

Prescription Drug Abuse and
Pain Management Clinics
2019 Report to the 111th Tennessee General Assembly



Tennessee Department of Health
Health Licensure and Regulation
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Executive Summary

Background

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 2017, 1,776 people died of a drug overdose in Tennessee, compared to 1,631 in 2016.** Although the proportion of drug deaths associated with opioids was approximately the same in 2017 (71%), this number includes illicit drugs. Nationwide, the proportion of deaths categorized by the CDC as associated with opioid pain relievers decreased from 45% to 36% in 2017.

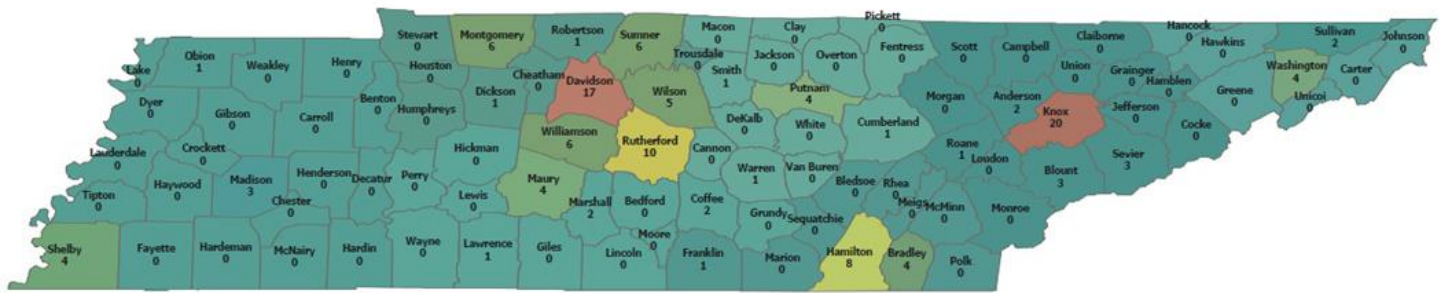
In 2012, the legislature enacted the Prescription Safety Act. One requirement of the Act is that, effective April 1, 2013, practitioners who prescribe certain controlled substances must query the Controlled Substance Monitoring Database (CSMD) prior to issuing a new prescription to a patient and at least 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 that dispensers check the database when filling a prescription for a new patient for certain controlled substances, and annually thereafter. *Tenn. Code Ann. § 53-10-310(e)(2)*. 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 a number of exceptions under certain circumstances.

Pain Clinic Certification and 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.* Further amendment to the pain clinic laws in 2015 and 2016 provided assurance that only qualified medical professionals (“pain management specialists”) act as medical directors for the clinics.

In 2015, prior to those amendments to the pain management clinic laws, over 300 pain management clinics were registered in Tennessee, equating to approximately one clinic per 21,000 Tennesseans. Following changes to the pain clinic laws in 2015 and 2016, the number of registered pain management clinics was reduced to 126 clinics by December of 2018. In a situation closely monitored by the Department, the closure of a large chain pain clinic practice was potentially a threat to the well-being of Tennessee residents. However, these clinics were acquired by other pain specialists to ensure that Tennesseans continued to receive the care they needed.



County	# of clinics
Knox	20
Davidson	17
Rutherford	10

As of January 29, 2019



Source – Tennessee Department of Health

Beginning July 1, 2017 all pain management clinics were required to become licensed. Those operating under an existing certificate may continue to operate on the certificate until its expiration but must become licensed upon the certificate’s expiration. 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.

Practice Guidelines for Treatment and Pain Management Clinics

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 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 multidisciplinary steering committee and recommendations from an advisory committee with strong representation by clinicians with specialty training in a variety of fields including pain medicine. Draft clinical guidelines were also circulated to a broader group of professional associations within Tennessee, including but not limited to mental health and substance abuse and workers’ compensation programs. The guidelines have been updated each year with additional input from the multidisciplinary advisory group and have been adopted by the various prescribing health related boards. Additionally in 2015 the statute was amended to direct the Department to create pain clinic guidelines. These were promulgated at the commencement of 2017 and have been revisited since, including at a public hearing led by the Department’s Chief Medical Officer to receive input from any members of the public who wished to make comment.

