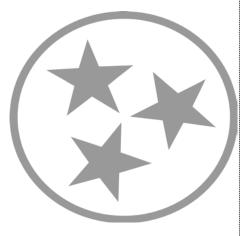


Controlled Substance Monitoring Database

2020 Report to the 111th Tennessee General Assembly

Tennessee Department of Health | Health Licensure & Regulation | March 1, 2020



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Tennessee Department of Health Key Points Related to the Drug Epidemic

The Tennessee (TN) Controlled Substance Monitoring Database (CSMD) is a prescription drug monitoring program designed to provide healthcare practitioners with a comprehensive view of a patient's controlled substance prescription history. The CSMD contains prescription information from all dispensers of controlled substances in Tennessee including Veteran's Affairs (VA) pharmacies in Tennessee. The CSMD collects and maintains dispensing data regarding all controlled substances in Schedules II, III, IV, and V controlled substances.

The purpose of the CSMD is to increase the quality of patient care by equipping healthcare practitioners with accurate, timely information that the practitioners can use to determine when patients acquiring controlled substances may require counseling or intervention for substance abuse, by collecting and maintaining data regarding all controlled substances in Schedules II, III, and IV dispensed in this state, and Schedule V controlled substances identified by the controlled substance database committee as demonstrating a potential for abuse. Further, the database is to be used to assist in research, statistical analysis, criminal investigations, enforcement of standards of health professional practice, and state or federal laws involving controlled substances.

In accordance with the Controlled Substance Monitoring Act of 2002, the CSMD was established. Data collection began for all dispensers on December 1, 2006. The Prescription Safety Acts of 2012 and 2016 enhanced the monitoring capabilities of the database especially with mandatory registration and use starting in 2013. The CSMD became more timely and meaningful in 2016 when data for human patients had to be submitted at least once every business day for all the controlled substances dispensed, but no later than the close of business on the following business day. Additional changes to the laws effecting the database were made by Tennessee Together legislation which increased the frequency for mandatory check of the CSMD for prescribing and dispensing of opioids and benzodiazepines from every 12 months to every 6 months. As of this year, prescribers and pharmacists are able to pull prescription information from many other states especially the southeast United States and the US Department of Defense.

This 2020 CSMD report is designed to provide the General Assembly an update on activities and outcomes related to the substance abuse crisis as it relates to the CSMD and the Tennessee Department of Health (TDH). 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 minimize 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 at risk patients. Provision of accurate and timely dispensing information is essential to wise clinical decision making; which can provide safe and effective treatment of pain.

Key Findings



•	Morphine Milligram Equivalent (MME) pres	scribed and dispensed to patients in Tennessee has
	decreased almost 53%	(2012-2019)

• MME prescribed by top 50 prescribers has decreased 49%	(2013-2019)
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•	Number of	pain clinics have be	en reduced by 62%	(2014-2019)

• Number of potential doctor shoppers have decreased 89% (2011-2019)

• Number of opioid prescriptions for pain have decreased by 38% (2012-2019)

• Patients receiving >120 MME/day decreased by 52% (2012-2019)

Cases of Neonatal Abstinence Syndrome decreased by 15% (2017-2018)



- Searches of CSMD have increased 603% and continue to increase (2012-2019)
- The number of CSMD requests increased 15% in 2019 to 13,111,746 compared with 2018.
- There was one search of the CSMD for every 1.3 prescriptions in Tennessee in 2019, up from one search for every 12 prescriptions in 2011.

Key Improvements in the CSMD in 2019:

- Since 2013, the number of controlled substance prescriptions reported to the CSMD has decreased 11%.
- TDH completed a contract amendment that will allow the CSMD to start the 2020 Gateway Electronic Health Record (EHR)/Pharmacy Management System workflow integration project to provide controlled substance prescribers and pharmacists the ability to integrate CSMD information into clinical workflow across the state.
- The CSMD system uptime was 99.9% for 2019
- Response time for searches in the CSMD was less than two seconds if request does not include data from another state.
- The CSMD program in 2019 added Delaware, Florida, Iowa, Rhode Island and one way data sharing (allowing Tennessee to receive data) with Military Health System and the St. Louis County Program to the other states or entities with which Tennessee partners.

Considerations for 2020:

- Mandatory e-prescribing of controlled substances in Tennessee starts January 2021. As of December 2019, only 23% of prescription reported to the CSMD are electronically prescribed.
- As prescribing and dispensing of most drug classes is declining, but the number of prescriptions
 for schedule II stimulants is currently almost 20% above the 2011 number of stimulant
 prescriptions.
- Among opioid-related overdose deaths, 27% also had benzodiazepines associated with the
 reported opioid, highlighting the critical importance of avoiding concomitant use of opioids and
 benzodiazepines.
- In 2018, less than half of individuals (40%) who died of drug overdose had any controlled substance dispensed within 60 days of death. The increase in overdose deaths due to opioids in 2018 was largely due to illicit fentanyl (48% increase) and heroin (18% increase). This reinforces the need for a three-pronged approach of prevention, treatment, and enforcement in turning the tide of this epidemic.

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

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 2017 to 2018, drug overdose deaths in Tennessee rose by 2%, increasing from 1,776 to 1,818. The increase in overdose deaths from 2017 to 2018 is relatively small compared to previous years and is consistent with a nationwide leveling off of overdose deaths in 2018.² Despite slower growth, deaths due to drug overdose in Tennessee remain at their highest level in over a decade. Although the proportion of drug deaths associated with opioids was approximately the same in 2018 (72%), this number includes illicit opioids such as heroin and illicitly manufactured fentanyl. The proportion of deaths categorized by the CDC as associated with opioid pain relievers continued to decrease, from 36% to 30%. Deaths associated with benzodiazepines continued to decrease as well, from 504 to 409 (a 19% decrease). Likewise, deaths that included a combination of benzodiazepines and opioids decreased 21% from 447 to 354. Just over one quarter (27%) of opioid associated deaths also included a benzodiazepine.

