best Food for Families, Infants, and Toddlers (Best Food FITS) Intervention, South Central Texas, 2010–2014*, 11 PREVENTING CHRONIC DISEASE: PUB. HEALTH RES., PRAC., & POL’Y 1 (2014), [https://www.cdc.gov/pcd/issues/2014/pdf/14\\_0361.pdf](https://www.cdc.gov/pcd/issues/2014/pdf/14_0361.pdf) (researching the effect of improving restaurant menus on children’s food habits).

11. See generally Renee E. Walker et al., *Disparities and Access to Healthy Food in the United States: A Review of Food Deserts Literature*, 16 HEALTH & PLACE 876 (2010), <https://doi.org/10.1016/j.healthplace.2010.04.013> (finding that food desert literature increasingly focuses on access to supermarkets, racial and ethnic disparities, income and socioeconomic status, and differences in chain versus non-chain stores).

12. UNIV. OF OTTAWA, *Categories of Prevention* (Jan. 26, 2015), [http://www.med.uottawa.ca/sim/data/Prevention\\_e.htm](http://www.med.uottawa.ca/sim/data/Prevention_e.htm).

13. *Id.*

14. See generally PETER SCHWARZ & PRASUNA REDDY, PREVENTION OF DIABETES (2013).

15. See generally *Tertiary Prevention*, ASS’N STATE & TERRITORIAL HEALTH OFFICIALS, <http://astho.org/addictions/Tertiary-Prevention/> (last visited Nov. 23, 2018) (listing “resources, tools, and strategies to prevent life-threatening adverse outcomes”).

constructs is not new,<sup>16</sup> but this Article focuses specifically on placing the *legal* response in the public health framework in the State of Tennessee.

Laws intended to affect initial prescriptions and prescribing patterns are primary prevention. Those laws intended to address current and increasing opioid use among groups at risk of substance use disorder and other health outcomes can be classified as “secondary,” and those intended to support the needs of individuals and groups with substance use disorder, with the goal of preventing further negative outcomes, can be classified as “tertiary.” In an epidemic, the law responds to these prevention needs simultaneously because, at the same time, segments of the population exist in each state (pre-exposure, preclinical, and clinical). Primary, secondary, and tertiary interventions can be aimed at individual patients, healthcare providers, or the population as a whole. Traditionally, public health efforts have been population-focused, but in the opioid epidemic, a combined intervention strategy all levels—patient, provider, and population—is essential.

In addition to intervening at the appropriate time, laws seek to identify the best lever for action and to target that lever through mandates, restrictions, penalization, and sometimes even exceptions. Patient-focused legislation includes laws requiring patients to honestly describe their medication history to their prescribers.<sup>17</sup> Provider-focused legislation includes mandates on provider continuing education.<sup>18</sup> Population health laws would be those that emphasize community response, including broad provision of the anti-overdose drug, naloxone.<sup>19</sup> This creates a population response by increasing the probability that, in the event of an overdose, reversal is more likely. Interestingly, the majority of the legal and policy response in public health, even when trying to effectuate population-health objectives, has focused on changing prescriber behavior, in large part through the

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16. See generally, e.g., Andrew Kolodny et al., *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, 36 ANN. REV. PUB. HEALTH 559 (2015).

17. See *infra* Section VI.A.

18. See *infra* Sections V.B, V.C.

19. See *infra* Section VI.C.

implementation and use of prescription drug monitoring programs.<sup>20</sup> To fully understand the public health response to the opioid epidemic, it is insightful to review the target of action for various laws that compose the public health levers used to find the right hammer for the right nail.

In reality, patients, prescribers, and the population are intertwined and act upon one another. The population is, in fact, made up of individual patients and of individual patient-prescriber relationships. Thus, changing the dynamic in that relationship has the potential to significantly affect the population. In this way, the effect of many individual “prescriber-patient interactions” improves the health of the population through the number of such interactions, but also by reducing the amount of drugs available in the community for use and misuse by non-patients.

For example, a primary-prevention initiative directed toward patients or the population would drive an educational program to alert them to the dangers of opioids. A primary-prevention activity directed to prescribers, however, alerts prescribers to a patient’s prescription history so that they would take into account opioid naiveté in making a decision about an initial prescription. The idea is to prevent exposure to the “causative agent,” in this case, the misuse of opioids. In secondary prevention, prescribers would be alerted to the potential for substance use disorder in their patients, potentially through a prescription history, and thus be able to manage their prescribing to prevent long term negative outcomes. Tertiary prevention would ensure access to treatment for people with substance use disorder to prevent longer term outcomes, including overdose. At the end of the day, public health treats the population, providers practice medicine, medicine treats the individual patients, and laws related to the opioid epidemic affect the population, provider, and patient. Each case balances control of individual behavior against a public good.

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20. This Article explores the legislative and policy-driven response to the opioid epidemic in Tennessee as observed by the authors. In Tennessee changing provider behavior through implementation of the PDMP has been a large focus of the response, but the same trend can be observed nation-wide. *See* Kolodny et al., *supra* note 16; *see also* NAT’L ALLIANCE FOR MODEL ST. DRUG L., RECENT LEGISLATIVE AND REGULATORY TRENDS IN PRESCRIPTION MONITORING PROGRAMS (2014), <http://www.namsdl.org/library/D651C2DC-B73E-DC6A-C450A4863CC1F73C/>.

The tension between the appropriate limits of public health and the law go back well into the 17th century, when the mayor of London used a set of orders that included quarantine to fight the plague, which was rapidly taking over the city.<sup>21</sup> Daniel Defoe, documenting the story at the time, noted that “[t]his shutting up of houses was at first counted a very cruel and unchristian method . . . but it was a public good that justified the private mischief.”<sup>22</sup> This tension is apparent in public health historically, including, for example, in the decision to require vaccinations or to regulate access to tobacco.<sup>23</sup> In the opioid crisis, there is the added aspect of regulation of healthcare practice, which introduces another level of careful balance, so as to carefully ensure that systems exist to support the best medical care without overly interfering with a clinician’s ability to practice his or her art for the benefit of the patient.

In this Article, we focus on how laws related to patients, providers, and the population fit within a construct of primary, secondary, and tertiary prevention of an *epidemic* and how legal constructs that act upon issues amenable to primary, secondary, and tertiary prevention among patients, providers, and populations combine to form a network of interventions. We do not attempt to describe every law passed in Tennessee to address the epidemic; rather, we analyze a selection of laws that demonstrate the ability to characterize the policy response by primary, secondary, and tertiary, and with a focus on the patient, prescriber, or population. We will organize our description of a selection of opioid-related laws according the following construct:

- Primary Prevention: patient, population, prescriber
- Secondary Prevention: prescriber, population, patient
- Tertiary Prevention: patient, prescriber, population

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21. See DANIEL DEFOE, A JOURNAL OF THE PLAGUE YEAR (1722).

22. *Id.*

23. See generally Kevin M. Malone & Alan R. Hinman, *Vaccination Mandate: The Public Health Imperative and Individual Rights*, in LAW IN PUBLIC HEALTH PRACTICE 262 (Richard A. Goodman et al., eds., 2002) (describing how laws requiring vaccination defeat a potential, society-wide “tragedy of the commons” of diseases that would otherwise result in the absence of incentives to inoculate individual members of a population), [https://www.cdc.gov/vaccines/imz-managers/guides-pubs/downloads/vacc\\_mandates\\_chptr13.pdf](https://www.cdc.gov/vaccines/imz-managers/guides-pubs/downloads/vacc_mandates_chptr13.pdf).

We begin in Part II with background on opioids and the development of the epidemic, including an example of a patient-focused state law that had serious unintended consequences. In Parts III through VI, we survey a set of laws that we place within public health objectives of primary, secondary, and tertiary prevention and denote their focus on patients, prescribers, and the population. We demonstrate that these disparate elements of the law are all part of a complex network that provides levers at multiple levels and with multiple purposes to support an ultimate reduction in prescription drug overdose in the State of Tennessee. Though it is not a perfect rubric, it does provide one organizing principle that combines the emphasis of public health and the law.

## II. OPIOIDS AND THE EPIDEMIC

Pain is common in the United States, and the desire to provide adequate pain management is not new.<sup>24</sup> Opioids help with pain management by acting on the brain's mu opioid receptors to exert an analgesic effect.<sup>25</sup> Because these opioid receptors are concentrated in the reward system of the brain, opioids also can create a euphoric effect in the user.<sup>26</sup> This can lead to a learned response in which the user associates the drug with its positive effects, both analgesic and euphoric, and in time that learned response becomes a craving.<sup>27</sup>

Prescription opioids can be a powerful tool for treating pain in acute settings and are particularly appropriate for use in the extreme pain associated with cancer and other high acuity conditions, as well as in palliative care. Used correctly and carefully, opioids are an important element in the medical system's toolbox.<sup>28</sup> Their use,

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24. INST. OF MED. OF THE NAT'L ACADS., RELIEVING PAIN IN AMERICA: A BLUEPRINT FOR TRANSFORMING PREVENTION, CARE, EDUCATION, AND RESEARCH 55 (2011); Catherine B. Johannes et al., *The Prevalence of Chronic Pain in United States Adults: Results of an Internet-Based Survey*, 11 J. PAIN 1230, 1230–39 (2010).

25. Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 NEW ENG. J. MED. 1253, 1254 (2016).

26. *Id.*

27. *Id.*

28. *Id.*



however, has far exceeded their utility in the United States,<sup>29</sup> and certainly in Tennessee,<sup>30</sup> and there is no doubt that both medical and nonmedical use of opioid pain relievers has caused significant harm.<sup>31</sup>

The scientific basis for widespread and long term use of opioids has a dubious history. In 1980, the *New England Journal of Medicine* published a one-paragraph letter in which the authors reported that, of more than 11,000 hospitalized patients, only four developed addiction after treatment with narcotics.<sup>32</sup> Although this was not a scientific study, and described only hospitalized patients receiving very limited doses of narcotics without any follow-up, many in the medical field gave far too much credence to it as an argument that opioids are non-addictive in the presence of pain, including in a 2013 textbook, *Complications in Regional Anesthesia and Pain Medicine*, which that referred to it as a “landmark report.”<sup>33</sup> In 1986, another low-quality study of thirty-eight patients concluded that patients could be treated

29. The latest available numbers show that, in 2015, the United States consumed more than 99% of the world’s hydrocodone, an opioid/acetaminophen combination. U.N. INT’L NARCOTICS CONTROL BD., COMMENTS ON THE REPORTED STATISTICS ON NARCOTIC DRUGS 36–37 (2016), [http://www.incb.org/documents/Narcotic-Drugs/Technical-Publications/2016/NAR\\_Part\\_II\\_Comments\\_EN.pdf](http://www.incb.org/documents/Narcotic-Drugs/Technical-Publications/2016/NAR_Part_II_Comments_EN.pdf).

30. See *infra* Part III.

31. Opioids can be either “natural”—made from opium—entirely synthetic (fentanyl, for example), or semi-synthetic. Andrew Kolodny, *Opioid Epidemic in 6 Charts*, THE CONVERSATION (Oct. 4, 2017, 8:52 PM), <https://theconversation.com/the-opioid-epidemic-in-6-charts-81601>. The term “opioid” shall be used throughout this article to refer to any of these three possibilities.

32. Jane Porter & Hershel Jick, *Addiction Rare in Patients Treated with Narcotics*, 302 NEW ENG. J. MED. 123 (1980), <http://www.nejm.org/doi/pdf/10.1056/NEJM198001103020221>; see also Nadia Kounang, *One Short Letter’s Huge Impact on the Opioid Epidemic*, CNN (June 1, 2017), <https://www.cnn.com/2017/06/01/health/opioid-epidemic-1980-letter-origins-study/index.html>; Pamela T.M. Leung et al., *A 1980 Letter on the Risk of Opioid Addiction*, 376 NEW ENG. J. MED. 22 (2017), <http://www.nejm.org/doi/pdf/10.1056/NEJMc1700150>; Sarah Zhang, *The One-Paragraph Letter from 1980 That Fueled the Opioid Crisis*, THE ATLANTIC (June 2, 2017), <https://www.theatlantic.com/health/archive/2017/06/nejm-letter-opioids/528840/>.

33. JOSEPH M. NEAL & JAMES P. RATHMELL, COMPLICATIONS IN REGIONAL ANESTHESIA AND PAIN MEDICINE 214 (2013) (discussing Porter & Jick, *supra* note 32).

safely over long periods of time with opioids,<sup>34</sup> and that paper was soon cited widely, as well.<sup>35</sup> That same year, the World Health Organization recommended that, for cancer pain, pain medications be given consistently on a schedule (as opposed to as-needed) and that, “if a drug ceases to be effective, do not switch to an alternative drug of similar strength, but prescribe a drug that is definitely stronger,” creating what was known as the “analgesic ladder” specifically for cancer pain management.<sup>36</sup>

This idea spread well beyond cancer pain. In 1995, Purdue Pharma, a large, privately held pharmaceutical company, introduced OxyContin and began an aggressive marketing campaign to promote the drug for use in chronic pain.<sup>37</sup> This occurred against a backdrop in which it was increasingly suggested that the medical community routinely underappreciated and undertreated their patients’ pain.<sup>38</sup> Finally, in 1996, the American Pain Society and other organizations developed a campaign to label pain as the “fifth vital sign,”<sup>39</sup> thus promoting its primacy in the clinicians’ responsibility for review and

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34. See generally Russell K. Portenoy & Kathleen M. Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases*, 25 PAIN 171 (1986).

35. See, e.g., D. Andrew Thompkins et al., *Providing Chronic Pain Management in the “Fifth Vital Sign” Era: Historical and Treatment Perspectives on a Modern-Day Medical Dilemma*, 173 DRUG & ALCOHOL DEPENDENCE 11, 13 (2017), <https://www.sciencedirect.com/science/article/pii/S0376871617300030>.

