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**Changing The Outlook Toward the Problem of Opioid Addiction:  
From “War on Drugs” to “Public Health Emergency”**

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## I. Introduction

Oxycontin, a schedule II substance, was approved by the Food and Drug Administration (FDA) in 1995 to treat chronic pain mainly in cancer patients.<sup>1</sup> However, in the last fifteen years, opioids have been prescribed to treat acute pain and chronic pain alike, driving up the amount of prescribed opioids.<sup>2</sup> For instance, in 2012, enough prescriptions of opioids for pain were written that every adult in the United States could have a full bottle of pills.<sup>3</sup> The unchecked access to opioid prescriptions led to a surge in the number of deaths from opioid abuse and addiction. As it currently stands, on average 130 Americans die every day from what is known as the opioid epidemic.<sup>4</sup>

The more recent federal laws that address the opioid epidemic attempt to improve and expand upon existing federal laws that address the issue of addiction as well as create new laws aimed at addressing what President Donald Trump has recently declared to be a public health emergency.<sup>5</sup> States have done their part by implementing programs to help tackle the opioid crisis in a more comprehensive manner to meet the varying needs of each state.

Society's perception about opioid addiction has significantly shifted since the time of President Richard Nixon. There is no longer a "war on drugs" mentality, and incarceration is no longer at the forefront of any major federal or state resource allocated towards combating the opioid

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<sup>1</sup> *What Is the U.S. Opioid Epidemic?*, U.S. Dep't of Health & Hum. Servs., <https://www.hhs.gov/opioids/about-the-epidemic/> (last visited Oct. 14, 2018).

<sup>2</sup> *Id.*

<sup>3</sup> Leonard J. Paulozzi et al., *Vital Signs: Variation Among States in Prescribing of Opioid Pain Relievers and Benzodiazepines* - United States, 2012, CDC, 63 MORBIDITY & MORTALITY WKLY. REP. 563 (July 4, 2014).

<sup>4</sup> CDC, National Center for Health Statistics, *Wide-ranging online data for epidemiologic research (WONDER)*, (2017), <http://wonder.cdc.gov>.

<sup>5</sup> *Acting Secretary Declares Public Health Emergency to Address National Opioid Crisis*, U.S. DEPARTMENT OF HEALTH & HUMAN SERVS., HHS (Oct. 26, 2017), <https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html>.

epidemic.<sup>6</sup> While the federal and state response seems promising, the efforts to fight the opioid epidemic comes with its shortfalls.

The Second part of this paper will introduce federal frameworks that existed before and after the FDA approved Oxiconin in 1995. Part three will focus on the federal laws passed in response to the increase in opioid overdose deaths and the public health emergency. Part four will discuss in depth two major pieces of legislation between the President Barack Obama and President Donald Trump administration and how they tackle the opioid epidemic with a non-punitive approach, focusing on opioid addiction as an illness rather than a choice as well as what the new perspective means for medication-assisted treatment and the resistance by practitioners to adopt this form of treatment. Part five will discuss the same similar efforts to combat the opioid epidemic but on a state level and whether the state level programs are helping or harming the cause. Finally, part six will focus on New Jersey, discussing on how it has become the ‘first’ in terms of the different types of approaches it has taken to combat the epidemic and what the implications of these ‘first’ mean in practice, as well as discuss related laws passed to combat the epidemic on a more local level.

## **II. Federal Framework**

### *Food, Drug, and Cosmetic Act of 1938*

The public demanded legal quality and identity standards that would prohibit false therapeutic claims for drugs and manage product advertising among other things.<sup>7</sup> In 1906, the Wiley Act only regulated product labeling rather than requiring pre-market approval, falling short

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<sup>6</sup> See Payan, Tony, *A War that Can't Be Won*, The University of Arizona Press, (2013).

<sup>7</sup> *Part II: 1938, Food, Drug, Cosmetic Act*, U.S. Food & Drug Admin., <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054826.html>.

of addressing concerns about false or misleading statements as to the curative effects of a drug.<sup>8</sup> It also lacked restriction upon use of poisons in drugs.<sup>9</sup>

Congressional response came through, and the Food, Drug, and Cosmetic Act was passed in 1938. Public opinion was a catalyst in the movement towards a change in the law<sup>10</sup> rather than reliance on amendments to remedy the failings of the existing Act.<sup>11</sup> The new law required that drugs be labeled with adequate directions for safe use<sup>12</sup> and mandated pre-market approval of all new drugs, such that a manufacturer would have to prove to the Food and Drug Administration (FDA) that a drug was safe before it could be sold.<sup>13</sup> The act required directions and warning labels on prescription medication to alert the public of the unsafe dosage, methods, or duration of administration or application.<sup>14</sup> Drug manufacturers were required to provide scientific proof that new products could be safely used before putting them on the market.<sup>15</sup>

#### *Comprehensive Drug Abuse Prevention and Control Act of 1970- Controlled Substance Act*

Although Congress found many drugs to have a legitimate medical purpose, it also found that there was illegal and improper use of these drugs, finding it necessary to establish a comprehensive system to meet these concerns under a single statute.<sup>16</sup> There was public pressure to increase the penalties for possession of narcotics and drugs that were improperly used.<sup>17</sup>

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<sup>8</sup> Vincent A. Kleinfeld, *Legislative History of the Federal Food, Drug, and Cosmetic Act*, 50 Food & drug L.J.65, 66 (1995).

<sup>9</sup> *supra* note 5.

<sup>10</sup> Wallace F. Janssen, *The Story of the Laws Behind the Labels*, FDA Consumer Magazine, (June 1981).

<sup>11</sup> Kleinfeld, *supra* note 8.

<sup>12</sup> 21 U.S.C.S. § 352(a).

<sup>13</sup> *Id.* at 352 (a)(1).

<sup>14</sup> *Id.* at 352 (f).

<sup>15</sup> Janssen, *supra* note 10.

<sup>16</sup> Lisa N. Sacco, *Drug Enforcement in the United States: History, Policy and Trends*, Congressional Research Service (2014), <https://fas.org/sgp/crs/misc/R43749.pdf>.

<sup>17</sup> Janssen, *supra* note 10 at 12.

The enforcement of drug laws was originally under the jurisdiction of the FDA in the Department of Health, Education, and Welfare.<sup>18</sup> This was the beginning of a shift from dealing with the issues of drug abuse from a concern for public health approach towards punitive, law enforcement approach.<sup>19</sup> For example, the Boggs Act of 1951 set mandatory minimums of prison sentences for drug convictions, while the Narcotic Control Act of 1956 established mandatory sentences for possession and sale.<sup>20</sup>

The Controlled Substance Act (CSA) of 1970 brought narcotics and dangerous drugs under a comprehensive scheme of federal control.<sup>21</sup> The Bureau of Narcotics, in the Treasury Department and the Bureau of Drug Abuse Control, in the Department of Health, Education and Welfare (at the time), were consolidated into the Bureau of Narcotics and Dangerous Drugs that was established in the Department of Justice, serving what President Nixon called “... notice to the pusher and the peddler that their criminal acts must stop.”<sup>22</sup> In 1973, the Drug Enforcement Administration (DEA) was established in the Department of Justice<sup>23</sup> and became a superagency in charge of enforcing the operations of criminal and non-criminal regulatory requirements of the CSA, like requiring persons who handle controlled substances or listed chemicals (including doctors, hospitals and pharmacies) to register with the DEA.<sup>24</sup>

CSA regulates the lawful possession, production and distribution of controlled substances through a system that categorizes substances based on how dangerous they are considered to be,

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<sup>18</sup> Thomas M. Quinn & Gerald T. McLaughlin, *The Evolution of Federal Drug Control Legislation*, 22 CATH. U. L. REV. 586 (1973).

