

MANAGING PAIN, MANAGING CARE:

THE INCOMPATIBILITY OF OPIOID EPIDEMIC DIRECTIVES WITH PAIN MANAGEMENT IN PALLIATIVE CARE, AND THE UNINTENDED CONSEQUENCES ON PALLIATIVE CARE¹

INTRODUCTION

The policy objectives of the United States (“U.S.”) federal government’s response to the opioid epidemic were shaped by the understanding of pain management in relation to chronic pain. This paper aims to explore how the lens of pain management has shaped attitudes towards opioid use in the medical community, and how this has affected the use of opioids in the palliative care context. Specifically, this paper will examine how pain management (in the chronic pain management context) and palliative care diverge in their goals and methods. This paper posits the regulation and medical practices that came about in response to concerns about the opioid epidemic were based primarily on concerns of opioid use within pain management. This understanding, informed by pain management principles, led to policy directives directed at the opioid epidemic which resulted in a fundamental conflict with the use of opioids in palliative care.

In Part I, this paper will begin with a discussion of pain, pain management, and the use of opioids in pain management, specifically in the context of chronic pain. Next, Part II will discuss what palliative care is, how opioids have been used in palliative care, and how the objectives of care in this arena differ from using opioids in other contexts. Part III will detail the emergence of the opioid epidemic in the U.S., the legislation that followed, and the objectives behind such legislation. Part IV will cover a fundamental disconnect behind applying the opioid policy directives to care in the palliative context, causing unintended effects on the use of opioids in the palliative care context.

¹ [Identifying Information Redacted].

I. PAIN MANAGEMENT

Pain is part of the human condition; at some point, for short or long periods of time, we all experience pain and suffer its consequences. While pain can serve as a warning to protect us from further harm, it also can contribute to severe and even relentless suffering, surpassing its underlying cause to become a disease in its own domains and dimensions. We all may share common accountings of pain, but in reality, our experiences with pain are deeply personal, filtered through the lens of our unique biology, the society and community in which we were born and live, the personalities and styles of coping we have developed, and the manner in which our life journey has been enjoined with health and disease.²

This section will provide a brief overview of pain management and the role that opioids have had in the management of pain. Essential to understanding the treatment of pain is a fundamental understanding of what pain is, why pain is such a complex medical issue to treat and understand, and how opioids factor into the pain management process.

While a deeper discussion of pain management and the direct connection to opioid use will be discussed in Part IV of this paper, it is important to note the intersection of the two concepts as an introductory point. Opioid use, and thus concerns over opioid misuse and abuse, are inextricably tied to pain management—specifically the practices of pain management that included the use of opioid treatment. Pain management and opioid use have each influenced the development of the other, and an understanding of one is incomplete without understanding the other. In other words, “[t]he ongoing opioid crisis lies at the intersection of two substantial public health challenges — reducing the burden of suffering from pain and containing the rising toll of the harms that can result from the

² INST. OF MEDICINE (IOM), RELIEVING PAIN IN AMERICA: A BLUEPRINT FOR TRANSFORMING PREVENTION, CARE, EDUCATION, AND RESEARCH, 2011, <http://www.ncbi.nlm.nih.gov/books/NBK91497> (last visited Apr. 20, 2019) [hereinafter RELIEVING PAIN IN AMERICA].

use of opioid medications.”³ Thus, this paper will begin by examining pain and pain management as the initial concerns which led to the opioid epidemic emerging in the way that it did.

As a preliminary matter, opioid and opioid use must be defined. Opioids are a class of drugs that interact with the opioid receptors on nerve cells in the body and brain.⁴ This class of drugs includes pain relievers available by prescription (such as Oxycodone, known by the brand name OxyContin, and hydrocodone, known as Vicodin), synthetic opioids (including fentanyl, a painkiller often manufactured illegally), and morphine, codeine, and heroin, among other drugs.⁵ According to the National Institute of Drug Abuse, “[o]pioid pain relievers are generally safe when taken for a short time and as prescribed by a doctor.”⁶ However, “because [opioid pain relivers] produce euphoria in addition to pain relief, they can be misused (taken in a different way or in a larger quantity than prescribed, or taken without a doctor’s prescription).”⁷ Regular use of opioids (including those prescribed by a doctor) can lead to opioid dependence, and misuse of opioid pain relievers or illegal opioid substances can lead to addiction, overdose incidents, and death.⁸

A. WHAT IS PAIN?

Pain, and the management of pain, have been constant themes in medical treatment for centuries.⁹ In 1994, the International Association for the Study of Pain produced the most widely used definition of pain in the clinic setting: pain is “[a]n unpleasant sensory and emotional experience associated with actual or potential tissue damage Pain is always subjective It is unquestionably

³ NAT. ACADEMIES OF SCI., ENG’G, AND MED., PAIN MANAGEMENT AND THE OPIOID EPIDEMIC: BALANCING SOCIETAL AND INDIVIDUAL BENEFITS AND RISKS OF PRESCRIPTION OPIOID USE 1, 2017 [hereinafter PAIN MANAGEMENT AND THE OPIOID EPIDEMIC].

⁴ Nat. Inst. on Drug Abuse (NIDA), *Opioids*, <https://www.drugabuse.gov/drugs-abuse/opioids#summary-of-the-issue> (last visited Mar. 26, 2019).

⁵ *Id.*

⁶ *Id.*

⁷ *Id.*

⁸ *Id.*

⁹ CHAPTER 62 THE LAW AND THE RELIEF OF PAIN: PAIN MANAGEMENT, *in* LEGAL MEDICINE BY AMERICAN COLLEGE OF LEGAL MEDICINE (2019) [hereinafter THE LAW AND THE RELIEF OF PAIN].

a sensation in a part or parts of the body, but it is also always unpleasant and therefore also an emotional experience.”¹⁰ Pain is thus “an unpleasant sensory and emotional experience associated with actual or potential tissue damage,”¹¹ and can manifest through a variety of physical and emotional symptoms.¹² Pain is clinically categorized as acute or chronic, where acute pain is described “as a psychological response to noxious stimuli that is sudden in onset and time limited.”¹³ Acute pain often follows after trauma, and is also considered a standard part of the perioperative period of surgery.¹⁴ Acute and chronic pain can be interlinked, with acute pain forming the beginning of a chronic pain condition, or acute pain systematically flaring up as part of a chronic medical problem, such as multiple sclerosis or arthritis.¹⁵

Acute pain is often treated with multimodal, nonopioid approaches, in conjunction with possible opioid treatments.¹⁶ Acute pain treatment is marked by frequent reevaluation of the patient, as “the use of medications to control acute pain should be for the shortest time necessary while also ensuring that the patient is able to mobilize and function to optimize outcome following surgery or injury.”¹⁷ Often, acute pain has a sudden onset and is linked to a specific injury, event, or illness.¹⁸ While opioids are effective in the treatment of acute pain, there is a concern that improper treatment of acute pain can lead to habitual abuse of opioids in the postsurgical setting. One recent study suggested that among a population of non-opioid using patients after surgery, patients given opioids to treat pain from the surgery became new habitual opioid users 6% of the time.¹⁹

¹⁰ RELIEVING PAIN IN AMERICA, *supra* note 2, at 25.

¹¹ *Id.*

¹² OFF. OF THE ASSISTANT SEC’Y OF HEALTH, DRAFT REPORT ON PAIN MANAGEMENT BEST PRACTICES: UPDATES, GAPS, INCONSISTENCIES, AND RECOMMENDATIONS, U.S. DEP’T HEALTH HUMAN SERVS. [hereinafter DRAFT REPORT].

¹³ *Id.* at 11.

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ RELIEVING PAIN IN AMERICA, *supra* note 2.

¹⁹ DRAFT REPORT, *supra* note 12, *citing* CM Brummett et al., *New Persistent Opioid Use After Minor and Major Surgical Procedures in US Adults*, 152 JAMA SURG. 1 (2017).

