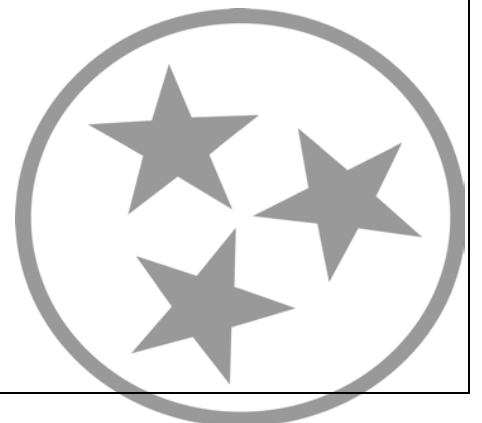


Prescription Drug Abuse and Pain Management Clinics

2022 Report to the 113th Tennessee General Assembly

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Contents

Introduction.....	1
Pain Management Clinic Licensure.....	2
High Risk Controlled Substance Providers.....	5
Conclusion.....	6

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 2019, 2,089 people died of a drug overdose in Tennessee, compared to 1,818 in 2018. 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 factors that contributes to this decline is a rise in drug overdoses.

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. 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 a requirement for the dispensers check the database the first time a patient was dispensed a substance at that practice site and again annually. 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, reasonable limits on the amount and duration of opioids used for acute pain. It limits opioid prescriptions to up to a three-day supply with a total of 180 MME (morphine milligram equivalents). Clinical judgement and the patient- prescriber relationship was preserved by providing several exceptions under certain circumstances. Some of the exemptions include patients seeing a pain management specialist, patients receiving active cancer treatment, patients who are undergoing a 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.

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 not any active pain management clinics operating on a certificate. The licensure requirements are more stringent than those of registration for a certificate, and new rules have been promulgated by the Department to govern the process of regulating the licensed clinics.

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 be the license holder. Previously, medical directors were not required to be the owner/certificate-holder and many certified clinics were owned by an advanced practice registered nurse or a physician assistant. Requiring the medical director to be the individual who applies for and is responsible for the license, gives medical directors both more power and control over what happens under their watch at a clinic, as well as more responsibility. 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. T.C.A. § 63-1-316.

Furthermore, though licensure inspections are now required, random clinic inspections had not been required by law prior to July 1, 2017; however, random inspections have been undertaken by the Department as a best practice. Prior to July 1, 2017, the Department randomly inspected one third of certified pain clinics each year. After July 2017, when the law was amended to require clinics to be licensed, and through the calendar year 2019, unannounced inspections have occurred pursuant to a licensure application instead of as previously conducted.

During the 2021 calendar year:

- Thirty-five (35) licensure inspections were conducted.
- Twenty-eight (28) biennial licensure inspections were conducted.
- Nine (9) pain clinics were granted conditional licenses.
- Fourteen (14) applications for licensure were granted.
- 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 forty-two (42) pain clinic licenses set to expire in 2021; twelve (12) of those clinics have closed and are no longer operating, licensure renewal has been granted for the remaining thirty (30).

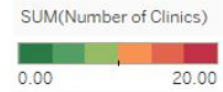
Licensed Pain Management Clinics



County	# of Clinics
Knox	17
Davidson	16
Rutherford	9

As of December 2021

Source – Tennessee Department of Health



Tennessee Pain Management Clinic Rules and Guidelines

In order to promulgate rules governing the new licensure process, the Department formed a task force of members of the Board of Medical Examiners, the Board of Osteopathic Examination, the Physician Assistant Committee, and the Board of Nursing. In December of 2016, the task force met to review a proposed draft of the rules and heard and responded to public comment. After incorporating much of the feedback from the task force and the public, the Department promulgated emergency rules in May of 2017, and held a rulemaking hearing in July of 2017 to hear public comment on those rules becoming permanent. After a lengthy public hearing and passage of a period for written comment, the updated, permanent rules became effective in November of 2017.

The pain clinic rules, the FAQ information, and pain clinic guidelines posted to the Department's Pain Management Clinic website give practitioners information they need to understand and comply with the new licensure process.

The Pain Clinic Guidelines: https://www.tn.gov/content/dam/tn/health/healthprofboards/pain-management-clinic/Pain_Clinic_Guidelines.pdf

FAQ Information: https://www.tn.gov/content/dam/tn/health/healthprofboards/pain-management-clinic/Pain_Clinic_FAQ.pdf

Practice Guidelines for Treatment of Chronic Pain

In response to the legislation passed by the General Assembly, in 2012 the Department created the position of medical director of special projects, whose duties include facilitating the creation and review of guidelines for prescribing opioids, benzodiazepines, barbiturates, and carisoprodol as required by T.C.A. § 63-1-401 *et seq.* 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. The Chronic Pain Guidelines were developed to provide guidance in treating chronic pain by practitioners who are not pain specialist or do not practice within a pain management clinic. The guidelines have been updated as needed with additional input from the chronic pain guidelines committee and have been adopted by the various prescribing health related boards.