Concomitant improvements 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 suggest that increased awareness among the medical community and statewide interventions may have lessened the impact of prescription drugs on overdose mortality. Among individuals who died of drug overdose in 2018, under half (40%) had a controlled substance dispensed within 60 days of death, a decrease from 43% the year before. This downward trend has been consistent, year over year since 2013, and suggests that other factors are playing a significant role in increasing overdose deaths, including illicit fentanyl, heroin, and diverted prescription opioids.

Overdose deaths involving illicit opioids increased substantially from 2017 to 2018. The number of overdose deaths in which fentanyl was involved increased 48%, from 500 to 742, accounting for 41% of all drug overdose deaths. Heroin deaths increased 18%, from 311 to 367. Among drugs typically used for treatment of opioid use disorder, overdose deaths involving methadone decreased slightly, from 69 to 66, and buprenorphine associated deaths increased 14%, from 73 to 83.

Over the past year, TDH has continued to make improvements in the way CSMD data are used to help stem the epidemic of overdose in Tennessee. The Office of Informatics and Analytics maintains the Integrated Data System which combines data from the CSMD with other patient health data to identify key markers for increased risk. Epidemiologists at TDH have conducted a number of studies and are developing several tools using these linked data to better understand patient trajectories as they move from prescription drugs into the illicit market, and to better understand what puts Tennesseans at higher risk for overdose and death. With these data, policy and prevention, and intervention programs, treatment 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 has developed a data driven method of identifying prescribers who may be engaging in high risk prescribing or who have high risk patient populations.

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

² Ahmad FB, Escobedo LA, Rossen LM, Spencer MR, Warner M, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2019. https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

The first high risk prescriber lists were created in 2019, and they continue to undergo refinement to better identify risky prescribing. Work also continues to identify patients at high risk of overdose, and the department is partnering with researchers at Vanderbilt University Medical Center (VUMC) to apply advanced machine learning techniques to better predict overdose risk among Tennesseans.

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. Through these partnerships, TDH is providing county-level data to stakeholders in communities across Tennessee. Data such as the CSMD is invaluable for planning and resource allocation for TDH prevention and response projects.

The Office of Informatics and Analytics (OIA) produces several public annual reports that present data on overdoses throughout Tennessee. The fatal overdose report is released when data are finalized in September and includes information on overdose decedent prescription histories using CSMD data. The non-fatal overdose report includes information on non-fatal overdoses for patients who were seen at a TN hospital and is released on March 1. An omnibus annual report that includes additional overdose information, prescription trends, and project updates is released in mid-February. These reports, including associated slides and infographics, can be found at: https://www.tn.gov/health/health-program-areas/pdo/pdo/facts-figures.html. OIA also produces interactive dashboard that includes overdose and prescription information can be found here: https://www.tn.gov/health/health-program-areas/pdo/pdo/data-dashboard.html. Updates to this dashboard are planned for Spring 2020.

Moving Upstream to Use Weekly Hospital and Emergency Medical Services (EMS) Data

For every drug overdose death, approximately 13 nonfatal overdoses are identified in discharge data from state emergency departments and hospitals. The proportion of these hospital visits due to opioids has steadily increased, with a particularly substantial increase in heroin related nonfatal overdoses in recent years. OIA estimates at least 13% of overdose decedents in 2017 had a non-fatal overdose in the year before their death.

These overdoses are treated in emergency departments and hospitals, but information about overdoses is not currently available to clinicians outside the hospital or through the CSMD. In 2016, Public Chapter 959 provided the Commissioner with the opportunity to require healthcare facilities to provide 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 Drug Overdose Reporting system (DOR) is now in its active stage, with 116 hospitals reporting to TDH from across the state. From the pilot stage through 2019, hospitals have only been required to report opioid overdoses. Beginning in 2020, hospitals are now being asked to report overdoses involving a number of other substances of concern, specifically stimulants, benzodiazepines, and muscle relaxants. This expanded range of reporting will provide better insights into the changing nature of Tennessee's overdose epidemic and potentially reveal timely trends in overdoses that equip the state to respond to new and emerging threats.

Preliminary estimates show that overdoses seen in a hospital are reported, on average, just over a week after the patient is discharged, making DOR one of the fastest sources of overdose information available to the department.

This speed makes DOR data one of the department's most important tools for planning and resource allocation for overdose response. Overdoses reported to DOR are used in several regular data briefs that are shared with regional epidemiologists, including information on those overdoses associated with active CSMD prescriptions. As of Fall 2019, record-level DOR data have been made available to regional and metro health departments to guide local response efforts. Additionally, TDH convenes a biweekly multi-agency workgroup made up of several divisions across TDH, the TN Department of Mental Health and Substance Abuse Services, the TBI, and others to discuss current temporal and geographic trends in the overdose data. These meetings play a vital role in state agency situational awareness and offer a valuable opportunity for state overdose stakeholders to share challenges, successes, and support.

Unfortunately, TDH does not currently have a reliable estimate of the number of overdoses which are managed in the field where the patient refuses transport to the hospital. TDH expects that this represents an even larger number of nonfatal overdoses that are not currently being systematically tracked. In order to overcome this gap, the Office of Informatics and Analytics is actively working with the Office of Emergency Medical Services (EMS) to obtain statewide emergency medical service data on overdoses seen in the field. Once these data are available, TDH anticipates creating a number of reports and public health surveillance products that will better inform stakeholders about the prevalence and trends in nonfatal overdose throughout the state. The department continues to explore ways to provide patient overdose information from these sources back to providers so that they might have additional patient history data to make better informed decisions about opioid prescribing.

Neonatal Abstinence Syndrome Surveillance Update

The number of infants with Neonatal Abstinence Syndrome (NAS) reported to TDH reached a high of 1,096 cases in 2017. ³In 2018, for the first time since surveillance began, the number of cases reported to TDH decreased by 15% to 927 reported cases. A majority of the mothers of these infants report exposure to prescription medications, most of which is attributable to prescribed buprenorphine or methadone for medication assisted treatment. Updated information through 2019 is expected to be available later this year.

The Role and Presence of Pain Clinics across Tennessee

Beginning July 1, 2017, all pain management clinics were required to become licensed under TCA § 63-1-301. All active pain management clinics have now been issued a license; there are not any active pain management clinics operating on a certificate. The licensure requirements are more stringent than those of registration for a certificate, and new rules have been promulgated by the Department to govern the process of regulating the licensed clinics.

