



# Prescription Drug Abuse and Pain Management Clinics

2023 Report to the 113<sup>th</sup> Tennessee General Assembly

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## Introduction

In recent years, the number of deaths in Tennessee caused by drug overdose has been higher than the number of deaths caused by motor vehicle accidents. In fact, in 2021, 3,814 people died of a drug overdose in Tennessee with the Tennessee Highway Patrol reporting 1,280 traffic accident deaths during the same year. According to the Centers for Disease Control and Prevention's National Center for Health Statistics the average life expectancy in the U.S. has been on decline for three consecutive years; one of the leading factors contributing to this decline is a rise in drug overdoses.<sup>1</sup>

In 2012, the legislature enacted the Prescription Safety Act. One requirement of the Act is that, effective April 1, 2013, practitioners who prescribe certain controlled substances must query the Controlled Substance Monitoring Database (CSMD) prior to issuing a new prescription to a patient and at least annually thereafter. See Tenn. Code Ann. § 53-10-310(e)(1). The purpose of the requirement is to allow practitioners to identify patients who may have a substance abuse problem and/or who may be doctor shopping (i.e., going to different doctors for treatment and obtaining prescriptions from each one).

Since the passage of the Prescription Safety Act of 2012, utilization of the database has significantly increased, and the prescription of opioids and benzodiazepines has decreased over that same time period. In 2016, an updated Prescription Safety Act passed which, among other changes, added the requirement that dispensers check the database the first time a patient is dispensed a substance at that practice site and at least annually thereafter. This assists pharmacists in their treatment of patients through acting as a check in the event a prescriber is unaware of a problem.

In July 2018, the General Assembly enacted Public Chapter 1039 which placed reasonable limits on the amount and duration of opioids used for acute pain. See Tenn. Code Ann. § 63-1-164. It limits opioid prescriptions to up to a three-day supply with a total of 180 MME (morphine milligram equivalents). This chapter preserved clinical judgement and the patient- prescriber relationship by providing several exceptions under certain circumstances. Some of the exemptions include patients who are seeing a pain management specialist, patients receiving active cancer treatment, patients who are undergoing palliative care treatment, patients receiving hospice care, patients with a diagnosis of sickle cell disease, and patients receiving opioids in a licensed facility.

In 2019, the legislature made a variety of small changes and additions to the TN Together opioid initiative. Among the changes were the inclusion of definitions for the terms palliative care, severe burn, and major physical trauma. Palliative care was added as an exception to the opioid dosage limits otherwise required under TN Together. The new legislation also made partial filling of opioids permissive. Finally, the opioid limits from the original act were simplified. Instances such as more than minimally invasive surgery, which previously fell under a twenty-day provision, were changed to be treated under the limits of the thirty- day category.

<sup>1</sup> Arias, Elizabeth, Betzaida Tejada-Vera, Kenneth D. Kochanek, and Farida B. Ahmad. "Provisional life expectancy estimates for 2021." (2022) (available at <https://www.cdc.gov/nchs/data/vsrr/vsrr023.pdf>).

## Pain Management Clinic Licensure

Prior to the Prescription Safety Act of 2012, the General Assembly passed legislation in 2011 regulating pain clinics and requiring that all pain management clinics register with the state. Tenn. Code Ann. § 63-1-301 et seq. This legislation created a certification process for pain management clinics and required that each clinic's owner register with the state to receive a certificate. Each clinic was required to have a medical director who met certain educational and training requirements. Effective July 1, 2016, medical directors of pain management clinics were required by Public Chapter 475 of the 109th General Assembly to meet the definition of a pain management specialist. In addition, all advanced practice registered nurses and physician assistants working in pain clinics must be supervised by pain management specialists.

Beginning July 1, 2017, all pain management clinics were required to become licensed Tenn. Code Ann. 63-1-301. All active pain management clinics have been issued a license; there are no longer any active pain management clinics operating on a certificate. The licensure requirements are more stringent than those of registration for a certificate and the Department has promulgated new rules to govern the process of regulating the licensed clinics. Each pain management clinic license is issued for a period of two (2) years and must be renewed biennially. Prior to issuing an applicant a clinic license, the Department must inspect the clinic. The Department also conducts clinic inspections as part of the biennial renewal process.

The Pain Management Clinic Act requires the medical director of a pain management clinic to be on-site at the clinic at least 20% of the clinic's weekly operating hours and prohibits the medical director from serving in that capacity at more than four (4) pain clinics. It also requires the medical director, rather than the clinic's owner, to be the license-holder. Previously, medical directors were not required to be the certificate-holder. Requiring the medical director to be the individual who applies for and is responsible for the license gives medical directors both more authority over and responsibility for what happens under their watch at a clinic.