In the Center for Disease Control’s (“CDC”) 2016 *Guidelines for Prescribing Opioids for Chronic Pain* (“CDC Guidelines”), chronic pain is defined as pain that lasts more than three months, or past the time of normal tissue healing.²⁰ Chronic pain can result from an injury, underlying disease, inflammation, medical treatment, or from an unknown source.²¹ Similar to the treatment of acute pain, chronic pain can be treated with nonpharmacological therapy, non-opioid pharmacological medication, or opioids.²² Today, an estimated 50 million U.S adults suffer from chronic pain.²³ Further, over 19.6 million of these adults experience such high-impact chronic pain that it interferes with their ability to participate in work or daily living activities.²⁴ Some reports place the number of adults suffering from chronic pain even higher, at 100 million individuals.²⁵

Chronic pain can have serious consequences. Those with chronic pain report general difficulty with productivity in daily life.²⁶ Specific types of chronic pain, such as migraine or headache pain, can cause loss of ability to work, engage in social or leisure activities, and serious functional impairment.²⁷ Further, those with chronic pain may be at a higher risk for suicide than the general public; while it is difficult to draw a direct correlation between chronic pain and cause of suicide, the risk of suicide for chronic pain sufferers are double that of non-chronic pain control groups.²⁸ As measured by a CDC report, the percentage of people with evidence of chronic pain who died by suicide rose from 7.4% in 2003 to 10.2% in 2014.²⁹

²⁰ CTR. FOR DISEASE CONTROL (CDC), CDC GUIDELINES ON PRESCRIBING OPIOIDS FOR CHRONIC PAIN— UNITED STATES, 2016 1, 3 [hereinafter CDC GUIDELINES].

²¹ *Id.*

²² *Id.*

²³ *Id.* at 4.

²⁴ *Id.* at 4–5.

²⁵ RELIEVING PAIN IN AMERICA, *supra* note 2, at 1.

²⁶ *Id.* at 87. “The economic analysis conducted for this study found that people with severe pain missed an average of 5.0-5.9 more days of work per year than people with no pain. The components of the cost of lost productivity included days of work missed (\$11.6-12.7 billion), hours of work lost (\$95.2-96.5 billion), and lost wages of (\$190.6-226.3 billion).” *Id.*

²⁷ *Id.* at 87–88.

²⁸ *Id.* at 88.

²⁹ CDC GUIDELINES, *supra* note 20, at 7, *citing* E. Petrosky et al., *Chronic Pain Among Suicide Decedents, 2003 to 2014: Findings from the National Violent Death Reporting System*, ANNALS INTERNAL MED. (2018). Numbers beyond 2014 as collected in the report are available at the time this paper was authored.

i. EMERGING IDEAS OF PAIN: THE 1990S AND 2000S

In recognition of the seriousness of managing pain, the Joint Commission (formerly known as the Joint Commission on Accreditation of Healthcare Organizations, or JCAHO) was first tasked with creating standards for pain management in 1997.³⁰ The goal of such an endeavor was to create standards that health care organizations could use to improve pain management practices.³¹ In 2001, the Joint Commission produced these standards, which emphasized systematic assessments of pain and quantitative measures of pain. The Joint Commission found an overall underassessment of pain, which was partially influenced by the fact that patients were not discussing pain with their physicians and by physician failure to ask proactively about pain.³² Consequently, the pain standards emphasized the responsibilities of health care organizations themselves in seeking out accurate valuations of pain, the general lack of knowledge surrounding pain, and misconceptions about drug tolerance and addiction.³³

The Joint Commission's guidelines represented a fundamental shift in how pain had been conceptualized during the 1990s.³⁴ The standards were a direct response to a national view of perceived underassessment and understanding of pain.³⁵ In particular, the inadequate treatment of pain, called "oligoanalgesia," garnered concern; the Joint Commission identified oligoanalgesia as a public health problem in 2001.³⁶ These concerns spurred federal governmental action to target pain control: in addition to the Joint Commission's standards, the 106th U.S. Congress passed H.R. 3244,

³⁰ DAVID W. BAKER, *THE JOINT COMM'N, THE JOINT COMMISSION'S PAIN STANDARDS: ORIGINS AND EVOLUTION* 1, 3 (2017).

³¹ *Id.*

³² *Id.*

³³ *Id.*

³⁴ DRAFT REPORT, *supra* note 12, at 5.

³⁵ BAKER, *supra* note 30, at 3.

³⁶ Jay M. Baruch, *CLINICAL CASE: Why Must Pain Patients Be Found Deserving of Treatment?* 10 AM. MED. ASS'N J. ETHICS: VIRTUAL MENTOR 5, 6 (2008).

Title VI, sec. 1603,³⁷ which established the Decade of Pain Control and Research,³⁸ matching the Pain Care Coalition's (consisting of the America Pain Society, the American Academy of Pain Medicine, and the American Headache Society) announcement of the same.³⁹ The Joint Commission consistently reviews its statements and standards, including its most recent January 2018 update on pain assessment and management standards.⁴⁰

One concept that grew out of the intense focus on pain during these years was the concept of pain as the “fifth vital sign.” In 1995, the American Pain Society first launched their “pain as a fifth vital sign” campaign, to encourage proper evaluation and treatment of pain.⁴¹ This idea received further support through the Veteran's Health Administration's adoption of the same concept in 1999.⁴² A piece of 1999 California legislation, Assembly Bill 791, is thought to be responsible for bringing the concept of the fifth vital sign further into the public sphere. This bill, which came into law the following year, proposed the inclusion of the following language into the California Health and Safety Code: “Every health facility licensed pursuant to this chapter shall, as a condition of licensure, include pain as an item to be assessed at the same time as the other four vital signs are taken. The pain assessment shall be noted in the patient's chart in a manner consistent with other vital signs.”⁴³ This was a recognition that pain itself was as significant as the other four vital signs—blood pressure, heart rate, respiratory rate and temperature.⁴⁴ Pain as the fifth vital sign captured the concern later elucidated in the Joint Commission's 2001 standards, that physicians were not actively asking

³⁷ Passed in 2000, this bill became part of P. Law No. 106-386, §1603 (2000). “The calendar decade beginning January 1, 2001, is designated as the ‘Decade of Pain Control and Research.’” *Id.*

³⁸ BAKER, *supra* note 30, at 3.

³⁹ THE LAW AND THE RELIEF OF PAIN, *supra* note 9.

⁴⁰ The Joint Comm'n, *Pain Management Standards- Hospitals*, https://www.jointcommission.org/topics/pain_management_standards_hospital.aspx (last visited Feb. 28, 2019).

⁴¹ Mark R. Jones et al., *A Brief History of the Opioid Epidemic and Strategies for Pain Medicine*, 7 PAIN THERAPY 13 (2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5993682/#CR20> (last visited Mar. 27, 2018).

⁴² *Id.*

⁴³ California Health and Safety Code §1254.7 (2000).

⁴⁴ Pat Anson, *AMA Drops Pain as A Vital Sign*, PAIN NEWS NETWORK (June 16, 2016), <https://www.painnewsnetwork.org/stories/2016/6/16/ama-drops-pain-as-vital-sign>.

about pain or accurately assess pain levels. This concept is not without controversy; as will be discussed in Part III of this paper, in 2016 the American Medical Association (“AMA”) recommended the removal of pain as a fifth vital sign.⁴⁵

B. THE DIFFICULTY OF QUALIFYING PAIN

Why is pain a particularly difficult medical concept to understand? Pain has both objective and subjective aspects, which makes measuring pain— and thus understanding and appropriately treating pain— a complex determination. Meeting the needs of those suffering from pain is a multifaceted task, requiring the acknowledgement of the difficulty of measuring pain, understanding the associated comorbidities (e.g. depression or disability) that present along with pain, as well as the social cost of absenteeism and increased utilization of medical resources that can accompany the treatment of pain.⁴⁶

i. MEASURING PAIN

Traditionally, pain charts have often been used to provide an objective measurement of pain.⁴⁷ Pain charts can range from categorical scales (mild, moderate, severe), to numerical rating scales (“NRS”), and visual analog charts (“VAS”).⁴⁸ Within these categories, there can be variances; NRS can employ different number scales, and all three methods described here can employ significant differences in language— for example, using “worst possible pain,” “worst pain imaginable,” or “most intense pain imaginable” to indicate the highest level of pain.⁴⁹ In addition to the scale of pain, the time frame over which pain is experienced, as well as the severity of the pain effect (how much the pain disrupts the life of the patient), factors into the overall pain burden of the patient.⁵⁰ The overall pain burden is especially important in the assessment of chronic pain, as opposed to acute pain that is

⁴⁵ *Id.*

⁴⁶ PAIN MANAGEMENT AND THE OPIOID EPIDEMIC, *supra* note 3.

⁴⁷ Roger B. Fillingim, et al., *Assessment of Chronic Pain: Domains, Methods, Mechanisms*, 17 J. PAIN 1 (2016).

⁴⁸ *Id.* at 2.