The Pain Management Clinic Act requires the medical director be on-site at the clinic at least 20% of the clinic's weekly operating hours, and prohibits the medical director from serving in that capacity at more than four (4) pain clinics. Beginning July 1, 2017, the medical director must be the license-holder of the pain management clinic. While many medical directors were owner/certificate-holders, many certified clinics were owned by an advanced practice registered nurse or a physician assistant. Requiring the medical director to be the individual who applies for and is

³ https://www.tn.gov/content/dam/tn/health/documents/nas/NAS-Annual-Report-2018.pdf

responsible for the license, gives medical directors both more control over what happens under their watch at a clinic, as well as more responsibility. Additionally the licensure laws require the department to inspect every pain management clinic before licensure. The department may deny licensure, or discipline an existing license, if anyone working in the clinic has been convicted for an offense involving the sale, diversion, or dispensing of controlled substances, has been disciplined for conduct that was the result of inappropriate prescribing, dispensing, or administering controlled substances, has had their license restricted, or if an owner of the clinic has pleaded to or been convicted of a felony under TCA § 63-1-316.

Furthermore, though licensure inspections are now required, random clinic inspections had not been required by law prior to July 1, 2017; however, random inspections have been undertaken by the department as a best practice. Prior to July 1, 2017, the department randomly inspected one third of certified pain clinics each year. Subsequent to July 2017, when the law was amended to require clinics to be licensed, and through the calendar year 2019, unannounced inspections have occurred pursuant to a licensure application instead of as previously conducted.

Following passage of these 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 law in 2015 and 2016, requiring medical directors of pain management clinics be certified in pain management, the number of registered pain management clinics was reduced to 126 clinics by December 2019. Such changes also improved access to quality care by eliminating clinics that may have served as portal for diversion and abuse of control substance.

Pain management clinic licenses are active for two (2) years. The fall of 2019 was the beginning of the renewal cycle for pain management clinic. There were a total of eight (8) pain clinic licenses to expire in 2019; three (3) of those clinics have closed, one (1) has relocated, three (3) have been approved and one (1) renewal license application remains in a pending status.

Pain Clinic Practice Guidelines have been developed and were published in January of 2017 with help from pain medicine specialists, pharmacists, physician assistants, and advanced practice registered nurses. The guidelines are available at: https://www.tn.gov/content/dam/tn/health/healthprofboards/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; additional text revisions were published January 2020. The guidelines and acknowledgement of 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

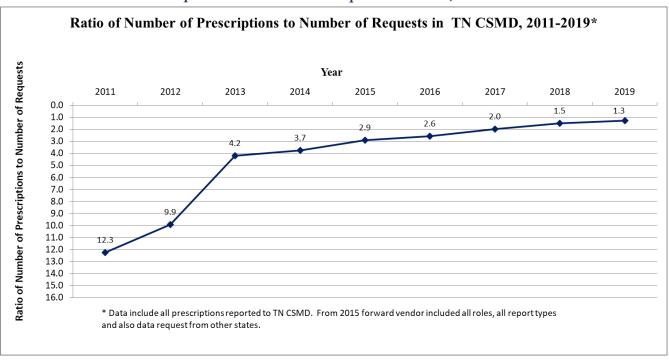
The Prescription Safety Act (PSA) of 2012 facilitated a substantial increase in utilization of the CSMD, and the PSA of 2016 and other legislation again expanded the requirement for when healthcare practitioners are to check the CSMD. Year after year, the CSMD continues to have significant increases in the number of registrants. By the end of 2019, the number of registrants had grown to 54,642. Prior to the PSA of 2012 and 2016, the graph below demonstrates that Tennessee had approximately 12 prescriptions reported for every CSMD patient query and now there are

approximately 1.3 prescriptions reported for each request. The number of queries increased around 15% in 2019 to 13,111,746 compared to 2018.

Number of Registrants of TN CSMD, 2011-2019

	Number of Registrants of TN CSMD, 2011 - 2019*							
Year	Registrants	Change (%)						
2011	15,323	-						
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						
2019	54,642	7.2						
	*Inclusion of VA registr	ants began in 2013						

Ratio of Number of Prescriptions to Number of Request in CSMD, 2011-2019

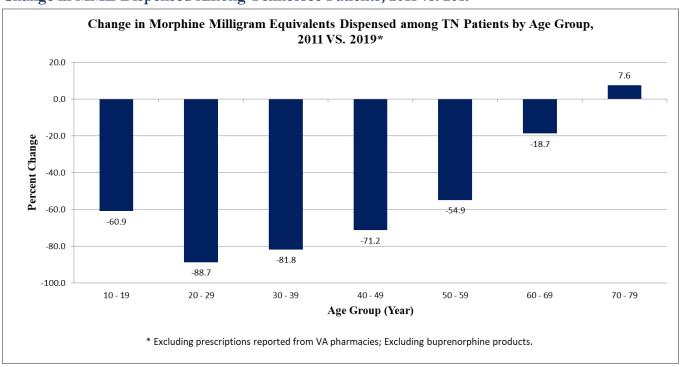


Law enforcement requests to the CSMD continue to be a critical use of the CSMD as TDH works together to address questionable controlled substance use in Tennessee. During 2019 there were 1,620 law enforcement related requests to the CSMD. Effective July 1, 2011, law enforcement officers were granted access to the CSMD. That access was further expanded through the PSA of 2016. During 2019, TDH added enhancements of the CSMD designed to provide direct access to law enforcement and drug courts to improve access to the CSMD.

MME Improvements and Concerns by Age Group

For 2019, 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 MME dispensed for patients between 10 to 69 years of age compared to 2011 data. These improvements for these age groups are an indicator that TDH's efforts are being successful at preventing individuals from being overexposed to opioids by the healthcare system. In the age groups over 69, the upward trending MME is slowing. In 2019, MME increased 7.6% compared to 2011 in the 70-79 age group. This is an improvement over 2018 when MME increased 18.4% compared to 2011 for the same age group.