Additionally, the law requires the Department to inspect every pain management clinic before licensure. The Department may deny licensure, or discipline an existing license, if anyone working in the clinic has been convicted for an offense involving the sale, diversion, or dispensing of controlled substances, has been disciplined for conduct that was the result of inappropriate prescribing, dispensing, or administering controlled substances, or has had their license restricted, or if an owner of the clinic has pleaded to or been convicted of a felony. *See* T.C.A. § 63-1-316.

Prior to July 1, 2017, random clinic inspections were not required by law. Since its passage, the Department has conducted random inspections as a best practice. Random inspections allow the Department to obtain a completed and unobscured view of the day-to-day operations of each clinic. Prior to July 1, 2017, the Department randomly inspected one third of certified pain clinics each year. Since July 2017, the Department has conducted unannounced inspections both as part of the initial license application process and during the biennial license renewal period. If the Department has concerns about its findings during an inspection, it may also conduct an unannounced reinspection at a later date.

During the 2022 calendar year:

- Forty-one (41) licensure inspections were conducted.
- Fifty-five (55) biennial licensure inspections were conducted.
- One (1) pain clinic was granted a conditional license.
- Fourteen (14) applications for licensure were granted.
- Three (3) clinics had disciplinary action taken.
- Zero (0) applications for licensure were denied.
- Zero (0) clinic licenses were revoked or surrendered.

### **Pain Clinic License Renewal**

Pain management clinic licenses are active for two (2) years. There was a total of fifty-eight (58) pain clinic licenses set to expire in 2022; fifteen (15) of those clinics have closed and are no longer operating; licensure renewal has been granted for the remaining forty-three (43).

### **Licensed Pain Management Clinics**

| <b>County</b> | <b># of Clinics</b> |
|---------------|---------------------|
| Knox          | 15                  |
| Davidson      | 14                  |
| Rutherford    | 9                   |
| Bradley       | 7                   |
| Hamilton      | 7                   |
| Shelby        | 7                   |

As of December 2022

**Source – Tennessee Department of Health**

Total number of active licensed clinics: 114

## **Practice Guidelines and Rules for Treatment of Chronic Pain**

In 2013, and as part of the Addison Sharp Prescription Regulatory Act, Tenn. Code Ann. 63-1-401 *et seq.*, the General Assembly directed the Department to create treatment guidelines for prescribing of opioids, benzodiazepines, and other drugs to be used by Tennessee practitioners in caring for patients. Under this mandate, the Department published the Tennessee Chronic Pain Guidelines. The Chronic Pain Guidelines were developed to provide chronic pain treatment guidance to practitioners who are not pain specialists or do not practice within a pain management clinic.

These guidelines were developed under the oversight of an advisory committee composed of clinicians with specialty training in a variety of fields, including pain medicine. The Department formulated these guidelines based on a review of national expert panel recommendations and state practice guidelines, as well as multiple listening sessions with clinicians throughout Tennessee. The guidelines are updated as necessary with additional input from the chronic pain guidelines committee and have been adopted by the various prescribing health related boards.

The 3<sup>rd</sup> edition – Text Revised of the Chronic Pain Guidelines was completed by the Chronic Pain Guidelines Expert Panel in 2019 and published in January 2020. The guidelines can be found at: <https://www.tn.gov/content/dam/tn/health/healthprofboards/pain-management-clinic/ChronicPainGuidelines.pdf>.

Additionally, the pain clinic rules and FAQ information, are also posted to the Department's Pain Management Clinic website to give practitioners information they need to understand and comply with the licensure process. This information can be found at: <https://www.tn.gov/health/health-program-areas/health-professional-boards/pm-board.html>

## High Risk Controlled Substance Prescribers

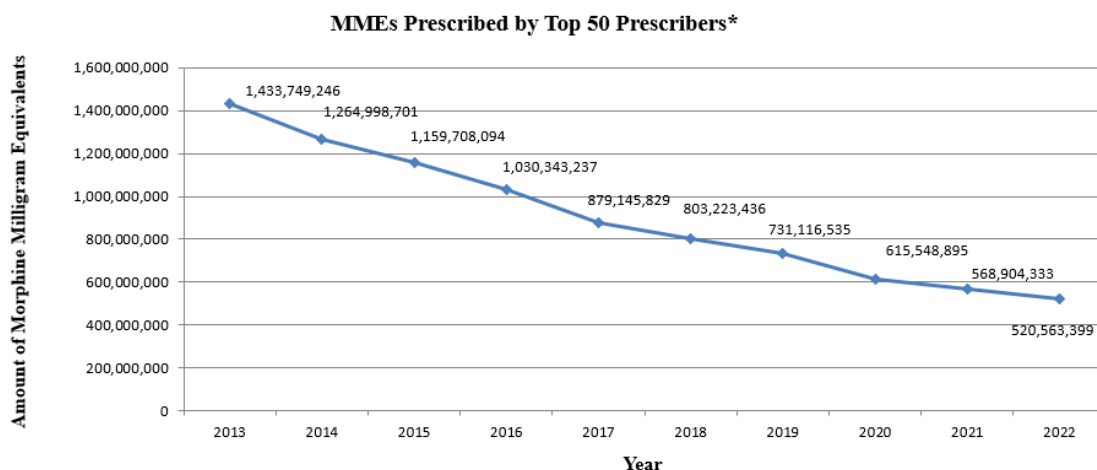
Tenn. Code Ann. § 68-1-128 requires the Department to identify and notify high-risk prescribers based on clinical outcomes, including patient overdoses. In July of 2022, the Department sent letters to the top ten (10) providers identified by the Department as high-risk based on prescribing data contained in the Controlled Substance Monitoring Database (CSMD). These letters informed the recipients to take the following remedial actions:

- Complete continuing education covering the risks, complications, and consequences of opioid addiction.
- Make educational material available in waiting rooms and other clinic areas accessible to patients that informs patients of the risks, complications, and consequences of opioid addiction.
- Obtain written consent from every patient who will receive opioid therapy for more than three (3) weeks with daily dosages of sixty (60) morphine milligram equivalents (MME) or higher that explains the risks of, complications of, medical and physical alternatives to, and consequences of opioid therapy and addiction.

High-risk prescribers are required to comply with these requirements for a period of one (1) year.

### Top 50 Prescribers

As required by Tenn. Code Ann. § 68-1-128, the Department must also identify and contact the top fifty (50) prescribers of controlled substances in the state. The Department identifies the top fifty (50) prescribers based on the total morphine milligram equivalent dosages (MME) they prescribed in the previous calendar year as reported in the CSMD. Once notified of their appearance on the list, these prescribers are required to respond to Department inquiries and provide justification for their prescribing practices. The medical director's team, along with the Office of General Counsel, reviews the data on the top 50 prescribing practitioners in Tennessee and uses that data to assist in identifying practitioners of concern as well as in educating practitioners. The total morphine equivalence prescribed in aggregate by the Top 50 prescribers has decreased each year since 2013. The MMEs prescribed by this group have decreased approximately 64% since the first analysis performed on data from 04/01/2012 – 03/31/2013, as noted in the line graph below:



\*MME in 2013 and 2014 covered 12-month opioid prescriptions written by the top 50 prescribers from April 1 of preceding year to March 31 of current year; MME in 2015 - 2022 covered opioid prescriptions filled by the patients of the top 50 prescribers in each preceding calendar year.

Despite the increasing death rate, analysis of the Controlled Substance Monitoring Database shows that progress has been made in many areas. The number of opioid prescriptions for pain has declined by 35.7% between 2016 and 2020. From 2013 through 2015, opioid prescriptions numbered around 2 million per quarter (representing a crude rate of about 300 – 325 prescriptions per 1000 residents). Opioid prescriptions for pain have fallen to 1.26 million filled prescriptions in Q4 2020 (a rate of 184 per 1,000 residents). While prescriptions declined quarter over quarter for most of this period, they increased from Q2 2020 to Q3 2020. This unusual trend is likely a result of the COVID-19 pandemic's effects on prescribing patterns. [Prescription Drug Overdose Program: 2021Report.](#)

The prescription rate for the top three most prescribed opioids for pain prescriptions in TN has generally declined from 2016 to 2020. Hydrocodone prescribing rates have dropped steadily for most of the period from a high of 133 per 1,000 residents in Q1 2016 to 79 per 1,000 residents in Q4 2020. Prescription rates for oxycodone decreased from 84 per 1,000 residents in Q1 2016 to 58 per 1,000 residents in Q4 2020. Tramadol prescriptions decreased from a rate of 37 per 1,000 residents in Q1 2016 to 28 per 1,000 residents in Q4 2020. [Prescription Drug Overdose Program: 2021Report.](#)

There has been a 91.8% decrease in potential doctor/pharmacy shopping (defined for the patients who filled controlled substance prescriptions obtained from 5 or more different prescribers at 5 or more dispensers within 3 months) from 2015 through 2022. Morphine Milligram Equivalent (MME) prescribed and dispensed to Tennessee patients has decreased 60.1% from 2015 to 2022.

### **Conclusion**

The Department is working diligently to protect the people of Tennessee from the devastating effects of prescription drug abuse. Our goal is to ensure that the citizens of the State of Tennessee have access to the highest-quality pain management services. In collaboration with health care experts, dispensers, and prescribers, we have continued our efforts to provide strict but focused and evidence-based regulation in order to reduce the number of patients adversely affected by inappropriate prescribing and dispensing of controlled substances.



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