<sup>19</sup> *Id.*

<sup>20</sup> Sacco, *supra* note 16.

<sup>21</sup> Reorganization Plan No.1 of 1968,

<https://uscode.house.gov/view.xhtml;jsessionid=9C0EBB87FAE7ED08F77CB46DDB85F5D1?path=&req=granuleid%3AUSC-prelim-title5a-node84-leaf171&f=&fq=&num=0&hl=false&edition=prelim>.

<sup>22</sup> *Id.*

<sup>23</sup> Executive Order 11727, 38 Fed. Reg. 18,357 (July 6, 1973).

<sup>24</sup> Sacco, *supra* note 16 at 7.

their potential for abuse and addiction, and whether they have a legitimate medical use.<sup>25</sup> Several factors considered in determining the control or removal of a drug from the schedules are:

- (1) Its actual or relative potential for abuse.
- (2) Scientific evidence of its pharmacological effect, if known.
- (3) The state of current scientific knowledge regarding the drug or other substance.
- (4) Its history and current pattern of abuse.
- (5) The scope, duration, and significance of abuse.
- (6) What, if any, risk there is to the public health.
- (7) Its psychic or physiological dependence liability.
- (8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.<sup>26</sup>

Drugs and substances that are considered controlled under the CSA are placed into one of five schedules.<sup>27</sup> Under schedule I, drugs and substances are classified as having no currently accepted medical use and a high potential for abuse.<sup>28</sup> Some examples of substances within this schedule include LSD, cannabis, and ecstasy.<sup>29</sup> Under schedule II, drugs and substances are classified as having similarly high potential for abuse with severe dependencies but are nonetheless accepted for medical use and may be prescribed, dispensed, or administered.<sup>30</sup> Examples of these include morphine, codeine, oxycodone, and fentanyl.<sup>31</sup> Schedule III and IV substances are classified as having less potential for abuse than substances in schedule I or II but still contain combinations of hydrocodone per dosage unit ranging from 15 milligrams to 90 milligrams per dosage unit.<sup>32</sup> Schedule V substances are classified as having lowest potential for abuse relative to

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<sup>25</sup> Sacco, *supra* note 16 at 6.

<sup>26</sup> 21 U.S.C.S. § 811(c).

<sup>27</sup> Office of Diversion Control, *Practitioner's Manual*, U.S. Dep't of Justice Drug Enforcement Admin., (2005), <https://www.deadiversion.usdoj.gov/pubs/manuals/pract/section2.htm>.

<sup>28</sup> *Id.*

<sup>29</sup> *Id.*

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

<sup>32</sup> *Id.*

those listed in schedule IV and include cough medicines containing no more than 200 milligrams of codeine per 100 milliliters.<sup>33</sup>

The DEA requires the registration of manufacturers, distributors, and dispensers of controlled substances unless otherwise exempted by law.<sup>34</sup> Registration may be revoked or suspended if it is found that the registrant materially falsified information on the application, if the registrant is convicted of a felony, if the registrant's state license has been suspended, revoked, or denied, or if the registrant has committed acts that would render the registration inconsistent with the public interest or has been excluded from participation in a program pursuant to section 1128(a) of the Social Security Act.<sup>35</sup> The CSA established a framework for the federal regulation of controlled substances, thereby addressing drug misuse through the criminal justice system.<sup>36</sup>

#### *Anti-Drug Abuse Acts of 1986 and 1988*

In an effort to establish a more aggressive enforcement against illicit synthetic drug trade and improve the federal drug laws by imposing more criminal penalties for simple possession of controlled substances, in 1986, Congress passed the Anti-Drug Abuse Act.<sup>37</sup> The Act is most notable for its mandatory prison terms on low-level crack offenses.<sup>38</sup> The Act required a minimum sentence of five years for the offenses of possession of cocaine, heroin, crack, fentanyl, and methamphetamine involving various amounts of weight for each substance.<sup>39</sup> The mandatory minimum sentencing provisions imposed restrictions upon federally appointed judges by

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<sup>33</sup> *Id.*

<sup>34</sup> 21 C.F.R. §1300.11(a).

<sup>35</sup> 21 C.F.R. §1301.36; 21 U.S.C. 824(a).

<sup>36</sup> Rural Health Information Hub, *Module 1: Substance use Disorders in Rural Communities: Historical Treatment of Substance Use Disorders*, <https://www.ruralhealthinfo.org/toolkits/substance-abuse/1/historical-treatment>.

<sup>37</sup> Anti-Drug Abuse Act of 1986. 99 P.L. 570.

<sup>38</sup> Deborah J. Vagins & Jesselyn McCurdy, Am. Civil Liberties Union, *Cracks in the System: Twenty Years of the Unjust Federal Crack Cocaine Law*, ACLU (2006),

[http://www.aclu.org/files/pdfs/drugpolicy/cracksinsystem\\_20061025.pdf](http://www.aclu.org/files/pdfs/drugpolicy/cracksinsystem_20061025.pdf).

<sup>39</sup> 21 U.S.C. 841(b)(1)(B).

prohibiting alternatives like probation or suspension of the sentence of any person sentenced under any of the mandatory minimum provisions.<sup>40</sup> The Act also provided mandatory minimum penalties for offenses involving the simple possession of controlled substances.<sup>41</sup> Considered to be a “sweeping legislation” according to the New York Times, the goal of reaching a “drug-free generation” meant increasing the federal funds available for law enforcement, drug treatment, and education programs.<sup>42</sup> While federal funding was allocated for drug treatment and education programs, the majority of the funding was for law enforcement.<sup>43</sup> Out of the \$1.7 billion in financing, only twelve percent was allocated to the states for educational programs addressing issues of drug use, while the rest was dedicated to federal and state law enforcement.<sup>44</sup>

### III. Addressing the “Public Health Emergency”

The response to the opioid epidemic we see today is a shift in how health care providers treat pain and a shift in how federal and state laws are addressing drug addiction.<sup>45</sup> In 1989, the World Health Organization (WHO) released a statement about the under-treatment of postoperative and cancer pain patients.<sup>46</sup> WHO’s priority was to advocate for effective pain management of cancer patients.<sup>47</sup> It argued that the relief of pain through analgesics was an essential component of pain management, and that restrictions on stronger opioids could interfere

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<sup>40</sup> Handbook On The Anti-Drug Abuse Act Of 1986 at 12, U.S. Dept. of Justice - Crim. Div. 63 (1987).

<sup>41</sup> *Id.*

<sup>42</sup> Gerald M. Boyd, *Reagan Signs Anti-Drug Measure; Hopes for 'Drug-Free Generation'*, N.Y. TIMES (Oct. 28, 1986), <http://www.nytimes.com/1986/10/28/us/reagan-signs-anti-drug-measure-hopes-for-drug-free-generation.html>.

<sup>43</sup> *Id.*

<sup>44</sup> Joel Brinkley, *Anti-Drug Law: Words, Deeds, Political Expediency*, N.Y. Times (Oct. 27, 1986), <http://www.nytimes.com/1986/10/27/us/anti-drug-law-words-deeds-political-expediency.html>.