⁴⁹ *Id.*

⁵⁰ *Id.*

generally expected to last a short, defined time. Other methods are used in addition to pain charts to assess pain levels. These can include temporal characteristics of pain, pain location and bodily distribution, and behavioral pain measurements.⁵¹

The utilization of pain charts to assess pain poses difficulties because they depend on patient self-reporting. While self-reporting is seen as the “gold standard” of pain measurement, it is an inherently subjective process.⁵² For example, one individual’s self-report of 8 on a 1–10 NRS scale may present the same objective level of pain that another patient might classify as a 4, with the only difference being how each patient subjectively experiences the pain. Thus, NRS scales meant to produce a quantitative measurement will still result in subjective data. However, the drawbacks of using pain charts and scales may pale in comparison to the benefits that these methods bring; at a minimum, pain charts provide of some type of objective quantifiable measure to physicians in assessing pain. Further, pain charts can provide an empirical basis for measurement of one individual’s pain levels over a course of time or treatment. These measurements of the characteristics of pain help in general to qualify pain levels, and can also assist in the diagnosis of certain underlying conditions itself— which can result in more accurate, targeted pain management and treatment. Consequently, pain charts and scales remain the standard for pain assessment across providers.⁵³

C. HOW IS PAIN BEING MANAGED?

Reducing both acute and chronic pain is often the impetus for many medical interventions. Proper pain management involves a multidisciplinary approach, utilizing a variety of treatment options including non-pharmacological therapies, non-opioid medication, and opioid medications. Pain management itself does not have one definition, nor is its meaning universal across the medical field. However, pain management is generally considered to involve a collaborative medical approach of

⁵¹ *Id.* at 5–6.

⁵² *Id.*

⁵³ *Id.*

relieving pain and improving the quality of life of those that suffer pain. The goal of pain management is clear; “[o]ptimal pain management promotes healing, comfort, and a feeling of well-being. Effective pain management permits performance of critical activities, improves quality of life, and reduces the length of hospital stay.”⁵⁴ It is important to note that pain management is not a cure for an underlying disease itself, but rather a treatment for the pain that a patient experiences— whether the pain is connected to an underlying disease, or is the sole medical issue being treated.

i. FOUNDATIONS OF PAIN MANAGEMENT AND OPIOID USE FOR PAIN

The use of opioids in pain management has historically been informed by the World Health Organization’s (“WHO”) pain ladder.⁵⁵ Originally developed in 1986 for use in cancer care, the pain ladder grew in popularity and use over the next few decades and is now considered to represent a worldwide consensus as the favored method to qualify pain in any etiology.⁵⁶ The WHO three-step pain ladder indicates which types of pain treatments are appropriate for a patient, depending on the rung of the ladder the patient is on. Generally, the ladder proceeds from non-opioid medication (such as aspirin), to mild opioids (codeine), then to strong opioids such as morphine, until a patient is free from pain.⁵⁷ The pain ladder also includes guidance on the timing of drug dosage (every three to six hours, as opposed to *ad hoc* on-demand dosages), and when used correctly has an 80–90% effective rate of treating pain.⁵⁸

⁵⁴ ACAD. OF MED.-SURGICAL NURSES (AMSN), *Position Statement: Pain Management*, <https://www.amsn.org/practice-resources/position-statements/archive/pain-management> (Last updated 11/7/2012). While there is a lack of comprehensive definition of “Pain Management” utilized by the medical community as a whole, this rationale of pain management from the Academy of Medical-Surgical Nurses provides a holistic view of the goals of pain management. *Id.*

⁵⁵ THE LAW AND THE RELIEF OF PAIN, *supra* note 9.

⁵⁶ WHO’s *Cancer Pain Ladder for Adults*, WORLD HEALTH ORG. (WHO), <https://www.who.int/cancer/palliative/painladder/en/> (last visited Mar. 1, 2019).

⁵⁷ *Id.*

⁵⁸ *Id.* WHO has a separate, 2-step pain ladder for cancer pain in children, which can be visited at https://www.who.int/medicines/areas/quality_safety/guide_perspainchild/en/.

Similarly, the CDC's Guidelines on the use of opioids to treat chronic pain recommend caution when prescribing opioids. While voluntary in nature,⁵⁹ the Guidelines represent a standard of opioid use that is respected in both the medical and political communities as a source of authority on the subject. According to the CDC, "[n]onpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient."⁶⁰ While the long-term benefits of nonpharmacological or non-opioid pharmacological treatment of chronic pain are limited, the risks are low and these alternative treatment options do produce short-term benefits.⁶¹ While nonpharmacological therapies and non-opioid pharmacological therapies are preferred, the CDC does note that a patient does not have to exhaust or "fail" all non-opioid options before proceeding to opioid therapy; rather any treatment decision should weigh the expected benefits to that patient's specific circumstances when determining when or if opioid therapy should be used.⁶² Thus, a physician's decision to prescribe opioids must rest on a cost-benefit analysis of an individual patient in the clinical context.

Further, "[i]f opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate."⁶³ The CDC recommends multimodal treatments (for example, combining exercise therapy with a non-opioid pharmacological treatment) for treatment of chronic pain. Certain nonpharmacological treatments have proven to be very effective in treating chronic pain: physical therapy, weight loss (for chronic knees, hip, or joint pain), and psychological therapy such as Cognitive Behavioral Therapy can ameliorate some chronic pain suffering.⁶⁴ Exercise

⁵⁹ CDC GUIDELINES, *supra* note 20, at 1.

⁶⁰ *Id.* at 12.

⁶¹ *Id.*

⁶² *Id.*

⁶³ *Id.*

⁶⁴ *Id.*

therapy has been shown to prevent pain and improve function for certain types of chronic pain as well. In addition, “[s]everal nonopioid pharmacologic therapies (including acetaminophen, NSAIDs, and selected antidepressants and anticonvulsants) are effective for chronic pain”⁶⁵ When opioid therapy is used, it is more effective when combined with nonpharmacological and non-opioid pharmacological therapy.⁶⁶

The CDC’s caution against using opioid treatment as the first-line or standard treatment for chronic pain arises from consequences connected to long-term opioid use for pain management.

Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy . . . While benefits for pain relief, function, and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant. Based on the clinical evidence review, long-term opioid use for chronic pain is associated with serious risks including increased risk for opioid use disorder, overdose, myocardial infarction, and motor vehicle injury.⁶⁷

This concern factored heavily into the policies that emerged as responses to the opioid crisis, which will be discussed in Part IV of this paper.

II. PALLIATIVE CARE

This paper will now turn to an examination of palliative care. Pain management and palliative care often intersect, with pain management often forming a segment of a patients’ overall palliative care plan. However, the goals and methods of pain management in palliative are different from those used to address chronic pain. This section will begin with an overall examination of what palliative care is, and then transition to how pain is managed within the palliative care context.

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ *Id.*

A. WHAT IS PALLIATIVE CARE?

The WHO defines palliative care as “an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness.”⁶⁸ The National Consensus Project for Quality Palliative Care, a project under the National Coalition for Hospice and Palliative Care (“NCHPC”), utilizes a similar definition:

Beneficial at any stage of a serious illness, palliative care is an interdisciplinary care delivery system designed to anticipate, prevent, and manage physical, psychological, social, and spiritual suffering to optimize quality of life for patients, their families and caregivers. Palliative care can be delivered in any care setting through the collaboration of many types of care providers. Through early integration into the care plan of seriously ill people, palliative care improves quality of life for both the patient and the family.⁶⁹

As palliative care is considered an interdisciplinary area of medicine, it is usually undertaken as a team-based approach armed with different clinical treatments focused on relief from pain and psychological and spiritual care.⁷⁰ Notably, palliative care is meant to cover both the patient and the patient’s family, and aims to provide support during the illness as well as bereavement services for the family after death.

⁶⁸ *WHO Definition of Palliative Care*, WHO (<https://www.who.int/cancer/palliative/definition/en/>) (last visited Feb. 24, 2019). The full definition is “an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual. Palliative care:

- provides relief from pain and other distressing symptoms;
- affirms life and regards dying as a normal process;
- intends neither to hasten or postpone death;
- integrates the psychological and spiritual aspects of patient care;
- offers a support system to help patients live as actively as possible until death;
- offers a support system to help the family cope during the patients illness and in their own bereavement;
- uses a team approach to address the needs of patients and their families, including bereavement counselling, if indicated;
- will enhance quality of life, and may also positively influence the course of illness;
- is applicable early in the course of illness, in conjunction with other therapies that are intended to prolong life, such as chemotherapy or radiation therapy, and includes those investigations needed to better understand and manage distressing clinical complications.”

⁶⁹ NAT. COAL. FOR HOSPICE AND PALLIATIVE CARE (NCHPC), *CLINICAL PRACTICE GUIDELINES FOR QUALITY PALLIATIVE CARE*, at i (4th ed. 2018).

⁷⁰ WHO, *supra* note 68.

