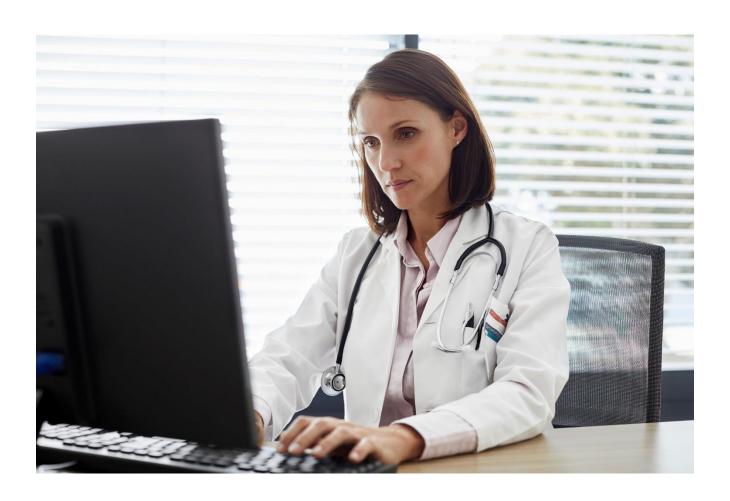
Controlled Substance Monitoring Database

2019 Report to the 111th Tennessee General Assembly





Health Licensure & Regulation Controlled Substance Monitoring Database Committee March 1, 2019

| Tennessee Department of Health Key Points Related To the Drug Epidemic | 4 |
|---|----|
| Key findings for 2018: | 4 |
| Key Improvements in the CSMD in 2018: | 4 |
| Tennessee Department of Health Important Lessons and Concerns during 2018: | 5 |
| Education and Survey Update: | 5 |
| Trends in Drug Overdose Deaths in Tennessee and the Role of the CSMD | 5 |
| Moving Upstream to Use Weekly Hospital Data | 7 |
| Neonatal Abstinence Syndrome Surveillance Update | 7 |
| The Role of and Presence of Pain Clinics across Tennessee | 7 |
| Fewer Prescriptions without CSMD Evaluation | 8 |
| Ratio of Number of Prescriptions to a Request in the CSMD, 2010-2018 | 9 |
| MME Improvements and Concerns by Age Group | 10 |
| Change in MME Dispensed Among Tennessee Patients, 2011 vs. 2018 | 10 |
| Trends Related to Utilization of Benzodiazepines | 11 |
| Number of Benzodiazepine Prescriptions Dispensed Among TN Patients by Age Group and Rep CSMD, 2010-2018 | = |
| Trends Related to Utilization of Stimulants | 12 |
| Number of Stimulant Prescriptions Dispensed Among TN Patients by Age Group and Reported CSMD, 2010-2018 | |
| Interventions Related to Top 50 Prescribers and Top 10 Prescribers for Small Counties | 13 |
| MMEs Prescribed by Top 50 Prescribers | 13 |
| Decline in Potential Doctor-Pharmacy Shopping | 13 |
| Potential Doctor and Pharmacy Shoppers Identified in the CSMD, 2010-2018 | 14 |
| User Satisfaction & Perception of the CSMD. | 14 |
| 2018 Prescriber User Survey | 14 |
| 2018 Dispensers User Survey | 15 |

2019 Report to the General Assembly

| Database Performance |
|--|
| Increased Interstate Data Sharing |
| Security Measures |
| TDH Provides Significant Educational Outreach |
| TDH Grants Update |
| TDH Recommends the Following Approaches to the Opioid Epidemic |
| Conclusion19 |
| 2018 Members of the CSMD Committee |
| Appendix |
| Number of Prescriptions Dispensed in TN and Reported to CSMD, 2010-201823 |
| Number of Prescriptions Dispensed among TN Patients and Reported to CSMD by Age Group, 2010- 2018 |
| Number of Prescriptions Reported to TN CSMD by Class of Controlled Substances, 2010 - 201825 |
| MME of Opioids Reported to TN CSMD, 2010-201826 |
| MME for Long Acting Opioids Reported to the TN CSMD, 2010-201827 |
| MME for Short Acting Opioids Reported to the TN CSMD, 2010-201827 |
| Distribution of the Top 10 Most Frequently Prescribed Controlled Substance Products in the CSMD for 2018 |
| 2018 Prescriber and Dispenser Survey Results |
| Acronyms31 |

Tennessee Department of Health Key Points Related To the Drug Epidemic

The 2019 Controlled Substance Monitoring Database (CSMD) report from Tennessee Department of Health (TDH) addresses activities and outcomes related to the substance abuse crisis as it relates to the CSMD. TDH is pleased to provide a concise update on the prescription drug abuse crisis in the state at

https://www.tn.gov/content/dam/tn/health/healthprofboards/csmd/2019%20Concise%20CSMD%20Annual%20 Report.pdf. The CSMD Committee reports annually on the outcome of the program with respect to its effect on distribution and abuse of controlled substances; along with recommendations for improving control, prevention, and diversion of controlled substances.

Prescription drug monitoring programs, like Tennessee's CSMD, are the cornerstone to state-level interventions to improve opioid prescribing, inform clinical practice, and protect patients at risk. Provision of accurate, timely dispensing information is essential to wise clinical decision making which can provide safe and effective treatment of pain.

Key findings for 2018:



- Morphine Milligram Equivalent (MME) dispensed has decreased 43% (2012-2018)
- MME prescribed by top 50 prescribers has decreased 44% (2013-2018)
- Pain clinics have been reduced by 62% (2014-2018)
- Number of potential doctor shoppers have decreased 85% (2011-2018)
- Number of opioid prescriptions for pain have decreased by 30% (2012-2018)
- Patients receiving >120 MME/day decreased by 48% (2012-2018)
- For the first time since 2013, cases of Neonatal Abstinence Syndrome (NAS) decreased



Searches of CSMD have increased 510% and continue to increase (2012-2018)

Key Improvements in the CSMD in 2018:

- Upgraded CSMD Data Collection to American Society for Automation in Pharmacy (ASAP 4.2A) (June 2017 version) so that CSMD could collect new data required from dispensers related to Public Chapter 1039.
- Added a new Clinical Risk Indicator (CRI) during February 2018 related to informing prescribers and dispensers of certain TennCare enrollees that have been locked into a single pharmacy.
- The CSMD system was up and functional 99.9% of the year.
- Response time for searches in the CSMD is less than two seconds if request does not include data from another state.
- The CSMD program in 2018 added, North Carolina, Georgia, Illinois, Indiana, Maine, Oklahoma, and Pennsylvania to the other 13 states with which TN shares data.

Tennessee Department of Health Important Lessons and Concerns during 2018:

- There was one search of the CSMD for every one and half prescriptions in TN in 2018, up from one search for every 14 prescriptions in 2010. This is a remarkably high number of searches and, combined with the continuing decrease in MME dispensed, indicates the ongoing effectiveness of providing timely and accurate decision support for prescribing of controlled substances.
- 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.
- Among opioid-related overdose deaths, 44% also had benzodiazepines present, highlighting the
 critical importance of avoiding concomitant use of opioids and benzodiazepines. Indeed, among
 polydrug deaths, the combination of an opioid and a benzodiazepine is the most common
 combination.
- 2017 was the second year where less than half of individuals (43%) who died of drug overdose had any controlled substance dispensed within 60 days of death. The increase in overdose deaths due to opioids in 2017 was largely due to illicit fentanyl (74% increase) and heroin (20% increase). This reinforces the need for a three pronged approach of prevention, treatment, and law enforcement in turning the tide of this epidemic.
- The number of patient reports requested increased 32% in 2018 to 11,361,388 compared with 2017.
- The amount of opioid medications from the top 50 prescribers declined 44%, a rate of decline that is faster than the overall rate of decline for the rest of the state.