<sup>45</sup> Marcia L. Meldrum, *The Ongoing Opioid Prescription Epidemic: Historical Context*, 106 AM. J. PUB. HEALTH 1365, 1365 (2016).

<sup>46</sup> World Health Organization, *Cancer Pain Relief*, (1986). Pg. 7-8, [https://apps.who.int/iris/bitstream/handle/10665/43944/9241561009\\_eng.pdf](https://apps.who.int/iris/bitstream/handle/10665/43944/9241561009_eng.pdf).

<sup>47</sup> *Id.*



with the necessary use of these drugs.<sup>48</sup> Furthermore, the WHO stated that the systems that regulated the distribution and prescription of opioid drugs were designed *before* the value of the oral use of opioid drugs for cancer pain management was recognized.<sup>49</sup> There was no intention of preventing use of opioids for pain relief in cancer.<sup>50</sup> The WHO called upon lawmakers to lift barriers that would impede the use of drugs that were otherwise necessary for relief of cancer pain.<sup>51</sup> An example of the increase in the liberalization of the use of opioids in the treatment of pain for cancer patients and chronic non-cancer patients was the FDA's approval of OxyContin in 1995, an oxycodone controlled release formulation that allowed dosing every 12 hours rather than immediate release given 4 times daily.<sup>52</sup>

### *The Danger of OxyContin, Rise of the Opioid Epidemic*

Oxycontin became the center of opioid abuse<sup>53</sup> after the FDA approved what would turn out to be an immediate 12-hour narcotic effect if the opioid was crushed and snorted or injected, causing overdose or death.<sup>54</sup> When approved, the FDA believed that Oxycontin did not have a greater potential for abuse based on experience with MS Contin, a controlled release formula of morphine without significant reports of abuse or misuse since the late 1980s.<sup>55</sup> Oxycontin was therefore marketed as being less likely to be abused in comparison to other prescriptions.<sup>56</sup>

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<sup>48</sup> *Id.*

<sup>49</sup> *Id.* at 27.

<sup>50</sup> *Id.*

<sup>51</sup> *Id.*

<sup>52</sup> Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 Am. J. Pub. Health 221-227 (2009).

<sup>53</sup> *Timeline of Selected FDA Activities and Significant Events Addressing Opioid Misuse and Abuse*. FDA.GOV, <https://www.fda.gov/drugs/information-drug-class/timeline-selected-fda-activities-and-significant-events-addressing-opioid-misuse-and-abuse>.

<sup>54</sup> Gardiner Harris, *Drug Panel Rejects Plea to Curb Sales of a Widely Abused Painkiller*, NY Times, (September 11, 2003).

<sup>55</sup> Art Van Zee, *supra* note 52.

<sup>56</sup> Caitlin Esch, *How One Sentence Helped Set Off the Opioid Crisis*, *Marketplace: The Uncertain Hour* (Dec. 13, 2017), <https://www.marketplace.org/2017/12/12/health-care/uncertain-hour/opioid>.

However, in a 2004 lawsuit against Purdue Pharma, officials of the company testified in a deposition that the company never held clinical trials to back up their claim that Oxycontin was in fact less likely to be an addictive or abused drug.<sup>57</sup> Advertising Oxycontin as having a delayed release that was believed to reduce abuse liability of the drug remained the only label on the product until 2001 when the FDA removed it and put a black box warning on the drug, signifying the drug's serious or life-threatening risks.<sup>58</sup> Oxycontin remains one of the most common drugs involved in prescription opioid overdose deaths to date, accounting for more than 35% of all opioid overdose death in the U.S. in 2017.<sup>59</sup>

#### **IV. Federal Law Responds**

##### *Comprehensive Addiction and Recovery Act*

Approximately four months before signing into law the Comprehensive Addiction and Recovery Act (CARA), President Obama shared his remarks at the National Prescription Drug Abuse and Heroin Summit in Atlanta Georgia, emphasizing the administration's commitment to fighting the opioid epidemic.<sup>60</sup> “[I]n this global economy of ours that the most important thing we can do is to reduce demand for drugs. And the only way that we reduce demand is if we're providing treatment and thinking about this as a public health problem and not just a criminal problem.”<sup>61</sup> In July of 2016, President Obama signed into law the Comprehensive Addiction and Recovery Act.<sup>62</sup> This was the first major federal legislation to address the opioid crisis by taking

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<sup>57</sup> *Id.*

<sup>58</sup> *Id.*

<sup>59</sup> Centers for Disease Control and Prevention, *Overdose Death Maps: Overdose Deaths Involving Prescription Opioids*, (August 13, 2019), <https://www.cdc.gov/drugoverdose/data/prescribing/overdose-death-maps.html>.

<sup>60</sup> Remarks During a Panel Discussion at the National Prescription Drug Abuse and Heroin Summit in Atlanta, Georgia (Mar. 29, 2016), <http://www.presidency.ucsb.edu/ws/index.php?pid=115136>.

<sup>61</sup> *Id.*

<sup>62</sup> Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-198, § 201, 130 Stat. 695, 711.

on a comprehensive approach through prevention, treatment, recovery, law enforcement, criminal justice reform, and overdose reversal.<sup>63</sup> The Act expanded and emphasized prevention and educational efforts aimed particularly at the young population as well as the aging population.<sup>64</sup> It also extended the availability of naloxone, a medication used to block the effects of opioids, making it possible for law enforcement and first responders to administer it upon arrival at the scene of an overdose.<sup>65</sup> As part of the treatment approach to the opioid epidemic, the Act also included an amendment to the Controlled Substance Act, increasing the total number of patients a prescriber can have for the purpose of dispensing buprenorphine from 30 to 100 per year.<sup>66</sup> Buprenorphine is a medication that is used in the treatment of adults addicted to opioids and has been found to be equally effective in promoting treatment of addiction as well as having less potential for abuse and overdose than methadone.<sup>67</sup> The Act also allowed for increased access to medication-assisted treatment<sup>68</sup> of buprenorphine by allowing more health care providers such as nurse practitioners and physician assistants to prescribe buprenorphine.<sup>69</sup>

The National Institute on Drug Abuse considers medication-assisted programs to be the first-line treatment for opioid abuse.<sup>70</sup> By providing more access to early intervention and

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<sup>63</sup> *Summary of the Comprehensive Addiction and Recovery Act*, Am. Soc'y of Addictive Med., <https://www.asam.org/advocacy/issues/opioids/summary-of-the-comprehensive-addiction-and-recovery-act>.

<sup>64</sup> *Id.*

<sup>65</sup> *Id.*

<sup>66</sup> *Id.*

<sup>67</sup> *Buprenorphine and the Opioid Crisis: A Primer for Congress*. CONGRESSIONAL RESEARCH SERVICE. R45279.

<sup>68</sup> “Medication-assisted treatment (MAT) is the use of Food and Drug Administration (FDA)-approved medication for the treatment of a specific substance use disorder in combination with clinically indicated behavioral or cognitive- behavioral counseling and other indicated services. Currently, medications are available to treat tobacco, alcohol, and OUD, and research is underway to identify effective medications for other substances as well.” *Use of Medication-Assisted Treatment for Opioid Use Disorder in Criminal Justice Settings*, Substance Abuse and Mental Health Services Administration.

<sup>69</sup> Jeffrey Fudin, *Considerations in Expanded Buprenorphine Access for Opioid Abuse Disorder*, Pharmacy Times, (Nov. 17, 2016), <https://www.pharmacytimes.com/contributor/jeffrey-fudin/2016/11/considerations-in-expanded-buprenorphine-access-for-opioid-abuse-disorder>.

