2025

The Undertreatment of Patients with Chronic Pain Due to the Opioid Crisis

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I. INTRODUCTION

Prescription opioids are used by millions of Americans to treat moderate-to-severe pain.[1] Over one in five Americans report experiencing pain almost daily, making pain one of the most prevalent health problems in the country.[2] Opioids are prescribed for acute pain, subacute pain, and chronic pain.[3] Acute pain is defined as pain that lasts for less than one-month, and is often caused by injury, trauma, or medical treatments.[4] Subacute pain is defined as pain that is present for a duration of one to three months.[5] Unresolved acute or subacute pain can evolve into chronic pain.[6] Over fifty million Americans suffer from chronic pain, and millions of these patients depend on daily prescription opioids because no other medication helps relieve their pain.[7]

Following this introduction, Part II of this paper will address what chronic pain is, prescription opioid usage for chronic pain, and the opioid crisis. Part III addresses the 2016 and 2022 Centers for Disease Control and Prevention (CDC) Guidelines on Prescribing Opioids, and how misapplication and misinterpretation of the 2016 CDC Guideline necessitated the release of the 2022 CDC Guideline.

Part IV addresses the current opioid prescribing practices in the United States and how clinicians are harming and undertreating patients with chronic pain due to these prescribing

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[1] *Prescription Opioids*, CENTERS FOR DISEASE CONTROL AND PREVENTION (Aug. 29, 2017), https://www.cdc.gov/opioids/basics/prescribed.html

[2] R. Jason Yong et al., *Prevalence of Chronic Pain Among Adults in the United States*, 163 PAIN 328, 328 (2022).

[3] CENTERS FOR DISEASE CONTROL AND PREVENTION, *CDC Clinical Practice Guideline for Prescribing Opioids for Pain – United States, 2022,* 71 MORBIDITY AND MORTALITY WEEKLY REPORT 1 (2022).

[4] *Id.*

[5] *Id.*

[6] *Id.*

[7] Allyson Cady, *Note: 50 Shades of Data Sharing: How A Uniform Fifty-State Prescription Drug Monitoring Program can Restore Discretion to Opioid Prescribers and Autonomy to Chronic Pain Patients*, 29 HEALTH MATRIX 463, 466 (2019).

practices. The implemented policy recommendations were out-growths from the opioid crisis and led to physicians over-reacting, and under-treating patients.

In conclusion, Part V presents suggestions to help better treat patients with chronic pain. These recommendations include state-mandated continuing medical education for opioid prescribers, a uniform fifty-state Prescription Drug Monitoring Program, and updated CDC Guidelines.

II. OPIOID USE FOR CHRONIC PAIN

a. What is Chronic Pain?

Chronic pain is defined as pain that lasts over three months and is caused by an underlying medical disease or condition, injury, medical treatment, inflammation, or unknown cause.[8] It can affect almost every aspect of a patient's life, and can lead to impaired physical functioning, poor mental health, and a reduced quality of life.[9] Patients with chronic pain are also at an increased risk for suicidal ideation and behaviors,[10] and often experience this pain with behavioral health conditions such as mental and substance disorders.[11]

In 2019, about one in fourteen adults experienced "high-impact" chronic pain, which is defined as "having pain on most days or every day during the past 3 months that limited life or work activities."[12] Data from eighteen states in a study conducted from 2003 to 2014 underestimated that about nine percent of suicide decedents had evidence of chronic pain at the time of death.[13]

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[8] *Id.*
[9] *Id.*
[10] CENTERS FOR DISEASE CONTROL AND PREVENTION, *supra* note 3, at 1.
[11] *Id.*
[12] *Id.*
[13] *Id.* at 2.

Patients with chronic pain need access to appropriate opioid therapy, pain care, and additional therapeutic options.[14] Pain is complex and can be influenced by biologic, psychological, and social factors which require different pain treatments depending on the type of underlying pain or condition to be treated.[15] Patients can experience chronic pain because of painful debilitating diseases such as sickle cell disease, multiple sclerosis, Parkinson's disease, spinal cord injury or amyotrophic lateral sclerosis (ALS). [16] Chronic pain can also affect survivors of HIV, cancer, and cardiovascular disease either through the disease itself or through interventions needed to treat the disease such as surgery, chemotherapy, or radiation therapy, and these patients may need opioids for a life without suffering.[17]

There are several clinical, psychological, and social consequences associated with pain.[18] These include "limitations in activities, lost work productivity, reduced quality of life, and pervasive stigma."[19] Patients also feel demoralized because of their inability "to work, socialize, or exercise."[20] In comparison, when chronic pain is adequately controlled, the patient is expected to experience "an enhanced quality of life, increased physical functionality, and an improvement in general overall health."[21]

Pain may go unnoticed in certain populations, such as members of marginalized racial and ethnic groups; women; older persons; or persons with cognitive impairment, and these persons

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[14] Paul J. Christo, *Symposium: Opioid Controversies: The Crisis – Causes and Solutions: Opioids May be Appropriate for Chronic Pain*, 48 J.L. MED. & ETHICS 241, 242 (2020).
[15] CENTERS FOR DISEASE CONTROL AND PREVENTION, *supra* note 3, at 1.
[16] Christo, *supra* note 14, at 244.
[17] *Id.*
[18] CENTERS FOR DISEASE CONTROL AND PREVENTION, *supra* note 3, at 2.
[19] *Id.*
[20] Christo, *supra* note 14, at 241.
[21] Cady, *supra* note 7, at 471.

will be at risk for inadequate pain treatment.[22] Over-reaction to the opioid crisis exacerbated the undertreatment of pain in these patient populations as well. Patients with sickle cell disease are often treated as drug seekers.[23]

There are also long-standing health disparities in the treatment of pain.[24] For example, Black, Hispanic and Asian patients receive fewer postpartum pain assessments compared to White patients; Black and Hispanic patients are less likely than White patients to receive analgesia for acute pain; Black patients are less likely to be referred to a pain specialist; and Black patients receive prescription opioids at lower dosages compared to White patients.[25] These disparities are further magnified for Black and Hispanic patients who live in socioeconomically disadvantaged neighborhoods.[26] People of all backgrounds use opioids, but opioid-involved deaths have affected demographic groups in different ways; racial and ethnic groups as well as other sociodemographic and economic characteristics have led to disparities.[27]

b. The Prescribing and Regulation of Prescription Opioids

The main agencies involved in the regulation of opioids and response to the opioid crisis are the Drug Enforcement Administration (DEA), the U.S. Food and Drug Administration (FDA), the U.S. Health and Human Services Office of Inspector General (HHS-OIG), and the Centers for Disease Control and Prevention (CDC).