Education and Survey Update:

- Educational programs by TDH staff reached approximately 3,000 attendees state wide. Education included information on regulatory changes, best practices for prescribing, dispensing, review of the Chronic Pain Guidelines and requirements related to pain clinics and pain specialists.
- The 2018 Prescriber Satisfaction Survey showed 89% of respondents reported that the CSMD is useful for decreasing doctor shopping; and 50% reported they are less likely to prescribe controlled substances after checking the CSMD.
- The 2018 Dispenser Satisfaction Survey showed 92% of respondents reported that the CSMD is useful for decreasing doctor shopping; and 73% reported that they refuse to fill a prescription as written after checking the CSMD.

Trends in Drug Overdose Deaths in Tennessee and the Role of the CSMD

In the past year, there has been continuing progress in key CSMD-related indicators. The proportion of individuals receiving high MME prescriptions (above 120 MME daily) continues to decrease (by 48% (from 2014 to 2018), and potential doctor shopping also continues to decrease. The TDH has built a tool to increase the efficiency and effectiveness of its review of clinician data to ensure focused investigations of clinicians and their charts.

The TDH uses methodology established by the CDC to understand and describe drug overdose deaths in our state (CDC, 2016)¹. Data from Vital Statistics indicates from 2016 to 2017, drug overdose deaths in Tennessee rose by 9%, increasing from 1631 to 1776, 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 2017 (71%), this number includes illicit drugs. The proportion of deaths categorized by the CDC as associated with opioid pain relievers decreased from 45% to 36%. Deaths associated with benzodiazepines decreased as well, from 573 to 504 (a 12% decrease). Deaths that included a combination of benzodiazepine and opioid decreased 14% from 522 to 447. Just over one-third (35%) of opioid associated deaths also included a benzodiazepine.

Under half (43%) of individuals who died of drug overdose had a controlled substance dispensed within 60 days of death, a decrease from 47% and a continuation of a five year trend. 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 percent, 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.

The TDH continues to improve how the CSMD is used in stopping the epidemic and is combining data from the CSMD with other patient data to identify key markers for increased risk. Epidemiologists at the TDH continue to map the natural history of addiction from prescription phase to what appears to be the danger zone, when individuals may move into the illicit market and are at higher risk for overdose and death. Policy and programs can be targeted more specifically to intervene early, when recovery is easier and more likely to be successful. In addition, the Office of Informatics and Analytics is developing a data driven method of identifying prescribers who may be engaging in high risk prescribing or who have high risk patient populations.

The TDH is working closely with a number of other departments, including the Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS) and the Tennessee Bureau of Investigation (TBI), to respond to the epidemic. This includes analyzing and providing county-level data to stakeholders on the ground, including drug coalitions, using data TDH epidemiologists are rapidly accumulating and analyzing and updating state-specific guidelines for use of controlled substances in pain management. In summary, the TDH is fighting an evolving epidemic that is invoking unprecedented collaboration among agencies and community partners.

¹ Rudd RA, Seth P, David F, Scholl L. Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015. MMWR Morb Mortal Wkly Rep 2016;65:1445–1452. DOI: http://dx.doi.org/10.15585/mmwr.mm655051e1



The CSMD is proving a key component to the TDH's response, by providing critical data when and where needed.

Moving Upstream to Use Weekly Hospital Data

In 2017, for every drug overdose death, more than 13 nonfatal overdoses were identified in state hospital discharge data having been treated in the emergency department or hospital. The proportion of these hospital visits due to opioids has steadily increased, with a particularly substantial increase in heroin related nonfatal overdoses continuing to be seen in 2017. We estimate at least 13% of overdose decedents in 2017 had a nonfatal overdose in the year before their death.

These overdoses are treated in emergency departments and hospitals, but information about those overdoses currently are not available to clinicians outside the hospital or to the CSMD. In 2016, Public Chapter 959 provided the Commissioner with the opportunity to require healthcare facilities to provide the TDH with near real-time data on nonfatal drug overdoses. Such a data collection system was implemented in 2017, with a pilot project involving 11 hospitals. The system is now in its active stage, with the expectation that all hospitals across the State will be on-boarded in the spring of 2019. At this time, 105 hospitals are sending weekly data extracts, 12 are submitting test files and an additional 6 are registered and beginning the onboarding process. On average, a hospital moves from test to production in approximately three weeks. As this program expands statewide, these data will be used in developing risk indicators to provide clinicians with the important information that their patients may be headed for serious risk of negative outcomes, including fatal overdose.

Neonatal Abstinence Syndrome Surveillance Update

Since surveillance of Neonatal Abstinence Syndrome (NAS) began in 2013, increasing numbers of babies diagnosed with NAS have been recorded every year through 2017. While a final number of NAS cases for 2018 is not yet available, it is clear that a significant decrease in babies diagnosed with NAS was seen. More information is expected to be available in March of 2019.

The Role of and Presence of Pain Clinics across Tennessee

The number of pain clinics declined to 126 in 2018 which represents a 62% decrease from the peak number of 333 in 2014. One of the goals of the TDH has been to increase access to quality pain management. As of July 1, 2016, TCA § 63-1-306 requires that pain management specialists be the medical directors of pain clinics. Medical directors who are pain specialists based on training as defined by statute should provide consistency in the quality of care for the citizens of Tennessee.

The certification system changed to a licensure system on July 1, 2017, TCA § 63-1-316 requiring more intensive reporting and inspection. Prior to licensure the clinics are inspected and patient charts are reviewed and must meet minimum standards of care to pass inspection.

2019 Report to the General Assembly



After a public hearing on July 24, 2017, the pain management clinic rules were adopted and posted on November 26, 2017 http://publications.tnsosfiles.com/rules/1200/1200-34/1200-34-01.20171126.pdf.

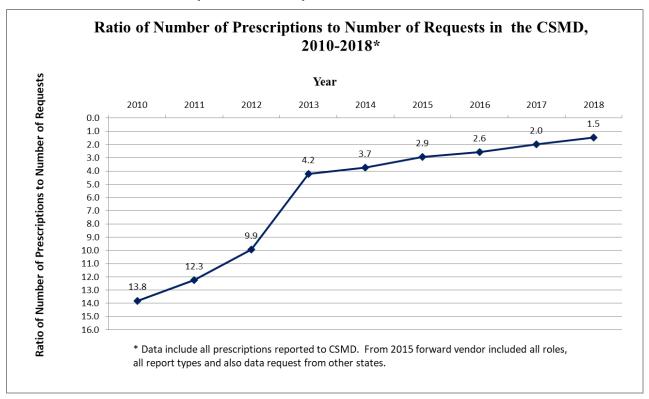
Pain Clinic Practice Guidelines have been developed and were published in January of 2017 with help from pain medicine specialists and other groups. The guidelines are available at: https://www.tn.gov/content/dam/tn/health/health/health/profboards/pain-management-clinic/Pain_Clinic_Guidelines.pdf

Additionally, 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

Fewer Prescriptions without CSMD Evaluation

The Prescription Safety Act (PSA) of 2012 facilitated a substantial increase in utilization of the CSMD and the PSA of 2016 and Public Chapter 1039 again expanded the requirement for when healthcare practitioners are to check the CSMD. Year after year the CSMD continues to have significant increases in the number of registrants. By the end of 2018 the number of registrants had grown to 50,991. Prior to the PSA of 2012 and 2016, Tennessee had 14 prescriptions reported for every CSMD patient request and now there are approximately one and half prescriptions reported for each request. The number of patient reports requested increased 32% in 2018 to 11,361,388 compared to 2017.