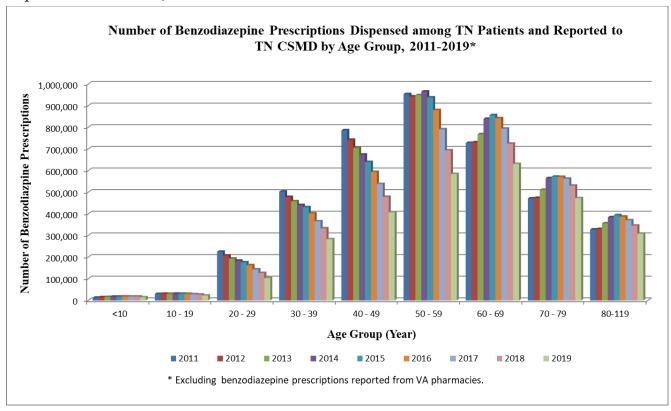
Change in MME Dispensed Among Tennessee Patients, 2011 vs. 2019



Trends Related to Utilization of Benzodiazepines

Benzodiazepines, such as alprazolam and diazepam, showed a 22% decrease in prescriptions from 2017 to 2019. For 2019, 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, 2011-2019

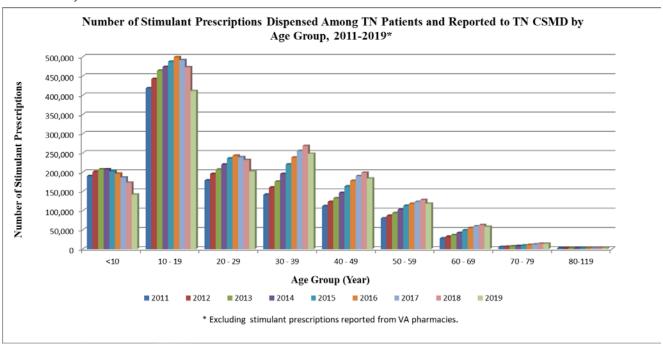


Number of Benzodiazepine Prescriptions Dispensed among TN Patients and Reported to TN CSMD by Age Group, 2011-2019*										
Age Group (Year)	2011	2012	2013	2014	2015	2016	2017	2018	2019	
<10	12,642	14,724	15,916	17,290	17,728	18,235	18,095	17,785	14,358	
10 - 19	29,672	30,626	30,254	30,983	30,760	30,183	28,646	26,830	22,800	
20 - 29	224,982	207,451	193,215	183,633	176,269	162,783	143,624	126,704	103,438	
30 - 39	502,685	478,168	458,180	440,780	430,957	402,270	365,480	333,145	283,058	
40 - 49	786,348	742,200	704,881	673,906	639,679	593,564	538,109	478,624	407,179	
50 - 59	953,618	942,991	948,570	965,456	938,105	879,763	790,927	693,462	584,300	
60 - 69	727,915	730,881	768,391	839,475	856,070	842,139	793,869	724,228	630,748	
70 - 79	471,437	474,123	511,161	565,131	572,026	570,913	562,836	530,212	472,737	
80-119	327,964	330,042	356,373	384,560	394,060	387,383	370,550	345,840	308,217	
Unknown	6	7	2	2	7	0	6	1	7	
		* Excluding	benzodiazep	oine prescript	ions reported	from VA pl	narmacies.			

Trends Related to Utilization of Stimulants

The number of prescriptions for stimulants has continued to increase, growing by 19% for patients in Tennessee from 2011 to 2019.

Number of Stimulant Prescriptions Dispensed Among TN Patients by Age Group and Reported to the CSMD, 2011-2019

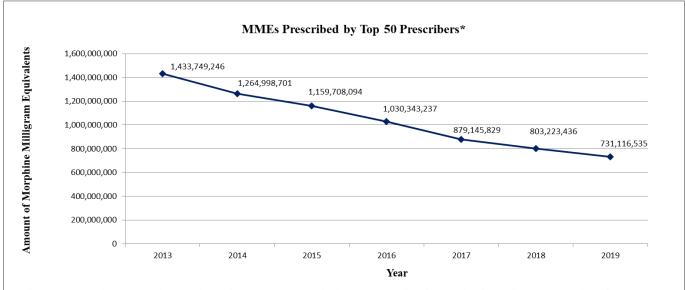


Number of Stimulant Prescriptions Dispensed among TN Patients and Reported to TN CSMD by Age Group, 2011-2019*									
Age Group (Year)	2011	2012	2013	2014	2015	2016	2017	2018	2019
<10	189,727	200,879	207,025	207,007	202,077	196,378	186,047	172,710	141,738
10 - 19	418,619	442,331	464,022	473,981	487,552	499,174	491,959	473,251	410,996
20 - 29	178,555	195,633	206,472	220,028	235,901	242,767	239,125	231,944	202,075
30 - 39	141,529	160,022	175,434	195,713	220,229	238,098	255,127	268,663	247,953
40 - 49	111,529	122,807	132,259	146,213	163,163	177,734	189,649	198,723	183,508
50 - 59	79,907	86,549	93,464	102,874	112,452	118,048	122,796	127,688	118,198
60 - 69	27,874	32,006	36,298	42,259	48,874	54,821	59,488	62,767	58,061
70 - 79	5,769	6,138	7,221	8,504	9,529	10,870	12,361	13,867	13,817
80-119	2,335	2,017	2,403	2,633	2,731	2,615	2,538	2,646	2,386
Unknown	1	0	0	6	4	0	0	0	0
		*Excludir	ng stimulant _l	prescriptions	reported fro	m VA phari	nacies.		

Interventions Related to Top Prescribers

TCA 68-1-128 (passed during 2015) required TDH to continue to identify the top 50 prescribers in Tennessee and added a new requirement for TDH to identify the top 10 prescribers from all of the combined counties having populations of fewer than 50,000 residents. The total morphine equivalence prescribed in aggregate by the Top 50 prescribers has decreased each year since 2013. After six years of experience with the top 50 prescriber analysis, the MME prescribed by this group have declined 49% since the first analysis performed on data from 04/01/2012 – 03/31/2013 as noted in the line graph below.

