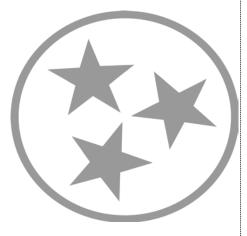


Controlled Substance Monitoring Database

2021 Report to the 112th Tennessee General Assembly

Tennessee Department of Health | Health Licensure & Regulation | March 1, 2021



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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 (PDMP) designed to provide healthcare practitioners with a comprehensive view of a patient's history of controlled substance prescriptions. The CSMD contains prescription information from all dispensers of controlled substances in Tennessee, including Veterans Health Administration (VHA) 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 (PSA) of 2012 and 2016 enhanced the monitoring capabilities of the database especially with mandatory registration and use starting in 2013. The CSMD became timelier and more 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 affecting 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. Prescribers and pharmacists can pull prescription information from greater than half of the states in the US, in addition to the US Department of Defense.

This 2020 CSMD report is designed to provide the General Assembly with an update on activities and outcomes related to the substance abuse crisis as it pertains 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 minimizing diversion of controlled substances.

PDMPs, like Tennessee's CSMD, are the cornerstone to state-level interventions to improve prescribing of controlled substances, to inform clinical practice, and to 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) prescribed and dispensed to patients in Tennessee has decreased almost 57%. (2012-2020)

• MME prescribed by the top 50 prescribers has decreased 57%. (2013-2020)

• Number of potential doctor shoppers has decreased 92%. (2012-2020)

Number of opioid prescriptions for pain has decreased by 43%. (2012-2020)

• Cases of Neonatal Abstinence Syndrome have decreased by 26%. (2017-2019)



Searches of CSMD have increased 684% and continue to increase. (2012-2020)

• The number of CSMD requests has increased 11% in 2020 to 14,611,465 compared with 2019.

• There was one search of the CSMD for every 1.1 prescriptions in Tennessee in 2020, which was up from one search for every 10 prescriptions in 2012.

Key Highlights for CSMD in 2020:

- Since 2013, the number of controlled substance prescriptions reported to the CSMD has decreased 14%, note that gabapentin was added as a new controlled substance in 2018 and had over 2 million prescriptions reported in 2020.
- Response time for searches in the CSMD was less than two seconds if request did not include data from another state.
- In 2020, the CSMD program added Arizona, Nevada, Wisconsin, South Dakota, and Maryland, allowing CSMD users to receive data from these additional PDMPs.
- Gateway Electronic Health Record (EHR)/Pharmacy Management System workflow integration
 project started across the state to provide controlled substance prescribers and pharmacists the
 ability to integrate CSMD information into clinical workflow.
- Independent of Tennessee's statewide Gateway project, VHA clinical facilities implemented Gateway in Tennessee and across the United States.

Considerations for 2021:

- Although the prescribing and dispensing of most drug classes is declining, the number of prescriptions for stimulants is currently 20% above that of 2012.
- Among opioid-related overdose deaths, 24% also had benzodiazepines associated with the
 reported opioid, highlighting the critical importance of avoiding concomitant use of opioids and
 benzodiazepines.
- In 2019, only 36% who died of drug overdose had any controlled substance dispensed within 60 days of death. The increase in overdose deaths due to opioids in 2019 was largely due to illicit fentanyl (48% increase) and heroin (4% increase) compared to 2018. This reinforces the need for a three-pronged approach of prevention, treatment, and enforcement in improving the 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 2018 to 2019, drug overdose deaths in Tennessee rose by 15%,

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

increasing from 1,818 to 2,089.² The increase in overdose deaths from 2018 to 2019 is one of the highest year to year increases in recent history, and deaths due to drug overdose in Tennessee are at their highest level in over a decade. The proportion of drug deaths in 2019 that involved opioids remained high (74%), and this number includes both opioids typically obtained through a prescription as well as illicit opioids such as heroin and illicitly manufactured fentanyl. The proportion of deaths in TN categorized by the CDC as associated with opioid pain relievers continued to decrease, from 30% to 25% of all overdose deaths. Deaths associated with benzodiazepines decreased modestly as well, from 409 to 395 (a 3% decrease). Deaths that included a combination of benzodiazepines and opioids increased for the first time since 2016, from 354 to 363 (a 3% increase). Just under one quarter (24%) 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 2019, just over a third (36%) had a controlled substance dispensed within 60 days of death, a decrease from 41% 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 opioid overdose deaths, including illicit fentanyl, heroin, and diverted prescription opioids.

Overdose deaths involving illicit opioids increased substantially from 2018 to 2019. The number of overdose deaths in which fentanyl was involved increased 46%, from 742 to 1,087, over half (52%) of all drug overdose deaths. Heroin deaths increased slightly (4%), from 367 to 380. Among drugs typically used for treatment of opioid use disorder, overdose deaths involving methadone decreased 20%, from 66 to 53, and buprenorphine associated deaths decreased 16%, from 85 to 71.

TDH is committed to improving the way CSMD data are used to help stem the epidemic of overdose in Tennessee. The Office of Informatics and Analytics (OIA) maintains the Integrated Data System (IDS) which combines data from the CSMD with other patient health data to identify key markers for increased risk of overdose. 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, OIA has developed a data driven method of identifying prescribers who may be engaging in high risk prescribing or who have high risk patient populations. The first high risk prescriber lists were created in 2019, and the method continues to undergo refinement to better identify risky prescribing. Work also continues to identify patients at high risk of overdose, and the department has partnered with researchers at Vanderbilt University Medical Center (VUMC) to apply advanced machine learning techniques to better predict overdose risk among Tennesseans. The initial phase of this work has concluded, and in the next year, OIA will begin to integrate these advanced models into the IDS. In the next year, TDH also plans to launch enhanced prescriber reports to registered CSMD users that leverage the power of OIA's analytics and data linkage efforts to provide prescribing and overdose information back to Tennessee's prescribers.

https://www.tn.gov/content/dam/tn/health/documents/pdo/2019%20Tennessee%20Drug%20Overdose%20Deaths.pdf

² 2019 Tennessee Drug Overdose Death Report.