36. WORLD HEALTH ORGANIZATION, *CANCER PAIN RELIEF* 51 app. 1 (1986), [http://apps.who.int/iris/bitstream/10665/43944/1/9241561009\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/43944/1/9241561009_eng.pdf).

37. Caitlin Esch, *How One Sentence Helped Set Off the Opioid Crisis*, MARKETPLACE: THE UNCERTAIN HOUR (Dec. 13, 2017, 2:00 AM), <https://www.marketplace.org/2017/12/12/health-care/uncertain-hour/opioid>. See also generally Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 AM. J. PUB. HEALTH 221 (2009), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/#bib2>.

38. Sam Allis Boston, *Less Pain, More Gain*, TIME (June 24, 2001), <http://content.time.com/time/magazine/article/0,9171,158154,00.html>.

39. Medicine has traditionally considered respiration and pulse rates, body temperature, and blood pressure to be the four “vital signs.” *Vital Signs (Body Temperature, Pulse Rate, Respiration Rate, Blood Pressure)*, JOHNS HOPKINS MED., [https://www.hopkinsmedicine.org/healthlibrary/conditions/cardiovascular\\_diseases/vital\\_signs\\_body\\_temperature\\_pulse\\_rate\\_respiration\\_rate\\_blood\\_pressure\\_85,P00866](https://www.hopkinsmedicine.org/healthlibrary/conditions/cardiovascular_diseases/vital_signs_body_temperature_pulse_rate_respiration_rate_blood_pressure_85,P00866) (last visited Dec. 3, 2018).

treatment.<sup>40</sup> In 2001, the Joint Commission on Accreditation of Healthcare Organizations (“JCAHO”) standards, which accredits health care organizations, including hospitals,<sup>41</sup> began to require assessment of pain in all patients and recording the results of a “comprehensive pain assessment.”<sup>42</sup> Notably, these organizations received funding from Purdue Pharma, and, importantly, these campaigns both underestimated the risks and magnified potential benefits of long-term treatment with opioids.<sup>43</sup> Subsequently, opioid prescribing in both inpatient and outpatient settings rose dramatically and continues to be extremely high, with sales of prescription opioids nearly quadrupling from 1999 to 2014.<sup>44</sup> In 2016, more than 61 million patients in the United States filled or refilled an opioid prescription for a rate of 19.1 patients per 100 persons.<sup>45</sup>

Opioids lead to increased tolerance fairly quickly and inevitably; they may lead to addiction in a subgroup of the population.<sup>46</sup> Patients ceasing use of opioids after developing

40. Mitchell B. Max et al., Abstract, *Quality Improvement Guidelines for the Treatment of Acute Pain and Cancer Pain*, 274 J. AM. MED. ASS’N 1874 (1995), <https://jamanetwork.com/journals/jama/article-abstract/392989>; NAT’L PHARM. COUNCIL, PAIN: CURRENT UNDERSTANDING OF ASSESSMENT, MANAGEMENT, AND TREATMENTS 29 (2001), [http://americanpainsociety.org/uploads/education/section\\_2.pdf](http://americanpainsociety.org/uploads/education/section_2.pdf).

41. The Joint Commission standards must be followed by healthcare organizations accredited or certified by the organization; currently, there are nearly 21,000 organizations certified in the United States. *Joint Commission FAQ Page*, JOINT COMM’N, <https://www.jointcommission.org/about/jointcommissionfaqs.aspx?CategoryId=10#2274> (last visited Nov. 23, 2018).

42. See JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS, PAIN STANDARDS FOR 2001, at 3, 9 (2001), [https://www.jointcommission.org/assets/1/6/2001\\_Pain\\_Standards.pdf](https://www.jointcommission.org/assets/1/6/2001_Pain_Standards.pdf).

43. Kolodny et al., *supra* note 16, at 562.

44. *Opioid Overdose: Prescribing Data*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/drugoverdose/data/prescribing.html> (last updated Aug. 30, 2017).

45. CTRS. FOR DISEASE CONTROL & PREVENTION, ANNUAL SURVEILLANCE OF DRUG-RELATED RISKS AND OUTCOMES: UNITED STATES, 2017, at 7–8 (2017) [hereinafter CDC, ANNUAL SURVEILLANCE], <https://www.cdc.gov/drugoverdose/pdf/pubs/2017-cdc-drug-surveillance-report>.

46. Volkow & McLellan, *supra* note 25, at 1256.

tolerance to them may experience significant physical effects,<sup>47</sup> even if they do not meet the clinical definition of addiction.<sup>48</sup> Poor clinical outcomes of opioid use can include substance use disorder and nonfatal and fatal overdose, but long-term use, even in the absence of addiction, can have serious detrimental effects, including the loss of productivity and hyperalgesia.<sup>49</sup> Recent data from the Centers for Disease Control and Prevention (“CDC”) suggest that, even after just 5 days of use from an initial prescription, the risk of becoming a long-term opioid user rises significantly.<sup>50</sup> Namely, the rate of long-term opioid use is low in individuals whose initial use is short-term—less than 8 days—but increases to 13.5% for individuals whose first episode of use is for at least 8 days, and to nearly 30% when the first episode of use is for 31 days or longer.<sup>51</sup> In addition to these concerning data regarding extended use, opioids have a high abuse potential, both by the patient to whom they are prescribed and by others when drugs are diverted through sharing medications, sales, or theft.<sup>52</sup> Most individuals who

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47. Physical side effects include issues with the gastrointestinal and respiratory systems, including constipation and respiratory depression, and can include cardiovascular, central nervous and endocrine system effects. AnGee Baldini et al., *A Review of Potential Adverse Effects of Long-Term Opioid Therapy*, 14 PRIMARY CARE COMPANION CNS DISORDERS 1, 8–15 (2012).

48. Addiction is characterized by an inability to abstain, behavioral impairment, craving for the drug or regarding experience, diminished recognition of the problem, particularly with relationships, and emotional dysfunction. *Definition of Addiction*, AM. SOC’Y ADDICTION MED., <https://asam.org/resources/definition-of-addiction> (last visited Nov. 23, 2018).

49. Hyperalgesia is a condition of oversensitivity to painful stimuli, either to the original pain treated with opioids or to a new pain. This could lead to perceived loss of efficacy of the drug and likely the taking of increasingly large doses. Marion Lee et al., *A Comprehensive Review of Opioid-Induced Hyperalgesia*, 14 PAIN PHYSICIAN 145, 145 (2011).

50. Anuj Shah et al., *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use: United States, 2005–2016*, 66 MORBIDITY & MORTALITY WKLY. REP. 265, 268 (2017).

51. *Id.*

52. More than half of those responding to a survey directed by the Substance Abuse and Mental Health Services Administration reported that their misused pain relievers were most recently obtained from friends or family. SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., DEP’T HEALTH & HUMAN SERVS., KEY SUBSTANCE USE AND MENTAL HEALTH INDICATORS IN THE UNITED STATES 30 (2017) [hereinafter

report that they misuse prescription drugs also report that they obtained their most recent misused medication from friends or family, suggesting that overprescribing has significant potential to increase the presence and availability of opioids in the community.<sup>53</sup>

### III. UNINTENDED CONSEQUENCES

In addition to national trends in use of opioids in medicine, state law contributed to setting the stage in Tennessee for an opioid epidemic. Specifically, the Intractable Pain Act,<sup>54</sup> passed in Tennessee in 2001, provided entitlements for Tennessee patients suffering from chronic intractable pain, which the statute defined as a “pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts.”<sup>55</sup> The law stated that the patient suffering this intractable pain had the option to refuse any or all modalities of relief.<sup>56</sup> While the law did not require healthcare providers to prescribe pain management medication, it required a healthcare provider choosing not to do so to inform their patient of the possible availability of opioids from another provider whose primary practice was the treatment of intractable pain with opioids.<sup>57</sup> The law derived from the best of intentions—a concern that patients were being undertreated and suffering needlessly,<sup>58</sup> when there could be relief available that was not being used. Based on a number of organizations propagating information as described above, the medical community now commonly referred to pain as the fifth vital sign.<sup>59</sup> While it is likely true that, in some circumstances, and particularly in some populations, pain was being undertreated, the resulting swing of the pendulum led

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KEY SUBSTANCE USE], <https://www.samhsa.gov/data/sites/default/files/NSDUH-FFR1-2016/NSDUH-FFR1-2016.pdf>.

53. *See id.*

54. 2001 Tenn. Pub. Acts 327.

55. *Id.* at § 3(3).

56. *Id.* at § 4(h).

57. *Id.* at § 4(k).

58. *See id.* at § 4.

59. *See* JOHNS HOPKINS MED., *supra* note 39.

to what experts now see as substantial overtreatment<sup>60</sup> and a shift in expectations that medical care could and should be pain-free. By requiring prescribers to justify not providing powerful pain medication, a well-meaning law likely had substantial unintended consequences in Tennessee, and increases in prescribing certainly suggest that this is true.

This law sought to ensure that patients would never suffer because preventing suffering from pain would be a dominant purpose of the medical system. After the passage of the Intractable Pain Act and the resulting shift in the medical community, it took more than a decade for policies to catch up with clinical reality and for the General Assembly to repeal the law in 2015,<sup>61</sup> by which time a great deal of damage had occurred. Data on prescribing levels consistently put Tennessee among the top states for opioid prescriptions, and even with significant decreases resulting from many policy initiatives, the state remains a high-prescribing state.<sup>62</sup> While national trends were reflected in Tennessee's drug epidemic, the specific role of state law in this case likely amplified the effect, and prescriptions flowed freely in the State.

With it becoming increasingly common to prescribe opioids and to do so in high doses, the use of large amounts of pain medication became normalized, which led to habituation and dependence on the drugs. Not surprisingly, this trend increased the numbers of individuals with substance use disorders.<sup>63</sup> It became part of the framework of our culture for patients to request, take, and share these powerful and addictive drugs. Of course, Tennessee is not alone. Substance use disorder is increasingly common in the United States. In 2016, national estimates suggest that 7.4 million people over the age of 12 had an illicit drug use disorder.<sup>64</sup> Of these, 1.8 million had a

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60. *Cf. infra* notes 87–95 and accompanying text (describing prescription drug monitoring programs that states implement to monitor and track patients' histories with opioid use and providers' prescribing behaviors).

61. *See* 2015 Tenn. Pub. Acts 26, § 3.

62. *See* CDC, ANNUAL SURVEILLANCE, *supra* note 45, at 7–8.

63. *See generally* XINQING DENG & RACHEL L. JONES, BEHAVIORAL HEALTH INDICATORS FOR TENNESSEE AND THE UNITED STATES (2017) [https://www.tn.gov/content/dam/tn/mentalhealth/documents/TN\\_US\\_Data\\_Book\\_FI\\_NAL\\_7-2017.pdf](https://www.tn.gov/content/dam/tn/mentalhealth/documents/TN_US_Data_Book_FI_NAL_7-2017.pdf).

64. *See* KEY SUBSTANCE USE, *supra* note 52, at 30.

substance use disorder specific to pain relievers; about 618,000 had a tranquilizer use disorder.<sup>65</sup> The 2016 National Survey of Drug Use and Health reported that, at some point in 2016, 11.8 million individuals misused opioids, and most of those patients specifically misused prescription pain relievers.<sup>66</sup> This is compared to 948,000 people who misused heroin.<sup>67</sup> Most individuals (62.3%) report that the reason for opioid misuse was relieving physical pain, and 12.9% report that the purpose of the misuse was to “feel good or get high.”<sup>68</sup> Most commonly, the user obtains the pain reliever in question from a friend or relative (53.0%).<sup>69</sup>

Drug overdoses associated with pain medicine are a public health issue. The CDC added prescription drug overdose to its list of top five public health challenges about which they were sounding the alarm as far back as December 2013, after opioid pain reliever deaths had quadrupled between 1999 and 2011.<sup>70</sup> It is not news at this point, then, that drug overdoses killed more than 60,000 people in 2016;<sup>71</sup> those numbers are well-publicized, and, as frequently noted, they exceed the number of deaths due to car wrecks at their peak in 1972<sup>72</sup> and HIV at the height of that epidemic in 1995.<sup>73</sup> Nationally, more

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65. *Id.*

66. *Id.* at 20.

67. *Id.*

68. *Id.* at 23.

69. *Id.* at 24.

70. Press Release, Ctrs. for Disease Control & Prevention, CDC Looks Back at 2013 Health Challenges, Ahead to 2014 Health Worries (Dec. 16, 2013), <https://www.cdc.gov/media/releases/2013/p1216-eoy2013.html>. See also Kolodny et al., *supra* note 16, at 560.

71. HOLLY HEDEGAARD ET AL., NAT'L CTR. FOR HEALTH STATISTICS, DRUG OVERDOSE DEATHS IN THE UNITED STATES, 1999–2016, at 1 (2017), <https://www.cdc.gov/nchs/data/databriefs/db294.pdf>.

72. ANDERS LONGTHORNE ET AL., NAT'L HIGHWAY TRAFFIC SAFETY ADMIN., AN ANALYSIS OF THE SIGNIFICANT DECLINE IN MOTOR VEHICLE TRAFFIC FATALITIES IN 2008, at 11 (2010), <https://crashstats.nhtsa.dot.gov/Api/Public/ViewPublication/811346> (noting that motor vehicle crash fatalities peaked at about 55,000 in 1972).