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[22] CENTERS FOR DISEASE CONTROL AND PREVENTION, *supra* note 3, at 2.
[23] Nadia S Ruta & Samir K Ballas, *The Opioid Drug Epidemic and Sickle Cell Disease: Guilt by Association,* PAIN MED. 1793, 1793 (2016).
[24] *Id.*
[25] *Id.*
[26] *Id.*
[27] CONGRESSIONAL BUDGET OFFICE, *The Opioid Crisis and Recent Federal Policy Responses* 11 (2022).

The DEA enforces the controlled substances laws and regulations of the United States by using the justice system.[28] It is responsible for enforcing the Controlled Substance Act (CSA), which places all regulated substances into one of five schedules, "based upon the substance's medical use, potential for abuse, and safety or dependence liability."[29] Schedule I drugs have a high potential for abuse and no currently accepted medical use, and include heroin, marijuana, and peyote.[30] Opioids are classified as Schedule II drugs because of their high potential for abuse and the potential of severe psychological or physical dependence.[31] Schedule III drugs have a moderate to low potential for physical and psychological dependence and less abuse potential, and Schedule IV and V drugs have decreasing potential for abuse.[32] The CSA also provides that every person who dispenses or who proposes to dispense any controlled substance must register with the DEA via the Attorney General.[33]

The FDA protects the public by ensuring and regulating the safety, efficacy, and security of drugs.[34] In response to the opioid crisis, the FDA required class-wide safety labeling changes in 2016.[35] In 2018, the FDA approved the Opioid Analgesic Risk Evaluation and Mitigation Strategy

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[28] *Our Mission,* DRUG ENFORCEMENT ADMINISTRATION, https://www.dea.gov/who-we-are/about (last visited Apr. 16, 2024).
[29] *The Controlled Substances Act*, DRUG ENFORCEMENT ADMINISTRATION, https://www.dea.gov/drug-information/csa (last visited Apr. 16, 2024).
[30] *Drug Scheduling*, DRUG ENFORCEMENT ADMINISTRATION, https://www.dea.gov/drug-information/drug-scheduling (last visited Apr. 16, 2024).
[31] *Id.*
[32] *Id.*
[33] Food and Drugs, 21 U.S.C. § 822(a).
[34] *What We Do,* U.S. FOOD AND DRUG ADMINISTRATION (Nov. 21, 2023), https://www.fda.gov/about-fda/what-we-do.
[35] *Timeline of Selected FDA Activities and Significant Events Addressing Substance Use and Overdose Prevention*, U.S. FOOD AND DRUG ADMINISTRATION (Apr. 4, 2024), https://www.fda.gov/drugs/information-drug-class/timeline-selected-fda-activities-and-significant-events-addressing-substance-use-and-overdose#:~:text=On%20March%2022%2C%20FDA%20announced,to%20addiction%2C%20overdose%20and%20death.

(OA REMS) to "reduce the risk of abuse, misuse, addiction, overdose, and deaths due to prescription opioid analgesics."[36] It requires education be available to all health care providers involved in the management of patients with pain, including nurses and pharmacists.[37] OA REMS also requires all opioid analgesic companies to provide "education for health care providers who participate in the treatment and monitoring of pain" as well as information for health care providers who counsel patients about the risks of opioid analgesic use.[38] In recent years, the FDA approved a number of new opioids,[39] as well as new products for the treatment of opioid use disorder and the reversal of opioid overdoses.[40]

HHS-OIG works to fight fraud, waste, and abuse, focusing on federally funded programs, particularly Medicare and Medicaid.[41] It aims to advance "prevention, detection, and enforcement of fraud, waste, and abuse in HHS programs that intersect with the opioid epidemic."[42] Its efforts are in three areas: 1) identify opportunities to improve the efficiency and effectiveness of HHS programs; 2) identify and hold accountable those engaged in fraud; and 3) empower and collaborate with partners through data sharding and education.[43]

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[36] *Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS)*, U.S. FOOD AND DRUG ADMINISTRATION (Nov. 14, 2023), https://www.fda.gov/drugs/information-drug-class/opioid-analgesic-risk-evaluation-and-mitigation-strategy-rems.
[37] *Id.*
[38] *FDA Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain*, U.S. FOOD AND DRUG ADMINISTRATION (Sept. 2018), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Opioid_analgesic_2018_09_18_FDA_Blueprint.pdf
[39] CONGRESSIONAL BUDGET OFFICE, *supra* note 27, at 29.
[40] *Id.* at 30.
[41] *About OIG*, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF THE INSPECTOR GENERAL, https://oig.hhs.gov/about-oig/ (last visited Mar. 10, 2024).
[42] *Combating the Opioid Epidemic*, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF THE INSPECTOR GENERAL (Jan. 10, 2024), https://oig.hhs.gov/reports-and-publications/featured-topics/opioids/#:~:text=OIG's%20actions%20in%20these%20areas,those%20in%20need%20of%20services.
[43] *Id.*

