

Controlled Substance Monitoring Database

2017 Report to the 110th Tennessee General Assembly



Health Licensure & Regulation
Controlled Substance Monitoring Database Committee
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Contents

Tennessee Department of Health Response to Substance Abuse Epidemic.....	2
Trends in Drug Overdose Deaths in Tennessee and the Role of the CSMD	2
Moving Upstream to Use Weekly Hospital Data	3
The Story of Neonatal Abstinence Syndrome	4
The Role of and Presence of Pain Clinics across Tennessee	4
Fewer Prescriptions without CSMD Evaluation.....	5
Ratio of Number of Prescriptions to a Request in the CSMD, 2010-2016*	5
MME Improvements and Concerns by Age Group	5
Change in MME for Tennessee Patients, 2011 to 2016.....	6
Trends Related to Utilization of Benzodiazepines and Stimulants.....	6
Increased Buprenorphine for Opioid Use Disorders.....	6
Interventions Related to Top 50 Prescribers and Top 10 Prescribers for Small Counties.....	7
MMEs Prescribed by Top 50 Prescribers and Dispensed in 2013 – 2016*	7
Decline in Potential Doctor-Pharmacy Shopping	7
Potential Doctor and Pharmacy Shoppers Identified in the CSMD, 2010-2016*	8
User Satisfaction & Perception of the CSMD	8
2016 Prescriber User Survey.....	8
2016 Dispensers User Survey	8
Database Performance	9
Increased Interstate Data Sharing	9
Security Measures.....	9
TDH Provides Significant Educational Outreach.....	9
TDH Grants Update	9
TDH Recommends the Following Approaches to the Opioid Epidemic.....	10
Conclusion	11
2017 Members of the CSMD Committee	12
Acronyms	13

Tennessee Department of Health Response to Substance Abuse Epidemic

The 2017 Controlled Substance Monitoring Database (CSMD) report from Tennessee Department of Health (TDH) addresses activities and outcomes related to the substance abuse crisis as it relates to the CSMD. TDH is pleased to provide a comprehensive update on the prescription drug abuse crisis in the state at

http://tn.gov/assets/entities/health/attachments/2017_Comprehensive_CSMD_Annual_Report.pdf. The CSMD Committee reports annually on the outcome of the program with respect to its effect on distribution and abuse of controlled substances; along with recommendations for improving control, prevention, and diversion of controlled substances.

The CSMD continues to be a valuable tool to the prescribers and dispensers in caring for patients who rely on it daily. TDH is concerned that overdose deaths for 2015 were up despite progress observed from the data including a noted decline in Morphine Milligram Equivalents (MMEs) prescribed in 2016 for long acting and short acting opioids, a decline in potential doctor/pharmacy shoppers and a significant decline in the total MMEs of top 50 prescribers in the state. The CSMD is being utilized more than ever to assure that fewer prescriptions are being prescribed and dispensed without a check to the CSMD. CSMD data suggests an increase in the prescribing of drugs associated with treatment of opioid use disorder through medication assisted therapy. Further, the TDH was successful in empowering pharmacists with naloxone collaborative practice agreements with the Chief Medical Officer to increase access to potentially life-saving naloxone. However, these public health improvements have not yet decreased the drug overdose death trend in the most recently released data covering 2015.

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

In the past year, there has been continuing progress in key CSMD-related indicators. The proportion of individuals receiving high MME prescriptions (above 120 MME daily) continues to go down, and potential doctor shopping remains substantially decreased. Specifically, the number of people receiving more than an average daily dose of 120 MME went down 40% between 2012 and 2015. The TDH has built a tool to increase the efficiency and effectiveness of its review of clinician data to ensure focused investigations of clinicians and their charts.