73. Erin Schumaker, *Drug Overdoses Are Killing A Lot More People than HIV or Guns at Their Worst*, HUFFINGTON POST, (Sept. 8, 2017), [https://www.huffingtonpost.com/entry/drug-overdoses-2016-cdc\\_us\\_59b1768be4b0dfaafcf62b26](https://www.huffingtonpost.com/entry/drug-overdoses-2016-cdc_us_59b1768be4b0dfaafcf62b26). See also Josh Katz, *Drug Deaths in America Are Rising Faster than Ever*, N.Y. TIMES, (June 5, 2017),

than 60% of drug deaths are associated with an opioid.<sup>74</sup> In Tennessee alone, 1,631 individuals lost their lives to drug overdose in 2016, an increase from 1,451 in 2015, for a rate of 24.6 per 100,000 residents.<sup>75</sup> In eighteen counties, drug deaths increased from 2012 to 2016 more than 100%.<sup>76</sup> Of drug associated deaths in 2016, about two-thirds were associated with the presence of an opioid, with 45% noting the presence of an opioid that we would associate as a prescription painkiller (for example, hydrocodone or oxycontin).<sup>77</sup> Among illicit opioids, deaths with fentanyl or fentanyl analogues<sup>78</sup> have increased 540% in just three years; in 2016 fentanyl was present in 294 of 1631 deaths, an increase of more than 400% since 2013.<sup>79</sup> At the same time, drug deaths associated with stimulants like cocaine and methamphetamine are rising quickly, as well.<sup>80</sup>

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<https://www.nytimes.com/interactive/2017/06/05/upshot/opioid-epidemic-drug-overdose-deaths-are-rising-faster-than-ever.html>.

74. Rose A. Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010-2015*, 65 MORBIDITY & MORTALITY WKLY. REP. 1445, 1445 (2016) (finding that opioids were involved in over 60% of drug overdose deaths in 2014).

75. OFFICE OF INFORMATICS & ANALYTICS, TENN. DEP'T OF HEALTH, PRESCRIPTION DRUG OVERDOSE PROGRAM 2018 REPORT: UNDERSTANDING AND RESPONDING TO THE OPIOID EPIDEMIC IN TENNESSEE USING MORTALITY, MORBIDITY AND PRESCRIPTION DATA 26 (2018), [https://www.tn.gov/content/dam/tn/health/documents/pdo/PDO\\_2018\\_Report\\_02.06.18.pdf](https://www.tn.gov/content/dam/tn/health/documents/pdo/PDO_2018_Report_02.06.18.pdf).

76. *See id.* at 27 (showing a graphic depiction of percentage changes in drug deaths per county from 2012–2016).

77. *Id.* at 28.

78. Fentanyl is a very strong synthetic opioid used to treat patients with severe pain. *Fentanyl*, U.S. DRUG ENF'T ADMIN., <https://www.dea.gov/factsheets/fentanyl> (last visited Dec. 3, 2018). It is 80 to 100 times more potent than morphine. *Id.* Fentanyl analogues share the chemical structure of fentanyl, have been found in illicit prescription drugs, and have been associated with an increasing number of overdose deaths. *See generally* S. Pichini et al., *Acute Intoxications and Fatalities from Illicit Fentanyl and Analogues: An Update*, 40 DRUG MONITOR 38 (2018), <https://www.ncbi.nlm.nih.gov/pubmed/29120973>.

79. *See* Josh Katz, *The First Count of Fentanyl Deaths in 2016: Up 540% in Three Years*, N.Y. TIMES (Sept. 7, 2017), <https://www.nytimes.com/interactive/2017/09/02/upshot/fentanyl-drug-overdose-deaths.html>; OFFICE OF INFORMATICS & ANALYTICS, *supra* note 75, at 30.

80. Katz, *supra* note 79.



Most drug overdoses occur with multiple drugs, and it is not uncommon for an individual to have both illicit drugs and prescription drugs present, and sometimes both opioids and stimulants. In Tennessee in 2016, 69% of drug overdose deaths involved more than one drug;<sup>81</sup> 80% of opioid-specific drug deaths involved multiple drugs.<sup>82</sup> These could be combinations of opioids or combinations of other types of drugs—for example, an opioid and a benzodiazepine (intended to treat anxiety). That said, the fact that toxicology testing identifies prescription drugs in the blood stream does not mean that those drugs were obtained legally, or that they were prescribed to that individual. Individuals may obtain drugs illegally when their family and friends provide them, or when the individuals purchase or steal drugs for their own use that have been prescribed to other people.<sup>83</sup> These individuals may also inadvertently purchase “fake” prescription drugs, in which case they would have no way of knowing what was actually in the drugs.<sup>84</sup> This is often the source of fentanyl analogues found in overdoses; an individual thinking that he or she is consuming a known drug, such as Percocet, in reality, consumes a drug that contains other substances, including fentanyl analogues.<sup>85</sup>

Deaths are, of course, the tip of the iceberg, and a parallel trend of increasing hospitalizations and emergency room visits, rescues in the field, and economic impacts are only now coming to light. In

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81. OFFICE OF INFORMATICS & ANALYTICS, *supra* note 75, at 40.

82. *Id.*

83. It is illegal to possess a controlled substance without a valid prescription. *See, e.g.*, TENN. CODE ANN. § 39-17-418 (2014); TENN. CODE ANN. § 53-10-105(a) (2008).

84. With the advent of reasonably available pill presses, dealers in illicit drugs can create pills which look remarkably like any number of prescription drugs, but which contain various substances including fentanyl in uneven strengths of dosage. Sarah Ganim, *Pill Presses for Counterfeit Drugs Seized in Record Numbers*, CNN (Mar. 17, 2017, 9:00 PM), <https://www.cnn.com/2017/03/17/health/pill-presses-counterfeit-fentanyl/index.html>.

85. Nadia Kouang, *This Is Fentanyl: A Visual Guide*, CNN (Oct. 27, 2017, 2:45 PM), <https://www.cnn.com/2017/10/24/health/fentanyl-visual-guide/index.html>; Katie Zezima, *Counterfeit Opioid Pills Are Tricking Users—Sometimes with Lethal Results*, WASH. POST (Nov. 19, 2017), [https://www.washingtonpost.com/national/counterfeit-opioid-pills-are-tricking-users—sometimes-with-lethal-results/2017/11/19/d34edb14-be4b-11e7-8444-a0d4f04b89eb\\_story.html](https://www.washingtonpost.com/national/counterfeit-opioid-pills-are-tricking-users—sometimes-with-lethal-results/2017/11/19/d34edb14-be4b-11e7-8444-a0d4f04b89eb_story.html).

Tennessee, hospital visits for drug overdoses have increased markedly even since 2013, with the most dramatic increases being outpatient—generally emergency department visits—for heroin overdose, increasing from 2.3 per 100,000 population in 2012 to 21.1 per 100,000 in 2016.<sup>86</sup>

In the presence of continued extraordinarily high rates of opioid prescribing, and the presence of prescription drugs in overdose deaths—whether obtained legally or not—it is reasonable to note that there is a role for law and policy related to controlling healthcare practices to address the overall drug epidemic. Curtailing prescribing theoretically should have the desired effect of reducing the overall presence of opioids in the community, akin to reducing bacterial or viral presence in a public health or infectious disease context, in which simply reducing the amount of infection circulating in a community can reduce the risk that any given individual will become infected. This demonstrates an underlying reason why Tennessee law has tried not just to influence, but to direct prescribers' actions.

#### IV. PRIMARY PREVENTION IN AN ERA OF EPIDEMIC: PREVENTING FURTHER SPREAD

In the public health paradigm, primary prevention—here, preventing overuse of opioids before misuse begins—involves the development and use of tools focused at both prescribers and population health. These tools are available for prescribers to identify trends with their patients' behaviors towards medication, trends in their own prescribing, and gaps in their knowledge or practice.

Much effort to date both nationally and in Tennessee has focused on curbing excess prescribing of opioids, in large part through the use of prescription drug monitoring programs (“PDMPs”) and the laws regulating them. Certainly, when describing the legal response to the opioid epidemic in Tennessee, the PDMP emerges as a clear backbone to the response. PDMPs track statewide dispensation of controlled substances.<sup>87</sup> PDMPs are populated with data provided by

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86. See OFFICE OF INFORMATICS & ANALYTICS, *supra* note 75.

87. Stephen W. Patrick et al., *Implementation of Prescription Drug Monitoring Programs Associated with Reductions in Opioid-Related Death Rates*, 35 HEALTH AFFAIRS 1324, 1327 (2016); see also Janet Weiner et al., *Prescription Drug Monitoring Programs: Evolution and Evidence*, UNIV. PA. INST. OF HEALTH ECON.

dispensers, usually pharmacies or pharmacy chains, that can be aggregated to provide a database of all dispensing statewide.<sup>88</sup> These data provide an opportunity to understand individual patients' prescribing histories, regardless of where they receive medical care or have their prescriptions dispensed, and conversely can be used to examine or describe individual prescribers' overall prescribing patterns.<sup>89</sup>

Lawmakers impose regulations to design PDMPs to affect prescribing practices at the individual level, ultimately leading to population effects in terms of reducing overuse and overdoses.<sup>90</sup> Even as illicit drug deaths rise, the largest category of drug overdoses results from prescription drug overdoses, and most people who die of a drug overdose in Tennessee have presences in the PDMP within the year prior to their deaths.<sup>91</sup> Those presences represent potential opportunities to change patients' trajectories if clinicians are aware that the patients are at risk and act upon that knowledge. The expectation, therefore, is that prescribing practices, which are documented in the PDMP, serve as a potentially powerful point of leverage in the epidemic. If the PDMP can provide information on risk factors in a patient—including, for example, increasing dosage, doctor shopping for drug seeking,<sup>92</sup> or dangerous combinations of medications—then prescribers may be less likely to overprescribe to those patients. Indeed, evidence suggests that, in states where PDMPs

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(June 2017), <https://ldi.upenn.edu/brief/prescription-drug-monitoring-programs-evolution-and-evidence>.

88. See Patrick et al., *supra* note 87; Weiner et al., *supra* note 87.

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

90. Erin P. Finley et al., *Evaluating the Impact of Prescription Drug Monitoring Program Implementation: A Scoping Review*, 17 BMC HEALTH SERVS. RES. 1, 2 (2017), <https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-017-2354-5>.

91. See OFFICE OF INFORMATICS & ANALYTICS, *supra* note 75.

92. Doctor shopping is most commonly patient behavior eliciting controlled substances from multiple providers absent the providers' awareness of the patient's other treatment. Randy A. Sansone & Lori A. Sansone, *Doctor Shopping: Phenomenon of Many Themes*, 9 INNOVATIONS IN CLINICAL NEUROSCIENCE 42 (2012); see also *infra* Part V.B.

are active, and especially where PDMP use is mandatory, opioid prescribing has decreased.<sup>93</sup>

Research has demonstrated that implementing a statewide PDMP correlates with reductions in prescribing patterns<sup>94</sup> and overdose deaths.<sup>95</sup> Despite this, particular patient populations seem to attenuate the PDMP effect on overdose deaths, with some research finding no effect on specific subpopulations, including younger, disabled Medicare patients.<sup>96</sup> From a population health perspective, PDMPs give insight into trends and concerning practices. From an individual prescriber perspective, PDMPs allow practitioners to see a complete picture of their patient's controlled substances prescription history, regardless of where, when, or from whom the patient obtained the controlled substances.

The Controlled Substance Monitoring Database ("CSMD") is Tennessee's PDMP.<sup>97</sup> The General Assembly established and housed it under the Tennessee Board of Pharmacy in 2003.<sup>98</sup> The goal of the CSMD is to aid health care providers in making informed medical determinations:

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93. See Rebecca L. Haffajee et al., *Mandatory Use of Prescription Drug Monitoring Programs*, 313 J. AM. MED. ASS'N 891 (2015).

94. See Yuhua Bao et al., *Prescription Drug Monitoring Programs Are Associated with Sustained Reductions in Opioid Prescribing by Physicians*, 35 HEALTH AFF. 1045 (2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5336205/>.

95. See Patrick et al., *supra* note 87.

96. Ellen Meara et al., *State Legal Restrictions and Prescription-Opioid Use Among Disabled Adults*, 375 N. ENGL. J. MED. 44, 50 (2016).

97. *Controlled Substance Monitoring Database Program*, TENN. DEP'T OF HEALTH, <https://www.tn.gov/health/health-program-areas/health-professional-boards/csmdb-board/csmdb-board/about.html> (last visited Nov. 23, 2018).

98. Originally established by Public Chapter 840 of the 102nd General Assembly, it is administered by the Controlled Substance Database Advisory Committee. TENN. CODE ANN. § 53-10-303(a) (2018). The law governing the CSMD has been amended repeatedly, and the changes have included a move, along with the Board of Pharmacy, from the Department of Commerce and Insurance to the Department of Health. See, e.g., TENN. CODE ANN. § 53-10-302(6) (2018) (defining "department" as the Department of Health); see also TENN. CODE ANN. § 53-10-304(a) (2018) ("There is created within the department a controlled substance database."). The governing law was most recently amended by the Prescription Safety Act of 2016, Public Chapter 1002 of the 109th General Assembly.

The purpose of the database is to increase the quality of patient care by equipping healthcare practitioners with accurate, timely information that the practitioners can use to determine when patients acquiring controlled substances may require counseling or intervention for substance abuse, by collecting and maintaining data as described in this part regarding all controlled substances in Schedules II, III, and IV dispensed in this state, and Schedule V controlled substances identified by the controlled substance database committee as demonstrating a potential for abuse. Further, the database is to be used to assist in research, statistical analysis, criminal investigations, enforcement of standards of health professional practice, and state or federal laws involving controlled substances.<sup>99</sup>

Housing the CSMD in the Tennessee Department of Health reflects that the tool's primary use is healthcare and public health. Of note, in some states, law enforcement houses the PDMP which may change its focus, use, and access.<sup>100</sup> Intuitively, there is a significant difference in approach to and use of a tool that is primarily health and secondarily law enforcement, as to one that is primarily law enforcement and only secondarily health. Importantly, the placement of PDMPs in health or law enforcement is not consistent across the country, so Tennessee's use of this tool may differ substantially from some other states.<sup>101</sup>

*A. Access to the CSMD: Making a Complex Tool Useful*

In Tennessee, many health care practitioners have access to the CSMD to guide their clinical care decisions. Healthcare providers who have access to CSMD information—which is otherwise confidential,

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99. § 53-10-304(c).