The CDC aims to "save lives and prevent opioid misuse, opioid use disorder, and overdose by equipping providers with the knowledge, tools, and guidance they need."[44] With this mission, it developed the *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016* which was updated by the *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2022*.[45]

Prescribers are the "gatekeepers" to all prescription medications, including opioids.[46] They face the obstacle of wanting to treat and help patients in pain, versus the fear of discipline for improperly prescribing medications.[47] Studies show that there is typically little to no education or training in medical school on proper pain management, even though general practitioners are able to prescribe pain medications, in addition to specialists, who had mandatory training in opioid prescribing and substance abuse prevention and detection.[48] OA REMS requires education be available to all health care providers involved in the management of patients with pain, but it does not require providers to take this education.[49]

On June 27, 2023, Section 1263 of the Consolidated Appropriations Act of 2023, also known as the Medication Access and Training Expansion (MATE) Act, required new and renewing

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[44] *Implementing the CDC Guideline for Prescribing Opioids for Chronic Pain*, CENTERS FOR DISEASE CONTROL AND PREVENTION (Nov. 3, 2022), https://www.cdc.gov/opioids/healthcare-admins/qi-cc.html#:~:text=The%20CDC%20aims%20to%20save,tools%2C%20and%20guidance%20they%20need.

[45] *Id.*

[46] Michael C. Barnes & Gretchen Arndt, *The Best of Both Worlds: Applying Federal Commerce and State Police Powers to Reduce Prescription Drug Abuse,* 16 J. HEALTH CARE L. & POL'Y 271, 274 (2013).

[47] *Id.* at 273.

[48] *Id.* at 276-77.

[49] *Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS)*, U.S. FOOD AND DRUG ADMINISTRATION (Nov. 14, 2023), https://www.fda.gov/drugs/information-drug-class/opioid-analgesic-risk-evaluation-and-mitigation-strategy-rems.

DEA registrants to have completed "at least 8 hours of training on opioid or other substance use disorders, as well as the safe pharmacological management of dental pain."[50] Besides this one time requirement, there is no requirement for more training under subsequent DEA registration renewals.[51]

As with most medical practices, opioid prescribing differs state by state. The CDC reported that between 2006 and 2017, the annual prescribing rate per 100 people in the country decreased from 72.4 to 58.5 for all opioids.[52] In 2017, the states with the highest opioid prescribing rates included Alabama, Arkansas, Tennessee, Mississippi, and Louisiana.[53] States with the lowest opioid prescribing rates included the District of Columbia, Hawaii, New York, California, and Massachusetts.[54] Opioid prescribing rates ranged from 28.5 prescriptions per 100 persons in the District of Columbia to 107 prescriptions per 100 persons in Alabama.[55] The Centers for Medicare & Medicaid Services (CMS) tracks Medicaid and Medicare Part D opioid prescribing rates per state.[56,57]

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[50] *Id.*
[51] *MATE Training Letter*, DRUG ENFORCEMENT ADMINISTRATION (Mar. 27, 2023), https://www.deadiversion.usdoj.gov/pubs/docs/MATE_Training_Letter_Final.pdf.
[52] 2018 Annual Surveillance Report of Drug-Related Risks and Outcomes, CENTERS FOR DISEASE CONTROL AND PREVENTION 11 (Aug. 31, 2018), https://www.cdc.gov/drugoverdose/pdf/pubs/2018-cdc-drug-surveillance-report.pdf.
[53] *Id.*
[54] *Id.*
[55] *Id.*
[56] CENTERS FOR MEDICARE & MEDICAID SERVICES, *Medicaid Opioid Prescribing Rates – by Geography* (2021), https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-opioid-prescribing-rates/medicaid-opioid-prescribing-rates-by-geography.
[57] CENTERS FOR MEDICARE & MEDICAID SERVICES, *Medicare Part D Opioid Prescribing Rates – by Geography* (2021), https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-opioid-prescribing-rates/medicare-part-d-opioid-prescribing-rates-by-geography.

As of 2023, 49 of 50 states, the District of Columbia, and Guam have prescription drug monitoring programs (PDMPs),[58] but only some states require providers to check a state PDMP before prescribing certain controlled substances.[59] A PDMP "is an electronic database that tracks the controlled substance prescriptions in a state."[60] Health care providers can see patients' prescribing histories which can inform their prescribing decisions.[61] Pharmacists also use PDMPs when dispensing controlled substances to patients by submitting the prescription data into the state PDMP.[62] However, the allotted time to enter this data ranges by state from "real-time" to monthly, risking PDMP users not having the most recent prescription data.[63] PDMPs can also be utilized as a public health tool by state health departments, and be accessed by state insurance programs, healthcare licensure boards, and law enforcement to keep the public and society safe.[64] PDMPs can be used to identify patients that are high risk or to identify inappropriate prescribing trends.[65] Studies have shown that PDMPs are best used when used as a clinical tool rather than a law enforcement tool, to placate provider fears and mitigate a chilling effect.[66]

Despite the use and necessity of prescription opioids for pain, there are serious risks of addiction, abuse, and overdose while using prescription opioids.[67] There are also numerous

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[58] Ryan S. D'Souza et al., *Prescription Drug Monitoring Program* (2023), https://www.ncbi.nlm.nih.gov/books/NBK532299/.
[59] *PDMPS: What States Need to Know*, CENTERS FOR DISEASE CONTROL AND PREVENTION (2021), https://www.cdc.gov/drugoverdose/pdmp/index.html.
[60] *Id.*
[61] *Id.*
[62] *Id.*
[63] *Id.*
[64] *Id.*
[65] *Id.*
[66] Kelly K. Dineen, *Addressing Prescription Opioid Abuse Concerns in Context: Synchronizing Policy Solutions to Multiple Complex Public Health Problems*, 40 LAW & PSYCHOL. REV.1, 60 (2016).
[67] *Prescription Opioids*, CENTERS FOR DISEASE CONTROL AND PREVENTION (Aug. 29, 2017), https://www.cdc.gov/opioids/basics/prescribed.html.