<sup>70</sup> Arthur R. Williams & Adam Bisaga, Perspective, *From AIDS to Opioids-How to Combat an Epidemic*, 375 NEW ENGL. J. MED. 813, 813-15 (2016).

treatment, Medicaid played a central role in the efforts to address the opioid epidemic.<sup>71</sup> The Affordable Care Act expanded Medicaid coverage for buprenorphine-focused medication-assisted treatment, enhancing the state capacity to provide for the early intervention and treatment.<sup>72</sup> However, despite the increase of federal expansion in prevention, treatment and recovery for opioid drug abuse, limited availability and challenges in administering medications like buprenorphine continue to restrict the use of this type of treatment.

First, Medicaid coverage for opioid addiction medications like buprenorphine vary among states.<sup>73</sup> While some states provide Medicaid coverage for a large share of the cost of buprenorphine, most states' Medicaid programs pay for a smaller share, putting a majority of the cost burden directly on the patient.<sup>74</sup>

Second, the doctor's fees and time-consuming paperwork does not attract providers to treat Medicaid enrollees with addictions.<sup>75</sup> There is a slow increase in the adoption of medication-assisted treatment because the Centers for Medicare and Medicaid Services (CMS) has not made maintenance treatments like buprenorphine a mandated benefit.<sup>76</sup> CMS finalized framework establishes a *voluntary* adoption by sponsors of drug management program for beneficiaries at risk of misuse or abuse of drugs.<sup>77</sup> Yet, a study that surveyed all rural physicians listed as being registered with the DEA and waived to prescribe buprenorphine as of April 2016, showed that more than half of the physicians were not actually treating patients with drug addiction.<sup>78</sup>

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<sup>71</sup> *Medicaid's Role in Addressing the Opioid Epidemic*, Kaiser Fam. Found. (Feb. 27, 2018), <https://www.kff.org/infographic/medicaids-role-in-addressing-opioid-epidemic/>.

<sup>72</sup> *Id.*

<sup>73</sup> Christine Vestal, *In Some States, Medicaid rules make it difficult to treat addiction*, Stateline PBS, (2016).

<sup>74</sup> *Id.*

<sup>75</sup> *Id.*

<sup>76</sup> See Williams & Bisaga *supra* note 70; See Medicare Part D Opioid Overutilization Strategies for 2019: Implementation of CARA and Other Policy Guidance. Centers for Medicare and Medicaid Services.

<sup>77</sup> *Id.*

<sup>78</sup> Chris Crawford, *Overcoming Barriers to Opioid Treatment Takes Center Stage*, AAFP (Aug. 11, 2017), <https://www.aafp.org/news/health-of-the-public/20170811opioidsstudy.html>.

Third, while CARA has expanded buprenorphine waivers to nurse practitioners and physician's assistant, which has helped address the limited time physicians have to implement a medication-assisted program,<sup>79</sup> underlying barriers remain. For instance, providing the mental health support services that are in some states required as part of the treatment program has also caused reluctance among providers to become involved in these kinds of programs.<sup>80</sup> Another reason for the limited adoption in specialty treatment programs is the stigma behind the concept of taking medications to treat opioid addictions.<sup>81</sup> While there is scientific research that has established that medication-assisted treatment of opioid addiction increases a patients retention and decreases drug use, infectious disease transmission, and criminal activity,<sup>82</sup>there has been significant resistance to the treatment of opioid abuse with medications.<sup>83</sup> Factors that perpetuate the stigma include, the misconception that opioid use is a moral weakness or willful choice rather than a medical illness.<sup>84</sup>

### *Lifting Some Barriers to Opioid Treatment Programs*

In order to overcome the obstacles to using medications to treat drug addiction, there has to be significant increase in the number of physicians or practitioners willing to adopt a medication-assisted treatment program.<sup>85</sup> According to a 2014 National Survey on Drug Use and Health, out of 2.27 million individuals who met the criteria for medication-assisted treatment, less

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<sup>79</sup> *Id.*

<sup>80</sup> *Id.*

<sup>81</sup> Sarah E. Wakeman & Josiah D. Rich, *Barriers to Medications for Addiction Treatment: How Stigma Kills*, Substance Use & Misuse Journal, <https://www.tandfonline.com/doi/abs/10.1080/10826084.2017.1363238?scroll=top&needAccess=true&journalCode=isum20>.

<sup>82</sup> NIDA, *Medication Assisted Treatment for Opioid Addiction*. (Apr. 2012),

<http://www.drugabuse.gov/publications/topics-in-brief/medication-assisted-treatment-opioid-addiction>.

<sup>83</sup> Yngvild Olsen & Joshua M. Sharfstein, *Confronting the Stigma of Opioid Use Disorder -- and Its Treatment*, 311 JAMA 1393, 1393-1394 (2014).

<sup>84</sup> *Id.*

<sup>85</sup> *Probuphine: A Game-Changer in fighting Opioid Dependence*, National Institute on Drug Abuse (NIDA), (May 26, 2016).

than half of them received some form of medication-assisted treatment.<sup>86</sup> One of the barriers reported was the lack of availability of providers that are adequately trained in addiction pathophysiology.<sup>87</sup> Most medical schools offer limited training programs in addiction treatment, but the possible solution to this obstacle would be for schools to implement addiction treatment training as part of the curriculum.<sup>88</sup>

While treatment is a central pillar of initiatives on combating the opioid problem through CARA,<sup>89</sup> the lack of funding for the programs expanded by CARA hinders CARA from having a substantial impact on the opioid epidemic.<sup>90</sup> Funding for programs extended by CARA relies on discretionary funds that must be approved every fiscal year, which means that access to medication-assisted programs is not guaranteed.<sup>91</sup> While there has been an increase in overall spending for treatment and recovery between fiscal year 2017 and 2018,<sup>92</sup> Medicaid spending on opioid treatment drug of buprenorphine has significantly decreased from approximately \$150 million between 2016 and 2017 to approximately \$9 million between 2017 and 2018.<sup>93</sup> Expanding Medicaid on a state level to cover a larger percentage of the cost of treatment for opioid addiction

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<sup>86</sup> Richard G. Frank, *How do We Finish the Job that the Comprehensive Addiction and Recovery Act Started*, Health Affairs Blog, (September 2016), <https://www.healthaffairs.org/doi/10.1377/hblog20160912.056506/full/>.

<sup>87</sup> *Id.*; Williams & Bisaga, *supra* note 70.

<sup>88</sup> In 2016 the American Board of Medical Specialties recognized addiction medicine as a new subspecialty. Such acknowledgment shows that the academic medicine community is committed to approaching addiction as a treatable disease and not perpetuating the stigma of addiction as a moral failing, bad behavior, or a crime. (Robert J. Sokol, *Training Future Physicians to Address Opioid Crisis*, Ass'n of American Med. C., (2017)).

<sup>89</sup> NIDA, *supra* note 85.

<sup>90</sup> U.S. Department of Health and Human Services (HHS), Office of the Surgeon General, *Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health*, Washington, DC: HHS, (Nov. 2016).

<sup>91</sup> Declaring a “public health emergency” and establishing mandatory spending; “There are two types of spending in the federal budget process: discretionary and mandatory, where discretionary spending is subject Congress setting new funding level each fiscal years and mandatory is spending that does not take place through the appropriations legislation.” (Education Policy, *Mandatory and Discretionary Spending*, <https://www.newamerica.org/education-policy/topics/federal-education-legislation-budget/federal-education-budget/federal-budget-process/mandatory-and-discretionary-spending/>).

