# Prescription Drug Abuse and Pain Management Clinics

2017 Report to the 110<sup>th</sup> Tennessee General Assembly



Our mission is to protect, promote and improve the health and prosperity of people in Tennessee.

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Office of General Counsel

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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. *Death Statistics*, Office of Policy, Planning and Assessment, TN Department of Health (1999-2012). In fact, in 2015, 1,451 people died of drug overdose in Tennessee compared to 970 people who died as the result of a motor vehicle accident. *Tennessee Department of Health News Release November 15, 2016.* 

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 passage, utilization of the database has significantly increased and the prescription of opioids and benzodiazepines has decreased over that same time period.

#### **Pain Clinic Certification**

Prior to the Prescription Safety Act of 2012, the General Assembly passed legislation in 2011 regulating pain clinics and requiring that all pain 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 further 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 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 clinics has been reduced to 182 clinics.

#### Clinical Practice Guidelines for Outpatient Management of Chronic Non-Malignant 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. 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 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.

#### **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 solely reviews and prosecutes cases involving inappropriate prescribing and overprescribing. The team handles those 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.

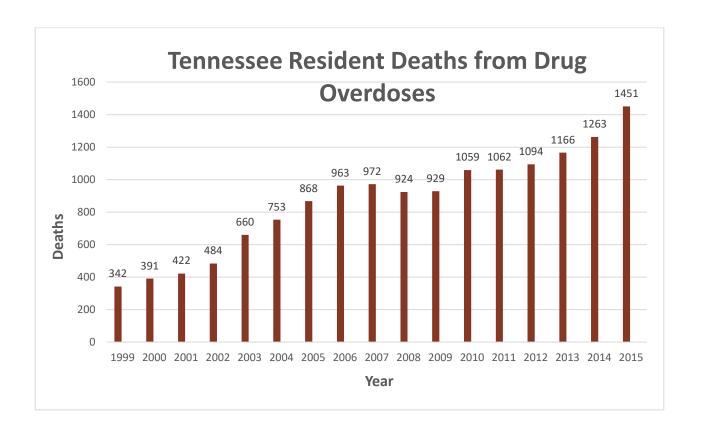
#### 2016 data reveals:

- The Office of Investigations received 132 complaints logged as related to overprescribing.
- OGC received 19 new cases against practitioners and 19 new cases against clinics. See Appendix A, Collective Charts – 2014 Prescribing Cases.
- OGC closed 27 prescribing cases against practitioners with public discipline, including 7 cases resulting in either the revocation, voluntary surrender, retirement or suspension of the practitioner's license. See Appendix A, Collective Charts – 2016 Prescribing Cases. An additional 5 cases were closed with public action against pain clinics.

## **Prescription Drug Abuse in Tennessee**

Prescription drug abuse is an increasingly serious problem in Tennessee. In 2000, there were 391 deaths resulting from drug overdose. In 2010, that number more than doubled to 1,059. Death Statistics, Office of Policy, Planning and Assessment, TN Department of Health (1999-2012). That number has steadily increased and the number of deaths in Tennessee resulting from drug overdose has outpaced the national death rate per 100,000 people since 2002. In 2011, there were approximately 13 overdose deaths per 100,000 nationally. Drug Poisoning Deaths in the United States, 1980-2008, Data Brief 81, National Center for Health Statistics (NCHS). In Tennessee, the rate was over 16 deaths per 100,000 people. Death Statistics, Office of Policy, Planning and Assessment, TN Department of Health. For 2015, the national rate had increased to 16.3 overdose deaths per 100,000. In that same year, the rate in Tennessee increased dramatically to 22 per 100,000. Id. Only about half (56%) of people who died of overdose had controlled substances dispensed in the 60 days prior to death, suggesting that other factors played a significant role in overdose deaths, including illicit fentanyl, heroin, and diverted prescription opioids. Deaths confirmed to have involved fentanyl rose significantly from 69 deaths in 2014 to 174 in 2015. Heroin-associated overdose deaths increased from 147 in 2014 to 205 in 2015. Public Health Advisory from the Tennessee Department of Health, November 15, 2016.

Notably, overdose deaths involving heroin nearly tripled from 2013 to 2015.