MME Prescribed by Top 50 Prescribers

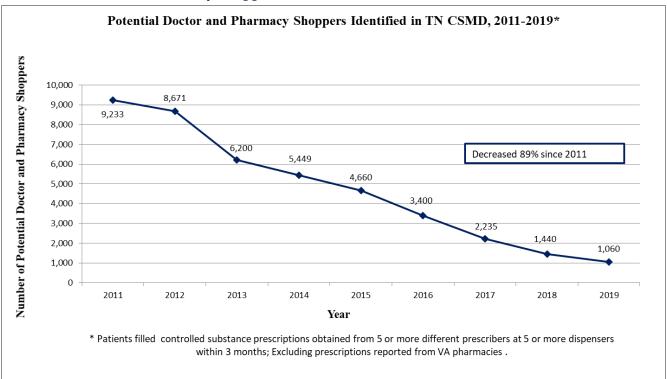


*MME in 2013 and 2014 covered 12-month opioid prescriptions written by the top 50 prescribers from April 1 of preceding year to March 31 of current year; MME in 2015, 2016, 2017, 2018 and 2019 covered opioid prescriptions filled by the patients of the top 50 prescribers in each preceding calendar year.

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 89% decrease of potential doctor and pharmacy shopping patients from 2011 to 2019.

Potential Doctor and Pharmacy Shoppers Identified in the CSMD, 2011-2019



Gateway Electronic Health Record (EHR)/Pharmacy Management System Workflow Integration

TDH has completed a contract amendment that will allow the CSMD to start the 2020 Gateway EHR/Pharmacy Management System project. The Gateway service will allow healthcare providers the ability to view their patient's controlled substance prescription history within their clinical application (EHR/Pharmacy Management System). During 2018, the Gateway functionality was reviewed and approved by CSMD Committee at the July 2018 meeting. This project proposes to integrate CSMD searches and Clinical Risk Indicators (CRI) into EHRs and pharmacy management systems workflow. The opportunity was presented to the prescribing boards for human patients and the Board of Pharmacy where each board agreed to allow TDH to utilize board reserve funds to fund a two year project to pilot this CSMD workflow integration project across the state to entities' EHR/Pharmacy Management Systems that desire to integrate using the Gateway service provided by Appriss.

Database Metrics and Browser Recommendations

The CSMD team works diligently with the vendor to continue providing a stable environment for healthcare providers. The CSMD system uptime was 99.9% for 2019. One attribute of the system is the CSMD responds in less than two seconds when a patient request is initiated that does not include data from another state. In order for healthcare providers to have the best performance experience the following browsers are recommended: Internet Explorer 11 or above, Safari, Chrome or Firefox.

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 entities. The CSMD program now shares data with many states now including the entire southeast United States. The CSMD program in 2019 added Delaware, Florida, Iowa, Rhode Island, and one way data sharing (allowing Tennessee to receive data) with Military Health System and the St. Louis County prescription monitoring program. Each state has unique regulations and requirements that require collaboration to share data to address state regulation compliance. The CSMD program has utilized at no cost to states the National Association Boards of Pharmacy PMP InterConnect (PMPi) to allow Tennessee to share data. The PMPi is a highly secure communications exchange platform that facilitates the transmission of PMP data across state lines to authorized requestors, while ensuring that each state's data-access rules are enforced.

TDH is in the process of connecting the CSMD with RxCheck, an interstate data sharing and integration system developed with support from the U.S. BJA and designed to complement current CSMD activities. It is of no cost to states or CSMD users and allows states to have an additional option for querying prescription data across state lines. RxCheck is governed jointly by the Integrated Justice Information Systems Institute (IJIS), BJA, and a board of PDMP administrators in connected states. Currently, BJA has made a commitment to fund RxCheck and support both the states and governing body with training and technical support. In the coming year, the CSMD team and the Office of Informatics and Analytics will be working closely to ensure a successful RxCheck connection with the appropriate technical and administrative processes and documentation in place. TDH will also be exploring the possibility of using RxCheck for electronic health record integration with CSMD data.

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 TCA § 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. 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 and its contractors 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.
- Requests by law enforcement personnel for information sent to, contained in, and reported from the database pursuant to TCA § 53-10-306(a)(8) can be obtained in two ways. The first method is a paper process whereby law enforcement personnel submit a written request with a case number corresponding to a criminal investigation. Before releasing any information, CSMD staff verifies the

- law enforcement personnel are on the approved list submitted by the TBI director or the appropriate district attorney general. The second method is via electronic registration and approval. Once electronic registration is obtained, law enforcement personnel can obtain the information directly from the CSMD web portal. Both of these processes create an audit trail.
- Requests for access by persons other than those individuals outlined in TCA § 53- 10-306(a)(1-7) and
 (9) are reviewed by Board of Pharmacy staff and Legal Counsel to determine if the person requesting access can be granted access pursuant to applicable laws and rules. Legal staff also reviews all subpoenas and court orders to ensure compliance with the law before releasing any information.
- In 2016, TDH expanded its internal access systems as part of the creation of the 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 partners including Strategic Technology Solutions (STS) staff, TDH Information Technology Services Division (ITSD) staff, the Office of General Counsel (OGC) and the Office of Informatics and Analytics staff in conjunction with oversight from the CSMD program. The TDH Integrated Data System and data storage, including certain 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 TDH Integrated Data System. Users of these tools have to receive permission
 from the Director of the Office of Informatics and Analytics and the Director of Tennessee
 Controlled Substances Monitoring Database Program in order to access CSMD data from the TDH
 Integrated Data System.

TDH Provides Significant Educational Outreach

Over 50 presentations were made across the state to approximately 4,500 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.

Eight 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). Programming included live audiences, live streaming, and archived efforts to reach all health care providers. Each of these educational opportunities allowed health care providers to earn Continuing Medical Education (CME) or other Continuing Education (CE) credits.