possible side effects, such as depression, nausea, vomiting, constipation, physical dependence, tolerance, low levels of testosterone, and confusion.[68] In 2014, the FDA required safety labeling changes for extended-release and long-acting opioids to include a boxed warning on "risks of addiction, abuse, and misuse, which can lead to overdose and death" which was then added to immediate-release opioids in 2016.[69] Required safety labeling also includes the increased risk for neonatal abstinence syndrome in pregnant patients.[70] Prescription opioids also have the potential to be diverted and nonmedically used by persons to whom they were not prescribed.[71] Drug diversion includes all instances when prescription medicines are obtained or used illegally.[72] In 2016, about 11.5 million people in the United States reported misuse of prescription pain relievers.[73]

c. The Opioid Crisis

Since the mid-1990s, the United States has been facing an opioid crisis, which has significantly affected public health and the nation's economic and social outcomes.[74] More than 500,000 opioid-involved deaths have occurred since 2000.[75] The first wave of the opioid crisis began in 1996 after the American Pain Society campaigned to characterize pain as the "fifth vital sign" to encourage healthcare providers to treat underassessed and undertreated chronic pain with

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[68] *Id.*
[69] CENTERS FOR DISEASE CONTROL AND PREVENTION, *supra* note 3, at 2.
[70] *Id.* at 2-3.
[71] *Id.* at 3.
[72] *Drug Diversion,* CENTERS FOR DISEASE CONTROL AND PREVENTION (Nov. 26, 2019), https://www.cdc.gov/injectionsafety/drugdiversion/index.html#:~:text=When%20prescription%20medicines%20are%20obtained,use%20put%20patients%20at%20risk.
[73] CENTERS FOR DISEASE CONTROL AND PREVENTION, s*upra* note 52, at 14.
[74] CONGRESSIONAL BUDGET OFFICE, *supra* note 27, at 6.
[75] *Id.*

prescription opioids.[76,77] In the same year, opioids were increasingly being prescribed due to aggressive marketing, especially with OxyContin by Purdue Pharma.[78,79] At this time, states also passed laws to encourage appropriate pain management.[80]

The following year, two other organizations advocated for the use of opioids to treat chronic, non-cancer-related pain.[81] Physician and hospital guidelines followed the Federation of State Medical Boards 1998 guideline, now revised, which recommended opioids for chronic, non-cancer-related pain and discouraged disciplinary action for physicians who prescribed opioids.[82] Prescription opioids were increasingly being prescribed for chronic conditions despite no evidence about their long-term effectiveness, and these prescription opioids were increasingly being used non-medically and being distributed through illegal means.[83] The second and third waves of the opioid crisis began in 2010 and 2013 and involved the use of illicitly manufactured heroin and fentanyl substances, respectively.[84]

The three main factors seen as contributing to the opioid crisis include increased prescribing of opioids, increased demand for opioids for self-medication, and the greater consumption of opioids from illegal sources.[85] There were also incentives that affected the way

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[76] *Id.* at 14-15.
[77] Autumn Seib, *Note: Too Old to Jump Through Hoops: How the Opioid Epidemic Has Impacted Elderly Persons Living in Nursing Homes*, 8 IND. J.L. & SOC. EQUALITY 379, 381 (2020).
[78] CONGRESSIONAL BUDGET OFFICE, *supra* note 27, at 8.
[79] Edward Helmore, *Enduring pain: how a 1996 opioid policy change had long-lasting effects*, THE GUARDIAN, (Mar. 30, 2018), https://www.theguardian.com/us-news/2018/mar/30/enduring-pain-how-a-1996-opioid-policy-change-had-long-lasting-effects#:~:text=Twenty%2Dtwo%20years%20ago,pressure%2C%20heart%20rate%20and%20breathing.
[80] Dineen, *supra* note 66, at 55.
[81] *Id.*
[82] *Id.*
[83] CONGRESSIONAL BUDGET OFFICE, *supra* note 27, at 8.
[84] *Id.*
[85] *Id.* at 14.

providers were assessed and reimbursed, as well as incentives that affected the way opioids were prescribed such as the reduction of "hassle factors" for prescription refills and restrictions placed on nonopioid alternatives to pain management.[86]

Between 2016 and 2018, Congress enacted three federal laws to address the opioid crisis: The Comprehensive Addiction and Recovery Act (CARA) of 2016, The 21st Century Cures Act, and The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act.[87] CARA and the SUPPORT for Patients and Communities Act aimed to lessen the availability of legal and illegal opioids,[88]and all three laws authorized grants to minimize the harmful effects of opioid use disorder and to reduce the demand and supply of opioids.[89]

President Obama signed CARA into law to address the opioid epidemic by authorizing action from key players as well as millions of dollars each year towards prevention, recovery, law enforcement, criminal justice reform, and overdose reversal.[90,91] It authorized over $181 million each year to fight the opioid epidemic and implemented programs and services across the country to address addiction recovery.[92]

The 21st Century Cures Act provided funding to National Institutes of Health (NIH) Innovation Projects, FDA activities, and HHS-OIG grants to states.[93] It gave NIH the flexibility and resources related to clinical trials, scientific conferences for in-person collaboration for

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[86] *Id.* at 15.
[87] *Id.* at 3.
[88] *Id.*
[89] *Id.* at 25.
[90] Comprehensive Addiction and Recovery Act of 2016, S. 524, 114th Cong. (2016).
[91] NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE, *Measuring Success in Substance Use Grant Programs: Outcomes and Metrics for Improvement* 10-11 (2020).
[92] *Id.*
[93] 21st Century Cures Act, H.R. 34, 114th Cong. (2016).