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. Overdose and controlled substance prescribing data has been invaluable for planning and resource allocation for TDH and TDMHSAS prevention and response projects.

OIA produces several public annual reports that present data on overdoses and prescribing throughout Tennessee that are greatly enhanced by the addition of CSMD data.

- The annual Tennessee Drug Overdose Death Report includes information on fatal overdose and decedent prescription histories using CSMD data and is released when data are finalized in September.
- The annual Drug Overdose Hospital Discharge Report includes information on nonfatal overdoses for patients who were seen at a TN hospital and is released on March 1.
- The Tennessee Annual Overdose Report is an omnibus report that includes additional fatal and nonfatal overdose information, prescription trends, and project updates, and 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. In late 2020, OIA released a special report on buprenorphine to provide an in depth look at prescription and patient trends as well as buprenorphine involvement in fatal overdoses and buprenorphine prescribing before and after nonfatal overdoses. A special report on stimulant prescriptions and overdoses is planned to be released in 2021.

OIA also produces an interactive online dashboard that includes overdose and prescription information and can be found at this address: https://www.tn.gov/health/health-program-areas/pdo/pdo/data-dashboard.html. The drug overdose data dashboard underwent a significant overhaul to enhance its usefulness and visual appeal and relaunched in late summer 2020. The new version of the dashboard was designed to accommodate more frequent updates to the data and content.

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 15% of overdose decedents in 2018 had a nonfatal overdose in the year before their death.³

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

³ Tennessee's Annual Overdose Report 2020. https://www.tn.gov/content/dam/tn/health/documents/pdo/Overdose%20Report%202020.pdf

TDH from across the state. Opioid drug overdose was included on the Tennessee Reportable Disease List in 2019.⁴ From the pilot stage through 2019, hospitals have only been required to report opioid overdoses. The Tennessee Reportable Disease List was expanded in 2020, and hospitals are now 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. In Fall 2020, TDH began to make monthly reports on statewide DOR data available to the public.⁵ Additionally, TDH convenes a biweekly multi-agency workgroup made up of several divisions across TDH, the TDMHSAS, 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 OIA is actively working with the Office of Emergency Medical Services 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.

TDH 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. In 2021, TDH plans to launch enhanced prescriber reports to registered users of the CSMD. These reports are expected to include information on patients of the prescribers who have overdoses that have been reported to TDH.

Neonatal Abstinence Syndrome Surveillance Update

TN hospitals have been required to report cases of infants with Neonatal Abstinence Syndrome (NAS) to TDH since 2013. In 2017, the number of cases reported reached a high of 1,096. In 2019, for the second year in a row, the number of cases reported to TDH decreased by 15% from 949 to 808 reported cases.⁶ A majority of the mothers of these infants report exposure to prescription medications, most of which is attributable to prescribed buprenorphine

⁴ Tennessee Reportable Disease List. https://www.tn.gov/health/cedep/reportable-diseases.html

⁵ Drug Overdose Facts & Figures. https://www.tn.gov/health/health-program-areas/pdo/pdo/facts-figures.html

⁶ Neonatal Abstinence Syndrome Surveillance Annual Report 2019. https://www.tn.gov/content/dam/tn/health/documents/nas/2019-NAS-Annual-Update.pdf

or methadone for Medication-Assisted Treatment (MAT). Regional variations of reported NAS births align with the known geographic distribution of buprenorphine prescriptions for MAT.⁷

Fewer Prescriptions without CSMD Evaluation

The PSA of 2012 facilitated a substantial increase in utilization of the CSMD, and the PSA of 2016 and other legislation further 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 2020, the number of registrants had grown to 58,379. Prior to the PSA of 2012 and 2016, the graph below demonstrates that Tennessee had approximately 12 prescriptions reported for every CSMD query, and now there are approximately 1.1 prescriptions reported for each request. The number of queries increased around 11% in 2020 compared to 2019.

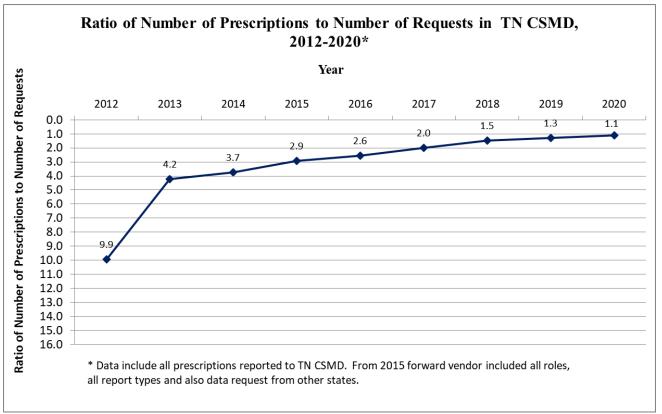
Number of Registrants of TN CSMD, 2012-2020

Number of Registrants of TN CSMD, 2012 - 2020*							
Year	Registrants	Change (%)					
2012	22,192	-					
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					
2020	58,379	6.8					

^{*}VA registrants were included in 2013 and forward as they were allowed to register.

⁷ TN Buprenorphine Report.