Prosecution of Prescribing Cases

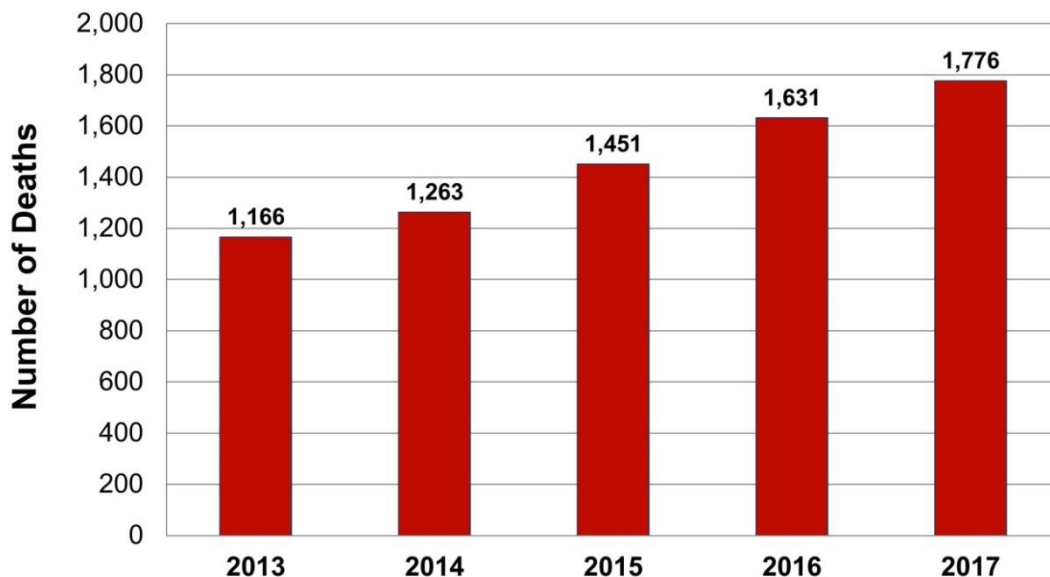
The Department's Division of Health Licensure and Regulation, Office of General Counsel (OGC) has assigned several of its attorneys to a team that focuses on review and prosecution of cases involving inappropriate prescribing, overprescribing, and pain management clinics. The team handles the overprescribing cases for all of the disciplines in which practitioners have the authority to prescribe controlled substances. The team ensures that cases are presented to the respective boards in a fair and consistent manner with special expertise, which allows the boards to better protect the health and safety of the people of Tennessee.

2018 data reveals:

- The Office of Investigations received 98 complaints logged as related to overprescribing.
- The Office of Investigation received 5 complaints against pain management clinics.
- OGC received 18 new cases against practitioners for prosecution and 1 case against a pain management clinic.
- OGC closed 34 prescribing cases against practitioners with public discipline, including 12 cases resulting in the revocation, voluntary surrender, or suspension of the practitioner's license.

Prescription Drug Overdose in Tennessee

Drug Overdose Deaths in Tennessee, 2013-2017



Source: Tennessee Department of Health, Office of Informatics and Analytics

Under half (43%) of individuals who died of drug overdose had a controlled substance dispensed within 60 days of death, a decrease from 47% in 2016. This continues to suggest that other factors are playing a significant role in overdose deaths, including illicit fentanyl, heroin, and diverted prescription opioids.

The number of deaths in which fentanyl was involved increased 70%, from 294 to 500, and now account for 28% of drug overdose deaths. Heroin deaths increased 20%, from 260 to 311. Methadone deaths decreased 16%, from 82 to 69 and buprenorphine associated deaths increased only 6 percent, from 69 to 73 despite substantial increases in the number of buprenorphine patients throughout the state.

Benzodiazepines, such as alprazolam and diazepam, showed a 9.5% decrease in prescriptions from 2017 to 2018. For 2018, this class has seen a decline in prescribing and dispensing for people of all age groups.

The number of prescriptions for stimulants continued to increase, growing by 51% from 2010 to 2018. This trend has been seen in previous epidemics of opioid abuse and highlights the urgent need for timely identification and treatment of substance use disorder.

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 between 2013 and 2018. 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 Q3, 2015, opioid prescriptions for pain have declined in each quarter, down to just over 1.3 million (199 per 1,000). Every year, about 70% of patients who fill prescriptions of opioids for pain had active prescriptions for only a month or less during the entire year. In 2018, as in many previous years, the top three most prescribed controlled substances in Tennessee were hydrocodone products (e.g., Lortab, Lorcet, Vicodin), alprazolam (brand name Xanax), and oxycodone products (e.g., OxyContin, Roxicodone). *Prescription Drug Overdose Program: 2019 Report.*

There has been an 85% 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 2013 to 2018 decreased for every county across the state, with an approximate 43% decrease statewide in opioid MME's dispensed from 2012 to 2018.

New Licensure Process for Pain Management Clinics

In 2011, the General Assembly enacted Public Chapter 340, which created Tennessee Code Annotated § 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.