scientific breakthroughs, and multiyear funding to four scientific initiatives.[94] In addition, it gave the FDA $500 million to accelerate medical product development and bring new innovations and advances to patients.[95]

The SUPPORT for Patients and Communities Act required CMS to reduce the demand for opioids by facilitating greater access to and use of treatment among people with opioid use disorder who are enrolled in Medicaid and Medicare.[96] State Medicaid programs are required to "cover all drugs and biologicals approved or licensed by the FDA to treat opioid use disorders," as well as "related counseling services and behavioral therapies."[97]

In response to the COVID-19 pandemic, Medicaid emergency authorities expanded eligibility and access to services, the government eased restrictions on methadone dispensing by allowing greater take-home doses, and the use of telemedicine to treat patients with opioid use disorder expanded.[98] The American Rescue Plan Act of 2021 appropriated $1.5 billion for grants to prevent and treat substance use disorder, and $3.4 billion for CARA, the 21st Century Cures Act, and the SUPPORT for Patients and Communities Act.[99]

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[94] *The 21st Century Cures Act*, NATIONAL INSTITUTES OF HEALTH, https://www.nih.gov/research-training/medical-research-initiatives/cures (last visited Mar. 9, 2024).
[95] *21st Century Cures Act*, U.S. FOOD AND DRUG ADMINISTRATION (Jan. 31, 2020), https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/21st-century-cures-act.
[96] CONGRESSIONAL BUDGET OFFICE, *supra* note 27, at 21.
[97] *CMS Issues Guidance about Expanded Medicaid Coverage for Treatment of Opioid Use Disorders*, U.S. CENTERS FOR MEDICARE & MEDICAID SERVICES (Dec. 20, 2020), https://www.cms.gov/newsroom/news-alert/cms-issues-guidance-about-expanded-medicaid-coverage-treatment-opioid-use-disorders.
[98] CONGRESSIONAL BUDGET OFFICE, *supra* note 27, at 32.
[99] *Id.*

III. The CDC Guidelines

a. The 2016 CDC Guideline

In 2016, the CDC recognized the need for a public and national guideline on pain management to improve appropriate opioid prescribing, while minimizing opioid-related risks.[100] The CDC released the *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016* to guide opioid prescribing "for patients over 18 years of age with chronic pain outside of active cancer treatment, palliative care, and end-of-life care.[101] The purpose of the 2016 CDC Guideline was to "improve communication between clinicians and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder, overdose, and death."[102] It was created using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) framework with the best-available evidence at the time, along with input from experts and the public, and it was reviewed by the Board of Scientific Counselors of the National Center for Injury Prevention and Control.[103]

The 2016 CDC Guideline sought to "1) ensure that clinicians and patients considered safer and more effective pain treatment ; 2) improve patient outcomes, such as reduced pain and improved function; and 3) reduce the number of persons who developed opioid use disorder, experienced overdose, or experienced other prescription opioid-related adverse events."[104]

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[100] *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, CENTERS FOR DISEASE CONTROL AND PREVENTION 65 MORBIDITY AND MORTALITY WEEKLY REPORT 3 (2016), https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf.
[101] *Id.* at 1.
[102] *Id.*
[103] *Id.*
[104] *Id.*

The 2016 CDC Guideline included twelve recommendations in three categories: 1) Determining When to Initiate or Continue Opioids for Chronic Pain; 2) Opioid Selection, Dosage, Duration, Follow-up, and Discontinuation; and 3) Assessing Risk and Addressing Harms of Opioid Use.[105] It prompted physicians to taper patient dosages or stop opioid treatment altogether.[106] A 2019 study found an increase in the rates of tapering and rapid tapering among patients with long-term opioid prescriptions, which coincided with the 2016 CDC Guideline release.[107] The 2016 CDC Guideline was only released as recommendations, but states and regulatory bodies made it the law, giving these recommendations "the force of legal mandates."[108]

Recommendation 5 of the 2016 CDC Guideline stated that clinicians should caution increasing opioid dosages equal to or greater than 50 morphine milligram equivalents (MME) per day.[109] It also stated that clinicians should abide by a recommended upper dose threshold and "avoid increasing opioid dosages to equal to or greater than 90 MME per day" or be able to justify their decision based on an individualized assessment.[110]

Recommendation 9 of the 2016 CDC Guideline stated that clinicians should use state PDMPs to review patient history of controlled substance prescriptions.[111] It noted that PDMP data is particularly helpful when a medical history is not available, either because a patient is from out-of-state or when patients transition to a new clinician.[112] Experts agreed that PDMPs are useful

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[105] *Id.*
[106] *Id.*
[107] Jason E. Goldstick et al., *Changes in Initial Opioid Prescribing Practices After the 2016 Release of the CDC Guideline for Prescribing Opioids for Chronic Pain*, JAMA NETWORK OPEN 2 (2021).
[108] Kelly K. Dineen, *Definitions Matter: A Taxonomy of Inappropriate Prescribing to Shape Effective Opioid Policy and Reduce Patient Harm*, 67 U. KAN. L. REV. 961, 962 (2019).
[109] CENTERS FOR DISEASE CONTROL AND PREVENTION, *supra* note 100, at 23.
[110] *Id.*
[111] *Id.* at 29.
[112] *Id.*

tools and should be consulted when a patient is starting opioid therapy and periodically during long-term therapy, but they disagreed on how frequently clinicians should check.[113]

The 2016 CDC Guideline led to results that were "inconsistent with a central tenant of the guideline: that the recommendations are voluntary and intended to be flexible to support, not supplant, individualized, patient-centered care."[114] Some prescribers went beyond the clinical recommendations and misapplied the 2016 CDC Guideline to patient populations not covered in the Guideline, implemented rapid opioid tapers and abrupt discontinuation without collaboration with patients, and followed rigid application of opioid dosage thresholds, duration limits by insurers and pharmacies, which led to patient dismissal and abandonment.[115] These actions "contributed to patient harm, including untreated and undertreated pain, serious withdrawal symptoms, worsening pain outcomes, psychological distress, overdose, and suicidal ideation and behavior."[116]