Ratio of Number of Prescriptions to Number of Request in CSMD, 2012-2020

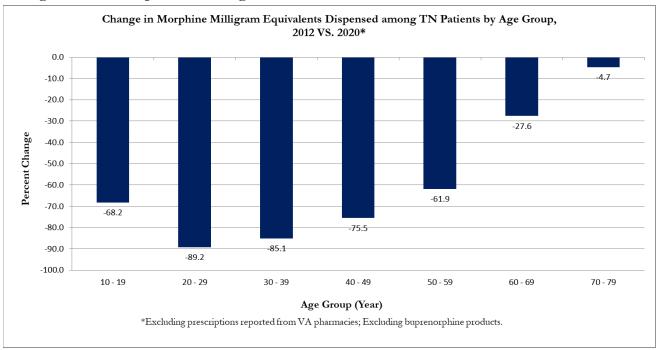


Law enforcement requests to the CSMD continue to be a critical use of the CSMD as TDH works together to address questionable controlled substance use in Tennessee. During 2020, there were 1,694 law enforcement related requests to the CSMD. Effective July 1, 2011, law enforcement officers were granted access to the CSMD. That access was further expanded through the PSA of 2016.

MME Improvements and Concerns by Age Group

The CSMD program provides an analysis of the MME for Tennessee patients by age groups (10-79). Encouragingly, there was a decline in MME dispensed for patients between 10 to 79 years of age compared to 2012 data. These improvements for these age groups are an indicator that TDH's efforts are successfully preventing individuals from being overexposed to opioids by the healthcare system. This is the first year in which MMEs for age group 70 to 79 have declined.

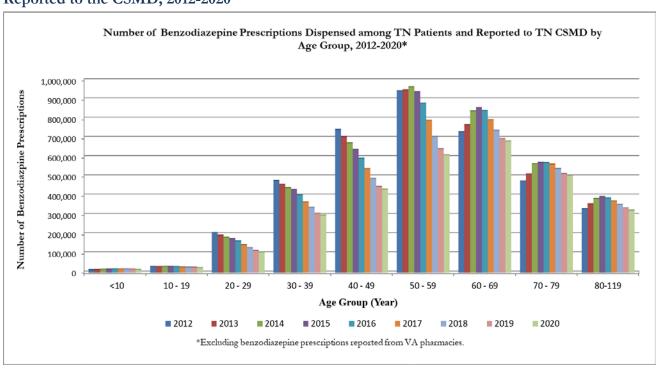
Change in MME Dispensed Among Tennessee Patients, 2012 vs. 2020



Trends Related to Utilization of Benzodiazepines and Stimulants

Benzodiazepines, such as alprazolam and diazepam, showed a 27% decrease in prescriptions from 2014 to 2020. For 2020, 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, 2012-2020



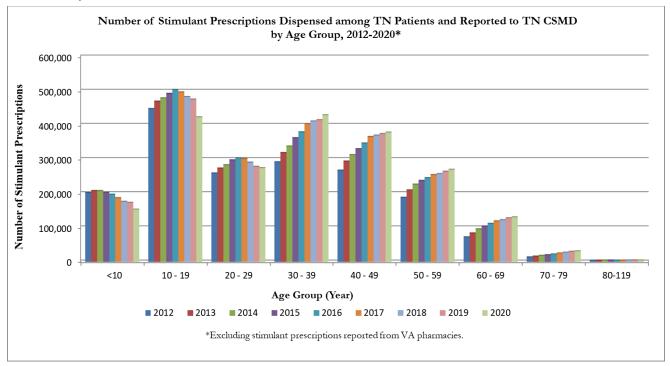
Number	Number of Benzodiazepine Prescriptions Dispensed among TN Patients and Reported to TN CSMD by Age Group, 2012-2020*									
Age Group (Year)	2012	2013	2014	2015	2016	2017	2018	2019	2020	
<10	14,997	15,946	17,296	17,730	18,243	18,105	18,184	17,746	16,411	
10 - 19	30,652	30,260	30,988	30,770	30,187	28,652	27,457	27,032	24,825	
20 - 29	207,521	193,223	183,644	176,271	162,790	143,629	128,706	113,578	105,192	
30 - 39	478,240	458,193	440,786	430,966	402,307	365,488	338,361	307,350	298,850	
40 - 49	742,522	704,923	673,927	639,705	593,597	538,120	487,759	446,376	432,451	
50 - 59	943,217	948,623	965,492	938,135	879,784	790,961	707,003	642,263	610,787	
60 - 69	731,437	768,479	839,500	856,117	842,152	793,882	739,022	695,656	683,307	
70 - 79	474,505	511,221	565,176	572,069	570,954	562,847	539,449	513,979	504,548	
80-119	330,979	356,531	384,640	394,187	387,483	370,670	352,885	335,337	323,202	
Unknown	7	2	2	7	0	6	1	9	24	

^{*} 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 20% for patients in Tennessee from 2012 to 2020.