100. See NAT'L ALLIANCE FOR MODEL STATE DRUG LAWS, PRESCRIPTION DRUG MONITORING PROGRAM (PMP) ADMINISTRATIVE AGENCY (2017), <http://www.namsdl.org/library/4421DC96-D2C0-7410-FA15C9C4E6C3BF56/>.

101. *State Profiles*, NAT'L ASS'N OF ST. CONTROLLED SUBSTANCES AUTHORITIES, <http://www.nascsa.org/stateprofiles.htm> (last visited Nov. 23, 2018).

not a public record, and not subject to subpoena<sup>102</sup>—include licensed prescribers and dispensers in appropriate circumstances:

A healthcare practitioner conducting medication history reviews who is involved in the care of a patient or making decisions regarding patient care or patient enrollment; a healthcare practitioner or supervising physician of a healthcare practitioner conducting a review of all medications dispensed by prescription attributed to that healthcare practitioner or a healthcare practitioner having authority to prescribe or dispense controlled substances, to the extent the information relates specifically to a current or bona fide prospective patient of the healthcare practitioner, to whom the healthcare practitioner has prescribed or dispensed, is prescribing, dispensing, approving of the prescribing or dispensing, or considering prescribing or dispensing any controlled substance.<sup>103</sup> [and]

A licensed pharmacist conducting drug utilization or medication history reviews who is actively involved in the care of the patient or making decisions regarding care of the patient or patient enrollment.<sup>104</sup>

In addition, the law explicitly attempts to increase ease of use of the CSMD in a busy clinical setting by allowing access to “[a] healthcare practitioner delegate, who is acting under the direction and supervision of a healthcare practitioner as an agent of a healthcare practitioner.”<sup>105</sup> The law defines these healthcare practitioner delegates to include anyone authorized to practice pursuant to Title 63 of the Tennessee Code,<sup>106</sup> and up to two additional unlicensed persons per provider

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102. TENN. CODE ANN. § 53-10-306(a) (2016).

103. § 53-10-306(a)(3).

104. § 53-10-306(a)(4).

105. § 53-10-306(a)(11).

106. See TENN. CODE ANN. § 53-10-302(10) (2016). This list includes many healthcare professionals who work with prescribers, but do not have prescriptive authority, such as: alcohol and drug abuse counselors; athletic trainers; professional counselors; marital and family therapists; clinical pastoral therapists; chiropractors;

licensed to prescribe or dispense.<sup>107</sup> This means a busy practice with multiple registered nurses, who are licensed but not prescribers, could establish individual access for each of those nurses, plus two office staff conducting otherwise clerical duties, allowing the time to check, print, or otherwise incorporate CSMD findings into the patient's chart for the prescribing provider.

Although the General Assembly initially established the CSMD years ago, a series of legal efforts have made it both more useful and more powerful over time. For example, in 2012, the Prescription Safety Act of 2012 *required* prescribers to register and begin checking the CSMD prior to prescribing an opioid or benzodiazepine<sup>108</sup> as a new course of treatment for a patient and annually thereafter.<sup>109</sup> In reality, despite its potential as a public health tool, many practitioners report that the primary reason they use the CSMD is because the law requires it.<sup>110</sup>

Since that time, Tennessee has seen substantial reduction in opioid prescribing, measured both by number of prescriptions and total morphine milligram equivalents.<sup>111</sup> Patients meeting the definition of “doctor shopping” have decreased by nearly 70%.<sup>112</sup> While these are positive results, the results are clearly inadequate. Overdose deaths related to pain relievers remain high, and while deaths associated with illicit drugs are rising quickly, younger individuals are primarily

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audiologists and speech pathologists; dietitians and nutritionists; optometrists; psychologists; nurses; physical and occupational therapists; and social workers. *Id.*

107. *Id.*

108. Benzodiazepines are used for numerous conditions including anxiety, muscle relaxation, and intraoperatively for amnesic and anxiolytic effect. *See generally* Charles E. Griffin III et al., *Benzodiazepine Pharmacology and Central Nervous System-Mediated Effects*, 13 *OCHSNER J.* 214 (2013), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3684331/>.

109. Tennessee Prescription Safety Act of 2012, 2012 Tenn. Pub. Acts 880 (codified as amended at TENN. CODE ANN. § 53-10-302 (2016)).

110. TENN. DEP'T OF HEALTH, CONTROLLED SUBSTANCE MONITORING DATABASE: 2017 REPORT TO THE 109TH TENNESSEE GENERAL ASSEMBLY 26 (2016), [https://www.tn.gov/content/dam/tn/health/documents/CSMD\\_AnnualReport\\_2016.pdf](https://www.tn.gov/content/dam/tn/health/documents/CSMD_AnnualReport_2016.pdf). 2015 CSMD prescriber survey responses showed that 67% of the respondents' CSMD checks were because the check was mandatory. *Id.* at 17.

111. Morphine Milligram Equivalents is a system to compare various strengths of opioids to a baseline of morphine.

112. *See* OFFICE OF INFORMATICS & ANALYTICS, *supra* note 75, at 24.

driving this phenomenon, with those above age 35 still more likely to die from prescription drug overdose.<sup>113</sup> Across all age groups, prescription drugs still dominate as the most common cause of overdose.<sup>114</sup>

Prescribers are not, however, the only individuals who can protect a patient from poor outcomes. Pharmacists review prescriptions before filling and dispensing drugs to patients, which functions as a sort of second check to the prescriber's determination.<sup>115</sup> This review can catch errors or misunderstandings, and, in the context of an epidemic, it can catch problematic prescribing. Pharmacists have a duty to exercise independent medical judgment in determining whether to fill a prescription.<sup>116</sup> While prescribers should exercise independent judgment themselves, pharmacists have a statutory protection to decline to fill prescriptions that they question for the patient's health and safety.<sup>117</sup>

In addition, the Tennessee Prescription Safety Act of 2016<sup>118</sup> added a requirement for dispensers to query the CSMD when they first dispense to a patient, and again annually thereafter.<sup>119</sup> By necessity this caused the second check aspect of the pharmacist-review of the prescriber's determinations to become more informed and robust. Though the CSMD has been available for years to prescribers and pharmacists to conduct medication reviews prior making healthcare

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113. *Id.* at 31–32. In this review of laws passed in Tennessee to address the opioid epidemic, this Article will focus on role of the law in addressing prescription drug use and overdose, specifically. This is a subset of the overall opioid epidemic and while the two are clearly intertwined, in the interests of clarity and length, this Article's focus is on laws specific to prescription drugs, particularly as they relate to the legislative efforts aimed at the patient and provider to ultimately impact population health.

114. *See id.*

115. *See, e.g.,* Hemant Kumar Sinha, *Role of Pharmacists in Retailing of Drugs*, 5 J. ADVANCED PHARMACEUTICAL TECH. & RES. 107 (2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4131399/>.

116. TENN. CODE ANN. § 53-10-112(c) (2016).

117. § 53-10-112(d). This, of course, creates a potential for prescribers and pharmacists to have conflicting clinical opinions. *See* TENN. CODE ANN. § 53-10-209 (2016).

118. Tennessee Prescription Safety Act of 2016, 2016 Tenn. Pub Acts 1002 (codified as amended at TENN. CODE ANN. § 53-10-302 (2016)).

119. TENN. CODE ANN. § 53-10-310(e) (2016).



decisions, the legal requirement to check under regularly recurring circumstances effectively increased use of this resource.<sup>120</sup> Both prescribing and doctor shopping have substantially decreased since that time.<sup>121</sup>

*B. Never Stop Learning: Leveraging Provider Education*

Required use of the CSMD is a big step, but only if prescribers know what to do with the information. If Tennessee's high-ranking position in a nation-wide epidemic evidences a gap in knowledge, then another key piece of the public health response was the development of guidelines for practice, particularly around opioid and benzodiazepine prescribing.<sup>122</sup> These laws mark a move to influencing prescriber practice even more prescriptively, while still focusing on primary prevention: keeping those yet unaffected safe from the spread of the epidemic.

With the passage of the Addison Sharp Prescription Regulatory Act of 2013,<sup>123</sup> the General Assembly charged the Tennessee Department of Health ("the Department") with creating treatment guidelines to assist healthcare providers in the state make determinations in caring for patients.<sup>124</sup> The Department subsequently created and promulgated the Tennessee Chronic Pain Guidelines for

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120. According to the 2017 Controlled Substance Monitoring Database Report to the 110th General Assembly, before passage of these two laws requiring prescriber and then dispenser checks, there were fourteen prescriptions reported for every CSMD patient request, and, by 2016, there were fewer than three prescriptions reported per patient request. See TENN. DEP'T OF HEALTH, CONTROLLED SUBSTANCE MONITORING DATABASE: 2017 REPORT TO THE 110TH TENNESSEE GENERAL ASSEMBLY 5 (2017) [hereinafter CONTROLLED SUBSTANCE MONITORING DATABASE 2017],

[https://www.tn.gov/content/dam/tn/health/documents/2017\\_Concise\\_CSMD\\_Annual\\_Report.pdf](https://www.tn.gov/content/dam/tn/health/documents/2017_Concise_CSMD_Annual_Report.pdf).

121. See OFFICE OF INFORMATICS & ANALYTICS, *supra* note 75, at 17–24.

122. See generally TENN. DEP'T OF HEALTH, TENNESSEE CHRONIC PAIN GUIDELINES: CLINICAL PRACTICE GUIDELINES FOR OUTPATIENT MANAGEMENT OF CHRONIC NON-MALIGNANT PAIN (2d ed. 2017) [hereinafter TENN. RX GUIDELINES], <https://www.tn.gov/content/dam/tn/health/healthprofboards/pain-management-clinic/ChronicPainGuidelines.pdf>.

123. Addison Sharp Prescription Regulatory Act of 2013, 2013 Tenn. Pub. Acts 430 (codified in scattered sections of 53 TENN. CODE ANN. and 63 TENN. CODE ANN.).

124. *Id.*

that purpose.<sup>125</sup> These guidelines, among other things, recommend what prescribers should do before prescribing opioids, such as making attempts at other reasonable, appropriate, and available modalities to treat the pain condition; examination and testing; and obtaining informed consent along with a written treatment plan.<sup>126</sup> These steps include referral for consultation or management by a pain management specialist if the opioid doses reach 120 morphine milligram equivalent daily doses (“MEDD”).<sup>127</sup> The guidelines further provide specific recommendations for contraceptive counseling in women of childbearing age to prevent neonatal abstinence syndrome.<sup>128</sup> They cover issues in the context of clinical care for pain, including both mental health assessments and the use of risk assessment and ongoing

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125. See John J. Dreyzehner, Comm’r, Tenn. Dep’t of Health, *Foreword to TENN. RX GUIDELINES*, *supra* note 122.

126. *TENN. RX GUIDELINES*, *supra* note 122.

127. *Id.* at 5. A morphine equivalent dose is a method to compare the equipotent amount in milligrams of various opioids, using morphine as a baseline. See, e.g., CTRS. FOR DISEASE CONTROL & PREVENTION, CALCULATING TOTAL DAILY DOSE OF OPIOIDS FOR SAFER DOSAGE (n.d.), [https://www.cdc.gov/drugoverdose/pdf/calculating\\_total\\_daily\\_dose-a.pdf](https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf). The MEDD is arrived at by multiplying drug strength, morphine equivalent multiplier, and drug quantity, divided by day supply. Cf. *id.* at 2. If oxycodone is 1.5 times stronger than morphine or hydrocodone (which is 1:1), then one can easily calculate that a prescription for oxycodone 10mg, taken three times daily over the course of 7 days is a total of 315 or a 45 MEDD. So 120 MEDD is the equivalent of taking 8 Percocet 10/325mg (oxycodone/acetaminophen) pills daily. See *id.*

The guidelines speak to the fact that national data suggests that opioid-naïve patients, or those new to taking opioids, are at risk of overdose death beginning at 40 MEDD in the first two weeks of treatment and the risk of overdose for patients overall increases tenfold at 100 MEDD. *TENN. RX GUIDELINES*, *supra* note 122, at 3. 120 MEDD is not a recommended dose, but rather the cap or cutoff point at which the guidelines state a patient should be referred to a pain specialist—someone with extra training who: (1) is boarded by the American Board of Medical Specialties with a subspecialty certification in pain medicine; (2) has attained diplomat status with the American Board of Pain Medicine; or (3) is certified by the American Board of Interventional Pain Physicians, for consultation and/or management, as these patients are at least eleven times more likely to suffer an adverse effect such as overdose death than their less medicated peers. *Id.* at 5. See also CONTROLLED SUBSTANCE MONITORING DATABASE 2017, *supra* note 120, at 4 (defining “pain management specialist”).

128. *Id.*

abuse potential through tools such as urine drug screens.<sup>129</sup> By providing tools such as a MEDD calculation to compare drug prescriptions, and links to mental health assessment tools in the appendices, the guidelines attempt to provide prescribers with concrete tools to better understand the care they are providing and the associated risks. The guidelines indicate that they are not meant to replace practice protocols or clinical acumen, but rather to be a supportive tool, intended to put lines on the road for good clinical practice, a prescriber-focused primary prevention initiative.<sup>130</sup>

Ensuring that practitioners actually learned something about those guidelines, the General Assembly required that all healthcare practitioners holding a current federal Drug Enforcement Administration license to prescribe controlled substances take at least two hours of continuing education biennially related to controlled substance prescribing, including instruction on the Department's treatment guidelines.<sup>131</sup> Though this law has an exception for those working in a pain management clinic,<sup>132</sup> the legislature did not let those practitioners go without extra guidance for long. In 2015, with the passage of Public Chapter 475 of the 109th General Assembly, the legislature required the Department to produce pain clinic guidelines as well.<sup>133</sup>

These laws all fit into a primary prevention public health paradigm, in which legal interventions are directed at the most “upstream” point, namely to prevent overuse and misuse of opioids before they even begin. The Intractable Pain Act, which the General Assembly ironically intended as “primary prevention” against intractable pain in a patient-focused manner, thus inadvertently created the need for additional interventions. These have included the CSMD, primary prevention with both prescriber and population foci, and treatment guidelines—primary prevention with a prescriber focus—to correct what became excessive use of highly addictive medications.

