Prescription Drug Abuse and Pain Management Clinics

2018 Report to the 110th Tennessee General Assembly

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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. *Drug Overdose Deaths*, Office of Informatics and Analytics, TN Department of Health. In fact, **in 2016, 1,631 people died of a drug overdose in Tennessee, compared to 1,451 in 2015.** Of the 1,631 deaths in 2016, 1,186 were associated with an opioid and of those, 739 included a prescription pain reliever.

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. 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.

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 182 clinics by the beginning of 2017.

Beginning July 1, 2017 all pain management clinics are 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.

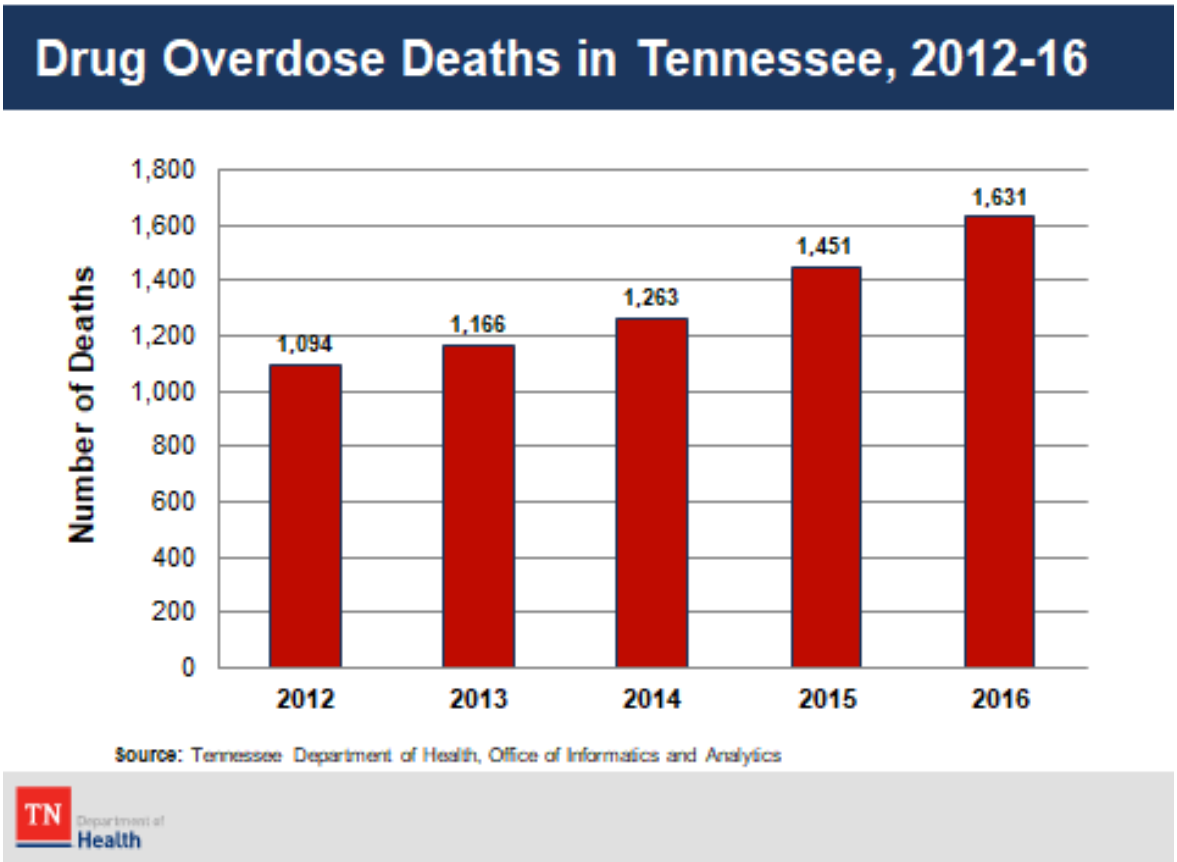
2017 data reveals:

- The Office of Investigations received 96 complaints logged as related to overprescribing.
- The Office of Investigation received 18 complaints against pain management clinics
- OGC received 13 new cases against practitioners and 4 new cases against pain management clinics. See Appendix A, Collective Charts – 2017 Prescribing Cases.
- OGC closed 28 prescribing cases against practitioners with public discipline, including 7 cases resulting in either the revocation, voluntary surrender, or suspension of the practitioner's license. See Appendix A, Collective Charts – 2017 Prescribing Cases. An additional 16 cases were closed with public action against pain clinics.