The TDH uses methodology established by the CDC to understand and describe drug overdose deaths in our state (CDC, 2016)¹. Data from Vital Statistics indicates from 2014 to 2015, drug overdose deaths in Tennessee rose by 14%, increasing from 1263 to 1451, despite improvement in a number of measures of good medical practice, including reductions in the amount of opioids prescribed and dispensed, fewer doctor shoppers, and increased utilization of the CSMD. Only about half (56%) of people who died of overdose had controlled substances dispensed in the 60 days prior to death, suggesting that other factors played a significant role in overdose deaths, including illicit fentanyl, heroin, and diverted prescription opioids. However, nearly three quarters (74%) of those who died had filled a prescription for a

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>

controlled substance within the past year. Taken together, these are likely signs that the epidemic is evolving and that changes are needed in how we identify and intervene prior to fatal overdose. Against a national backdrop of large increases in opioid deaths, the proportion of Tennessee drug overdose deaths in which an opioid was involved rose only slightly in 2015, from 68% to 71% of deaths compared to 2014. This may suggest that the role of opioids in drug overdose deaths overall is leveling off. However, the number of deaths in which fentanyl was involved rose significantly, from 69 (5.5%) to 174 (12%). Of special concern is that approximately one third of drug overdose deaths include a combination of opioids and benzodiazepines, an interaction that is known to have high risk for respiratory suppression, the main cause of overdose death.

The TDH continues to improve how the CSMD is used in stopping the epidemic and is combining data from the CSMD with other patient data to identify key markers for increased risk. Epidemiologists at the TDH are beginning to map the natural history of addiction from prescription phase to what appears to be the danger zone, when individuals may move into the illicit market and are at higher risk for overdose and death. Policy and programs can be targeted more specifically to intervene early, when recovery is easier and more likely to be successful.

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

Moving Upstream to Use Weekly Hospital Data

In 2014, for every drug overdose death, more than 15 nonfatal overdoses were identified in state hospital discharge data having been treated in the emergency department or hospital. The proportion of these hospital visits due to opioids has steadily increased, with a particularly substantial increase in heroin related nonfatal overdoses. The data for 2015 is complicated by the fact that hospitals moved to a new coding system (ICD-10) mid-year, and methods are still being developed to analyze those data correctly. However, preliminary data suggests nonfatal overdose care continues to increase, with high medical costs, particularly for heroin.

These overdoses are treated in emergency departments and hospitals, but information about those overdoses currently are not available to clinicians outside the hospital or to the CSMD. In 2016, Public Chapter 959 provided the Commissioner with the opportunity to require healthcare facilities to provide the TDH with near real-time data on nonfatal drug overdoses. Such a data collection system is being implemented in 2017, with pilot data being collected in January. Eleven hospitals across the State are working with TDH to pilot the reporting system and provide weekly uploads of key information on drug overdoses. As this program expands statewide, these data will be used in developing risk indicators to provide clinicians with the important information that their patients may be headed for serious risk of negative outcomes, including fatal overdose.

The Story of Neonatal Abstinence Syndrome

In 2016, 1057 cases of Neonatal Abstinence Syndrome (NAS) were reported, as compared to 1039 cases in 2015, representing a very minimal increase (the rate per 1000 live births went from 12.9 in 2015 to 13.0 in 2016 which is < 1% increase). Of the reported cases, approximately 70% were among women receiving medication-assisted treatment (MAT) for substance abuse. Approximately 10% included the legal prescription of an opioid pain reliever. The largest rates of NAS continued to be in the East and Northeast regions of the state.

The CSMD is providing an opportunity to explore the potential role of prescribing in NAS, and the TDH is using a linkage of the data with NAS reporting to develop models that describe the risk for NAS among women who receive opioid prescriptions. In 2013 and 2014, 588 of approximately 2000 NAS cases in Tennessee were to women who appeared in the CSMD database as having prescriptions during their pregnancy. Most (74%) were white, one third had a household income of less than \$10,000 and about half had no more than a high school education. TDH analyses suggest that there is an increase in risk with increasing cumulative MME, and that risk of NAS is increased among women receiving opioid medication during their third trimester, especially with increasing doses of opioids. Notably, this analysis does not include data on methadone use, although it does include buprenorphine. These results will be fully available in the spring, and TDH epidemiologists anticipate developing risk scoring tools and educational materials for clinicians in the state. Identifying factors that increase risk of a negative outcome, including potentially types of drugs, prescribing patterns, and MME, may help in developing interventions to support pregnant women and prevent NAS. The CSMD has implemented an indicator encouraging clinicians to be particularly thoughtful about prescribing to women of childbearing age, and to facilitate clinicians in counseling and treating these women.