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129. *Id.*

130. *Id.*

131. TENN. CODE ANN. § 63-1-402 (2016).

132. § 63-1-402(c).

133. TENN. CODE ANN. § 63-1-401 (2016).

## V. SECONDARY PREVENTION TO ADDRESS A NEW REALITY

One can describe another set of interventions as “secondary prevention,” and these also have patient, prescriber, and population foci. These laws control prescriber practice through regulatory requirements and disciplinary actions, drive population oversight through large-scale prescriber review, and proscribe inappropriate patient activities that lead to the spread of illicit prescription drugs in the populace. The regulations focus on prescribers that prescribe high levels of opioids to a population of patients—a population at risk of addiction and poor clinical outcomes. In this Part, we begin with prescriber-focused intervention, followed by population, and then the patient.

Given the Intractable Pain Act and its aftermath, poor patterns of prescribing became ingrained in Tennessee. The populace of Tennessee certainly includes many people who are susceptible to primary prevention (or those not yet using opioids), but many others are habituated to use of high levels of opioids.<sup>134</sup> Primary prevention efforts are less likely to affect this second group, as it represents a group of individuals potentially affected by secondary prevention. They have underlying “symptoms” in the form of increasing tolerance and dependence, they have not been diagnosed with a substance use disorder, and they could easily fly under the radar without additional intervention. Some prescribers may work against the best interests of patients, namely in over- or mis-prescribing, either through lack of knowledge or intentionally, and often with strong financial incentives.<sup>135</sup> Secondary prevention laws bring about prevention both through requirements on practitioners, and sometimes their prescribing behavior, as well as health oversight agency investigation and discipline.

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134. See OFFICE OF INFORMATICS & ANALYTICS, *supra* note 75.

135. Marty Makary, *How Doctors Can Stop the Opioid Crisis at Its Source: Quit Overprescribing*, USA TODAY (Aug. 4, 2017, 8:02 AM), <https://www.usatoday.com/story/opinion/2017/08/04/doctors-stop-opioid-crisis-quit-overprescribing-marty-makary-column/504860001/> (describing incentives for opioid distribution). See also Robert Moore, *Pill-Mill Doctor Surrenders License*, CITIZEN TRIBUNE (Feb. 16, 2018), [http://www.citizentribune.com/news/local/pill-mill-doctor-surrenders-license/article\\_0f91ad76-1334-11e8-a6ce-bb0155190a6b.html](http://www.citizentribune.com/news/local/pill-mill-doctor-surrenders-license/article_0f91ad76-1334-11e8-a6ce-bb0155190a6b.html) (exemplifying the risk of improperly prescribing opioids).

A. *Provider Proscriptions for Treatment of At-Risk Populations*

Although healthcare providers have traditionally had broad leeway in dispensing directly from their own practices, now, with some exceptions, prescribers cannot *dispense* an opioid or a benzodiazepine. In 2014, the 108th General Assembly passed Public Chapter 983, which prohibits most prescribers from dispensing these two substances to their patients.<sup>136</sup> This law ensures that patients receiving prescriptions for opioids or benzodiazepines from their healthcare provider must retrieve them from a pharmacy, with the added safety of a pharmacist, a third party, reviewing the prescriptions.

Generally speaking, providers can and should exercise judgment in how to treat their patient population, and detailed oversight of clinical decisions that fall within the range of appropriate care is not the province of a governmental body absent an indication for raised concern.<sup>137</sup> In both theory and reality, this exercise of judgment manifested in all or nearly all of a given patient population of certain practices receiving an opioid prescription chronically.<sup>138</sup> The vast majority of practices treat a range of patients, and there could be several circumstances under which one would expect an entire patient population to receive legitimate treatment with opioids.<sup>139</sup> In some circumstances, however, so-called “pill mills” arose: clinical practices engaging in the unrestrained chronic provision of opioids without appropriate clinical decision-making.<sup>140</sup> The potential for

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136. TENN. CODE ANN. § 63-1-154 (2016).

137. See generally Steven E. Weinberger et al., *Legislative Interference with the Patient–Physician Relationship*, 376 NEW ENG. J. MED. 1557 (2012), <https://www.nejm.org/doi/pdf/10.1056/NEJMs1209858>.

138. The creation of Tennessee’s pain management clinic laws, setting the threshold for pain management clinics as those treating a majority of their patient population with certain controlled substances for pain, evidences the unfortunate proliferation of these practices and the so called “pill mills.” See, e.g., TENN. CODE ANN. § 63-1-101 (2016); see also generally Karry K. Rigg et al., *Prescription Drug Abuse and Diversion: Role of the Pain Clinic*, 40 J. DRUG ISSUES 681 (2010) (discussing an increase in the number of “pill-mills” in South Florida).

139. See generally Lotfi Chouchane et al., *Personalized Medicine: A Patient-Centered Paradigm*, 9 J. TRANSLATIONAL MED. 206 (2011), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3269464/>.

140. Jamie Satterfield, *Feds Prosecute Tennessee Pain Clinic Workers as Drug Dealers*, TENNESSEAN (Nov. 22, 2016, 1:55 PM),

abuse at such facilities became well-known both in Tennessee and elsewhere in the country.<sup>141</sup> Thus, it became important for protecting the public's health to separate the good actors, who provided appropriate and necessary treatment to patients suffering from pain, from those engaged in what was often a lucrative medication-focused business.

In 2011, the 107th General Assembly responded to the opioid epidemic with Public Chapter 340, requiring pain management clinics to register with the Department by January 2012.<sup>142</sup> All providers who prescribed opioids, benzodiazepines, barbiturates, or carisoprodol,<sup>143</sup> to the majority of their patient population for 90 days or more in a 12-month period qualified as a pain management clinic, requiring registration.<sup>144</sup> This created a framework for state oversight of those clinics that were largely treating chronic pain with opioids, whose patient populations were therefore potentially at risk of poor outcomes, including dependence and overdose.

Numerous updates to the pain management clinic laws have emerged since 2011, many of which have included further restrictions on what would ordinarily be provider judgment calls. Examples of these restrictions include prohibitions on accepting cash or money orders or dispensing opioids; requirements for policies regarding patients taking regular urine drug screens; and requirements that a medical director may oversee no more than four clinics, at each of which he must be present 25% of the time.<sup>145</sup> Notably, the requirement

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<https://www.tennessean.com/story/money/2016/11/22/feds-prosecute-pain-clinic-workers-as-drug-dealers/94279560/>.

141. See generally Alene Kennedy-Hendricks et al., *Opioid Overdose Deaths and Florida's Crackdown on Pill Mills*, 106 AM. J. PUB. HEALTH 291 (2016); see also generally SAM QUINONES, *DREAMLAND: THE TRUE TALE OF AMERICA'S OPIOID EPIDEMIC* (2015).

142. 2011 Tenn. Pub. Acts 340, § 3.

143. Barbiturates are sedative drugs used to promote sleep. Omudhome Ogbu, *Barbiturates*, MEDICINET (Feb. 6, 2017), [https://www.medicinenet.com/barbiturates-oral/article.htm#what\\_are\\_barbiturates?](https://www.medicinenet.com/barbiturates-oral/article.htm#what_are_barbiturates?). Carisoprodol is a muscle relaxant. Both can interact dangerously with opioids.

144. 2011 Tenn. Pub. Acts 340, § 3. It is worth noting that the wording of the threshold definition has been amended from time to time.

145. One amendment prohibited dispensing of controlled substances from a pain clinic with the exception of some sample-size allowances. 2013 Tenn. Pub. Acts 336, § 1. Another limited medical directors to service as medical director at no more

that a medical director be a pain management specialist was one of the most significant changes. This requirement reflects the reality that pain management is complex; prior to this time, though there were requirements for the medical director, the law did not require substantial, specific training and certification in managing pain and pain medicine before treating a patient population that one could describe as primarily chronic pain patients.<sup>146</sup> In 2015, the 109th General Assembly passed Public Chapter 475, requiring that the medical director of each pain management clinic be a pain management specialist, giving each clinic until July 1, 2016 (over a year later), to comply.<sup>147</sup> The law defined “pain management specialist” as someone with extended training and certification in one of four areas:

“Pain management specialist” means a [licensed] physician . . . who:

- (A)
  - (i) Has a subspecialty certification in pain medicine or pain management as accredited by the Accreditation Council for Graduate Medical Education (ACGME) through either the American Board of Medical Specialties (ABMS) or the American Osteopathic Association (AOA), or is eligible to sit for the board examination offered by ABMS or AOA;
  - (ii) Holds an unencumbered Tennessee license; and

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than four pain management clinics and clinics were restricted to only taking check or credit card in payment. 2013 Tenn. Pub. Acts 430, §§ 9–10. Additionally, the General Assembly enacted rules requiring urine drug screens. 2014 Tenn. Pub. Acts 700, § 2.

146. 2011 Tenn. Pub. Acts 340, § 3.

147. 2016 Tenn. Pub. Acts 475, § 2.

- (iii) Maintains the minimum number of continuing medical education (CME) hours in pain medicine or pain management to satisfy retention of ABMS or AOA certification. Any exceptions to this requirement shall be approved by the respective regulatory board;
- (B)
- (i) Attains American Board of Pain Medicine (ABPM) diplomate status;
  - (ii) Holds an unencumbered Tennessee license; and
  - (iii) Maintains the minimum number of CME hours in pain management to satisfy retention of ABPM diplomate status. Any exceptions to this requirement shall be approved by the respective regulatory board;
- (C) Is board certified by the American Board of Interventional Pain Physicians (ABIPP) by passing exam 1 on or before June 30, 2016, and holds an unencumbered Tennessee license and maintains the minimum number of CME hours in pain management to satisfy retention of ABIPP diplomate status; provided, that on and after July 1, 2016, a new applicant shall only qualify as a pain management specialist under this subdivision (9)(C) if the applicant is board certified by ABIPP by passing parts 1 and 2 of its examination, and holds an unencumbered



Tennessee license and maintains the minimum number of CME hours in pain management to satisfy retention of ABIPP diplomate status; or

- (D) Has an active pain management practice in a clinic accredited in outpatient interdisciplinary pain rehabilitation by the commission on accreditation of rehabilitation facilities or any successor organization and holds an unencumbered Tennessee license.<sup>148</sup>

Prior to the passage of this law, there were more than 300 pain management clinics in Tennessee.<sup>149</sup> By the end of 2016, there were approximately 185 pain management clinics registered with the Department.<sup>150</sup>

In 2016, the pain management clinic regulation went a step further by requiring *licensure* of pain clinics, including requirements that reached beyond those of the previous registration scheme.<sup>151</sup> From the enactment of the registration requirement in January 2012 until July 1, 2017, pain management clinics had to obtain a certificate, and the certificate holder had to be one of the owners.<sup>152</sup> Beginning July 1, 2017, however, the medical director—the individual who has to be a pain management specialist and assume responsibility for the care provided at the clinic—must be the actual license holder.<sup>153</sup> This rule holds the clinic’s medical director responsible, not only with his or her own medical license for any inappropriate and dangerous prescribing patterns that might take place in the clinic, but also with the pain management clinic license itself. It simultaneously grants the medical director additional authority and responsibility compared to the clinic model, in which the owner holds the certificate, or the property

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148. TENN. CODE ANN. § 63-1-301(8) (2016).

149. See CONTROLLED SUBSTANCE MONITORING DATABASE 2017, *supra* note 120, at 4.

150. *Id.*

151. 2016 Tenn. Pub. Acts 1033, § 2.

152. 2011 Tenn. Pub. Acts 340, § 3.

153. See TENN. CODE ANN. § 63-1-306, -316 (2016).

interest.<sup>154</sup> If an owner wants a new medical director, the existing medical director (the licensee), takes the license to operate the pain management clinic when they leave. Conversely, if a medical director wants to inactivate the license and shut down the clinic, though he or she has that control, it goes hand-in-hand with the responsibility to arrange for continuity of care.<sup>155</sup>

*B. Population Protections Through Provider Penalties*

The laws described thus far are provider-focused, and they exhibit their effect by restricting certain practices and setting boundaries for appropriate behavior. Nonetheless, in any profession, there exists a small group of bad actors. Medicine is no different. Protecting the public, population health-focused laws must create a consequence for those providers who practice outside the boundaries of safe behavior, either through licensure or law enforcement. Licensure is in the purview of the Department of Health.<sup>156</sup>

Each of the healthcare providers discussed in this Article has a licensing entity, a board or committee, housed administratively within the Tennessee Department of Health, Division of Health Related Boards.<sup>157</sup> As a function of their duty to protect the public, each of those health-related boards has, among other duties, both the duty and power to grant or deny licensure to applicants, as well as to discipline those licensees who have violated their practice act.<sup>158</sup> These boards carry out that duty in a variety of forms, including private warnings and public discipline, such as: reprimands; civil penalties; monitoring; practice limitations; or extra requirements. These may be issued alone, or in combination with probation or suspension, and disciplinary action can even result in the revocation of the licensee's ability to practice their chosen profession.<sup>159</sup> The licensing boards have broad statutory-

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154. See § 63-1-306 for the provision governing medical directors. See § 63-1-316 for the provision governing clinic directors.

