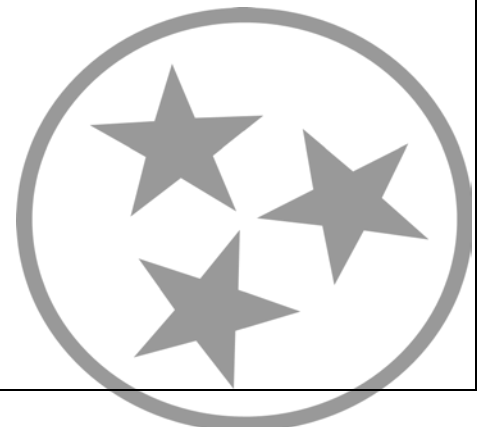




Prescription Drug Abuse and Pain Management Clinics

2021 Report to the 112th 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 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, the General Assembly enacted Public Chapter 1039 which placed 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.

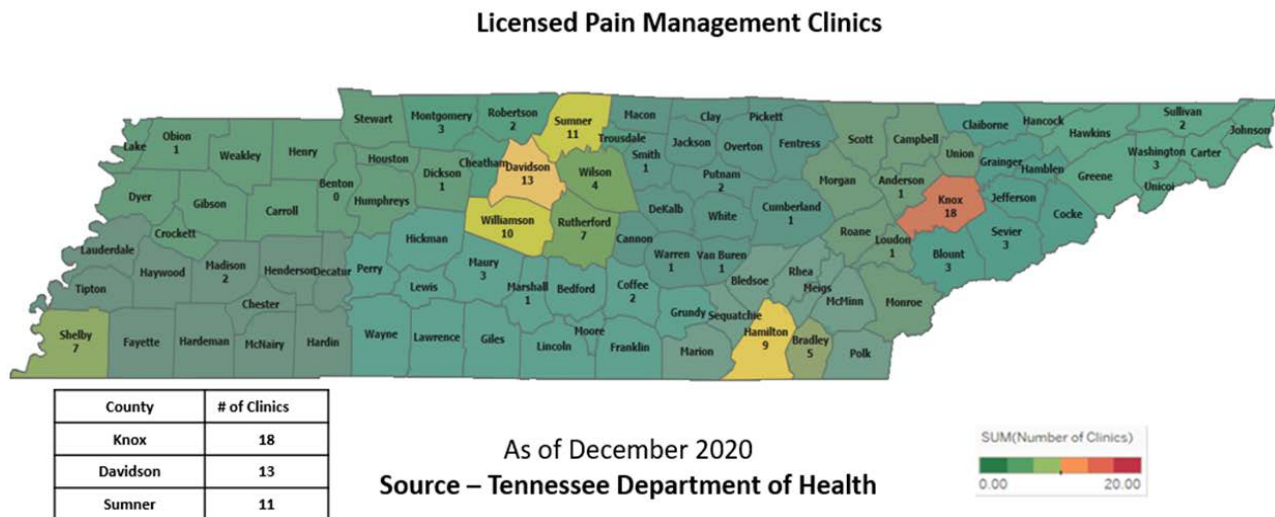
Furthermore, though licensure inspections are now required, random clinic inspections had not been required by law prior to July 1, 2017; however, random inspections have been undertaken by the Department as a best practice. Prior to July 1, 2017, the Department randomly inspected one third of certified 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 2020 calendar year:

- Thirty-five (35) licensure inspections were conducted. Due to the pandemic, inspections were suspended resulting in the decrease from sixty-two (62) in 2019 to thirty-five (35) in 2020.
- Twenty-eight (28) biennial licensure inspections were conducted.
- Zero (0) applications for licensure were denied.
- Three (3) pain clinics were granted conditional licenses.
- Zero (0) clinic license was revoked or surrendered.

Pain Clinic License Renewal

Pain management clinic licenses are active for two (2) years. The fall of 2019 was the beginning of the renewal cycle for licensed pain management clinics. There was a total of sixty-six (66) pain clinic licenses set to expire in 2020; nineteen (19) of those clinics have closed and are no longer operating, forty-two (42) have been renewed and five (5) renewal applications remain in a pending status and are awaiting deficient documentation for the application to be reviewed.