<sup>92</sup> *Tracking Federal Funding to Combat the Opioid Crisis 2019*, Bipartisan Policy Center, (2019).

<sup>93</sup> *Id.*

could significantly contribute to the CARA efforts.<sup>94</sup> If states rely on congressional grants alone, then funding for these integral prevention and treatment services falls at the mercy of the standing administration.

### *SUPPORT ACT*

As part of her Be Best campaign, First Lady Melania Trump, delivered remarks at an Opioid Town Hall in Las Vegas, Nevada, encouraging people to break through the stereotypes of drug addiction.<sup>95</sup> “Whether it is because of personal use, or that of family members, friends, co-workers or neighbors, opioid addiction is an illness.”<sup>96</sup> On October of 2018, President Donald Trump signed into law the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT).<sup>97</sup> The administration continued the initiative to combat the opioid crisis through comprehensive legislation that tackled many aspects including treatment, recovery, and prevention.<sup>98</sup> The majority of the Act’s provisions were Medicaid related and were aimed at helping states provide much needed coverage and services to treat opioid addiction, a significant barrier under CARA efforts.<sup>99</sup> Among the Medicaid-related provisions, a section of the Act will require covered providers to consult the state drug monitoring program before prescribing a controlled substance beginning October 1, 2021.<sup>100</sup> In addition, the Act calls for the Secretary of Health and Human Services to devise an action plan that will include

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<sup>94</sup> Abby Goodnough, *Opioid Treatment Is Used Vastly More in States That Expanded Medicaid*, N.Y. York Times (Aug. 21, 2019).

<sup>95</sup> The White House, *First Lady Melania Trump Attends an Opioid Town Hall in Las Vegas, Nevada*, You Tube (Mar. 12, 2019), <https://youtu.be/wThyV5ZF0us>.

<sup>96</sup> *Id.*

<sup>97</sup> Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, Pub. L. 115-271, 132 Stat. 3894 (2018) [hereinafter *SUPPORT Act*].

<sup>98</sup> MaryBeth Musumeci & Jennifer Tolbert, *Federal Legislation to Address the Opioid Crisis: Medicaid Provisions in the SUPPORT Act*, Henry J. Kaiser Family Found. (Oct. 5, 2018), <https://www.kff.org/medicaid/issue-brief/federal-legislation-to-address-the-opioid-crisis-medicaid-provisions-in-the-support-act/>.

<sup>99</sup> *Id.*

<sup>100</sup> SUPPORT Act, Pub. L. 115-271, 132 Stat. 3894 at § 5042.

review of potential obstacles to Medicaid and Medicare payment and coverage policies that could inhibit the effectiveness of the response to the opioid crisis.<sup>101</sup> The plan also calls for a review of beneficiaries' access to medication-assisted treatment approved by the FDA for the treatment of opioid use disorder, especially for individuals living in rural or underserved communities.<sup>102</sup> This plan is to be presented to Congress by the Secretary no later than June 1, 2020.<sup>103</sup> Furthermore, the Opioid Quota Reform provision establishes additional mandatory factors that the DEA must consider when setting the annual opioid quota.<sup>104</sup> Factors the DEA Administrator must consider are:

- (1) the total disposal of the controlled substance during the current and two preceding years
- (2) trends in new disposal of the controlled substance;
- (3) total inventories (actual or estimated) of “the class and all substances manufactured from the class [of controlled substances listed in Schedule I or II]”;
- (4) projected demand for a particular controlled substance; and
- (5) other relevant factors affecting the use of controlled substances, including changes in the currently accepted medical use of a controlled substance, the economic and physical availability of the raw materials necessary to produce a controlled substance, and recent unforeseen emergencies (i.e., natural disasters).<sup>105</sup>

Section 3282 of SUPPORT amends Section 306 of the CSA to provide that the Attorney General may, if necessary to avoid the overproduction, shortage, or diversion of a controlled substance, establish an aggregate or individual production quota by estimating the amount of possible diversion.<sup>106</sup> The Attorney General, in consultation with the Health and Human Services Secretary, must rely on data of rates of overdose deaths as well as overall public health impact related to the controlled substance.<sup>107</sup> Based on this information, the Attorney General then makes an

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<sup>101</sup> *Id.* at §6042.

<sup>102</sup> *Id.* at §6032(a)(4).

<sup>103</sup> *Id.* at §6032(e).

<sup>104</sup> *Id.* at § 3282.

<sup>105</sup> 21 C.F.R. 1303.11(b)(1)-(5).

<sup>106</sup> SUPPORT Act, Pub. L. 115-271, 132 Stat. 3894 at § 3282.

<sup>107</sup> *Id.*



appropriate quota reduction from the quota the Attorney General would have otherwise established had potential diversion of the controlled substance not been considered.<sup>108</sup>

SUPPORT also expands the conditions under which a physician may become qualified to prescribe buprenorphine as part of medication-assisted treatment programs.<sup>109</sup> SUPPORT advances the efforts of CARA in expanding access to medication-assisted treatment by amending section 303(g) of the CSA to allow physicians to practice in a medication-assisted treatment program if the physician graduated in good standing from an accredited U.S. school of allopathic or osteopathic medicine and received no less than 8 hours of training on treating and managing opioid-dependent patients, as well as other training that the Secretary deems fit to be included as part of the osteopathic or allopathic medicine curriculum.<sup>110</sup>

The SUPPORT Act was passed a year ago and the advantages of the Act seem promising once all provisions are in full force. There are still lingering concerns that remain unaddressed. With SUPPORT requiring that PDMPs be consulted prior to any prescription of opioids, more clinicians may be inclined to not prescribe opioid medication at all.<sup>111</sup> Those negatively affected would be patients who suffer from chronic pain.<sup>112</sup> In response to this concern, clinicians are highly encouraged to address the root of the issue, which is addiction, rather than completely cut off prescribing opioids.<sup>113</sup> The Centers for Disease Control offers a guideline for prescribing opioids for chronic pain and recommends that in addition to consulting PDMP data, clinicians should also

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<sup>108</sup> *Id.*

<sup>109</sup> SUPPORT Act, Pub. L. 115-271, 132 Stat. 3894 at § 3202.

<sup>110</sup> *Id.*

<sup>111</sup> ICANotes Behavioral Health HER, *SUPPORT Act for Opioid Recovery: Effects on Healthcare and Clinicians*, 2019, <https://www.icanotes.com/2019/01/04/support-act-for-opioid-recovery-effects-on-healthcare-and-clinicians/>.

<sup>112</sup> *Id.*

<sup>113</sup> *Id.*

be actively engaged in assessing the risks of opioid abuse, addressing the harms, and if necessary, offer a form of medication-assisted treatment for patients with opioid use disorder.<sup>114</sup>

## V. State Level Response to Opioid Epidemic

### *Prescription Drug Monitoring Programs*

Prescription Drug Monitoring Programs (PDMPs) are state-level electronic databases that track prescribing and dispensing data of controlled substances and stores them in a centralized database accessible to authorized users, including prescribers, pharmacists and law enforcement.<sup>115</sup> PDMPs are used to help identify patients who may be at risk of prescription misuse or overdose,<sup>116</sup> as well as to help identify where the major sources of prescription drug diversion occur by identifying improper prescribing and dispensing.<sup>117</sup> Out of fifty-three types of state agencies that administer PDMPs, the two most common agencies are Boards of Pharmacy and Departments of Health, with law enforcement agency trailing right behind.<sup>118</sup> The databases for the information collected from the PDMP in most states are housed within either the licensing or public health agency, but very few are located within the law enforcement agency.<sup>119</sup>

Several states have implemented policies that require providers to consult with the state PDMP before prescribing certain controlled substances in certain circumstances,<sup>120</sup> while other states

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<sup>114</sup> CDC, *Guideline for Prescribing Opioids for Chronic Pain - United States*, (March 2016), <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.