155. See TENN. COMP. R. & REGS. 1200-34-01-.09(1)(f) (2017).

156. TENN. CODE ANN. § 68-1-306 (2016).

157. TENN. CODE ANN. § 68-1-101(a)(8) (2016).

158. *Id.*

159. Each licensing board or agency has its own statutory and rule-based disciplinary direction. See TENN. CODE ANN. § 63-6-214 (2016) for the statutory authority of the Board of Medical Examiners.

and rule-based authority to take disciplinary actions, generally through a contested case proceeding governed by the Uniform Administrative Procedures Code.<sup>160</sup> In these are trial proceedings, the Department's Office of General Counsel, representing the state's interest, and the respondent—the licensee defending against the charges—present evidence to an administrative law judge, either sitting alone or with the board, but typically sitting with the board, which acts as the fact finder and determiner of discipline.<sup>161</sup> While a separate chapter of Title 63 creates each board or committee, an example of this disciplinary authority for medical doctors in the area of inappropriate opioid prescribing is Tennessee Code Annotated section 63-6-214, which allows disciplinary assessments for

- (1) Unprofessional, dishonorable, or unethical conduct;
- ....
- (4) Gross health care liability, or a pattern of continued or repeated health care liability, ignorance, negligence, or incompetence in the course of medical practice;
- ....
- (12) Dispensing, prescribing or otherwise distributing any controlled substance or any other drug not in the course of professional practice, or not in good faith to relieve pain and suffering, or not to cure an ailment, physical infirmity or disease, or in amounts and/or for durations not medically necessary, advisable or justified for a diagnosed condition;
- (13) Dispensing, prescribing or otherwise distributing to any person a controlled

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160. See TENN. CODE ANN. § 4-5-301 (2016).

161. *Id.*

substance or other drug if such person is addicted to the habit of using controlled substances without making a bona fide effort to cure the habit of such patient; or

- (14) Dispensing, prescribing or otherwise distributing any controlled substance, controlled substance analogue or other drug to any person in violation of any law of the state or of the United States.<sup>162</sup>

The various restrictions throughout statute and rule for each of the healthcare providers' boards differ slightly, but they all aim to protect the public—the population as a whole—from the ignorance or incompetence of particular physicians who have demonstrated a risk to their past, current, or potential future patient population. In this way, these rules are population health-focused laws within the secondary prevention model.

The laws have also shifted in an attempt to ensure that these licensing agencies have swift access to knowledge about their licensees' indiscretions. Beginning in 2013, the law began requiring healthcare practitioners to report indictments under state or federal law involving the sale or dispensing of controlled substances within seven days of obtaining actual knowledge of the indictment.<sup>163</sup> State and federal prosecuting attorneys are encouraged to notify the licensing agencies, who may then determine if an expedited investigation of the healthcare practitioner is warranted.<sup>164</sup>

These laws are population-health-focused, but they essentially effectuate public protection one practitioner at a time, placing these laws somewhere on the line between prescriber- and population-focused secondary response laws. The opioid epidemic, however, has increasingly encouraged broader population health initiatives to distinguish problematic prescribing and identifying areas that need assessment. One explicit purpose of the CSMD is to serve as a health

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162. TENN. CODE ANN. § 63-6-214(b) (2016).

163. TENN. CODE ANN. § 63-1-151(a)(1) (2016).

164. § 63-1-151(a)(2).

oversight agency tool to identify poor prescribing practices.<sup>165</sup> The legal requirements to identify the top-fifty prescribers statewide and examine their prescribing patterns as a way to ensure that they are appropriate (“the Top 50 law”) exemplifies this purpose.<sup>166</sup> The Department is required to notify certain healthcare professionals that it has identified them as a top prescriber, and these prescribers receive information about their prescribing patterns, including numbers of patients, significant substances prescribed, and total MME.<sup>167</sup> When the Department determines that an advanced-practice registered nurse or physician assistant is a top prescriber, the Department notifies their supervising physician, too.<sup>168</sup>

In 2017, the General Assembly directed the Department to identify high-risk prescribers using clinical outcomes, including patient overdoses (“the High Risk Prescriber law”).<sup>169</sup> Whereas the Top 50 law required notification, the High Risk Prescriber law triggers responsibilities on the part of the prescriber:

- (3) Upon receiving information pursuant to subdivision (c)(2), the licensing board shall notify the prescriber and, if applicable, the prescriber’s collaborating physician or supervising physician, as appropriate, of the prescriber’s identification as a high-risk prescriber and, as applicable, require the prescriber to:
  - (A) Participate in continuing education that is designed to inform providers about the risks, complications, and consequences of opioid addiction. The specific continuing education courses

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165. TENN. CODE ANN. § 53-10-304(c) (2016).

166. TENN. CODE ANN. § 68-1-128(a) (2016).

167. *Id.*

168. *Id.* at § 68-1-128(a)(2).

169. § 68-1-128(c).

and number of hours to be completed by the prescriber shall be determined by the licensing board;

- (B) Make available, in the prescriber's waiting room and clinic areas where the prescriber's patient can view, educational literature that warns persons of risks, complications, and consequences of opioid addiction. The specific literature to be made available pursuant to this subdivision (c)(2)(B) shall be determined by the department and made available on the department's website;
- (C) Obtain written consent on a form that explains the risks of, complications of, medical and physical alternatives to, and consequences of opioid therapy and addiction to any patient who will receive opioid therapy for more than three (3) weeks with daily dosages of sixty (60) morphine milligram equivalents (MME) or higher. The consent shall include a certification from the patient that the patient understands the information. In order to continue to treat the patient, the provider must assure that the consent is signed by the patient

and made part of the patient's health record; and

- (D) Renew the consent described in subdivision (c)(3)(C) at four-week intervals for patients who continue to receive opioid therapy. In order to continue to treat the patient, the provider must assure that the consent is signed by the patient and made part of the patient's health record.
- (4) An identified high-risk prescriber must comply with the requirements set out in subdivision (c)(3) for a period of one (1) year from the time the provider was notified of the provider's identification as a high-risk prescriber of opioids. Failure of a prescriber to comply with the requirements set out in subdivision (c)(3) shall be treated as an act constituting unprofessional conduct for which disciplinary action may be instituted under the authority of the board that issued the prescriber's license.<sup>170</sup>

These laws are focused at broad population health initiatives, rather than taking action one prescriber at a time. By distinguishing problematic prescribing, tying supervising physicians and the mid-level professionals practicing under their guidance, and highlighting poor clinical outcomes, these laws have the potential to proactively impact practices: individual practices, group practices, and even practice by geographic area. In this manner, the CSMD can serve as a health oversight agency tool to identify poor prescribing practices.

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170. § 68-1-128(c)(3)-(4).

*C. Doctor Shopping: Patient-Developed Need Meets  
Need-Based Repercussions*

These laws attempted to create controls on the population through the care environment where that population receives treatment, as well as on the prescriber, and these are important levers. In reality, however, patients are not always innocent actors in their own fate. In a phenomenon known as “doctor shopping,” patients obtain care from multiple prescribers and may acquire their medications from multiple dispensers. These patients may be engaging in drug seeking behavior for their own use or for criminal diversion, giving or selling to others.<sup>171</sup> If patients are suffering from substance use disorder, then identifying multiple provider episodes may be an opportunity to intervene; if they are engaging in criminal activity, then identifying them has the potential to help others in the community by preventing the sale of drugs obtained from healthcare providers under false pretenses.<sup>172</sup>

With the intent to curtail drug-seeking behavior, Tennessee Code Annotated section 53-11-402(a)(6) prohibits lying to one’s health care practitioner about having already received a controlled substance.<sup>173</sup> This law specifically makes it unlawful for someone to deceive, or even fail to disclose, to a healthcare practitioner from whom the patient is obtaining a controlled substance that the patient has received the same controlled substance, or one of similar therapeutic use, from another healthcare practitioner within the last 30 days.<sup>174</sup> It is a Class A misdemeanor, unless it involves more than 250 single doses of the controlled substance, in which case it is a Class E felony.<sup>175</sup>

Furthermore, where physicians, dentists, optometrists, podiatrists, veterinarians, pharmacists, advanced practice registered

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171. See Sansone & Sansone, *supra* note 92 and accompanying text.

172. See, e.g., Press Release, U.S. Dep’t of Justice, Drug Enforcement Administration Collects Record Number of Unused Pills as Part of its 14th Prescription Drug Take Back Day (Nov. 7, 2017), <https://www.justice.gov/opa/pr/drug-enforcement-administration-collects-record-number-unused-pills-part-its-14th-0>.

173. TENN. CODE ANN. § 53-11-402(a)(6) (2016).

174. *Id.*

175. § 53-11-402(b)(1).



nurses, and physician assistants have actual knowledge that a person has knowingly, willfully, and with intent to deceive, obtained or attempted to obtain controlled substances by deceiving or failing to disclose to the healthcare practitioner that the patient has received the same controlled substance or one of similar therapeutic use from another healthcare practitioner within the last 30 days, those healthcare practitioners have a duty to submit a report the patient's activity within 5 business days.<sup>176</sup> Providers could obtain knowledge of this behavior through a combination of patient communication and use of CSMD.<sup>177</sup> Though the primary purpose of the CSMD is to support prescribing practices,<sup>178</sup> this marks an area where the General Assembly considers there to be an appropriate use by law enforcement and allows law enforcement its own access to the CSMD, albeit with limitations. Specifically, law enforcement personnel must be "engaged in the official investigation and enforcement of state or federal laws involving controlled substances or violations," and pursuant to these statutory limitations, the Department grants them access only if they provide a specific case number to the CSMD.<sup>179</sup>

As part of secondary prevention, this series of laws is intended to drive prescriber control, population oversight, and patient punishment when actions are illegal as described above. This set of regulations largely focuses on addressing the epidemic as it is reflected in a population currently using opioids, potentially habituated to high levels of use, and at risk of addiction and poor clinical outcomes.

#### VI. TERTIARY PREVENTION: ENSURING THE AVAILABILITY OF TREATMENT TO PREVENT WORSENING OUTCOMES

This third set of laws focuses on tertiary care, or the care for individuals already suffering from substance use disorder. These laws recognize that substance use disorder is a disease that affects an increasing numbers of individuals in Tennessee, and that increasing access to appropriate treatment is an essential part of the response. These tertiary prevention laws focus on individuals who are already suffering from addiction, ensuring that both patients and providers

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176. TENN. CODE ANN. § 53-11-309(a) (2016).

177. *See supra* notes 102–104 and accompanying text.

178. *See supra* notes 95–96 and accompanying text.

179. TENN. CODE ANN. § 53-10-306(a)(5) (2016).

have access to treatment for recovery. They encourage assistance from many sources including regulatory safety nets.

*A. Patient Assistance: Ensuring A Range of Treatment Options*

Medication-assisted treatment is an evidence-based approach that combines medication with therapeutic support, and it is the primary focus of health-related laws to increase access to treatment.<sup>180</sup> Other treatment options exist, including psychotherapy and support groups, among others, but the strongest scientific evidence available supports medication-assisted approaches.<sup>181</sup>

These medication-assisted treatments may include methadone (agonist maintenance<sup>182</sup>) or buprenorphine or naltrexone.<sup>183</sup> Buprenorphine is an opioid partial agonist that exerts a relatively weak effect at the opioid receptor sites; although it is an opioid, it has a leveling-off or ceiling effect past which the effects do not continue to

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180. *Medication and Counseling Treatment*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., (Sept. 28, 2015), <https://www.samhsa.gov/medication-assisted-treatment/treatment>.

181. See, e.g., Rolley E. Johnson et al., *A Comparison of Levomethadyl Acetate, Buprenorphine, and Methadone for Opioid Dependence*, 343 NEW ENG. J. MED., 1290, 1293, 1295–96 (2000); see also Richard P. Mattick et al., *Buprenorphine Maintenance Versus Placebo or Methadone Maintenance for Opioid Dependence*, COCHRANE DATABASE OF SYSTEMATIC REV. 2 (2014), <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD002207.pub4/epdf/full>; Suzanne Nielsen et al., *Opioid Agonist Treatment for Pharmaceutical Opioid Dependent People*, COCHRANE DATABASE OF SYSTEMATIC REV. 2 (2016), <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD011117.pub2/epdf/full>; Luis Sordo et. al., *Mortality Risk During and After Opioid Substitution Treatment; Systematic Review and Meta-Analysis of Cohort Studies*, 357 BRIT. MED. J. 1550 (2017), <https://www.bmj.com/content/bmj/357/bmj.j1550.full.pdf>.

182. An opioid receptor agonist is a substance that stimulates physiological activity in the central nervous system that would be stimulated by opioids. SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., *MEDICATIONS FOR OPIOID USE DISORDER 1* (Feb 2018), <https://store.samhsa.gov/system/files/sma18-5063fulldoc.pdf>.

183. Naltrexone is a medication used to manage alcohol and opioid dependence. *Naltrexone*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., <https://www.samhsa.gov/medication-assisted-treatment/treatment/naltrexone> (last updated Sept. 12, 2016).

increase, thus lowering its abuse potential.<sup>184</sup> It can be delivered orally, via tablet, or by sublingual film, and it is available alone as a mono drug or combined with naloxone,<sup>185</sup> which reduces the likelihood that someone can repurpose or reformulate it as an illicit drug.<sup>186</sup> The purpose of buprenorphine treatment is to control individuals' cravings without engendering the euphoric effects they often seek in opioids,<sup>187</sup> hopefully reducing the drug's appeal since it has no euphoric effect. Ideally, healthcare professionals provide these treatments in combination with other therapeutic techniques (hence medication-*assisted* therapy) to achieve individual patient goals that may include either long-term maintenance or complete abstinence. The U.S. Food and Drug Administration ("FDA") has approved buprenorphine to treat opioid substance use disorder.<sup>188</sup> Unfortunately, many patients remain unable to access treatment.<sup>189</sup>

In order to prescribe buprenorphine, a physician must complete 8 hours of training and obtain a data-waiver from the Substance Abuse and Mental Health Services Administration ("SAMHSA").<sup>190</sup> For the first year that a physician engages in prescribing buprenorphine for medication-assisted treatment, he or she may treat no more than thirty such patients.<sup>191</sup> After the first year, however, the physician may treat up to 100 patients.<sup>192</sup> Recently, a SAMHSA rule increased the long-

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184. Mattick et al., *supra* note 181.