Ratio of Number of Prescriptions to a Request in the CSMD, 2010-2018



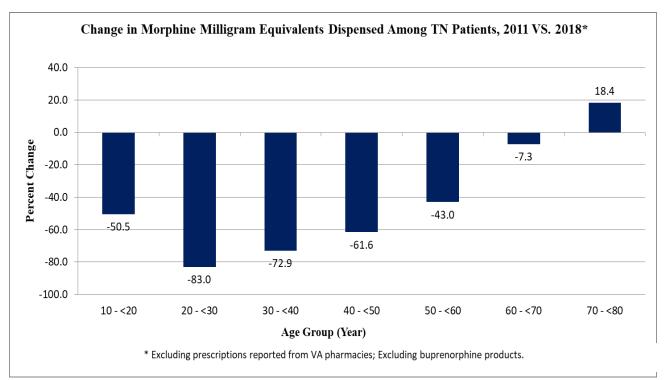
| Number of Registrants of the CSMD, 2010 - 2018* | | | | | | |
|---|-------------|------------|--|--|--|--|
| Year | Registrants | Change (%) | | | | |
| 2010 | 13,182 | - | | | | |
| 2011 | 15,323 | 16.2 | | | | |
| 2012 | 22,192 | 44.8 | | | | |
| 2013 | 34,802 | 56.8 | | | | |
| 2014 | 38,871 | 11.7 | | | | |
| 2015 | 42,835 | 10.2 | | | | |
| 2016 | 46,576 | 8.7 | | | | |
| 2017 | 47,294 | 1.5 | | | | |
| 2018 | 50,991 | 7.8 | | | | |
| *VA registrants were included in 2013 and forward as they were allowed to register. | | | | | | |

Law enforcement requests to the CSMD continue to be a critical use of the CSMD as TDH works together to address questionable controlled substance use in Tennessee. Of the 11,361,388 requests 1,738 were from law enforcement officers. Effective July 1, 2011, law enforcement officers were granted access to the CSMD. That access was further expanded through the PSA of 2016. During 2019, the TDH plans an enhancement of the CSMD to provide law enforcement and drug courts improved access to the CSMD.

MME Improvements and Concerns by Age Group

For 2018, the CSMD program provided a more detailed analysis of the MME for trends by age group for Tennessee patients. Encouragingly, there was a decline in MMEs dispensed for the 10 to 69 age ranges compared to 2011 data. These improvements for these age groups are an indicator that the TDH's efforts are being successful at preventing individuals from being overexposed to opioids by the healthcare system. In the age groups over 70 the upward trending MME is slowing. In 2018, MME increased 18.4% compared to 2011 in the 70-79 age group. This is an improvement over 2017 when MME increased 25.3% compared to 2011 for the same age group.

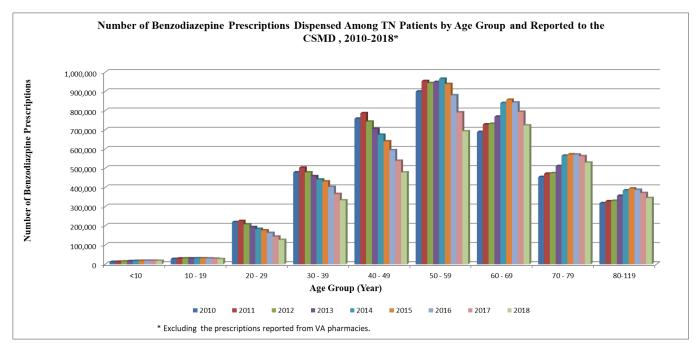
Change in MME Dispensed Among Tennessee Patients, 2011 vs. 2018



Trends Related to Utilization of Benzodiazepines

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.

Number of Benzodiazepine Prescriptions Dispensed Among TN Patients by Age Group and Reported to the CSMD, 2010-2018

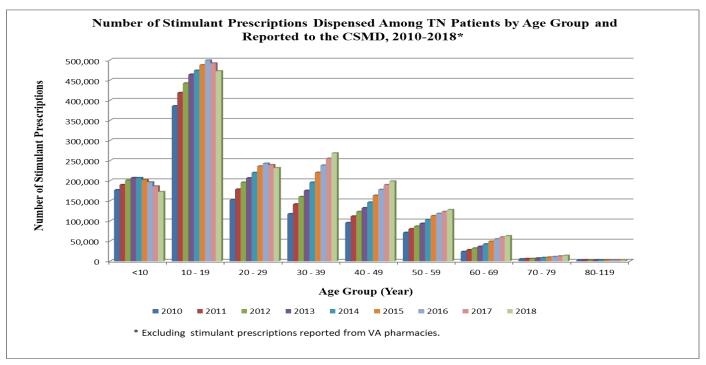


| Number of Benz | Number of Benzodiazepine Prescriptions Dispensed Among TN Patients and Reported to the CSMD by Age | | | | | | | | |
|-------------------|--|---------|---------|---------|---------|---------|---------|---------|---------|
| | Group, 2010-2018* | | | | | | | | |
| Age Group (Year) | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 |
| <10 | 11,946 | 12,642 | 14,724 | 15,916 | 17,290 | 17,728 | 18,229 | 18,057 | 17,629 |
| 10 - 19 | 27,436 | 29,672 | 30,626 | 30,254 | 30,983 | 30,760 | 30,181 | 28,612 | 26,685 |
| 20 - 29 | 219,382 | 224,979 | 207,450 | 193,215 | 183,632 | 176,268 | 162,781 | 143,609 | 126,564 |
| 30 - 39 | 478,258 | 502,673 | 478,155 | 458,167 | 440,778 | 430,956 | 402,261 | 365,449 | 332,585 |
| 40 - 49 | 757,839 | 786,336 | 742,190 | 704,872 | 673,903 | 639,669 | 593,543 | 538,029 | 477,821 |
| 50 - 59 | 899,158 | 953,570 | 942,962 | 948,552 | 965,433 | 938,101 | 879,744 | 790,690 | 692,044 |
| 60 - 69 | 688,340 | 727,862 | 730,867 | 768,372 | 839,432 | 856,048 | 842,108 | 793,561 | 722,719 |
| 70 - 79 | 454,109 | 471,375 | 474,104 | 511,156 | 565,106 | 572,011 | 570,893 | 562,681 | 528,903 |
| 80-119 | 317,766 | 327,880 | 330,021 | 356,356 | 384,520 | 394,045 | 387,353 | 370,436 | 344,331 |
| Unknown | 2 | 6 | 7 | 2 | 2 | 7 | | 6 | 1 |
| * Excluding benzo | * Excluding benzodiazepine prescriptions reported from VA pharmacies. | | | | | | | | |

Trends Related to Utilization of Stimulants

The number of prescriptions for stimulants has continued to increase, growing by 51% for patients in Tennessee from 2010 to 2018.