<sup>115</sup> CDC, *What States Need to Know About PDMP's*, (Oct. 3, 2017), <https://www.cdc.gov/drugoverdose/pdmp/states.html>.

<sup>116</sup> *Id.*

<sup>117</sup> Prescription Drug Monitoring ctr. of Excellence at Brandeis, *Briefing on PDMP Effectiveness 2* (2013), <https://www.pdmpassist.org/pdf/Resources/Briefing%20on%20PDMP%20Effectiveness%203rd%20revision.pdf>.

<sup>118</sup> PDMP TTAC, *PDMP Frequently Asked Questions (FAQs)*, (Sep.20, 2019), [https://www.pdmpassist.org/pdf/PDMP\\_FAQs.pdf](https://www.pdmpassist.org/pdf/PDMP_FAQs.pdf).

<sup>119</sup> SAMSHA, *Prescription Drug Monitoring Program: A Guide for Healthcare Providers*, Vol. 10, Issue 1., (2017), <https://store.samhsa.gov/system/files/sma16-4997.pdf>.

<sup>120</sup> *Id.*

leave it to the discretion of the practitioners to decide if they want to refer to the PDMP.<sup>121</sup> Access to the information collected in the PDMP state database varies by state, with most states allowing practitioners and pharmacists to obtain reports about prescribed substances to patients under their care.<sup>122</sup> Depending on the state, this information may also be available to law enforcement, licensing and regulatory boards, and state Medicaid programs for Medicaid member or provider reviews.<sup>123</sup> How often data is collected and when it may or must be accessed also varies by state.<sup>124</sup> Some states only track prescriptions for schedule II-V controlled medications, while other states also track uncontrolled medications with a potential for misuse, such as ephedrine.<sup>125</sup>

#### *Effectiveness of PDMP/ Consistency and Heterogeneity/ Harmful or Helpful?*

The rise in opioid overdoses has been the catalyst for more states to implement PDMPs that support clinical practice and monitoring efforts.<sup>126</sup> As of September 2019, forty-nine states, the District of Columbia, and Guam have operational PDMPs, while Missouri only has a county based PDMP service.<sup>127</sup> While almost the entire country is participating in a unified PDMP, Missouri is not only suffering the consequences of not being able to monitor possible abuse of opioid prescriptions but has also attracted an influx of people from neighboring states looking to stock up on multiple prescriptions.<sup>128</sup> Benefits of state level PDMP programs are promising if there is minimal variation of how the programs are implemented from state to state.

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<sup>121</sup> *Id.*

<sup>122</sup> PDMP TTAC, *supra* note 118.

<sup>123</sup> *Id.*

<sup>124</sup> *Prescription Drug Monitoring Program*. CONGRESSIONAL RESEARCH SERVICES, 42593.

<sup>125</sup> SAMSHA, *supra* note 119 at 2.

<sup>126</sup> Rebecca L. Haffajee, J.D., Ph.D., M.P.H., *Prescription Drug Monitoring Programs- Friend or Folly in Addressing the Opioid-Overdose Crisis?*, *New Eng. J. of Med.*, (2019).

<sup>127</sup> Federation of State Medical Boards, *Prescription Drug Monitoring Programs: State by State Overview*. <http://www.fsmb.org/siteassets/advocacy/key-issues/prescription-drug-9monitoring-programs-by-state.pdf>

<sup>128</sup> Alan Schwarz, *Missouri Alone in Resisting Prescription Drug Database.*, *N.Y. Times* (2014).

For example, as mentioned earlier, access to PDMPs is determined by state law.<sup>129</sup> However, the *requirement* that prescribers or clinicians consult their PDMP vary by state.<sup>130</sup> In New Jersey, direct access to the Prescription Monitoring Program (PMP) is limited to prescribers, delegates and pharmacists who are licensed by the State of New Jersey, are in good standing with their respective licensing board and have registered with the private vendor, Appriss, contracted to maintain the NJPMP.<sup>131</sup> However, in New York, the PDMP excludes veterinarians from having access to the registry and does not require them to consult prior to dispensing or prescribing controlled substances.<sup>132</sup> This variation raises similar concerns of individuals seeking access to controlled substance prescriptions from neighboring states.<sup>133</sup> Although veterinarians prescribe or dispense opioids for limited uses, there are still concerns of diversion of opioids prescribed to animals who are presented as ill or injured,<sup>134</sup> and the Food and Drug Administration recognizes that this is a legitimate concern especially when veterinarians are responsible for stocking and administering these drugs.<sup>135</sup>

Most states originally made the use of PDMP optional, but as the number of deaths from overdose have increased throughout the years, most states now require prescribers to register and consult the databases.<sup>136</sup> Despite these trends, heterogeneity among state PDMPs persists.<sup>137</sup> For instance, consulting requirements vary from state to state, thereby increasing the risk of diversion

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<sup>129</sup> PDMP TTAC, *supra* note 118.

<sup>130</sup> Alan Schwarz, *supra* note 128.

<sup>131</sup> N.J.S.A. 45:1-45 et. seq.

<sup>132</sup> New York State Department of Health, Bureau of Narcotic Enforcement, *NYS Prescription Monitoring Program Registry*, (June 2017).

<sup>133</sup> See Schwarz, *supra* note 128; see PDMP Report for the Board of Veterinary Examiners, (Oct. 2, 2018), [https://www.commerce.alaska.gov/web/Portals/5/pub/PDMP\\_VETreport\\_2018.09.pdf](https://www.commerce.alaska.gov/web/Portals/5/pub/PDMP_VETreport_2018.09.pdf).

<sup>134</sup> American Veterinary Med. Ass'n., *Opioid Resources for veterinarians*, <https://www.avma.org/KB/Resources/Reference/Pages/opioid-resources-for-veterinarians.aspx>.

<sup>135</sup> FDA, *The Opioid Epidemic: What Veterinarians Need to Know*, (Aug. 20, 2018).

<sup>136</sup> Haffajee, *supra* note 126.

<sup>137</sup> *Id.*

through doctor shopping.<sup>138</sup> In New Jersey, prescribers are required to consult the PDMP for information on a patient under specified conditions.<sup>139</sup> For example, prescribers must consult the PDMP if it is the first time the practitioner is prescribing a Schedule II controlled substance to a new or current patient.<sup>140</sup> On the other hand, New York imposes on prescribers a duty to consult the state PDMP prior to prescribing any controlled substance listed under Schedule II-IV, regardless if it is the same patient being prescribed the same controlled substance every month.<sup>141</sup>

Data has shown that use of PDMPs on a state level helps health care professionals in reducing doctor shopping and overdoses, thereby minimizing the risk of diversion.<sup>142</sup> However, the information gathered and the way of tracking the effectiveness of the program on a national level is difficult and produces inconsistent results, reflecting in part the heterogeneity of state level PDMPs.<sup>143</sup> It is difficult to determine with some sort of certainty whether differences in PDMPs across states has a significant impact on the opioid crisis because the use effects of PDMPs remain mixed.<sup>144</sup>

Perhaps the most chilling, unintended consequence of implementing a PDMP is that there has been an increase in the number of heroin overdoses correlated to the implementation of drug monitoring programs.<sup>145</sup> The sharp reduction in access to controlled substances may divert patients

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<sup>138</sup> Nora D. Volkow, M.D., & Thomas McLellan, Ph.D., *Opioid Abuse in Chronic Pain-Misconceptions and Mitigation Strategies*, *New Eng. J. of Med.*, (Mar. 31, 2016), <https://www.nejm.org/doi/full/10.1056/NEJMra1507771>.