185. *Id.*

186. *Id.*

187. *Id.*

188. APPROVAL LETTER(S): APPLICATION NUMBER 20-732, 20-733, CTR. FOR DRUG EVALUATION & RES., U.S. FOOD & DRUG ADMIN. (n.d.), [https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2002/20-733\\_Subutex\\_Approv.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/20-733_Subutex_Approv.pdf).

189. Christine Vestal, *Waiting Lists Grow for Medicine to Fight Opioid Addiction*, PEW CHARITABLE TRS. (Feb. 11, 2016), <http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2016/02/11/waiting-lists-grow-for-medicine-to-fight-opioid-addiction>.

190. *Buprenorphine Waiver Management*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., <https://www.samhsa.gov/programs-campaigns/medication-assisted-treatment/training-materials-resources/buprenorphine-waiver> (last updated Jan. 18, 2018).

191. 21 U.S.C. § 823(g)(2)(B)(iii)(I) (2012 & Supp. IV 2017).

192. § 823(g)(2)(B)(iii)(II).

standing cap of 100 patients to 275 patients for some providers.<sup>193</sup> To qualify for treating this additional number of patients, a physician who already had a data waiver for 100 patients must also be board certified in addiction medicine or addiction psychiatry by the American Board of Addiction Medicine, American Board of Medical Specialties, or American Osteopathic Academy of Addiction Medicine.<sup>194</sup> Such a physician must also practice in a qualified practice setting, which requires, among other features, contingencies for medical emergencies after hours; case-management services, such as referral or follow-up with behavioral or social service programs; and registration with the State's PDMP—the CSMD in Tennessee.<sup>195</sup>

In addition to these federal requirements, Tennessee physicians must also comply, in certain circumstances, with additional state requirements. Tennessee practitioners in clinics treating 50% or more of their patients, or 150 or more patients, for substance use disorder with buprenorphine products must also obtain a license from the Tennessee Department of Mental Health and Substance Abuse Services.<sup>196</sup> In a further effort to protect population health, Public Chapter 112 passed in 2017, requiring the Department of Mental Health and Substance Abuse Services to develop nonresidential buprenorphine treatment guidelines to assist practitioners in understanding best practices with regard to opioid use disorder.<sup>197</sup>

These treatment programs, existing as standalone clinics or in healthcare providers' offices, are available to those who, whether through legal or illicit drug use, have developed an opioid use disorder. They are typically entirely voluntary;<sup>198</sup> our criminal justice system, however, is dealing with all the societal opioid use disorders in its own microcosm. In recognition of the need to reduce the incidence of both substance use disorder and crimes committed as a result thereof, the General Assembly passed the Drug Court Treatment Act of 2003,

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193. 42 C.F.R. § 8.610 (2018).

194. *Id.*

195. *Id.*; 42 C.F.R. § 8.615 (2018).

196. TENN. CODE ANN. § 33-2-402(10) (2016); TENN. COMP. R. & REGS. 0940-05-35-.04.

197. 2017 Tenn. Pub. Acts 112.

198. Any one may be referred to, or self-refer to, substance use treatment.

creating drug court programs state-wide for judges who choose to participate.<sup>199</sup> The drug court program states its goals as follows:

- (1) To reduce the use of jail and prison beds and other correctional services by nonviolent chemically dependent offenders by diverting them into rehabilitative programs;
- (2) To reduce incidences of drug use and drug addiction among offenders;
- (3) To reduce crimes committed as a result of drug use and addiction;
- (4) To promote public safety through these reductions;
- (5) To increase the personal, familial and societal accountability of offenders; and
- (6) To promote effective interaction and the use of resources among local criminal justice agencies and community agencies.<sup>200</sup>

These programs involve a joint effort by the state courts and the Department of Mental Health and Substance Abuse Services, which the General Assembly tasked with developing standards of operation and outcome measures.<sup>201</sup> Any court in the state exercising criminal jurisdiction can apply for a grant to fund a drug court director and staff, substance abuse treatment, mental health services for the participants, and drug testing.<sup>202</sup> In addition to the criminal courts, those courts exercising jurisdiction of juveniles may establish similar drug court treatment programs.<sup>203</sup> Participation in these programs, while

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199. TENN. CODE ANN. § 16-22-102(b) (2016).

200. *Id.*

201. TENN. CODE ANN. § 16-22-105 (2016).

202. TENN. CODE ANN. § 16-22-106 (2016).

203. TENN. CODE ANN. § 16-22-114 (2016).

voluntary for the participants, is strongly incentivized by the fact that those entering them are individuals both suffering from substance use disorder and already enthralled in the judicial system, though violent offenders may not participate.<sup>204</sup> Thus, drug courts hold a large incentive to participation and recovery for patients who may otherwise be unwilling or unable to motivate themselves to participate in substance use disorder treatment. Beginning in 2014, the judge of a drug court treatment program could access the CSMD to the extent that it related to a current participant in the program, whom the judge reasonably believes may not be complying with the guidelines or rules of participation pertaining to the participant's use of controlled substances.<sup>205</sup> Thus, a tool aimed at assisting both providers in making informed decisions about their patients and the Department of Health in its population- and provider-specific oversight roles also assists judges in making informed decisions regarding the efforts of those to whom the criminal justice system has granted a second chance.

Another form of patient assistance that has both voluntary and participation-incentive aspects are laws that have developed around opioid-using mothers and their babies. Neonatal Abstinence Syndrome is a postnatal opioid withdrawal syndrome that can occur in newborns whose mothers use opioids while pregnant.<sup>206</sup> For those

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204. TENN. CODE ANN. § 16-22-113 (2016). Violent offenders are people convicted of an offense during which:

- (a) The person carried, possessed or used a firearm or dangerous weapon;
- (b) There occurred the death of or serious bodily injury to any person; or
- (c) There occurred the use of force against the person of another . . . .

TENN. CODE ANN. § 16-22-103(4)(A)(i) (2018). The definition also includes anyone with one or more prior convictions for a felony crime of violence involving the use or attempted use of force against a person with the intent to cause death or serious bodily harm. § 16-22-103(4)(ii) (2018).

205. 2014 Tenn. Pub. Acts 791; TENN. CODE ANN. § 53-10-306(9) (2016).

206. See generally Karen McQueen & Jodie Murphy-Oikonen, *Neonatal Abstinence Syndrome*, 375 *NEW ENG. J. MED.* 2468 (2016), <http://www.nejm.org/doi/full/10.1056/NEJMra1600879>; see also generally Veeral N. Tolia et al., *Increasing Incidence of the Neonatal Abstinence Syndrome in U.S. Neonatal ICUs*, 372 *NEW ENG. J. MED.* 2118 (2015), <http://www.nejm.org/doi/full/10.1056/NEJMs1500439>.

infants born with neonatal abstinence syndrome that need pharmacologic treatment, providers must first wean them from the drug to which they became accustomed *in utero*, typically providing doses of morphine or methadone during the infant's first few days to weeks of life.<sup>207</sup> In an effort to recognize the increasing misuse of opioids and the adverse impact that they can have on a newborn child when the mother takes them during pregnancy, the Safe Harbor Act of 2013 prevented the Department of Children's Services from filing a petition to terminate a mother's parental rights or seek protection in certain circumstances. Specifically, these circumstances require that the mother's obstetrical provider determined substance use treatment was indicated before the end of the 20th week of pregnancy, and the mother both initiated substance use treatment before her next regularly scheduled appointment and maintained it throughout the pregnancy.<sup>208</sup>

The next year, the law shifted from this encouragement and protection for mothers seeking substance use treatment to a more punitive approach. In 2014, a law that became known in common parlance as "the fetal assault bill" passed.<sup>209</sup> This bill allowed criminal prosecution of a woman for the illegal use of controlled substances while pregnant if her child was born harmed by those drugs.<sup>210</sup> To encourage pregnant women to seek assistance, the law allowed them to avoid criminal conviction if they enrolled in an addiction recovery program before the child's birth and successfully completed the program, regardless of harm to the child evidenced at birth.<sup>211</sup> Before it passed, this law raised concerns that women would avoid seeking pre-natal care to avoid identification as drug users, thus further

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207. McQueen & Murphy-Oikonen, *supra* note 206.

208. 2013 Tenn. Pub. Acts 398, § 2 (codified at TENN. CODE ANN. § 33-10-104(f) (2015)).

209. 2014 Tenn. Pub. Acts 820, §§ 1–2 (codified at Tenn. Code Ann. § 39-13-107(c)(2)–(3) (2014) (repealed 2016)); Tom Humphrey, *Legislators Clash with Doctors, Judges over Renewing Fetal Assault Law*, KNOXVILLE NEWS SENTINEL (Mar. 20, 2016, 3:00 AM), <https://www.knoxnews.com/story/news/politics/2016/03/20/legislators-clash-with-doctors-judges-over-renewing-fetal-assault-law/90887068/>.

210. 2014 Tenn. Pub. Acts 820, §§ 1–2 (codified at TENN. CODE ANN. § 39-13-107(c)(2)–(3) (2014) (repealed 2016)).

211. *Id.*

harming their pregnancy.<sup>212</sup> Due to the level of concern raised while the General Assembly debated the bill, lawmakers incorporated a sunset clause, whereby it would cease to have effect after a certain date, which indeed triggered on July 1, 2016, after a bill to extend the fetal assault bill failed.<sup>213</sup> The majority of patient-centered laws regarding those tertiary portions of the population already suffering from substance use disorder focus on helping the patient recover in a supported environment, even when that patient has made decisions which may be detrimental to those around them.

*B. Disease Can Spread Universally:  
When Provider Becomes Patient*

Though it is easy to dichotomize healthcare providers and patients, in reality our healthcare providers are also patients, as they can suffer from substance use disorders as well. This can lead to an impaired practitioner providing patient care, diverting drugs from patients, or prescribing within the context of a codependent relationship. This is a particularly interesting area for the laws surrounding public policy and for licensure regulation because it includes issues involving both the oversight of medical practice for the patients' wellbeing, as well as commitment to providing good clinical care to providers who have become patients, suffering from substance use disorder themselves.

Healthcare professionals licensed or registered in Tennessee are governed by boards and committees.<sup>214</sup> Since 1992, the General Assembly has charged these regulatory bodies with assisting their impaired licensees.<sup>215</sup> These regulatory agencies may enter into agreements with state-wide nonprofit peer assistance programs<sup>216</sup> to

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212. Humphrey, *supra* note 209.

213. House Bill 1660 failed on March 23, 2016, in Criminal Justice Subcommittee of Criminal Justice Committee. H.B. 1660, 109th Gen. Assemb., Reg. Sess. (Tenn. 2016).

214. See TENN. CODE ANN. § 68-1-101(a)(8) (2016).

215. TENN. CODE ANN. § 63-1-136(a) (2016).

216. The Tennessee Medical Foundation and Tennessee Professional Assistance Program are two such programs that have contracted with some of the Health Related Boards. See *Physician's Health Program*, TENN. MED. FOUND.,



identify and assist impaired licensees, including using licensure fees to fund assistance.<sup>217</sup> Because of this charge, disciplinary actions from the licensing agencies often take into consideration the impaired nature of a practitioner who commits a violation of their practice act, frequently employing the use of an agreement with a peer assistance program as part of their disciplinary practices.

Though assistance to impaired members of their own profession is a long-standing purpose of these agencies, this charge grew sharp teeth in 2017 with the passage of Public Chapter 481 of the 110th General Assembly. Employers of healthcare providers are now responsible for ensuring that an employee who fails a drug test and does not have a lawful prescription for the substance found in their system either submits to a peer-assistance program, or reporting the employee to their licensing body for discipline.<sup>218</sup> This law also creates a practice act violation for failing or refusing to take a drug test, stating:

A healthcare practitioner violates the practitioner's practice act by refusing to submit to a drug test, or by testing positive for any drug, on any government or private sector pre-employment or employer-ordered confirmed drug test when the practitioner does not have a lawful prescription for using the drug or a valid medical reason for using the drug.<sup>219</sup>

From the time the healthcare practitioner refuses a drug test, or receives notification that he or she failed one, he or she must produce a valid prescription or report to the peer assistance program in an agreement with their licensing agency within 3 days.<sup>220</sup> If a healthcare professional is able to enroll in and remain compliant with the terms and conditions of, obtain and maintain the advocacy of, that peer-assistance program, then that healthcare professional's licensing board will not suspend or revoke the practitioner's license for failing or

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<https://e-tmf.org/> (last visited Nov. 23, 2018); *About Us*, TENN. PROF'L ASSISTANCE PROGRAM, <http://www.tnpap.org/about.htm> (last visited Nov. 23, 2018).

217. TENN. CODE ANN. § 63-1-136(b)–(c) (2016).

218. *See generally* 2017 Tenn. Pub. Acts 481.

219. TENN. CODE ANN. § 63-1-126(b) (2016).

220. § 63-1-126(c).

refusing a drug screen—although conduct that triggered the test may yet lead to suspension or revocation of a license.<sup>221</sup> If the practitioner fails to comply with the terms of the program, however, their licensing agency must suspend their license.<sup>222</sup> Whereas the law had previously created an incentive for licensing agencies to provide a method through which their licensees could voluntarily seek help (an incentive often employed in disciplinary actions as well), there now exists an inducement of sizable proportion, encouraging immediate enrollment in a program and threatening suspension where that opportunity is declined.