Number of Stimulant Prescriptions Dispensed Among TN Patients by Age Group and Reported to the CSMD, 2010-2018



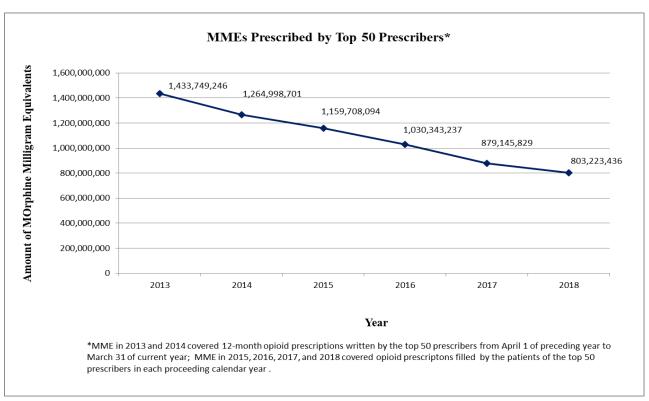
| Number o | Number of Stimulant Prescriptions Dispensed Among TN Patients and Reported to the CSMD by Age | | | | | | | | |
|---------------|---|-------------|-------------|------------|---------|---------|---------|---------|---------|
| | Group, 2010-2018* | | | | | | | | |
| Age Group | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 |
| (Year) | | | | | | | | | |
| <10 | 176,825 | 189,708 | 200,863 | 207,017 | 207,004 | 202,077 | 196,378 | 186,046 | 172,458 |
| 10 - 19 | 385,488 | 418,612 | 442,318 | 464,010 | 473,974 | 487,542 | 499,167 | 491,926 | 472,457 |
| 20 - 29 | 151,844 | 178,553 | 195,633 | 206,472 | 220,028 | 235,900 | 242,767 | 239,120 | 231,747 |
| 30 - 39 | 117,353 | 141,529 | 160,022 | 175,434 | 195,713 | 220,228 | 238,095 | 255,127 | 268,403 |
| 40 - 49 | 95,350 | 111,529 | 122,807 | 132,257 | 146,214 | 163,162 | 177,733 | 189,635 | 198,509 |
| 50 - 59 | 70,847 | 79,906 | 86,549 | 93,462 | 102,874 | 112,461 | 118,050 | 122,762 | 127,513 |
| 60 - 69 | 23,474 | 27,874 | 32,006 | 36,298 | 42,258 | 48,871 | 54,821 | 59,476 | 62,677 |
| 70 - 79 | 5,133 | 5,769 | 6,138 | 7,221 | 8,504 | 9,529 | 10,870 | 12,360 | 13,845 |
| 80-119 | 2,183 | 2,335 | 2,017 | 2,403 | 2,633 | 2,731 | 2,615 | 2,538 | 2,636 |
| Unknown | 0 | 1 | 0 | 0 | 6 | 4 | 0 | 0 | 0 |
| * Excluding s | timulant pr | escriptions | reported fr | om VA phar | macies. | | | | |



Interventions Related to Top 50 Prescribers and Top 10 Prescribers for Small Counties

TCA 68-1-128 (passed during 2015) required the TDH to continue to identify the top 50 prescribers in Tennessee and added a new requirement for the TDH to identify the top 10 prescribers from all of the combined counties having populations of fewer than 50,000 residents to the top prescriber annual identification process. 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.

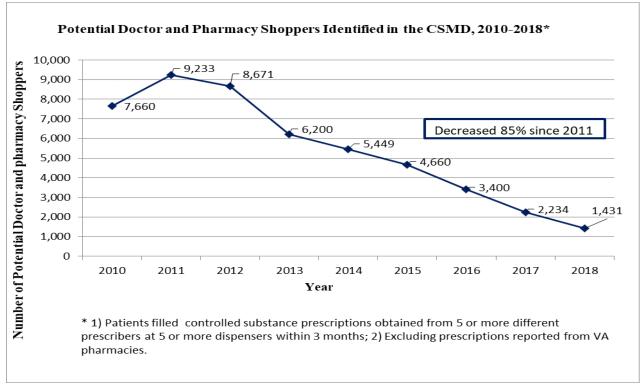
MMEs Prescribed by Top 50 Prescribers



Decline in Potential Doctor-Pharmacy Shopping

The past few years, TDH has defined a potential doctor and pharmacy shopper as an individual visiting five or more prescribers and five or more dispensers in a 3 month period, referred to as 5-5-3 criteria. Within Tennessee, there has been an 85% decrease of potential doctor and pharmacy shopping patients from 2011 to 2018.

Potential Doctor and Pharmacy Shoppers Identified in the CSMD, 2010-2018



User Satisfaction & Perception of the CSMD

The 2018 CSMD survey was the fourth for prescribers and the third for dispensers. Highlights of the 2018 survey are listed below.

2018 Prescriber User Survey

As a measure of satisfaction with improvements to the CSMD, a survey of prescribers was conducted in 2018 with 2,077 prescribers responding:

- 69% use the CSMD at least monthly;
- 64% of responders have changed a treatment plan after viewing a CSMD report;
- 69% report discussing the CSMD report with their patients;
- 44% of responders are more likely to refer a patient for substance use disorder treatment;
- 89% of respondents report that the CSMD is useful for decreasing doctor shopping;
- 50% report that they are less likely to prescribe controlled substances after checking the CSMD;



- 67% of respondents received a clinical risk indicators which are sent proactively to prescribers recently associated with the patient and of those 70% felt information useful;
 - o Increase awareness (respondents could choose more than one):
 - 91% more aware of patients going to multiple prescriber;
 - 60% more aware of patients going to multiple dispensers;
 - 65% more aware of patients receiving highest dose of opioids.

2018 Dispensers User Survey

A survey of dispensers was conducted in 2018 with 554 responding:

- 92% use the CSMD at least monthly;
- 64% of responders communicate with the prescriber after viewing a CSMD report;
- 69% report discussing the CSMD report with their patients;
- 56% of responders are more likely to communicate with the prescriber regarding a patient with potential for referral to substance abuse treatment;
- 92% of respondents report that the CSMD is useful for decreasing doctor shopping;
- 73% report that they refuse to fill a prescription as written after checking the CSMD.

Database Performance

In 2018, the CSMD system was up and functional 99.9% of the year. Due to the CSMD team working with its vendor the system stabilized in 2018. The CSMD responds in less than two seconds when a patient request is initiated that does not include data from another state.

The supported browsers that provide the best performance of the CSMD include Internet Explorer 8 or above, Safari, Chrome, and Firefox. At this time Edge is incompatible with CSMD. Language has been added to the login page of the CSMD to make users aware of which browsers are compatible with the CSMD.

Increased Interstate Data Sharing

The PSAs of 2012 and 2016 permit data sharing with other states. One of the areas of focus for 2018 was to enhance the sharing of prescription data with other authorized states. The CSMD program shared data with Alabama, Arkansas, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, North Dakota, Ohio, South Carolina, Texas, Virginia, and West Virginia practitioners to give them a more complete picture of patients' controlled substance prescription history. The CSMD program in 2018 added Georgia, Illinois, Indiana, Maine, North Carolina, Oklahoma, and Pennsylvania and has been in communication with Florida and Iowa to share data. Each state has unique regulations and requirements that require collaboration to share data to insure both states regulations are incompliance.