The 2020 TDH Educational Outreach is focusing on high risk rural communities. The criteria for educational sites and efforts are as follows:

- Areas with high Department of Child Services (DCS) referrals
- Non-fatal inpatient/outpatient overdoses
- Overdoses (both fatal and nonfatal)

- Increasing incidence of HIV and hepatitis C
- 2017 to 2018 Prescriptions, prescription per capita, and prescription growth

TDH Grants Update

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, 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 PfS grant came to a close in 2019 with many of the activities continuing under a new grant. The purpose of the PfS grant was 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 supported 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. This work has allowed the team to generate several publications and public health surveillance products 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 were a number of key areas of activity:
 - o 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.

o 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, TDH was awarded a grant from the Department of Justice (DOJ) under the Harold "Hal" Rogers program to create rapid data based collaboration between TDH, TBI, and TDMHSAS. This grant is currently in its final year. The grant funded 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. Under the Hal Rogers funding, TDH has convened biweekly meetings of stakeholders from TDH, TDMHSAS, TBI, and other state agencies to discuss ongoing activities and trends in the data. The grant supports a full time junior epidemiologist to develop visualizations and data analytics on which the team can act, as well as partial funding for the development of overdose risk prediction models by VUMC.

In 2017, TDH received another CDC grant to enhance surveillance of opioid overdoses, called Enhanced Surveillance of Opioid Overdose in States (ESOOS). For this grant, TDH worked to expand nonfatal overdose data gathering from TDH's syndromic surveillance system; the Electronic Surveillance System for the Early Notification of Community Epidemics (ESSENCE). TDH also gathered and submitted expanded information on fatal overdoses in collaboration with the Office of the State Chief Medical Examiner. These fatal overdose data were submitted to a nationwide system called the State Unintentional Drug Overdose Reporting System (SUDORS). SUDORS data submitted under the ESOOS grant contain detailed information on toxicology and scene investigation for opioid overdose deaths in Tennessee SUDORS is a part of the National Violent Death Reporting System, also sponsored by the CDC.

In 2018, TDH received two grants from the DOJ's BJA Comprehensive Opioid Abuse Program (COAP). One of these grants funds the work to connect the CSMD to RxCheck and partially supports the predictive modeling work that is being conducted by VUMC. The other grant funds the integration of EMS overdose data into TDH's Integrated Data System, the expansion of overdose and drug surveillance to other substances of concern, and continues the interagency collaborations started under the Hal Rogers funding.

In 2019, the CDC combined PfS and ESOOS activities into a single, more expansive grant opportunity called Overdose Data to Action (OD2A). In addition to the surveillance activities undertaken for the ESOOS grant and the CSMD-related data work for PfS, the OD2A grant expands the funding available for overdose prevention activities across the state. TDH will be working closely with regional and metro health departments across the state to start or expand local prevention activities, academic detailing and opioid and overdose education for prescribers, and treatment resource locators. Funding for these activities is anticipated to last through 2022.

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. Adolescents need ongoing education that will foster resistant's to substance abuse. Healthcare practitioners need to be reminded of the need for increasing screening of opioid abuse using tools such as Screening, Brief Intervention and Referral to Treatment (SBIRT) and increasing the availability of substance use disorder treatment and the need to reduce the stigma of substance use disorders. The educational focus

should also include adopting effective safe syringe programs, and increased use of naloxone while working with community partners.

• 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.

• Collaboration and data driven approaches can be effective in fighting this evolving epidemic TDH has worked to improve infrastructure needed to maximize utilizing various data sources providing a more comprehensive view of this epidemic. This would not be possible without building and strengthening partnerships and promoting collaboration to not only make data available, but to more effectively use the information produced, to drive action and response where it is needed most.

• In summary

By focusing on minimizing opioid exposure for people who are opioid naïve, partners can "block the onramp 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, TDH can work with communities to address developing problems before they become more entrenched in our communities. By working to eliminate the stigma of substance use disorder, patients struggling with addictions can access help earlier, 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 before a decision is made about any future prescribing. The CSMD is reliably available, and clinicians are making more frequent use of searches, with one search for every 1.3 dispensed prescriptions in 2019. 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 potential doctor shoppers. For the first time in five years, 2018 saw a decrease in babies born with neonatal abstinence syndrome, and 2019 data is expected to continue to demonstrate a decreased trend.

At the same time, the epidemic of opioid misuse and abuse has continued to change. Although more people died of drug overdoses in 2018 than ever before, overdose deaths did not increase as much as they had in prior years. The proportion of deaths categorized by the CDC as associated with opioid pain relievers continued to decrease from last year, as well as deaths associated with benzodiazepines. The most notable developments were the rapid rise of fentanyl as a frequent cause of overdose death and the milder, but sustained rise in heroin as a cause. 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 valuable 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 SUD, preventing early conversations that can lead to timely interventions.

ee Chronic Pain Guideline Ex o work together in preventing		

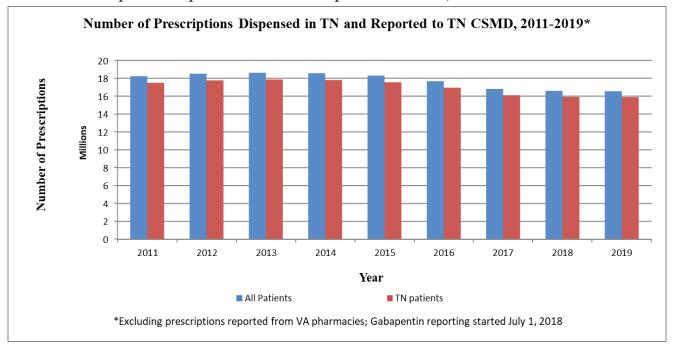
2019 Members of the CSMD Committee

Member Name	Board
Melanie Blake, M.D.	Board of Medical Examiners
Thomas Williams, D.D.S.	Board of Dentistry
Mark Young, APRN	Board of Nursing
Tonya Reynoldson, O.D.	Board of Optometry
Shant Garabedian, D.O.	Board of Osteopathy
Adam Rodgers, D.Ph.	Board of Pharmacy
Bhekumuzi Khumalo, 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
Vacant	Public Member Board of Pharmacy