Number of Stimulant Prescriptions Dispensed Among TN Patients by Age Group and Reported to the CSMD, 2012-2020

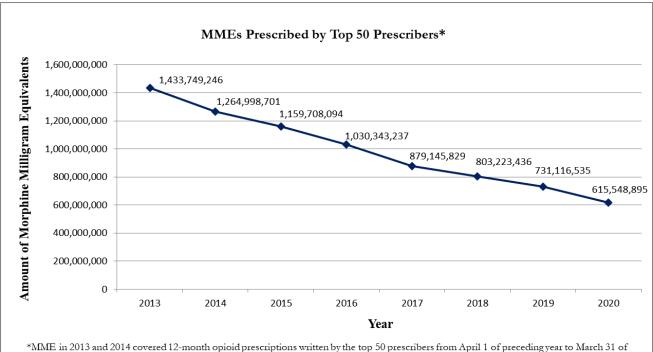


Numbe	Number of Stimulant Prescriptions Dispensed among TN Patients and Reported to TN CSMD by Age Group, 2012-2020*								
Age Group (Year)	2012	2013	2014	2015	2016	2017	2018	2019	2020
<10	201,270	207,367	207,387	202,371	196,610	186,474	175,804	172,810	153,100
10 - 19	447,427	468,980	478,690	491,850	503,286	496,238	482,711	475,189	423,320
20 - 29	258,838	273,173	282,849	297,185	303,032	300,918	290,490	278,345	274,532
30 - 39	291,552	318,461	337,702	362,045	379,293	402,835	411,043	414,802	429,338
40 - 49	267,060	293,573	312,526	329,738	346,597	365,705	369,664	374,110	378,499
50 - 59	187,662	209,076	226,157	237,131	245,067	254,151	257,155	263,963	269,678
60 - 69	71,810	83,125	95,222	103,553	111,229	118,585	122,018	127,570	130,374
70 - 79	13,009	15,425	17,884	19,389	21,679	24,540	26,985	29,501	30,994
80-119	3,253	3,703	3,983	3,928	3,838	3,917	4,208	4,398	4,207
Unknown	10	9	8	4	0	2	3	4	7
	*Excluding stimulant prescriptions reported from VA pharmacies.								

Interventions Related to Top Prescribers

As required by Tenn. Code Ann. § 68-1-128, the Department must also identify and notify the top fifty (50) prescribers of controlled substances in the state. The medical director's team, along with the Office of General Counsel, reviews the data on the top 50 prescribing practitioners in Tennessee and uses that data to assist in identifying practitioners of concern as well as educating practitioners. The total morphine equivalence prescribed in aggregate by the Top 50 prescribers has decreased each year since 2013. The MMEs prescribed by this group have declined 57% 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

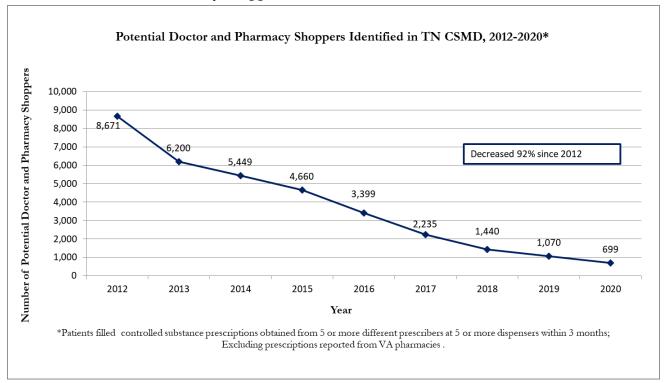


*MME in 2013 and 2014 covered 12-month opioid prescriptions written by the top 50 prescribers from April 1 of preceding year to March 31 of current year; MME in 2015, 2016, 2017, 2018, 2019 and 2020 covered opioid prescriptions filled by the patients of the top 50 prescribers in each proceeding calendar 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 a 92% decrease of potential doctor and pharmacy shopping patients from 2012 to 2020.

Potential Doctor and Pharmacy Shoppers Identified in the CSMD, 2012-2020



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

During 2020, CSMD started the Gateway EHR/Pharmacy Management System project. The Gateway service allows healthcare providers the ability to view their patient's history of controlled substance prescriptions within their clinical application (EHR/Pharmacy Management System). This project integrates CSMD searches and Clinical Risk Indicators (CRI) into EHRs and pharmacy management systems clinical workflow. Prior to 2020, the prescribing boards for human patients and the Board of Pharmacy agreed to allow TDH to authorize funding for a two year CSMD workflow integration pilot project across the state to entities' EHR/Pharmacy Management Systems that desire to integrate using the Gateway service provided by Appriss. TDH received a Department of Justice's (DOJ) Bureau of Justice Assistance (BJA) grant to provide funding for a third year on this project during 2020.

Independent of the Tennessee statewide Gateway project, VHA clinical facilities implemented Gateway in Tennessee and across the United States. Tennessee is proud to support the VHA's efforts to slow the spread of Substance Use Disorder (SUD) among veterans.

Database Metrics and Browser Recommendations

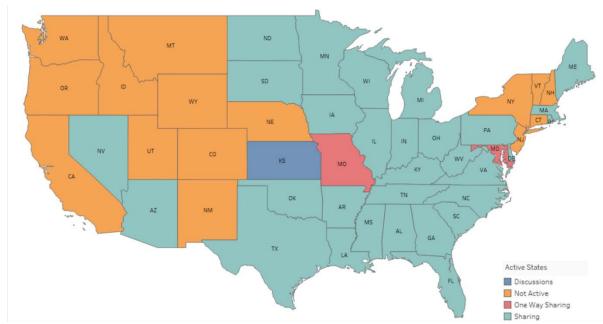
The CSMD team works diligently with the vendor to continue providing a stable environment for healthcare providers. The CSMD system uptime was 99.9% for 2020. One attribute of the CSMD system is the less than two-second response time when a patient request is initiated, given that the request does not 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, Edge, Safari, Chrome, or Firefox.

Increased Interstate Data Sharing

The PSAs of 2012 and 2016 permit data sharing with other states. The CSMD program now shares data with many states in addition to the entire southeast United States. In 2020, the CSMD program added Arizona, Nevada, Wisconsin, South Dakota, and Maryland to the list of jurisdictions from which CSMD users can receive PDMP partners' data.