Security Measures

In order to ensure that only those individuals and entities authorized pursuant to the PSA of 2016 have access to the information contained in the database, the CSMD employs the following security measures:

- All authorized entities and individuals that have been granted access to the database pursuant to TENN. CODE ANN. § 53-10-306(a)(1-7) are allowed to enter the database through a registration process where identifying credentials are validated before the creation of a unique user name and password are generated. For healthcare practitioner delegates an additional approval from their supervising healthcare practitioner is required.
- Before the Office of Inspector General, the Medicaid Fraud Control Unit, and the TennCare personnel identified in statute are able to access the database, the individuals requesting access must submit a written request approved by his or her supervisor. The CSMD administrative staff verifies the requester's employment and only then are they supplied with unique individual user names and passwords. TDH and the CSMD Committee have partnered with TennCare to provide data sets which are subject to different security protocols imposed on TennCare via contract.
- The CSMD staff has oversight of the data accessed, updated or viewed by a specific user through the
 creation of an audit trail for each user. This audit trail tracks each piece of data accessed or updated by
 end users.
- Requests by law enforcement personnel for information sent to, contained in, and reported from the database pursuant to TENN. CODE ANN. § 53-10-306(a)(8) must submit a written request with a case number corresponding to a criminal investigation. Before releasing any information, the Board of Pharmacy/CSMD staff verifies that the law enforcement personnel are on the approved list submitted by the TBI director or the district attorney general in the judicial district in which the law enforcement agency or judicial district drug task force has jurisdiction.
- Requests for access by persons other than those individuals outlined in TENN. CODE ANN. § 53- 10-306(a)(1-7) and (9) were reviewed by Board of Pharmacy staff and Legal Counsel to determine if the person requesting access could be granted access pursuant to applicable laws and rules. Legal staff also reviewed all subpoenas and court orders to ensure compliance with the law before releasing any information.
- In 2016, the Department expanded its internal access systems as part of the creation of the Health Enterprise Warehouse (HEW) also known as TDH Integrated Data System, which works to more efficiently provide usable data access to a limited number of authorized users. The security and access related to these projects is handled by a variety of actors including Strategic Technology Solutions (STS) staff, TDH Information Technology Services Division (ITSD) staff, the Office of General Counsel (OGC) and the Informatics Staff in conjunction with oversight from the CSMD program. The HEW also known as TDH Integrated Data System and data storage including CSMD data reside in the



State Data Center, are behind the State network firewalls preventing outside access without the proper approved connection through a Virtual Private Network. All data on these servers are encrypted.

• Currently only administrators and a select group of individuals have access to the CSMD data associated with the HEW also known as TDH Integrated Data System. Users of these tools have to receive permission from Dr. Melissa McPheeters, Director, Office of Informatics and Analytics Tennessee Department of Health; and Dr. David Bess, Director of Tennessee Controlled Substances Monitoring Database Program Department of Health in order to access CSMD data from the HEW also known as TDH Integrated Data System. As the HEW also known as TDH Integrated Data System grows, fewer users will have direct access and instead will be able to request and receive specific datasets.

TDH Provides Significant Educational Outreach

Over 50 presentations were made live across the state to approximately 3,000 attendees to educate on regulatory changes related to the best practices of controlled substance prescribing, dispensing, and monitoring as well as the Chronic Pain Guidelines and requirements related to pain clinics and pain specialists. The audiences consisted of consumers, health care providers, law enforcement officers, drug enforcement officials, and attorneys.

Ten of these events were accredited courses complying with the education requirement in TCA § 63-1-402 and provided in partnership with East Tennessee State University (ETSU) and Vanderbilt University. 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. During 2018, 907 healthcare providers successfully completed the online course through Vanderbilt, and 149 healthcare providers successfully completed the online course through ETSU.

The 2019 Educational Outreach is focusing on high risk rural communities. The criteria for educational sites and efforts are as follows:

- Opioid prescriptions per capita;
- Illicit substance use disorders;
- Overdoses (both fatal and near misses); and
- Increasing incidence of HIV and hepatitis C

TDH Grants Update

CDC Grant – In September 2015, TDH was awarded a grant of \$3.4 million from the Centers for Disease Control and Prevention (CDC) to assist with funding epidemiologic studies pertaining to the nation's



prescription drug overdose (PDO) epidemic. Funding for this initiative, "PDO: Prevention for States" (PFS), was awarded to sixteen states. The grant expanded upon the work already under way through the "PDO: Boost" grant. In 2016, the TDH was awarded additional, supplemental funding to expand use of data and allow for better, complex linkages across data sources. In 2017, TDH was awarded an additional supplement to coordinate regional planning summits for opioid response, and to support public education about the risks associated with opioids. The purpose of the PFS grant is to provide state health departments with additional resources and support needed to advance interventions for preventing prescription drug overdoses within their own jurisdictions.

- Overall, the funding supports part of the Director of Informatics and Analytics salary, a statistical research specialist, seven epidemiologists and costs for building, maintaining and conducting analysis in the TDH Integrated Data System also known as HEW. It is this work that is allowing the team to generate learning using combined data about prescriptions, hospital based care for overdoses, births and deaths and other important data subsets, such as Worker's Compensation data.
- Included in the grant work are a number of key areas of activity:
 - Enhancing and Maximizing CSMD
 Using data to better understand the behavior of the prescription drug overdose epidemic.
 - Expanding and Improving Proactive CSMD Reporting
 To identify and address inappropriate prescribing patterns.
 - Implementing Community or Insurer/Health Systems Interventions
 Improving opioid prescribing interventions for insurers and health systems, as well as enhancing the use of evidenced based opioid prescribing guidelines.
 - Conducting Policy Evaluations
 Evaluation of policies and legislation currently in place to further understand what is working well and areas for improvement to prevent prescription drug overdoses.
 - Developing and Implementing Rapid Response Projects
 Implementing a project to advance an innovative prevention approach and respond to new and emerging crises and opportunities.

In addition, in 2016, the TDH was awarded a grant from the Department of Justice (DOJ) under the Harold Rogers program; to create rapid data based collaboration between TDH, TBI and TDMHSAS. The grant will fund improved access for law enforcement and drug courts to the CSMD, and the collection and integration of law enforcement and mental health data to better identify and react to emerging and existing hotspots, as well as changes in the drug epidemic. The grant supports a full time junior epidemiologist to develop visualizations and data analytics on which the team can act.

In 2017, TDH received another CDC grant, this one to enhance surveillance of opioid overdoses. For this grant, we are working to expand the nonfatal overdose reporting from hospitals and to validate those data, and we are working on establishing methods of early identification of fatal overdoses, in collaboration with the Office of the State Medical Examiner.

In 2018, TDH received two grants from the DOJ's Comprehensive Opioid Abuse Program (COAP)...



TDH Recommends the Following Approaches to the Opioid Epidemic

- Prevention is the best medicine: Reduce use, dose, and duration of opioids

 For patients who are not already taking opioids, consider non-pharmacologic and non-opioid

 medications before choosing opioids. When opioids are used, the medical literature increasingly
 supports very limited use for moderate and moderately severe pain for short periods of time (often 3 to 5
 days). This has been shown to be safer and often more effective for patients, even postoperative patients.
- Educating patients and communities on prevention is critical

 Educational materials and staff time spent educating patients is often very limited. Patients, healthcare practitioners, and healthcare trainees need to clearly communicate the risks of even short duration opioid exposure. Additionally, education is important for adolescents to foster resistance to substance abuse, other patient and community based interventions include increasing screening for opioid abuse (SBIRT), increasing the availability of SUD treatment and increasing oversight of clinics offering medication assisted therapy (MAT) (through TDMHSAS), expanding support for community drug coalitions including their important work to reduce the stigma of SUDs, adopting effective safe syringe programs, and increased use of naloxone (estimated to decrease overdose deaths by 10%).
- Realize that this epidemic is not just about opioids. It is an epidemic of Substance Use Disorders where opioids are often central, but increasingly stimulants and sedatives (benzodiazepines) are very important.
- In summary

By focusing on minimizing opioid exposure for people who are opioid naïve, together we can "block the on-ramp to addiction" and avoid the difficult and expensive physical, legal and mental health implications of progression to dependence and substance use disorder. By better integrating actions thorough rapid analysis and coordinated responses we can work with communities to address developing problems before they become more entrenched in our communities. By working to eliminate the stigma of SUD we can help people who have substance use disorders to get help early, when treatment is easier and more successful.