The 3rd. edition of the Chronic Pain Guidelines was completed by the Chronic Pain Guidelines Expert Panel in 2018 and posted in January 2019. The guidelines and those who gave of their time and expertise to make the guidelines a reality can be found at:

<https://www.tn.gov/content/dam/tn/health/healthprofboards/pain-management-clinic/ChronicPainGuidelines.pdf>

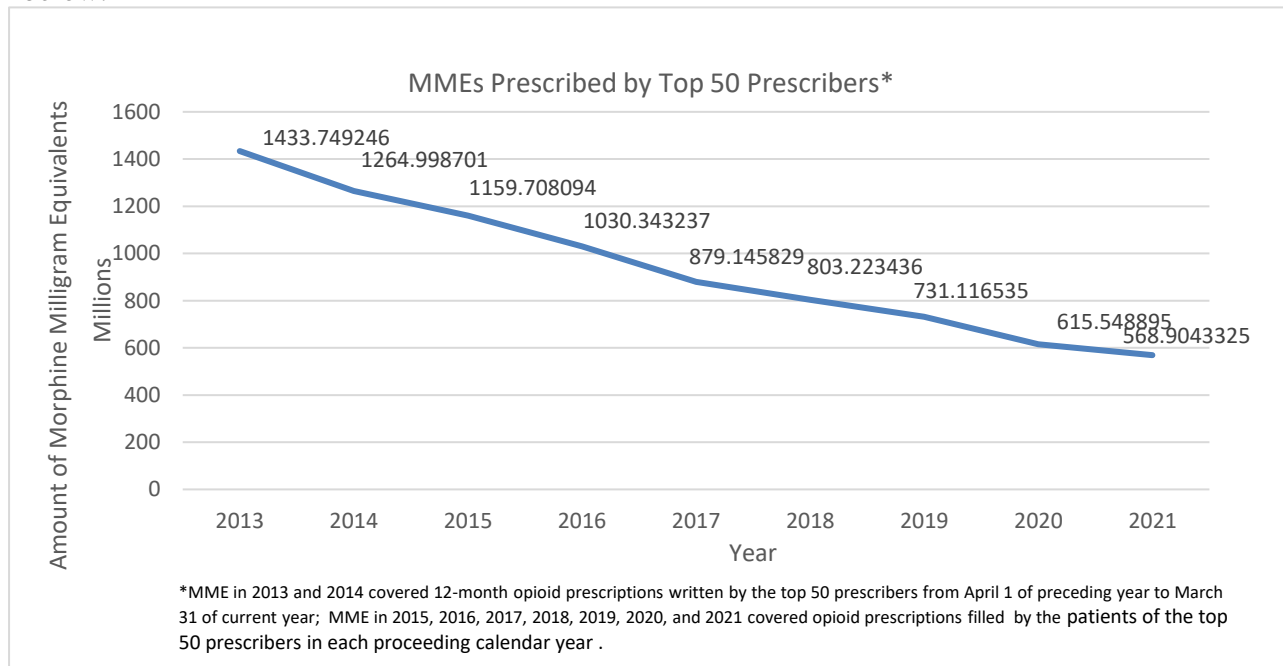
High Risk Controlled Substance Prescribers

Tenn. Code Ann. §68-1-128 requires the Department to identify and notify high-risk prescribers based on clinical outcomes, including patient overdoses. In August of 2021, letters were sent 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) to inform them to take the following remedial actions:

- Required to complete continuing education designed about the risks, complications, and consequences of opioid addiction.
- Make educational material available in waiting room and clinic areas accessible to patients that warn 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. The 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 notify the top fifty (50) prescribers of controlled substances in the state. 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 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 declined 60% since the first analysis performed on data from 04/01/2012 – 03/31/2013 as noted in the line graph below.



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 93.1% decrease in potential doctor/pharmacy shopping (defined for these purposes as visiting five or more prescribers or dispensers in a three-month period) from 2013 through 2021. Morphine Milligram Equivalent (MME) prescribed and dispensed to patients in Tennessee has decreased almost 57% from 2012 to 2020.).

Conclusion

The Department is working diligently to protect the people of Tennessee from the effects of prescription drug abuse. Our goal for the citizens of the State of Tennessee is to provide access to quality pain management. In collaboration with health care experts, dispensers and prescribers, we attempted to provide stricter regulations for practitioners to reduce the number of patients being adversely affected by inappropriate prescribing and dispensing.



**Pain Management Clinic Licensure
665 Mainstream Drive, 2nd Floor
Nashville, Tennessee 37243**