The most prescribed controlled substances are prescription opioids used to treat pain. In 2015, 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). *Report to the 109<sup>th</sup> Tennessee General Assembly*, TN Department of Health Controlled Substance Monitoring Database Committee (2016).

Despite the increasing death rate, analysis of the Controlled Substance Monitoring Database shows that progress has been made in many areas. There has been a sustained decrease of 50% in doctor/pharmacy shopping (defined for these purposes as visiting five or more prescribers or dispensers in a three-month period) from 2011 to 2015. *Report to the 109<sup>th</sup> Tennessee General Assembly*, TN Department of Health Controlled Substance Monitoring Database Committee (2016). Prescribing of methadone, one of the most potent opioids and frequently associated with overdose deaths, is down 21% since 2010. *Id.* The amount of MME's (morphine milligram equivalence) dispensed per capita from 2013 to 2015 decreased for all counties across the state, with over a 14% decrease in opioid MME's from 2012 to 2015. *Id.* 

#### **New Certification Process for Pain 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 all clinics register with the state. Id. Each clinic must have a medical director who meets certain educational and training requirements. The medical director must be on-site at the clinic at least 20% of the clinic's weekly operating hours and may serve as medical director for no more than 4 pain clinics. Additionally, neither the medical director nor any owner or prescriber at the clinic may have any prior disciplinary action related to inappropriately prescribing, dispensing, administering, supplying or selling a controlled substance or any criminal convictions for offenses involving the distribution of illegal prescription drugs or controlled substances as defined in T.C.A. § 39-17-402. T.C.A. § 63-1-309(b)(1), (2). Convicted felons are prohibited from owning a pain clinic. Id.

Effective July 1, 2016, medical directors of pain clinics were required by Public Chapter 475 of the 109<sup>th</sup> 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. Following passage of this law, the number of pain clinics in Tennessee was reduced from over 300 to 182.

Random clinic inspections have not been required by law, but have been undertaken by the department as a best practice. During the 2016 calendar year:

- Ninety-seven (97) clinic inspections were conducted.
- Nineteen (19) cases against pain clinics have been referred to the Office of General Counsel for prosecution, with the majority of those violations relating to operating or retaining a pain clinic certificate after July 1, 2016 without a medical director who qualifies as a pain management specialist.
- Five (5) clinic certifications were revoked or surrendered, and one clinic certification was suspended.

# **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 has traveled throughout the state discussing pain management with practitioners and getting feedback on the guidelines.

These guidelines are available at the following URL:

#### http://health.state.tn.us/Downloads/ChronicPainGuidelines.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 draft guidelines for pain clinics.

Additionally, as required by Tenn. Code Ann. § 68-1-128, the medical director 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. On the most recent Top 50 survey, 29 of the top 50 prescribers were advanced practice nurses, 15 were medical doctors, 4 were physician assistants and 2 were osteopathic physicians. The total morphine equivalence prescribed in aggregate by the Top 50 prescribers has decreased each year since 2013, with a 12% decrease in the morphine milligram equivalents prescribed by the Top 50 Prescribers in 2014 compared to 2013, an 8% decrease from 2014 to 2015, and an 11% decrease from 2015 to 2016. 109<sup>th</sup> Tennessee General Assembly, TN Department of Health Controlled Substance Monitoring Database Committee (2016).

#### **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 solely reviews and prosecutes cases involving inappropriate prescribing and overprescribing. 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. approach allows for expertise and consistency in the handling of disciplinary actions against practitioners who are accused of inappropriate prescribing or overprescribing.

In 2016, the Office of Investigations received 132 complaints of overprescribing against practitioners.

In 2016, OGC was assigned 19 new cases for prosecution against practitioners for overprescribing. See Appendix A, Collective Charts – 2016 Prescribing Cases. Such prosecution resulted in the closure with public discipline of 27 cases in 2016. Seven cases resulted in the revocation, surrender, retirement or suspension of a practitioner's license. Fourteen practitioners were placed on probation. 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. Appropriate measures have been taken to impose stricter regulations on practitioners who prescribe controlled substances in an effort to reduce the number of patients being adversely affected by inappropriate prescribing or overprescribing.