Palliative care is often used in conjunction with other medical treatments aimed at prolonging life,⁷¹ such as chemotherapy or radiation for the treatment of cancer.⁷² In fact, the collaborative nature of palliative care is fundamental to its success; often a palliative care interdisciplinary team is charged with carrying out an individual's palliative care plan. Palliative care teams could include, but are not limited to: medical professionals (e.g. physicians and nurses), spiritual advisors, and others.⁷³ Palliative care is generally not intended to treat an underlying illness itself; while palliative care can “positively influence the course of illness,”⁷⁴ that is not its primary goal.⁷⁵ Rather, the goal of palliative care is to maximize the quality of life of the patient and family in the context of a serious or advanced illness. Due to this consideration, palliative care is sometimes referred to as end-of-life care.⁷⁶

Although there is significant overlap, palliative care is different from hospice care. In general, “[t]he primary focus of palliative care is to improve the quality of life for patients and their families, with an emphasis on the needs and goals of the patient and family, independent of prognosis.”⁷⁷ In contrast, hospice care as defined by the Centers for Medicare and Medicaid (“CMS”) applies to patients who have been diagnosed with a terminal illness (with a life expectancy of less than six months, if the disease follows its natural course).⁷⁸ CMS finds palliative care to fall under the umbrella

⁷¹ Laura P. Gelfman & Diane E. Meier, *Making the Case for Palliative Care: An Opportunity for Health Care Reform*, 8 J. HEALTH & BIOMED. L. 57-58 (2012).

⁷² This paper does not discuss cancer care in the palliative context, as this is a specific type of palliative care with different concerns. Notably, the conception of quality of life is construed differently in cancer-care palliative care. For more information, see *Palliative Care in Cancer*, NAT. INST. HEALTH: NAT. CANCER INST., <https://www.cancer.gov/about-cancer/advanced-cancer/care-choices/palliative-care-fact-sheet> (last visited Apr. 5, 2019).

⁷³ NCHPC, *supra* note 69, at 1.

⁷⁴ WHO, *supra* note 68.

⁷⁵ This differs in the cancer-palliative care context, in which chemotherapy or other cancer treatment is utilized in a curative aspect. See *Palliative Care in Cancer*, *supra* note 72.

⁷⁶ See e.g., Fehlberg et al., *End-of-Life Care and the Opioid Crisis: Potential Implications and Unintended Consequences*, RTI INT'L (June 6, 2018), <https://www.rti.org/insights/end-life-care-and-opioid-crisis-potential-implications-and-unintended-consequences> (last visited Mar. 3, 2019); *but see* CDC GUIDELINES, *supra* note 20, at 3. This paper will examine palliative care and end of life care as having a similar goal and population involving those with serious or life-threatening diseases. However, it is important to note, as the CDC Guidelines do, that not all who enter palliative care have a life-threatening illness or are at the end of their life.

⁷⁷ Gelfman & Meier, *supra* note 71, at 58.

⁷⁸ CTRS. FOR MEDICARE & MEDICAID (CMS), MEDICARE HOSPICE BENEFITS 4 (2019), <https://www.medicare.gov/pubs/pdf/02154-medicare-hospice-benefits.pdf>.

of hospice care,⁷⁹ while others view palliative care as the broader concept, covering both *hospice* palliative care (which utilizes the Medicare Hospice benefit in a medical setting) and *non-hospice* palliative care.⁸⁰ There is a distinct difference between palliative and hospice care in the United States, due to the requirements placed on CMS and Medicare benefits. The salient difference is prognosis: while hospice care is restricted to those with a short prognosis, palliative care has no such prognosis restriction. While common, those in palliative care are not necessarily at the end of their life; by prognosis, those in hospice are expected to have only months to live.

B. WHERE PAIN MANAGEMENT AND PALLIATIVE CARE MEET

Palliative care often addresses some form of acute and/or chronic pain, and thus palliative care often includes pain management treatments. In fact, pain management strategies aimed at alleviating or mitigating pain symptoms, thus improving the quality of life for the patient and family, are often essential to a palliative care plan.⁸¹ Opioid use for pain management is particularly common in palliative care, and even more common is hospice care: approximately one-third of hospice patients have or receive an opioid prescription upon admission— a rate which increases the closer an individual comes to the end of their life.⁸² With opioid use commonly utilized in the palliative care context, the natural question arises as to if there are any differences in the provision of pain management in the palliative care context as opposed to the context of chronic disease— especially in the case of opioid pharmacological therapies.

⁷⁹ *Id.*

⁸⁰ Gelfman & Meier, *supra* note 71, at 59.

⁸¹ NCHPC, *supra* note 69, at 4.

⁸² Fehllberg et al., *supra* note 76. While this source analyzed only hospice data, rather than palliative care as a whole, the author is confident in extending the correlation between opioid use in hospice to opioid use in palliative care.

i. IMPROVING QUALITY OF LIFE

The overarching goal of both pain management and palliative care is similar— the optimization of quality of life for the individual.⁸³ However, this overarching goal of improved quality of life is construed differently in palliative care as compared to an individual suffering from chronic pain. This difference makes the seemingly analogous concepts different upon closer examination. Specifically, the advanced or life-threatening illness that marks the need for palliative care makes the conception of quality of life fundamentally different from that of a chronic pain sufferer.

The quality of life of an individual in palliative care is marked by a serious illness, which may considerably shorten their lifespan. While palliative care itself may increase the length of an individual's life as compared to the same patient outside of palliative care,⁸⁴ most patients in palliative care have an advanced and serious illness, which may lead to shorter life-span. This is even more prevalent in hospice care; once a patient is in hospice care, as defined by CMS, the lifespan of the patient is likely no longer than six months.⁸⁵ Thus, in the palliative care setting, the conception of quality of life accounts for the effects of such a serious illness on the quality of life— which in some cases, includes the potential for a shorter lifespan. For example, a patient with a terminal disease may be willing to accept a treatment plan including medication with long-term risks, if it is unlikely that the patient will live long enough to feel the effects. Or, a terminally ill patient in extreme pain may opt for aggressive opioid treatment which impairs some mental functioning or induces an altered mental state, but will allow the patient to spend their final days with their family free from pain. Thus, in palliative care, the mitigation or elimination of pain must be considered in light of the context of the individual's condition as it affects his or her quality of life. Specifically, pain management must be considered in

⁸³ See AMSN, *supra* note 54.

⁸⁴ For more information, see Kate Rowland & Sarah-Anne Shurmann, *Palliative Care: Earlier is Better*, 59 THE J. FAM. PRAC.: PURLS 695 (2010), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3183935/pdf/JFP-59-695.pdf> (.).

⁸⁵ CMS, *supra* note 78, at 4.

relation to the patient's condition, the symptoms they experience, the life expectancy associated with a patient's disease, and the patient's pain treatment goals; "[i]nterdisciplinary care plans to address physical symptoms, maximize functional status, and enhance quality of life are *developed in the context of the patient's goals of care, disease, prognosis, functional limitations, culture, and care setting.*"⁸⁶

This provides a contrast to the improvement of the quality of life for an individual suffering from chronic pain. In the context of treating chronic pain, it is primarily the reduction of the pain itself that leads to the improvement in the quality of life; the pain itself is the impetus for pain management treatment and therefore the goal of pain management in chronic pain is to alleviate or eliminate the pain itself. In palliative care, the goal of improving quality of life is not so singularly focused on reducing pain.⁸⁷ In addition, quality of life considerations for chronic pain sufferers must consider future effects of any pain treatment plan, including other treatment options, long-term treatment effects, and potential for addiction or abuse of opioid medication.⁸⁸ These concerns may be less of a factor— or not a factor at all— in the conception of quality of life for a patient in palliative care facing a life-threatening illness.

ii. CONCERN OVER OPIOID ADDICTION

The potential for opioid abuse and addiction is another concern influenced by the potentially short lifespan in palliative care. As will be discussed in Part III of this paper, the concern over opioid abuse underlies much of the policy directives and regulations which restrict the prescription of opioids in the management of chronic pain.⁸⁹ However, the potential for opioid abuse is radically different for palliative care patients, as compared to chronic pain patients. While an opioid prescription to any patient should be given only after careful consideration of the benefits to the patient as weighed against

⁸⁶ NCHPC, *supra* note 69, at 14. *Emphasis added.*

⁸⁷ *Id.*

⁸⁸ See *infra* Part II.B.ii.