Each jurisdiction has unique regulations and requirements that require collaboration to share data to address regulatory compliance. The CSMD program utilizes, at no cost to state, the National Association of Boards of Pharmacy Prescription Monitoring Program InterConnect (PMPi) to allow Tennessee to share data. The PMPi is a highly secure communications exchange platform that facilitates the transmission of PDMP data across jurisdictions to authorized requestors, while ensuring that each PDMP'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 BJA and designed to complement current CSMD activities. It is of no cost to jurisdictions or CSMD users and allows jurisdictions to have an additional option for querying prescription data across jurisdictions, as well as provides for integration with EHRs using nationally recognized interoperability standards. RxCheck is governed jointly by the Integrated Justice Information Systems Institute (IJIS), BJA, and a board of PDMP administrators in connected jurisdictions. Currently, BJA has made a commitment to fund RxCheck and support both the jurisdictions and governing body with training and technical support. In the coming year, the CSMD team and the OIA will be working closely to ensure a successful RxCheck connection with the appropriate technical and administrative processes and documentation in place. Once connectivity is established, TDH will begin a pilot focused on using RxCheck for EHR integration with CSMD data. The figure below provides a diagram of our partnerships with other jurisdictions:



1. Tennessee receiving data one way with Military Health System, Maryland, and St. Louis County, Missouri

Vermont discussions on hold due to Covid-19

^{2.} Tennessee had discussion with Kansas (currently solutions are not available for challenges identified such as the other state does not allow any of their data to be placed in a medical record)

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)-(6), and (13) are allowed to enter the database through a registration process where identifying credentials are validated before the creation of a unique username and password. For healthcare practitioner delegates, an additional approval from their supervising healthcare practitioner is required.
- All access allowed pursuant to TCA § 53-10-306(a)(9) and (10) involves the sharing of information obtained by an individual authorized pursuant to TCA § 53-10-306(a)(2), (4), or (5) above with a quality improvement committee of a hospital or practice group, as allowed by statute. The quality improvement committees are prohibited from sharing any information obtained, including information obtained from the CSMD by the healthcare practitioner and provided to the committee.
- Before the Office of Inspector General, the Medicaid Fraud Control Unit, and the TennCare personnel identified in TCA § 53-10-306(a)(7) 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 before creating an account for the requester. The requester is then provided with a unique, individual username and instructions to create a password. 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 datasets provided to TennCare are defined datasets limited to TennCare recipients.
- 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)(11) 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), (9), and (10) are reviewed by Board of Pharmacy staff and Legal Counsel to determine if the person requesting access can be granted the requested 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 IDS, which works to more efficiently provide usable data access to a limited number of authorized users for various TDH data systems. The security and access related to these projects is handled by a variety of partners including Strategic Technology Solutions (STS) staff, the Office of General Counsel (OGC), and the OIA staff, in conjunction with oversight from the participating data source programs. The TDH IDS, which houses certain CSMD data, resides in the State Data Center and is behind the State network firewalls preventing any access outside of the state firewall without the proper approved connection through the state's Virtual Private Network. All data on these servers are encrypted.

- Currently only administrators and a select group of individuals that have been granted authority from
 the CSMD program have access to the CSMD data made available through the TDH IDS. Authorized
 users of the IDS have to receive permission from the Director of the OIA and the Director of the
 Tennessee CSMD Program in order to access CSMD data from the TDH Integrated Data System.
- Requests made for de-identified, aggregate data not publicly available pursuant to TCA § 53-10-306(l)(2) must initially be reviewed by the TDH Data Governance program. Based upon that review of the request and the data requested therein, the request may be referred for additional review and consideration, including but not limited to review by the CSMD operations committee, to ensure that there is no risk of re-identification of the data.

TDH Grants Update

Over the last five years, TDH has been awarded a number of federal grants aimed at building capacity for public health surveillance and prevention of drug overdose. Recognizing the important role that prescribers and PDMPs play in both surveillance and prevention activities, most of these grants have included activities intended to enhance the CSMD directly or to better utilize CSMD data in prevention, planning, and enforcement. The following grants all support enhancements to the CSMD or analytics projects using data from the CSMD:

- In September 2015, TDH was awarded a grant 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, enhance and maximize the CSMD, and develop community, insurer, and health system interventions. PDO: Prevention for States (PfS) funding was initially awarded to sixteen states and expanded upon the work already under way through the earlier "PDO: Boost" 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. The PfS grant ended in 2019 with many of the activities continuing under the Overdose Data to Action (OD2A) grant (see below).
- In 2016, TDH was awarded a grant from the DOJ under the Harold "Hal" Rogers program to create rapid data-based collaboration between TDH, TBI, and the TDMHSAS. This grant, which ended in 2020, funded improved access for law enforcement and drug courts to the CSMD. It also supported 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 overdose epidemic. Under the Hal Rogers funding, TDH began convening biweekly meetings of stakeholders from TDH, TBI, and TDMHSAS other state agencies to discuss ongoing activities and trends in the data.
- 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 fund work to connect the CSMD to RxCheck and partially supported predictive modeling of overdose risk, conducted by VUMC. The other grant funds the integration of EMS overdose data into TDH's IDS, expands overdose and drug surveillance to other substances of concern, and continues the interagency collaborations started under the 2016 Hal Rogers funding.