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.* The medical director of special projects has traveled throughout the state discussing pain management with practitioners and getting feedback for consideration in developing courses for the upcoming year Opioid symposia.

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 method used to formulate these guidelines included a review of national expert panel recommendations and state practice guidelines, multiple listening sessions with clinicians in Tennessee, oversight by a chronic pain guidelines committee and recommendations from an advisory committee with strong representation by clinicians with specialty training in a variety of fields including pain medicine. The guidelines have been updated each year 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>

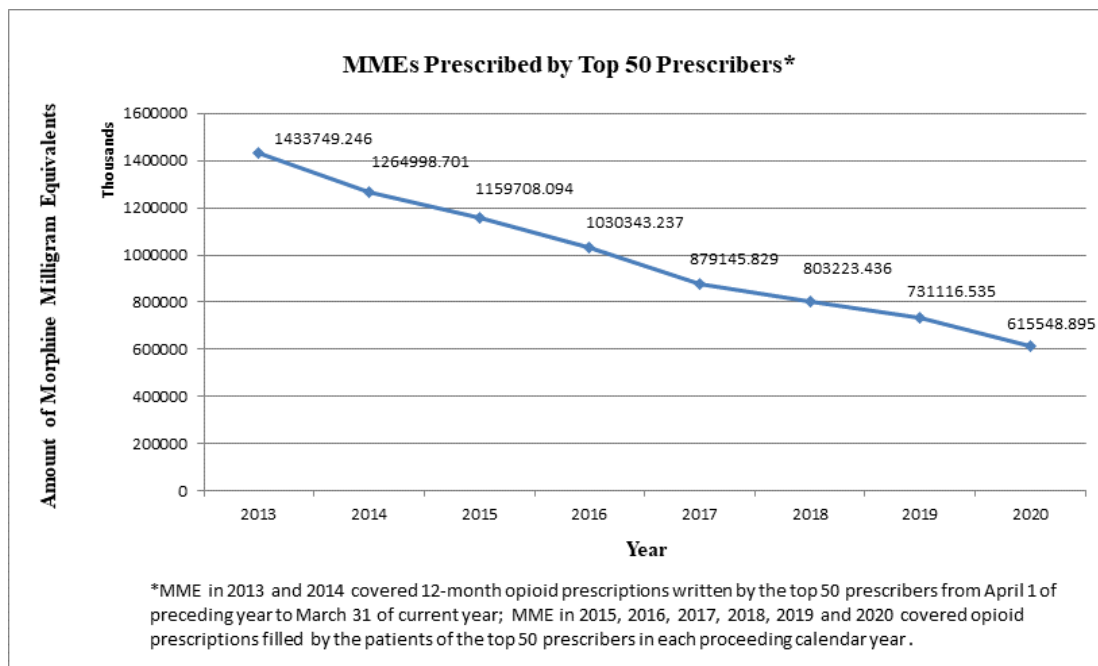
High Risk Controlled Substance Prescribers

Tenn. Code Ann. §68-1-128 requires the Department to identify and notify high-risk prescribers based on clinical outcomes, including patient overdoses. In July of 2020, 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 57% since the first analysis perform 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 has declined by 43% between 2012 and 2019. From 2013 through 2015, opioid prescriptions numbered around 2 million per quarter (representing a crude rate of about 300 – 325 prescriptions per 1000 residents).

After Q4 2019, opioid prescriptions for pain have declined in each quarter, down to just over 1.3 million (189 per 1,000). In 2019, about 73% of patients who filled prescriptions of opioids for pain had active prescriptions for only a month or less during the entire year. In 2020, as in many previous years, the top three most prescribed controlled substances in Tennessee were hydrocodone products (e.g., Lortab, Lorcet, Vicodin, gabapentin, and oxycodone products (e.g., OxyContin, Roxicodone). Prescription Drug Overdose Program: 2019 Report.

There has been an 92% decrease in doctor/pharmacy shopping (defined for these purposes as visiting five or more prescribers or dispensers in a three-month period) from 2013 through 2018. The amount of MME's (morphine milligram equivalents) dispensed per capita from 2012 to 2020 decreased for every county across the state, with an approximate 57% decrease statewide in opioid MME's dispensed from 2012 to 2019.

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.



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