⁸⁹ *Infra* Part III.

the cons of such a treatment,⁹⁰ the cost-benefit analysis for a palliative care patient must weigh the risk of possible opioid addiction against the potential short lifespan of the patient. In other words, “[t]he risk of addiction, and its consequences, can be acceptable for patients who are dying.”⁹¹

The CDC recognizes the difference in goals between pain management in the chronic pain context, as opposed to the palliative context. The CDC Guidelines specifically apply to the prescription of opioids for chronic pain “outside of active cancer treatment, palliative care, and end-of-life care.”⁹² However, as this paper will argue in Part IV, provisions such as the ones in the CDC Guidelines which exempt palliative care from the opioid epidemic policies have not prevented the palliative care community from being affected.⁹³

III. THE OPIOID EPIDEMIC: AN AMERICAN HISTORY AND POLICY OVERVIEW

Against the background of pain management discussed in Part I of this paper, the concern of over-prescription of opioids and resulting opioid abuse emerged. This section of the paper will discuss the origins of the opioid epidemic in the United States, then will review a brief summary of policy directives created to counter the opioid epidemic and the current status of the opioid epidemic. Finally, this section will discuss the policies aimed at managing and mitigating the opioid epidemic moving forward.

⁹⁰ See Part I.C.i, above.

⁹¹ Fehlberg et al., *supra* note 76.

⁹² CDC GUIDELINES, *supra* note 20, at 3. “The guideline is not intended for patients undergoing active cancer treatment, palliative care, or end-of-life care because of the unique therapeutic goals, ethical considerations, opportunities for medical supervision, and balance of risks and benefits with opioid therapy in such care.” *Id.*

⁹³ *Infra* Part IV.

A. HISTORY

After the widespread change in attitude toward pain and pain management in the 1990s and 2000s towards better recognition and assessment of pain,⁹⁴ a concern arose that the standards promulgated by the Joint Commission had led to inappropriate opioid prescription levels.⁹⁵

Prior to the release of the 2001 standards, there had been a steady increase in opioid prescriptions over the preceding decade in the U.S.⁹⁶ Between 1991 and 1997, the number of opioid prescriptions swelled from 76 million to 97 million, likely due to the advocacy work of pain management specialists and concern over inadequate assessment of pain in the clinical setting.⁹⁷ From 1997 to 2013, the increase in prescription of opioids grew even more rapidly, from 97 to 207 million (with a high of 219 million in 2010).⁹⁸ Part of this rapid increase in opioid prescription may be due to the 1995 release of the popular opioid OxyContin (oxycodone), which included labeling saying that iatrogenic addiction was “very rare” and that the long term absorption of the drug reduced potential for abuse.⁹⁹ Similar ideas regarding a low potential for abuse were announced to physicians at pain-management conferences and marketing campaigns for opioids during this decade, contributing to an idea that opioids were a low-risk treatment option for pain management.¹⁰⁰

The concept of pain as the fifth vital sign exemplifies the strong push for better understanding of pain management in relation to opioid use. In 2001, an example of implementation from the Joint Commission’s report stated that “[p]ain is considered a ‘fifth’ vital sign in the hospital’s care of

⁹⁴ *Supra* Part I.

⁹⁵ BAKER, *supra* note 30, at 5.

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ *Id.* For more information on how OxyContin contributed to the opioid epidemic, see Art Van Zee, *The Promotion and Marketing of Oxycontin: Commercial Triumph, Public Health Tragedy*, 99 AM. J. PUB. HEALTH 221 (2009).

⁹⁹ Van Zee, *supra* note 97, at 221–27. The FDA required the removal of such claims from OxyContin’s labeling in 2001, however, the idea of safety towards opioid use that this labeling bolstered may have already done its damage by this time. *Id.*

¹⁰⁰ BAKER, *supra* note 30, at 5.

patients.”¹⁰¹ This concept, as described above,¹⁰² reflected the idea that pain should be asked about as part of routine medical assessments, on equal status with the other vital signs.¹⁰³ Pain as the fifth vital sign grew strong acceptance within the medical community as an acknowledgement of the seriousness of chronic pain and the concerns about undertreatment related to patient disclosure of pain.¹⁰⁴

It is hard to pinpoint whether the Joint Commission Standards created the openness to opioid use, or merely codified an existing idea into a medical standard

Because of the steady rise in opioid prescriptions in the decade preceding release of The Joint Commission standards and the other forces encouraging opioid prescribing in the years before the release of the standards, it is difficult to draw conclusions about whether the standards or educational materials related to the standards had an independent effect on the upward trend.¹⁰⁵

What is clear, however, is that this openness to prescribing opioids soon took on a life of its own. By the late 2000s, opioid prescriptions— and opioid misuse— had significantly increased. Opioid prescriptions per capita increased 7.3% from 2007 to 2012.¹⁰⁶ By 2012, “health care providers wrote 259 million prescriptions for opioid pain medication, enough for every adult in the United States to have a bottle of pills.”¹⁰⁷ There had been “an almost fourfold increase in overdose deaths from 1999 to 2008.”¹⁰⁸ In 2016 alone, over 64,000 lives were lost due to opioid overdose.¹⁰⁹

¹⁰¹ *Id.* at 6.

¹⁰² *Id.*

¹⁰³ Anson, *supra* note 44.

¹⁰⁴ See *supra* discussion in 1.A.i.

¹⁰⁵ BAKER, *supra* note 30, at 5.

¹⁰⁶ CDC GUIDELINES, *supra* note 20, at 1.

¹⁰⁷ *Id.*

¹⁰⁸ Jones et al., *supra* note 41, at 13.

¹⁰⁹ *Id.*

B. POLICY DIRECTIVES

This section will briefly describe how the policy directives of the war on opioids have shaped regulatory action in the U.S.¹¹⁰ There has been a significant regulatory push to control the over prescription of opioids to address the opioid epidemic that unfolded in the U.S. since the late 1990s and early 2000s. Once the extent of opioid prescriptions increases and its consequences became clear during the 2010s, the prevailing public opinion and medical community attitude towards opioid use swung back against the earlier openness to utilize opioids to treat pain. The response from the federal government in combating the opioid epidemic has been multifarious; in 2016, then-President Obama signed the Comprehensive Addiction and Recovery Act of 2016 (“CARA”)¹¹¹ into law.¹¹² This sweeping bill, the first to target addiction in over forty years, targets multiple aspects of opioid addiction from “primary prevention to recovery support.”¹¹³

In addition to the enactment of CARA, a large push against opioid abuse came from the Department of Justice’s (“DOJ”) enforcement of drug laws, which included the creation of the President’s Commission on Combating Drug Addiction and the Opioid Crisis in 2017.¹¹⁴ Similarly, the concern over opioid use is reflected in the 2018 passage of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, or SUPPORT for Patients and Communities (“SUPPORT Act”).¹¹⁵ This bipartisan law represents a far-reaching effort

¹¹⁰ See also [Identifying Information Redacted].

¹¹¹ Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-198, 130 Stat. 695 (codified as amended in scattered sections of 42 U.S.C and 21 U.S.C.).

¹¹² *Summary of the Comprehensive Addiction and Recovery Act*, AM. SOC’Y. ADDICTION MED., <https://www.asam.org/advocacy/issues/opioids/summary-of-the-comprehensive-addiction-and-recovery-act> (last visited Apr. 5, 2019).

¹¹³ *Id.*

¹¹⁴ DEP’T OF JUSTICE PRESS RELEASE, *Attorney General Jeff Sessions Delivers Remarks on Efforts to Combat Violent Crime and Restore Safety Before Federal, State and Local Law Enforcement*, (Mar. 15, 2017), <https://www.justice.gov/opa/speech/attorney-general-jeff-sessions-delivers-remarks-efforts-combat-violent-crime-and-restore>.

¹¹⁵ Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, Pub. L. No. 115-271 (2018).

to address issues connected to opioid use and abuse.¹¹⁶ The SUPPORT Act is a combination of over seventy bills which affect various aspects of the healthcare industry in relation to combating opioid abuse.¹¹⁷ Specifically, the law features a revised and expanded Medicaid and Medicare service coverage related to substance use disorders and abuse, increased telehealth access under Medicare, and “sunshine” disclosures requirements for pharmaceutical and device manufacturers, among other provisions.¹¹⁸ This law is a promising effort from the federal government in line with the policy directives of action from federal agencies, however it remains to be seen as to what effect it will have in reducing rates of opioid use and abuse in the coming years. Most recently, in January 2019, the Office of the National Drug Control Policy released the National Drug Control Strategy (the “Strategy”), which aimed to combat the opioid epidemic through “prevention, treatment and recovery, and reducing the availability of drugs in America.”¹¹⁹ Notably, these actions, along with the CDC Guidelines, share a strong aim to prevent the abuse or misuse of opioids.

As suggested in a 2019 AMA lecture from the Department of Health and Human Services (“HHS”) Assistant Secretary Of Health Brett P. Giroir, MD, the opioid epidemic has expanded into a “multi-problematic phenomenon” that must be addressed differently from the way it was addressed in the past.¹²⁰ Specifically, Doctor Giroir discussed two important aspects of a five-point federal strategy to combat the opioid epidemic that focuses on better treatment and management of pain, as well as “transitioning the response away from a ‘crisis framework’ financed by grants and toward an

¹¹⁶ *The SUPPORT Act of 2018: New All-Payer Anti-Kickback Provisions; Broader Telehealth and Other Coverage*, ROPES & GRAY: NEWSROOM (Oct. 30, 2018), <https://www.ropesgray.com/en/newsroom/alerts/2018/10/The-SUPPORT-Act-of-2018-New-All-Payer-Anti-Kickback-Provisions-Broader-Telehealth-and-Other-Coverage>.