<sup>139</sup> N.J. Div. of Community Affairs. NJ Prescription Monitoring Program. FAQ.

<sup>140</sup> N.J.A.C.13:45A-35.9.

<sup>141</sup> New York State Department of Health, Bureau of Narcotic Enforcement, *NYS Prescription Monitoring Program Registry*, (June 2017), [https://www.health.ny.gov/professionals/narcotic/prescription\\_monitoring/docs/pmp\\_registry\\_faq.pdf](https://www.health.ny.gov/professionals/narcotic/prescription_monitoring/docs/pmp_registry_faq.pdf).

<sup>142</sup> Volkow & McLellan, *supra* note 138.

<sup>143</sup> *See* Volkow, *supra* note 138; *See* Haffajee, *supra* note 126.

<sup>144</sup> Jessica Davis, *Opioid Epidemic: Why aren't Prescription Drug Monitoring Programs More Effective?*, *Healthcare IT News*, (Apr. 30, 2018).

<sup>145</sup> Aaron Sarvet et al., *Prescription Drug Monitoring Programs May Have Negative Unintended Consequences*, *Columbian University, Mailman School of Public Health*, (May 8, 2018).

to seek illicit substances such as heroin, morphine, or fentanyl as an alternative.<sup>146</sup> For instance, Injury Prevention Research Center of the University of North Carolina conducted a study of North Carolina residents from 2007 through 2013 to determine the ratio of opioid-to-heroin overdose deaths.<sup>147</sup> In January of 2007, for every heroin overdose, there were sixteen opioid deaths, but by December of 2013, there were 3 opioid deaths for every heroin death.<sup>148</sup> This information suggests that heroin substitution may have increased after the implementation of the state's PDMP and the restrictions it imposes on the prescribing practices of opioid.<sup>149</sup>

Another study similarly indicated that, when the number of opioid prescriptions dropped by more than fifty percent in the United States between 2012 and 2017,<sup>150</sup> the number of opioid deaths continued to rise as the use of more dangerous, illicit opioids like fentanyl and heroin replaced once readily accessible prescription opioids.<sup>151</sup> While the use of PDMPs aims at reducing the prescription of opioids for individuals who are misusing opioids, there are many patients who depend on opioid treatment to manage their pain.<sup>152</sup>

It is too often that patients with legitimate chronic pain are turned away empty handed as more prescribers lean on PDMPs as a platform to completely cut off opioid prescriptions to any kind of patient. PDMPs are intended to be a tool used by prescribers to properly manage patients' pain,

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<sup>146</sup> 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>.

<sup>147</sup> Nabarun Dasgupta & Scott K. Proescholdbell, *Observed Transition from Opioid Analgesic Deaths Toward Heroin*, Drug and Alcohol Dependence Vol. 145, 238-241, (Dec. 2014).

<sup>148</sup> *Id.*

<sup>149</sup> Sarvet et al., *supra* note 145.

<sup>150</sup> Zhu, W., Chernew, M. E., Sherry, T. B. & Maestas, *Initial Opioid Prescriptions Among U.S. Commercially Insured Patients, 2012-2017*, New Eng. J. of Med., 380, 1043–1052 (2019).

<sup>151</sup> Michael Eisenstein, *Treading the Tightrope of Opioid Restrictions*, Nature Research, (Sep. 11, 2019).

<sup>152</sup> Stephen P. Wood, MS, ACNP-BC, *Prescription Monitoring Programs: Helpful or Harmful?* Harvard Health Publishing, Harvard Medical School, (June 8, 2018).

talk to them about substance use disorder, and avoid possible risks of abuse, rather than to completely turn them away from legitimate necessary opioid prescription.<sup>153</sup> In September 2019, the U.S. Department of Health and Human Services published a guide urging clinicians to take caution on the appropriate manner to implement dosage reduction or discontinuation of long-term opioid analgesics.<sup>154</sup> The guide called for a more “thoughtful, deliberative, collaborative, and measured manner” when considering reducing or discontinuing opioid analgesics because of the high risk of acute withdrawal symptoms, exacerbation of pain and potential to seek other sources of opioids including illicit opioids.<sup>155</sup> It is important to recognize that laws that heavily regulate opioid prescription practices do not necessarily mandate an involuntary dose reduction or discontinuation.<sup>156</sup> Many physicians lack the formal training necessary to help identify prescription drug abuse which often leads to failure to detect signs of substance abuse and PDMP’s wrongfully categorizing conscientious physicians as fraudulent prescribers.<sup>157</sup> This concern can be addressed through the implementation of drug addiction education in medical education curriculums as well as continuing programs.<sup>158</sup> Ultimately the treatment decisions for patients with chronic pain should be left to their doctors and the PDMP programs should not be used as the basis for a complete cut off from opioid treatment.

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<sup>153</sup> Davis, *supra* note 144.

<sup>154</sup> U.S. Department of Health and Human Services, *HHS Guide for Clinicians on The Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics*, (Sep. 2019), [https://www.hhs.gov/opioids/sites/default/files/2019-10/8-Page%20version\\_\\_HHS%20Guidance%20for%20Dosage%20Reduction%20or%20Discontinuation%20of%20Opioids.pdf](https://www.hhs.gov/opioids/sites/default/files/2019-10/8-Page%20version__HHS%20Guidance%20for%20Dosage%20Reduction%20or%20Discontinuation%20of%20Opioids.pdf).

<sup>155</sup> *Id.*

<sup>156</sup> Goodnough, *supra* note 94.

<sup>157</sup> Islam, M.M. & McRae, I.S. *An inevitable wave of prescription drug monitoring programs in the context of prescription opioids: pros, cons and tensions*. BMC Pharmacol Toxicol 15, 46 (2014).

<sup>158</sup> *Id.*

## VI. State Level Response- New Jersey

### *Governor Chris Christie Administration*

New Jersey is one out of ten states that has legislation that limits opioid prescriptions to 7 days or less.<sup>159</sup> In February 2017, Governor Chris Christie signed into law one of the toughest laws aimed at curbing the opioid epidemic,<sup>160</sup> which limits the initial opioid prescription to a 5-day supply for treatment of acute pain and only for the lowest effective dose of immediate-release opioid drug, making New Jersey the first and only state with the most restrictive limit.<sup>161</sup> The law also mandated that state regulated health insures cover the first 4 weeks of substance abuse treatment without requiring pre-authorization, a requirement that takes weeks to complete.<sup>162</sup> In addition, prior to prescribing opioids for acute or chronic pain, practitioners must document a thorough medical history that includes patients' response to non-opioid medications as well as any history of substance abuse.<sup>163</sup> The law does not apply to patients who receive cancer treatment, hospice care or are a resident at a long-term care facility.<sup>164</sup>

While legal prescriptions for opioids has significantly declined in New Jersey, the number of overdose deaths continues to rise based on data from the CDC.<sup>165</sup> This increase is largely attributed to an increase in the use of synthetic drugs that are analogues to opioids, such as heroin

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<sup>159</sup> Sarah Frostenson, *Gov. Chris Christie Passed One of The Most Aggressive Laws to Combat The Opioid Epidemic*, Vox, (Mar. 29, 2017). <https://www.vox.com/policy-and-politics/2017/3/29/15107526/chris-christie-opioid-law-new-jersey-commission>.