- In 2019, the CDC combined activities from previous opioid-focused grants into a single, more expansive grant opportunity called 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. The TDH Opioid Response Coordination Office has spent the last year 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.
- In 2020, TDH was awarded for three years under the FY2020 Hal Rogers grant opportunity to continue enhancements to the CSMD and related data systems. These funds will be used to extend the amount of time that TDH can offer support for Gateway workflow integration to CSMD users and expand the use of RxCheck for EHR integration. Funds will also be used to improve the system for receiving drug shipment data from distributors and wholesalers. Another activity supported by this grant continues and expands integration of data from the TBI with TDH data.

TDH Recommends the Following Approaches to the Drug Epidemic

- 1. Prevent opioid and other drug misuse and addiction through an effective and comprehensive approach to prevention.
 - Implement effective public education/awareness campaigns.
 - Ensure that schools and communities implement effective prevention initiatives.
 - Reduce availability of and accessibility to addictive opioids and other controlled substances.
 - Utilize Prescription Drug Monitoring Programs (PDMPs).
 - Participate in Safe Prescribing Initiatives for pain management.
 - Utilize the Tennessee Chronic Pain Guidelines located on the TDH website at: https://www.tn.gov/content/dam/tn/health/healthprofboards/pain-management-clinic/ChronicPainGuidelines.pdf
 - Support and maximize use of Prescription Take-Back Programs and related options.
 - Continue to regulate Pain Management Clinics. (See most recent report on Prescription Drug Abuse and Pain Management Clinics at https://www.tn.gov/content/dam/tn/health/program-areas/reports and https://www.tn.gov/content/dam/tn/health/program-areas/reports and publications/2020-Pain-Management-Clinic-Annual-Report.pdf)
- 2. Reduce overdose deaths and other harmful consequences through harm reduction strategies.
 - Increase community access to naloxone through co-prescribing.
 - Implement Syringe Exchange Programs (SEPs).
 - Monitor and react rapidly to emerging drug trends.
- 3. Improve opioid addiction treatment through an effective and comprehensive approach.
 - Increase treatment capacity.
 - Increase availability of MAT.
 - Provide comprehensive recovery support services following treatment.
 - Work to alleviate the stigma associated with seeking treatment for substance use disorder.

In summary, the drug epidemic continues to have a major impact on the State of Tennessee, taking more lives than motor vehicle accidents and suicides combined. Real, effective solutions will require a shift in the way TDH thinks about and respond to substance use disorders, including our abilities to prevent, treat, destignatize, and advance harm reduction through the dissemination of evidence-based practices.

Conclusion

The CSMD provides a powerful tool to allow healthcare providers access to a patient's history of controlled substance prescriptions before making a decision about the prescribing or dispensing of these high risk medications. The CSMD is reliably available, and clinicians are making more frequent use of searches, with one search for every 1.1 dispensed prescriptions in 2020. The information in the CSMD continues to be used to improve patient safety and quality of care. The last two years have demonstrated declines in babies born with neonatal abstinence syndrome resulting in a 26% decrease compared to 2017.

At the same time, the epidemic of opioid misuse and abuse has continued to change. More people died of drug overdoses in 2019 than ever before. Overdose deaths involving illicit opioids increased substantially from 2018 to 2019. The number of overdose deaths involving fentanyl increased by 46%. For every drug overdose death, approximately 13 nonfatal overdoses are identified in discharge data from state emergency departments and hospitals. Therefore, TDH is working hard to better understand data from various reporting systems and work collaboratively with other agencies to improve prevention opportunities.

A multi-pronged approach including prevention of exposure to opioids and other controlled substances, 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 level.

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 in preventing harm to the public health from the drug epidemic.

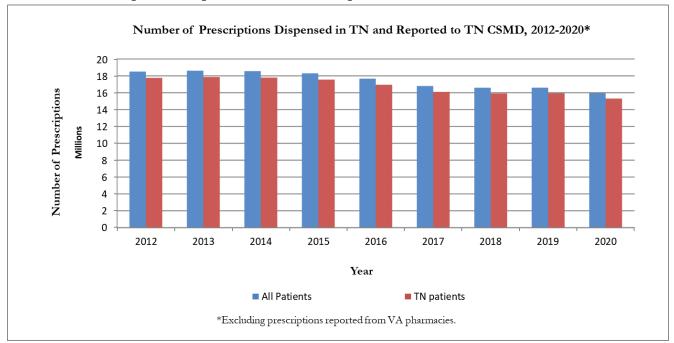
2021 Members of the CSMD Committee

Member Name	Board
Melanie Blake, M.D.	Board of Medical Examiners
Robert Caldwell, D.M.D.	Board of Dentistry
Amber Wyatt, 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
Jake Bynum	Public Member Board of Pharmacy

Appendix

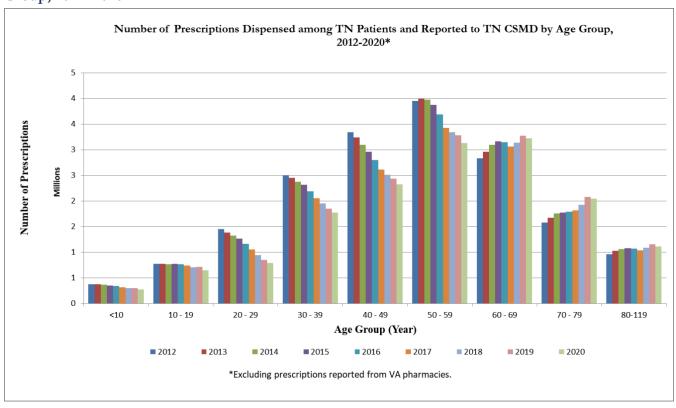
The CSMD data used for this report were downloaded on January 5, 2021. MME calculations were only limited to the opioid products that were listed in CDC's MME conversion tables from 2011 to 2020. The CDC has adjusted certain drug conversion factors over time for various reasons. If a drug had different MME conversion factors in different version tables, the data analysis provided through 2020 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 the patient's address associated with a prescription. Otherwise, the patient was identified as a non-TN patient. Classification of controlled substances was based on combination of CDC tables and 2020 IBM Micromedex Red Book Select file. If a drug in the CSMD was not classified, the drug was classified as 'other' in this report. Due to improvements in the classification of prescriptions reported to the CSMD, some totals in this year's report may appear larger than in previous years. In particular, stimulant counts have increased with the addition of Schedule III and IV stimulants, and gabapentin prescriptions are now classified separately. These prescriptions were previously classified in the 'other' category. Please note that human and animal prescription data are included in this report as it relates to the data analysis through 2020.