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ JAMES W. CARROLL, NAT. DRUG CONTROL STRATEGY, REPORT BY THE OFFICE OF NATIONAL DRUG CONTROL POLICY, 1 (Jan. 2019), <https://www.whitehouse.gov/wp-content/uploads/2019/01/NDCS-Final.pdf>.

¹²⁰ Andis Robenzniek, *HHS Official: Better Pain Treatment a Key to Ending Opioid Crisis*, AM. MED ASS’N; OPIOIDS (Feb. 20, 2019) (discussing HHS Assistant Secretary of Health Brett P. Giroir’s 2019 speech to the AMA on the status on the opioid epidemic regarding improving treatment).

integrated and sustainable system with predictable funding.”¹²¹ To aid in this new vision for fighting opioid abuse and misuse, the HHS’s five-point plan published in 2017 stresses the integration of opioid management into the public health narrative as opposed to a crisis response. The five points are: “[1] Prevention, treatment and recovery services; [2] Data to find out what is happening and where; [3] Pain management; [4] Targeted distribution of naloxone; and [5] Research.”¹²² This shows a significant expansion of the acknowledgement of pain management improvement in relation to the opioid epidemic, and a need for the development of policies toward opioid use that work in tandem with, not against, the considerations of pain management.

C. CURRENT STATUS ON THE OPIOID EPIDEMIC

The number of opioid prescriptions has been steadily decreasing since its high in 2011. According to the AMA’s Opioid Task Force Progress Report 2018, there was a 22.2% national decrease in opioid prescriptions from 2012 to 2017.¹²³ Further, all 50 states have seen a decrease in opioid prescriptions between 2013 and 2017.¹²⁴ While not signaling a total end to the opioid epidemic, these statistics point to the responses enacted to the opioid epidemic as being partially successful.

The AMA credits this reduction in part to Prescription Drug Monitoring Programs (“PDMPs”), which are databases used by physicians to inform their clinical decisions.¹²⁵ More specifically, PDMPs are:

state-managed electronic databases of controlled substances dispensed (typically schedule II – IV), with the majority of the data being reported by community-based pharmacies. PDMPs allow prescribers and pharmacists (and in some states, insurers, researchers, and medical licensing boards) to access the data, monitor use by patients, monitor

¹²¹ *Id.*

¹²² *Id.*; see also HHS, OPIOID TASK FORCE 2018 PROGRESS REPORT, *infra* note 123.

¹²³ AM. MED. ASS’N (AMA), AMERICAN MEDICAL ASSOCIATION OPIOID TASK FORCE 2018 PROGRESS REPORT 2 [hereinafter OPIOID TASK FORCE 2018 PROGRESS REPORT].

¹²⁴ *Id.*

¹²⁵ *Id.*

prescribing practices by practitioners, and check population-level drug use trends.¹²⁶

Practically, a PDMP allows a physician to identify patients who are at risk of prescription abuse. The PDMP report will allow a physician to identify the patient's history with prescriptions (paying special attention to patterns of behavior that indicate opioid abuse), if patients have sought to have prescriptions filled by multiple providers, and whether a patient is at risk of a potentially harmful drug combination.¹²⁷ PDMPs can allow physicians to become aware of their own prescribing habits, and improve patient safety by intervening when there is an uncertain or unsafe prescription history. Prescribers who have utilized PDMPs at the point of care have reported altered prescribing behavior.¹²⁸ Almost all states¹²⁹ employ some form of PDMPs, and some state statutes regarding PDMPs require physicians to access the PDMP at the point of care prior to prescribing certain substances.¹³⁰

The AMA has recommended that PDMPs be integrated into the clinical workflow of a physician's practice so that the physician can access data at the point of care and factor results from the PDMP into their prescribing habits.¹³¹ Similarly, the SUPPORT Act provides a robust focus on PDMPs, by requiring state Medicaid programs have providers check prior to the prescription of certain controlled substances.¹³² Use of PDMPs has significantly increased in the past decade; as of 2017, there were

¹²⁶ DRAFT REPORT, *supra* note 12, at 20. According to the United States Drug Enforcement Administration ("DEA"), "Drugs, substances, and certain chemicals used to make drugs are classified into five (5) distinct categories or schedules depending upon the drug's acceptable medical use and the drug's abuse or dependency potential. The abuse rate is a determinate factor in the scheduling of the drug." Schedule II drugs include some hydrocodone medications (such as Vicodin), cocaine, methamphetamines, fentanyl, and oxycodone. Schedule III drugs include ketamine, anabolic steroids, testosterone, and products containing less than 90 milligrams of codeine per dosage unit. *Id.* For more information, see DEA, *Drug Scheduling*, <https://www.dea.gov/drug-scheduling> (last visited Mar. 26, 2019).

¹²⁷ *Id.* at 21.

¹²⁸ *Id.*, citing MW McAllister et al., *Impact of Prescription Drug-Monitoring Program on Controlled Substance Prescribing in the ED*, 33 AM. J. EMERGING MED. 781 (2015).

¹²⁹ *Id.* at 20. "Forty-nine states and most of Missouri (so, almost all 50 states) and the District of Columbia have operational PDMPs." *Id.*

¹³⁰ *Id.* at 21.

¹³¹ OPIOID TASK FORCE 2018 PROGRESS REPORT, *supra* note 123, at 2.

¹³² Pub. L. No. 115-271, §5041-5042(2018). This provision exempts those receiving cancer-care treatment or hospice/palliative care, however palliative care and hospice care not exempted from the bill overall.

over 1.5 million physicians and other health care professionals registered in a PDMP, which represented an increase of over three times the number in 2014.¹³³

In addition, the AMA also acknowledged the increased use of naloxone in treating opioid overdoses as an important factor in combating the opioid epidemic.¹³⁴ Naloxone is an opioid antagonist that can be administered for opioid exposure and overdose,¹³⁵ and can reverse an opioid overdose when administered immediately.¹³⁶ First synthesized in 1961, naloxone was approved by the FDA in 1971 as a “diagnostic and therapeutic agent for the treatment of opioid-induced respiratory depression,” and is currently on the WHO Model List of Essential Medicines.¹³⁷ While there are several side effects from naloxone, and issues regarding access (as naloxone is only available by prescription, with a high cost to individual patients), both the U.S. Food and Drug Administration (“FDA”) and the AMA recommend improved research and data regarding the use of naloxone in relation the opioid epidemic.¹³⁸ Specifically, as naloxone can stop a drug overdose from resulting in death (when administered correctly and immediately after an overdose) and can also be used in extended release formulations for opioid addiction, the benefits of naloxone show significant promise in diminishing the scope of opioid epidemic.¹³⁹

While the overall number of deaths due to opioid use has decreased in the past few years as compared to the early 2000s, there are still a large number of individuals suffering– and dying from– the use of opioids. One specific concern that has emerged in the past few years is that the “third wave” of the opioid epidemic is coming into its prime.¹⁴⁰ The “third wave” describes the increase in overdose

¹³³ *Id.*

¹³⁴ *Id.* at 3.

¹³⁵ PAIN MANAGEMENT AND THE OPIOID EPIDEMIC, *supra* note 3, at 245.

¹³⁶ NIDA, *supra* note 4.

¹³⁷ PAIN MANAGEMENT AND THE OPIOID EPIDEMIC, *supra* note 3, at 245.

¹³⁸ *Id.* at 248-49; *see also* OPIOID TASK FORCE 2018 PROGRESS REPORT, *supra* note 123, at 2.

¹³⁹ NIDA, *supra* note 4.

¹⁴⁰ Martha Bebinger, *Fentanyl–Linked Deaths: The U.S. Opioid Epidemic’s Third Wave*, NAT. PUB. RADIO: PUB. HEALTH (Mar. 21, 2019 12:02 AM), <https://www.npr.org/sections/health-shots/2019/03/21/704557684/fentanyl-linked-deaths-the-u-s-opioid-epidemics-third-wave-begins>.

deaths due to fentanyl.¹⁴¹ The “first wave” of opioid use concerned the use of prescription pain killers (such as OxyContin), which moved into the “second wave” focused on heroin use.¹⁴² During this “third Wave,” the use of the synthetic opioid fentanyl has surged. Since 2013, fatal overdoses which involved fentanyl use have doubled each year, with a 113% annual increase from 2013 to 2016.¹⁴³ Fentanyl overdose and death disproportionately affects males over females, affecting African-American and Latino men in higher number than Caucasian males.¹⁴⁴ With such a significant increase in fentanyl use in just the past few years alone, the emergence of the “third wave” may indicate that the opioid epidemic is far from over.