Appendix

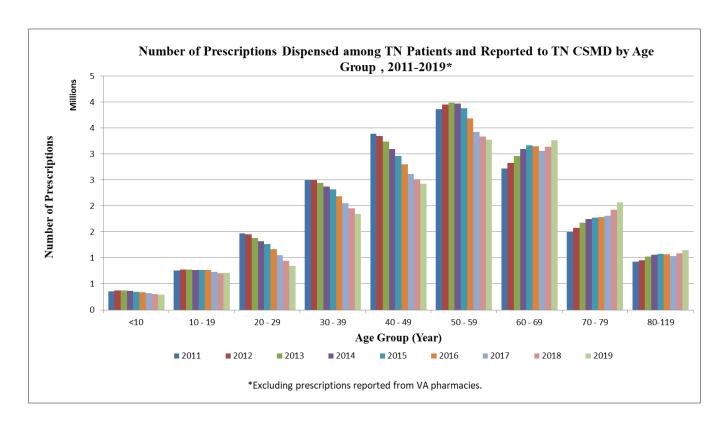
The CSMD data used for this 2020 report were downloaded on January 7, 2020. MME calculations and classification of controlled substances were completed based on a combination of CDC's MME conversion tables from 2011 to 2018. The CDC adjusted certain drug conversion factors over time for various reasons. 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 Federal Information Processing Standard (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 2019. The reader is advised to interpret any trends involving drug class and MME in 2019 with caution. Due to a delay in the CDC's reporting of drug information, drug class and MME information for some prescriptions drugs may not have been available when this report was compiled. Some prescription counts and MME totals in 2019 are likely to be higher when updated drug information becomes available. For example, if a generic opioid drug was released to the market in Spring 2019, drug class and MME information for this drug would not have been available for the analyses included in this report. Any prescriptions filled for this drug would therefore not be represented in the counts of opioid prescriptions or the total MME.

Number of Prescriptions Dispensed in TN and Reported to CSMD, 2011-2019



	Number of Prescriptions Dispensed in TN and Reported to TN CSMD, 2011-2019*								
Year	All Patients	Change (%)	TN Patients	Change (%)					
2011	18,226,992	-	17,489,329	-					
2012	18,506,493	1.5	17,756,183	1.5					
2013	18,606,098	0.5	17,856,953	0.6					
2014	18,558,561	-0.3	17,792,955	-0.4					
2015	18,294,241	-1.4	17,550,402	-1.4					
2016	17,664,367	-3.4	16,942,738	-3.5					
2017	16,795,907	-4.9	16,101,273	-5.0					
2018	16,592,356	-1.2	15,907,634	-1.2					
2019	16,548,104	-0.3	15,888,097	-0.1					
*Ex	cluding prescriptions repo	rted from VA ph	armacies; Gabapentin reporting star	ted July 1, 2018					

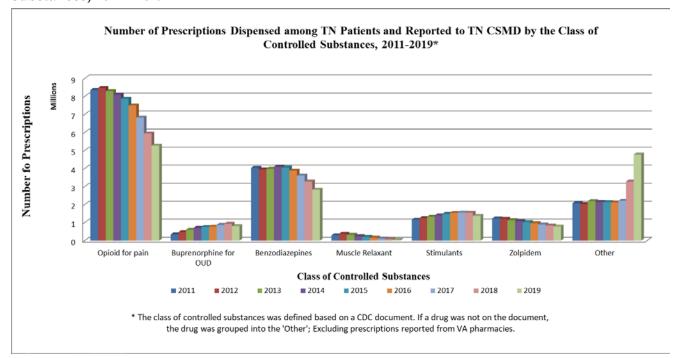
Number of Prescriptions Dispensed among TN Patients and Reported to CSMD by Age Group, 2011- 2019



Number	Number of Prescriptions Dispensed among TN Patients and Reported to TN CSMD by Age Group, 2011-2019*									
Age Group (Year)	2011	2012	2013	2014	2015	2016	2017	2018	2019	
<10	357,903	371,000	375,805	366,833	352,419	340,160	318,972	299,700	298,552	
10 - 19	757,631	776,865	776,543	764,438	768,981	766,017	735,177	708,285	709,594	
20 - 29	1,474,530	1,449,843	1,379,432	1,320,217	1,262,907	1,164,837	1,053,125	942,221	849,164	
30 - 39	2,500,104	2,501,257	2,446,473	2,373,702	2,318,598	2,186,368	2,050,569	1,953,284	1,841,701	
40 - 49	3,388,443	3,343,708	3,234,411	3,090,580	2,957,584	2,797,177	2,611,542	2,512,761	2,428,649	
50 - 59	3,859,547	3,951,031	3,989,639	3,972,442	3,875,149	3,686,476	3,425,014	3,335,182	3,273,517	
60 - 69	2,715,691	2,830,281	2,957,270	3,093,080	3,162,442	3,147,229	3,059,795	3,140,293	3,264,966	
70 - 79	1,509,263	1,574,610	1,673,677	1,751,623	1,772,709	1,787,529	1,811,631	1,926,158	2,069,333	
80-119	926,171	957,510	1,023,674	1,060,019	1,079,577	1,066,940	1,035,424	1,089,717	1,152,404	
Unknown	46	78	29	21	36	5	24	33	217	

*Excluding prescriptions reported from VA pharmacies

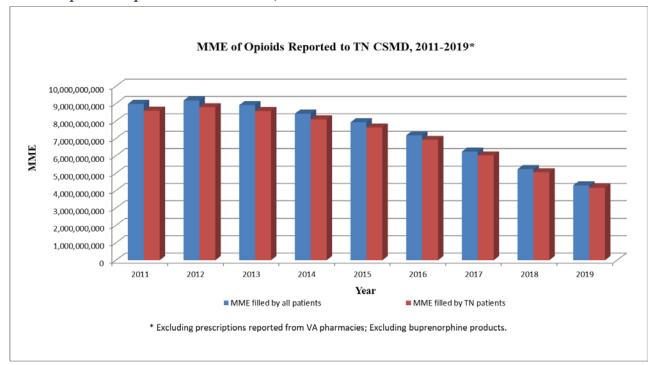
Number of Prescriptions Dispensed and Reported to TN CSMD by Class of Controlled Substances, 2011 - 2019