Number of Prescriptions Dispensed in TN and Reported to CSMD, 2012-2020



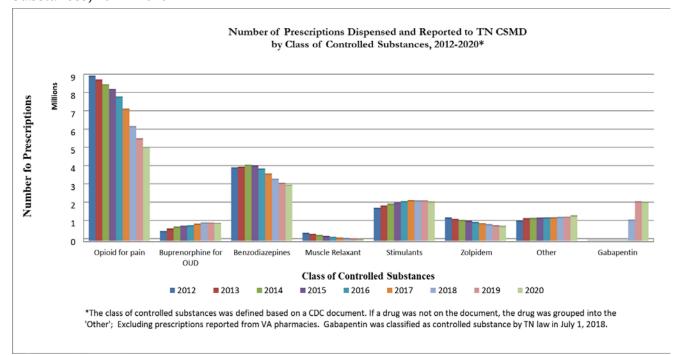
	Number of Prescriptions Dispensed in TN and Reported to TN CSMD, 2012-2020*							
Year	All Patients	Change (%)	TN Patients	Change (%)				
2012	18,506,531	-	17,756,354	-				
2013	18,606,159	0.5	17,857,161	0.6				
2014	18,558,614	-0.3	17,793,066	-0.4				
2015	18,294,339	-1.4	17,550,600	-1.4				
2016	17,664,674	-3.4	16,943,222	-3.5				
2017	16,796,279	-4.9	16,101,846	-5.0				
2018	16,593,711	-1.2	15,909,390	-1.2				
2019	16,596,165	<0.1	15,933,083	0.1				
2020	15,942,886	-3.9	15,307,300	-3.9				
*Excluding prescriptions reported from VA pharmacies.								

Number of Prescriptions Dispensed among TN Patients and Reported to CSMD by Age Group, 2012- 2020



Number	Number of Prescriptions Dispensed among TN Patients and Reported to TN CSMD by Age Group, 2012-2020*								
Age Group (Year)	2012	2013	2014	2015	2016	2017	2018	2019	2020
<10	371,014	375,824	366,838	352,424	340,168	318,977	299,802	302,443	274,707
10 - 19	776,862	776,548	764,454	768,988	766,028	735,191	708,423	714,629	642,995
20 - 29	1,449,868	1,379,457	1,320,231	1,262,913	1,164,854	1,053,142	942,317	850,744	792,881
30 - 39	2,501,284	2,446,506	2,373,742	2,318,641	2,186,444	2,050,645	1,953,554	1,845,303	1,774,632
40 - 49	3,343,772	3,234,461	3,090,603	2,957,631	2,797,330	2,611,684	2,513,092	2,434,828	2,322,872
50 - 59	3,951,035	3,989,665	3,972,444	3,875,206	3,686,610	3,425,258	3,335,684	3,282,607	3,126,767
60 - 69	2,830,306	2,957,305	3,093,086	3,162,460	3,147,283	3,059,869	3,140,545	3,272,721	3,218,911
70 - 79	1,574,624	1,673,691	1,751,628	1,772,718	1,787,547	1,811,645	1,926,218	2,073,881	2,043,938
80-119	957,511	1,023,675	1,060,019	1,079,583	1,066,953	1,035,411	1,089,722	1,155,688	1,109,230
Unknown	78	29	21	36	5	24	33	239	367
	*Excluding prescriptions reported from VA pharmacies								

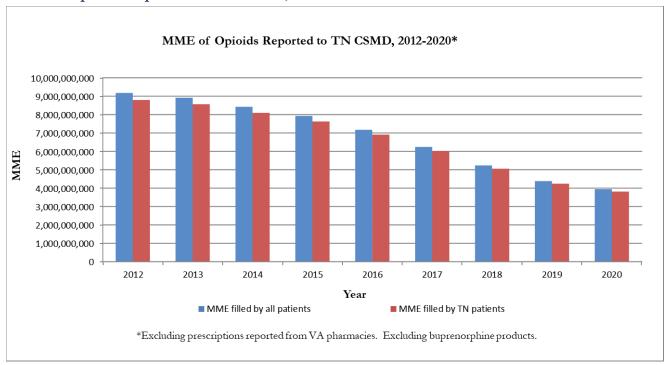
Number of Prescriptions Dispensed and Reported to TN CSMD by Class of Controlled Substances, 2012 - 2020