IV. INCOMPATIBLE DIRECTIVES: OPIOID POLICY DIRECTIVES IN PALLIATIVE CARE

A. HOW THE DIRECTIVES AND GOALS DIFFER

As discussed above, there are significant differences in the goals of providing palliative care utilizing opioids and the goals of legislation and regulation in the opioid epidemic directives. The root of this difference is that the policy directives aimed at combating the opioid epidemic are fundamentally based on ideas of pain management in the chronic pain context. When examining the role that pain management has played in the evolution of the opioid epidemic, this paper argues that pain management in palliative care developed with different goals and aims as compared to opioid use in the chronic pain setting. Thus, the policy directives that have emerged in response to the opioid epidemic fundamentally differ, and in some cases harm, pain management within palliative care.

¹⁴¹ *Id.*

¹⁴² *Id.*

¹⁴³ *Id.*

¹⁴⁴ *Id.*

B. HOW DOES THIS DIVERGENCE AFFECT PALLIATIVE CARE?

The general anti-opioid policy directives of the CDC Guidelines and other regulation has had a significant effect on palliative care— even with palliative care being exempted from the CDC Guidelines. Specifically, the CDC Guidelines exempt palliative care, end-of-life care, and pain management of those under 18 from their pain management provisions.¹⁴⁵ The CDC notes that this guide exempts palliative care “because of the unique therapeutic goals, ethical considerations, opportunities for medical supervision, and balance of risks and benefits with opioid therapy in such care.”¹⁴⁶

This paper argues, however, that the difference in policy directives that stems from the influence of pain management practices and the history of chronic pain have caused significant effects on pain management in palliative care, despite the CDC’s exemptions. Moreover, while the CDC Guidelines provide an authoritative source on appropriate opioid use, it is important to note that federal legislation on opioid use has not exempted palliative care. Neither CARA, nor the SUPPORT Act, exempts palliative or hospice care on a whole.¹⁴⁷

Thus, “the current regulatory climate and public fear that surrounds opioids could restrict the ability of hospices to provide palliative care at the end-of-life – and some hospices and their patients have begun to experience the spillover effects and unintended consequences.”¹⁴⁸ The CDC

¹⁴⁵ CDC GUIDELINES, *supra* note 20, at 3. The CDC differentiates palliative care from end-of-life care, by defining the two terms as follows:

For this guideline, palliative care is defined in a manner consistent with that of the Institute of Medicine as care that provides relief from pain and other symptoms, supports quality of life, and is focused on patients with serious advanced illness. Palliative care can begin early in the course of treatment for any serious illness that requires excellent management of pain or other distressing symptoms. End-of-life care is defined as care for persons with a terminal illness or at high risk for dying in the near future in hospice care, hospitals, long-term care settings, or at home. *Id.*

¹⁴⁶ *Id.*

¹⁴⁷ See *supra* notes 111-12. CARA exempts palliative care from certain reporting and information gathering provisions. The Support Act includes a palliative care exemption for two Medicaid provisions. However, both bills are inexplicably silent on palliative or hospice care, or any relevant exemptions for these two categories of care.

¹⁴⁸ Fehlberg et al., *supra* note 76.

Guidelines— in addition to other action from the federal government aimed at restricting opioid use, such as CARA and the SUPPORT Act— “combined with all of the recent negative messaging about opioids, are likely to have a chilling impact on pain management efforts, even for those groups of patients for whom the guidelines were not intended, leading to the under-treatment of disabling pain in those with serious or advanced illness.”¹⁴⁹

i. OPIOID SHORTAGES

Policies limiting production of opioids may lead to shortages of opioids.¹⁵⁰ Federal legislation to restrict initial opioid prescriptions to seven days, as well as state-specific legislation, have limited the availability of opioids in general. As of April 2018, at least 28 states have enacted some type of opioid prescription limitation, such as dosage limits or limited duration initial opioid prescriptions (often for three to seven days at a time).¹⁵¹ In addition, in 2017 and 2018, the DOJ and the U.S. Drug Enforcement Agency (“DEA”) took steps to implement opioid production quotas.¹⁵² While these quotas were enacted due to concerns of oversupply, these policies may have reduced the amount of certain opioid drugs being produced to unsustainable levels.¹⁵³ This affects the ability of pharmacies to stock and carry enough opioid medications to fill prescriptions for opioids. Similar to the CDC Guidelines, both federal and state policies regarding opioid use exempt certain types of care involving opioids— such as palliative care.¹⁵⁴ However, exempting palliative care patients from regulation does not address the issue of a shortage in supply. Palliative care patients may need a regular supply of

¹⁴⁹ Sarah Karlin-Smith & Brianna Ehley, *5 Unintended Consequences of Addressing the Opioid Crisis*, POLITICO: OPIOIDS IN AM. (May 8, 2018 5:07 AM), <https://www.politico.com/story/2018/05/08/opioid-epidemic-consequences-502619>.

¹⁵⁰ Fehlberg et al., *supra* note 76.

¹⁵¹ *Id.*

¹⁵² Dep’t of Justice, Drug Enforcement Admin. (DEA), Established Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2017, [Docket No. DEA-443F]. These quotas were enacted pursuant to the Controlled Substances Act, Pub. L. No. 91-513, 21 U.S.C. ch. 13 § 801 et seq. (2018).

¹⁵³ Fehlberg et al., *supra* note 76.

¹⁵⁴ *Id.*

opioid medication if the medication is part of the patient’s care plan, and opioid shortages or reduction in available supply may affect a patient’s ability to ensure they can receive their regular medication.

ii. OVERALL PRESCRIPTION ACCESS

A related concern regarding the provision of care using opioids in the palliative care setting is overall access to opioid prescription medication. There is a concern over both state and federal policies affecting the ability of patients to access their appropriate opioid medication. “Local policies intended to curb illicit opioid use, such as pharmacy dispensing limits or insurance requirements for prior authorization, can also affect end-of-life patients’ access to their pain medications.”¹⁵⁵ For example, a palliative care patient with limited mobility may be affected by a pharmacy’s dispensing limit, causing the patient to be unable to receive a month’s worth of pain medications in a single trip. This could cause a burden on the patient or caregiver, requiring them to take multiple trips to a pharmacy or cause a delay in receiving pain medication— during, in an extreme case, what could be the last days of life for a terminal palliative care patient.¹⁵⁶

iii. PROVISION OF CARE

“The opioid crisis and policy reactions to the crisis may also be affecting hospices’ delivery of end-of-life care.”¹⁵⁷ In a broader sense, policies and best practices designed to prevent opioid abuse or misuse may prevent palliative or hospice care provider’s ability to provide the highest level of care in the palliative care environment. “. . . [S]trategies to prevent illicit drug use and drug diversion in hospice may cause friction in the relationships among providers, patients, and their families and caregivers.”¹⁵⁸ Even in non-hospice palliative care, the support the palliative care team should be

¹⁵⁵ *Id.* This article discusses access in terms of patients near the end of their lives, however patients in palliative care who are not at the end of their lives, but rather are dealing with a serious advanced illness, may experience the same accessibility problems.

¹⁵⁶ *See id.*

¹⁵⁷ *Id.*

¹⁵⁸ *Id.*

providing to the patient and family may be lessened by a hospital or service provider's internal regulations meant to curb inappropriate opioid use.

Drug diversion policies may prevent the appropriate use of opioids in the palliative care setting. Drug diversion occurs when prescription drugs are given to, or taken by, a third party for illicit use.¹⁵⁹ Many hospice or palliative care treatment centers or hospitals enact policies to prevent drug diversion, such as prescribing guidelines that favor the prescription of nonopioid medications, or requiring patients and families to sign pain management agreements prior to receiving their prescriptions.¹⁶⁰ In addition, measures such as daily medication deliveries, counting pills to monitor usage, or lock-box storage of medication can be used by a palliative care provider to restrict a patient's access to their opioid medication.¹⁶¹

Drug diversion policies, and overall distrust over inappropriate opioid use in general, can erode a critical feature of palliative care: support. Internal opioid control measures enacted by palliative care provider may cause feelings of distrust or suspicion among the patient and family, which can erode the positive relationship and support that palliative care is premised upon: affecting the ability of palliative care providers to support the difficult management of a serious illness, or even the end of life process, with compassion. When palliative care providers pursue drug diversion policies or other opioid control measures, it may cause the patient and the patient's family to feel that the providers are "prioritizing policing families over providing emotional, spiritual and physical support."¹⁶² This directly contradicts the goals of the care provider within the palliative care context.