The misapplication of the 2016 CDC Guideline led to misconstruction by providers, lawmakers, and law enforcement throughout the country, leading to many states adopting the non-prescriptive daily dosage recommendations as black letter law.[117] The American Medical Association reported that payers applied the 2016 CDC Guideline in ways that denied coverage for opioids and required extensive prior authorizations for patients with non-cancer pain conditions.[118] Even though the Guideline was released only for physicians, regulators and health

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[113] *Id.*
[114] CENTERS FOR DISEASE CONTROL AND PREVENTION, *supra* note 3, at 3.
[115] *Id.*
[116] *Id.* at 3-4.
[117] Dineen, *supra* note 108, at 962.
[118] Christo, *supra* note 14, at 243.

care organizations reduced the opioid supply without an expansion of other resources of pain care, which led to some patients turning to the illicit opioid market.[119]

b. The 2022 CDC Guideline

In 2022, the CDC released its updated *CDC Clinical Practice Guideline for Prescribing Opioids for Pain – United States, 2022*. The CDC released the updated guideline because of new evidence on the benefits and risks of prescription opioids for pain, comparisons with nonopioids, dosing strategies, opioid dose-dependent effects, risk mitigation strategies, and opioid tapering and discontinuation.[120] This evidence included studies on misapplication of the 2016 CDC Guideline,

> benefits and risks of different tapering strategies and rapid tapering associated with patient harm, challenges in patient access to opioids, patient abandonment and abrupt discontinuation of opioids, a seminal randomized clinical trial comparing prescription opioids to nonopioid medications on long-term pain outcomes, the association of characteristics of initial opioid prescriptions with subsequent likelihood for long-term opioid use, and the small proportion of opioids used by patients compared with the amount prescribed to them for postoperative pain.[121]

The updated guideline recognized that pain management requires trust between patients and clinicians, and urges clinicians to "consider the full range of pharmacologic and nonpharmacologic treatment for pain care, and that health systems, payers, and governmental programs and entities make the full spectrum of evidence-based treatments accessible to patients with pain and their treating clinicians."[122] It includes twelve recommendations in four areas: 1) Determining Whether or Not to Initiate Opioids for Pain; 2) Selecting Opioids and Determining Opioid Dosages; 3) Deciding Duration of Initial Opioid Prescription and Conducting Follow-Up;

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[119] *Id.*
[120] CENTERS FOR DISEASE CONTROL AND PREVENTION, *supra* note 3, at 4.
[121] *Id.* at 2.
[122] *Id.*

and 4) Assessing Risk and Addressing Potential Harms of Opioid Use.[123] The 2022 CDC Guideline was developed using the same GRADE framework as the 2016 CDC Guideline.[124]

The 2022 CDC Guideline states that the scope of the updated guideline is expanded beyond primary care physicians.[125] It recommends that opioids should be prescribed for the lowest effective dose and for the shortest expected duration for acute pain.[126] Tapering is recommended when opioids are discontinued after being used continuously for more than a few days.[127] It advises clinicians to avoid continuing opioids for patients with subacute pain unless there is a careful reassessment of treatment goals, benefits, and risks to prevent unintentional initiation of long-term opioid therapy.[128] It aims to delineate recommendations for patients considered for initial opioid therapy versus patients who have been receiving opioids for ongoing pain management.[129]

As per Recommendation 4 of the 2022 CDC Guideline, the CDC no longer cautions or recommends threshold MME per day.[130] It states clinicians should "pause" and reassess benefits and risks when increasing total opioid dosages equal to or greater than 50 MME per day, and still use caution when increasing to 90 MME or more.[131] It states once again that this recommendation is "not intended to be used as an inflexible, rigid standard of care" and instead "[is] intended to be guideposts to help inform clinician-patient decision-making."[132]

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[123] *Id.*
[124] *Id.* at 10.
[125] *Id.* at 8.
[126] Deborah Dowel et al., *Prescribing Opioids for Pain – The New CDC Clinical Practice Guideline*, N ENGL J MED (Nov. 3, 2022), https://www.nejm.org/doi/full/10.1056/NEJMp2211040.
[127] *Id.*
[128] *Id.*
[129] CENTERS FOR DISEASE CONTROL AND PREVENTION, *supra* note 3, at 4.
[130] *Id.* at 30.
[131] *Id.* at 31.
[132] *Id.* at 30.

As per Recommendation 9, the CDC now recommends clinicians review PDMP data at least every 3 months during long-term opioid therapy.[133]

Unlike the 2016 CDC Guideline, the 2022 CDC Guideline outlines the benefits and risks of nonopioid pain treatments.[134] A new recommendation outlines how clinicians can work with patients on opioid treatment to determine whether and how to taper these opioids.[135] New guidance advises clinicians to carefully weigh the benefits and risks of tapering opioids along with the benefits and risks of continuing opioids, and emphasizes opioids should not be discontinued abruptly or reduced rapidly.[136]

Despite the improvements in the 2022 CDC Guideline, the health care industry and health care providers still have questions and issues with the updated version. Some concerns include inappropriate emphasis on risk, emphasis on nonpharmacologic therapies, maximum thresholds, and the failure to consider opioid metabolism.[137] The 2022 CDC Guideline is criticized as "hav[ing] over-generalized or misinterpreted from very weak medical evidence."[138] The references in the 2022 CDC Guideline reveal that benefits from non-drug therapies are usually temporary and very limited in scope.[139] In addition, even though the Guideline recommends the usage of other medications such as non-steroidal anti-inflammatory drugs (NSAIDs) like ibuprofen, these medications have other safety concerns that could render them contraindicated in patients with severe pain.[140] The American Medical Association even recommended "the CDC . . . remove all