Conclusion

The CSMD remains an essential service to allow accurate and timely information about dispensing of controlled substances in Tennessee and many other states to be available before a decision is made about any future prescribing. The CSMD is reliably available and clinicians are making more frequent use of searches, with 1 search for every 1.5 dispensed prescriptions in 2018. The information in the CSMD continues to be used to improve patient safety and quality of care, with fewer patients on high doses and fewer doctor shoppers. And thankfully, for the first time in five years, 2018 saw a decrease in babies with neonatal abstinence syndrome.

At the same time, the epidemic of opioid misuse and abuse has continued to change. Although more people died in 2017 than ever before, overdose deaths did not increase as much as they had in prior years. The most notable developments were the rapid rise of fentanyl as a frequent cause of overdose death and the milder, but sustained

2019 Report to the General Assembly



rise in heroin as a cause. The use of benzodiazepines, such as alprazolam, continues to be a major problem which contributes significantly to unintentional overdose deaths. The striking rise of stimulants, such as methamphetamine and cocaine, is a growing problem.

Such developments are stark reminders of how far we have to go in resolving this epidemic of substance abuse disorders. A multi-pronged approach including prevention of exposure to opioids, early diagnosis and treatment of SUD, and the life-saving work of law enforcement to reduce availability of illicit addictive substances are all needed to turn the tide. Strong actions are needed most acutely at the community level, but also at the state and federal levels. Public – private partnerships are essential, and essential tools, such as the CSMD and evidence-based continuing education, need to be more readily available, having been integrated into the routine work flow of clinical practice. Finally, stigma remains very common with substance use disorder, preventing early conversations that can lead to timely interventions.

The TDH would like to provide a special thanks to the current and past members of the legislature, the CSMD Committee, the Tennessee Chronic Pain Guideline Expert Panel and the leadership of other federal and state agencies as we continue to work together to form a team of teams that will be successful in preventing harm to the public health from the prescription drug abuse crisis.

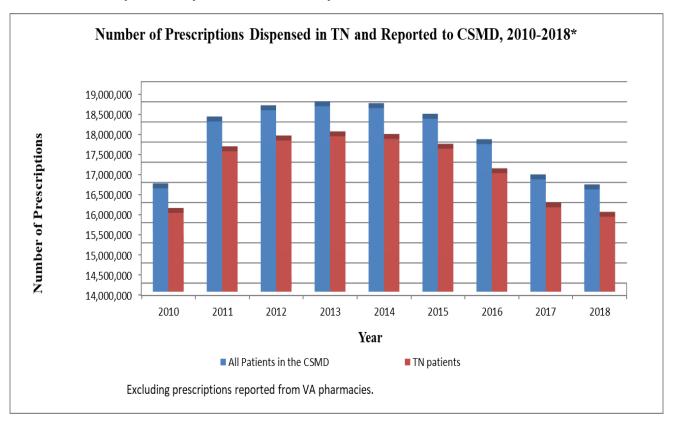
2018 Members of the CSMD Committee

| Member Name | Board |
|----------------------------|--|
| Melanie Blake, M.D. | Board of Medical Examiners |
| Katherine N. Halls, D.D.S. | Board of Dentistry |
| Juanita Turnipseed, APRN | Board of Nursing |
| Linda Tharpe, O.D. | Board of Optometry |
| Shant Garabedian, D.O. | Board of Osteopathy |
| Michael Dickerson, D.Ph. | Board of Pharmacy |
| Sheila Schuler, D.P.M. | Board of Podiatry |
| Robert Simpson, D.V.M. | Board of Veterinary Medical Examiners |
| Brett Reeves, PA-C | Committee on Physician Assistants |
| Robert Ellis | Public Member Board of Medical Examiners |
| Lisa Tittle | Public Member Board of Pharmacy |

Appendix

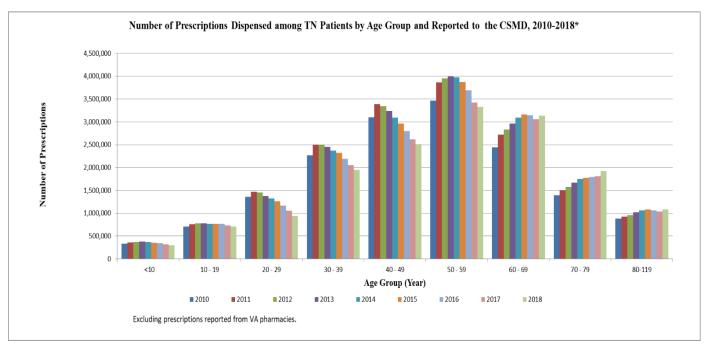
The CSMD data used for the 2018 report were downloaded on January 8, 2019. MME calculations and classification of controlled substances were completed based on a combination of CDC's MME conversion tables from 2011 to 2018. The CDC adjusted certain drug conversion factors over time for various reasons. If a drug had different MME conversion factors in different version tables, the data analysis provided through 2018 used the conversion factor provided in the latest CDC version table. Therefore different MME results for a similar indicator would be expected for CSMD annual reports published in previous years. Prescriptions and MME identified for TN patients were based on a patient's state listed as 'TN' or state FIPS code of '47' on his/her address associated with a prescription. Otherwise, the patient was identified as a non-TN patient. If a drug in the CSMD was not classified by the CDC table, the drug was classified as 'other' in this report. Please note that human and animal prescription data are included in this report as it relates to the data analysis through 2018.

Number of Prescriptions Dispensed in TN and Reported to CSMD, 2010-2018



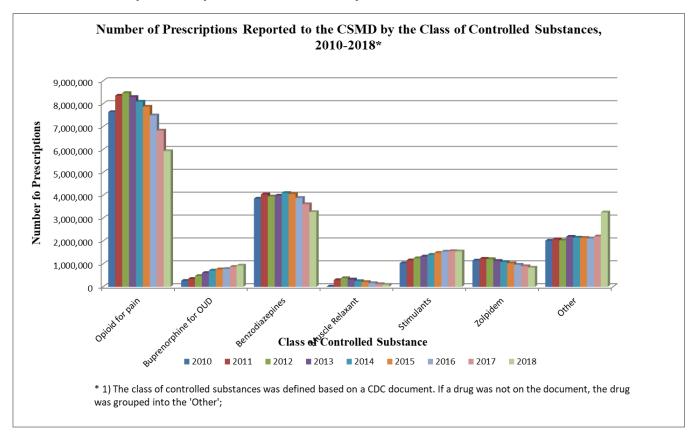
| | Number of Prescriptions | s Dispensed in TN a | nd Reported to the CSM | ID, 2010-2018* | | |
|--------|---|---------------------|------------------------|----------------|--|--|
| Year | All Patients in the CSMD | Change (%) | TN Patients | Change (%) | | |
| 2010 | 16,567,571 | - | 15,956,982 | - | | |
| 2011 | 18,225,973 | 10.0 | 17,488,326 | 9.6 | | |
| 2012 | 18,505,671 | 1.5 | 17,755,377 | 1.5 | | |
| 2013 | 18,605,179 | 0.5 | 17,856,161 | 0.6 | | |
| 2014 | 18,557,359 | -0.3 | 17,792,234 | -0.4 | | |
| 2015 | 18,293,500 | -1.4 | 17,549,962 | -1.4 | | |
| 2016 | 17,662,489 | -3.4 | 16,941,307 | -3.5 | | |
| 2017 | 16,789,893 | -4.9 | 16,096,110 | -5.0 | | |
| 2018 | 16,540,799 | -1.5 | 15,862,053 | -1.5 | | |
| *Exclu | *Excluding prescriptions reported from VA pharmacies. | | | | | |