¹⁵⁹ *Id.*

¹⁶⁰ *Id.*

¹⁶¹ *Id.*

¹⁶² *Id.*

C. CONTINUED INVESTIGATION INTO PAIN MANAGEMENT

Pain management, and its connection to opioid use, continues to receive attention from the federal government through its health agencies. Under a provision of the Affordable Care Act,¹⁶³ the Institute of Medicine (“IOM”), upon request from HHS and the National Institute of Health,¹⁶⁴ was charged with undertaking “a study to assess the state of the science regarding pain research, care, and education and to make recommendations to advance the field.”¹⁶⁵ In 2010, the IOM assembled a committee to study and assess pain management and research, producing a report entitled *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research* in 2011.¹⁶⁶ The IOM report provided a comprehensive analysis of pain and pain management, which continued and expanded the discussion surrounding opioid use as a pain management technique.¹⁶⁷

More recently, CARA established the creation of a task force for better pain management practices.¹⁶⁸ The resulting Pain Management Best Practices Inter-Agency Task Force (“Task Force”), comprised of 29 experts in areas of pain management, patient advocacy, substance abuse, and other related fields, was charged “to determine whether gaps in or inconsistencies between best practices for acute and chronic pain management exist and to propose updates and recommendations to those best practices.”¹⁶⁹ The Task Force prepared a *Draft Report on Pain Management Best Practices*,¹⁷⁰ to be delivered to Congress in 2019. Issued on December 28, 2018, the draft report was submitted for a 90-

¹⁶³ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 42 U.S.C. 18001 et seq. (2018).

¹⁶⁴ RELIEVING PAIN IN AMERICA, *supra* note 2, at 1. “Section 4305 of the 2010 Patient Protection and Affordable Care Act required the Secretary, Department of Health and Human Services (HHS), to enter into an agreement with the Institute of Medicine (IOM) for activities ‘to increase the recognition of pain as a significant public health problem in the United States.’” The resulting report was the conclusion of this charge. *Id.*

¹⁶⁵ *Id.*

¹⁶⁶ See RELIEVING PAIN IN AMERICA, *supra* note 2.

¹⁶⁷ PAIN MANAGEMENT AND THE OPIOID CRISIS, *supra* note 3, at 15.

¹⁶⁸ DRAFT REPORT, *supra* note 12.

¹⁶⁹ *Id.*

¹⁷⁰ *Id.*

day public comment period on December 31, 2018.¹⁷¹ As the final comment period ended on April 1, 2019, the draft report is currently in the process of being compiled into a Final Report to be submitted to Congress in the coming months.¹⁷²

Further, the FDA requested that the National Academies of Sciences, Engineering, and Medicine establish a committee to look further into pain management in 2016, with a focus on opioid use.¹⁷³ Specifically, this committee was charged with providing an update on the science of pain and pain management since the 2011 release of the IOM report *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*, with a focus on the role of opioids in pain management.¹⁷⁴ This report, *Pain Management and the Opioid Crisis*, included a number of recommendations to advance research on pain and opioid use disorder, improve data reporting on these topics, and incorporate public health considerations into opioid-related regulatory decisions.¹⁷⁵ The report states that despite recent regulatory efforts and a decrease in the overall number of overdose deaths from prescription opioids from 2011 to 2015, there is still serious concern over opioid use in the United States.¹⁷⁶

Despite the work on elucidating standards and studying pain management by various bodies and agencies as briefly described above, there is still a large concern over appropriate and effective pain management.¹⁷⁷ Notably absent from the efforts to continue research in pain management is a

¹⁷¹ Dep't. of Health & Human Servs., Request for Public Comments on the Pain Management Best Practices Inter-Agency Task Force Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations, FED. REGISTER (Dec. 31, 2018), available at <https://www.federalregister.gov/documents/2018/12/31/2018-28403/request-for-public-comments-on-the-pain-management-best-practices-inter-agency-task-force-draft>.

¹⁷² *Id.*

¹⁷³ PAIN MANAGEMENT AND THE OPIOID CRISIS, *supra* note 3, at 1. In addition, the committee was asked to characterize the epidemiology and strategies for fighting the opioid epidemic, identify actions that the FDA and other agencies should be taking, and identify any research questions that would assist the FDA in its response. The 2017 report followed the launch of the FDA's Opioid Action Plan in early 2016, which specifically called for an assessment of the agency's behavior over opioid approval and monitoring. *Id.*

¹⁷⁴ *Id.* at 2.

¹⁷⁵ *Id.* at 5–7.

¹⁷⁶ *Id.* at 2.

¹⁷⁷ See Robenzniek, *supra* note 120.

similarly robust investigation into pain management in the palliative care context, and specifically, opioid treatment for pain management in palliative care. As this paper will conclude, this lack of research into this area is a significant gap in efforts to mitigate the unintended consequences on palliative care which emerged from the opioid epidemic directives.

V. CONCLUSION

The consequences of the policy directives which emerged to fight the opioid epidemic have had a significant and long-lasting effect on palliative care. Specifically, the policies enacted in light of concerns over the opioid epidemic and the general disapproval of opioid use in the medical community based on these policies have affected how palliative care has been able to utilize opioids. “The current regulatory climate and public fear that surrounds opioids could restrict the ability of [palliative care providers]— ... and their patients have begun to experience the spillover effects and unintended consequences.”¹⁷⁸ Unless the federal government addresses this concern through direct legislation or administrative action— both the tangible limits on accessibility of drugs, as well as the overall stigma against opioid use within the medical community and federal government policies on opioids— patients in palliative care will continue to be negatively affected by the opioid epidemic policy directives.

While palliative care has been exempted from many laws and practice guides, these exemptions have not stopped opioid regulation from affecting the provision of care in the palliative and hospice care contexts. “Although hospices have been exempt – on paper – from the recent slew of opioid prescription limits and policies, the regulatory climate and the variation in state and local policies may make it challenging for hospice providers to determine how to best respond to the opioid crisis.”¹⁷⁹

¹⁷⁸ Fehlberg et al., *supra* note 76.

¹⁷⁹ *Id.*

Further, it has made it difficult for palliative care providers to offer the most robust care for their patients, if that care includes opioid medication— whether that difficulty comes from the access of the opioids themselves, or due to the pervasive fear and reluctance to prescribe opioids.

Moving forward, it is imperative that opioid epidemic policy directives no longer provide a barrier to care in the palliative context. One pragmatic way to eliminate this barrier is continuing education for palliative care providers and hospice workers on appropriate use in opioid prescriptions for palliative care. As discussed above, policies enacted as a result of the opioid epidemic, such as drug diversion policies, have affected the ability of palliative care providers to create the compassionate and supportive environment that is central to the goals of palliative care.¹⁸⁰ Education for medical professionals in this field focused on incorporating the policy directives generated by the opioid epidemic in limiting opioid abuse, while maintaining the goals of palliative care in general, could result in better care; “to better support hospice providers, explicit guidance surrounding the ‘appropriateness’ and ‘misuse’ of opioids in end-of-life care should be explored because these terms may require different, explicit definitions among dying patients.”¹⁸¹

Further, this paper suggests that in order to better incorporate the policy directives responsive to the opioid epidemic into palliative care without causing undue harm, a thorough research study should be conducted on the subject of opioid use in palliative care. While palliative care guides generally include some brief information on the use of opioids,¹⁸² it is not enough to appropriately mitigate the current effects the palliative care community is experiencing due to overall opioid restrictions. Instead, a comprehensive study and guidance report, such as the one published by the CDC on opioid use for chronic pain, would provide better guidance on opioid use in this context.¹⁸³

¹⁸⁰ See *infra* Part IV.B.

¹⁸¹ *Id.*

¹⁸² See NCHPC, *supra* note 69.

¹⁸³ See text at notes 59–67.

A practice guide or comprehensive study on opioids within palliative care will allow palliative care providers to better understand how the opioid epidemic policy directives may be affecting the palliative care community, and thus better respond to these policy directives.

On a more fundamental level, the federal government must contemplate the effects of opioid regulation on the palliative care community. This rests on an understanding that pain management fundamentally differs for chronic pain and palliative care, and that policies enacted to address pain management in one setting will have an effect on the other. While a full legislative reform is beyond the contemplation of this paper, the motivation for a reform stems from the same incompatibility of opioid epidemic policy directives in palliative care which this paper discusses. Rather than simply exempting palliative care from opioid use regulation, the federal government must take a further step in acknowledge how pain management legislation and regulations for opioids will affect the provision of palliative care— whether or not palliative care patients are exempted from legislation or practice guides.