In 2016, the 109th General Assembly also enacted Public Chapter 1033, which required licensure of all pain management clinics beginning July 1, 2017. Although previous iterations of the Pain Management Clinic Act required the medical director be on-site at the clinic at least 20% of the clinic's weekly operating hours, and prohibited the medical director from serving in that capacity at more than 4 pain clinics, beginning July 1, 2017, the medical director must be the license-holder. While many medical directors were owner/certificate-holders, many certified clinics were owned by an advanced practice registered nurse or 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 licensure laws require 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. Those pain management clinics currently operating under an existing certificate may continue to operate on the certificate until its expiration; however, their certificate will operate as a license until its expiration, and they must become licensed upon the certificate's expiration. Following passage of these laws, the number of pain clinics in Tennessee was reduced from 333 in 2014 to 126 by the end of 2018.

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. Both the rules and the FAQ information posted to the Department's Pain Management Clinic website give practitioners information they need to understand and comply with the new licensure process. In July 2017, the Department added a part time physician who is certified in pain medicine to oversee the licensure process for pain clinics and to work directly with the director of special projects.

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. Subsequent to July 2017, when the law was amended to require clinics to be licensed, and through the calendar year 2018, unannounced inspections have occurred pursuant to a licensure application instead of as previously conducted.

During the 2018 calendar year:

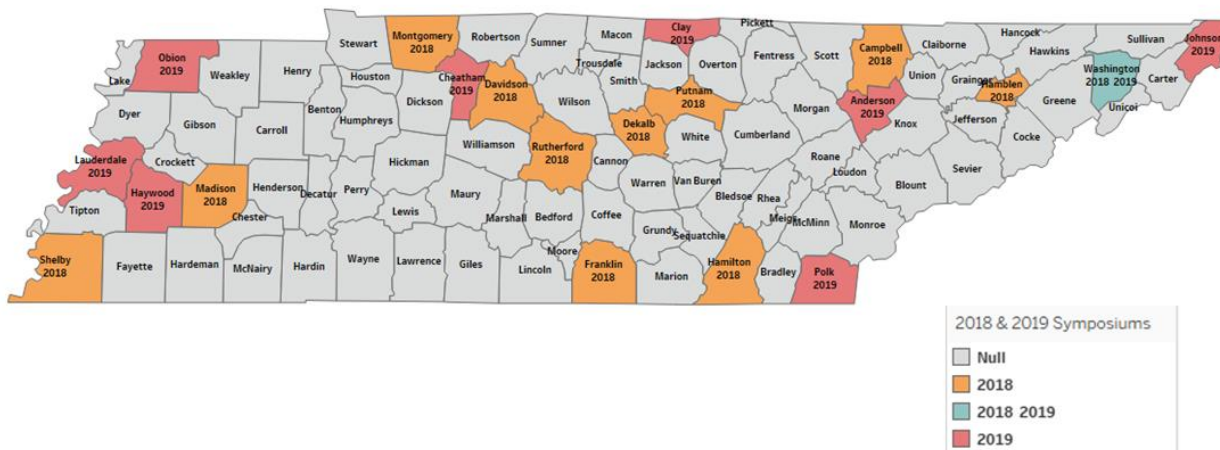
- One hundred ten (110) licensure inspections were conducted.

- Five (5) applications for licensure were denied.
- One (1) case against a pain clinic has been referred to the Office of General Counsel for prosecution.
- One (1) clinic license was revoked or surrendered.

Regulating the 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 on the chronic pain guidelines.

The audiences consisted of consumers, health care providers, law enforcement officers, drug enforcement officials, and attorneys. Programming included live audiences, live streaming, and archived efforts to reach all health care providers. The streaming and archived programs reached additional health care providers. Each of these educational opportunities allowed health care providers to earn Continuing Medical Education (CME) or other Continuing Education (CE) credits.



Version 3 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 are available at:

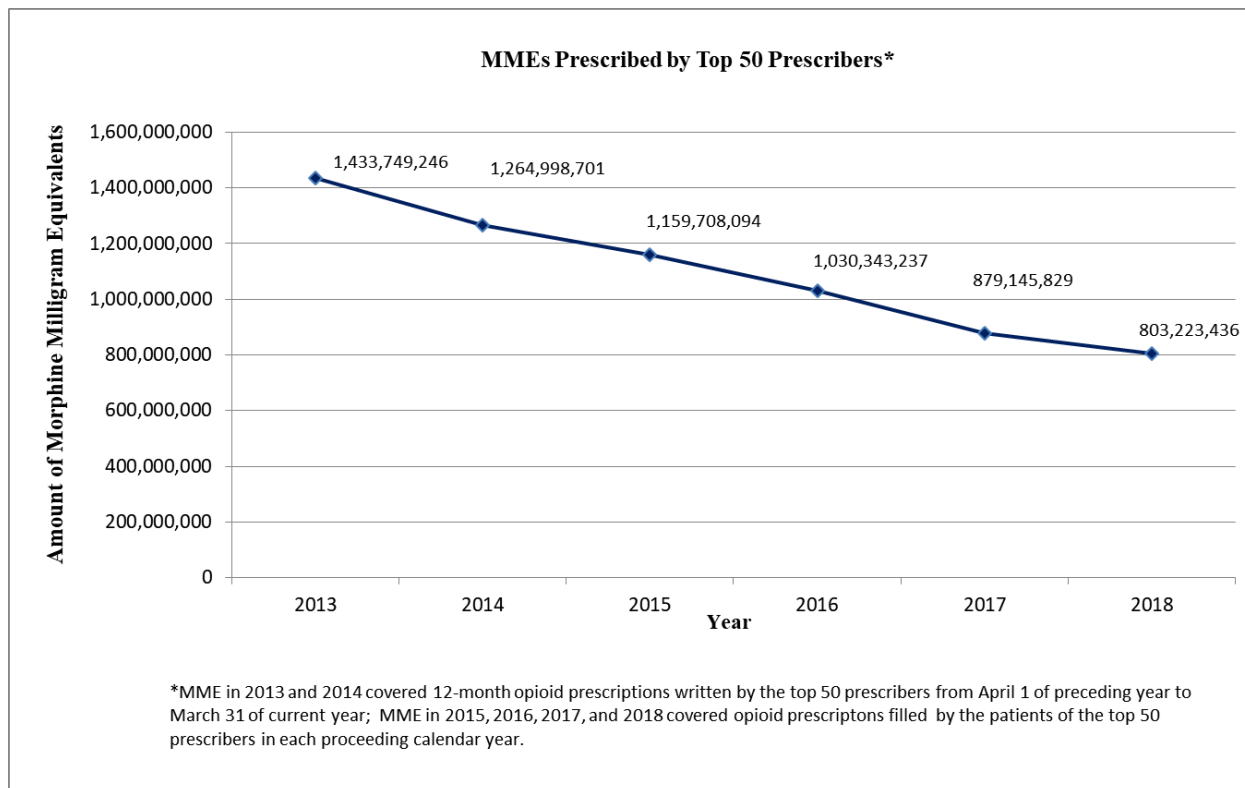
<https://www.tn.gov/content/dam/tn/health/healthprofboards/pain-management-clinic/Chronic%20Pain%20Guidelines%202019.pdf>

Pursuant to amendment to T.C.A. § 63-1-401 in 2015, the medical director of special projects, again with input from appropriate specialists in the industry, has also created guidelines for pain clinics.

The Pain Clinic Guidelines are available at the following URL:

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

Additionally in 2015 the Department added an advanced practice registered nurse to the medical director of special projects team who has joined him in his work to review and educate around the state. As required by *Tenn. Code Ann. § 68-1-128*, the medical director’s team, along with the Office of General Counsel, has reviewed data on the top 50 prescribing practitioners in Tennessee and has used 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. After five years of experience with the top 50 prescriber analysis, the MMEs prescribed by this group have declined 44% since the first analysis perform on data from 04/01/2012 – 03/31/2013 as noted in the line graph below.



Enforcement

In addition to the Department’s creation of the position of medical director of special projects, the Department’s Office of General Counsel created a team (the “prescribing team”) that focuses on review and prosecution of cases involving inappropriate prescribing, overprescribing, and pain clinics. The team handles cases for all of the disciplines in which practitioners have the authority to prescribe controlled substances, such as medical doctors, osteopathic physicians, advanced practice nurses and physician assistants. This approach allows for expertise and consistency in the handling of disciplinary actions against practitioners who are accused of inappropriate prescribing or overprescribing. Beginning in 2017, the medical director for pain clinics became a member of the overprescribing team.

In 2018, OGC was assigned 18 new cases for prosecution against practitioners for overprescribing. Prosecution of overprescribing cases by OGC resulted in the closure with public discipline of 34 cases in 2018. Twelve cases resulted in the revocation, surrender, or suspension of a practitioner's license. Eleven practitioners were placed on probation. Nine practitioners were publicly reprimanded and required to comply with various conditions such as surrender their Drug Enforcement Administration registration, which authorizes prescribing of controlled substances, or close monitoring and reporting of their prescribing practices. Seven additional cases have been closed with a Letter of Warning or no action. Sometimes, after a case arrives in OGC and the Respondent (i.e., the accused practitioner) is contacted, the Respondent presents additional information that is sufficient to refute the allegations against him/her. Other times, further investigation, including review by an expert, determines that there is insufficient evidence to pursue a contested case before the respective board. Letters of warning are distributed when the allegations against the practitioner raise concern, but there is insufficient evidence to pursue a contested case.

Conclusion

The Department is working hard 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 practitioner to reduce the number of patients being adversely affected by inappropriate prescribing and dispensing.

The Chronic Pain Guidelines are reviewed and updated by prescribers and dispensers annually.