In addition to the use of drug screens, one system support for identifying and addressing impaired prescribers is access to the CSMD for Quality Improvement Committees of healthcare systems. The law states:

A quality improvement committee, as defined in § 68-11-272, of a hospital licensed under title 68 or title 33, as part of the committee's confidential and privileged activities under § 68-11-272(b)(4) with respect to the evaluation, supervision, or discipline of a healthcare provider employed by the hospital or any of its affiliates or subsidiaries, who is known or suspected by the hospital's administrator to be prescribing controlled substances for the healthcare practitioner's personal use . . . .<sup>223</sup>

Thus, the CSMD, in addition to uses ranging from assisting a provider in making determinations about prescribing to a patient and health oversight agency activities, to law enforcement investigation and judicial identification of appropriate or inappropriate behavior with regard to controlled substances, is also a tool for healthcare systems' Quality Improvement Committees that want to identify an impaired

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221. Section 63-1-126(c)(2)(B)(i) states that the practitioner shall not be suspended for the positive result itself on a drug screen where the practitioner complied with the terms of the peer assistance program, and Section 63-1-126(2)(B)(iii) states that the licensing board is not prohibited from taking other disciplinary action for conduct other than the positive result on the drug test itself.

222. § 63-1-126(c).

223. TENN. CODE ANN. § 53-10-306(a)(8) (2016).

practitioner before any harm occurs to their patients. Impaired healthcare providers can inflict great harm on their patients; catching it early, catching it swiftly, and assisting (or sometimes requiring) that provider obtain needed help are goals that have developed over time in dealing with this particular aspect of the opioid epidemic in Tennessee.

### *C. Encouraging the Population's Participation in the Rebound*

Even with all of these potential interventions at the individual level, both patient and provider, several laws serve to create a potential safety net at the tertiary, population health, level. These laws focus on ensuring that individuals who are at risk of overdose are more likely to have access to both naloxone, an overdose-reversal drug, and individuals who are willing to help them.

As a result of increased substance use disorder leading to increased overdose deaths, the laws have changed to allow for increased access to reversal drugs. Naloxone, an opioid antagonist, is a drug that counteracts the effects of an opioid overdose.<sup>224</sup> The FDA approved it for the treatment of an opioid overdose,<sup>225</sup> but it should be readily available to administer when a victim is experiencing the overdose event. To battle the impact of the epidemic and increasing number of overdose deaths, the General Assembly passed a series of laws intended to promote the use of these drugs.

In 2014, Public Chapter 623 of the 108th General Assembly permitted healthcare providers in Tennessee to prescribe naloxone not only to a person at risk of experiencing an opioid-related overdose, but also to a family member or friend in a position to assist a person at risk of an opioid-related overdose.<sup>226</sup> It also created civil immunity, absent gross negligence or willful misconduct, for prescribing, dispensing, or administering naloxone, as well as immunity from board-imposed discipline for those healthcare providers acting in good faith by prescribing, dispensing, or administering the drug to someone

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224. See generally Edward W. Boyer, *Management of Opioid Analgesic Overdose*, 367 NEW ENG. J. MED. 146 (2012).

225. See generally U.S. Dep't of Health & Human Servs., *Information About Naloxone*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm472923.htm> (last updated Apr. 23, 2018).

226. TENN. CODE ANN. § 63-1-152(b) (2016).

suffering an opioid related overdose.<sup>227</sup> It further provided that the recipient of the naloxone could administer the drug to their friend or family member in need, if he or she had received instruction on administering the drug, including completion of an education program provided online by the Tennessee Department of Health, and had a good-faith belief the at-risk individual was experiencing a drug-related overdose.<sup>228</sup> Employing the Department's public health role, it charged:

The commissioner of health or the commissioner's designee, in consultation with other state, federal or local government personnel, including contractors, shall create and maintain an online education program with the goal of educating laypersons and the general public on the administration of opioid antagonists and appropriate techniques and follow-up procedures for dealing with opioid related drug overdose.<sup>229</sup>

In 2015, Public Chapter 396 of the 109th General Assembly, added further requirements of the Department:

The commissioner of health or the commissioner's designee shall make available recommendations for training of first responders, as defined in § 29-34-203, in the appropriate use of opioid antagonists. The recommendations shall include a provision concerning the appropriate supply of opioid antagonists to first responders to administer consistent with the requirements of this section.<sup>230</sup>

In 2017, Public Chapter 484 of the 110th General Assembly required that those receiving naloxone treatment from a first responder be transported to a medical facility by emergency medical services for evaluation unless the patient is both competent to refuse and refuses

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227. § 63-1-152(h)–(i).

228. § 63-1-152(d)–(e).

229. § 63-1-152(f).

230. § 63-1-152(i).

treatment.<sup>231</sup> One administration of naloxone is often insufficient to fully reverse an opioid overdose, in part because naloxone will leave the brain faster than the opioid, essentially re-inducing the overdose symptoms after the naloxone has been eliminated.<sup>232</sup> A subsequent administration of naloxone can be necessary to fully overcome the overdose.<sup>233</sup> Individuals treated with naloxone could die even after administration. This can occur because the individual received one administration of naloxone, but emergency services did not transport them to a hospital for observation, possible further naloxone administration, or treatment for underlying conditions that the overdose made worse.<sup>234</sup> In the vein of public health laws putting lines on the road for healthcare practitioners to follow, this law removed discretion regarding whether the patient should be taken to the hospital.

The Addiction Treatment Act of 2015 also outlined immunity from drug-charge arrest and prosecution for those seeking assistance for an individual suffering from a first-time drug overdose where the evidence for the arrest or charge resulted from the individual seeking assistance.<sup>235</sup> It further afforded that providing first aid could be a mitigating factor in a criminal prosecution for those who did not qualify for immunity.<sup>236</sup>

These laws created incentives for members of the public to look out for those around them who might be suffering. The General Assembly prioritized encouragement of intervention to protect a family member or friend suffering an overdose above law enforcement's interest in prosecuting those involved in drug use.

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231. 2017 Tenn. Pub. Acts 484, §2.

232. See Barry A. Berkowitz, *The Relationship of Pharmacokinetics to Pharmacological Activity: Morphine, Methadone, and Naloxone*, 1 CLINICAL PHARMACOKINETICS 219, 226–28 (1976); SFJ Clarke et al., *Naloxone in Opioid Poisoning: Walking the Tightrope*, 22 EMERGENCY MED. J. 612, 612–16 (2005); see also FDA ADVISORY COMMITTEE ON THE MOST APPROPRIATE DOSE OR DOSES OF NALOXONE TO REVERSE THE EFFECTS OF LIFE-THREATENING OPIOID OVERDOSE IN THE COMMUNITY SETTINGS, ADAPT PHARM. OPERATIONS LTD. 5–6 (2016), <https://bit.ly/2T4Uahe>.

233. Berkowitz, *supra* note 232, at 227.

234. Clarke, *supra* note 232, at 613–15.

235. 2015 Tenn. Pub. Acts 396, §2; TENN. CODE ANN. § 63-1-156(b) (2016).

236. § 63-1-156(c).

In 2014, the General Assembly gave pharmacists in Tennessee prescriptive authority.<sup>237</sup> Their scope of practice expanded to include provision of care and prescription orders pursuant to a collaborative pharmacy practice agreement. Pharmacists can, subject to restrictions, collaborate with other healthcare professionals to treat patients through initiation and discontinuation of drug therapy.<sup>238</sup> The prescriber signing the collaborative agreement for one or more pharmacists licensed in the state will approve the authorized scope of provision of patient care services in that agreement, which must include a listing of the drugs or categories of drugs that the collaborating pharmacist may prescribe under the terms of the agreement.<sup>239</sup> While this additional authority was not directly related to the opioid epidemic, it meant that pharmacists in a collaborative agreement could dispense drugs based upon a collaborating physician's diagnosis and treatment plan. Both the collaborative agreement rules and a statute that authorizes a state-wide collaborative pharmacy agreement specifically for the dispensing of naloxone demonstrate population-health focused laws intended to save lives. In 2016, the General Assembly statutorily authorized the Tennessee Department of Health's Chief Medical Officer to enter a state-wide collaborative pharmacy practice agreement for the purpose of providing opioid antagonist therapy with pharmacists licensed in the state.<sup>240</sup> This allowed those pharmacists who enter the agreement to dispense naloxone not only to a person at risk of experiencing an opioid related overdose, but to a family member or friend in a position to assist a person at risk of experiencing an opioid related overdose with both civil immunity, absent gross negligence or willful misconduct, and immunity from board-imposed discipline.<sup>241</sup>

This third set of laws is focused on ensuring that individuals suffering from substance use disorder have the best possible opportunity for treatment and recovery. They seek to ensure that patients are empowered to seek and access care, and that providers have the same opportunities, though with additional provisions to protect their patient population. Finally, they ensure that a safety net

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237. 2014 Tenn. Pub. Acts 832, §4.

238. TENN. CODE ANN. § 63-10-204(35)(A)(vii), (38) (2016).

239. TENN. CODE ANN. § 63-10-217 (2017); TENN. COMP. R. & REGS. 1140-03-.17(5) (2016).

240. 2016 Tenn. Pub. Acts 596, §1(b)(1).

241. TENN. CODE ANN. § 63-1-157(b) (2016).

provides additional support, as a last resort, in the form of protection for patients, families, communities and first responders when they act as good Samaritans.

## VII. CONCLUSION

This Article has provided a survey of select laws related to the opioid epidemic in Tennessee as they pertain to efforts to induce primary, secondary, and tertiary prevention while focusing on patients, prescribers, and populations. Each of these levers is necessary to address a complex and evolving epidemic, and they combine proscriptive and protective elements to support the best opportunity for Tennessee to turn the tide on the epidemic. That said, although this Article placed these laws in a logical, structured framework, there is no indication in the legislative history that this or any other particular structure has guided the General Assembly in its determinations, and we do not know at this point which legal interventions have been most effective or why. Those studies are ongoing. The reality is that laws take time to settle in and have an effect, whether the intended effect or not. There is an educational process, as well as an implementation process, that becomes the responsibility of the assigned department, and the laws as written often do not account for that timeframe. Trying to introduce legal ramifications into the patient-provider relationship, where a fine line exists between laying appropriate guiding lines on the road and introducing too much protocol into clinical realities of complex and diverse patients, further complicates this dynamic.

It is furthermore true that legislating our way out of this problem is unlikely to be adequate. The mindset of both the patient and provider must shift to acknowledge the danger of opioids and the importance of exhausting other remedies before resigning to chronic drug use. Societal changes, including de-stigmatizing substance abuse, addiction, and mental health are essential to lay the ground work for communities to support their residents and to heal.

At this time, deaths due to drug overdose continue to rise, although the trajectory of those deaths that are specific to prescription drugs may be plateauing.<sup>242</sup> That said, the majority of drug deaths continue to include an opioid, and most of those are a prescription

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242. See *supra* notes 70–86 and accompanying text.

opioid, whether obtained legally or illicitly.<sup>243</sup> Some, however, are touting the rapid rise in illicit drug deaths, including fentanyl and heroin, as a direct and unintended consequence of a reduction in access to legal prescriptions, much like that seen in prohibition.<sup>244</sup> This idea is in dispute.<sup>245</sup> There is significant concern that the balance of laws may have focused too much on reducing use and spread of prescription opioids and not enough on ensuring treatment access to individuals with substance use disorders. Conversely, if patients did not seek, and providers did not so commonly prescribe opioids, there would arguably be fewer individuals in need of access to treatment.

In reality, patient, prescriber, and population are intertwined and act upon one another, and the laws in Tennessee relative to public health and the opioid crisis demonstrate recognition of that reality on some level. Public health objectives are population-health centered. As the population is made of individual patient-prescriber relationships, the laws must change that dynamic in many different, single patient-prescriber interactions to shift and improve population health. This shift in many small interactions can, in a multiplicative manner, reduce the prescriptions drugs available to a community and ultimately thereby reduce the number of individuals with substance use disorder.

Here in Tennessee, people continue to call for legislation as a response to the opioid epidemic. New legislation is under consideration this year,<sup>246</sup> and it is unlikely that this trend will stop. The Governor has proposed an extensive set of changes to take advantage of our ability to affect the key actors—namely patients and providers—in the hope of achieving a healthier population.<sup>247</sup> This set

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243. See *supra* notes 70–80 and accompanying text.

244. Leo Beletsky & Corey S. Davis, *Today's Fentanyl Crisis: Prohibition's Iron Law, Revisited*, 46 INT'L J. DRUG POL'Y 156, 156–59 (2017).

245. Kolodny, *supra* note 31.

246. Though there are multiple bills intended to impact the opioid epidemic, there are three particularly pertinent bills related to this Article. H.R. 1831, 110th Gen. Assemb., 2d Reg. Sess. (Tenn. 2018) (proposing opioid legislation to change requirements for prescribing, dispensing); H.R. 1774, 110th Gen. Assemb., 2d Reg. Sess. (Tenn. 2018) (expanding the juvenile drug court treatment program); H.R. 2417, 110th Gen. Assemb., 2d Reg. Sess. (Tenn. 2018) (creating first responder treatment court programs).

247. Cf. Hon. William E. Haslam, *Tennessee Together: Governor's Welcome*, 48 U. MEM. L. REV. 1025 (2018).



of proposed changes, much like the laws discussed here, have patient, provider, and population foci. Though we cannot legislate our way out of this problem, population health-level primary prevention in the form of guidelines and availability of tools such as the CSMD have proven insufficient in this culture when the law does not mandate its use. For a population that is already suffering, through mindset, overuse, and abuse at the primary, secondary, and tertiary levels—and although trends are slightly improved, continues to suffer—these public health laws, mandating lines on the road for all involved are necessary. Which ones will be effective at moving the societal needle to the point where they are no longer necessary—and what the unintended consequences along the way may be—remains to be seen and studied.