# Appendix A. – 2016 Prescribing Cases

# **Cases Opened in the Office of General Counsel**

New Cases Received	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	YTD
D.D.S.	0	0	0	0	0	0	0	0	0	0	0	0	0
M.D.	0	0	0	0	1	0	0	0	2	1	1	3	8
P.A.	0	0	0	0	0	0	0	0	0	1	0	0	1
A.P.N./R.N.	3	0	1	1	0	0	1	0	2	2	0	0	10
D.O.	0	0	0	0	0	0	0	0	0	0	0	0	0
D.P.M.	0	0	0	0	0	0	0	0	0	0	0	0	0
TOTAL:	3	0	1	1	1	0	1	0	4	4	1	3	19

#### **Case Closures in the Office of General Counsel**

Cases Closed - by													
Respondent	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	YTD
Closed - No Action	0	0	0	0	0	0	0	1	0	0	1	1	3
Closed - Warning	0	0	0	0	1	2	0	0	0	0	1	0	4
Closed – Reprimand	0	1	2	0	0	0	0	0	2	0	0	1	6
Closed - Probation	0	0	2	1	2	0	1	2	2	0	4	0	14
Closed - Suspension	0	0	0	0	1	0	0	0	0	0	1	0	2
Closed - Lic.													
Surrendered	0	0	0	0	1	0	0	0	0	0	1	0	2
Closed - Revocation	0	0	0	0	0	0	0	0	0	0	1	0	1
Closed - Other	0	0	0	1	0	0	1	0	0	0	0	0	2
<b>Total Closed Cases</b>	0	1	4	2	5	2	2	3	4	0	9	2	34

# **By Specific Board**

#### **Dental**

Cases Closed - by	_			_		_		_	_				
Respondent	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	YTD
Closed - No Action	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Warning	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Reprimand	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Probation	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Suspension	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Lic.													
Surrendered	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Revocation	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Other	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>Total Closed Cases</b>	0	0	0	0	0	0	0	0	0	0	0	0	0

## **Board of Medical Examiners**

Cases Closed - by													
Respondent	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	YTD
Closed - No Action	0	0	0	0	0	0	0	1	0	0	1	1	3
Closed - Warning	0	0	0	0	0	1	0	0	0	0	1	0	2
Closed - Reprimand	0	0	2	0	0	0	0	0	2	0	0	1	5
Closed - Probation	0	0	2	1	2	0	1	0	2	0	1	0	9
Closed - Suspension	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Lic.													
Surrendered	0	0	0	0	1	0	0	0	0	0	1	0	2
Closed - Revocation	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Other	0	0	0	1	0	0	1	0	0	0	0	0	2
<b>Total Closed Cases</b>	0	0	4	2	3	1	2	1	4	0	4	2	23

**Board of Medical Examiners Committee** 

# on Physician Assistants

Cases Closed - by													
Respondent	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	YTD
Closed - No Action	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Warning	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Reprimand	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Probation	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Suspension	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Lic.													
Surrendered	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Revocation	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Other	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>Total Closed Cases</b>	0	0	0	0	0	0	0	0	0	0	0	0	0

# Nursing

Cases Closed - by				_				_				_	
Respondent	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	YTD
Closed - No Action	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Warning	0	0	0	0	1	1	0	0	0	0	0	0	2
Closed - Reprimand	0	1	0	0	0	0	0	0	0	0	0	0	1
Closed - Probation	0	0	0	0	0	0	0	2	0	0	3	0	5
Closed - Suspension	0	0	0	0	1	0	0	0	0	0	1	0	2
Closed - Lic.													
Surrendered	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Revocation	0	0	0	0	0	0	0	0	0	0	1	0	1
Closed - Other	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>Total Closed Cases</b>	0	1	0	0	2	1	0	2	0	0	5	0	11

**Board of Osteopathic** Examination

Cases Closed - by													
Respondent	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	YTD
Closed - No Action	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Warning	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Reprimand	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Probation	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Suspension	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Lic.													
Surrendered	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Revocation	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Other	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>Total Closed Cases</b>	0	0	0	0	0	0	0	0	0	0	0	0	0

# **Board of Podiatric Medical Examiners**

Cases Closed - by													
Respondent	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	YTD
Closed - No Action	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Warning	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Reprimand	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Probation	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Suspension	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Lic.													
Surrendered	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Revocation	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Other	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>Total Closed Cases</b>	0	0	0	0	0	0	0	0	0	0	0	0	0