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[133] *Id.* at 48
[134] Dowel, *supra* note 126.
[135] *Id.*
[136] *Id.*
[137] Richard A Lawhren, EUROPEAN SOCIETY OF MEDICINE, *US Opioid Guidelines 2022 – More and Less Than Meets the Eye* 5-11 (Aug. 31, 2023).
[138] *Id.* at 11.
[139] *Id.* at 8.
[140] *Id.*

vestiges of inflexible numeric thresholds based on the 2016 guideline . . . and should have a disclaimer on every page that the CDC's recommendation should not be used or interpreted as an inflexible law or policy."[141] Lastly, genetic opioid metabolism leads to a range of minimum effective doses and sensitivity to side effects amongst patients, emphasizing the necessity for individualized patient care and treatment plans.[142]

c. Nonopioid Treatment for Chronic Pain

It is important to note that nonpharmacologic and nonopioid therapies can be implemented for acute, subacute, and even chronic pain.[143] It is recommended that not only clinicians consider the full range of pharmacologic and nonpharmacologic treatment for pain therapy, but also that health systems, payers, and government programs and entities make these treatments accessible to patients and their treating clinicians.[144] Recommendation 2 of the 2022 CDC Guideline states that "nonopioid therapies are preferred for subacute and chronic pain."[145] There are numerous noninvasive nonpharmacologic approaches that can help manage chronic pain, such as exercise or exercise therapy, mind-body practices, psychological therapy, and spinal manipulation.[146] There are other medications that can also be used in conjunction with nonpharmacologic approaches such as NSAIDs, anti-depressants and selected anticonvulsants for neuropathic pain.[147]

Historically, the full range of therapeutic options has been inaccessible to patients because of numerous factors, including inadequate clinician education, training, and guidance; unconscious

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[141] *Id.*
[142] *Id.* at 11.
[143] *Nonopioid Therapies for Pain Management*, CENTERS FOR DISEASE CONTROL AND PREVENTION (June 14, 2023), https://www.cdc.gov/opioids/healthcare-professionals/prescribing/nonopioid-pain-therapies.html.
[144] CENTERS FOR DISEASE CONTROL AND PREVENTION, *supra* note 3, at 2.
[145] *Id*. at 21.
[146] *Id.* at 21-22.
[147] *Id.* at 22.

bias; a shortage of pain management specialists; insufficient access to treatment modalities, insurance coverage and reimbursement policies; and lack of clarity about the evidence supporting different treatments.[148] While the 2022 CDC Guideline still encourages nonopioid therapies when possible and emphasizes alternative, nonopioid treatments, these alternatives to opioids can be effective for some patients, but not for everyone.[149]

IV. OPIOID PRESCRIBING IN THE UNITED STATES

The Veterans Health Administration and the Joint Commission recognize pain as the fifth vital sign.[150] However, in practice, this has exposed an inadequate approach in the pain examination and management of patients in pain.[151] Physicians who treat patients with chronic pain must spend time assessing "pain interference, mood, and social and psychological factors."[152]

Physicians take the Hippocratic Oath, which encompasses the ethical duty to do no harm, and obligates them to balance the twin duties of action and inaction in medicine.[153] This translated into the opioid crisis, having physicians justify opposing positions on opioid prescribing.[154] Today, this ethical duty is often used as a rationale for discouraging doctors from prescribing opioids.[155] It is true that physicians are put in a very tough spot when having to decide to take action and prescribe opioids, or to take inaction and not prescribe opioids. There is a sense of uncertainty, with the idea of not knowing what will happen if they do or do not prescribe.[156] If they do not

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[148] *Id.* at 2.
[149] Stodola, *supra* note 50, at 820-21.
[150] Natalie E. Morone & Debra K. Weiner, *Pain as the Fifth Vital Sign: Exposing the Vital Need for Pain Education*, 35 ELSEVIER HS JOURNALS 1728 (2013).
[151] *Id.* at 1729.
[152] *Id.*
[153] Kate M. Nicholson, *Article: Opioid Prescribing and the Ethical Duty to Do No Harm*, 46 AM. J. L. AND MED. 297, 301 (2020).
[154] *Id.* at 298.
[155] *Id.*
[156] *Id.* at 301.

prescribe, then the patient can be harmed, while if they do prescribe, this can harm third parties and society as a whole.[157] But pain is a persistent, present condition, and clinicians should make decisions in favor of the patient; the presence of pain should "reduce" the uncertainty about the need for action.[158]

Prescribers should be concerned about the patient in front of them when prescribing opioids; they have an obligation to their patients and thus need to make an individualized assessment for each patient.[159] They should not have to be concerned about the harm opioids have caused to society or fear making decisions that may lead to lawsuits and jail time.[160]

Pharmacists are medication experts who can educate patients and physicians about safe opioid practices.[161] They are on the "front lines" because they are the health care professionals who dispense opioid pain medications and provide medication-related services.[162] Research has shown that an inter-professional team-based approach for chronic disease management can enhance clinical outcomes.[163]

Many elderly persons in nursing homes depend on opioids for chronic pain relief.[164] About 45% to 80% of nursing home residents have persistent pain.[165] A study reported nearly 6.4% of 1.4