	Number of Prescriptions Dispensed and Reported to TN CSMD by Class of Controlled Substances, 2012-2020*									
Year	Opioid for pain	Buprenorphine for OUD	Benzo- diazepines	Muscle Relaxant	Stimulants	Zolpidem	Other	Gabapentin		
2012	8,962,085	473,893	3,954,077	378,026	1,741,891	1,209,714	1,036,462	-		
2013	8,758,162	605,682	3,987,401	322,081	1,872,892	1,133,862	1,176,126	-		
2014	8,493,011	714,096	4,101,451	250,312	1,962,408	1,085,119	1,186,487	-		
2015	8,245,275	764,701	4,055,957	208,061	2,047,194	1,029,153	1,199,396	-		
2016	7,819,950	782,887	3,887,497	159,852	2,110,631	965,350	1,213,476	-		
2017	7,163,789	875,391	3,612,360	117,483	2,153,365	900,995	1,219,285	-		
2018	6,210,594	937,791	3,338,827	88,395	2,140,081	839,965	1,251,711	1,102,026		
2019	5,544,990	934,127	3,099,326	65,311	2,140,692	786,584	1,259,367	2,102,686		
2020	5,073,009	920,281	2,999,597	52,605	2,094,049	760,274	1,333,451	2,074,034		

^{*}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. Gabapentin was classified as controlled substance by TN law in July 1, 2018.

MME of Opioids Reported to TN CSMD, 2012-2020



	MME of Opioid Reported to TN CSMD, 2012-2020*								
Year	MME Filled by All Patients	Change (%)	MME Filled by TN Patients	Change (%)					
2012	9,176,205,676	-	8,793,572,420	-					
2013	8,914,403,607	-2.9	8,565,566,718	-2.6					
2014	8,422,272,229	-5.5	8,091,349,394	-5.5					
2015	7,925,664,031	-5.9	7,624,627,813	-5.8					
2016	7,171,942,918	-9.5	6,909,828,470	-9.4					
2017	6,238,821,186	-13.0	6,018,951,151	-12.9					
2018	5,233,695,453	-16.1	5,055,437,949	-16.0					
2019	4,381,098,948	-16.3	4,241,258,970	-16.1					
2020	3,942,812,127	-10.0	3,810,820,624	-10.1					

^{*} Excluding Buprenorphine products; Excluding prescriptions reported from VA pharmacies.

MME for Long-Acting Opioids Reported to the TN CSMD, 2012-2020

	MME for Long-Acting Opioids Dispensed in TN and Reported to TN CSMD, 2012-2020*								
Year	All patients	TN patients	Change among TN patients (%)						
2012	3,285,117,836	3,148,409,148	-						
2013	3,238,223,144	3,106,178,957	-1.3						
2014	2,924,800,617	2,806,117,935	-9.7						
2015	2,552,372,261	2,454,217,418	-12.5						
2016	2,125,042,337	2,046,014,999	-16.6						
2017	1,630,473,227	1,569,066,136	-23.3						
2018	1,208,006,345	1,164,883,880	-25.8						
2019	909,241,155	877,932,403	-24.6						
2020	733,493,577	705,597,298	-19.6						

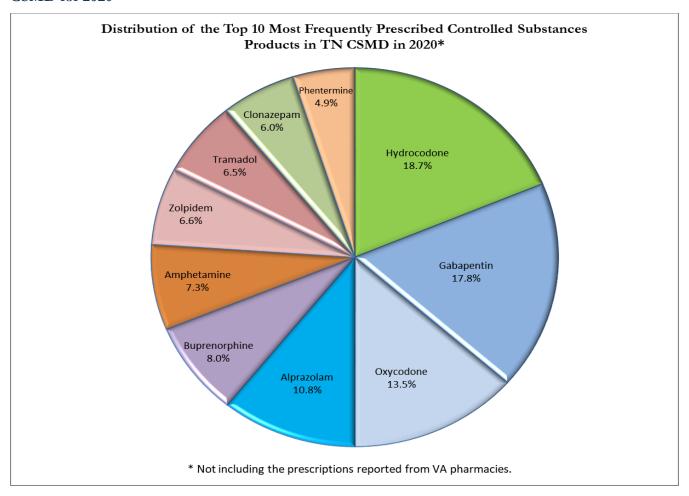
^{*}The classes of controlled substances were defined based on a CDC document; Excluding prescriptions reported from VA pharmacies. Excluding buprenorphine products.

MME for Short-Acting Opioids Reported to the TN CSMD, 2012-2020

	MME for Short-Acting Opioids Dispensed in TN and Reported to TN CSMD, 2012-2020*							
Vann	A11	TNI Detients	Change are TNI Betieves (0/)					
Year	All patients	TN Patients	Change among TN Patients (%)					
2012	E 004 00E 040	5 (45 4 (2 25)						
2012	5,891,087,840	5,645,163,272	-					
2013	5,676,170,486	5,459,378,136	-3.3					
2014	5,495,896,687	5,283,718,580	-3.2					
2015	5,371,361,116	5,168,556,547	-2.2					
2016	5,046,482,089	4,863,419,348	-5.9					
2017	4,607,877,476	4,449,466,543	-8.5					
2018	4,024,015,019	3,888,983,012	-12.6					
2019	3,470,125,781	3,361,697,254	-13.6					
2020	3,207,567,373	3,103,569,942	-7.7					

^{*}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 2020



Acronyms	
Bureau of Justice Assistance	BJA
Centers for Disease Control and Prevention	CDC
Clinical Risk Indicator	CRI
Comprehensive Opioid Abuse Program	COAP
Controlled Substance Monitoring Database	CSMD
Controlled Substance Monitoring Database Committee	CSMD Committee
Department of Justice	DOJ
Drug Overdose Reporting	DOR
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
Integrated Data System	IDS
Integrated Justice Information Systems Institute	IJIS
Medication-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 Monitoring Program InterConnect	PMPi
Prescription Drug Monitoring Program	PDMP
Prescription Drug Overdose	PDO

Prevention for States	PfS
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 Health Administration	VHA



Tennessee Controlled Substance Monitoring Database

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