Number of Prescriptions Dispensed among TN Patients and Reported to CSMD by Age Group, 2010- 2018



| | Number of Prescriptions Dispensed in TN among TN Patients and Reported to CSMD by Age Group, 2010-2018* | | | | | | | | |
|------------------------|---|---------------|-------------|-----------|-----------|-----------|-----------|-----------|-----------|
| Age Group (year) | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 |
| <10 | 337,917 | 357,878 | 370,977 | 375,793 | 366,826 | 352,414 | 340,150 | 318,827 | 296,431 |
| 10 - 19 | 708,281 | 757,615 | 776,838 | 776,531 | 764,434 | 768,973 | 765,991 | 734,954 | 704,218 |
| 20 - 29 | 1,356,402 | 1,474,516 | 1,449,839 | 1,379,437 | 1,320,218 | 1,262,917 | 1,164,826 | 1,053,031 | 940,969 |
| 30 - 39 | 2,269,260 | 2,500,055 | 2,501,221 | 2,446,458 | 2,373,717 | 2,318,630 | 2,186,256 | 2,050,232 | 1,949,619 |
| 40 - 49 | 3,101,350 | 3,388,401 | 3,343,643 | 3,234,348 | 3,090,575 | 2,957,606 | 2,797,085 | 2,610,966 | 2,507,101 |
| 50 - 59 | 3,467,150 | 3,859,299 | 3,950,769 | 3,989,487 | 3,972,355 | 3,875,158 | 3,686,235 | 3,423,713 | 3,326,212 |
| 60 - 69 | 2,444,464 | 2,715,469 | 2,830,123 | 2,957,062 | 3,092,883 | 3,162,316 | 3,146,866 | 3,058,468 | 3,132,174 |
| 70 - 79 | 1,392,973 | 1,509,062 | 1,574,472 | 1,673,530 | 1,751,430 | 1,772,534 | 1,787,265 | 1,810,992 | 1,920,459 |
| 80-119 | 879,142 | 925,985 | 957,417 | 1,023,486 | 1,059,775 | 1,079,378 | 1,066,628 | 1,034,903 | 1,084,837 |
| Unknown | 43 | 46 | 78 | 29 | 21 | 36 | 5 | 24 | 33 |
| *Excluding | prescriptions | reported fror | n VA pharma | cies | | | | | |

Number of Prescriptions Reported to TN CSMD by Class of Controlled Substances, 2010 - 2018

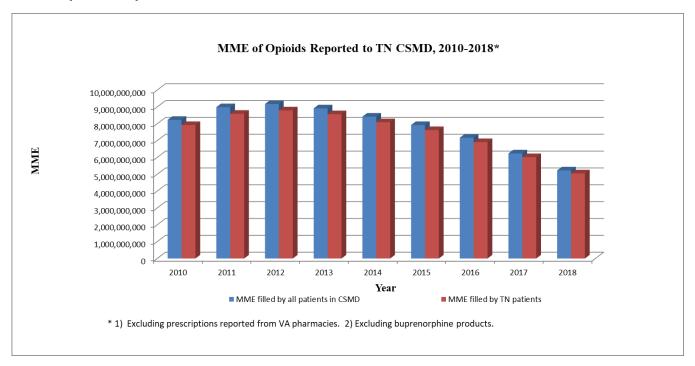


| Numb | Number of Prescriptions Dispensed Among TN patients and Reported to the CSMD by the Class of Controlled Substances, 2010-2018* | | | | | | |
|------|--|-----------------------|-----------------|--------------------|------------|-----------|-----------|
| Year | Opioid for pain | Buprenorphine for OUD | Benzodiazepines | Muscle Relaxant | Stimulants | Zolpidem | Other |
| 2010 | 7,637,331 | 259,105 | 3,854,236 | 11,630 | 1,028,497 | 1,149,873 | 2,016,310 |
| 2011 | 8,358,207 | 343,401 | 4,036,995 | 293,787 | 1,155,816 | 1,225,054 | 2,075,066 |
| 2012 | 8,469,520 | 472,474 | 3,951,106 | 377,900 | 1,248,353 | 1,209,688 | 2,026,336 |
| 2013 | 8,297,541 | 604,171 | 3,986,862 | 322,056 | 1,324,574 | 1,133,861 | 2,187,096 |
| 2014 | 8,095,168 | 711,110 | 4,101,079 | 250,306 | 1,399,208 | 1,085,122 | 2,150,241 |
| 2015 | 7,874,664 | 762,410 | 4,055,593 | 208,056 | 1,482,505 | 1,029,161 | 2,137,573 |
| 2016 | 7,493,147 | 780,213 | 3,887,093 | 159,837 | 1,540,496 | 965,378 | 2,115,143 |
| 2017 | 6,829,890 | 873,301 | 3,611,130 | 117,408 | 1,558,990 | 900,803 | 2,204,588 |
| 2018 | 5,931,344 | 932,041 | 3,269,282 | 88,037 | 1,550,245 | 838,751 | 3,252,353 |

*1) The class of controlled substances was defined based on CDC document. If a drug was not on the document the drug

was grouped into the "Other; Excluding prescriptions reported from VA pharmacies.

MME of Opioids Reported to TN CSMD, 2010-2018



| N | umber of Opioid Prescription | s Dispensed in T | 'N and Reported to CSMD, 2 | 2010-2018* | | |
|----------|---|------------------|----------------------------|------------|--|--|
| Year | Number of Rx in CSMD | Change (%) | Number of Rx Filled by | Change (%) | | |
| | | | TN Patients | | | |
| 2010 | 7,898,846 | - | 7,637,331 | - | | |
| 2011 | 8,681,029 | 9.9 | 8,358,207 | 9.4 | | |
| 2012 | 8,793,948 | 1.3 | 8,469,520 | 1.3 | | |
| 2013 | 8,598,009 | -2.2 | 8,297,541 | -2.0 | | |
| 2014 | 8,393,632 | -2.4 | 8,095,168 | -2.4 | | |
| 2015 | 8,171,139 | -2.7 | 7,874,664 | -2.7 | | |
| 2016 | 7,777,791 | -4.8 | 7,493,147 | -4.8 | | |
| 2017 | 7,087,718 | -8.9 | 6,829,890 | -8.9 | | |
| 2018 | 6,153,619 | -13.2 | 5,931,344 | -13.2 | | |
| * 1) Exc | * 1) Excluding prescriptions reported from VA pharmacies. 2) Excluding buprenorphine products for opioid use disorders. | | | | | |

MME for Long Acting Opioids Reported to the TN CSMD, 2010-2018

| MME for Long Acting Opioids Reported to the CSMD, 2010-2018* | | | | | | | |
|--|--------------------------|---------------|------------------------------|--|--|--|--|
| Year | Overall patients in CSMD | TN patients | Change among TN patients (%) | | | | |
| | | | | | | | |
| 2010 | 3,190,989,273 | 3,057,991,206 | - | | | | |
| 2011 | 3,254,786,743 | 3,121,293,556 | 2.1 | | | | |
| 2012 | 3,285,062,156 | 3,148,353,468 | 0.9 | | | | |
| 2013 | 3,238,216,544 | 3,106,161,557 | -1.3 | | | | |
| 2014 | 2,924,795,127 | 2,806,107,045 | -9.7 | | | | |
| 2015 | 2,552,291,111 | 2,454,148,868 | -12.5 | | | | |
| 2016 | 2,124,916,097 | 2,045,899,859 | -16.6 | | | | |
| 2017 | 1,630,298,000 | 1,568,894,509 | -23.3 | | | | |
| 2018 | 1,204,793,575 | 1,162,067,475 | -25.9 | | | | |