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[157] *Id.*
[158] *Id.* at 302.
[159] Kate M. Nicholson & Deborah Hellman, *ARTICLE: Opioid Prescribing and the Ethnical Duty to Do No Harm,* 46 AM. J. L. AND MED. 297, 304 (2020).
[160] *Id.*
[161] Lucas Kosobuski et al., *The Role of the Pharmacist in Combating The Opioid Crisis: An Update,* SUBST ABUSE REHABIL (2022).
[162] Pharmacists: On the Front Lines, CENTERS FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/drugoverdose/pdf/pharmacists_brochure-a.pdf (last visited Apr. 16, 2024).
[163] Nyasha Gondora et. al, *The role of pharmacists in opioid stewardship: A scoping review*, RESEARCH IN SOCIAL AND ADMINISTRATIVE PHARMACY (MAY 2022), https://www.sciencedirect.com/science/article/pii/S1551741121002357.
[164] Seib, *supra* note 77, at 380.
[165] *Id.*

million nursing home residents experience persistent pain with no pharmacologic pain management, and over 30% of residents received no scheduled analgesics.[166] The main way to determine pain is self-reporting, which leads to many cognitively impaired elders' pain left underassessed and undertreated.[167] The prescribing laws enacted due to the 2016 CDC Guideline decreased the quality of life of nursing home residents "forced to endure unnecessary pain."[168] The prescribing practices put into place because of the opioid epidemic greatly affected these patients because of "require[ed] non-opiate therapy first, mandat[ed] decreased dosages, and forc[ed] frequent return assessments."[169]

Elderly patients in nursing homes with chronic pain can experience a decrease in quality of life because of altered physical and psychological health.[170] Untreated chronic pain can lead patients to retreat from their regular activities, isolate themselves, and develop depression.[171] Patients who are cognitively impaired are a particularly vulnerable population in these homes.[172] The 2016 CDC Guideline made nursing home residents "jump through hoops," hindered their quality of life, and failed to recognize how these patients are more susceptible.[173]

V. REMOVING BARRIERS TO EVIDENCE-BASED CARE

Policy makers are humans and therefore, prone to the same decisional errors as regular citizens.[174] The 2022 Guideline is unlikely to shift the standard back to more care about patients because the United States needs legislative action, not just course-corrective measures by the

[166] *Id.*
[167] *Id.*
[168] *Id.* at 382.
[169] *Id.* at 381-82.
[170] *Id.* at 397.
[171] *Id.* at 398.
[172] *Id.*
[173] *Id.* at 400.
[174] Dineen, *supra* note 108, at 981.

CDC.[175] Despite the release of the updated 2022 CDC Guideline, the 2016 CDC Guideline was not rescinded, allowing states and entities to still rely on it.[176]

Provider education is necessary to help solve this problem, starting at medical school and continuing in practice. Only four of the 104 medical schools in the United States reported having mandatory pain management courses.[177] States could also require opioid prescribers complete continuing medical education to maintain their ability of prescribing opioids.[178]

A uniform fifty-state PDMP would allow doctors to adequately treat chronic pain patients with their best judgment while also combating the opioid epidemic.[179] Studies show that states who mandate PDMP use have less prescription opioid poisonings.[180] PDMP software uses algorithmic logic and machine learning to calculate patient-specific risk scores, which are numerical values that represent the overall level of risk associated with prescribing the specific patient a controlled substance.[181] The term "risk" in this context includes the potential for "drug misuse, abuse, diversion, addiction, and overdose."[182] The information imputed may include the patient's name, age, gender, prescription history, payment method, distance travelled, and criminal histories.[183]

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[175] Robert Stodola, *Note: Public Health Law Punishing Pain: Why Treating Chronic Pain With Opioids Needs A New Standard of Care*, 45 U. ARK. LITTLE ROCK L. REV. 783, 789 (2023).
[176] Mark A. Rothstein & Julia Irzyk, *The CDC should rescind, not 'update,' its 2016 opioid guideline,* THE HILL, (Feb. 18, 2022), https://thehill.com/opinion/healthcare/594726-the-cdc-should-rescind-not-update-its-2016-opioid-guideline/.
[177] Tori Collins, *Article: Moving Away from Masking Pain: A Need for Modernization in Pain Management*, 44 MITCHELL HAMLINE L.J. PUB. POL'Y & PRAC. 42, 53 (2023).
[178] *Id.* at 74.
[179] Cady, *supra* note 7, at 467.
[180] Lucas Kosobuski et al., *supra* note 161.
[181] Jennifer D. Oliva, *Dosing Discrimination: Regulating PDMP Risk Scores,* 110 CALIF. L. REV. 47, 81-82 (2022).
[182] *Id.* at 82.
[183] *Id.* at 83-84.

There is an argument that clinician reliance on PDMP risk scores "reinforces the stigma and distrust attached to chronic pain patients.[184] Research has indicated that mandatory usage of PDMPs influence clinical behavior and could deter opioid prescribing, lead physicians to refer patients elsewhere, or substitute opioid prescriptions to nonmonitored drugs.[185] This could cause legitimately suffering patients to go to the illegal market, or become more susceptible to suicide.[186]

VI. CONCLUSION

There is a need for a solution that addresses opioid substance abuse but provides necessary help and relief to patients with chronic pain.[187] The opioid crisis in the United States led the CDC to create the 2016 CDC Guideline. The 2016 CDC Guideline resulted in states implementing strict protocols, and prescribers misapplying the guideline and undertreating patients with chronic pain.[188] The CDC realized these obstacles and barriers to pain management for these patients and released the updated CDC 2022 Guideline.[189] The 2022 CDC Guideline is a step in the right decision, because it emphasizes individualized decision-making process for each patient and eliminates the previous daily dosage threshold imposed by the previous guideline.

However, the 2022 CDC Guideline is still too broad, and despite increasing the number of pain patients being better or adequately treated, there is still room for improvement. There are also some issues with the 2022 CDC Guideline, as noted above. Some possible solutions to these deficiencies include state-mandated continuing medical education for opioid prescribers, a uniform fifty-state Prescription Drug Monitoring Program, and updated CDC Guidelines.

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[184] *Id.* at 90.
[185] *Id.* at 78-79.
[186] *Id.* at 80.
[187] *Id.*
[188] Dineen, *supra* note 108, at 962.
[189] CENTERS FOR DISEASE CONTROL AND PREVENTION, *supra* note 3, at 1.