<sup>160</sup> Timothy O'Shea, MS, *New Jersey Enacts Strict Opioid Prescribing Law*, Pharmacy Times (Feb. 21, 2017).

<sup>161</sup> *Id.*

<sup>162</sup> *Id.*; O'Shea, *supra* note 160.

<sup>163</sup> N.J. Stat. § 24:21- §15.2(b)(1)-(5).

<sup>164</sup> NJAFP, *New Prescribing Law for Treatment of Acute and Chronic Pain*, <https://njafp.org/content/new-prescribing-law-treatment-acute-and-chronic-pain>.

<sup>165</sup> Lilo H. Stainton, *Latest Opioid data: Good and Bad News for New Jersey*, NJ Spotlight, (Oct. 1, 2018), <https://www.njspotlight.com/2018/10/18-09-30-latest-opioid-data-good-and-bad-news-for-new-jersey/>.



and fentanyl.<sup>166</sup> Thus, the focus should not be solely on limiting the number of prescription opioids but also tackling the problem from a broad spectrum such as educating prescribers in their practice and expanding their training in medication-assisted treatment.<sup>167</sup>

#### *Governor Phil Murphy Administration*

More recently, under Governor Phil Murphy’s administration, New Jersey has continued the efforts to strengthen opioid-related laws.<sup>168</sup> As part of the ongoing efforts of the state to help battle the nationwide opioid epidemic, in July of 2019 Governor Murphy signed into law three- opioid related laws.<sup>169</sup> First, effective February 1, 2020, a pharmacist, other than those dispensing to an institutional pharmacy, will be required to affix to opioid medication containers a warning label or sticker describing the risks associated with opioid medications.<sup>170</sup> One of the primary sponsors of this bill, Assemblyman John Armato, called it a necessary tool in the arsenal that would serve as a cost-effective means of increasing awareness and education about the effects of opioid abuse.<sup>171</sup> Second, a new law now requires that the Department of Human Services provide individuals who are on Medicaid access to opioid addiction treatment medications like methadone, buprenorphine, naltrexone and naloxone without any prior authorization requirements.<sup>172</sup> Finally, in an effort to raise awareness about opioid abuse and heroin addiction, Governor Murphy signed a law that designates October 6<sup>th</sup> of each year as “Knock Out Opioid Abuse Day”.<sup>173</sup>

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<sup>166</sup> *Id.*

<sup>167</sup> *Id.*

<sup>168</sup> Brent Johnson, *N.J. Will Soon Require Warning Labels On Opioid Prescriptions*, NJ-Politics, (July 15, 2019), <https://www.nj.com/politics/2019/07/nj-will-soon-require-warning-labels-on-opioid-prescriptions.html>.

<sup>169</sup> Official Site of the State of New Jersey, *Governor Murphy Signs Legislation to combat Opioid Crisis*, (Jul. 15, 2019), <https://www.nj.gov/governor/news/news/562019/approved/20190716a.shtml>.

<sup>170</sup> N.J. Stat. § 24:21-17.

<sup>171</sup> Governor Murphy Signs Legislation to combat Opioid Crisis, *supra* note 170.

<sup>172</sup> N.J. Stat. § 30:4D-6m.

<sup>173</sup> 2018 Bill Tracking NJ S.J.R. 35.

The efforts to address the opioid epidemic on a state level in theory seem promising and only time will tell what impact it may have, but in practice it leaves important questions unanswered. For instance, there are laws like those that Governor Murphy signed, which now facilitate the accessibility of medication-assisted treatment for Medicaid insured individuals with opioid addiction without going through the tedious process of getting preauthorization. Unfortunately, more clinics than primary doctors, are offering the medication-assisted treatments.<sup>174</sup> Dr. Lewis Nelson, chair of the Department of Emergency Medicine at Rutgers New Jersey Medical School says, “It’s kind of paradoxical in a way that you don’t need any sort of licensing, other than a DEA number, to prescribe an opioid, but you need this whole training program and a special license to prescribe a treatment for opioid addiction, buprenorphine.”<sup>175</sup> This concern has led to primary doctors not wanting to engage in providing medication-assisted treatment because of a fear of the “type of clientele” that it may bring into their office practice.<sup>176</sup> Opioid addiction has become a public health problem nationwide, but the issue continues to be approached as an area outside of the medical profession field, where there is no required coursework in the curriculum for medical schools or even psychology and social work.<sup>177</sup> Dr. Alicia Agnoli, a family practice doctor at University of California Davis, suggests that one way to approach the stigma is by demystifying addiction treatment and culturally shifting addiction treatment away from what historically has not been part of the primary care practice.<sup>178</sup> For instance, Rutgers Medical School has become first in the nation to equip its graduates with the

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<sup>174</sup> Michael Hill, *Rutgers Medical School trains future doctors to deal with opioid addiction*, NJTV News, (Jan. 19, 2018), <https://www.njtvonline.org/news/video/rutgers-medical-school-trains-future-doctors-deal-opioid-addiction/>.

<sup>175</sup> *Id.*

<sup>176</sup> *Id.*

<sup>177</sup> Judy George, *Why Do So Few Docs Have Buprenorphine Waivers?*, MedPage Today, (Feb. 14, 2018), <https://www.medpagetoday.com/psychiatry/addictions/71169>.

<sup>178</sup> *Id.*

federal certification required to provide medication assisted treatment.<sup>179</sup> While medical schools throughout the nation have slowly started to implement opioid addiction treatment into the curricula, many of the programs still do not include the federal certification process.<sup>180</sup>

## **VII. Conclusion**

The response to the opioid epidemic and drug abuse has shifted since the “war on drugs” was first declared by President Nixon. The way federal and state law have approached the opioid addiction has shifted from a punitive approach to a public health approach. The response to the opioid crisis has been considerably more benign, focusing more on prevention, treatment, and rehabilitation rather criminalizing or imposing harsher sentences. However, it is still too early to know with certainty how effective the various laws will be in addressing the opioid crisis. What we have seen so far is that implementation of programs like the PDMP’s or strict limits on prescription drugs have actually increased overdose death rates. While we see more efforts to educate and bring awareness to the problem of opioid addiction, there is still a stigma surrounding opioid addiction and the medical profession has not been entirely on board with recognizing the need to implement training on opioid treatment into the curricula. The issue has to be looked at through the lens of opioid addiction as an illness rather than as moral or personal weakness before we can see significant progress in combating the opioid epidemic.

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<sup>179</sup> Lilo H. Stainton, *Rutgers Med First In U.S. to Offer Certified Medication-Assisted Treatment*, NJ Spotlight, (Feb. 28, 2018), <https://www.njspotlight.com/2018/02/18-02-27-rutgers-med-first-in-u-s-to-teach-medication-assisted-treatment/>.

<sup>180</sup> *Id.*