Prescription Drug Abuse in Tennessee

From 2015 to 2016, drug overdose deaths in Tennessee rose by 12%, increasing from 1,451 to 1,631, despite improvement in a number of measures of good medical practice, including reductions in the amount of opioids prescribed and dispensed, fewer doctor shoppers, and increased utilization of the CSMD. Although the proportion of drug deaths associated with opioids was approximately the same in 2016 (72%), this number includes illicit drugs and the proportion of deaths categorized by the CDC as associated with opioid pain relievers decreased from 48% to 45%. Deaths associated with benzodiazepines increased 16% from 492 to 573. Deaths that included a combination of benzodiazepine and opioid increased 17% from 447 to 522. Just under half (44%) of opioid associated deaths included a benzodiazepine.

Under half (47%) of individuals who died of drug overdose had a controlled substance dispensed within 60 days of death, a decrease from 56% in 2015. This continues to suggest that other factors are playing a significant role in overdose deaths, including illicit fentanyl, heroin, and diverted prescription opioids.



Once again, the number of deaths in which fentanyl was involved rose significantly, from 169 to 294, and now account for 18% of drug overdose deaths. Heroin deaths increased 26 percent, from 205 to 260. Methadone deaths increased 22 percent, from 67 to 82 and buprenorphine associated deaths increased from 34 percent, from 50 to 67. Of the 67 deaths that included buprenorphine, 41 (61.2%) also had a benzodiazepine involved, and 10 (14.9%) had fentanyl involved.

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 2017. 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 1.7 million (257.3 per 1000). Every year, nearly 70% of patients who fill prescriptions of opioids for pain only have active prescriptions for a month or less during the year. However, about 12% have active prescriptions for three quarters of the year, or more than 270 days. In 2016, 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: 2018 Report*.

There has been a sustained decrease of 65% in doctor/ pharmacy shopping (defined for these purposes as visiting five or more prescribers or dispensers in a six-month period) from 2013 to 2017. The amount of MME's (morphine milligram equivalence) dispensed per capita from 2013 to 2017 decreased for nearly every county across the state, with over a 30% decrease in opioid MME's from 2013 to 2017.

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. Following passage of this law, the number of pain clinics in Tennessee was reduced from over 300 to 182 by the beginning of 2017. 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 of 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 licensing it. 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. As of December 2017 there were 172 pain management clinics in Tennessee with either a license or certificate.

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.

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. During the 2017 calendar year:

- Twenty-Three (23) random clinic inspections were conducted.
- Twenty-Two (22) licensure inspections were conducted.
- Four (4) cases against pain clinics have been referred to the Office of General Counsel for prosecution.
- Fifteen (15) clinic certifications were 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 has traveled throughout the state discussing pain management with practitioners and getting feedback on the guidelines.

The Chronic Pain Guidelines are available at the following URL:

https://www.tn.gov/content/dam/tn/health/healthprofboards/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 guidelines for pain clinics.

The Pain Clinic Guidelines are available at the following URL:

https://www.tn.gov/content/dam/tn/health/documents/Pain_Clinic_Guidelines.pdf

Additionally in 2017 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, 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, and a 15% decrease from 2016 to 2017.

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.

In 2017, the Office of Investigations received 96 complaints of overprescribing against practitioners. The complaint review process involved consultants licensed by the Board of Medical Examiners, Physician Assistant Committee, Board of Podiatric Examiners, and Board of Nursing, as well as attorneys from OGC's prescribing team. While some cases reviewed are closed after violation without any action, many of the cases are closed with a Letter of Concern or Warning being issued to the Respondent.