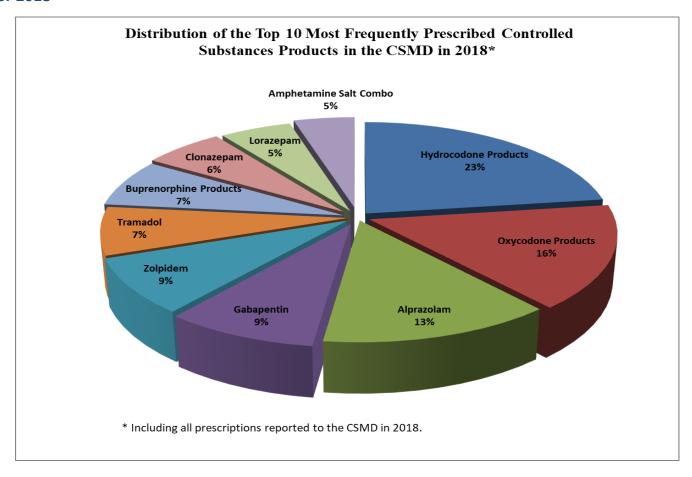
^{* 1)} The classes of controlled substances were defined based on a CDC document; 2) Excluding prescriptions reported from VA pharmacies; 3) Excluding buprenorphine products.

MME for Short Acting Opioids Reported to the TN CSMD, 2010-2018

| MME for Short Acting Opioids Reported to the CSMD, 2010-2018* | | | | | | | |
|---|--------------------------|---------------|------------------------------|--|--|--|--|
| Year | Overall patients in CSMD | TN Patients | Change among TN Patients (%) | | | | |
| 2010 | 5,039,428,269 | 4,864,582,321 | - | | | | |
| 2011 | 5,727,903,926 | 5,469,306,918 | 12.4 | | | | |
| 2012 | 5,891,039,406 | 5,645,050,796 | 3.2 | | | | |
| 2013 | 5,676,117,306 | 5,459,300,461 | -3.3 | | | | |
| 2014 | 5,495,823,563 | 5,283,695,020 | -3.2 | | | | |
| 2015 | 5,371,326,766 | 5,168,525,477 | -2.2 | | | | |
| 2016 | 5,046,357,775 | 4,863,320,231 | -5.9 | | | | |
| 2017 | 4,606,843,191 | 4,448,492,750 | -8.5 | | | | |
| 2018 | 4,025,049,294 | 3,890,868,224 | -12.5 | | | | |

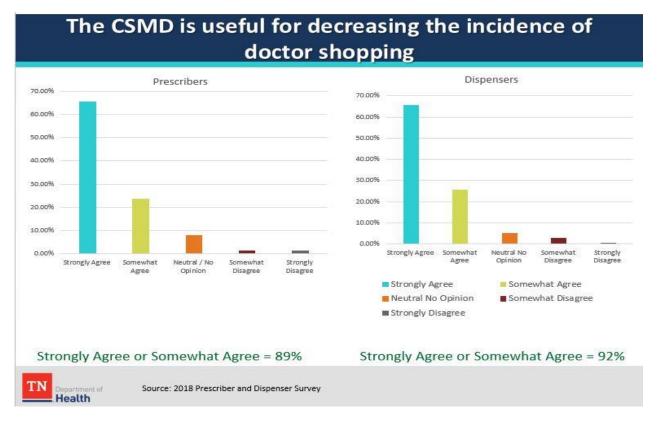
^{* 1)} The classes of controlled substances were defined based on a CDC document; 2) Excluding prescriptions reported from VA pharmacies; 3) Excluding buprenorphine products.

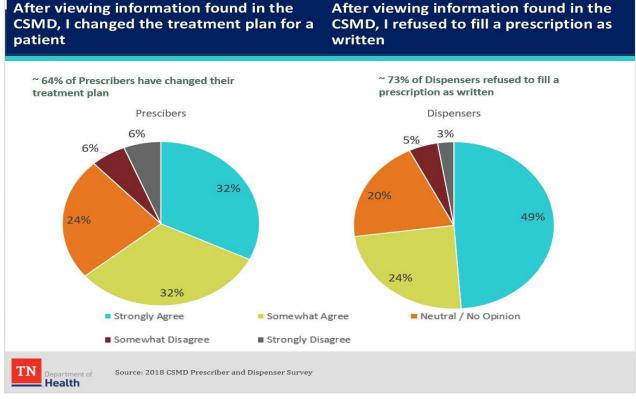
Distribution of the Top 10 Most Frequently Prescribed Controlled Substance Products in the CSMD for 2018



This information above was obtained from the CSMD web application downloaded on January 14, 2019.

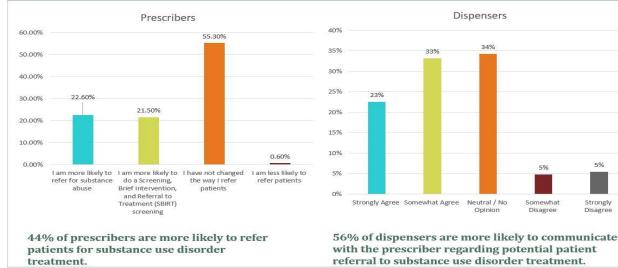
2018 Prescriber and Dispenser Survey Results







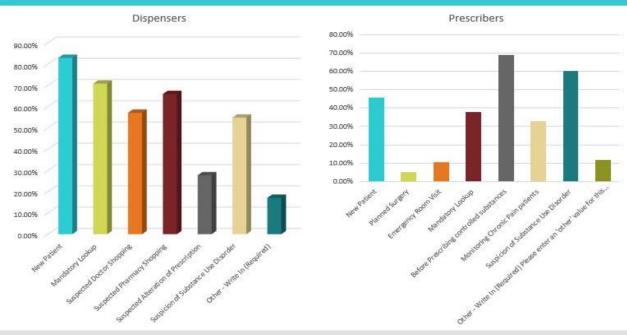
The CSMD has changed my practice of communicating with the prescriber regarding a patient whom I believe needs referred for Substance Use Disorder(SUD) treatment



Health

Source: 2018 CSMD Prescriber and Dispenser Survey

Why do prescribers and dispensers check the CSMD?



Health

Source: 2018 Prescriber and Dispenser Survey

| Acronyms | |
|--|----------------|
| Advance Practice Registered Nurse | APRN |
| Advance Fractice Registered Purse | AI MV |
| American Society for Automation in Pharmacy | ASAP |
| Centers for Disease Control and Prevention | CDC |
| Clinical Risk Indicator | CRI |
| Comprehensive Opioid Abuse Program | COAP |
| Continuing Education | CE |
| Continuing Medical Education | CME |
| Controlled Substance Monitoring Database | CSMD |
| Controlled Substance Monitoring Database Committee | CSMD Committee |
| Department of Justice | DOJ |
| East Tennessee State University | ETSU |
| Emergency Department | ED |
| Food and Drug Administration | FDA |
| Health Enterprise Warehouse | HEW |
| Medicated Assisted Treatment | MAT |
| Morphine Milligram Equivalents | MME |
| Neonatal Abstinence Syndrome | NAS |
| Physician Assistant Certified | PA-C |
| Prescription Drug Overdose | PDO |
| Prevention for States | PFS |

| Prescription Safety Act | PSA |
|--|---------|
| Screening, Brief Intervention and Referral to Treatment | SBIRT |
| Substance Use Disorder | SUD |
| Tennessee | TN |
| Tennessee Bureau of Investigations | TBI |
| Tennessee Code Annotated | TCA |
| Tennessee Department of Health | TDH |
| Tennessee Department of Mental Health and Substance Abuse Services | TDMHSAS |
| Veterans Affairs | VA |