Number of Prescriptions Dispensed and Reported to TN CSMD by Class of Controlled Substances, 2011-2019*							
Year	Opioid for Pain	Buprenorphine for OUD	Benzodiazepines	Muscle Relaxant	Stimulants	Zolpidem	Other
2011	8,358,419	343,412	4,037,269	293,795	1,155,845	1,225,071	2,075,518
2012	8,469,582	472,490	3,951,213	377,908	1,248,382	1,209,704	2,026,904
2013	8,297,583	604,171	3,986,943	322,079	1,324,598	1,133,849	2,187,730
2014	8,095,201	711,112	4,101,216	250,308	1,399,218	1,085,082	2,150,818
2015	7,874,681	762,410	4,055,661	208,056	1,482,512	1,029,094	2,137,988
2016	7,493,521	779,916	3,887,233	159,843	1,540,505	965,291	2,116,429
2017	6,831,713	872,642	3,612,142	117,470	1,559,090	900,905	2,207,311
2018	5,944,343	932,063	3,276,831	88,308	1,552,259	839,805	3,274,025
2019	5,273,692	803,284	2,826,842	43,749	1,378,732	784,994	4,776,804

^{*} The class of controlled substances was defined based on a 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, 2011-2019



MME of Opioid Reported to TN CSMD, 2011-2019*				
Year	MME Filled by All Patients	Change (%)	MME Filled by TN Patients	Change (%)
2011	8,982,851,664	-	8,590,761,265	-
2012	9,176,198,286	2.2	8,793,501,818	2.4
2013	8,914,378,275	-2.9	8,565,517,521	-2.6
2014	8,420,691,909	-5.5	8,089,871,090	-5.6
2015	7,923,640,952	-5.9	7,622,734,410	-5.8
2016	7,171,348,529	-9.5	6,909,266,402	-9.4
2017	6,238,174,731	-13.0	6,018,372,693	-12.9
2018	5,230,925,944	-16.1	5,052,807,059	-16.0
2019	4,300,086,039	-17.8	4,163,023,971	-17.6

MME for Long Acting Opioids Reported to the TN CSMD, 2011-2019

MME for Long Acting Opioids Dispensed in TN and Reported to TN CSMD, 2011-2019*				
Year	All patients	TN patients	Change among TN patients (%)	
2011	3,254,860,588	3,121,367,401	-	
2012	3,285,114,236	3,148,405,548	0.9	
2013	3,238,223,144	3,106,169,957	-1.3	
2014	2,924,800,617	2,806,112,535	-9.7	
2015	2,552,296,511	2,454,154,268	-12.5	
2016	2,124,952,277	2,045,933,339	-16.6	
2017	1,630,448,474	1,569,042,283	-23.3	
2018	1,207,895,073	1,164,779,508	-25.8	
2019	861,215,258	831,818,929	-28.6	

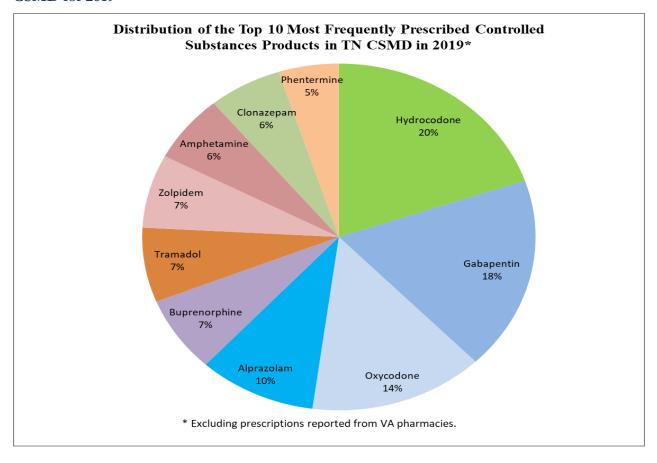
^{*} The classes of controlled substances were defined based on a CDC document; Excluding prescriptions reported from VA pharmacies; Excluding buprenorphine products.

MME for Short Acting Opioids Reported to the TN CSMD, 2011-2019

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MME for Short Acting Opioids Dispensed in TN and Reported to TN CSMD, 2011-2019*				
			Change among	
Year	All patients	TN Patients	TN Patients (%)	
2011	5,727,991,076	5,469,393,863	-	
2012	5,891,084,050	5,645,096,270	3.2	
2013	5,676,155,131	5,459,347,564	-3.3	
2014				
2014	5,495,891,292	5,283,758,555	-3.2	
2015	5,371,344,441	5,168,580,142	-2.2	
2016	5,046,396,252	4,863,333,064	-5.9	
2017	4,607,726,257	4,449,330,410	-8.5	
2018	4,023,030,871	3,888,027,552	-12.6	
2019	3,438,870,781	3,331,205,043	-14.3	

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

Distribution of the Top 10 Most Frequently Prescribed Controlled Substance Products in the CSMD for 2019



Acronyms	
Advanced Practice Registered Nurse	APRN
American Society for Automation in Pharmacy	ASAP
Bureau of Justice Assistance	BJA
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 Child Services	DCS
Department of Justice	DOJ
Drug Overdose Reporting	DOR
East Tennessee State University	ETSU
Electronic Health Record	EHR
Electronic Surveillance System for the Early Notification of Community Epidemics	ESSENCE
Emergency Medical Services	EMS
Enhanced Surveillance of Opioid Overdose	ESOOS
Federal Information Processing Standard	FIPS
Human Immunodeficiency Virus	HIV
Medicated Assisted Treatment	MAT
Morphine Milligram Equivalents	MME
Neonatal Abstinence Syndrome	NAS
Office of Informatics and Analytics	OIA

Overdose Data to Action	OD2A
Physician Assistant Certified	PA-C
Prescription Drug Overdose	PDO
Prevention for States	PfS
Prescription Monitoring Program	PMP
Prescription Safety Act	PSA
Screening, Brief Intervention and Referral to Treatment	SBIRT
State Unintentional Drug Overdose Reporting System	SUDORS
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
Vanderbilt University Medical Center	VUMC
Veterans Affairs	VA



Tennessee Controlled Substance Monitoring Database

Director TN CSMD 665 Mainstream Drive, 2nd Floor Nashville, Tennessee 37243 https://www.tn.gov/health/csmd/