In 2017, OGC was assigned 13 new cases for prosecution against practitioners for overprescribing. See Appendix A, Collective Charts – 2017 Prescribing Cases. Prosecution of overprescribing cases by OGC resulted in the closure with public discipline of 33 cases in 2017. Seven cases resulted in the revocation,

surrender, or suspension of a practitioner's license. Fourteen practitioners were placed on probation. Seven 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. Five 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. – 2017 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.	2	0	0	0	0	1	0	2	0	0	0	0	5
P.A.	0	0	0	0	0	0	0	0	1	0	0	0	1
A.P.N./R.N.	0	0	1	0	0	0	0	0	0	2	1	1	5
D.O.	0	0	0	0	0	0	0	0	0	0	0	0	0
D.P.M.	0	0	1	0	0	0	1	0	0	0	0	0	2
TOTAL:	**2**	**0**	**2**	**0**	**0**	**1**	**1**	**2**	**1**	**2**	**1**	**1**	**13**

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	1	4	2	0	0	0	0	0	0	0	0	0	7
Closed - Warning	1	1	0	0	0	0	0	0	0	0	0	0	2
Closed – Reprimand	1	1	0	0	0	0	3	0	1	0	1	0	7
Closed - Probation	1	1	0	0	1	0	2	1	0	0	8	0	14
Closed - Suspension	0	0	0	0	0	0	0	0	1	0	1	0	2
Closed - Lic. Surrendered	2	0	0	1	0	2	1	0	0	2	0	1	9
Closed - Revocation	0	0	5	1	1	1	1	0	0	0	1	1	11
Closed - Other	0	0	0	0	0	0	0	0	1	0	0	0	1
Total Closed Cases	**6**	**7**	**7**	**2**	**2**	**3**	**7**	**1**	**3**	**2**	**11**	**2**	**53**

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
Total Closed Cases	**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	2	1	0	0	0	0	0	0	0	0	0	3
Closed - Warning	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Reprimand	1	0	0	0	0	0	3	0	1	0	1	0	6
Closed - Probation	1	0	0	0	0	0	2	0	0	0	0	0	3
Closed - Suspension	0	0	0	0	0	0	0	0	1	0	0	0	1
Closed - Lic. Surrendered	0	0	0	0	0	0	0	0	0	0	0	0	0
Closed - Revocation	0	0	3	0	1	0	0	0	0	0	0	0	4
Closed - Other	0	0	0	0	0	0	0	0	0	0	0	0	0
Total Closed Cases	**2**	**2**	**4**	**0**	**1**	**0**	**5**	**0**	**2**	**0**	**1**	**0**	**17**

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	1	0	0	0	0	0	0	0	0	0	0	1
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
Total Closed Cases	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**

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	1	0	0	0	0	0	0	0	0	0	0	1
Closed - Reprimand	0	1	0	0	0	0	0	0	0	0	0	0	1
Closed - Probation	0	1	0	0	1	0	0	1	0	0	8	0	11
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	1	0	1
Closed - Other	0	0	0	0	0	0	0	0	0	0	0	0	0
Total Closed Cases	**0**	**3**	**0**	**0**	**1**	**0**	**0**	**1**	**0**	**0**	**9**	**0**	**14**

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
Total Closed Cases	**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	1	0	1
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
Total Closed Cases	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**1**

Pain Clinics

Cases Closed - by Respondent	*Jan*	*Feb*	*Mar*	*Apr*	*May*	*Jun*	*Jul*	*Aug*	*Sep*	*Oct*	*Nov*	*Dec*	*YTD*
Closed - No Action	1	1	1	0	0	0	0	0	0	0	0	0	3
Closed - Warning	1	0	0	0	0	0	0	0	0	0	0	0	1
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	2	0	0	1	0	2	1	0	0	2	0	1	9
Closed - Revocation	0	0	2	1	0	1	1	0	0	0	0	1	6
Closed - Other	0	0	0	0	0	0	0	0	1	0	0	0	1
Total Closed Cases	**4**	**1**	**3**	**2**	**0**	**3**	**2**	**0**	**1**	**2**	**0**	**2**	**20**