The Role of and Presence of Pain Clinics across Tennessee

The number of pain clinics declined to 185 in 2016 which represents a 44% decrease from the peak number of 333 in 2014. One of the goals of the TDH has been to increase access to quality pain management. As of July 1, 2016, TCA § 63-1-306 requires that pain management specialists be the medical directors of pain clinics. Medical directors who are pain specialists based on training as defined by statute should provide consistency in the quality of care for the citizens of Tennessee.

Pain Clinic Practice Guidelines have been developed and were published in January of 2017 with help from pain medicine specialists and other groups. The guidelines are available at: http://tn.gov/assets/entities/health/attachments/Pain_Clinic_Guidelines.pdf.

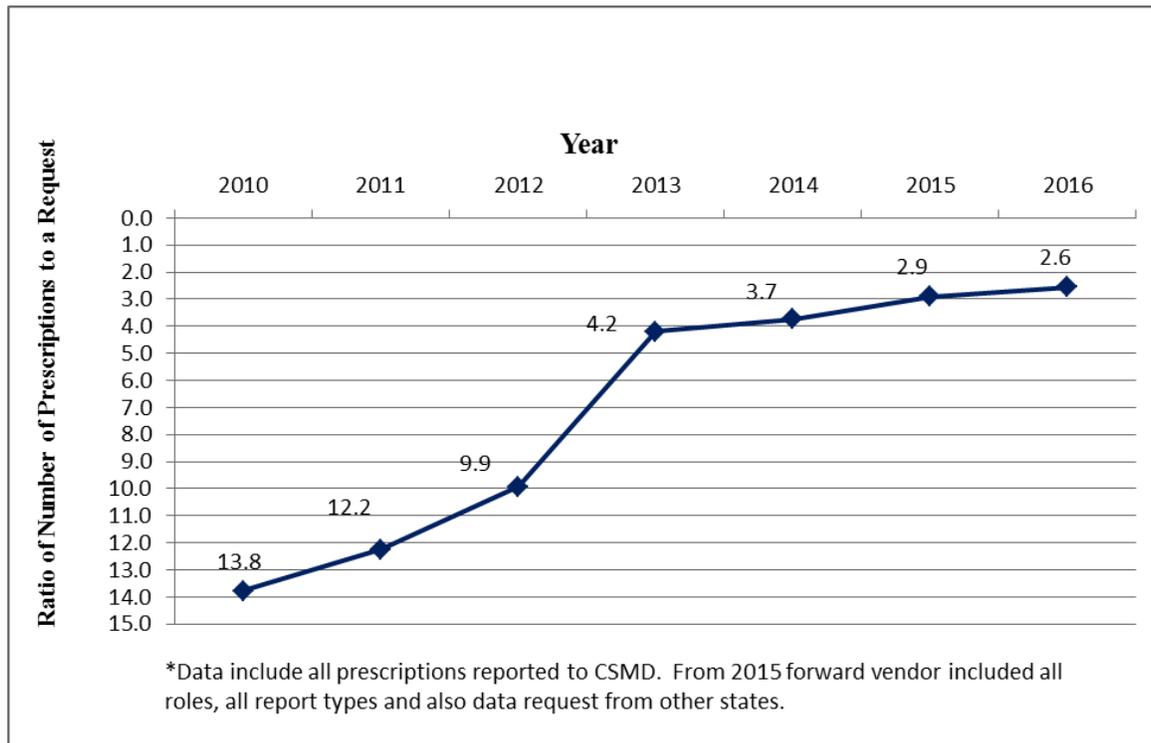
Pain Clinic Rules are in the process of being finalized and input was received from the Chronic Pain Guidelines Expert Panel. The expert panel consists of pain experts across the state. TDH is in the process of scheduling a public hearing for these rules.

Additionally, version 2 of the Chronic Pain Guidelines was completed by the Chronic Pain Guidelines Expert Panel in 2016 and posted in January 2017. The guidelines and those who gave of their time and expertise to make the guidelines a reality are available at: <http://tn.gov/assets/entities/health/attachments/ChronicPainGuidelines.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 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 2016 the number of registrants had grown to 46,576, an increase of 8.7% over 2015. Prior to the PSA of 2012 and 2016, Tennessee had 14 prescriptions reported for every CSMD patient request and now there are fewer than 3 prescriptions reported for each request. The number of patient reports requested increased 9.7 % in 2016 to 7,071,199.

Ratio of Number of Prescriptions to a Request in the CSMD, 2010-2016*



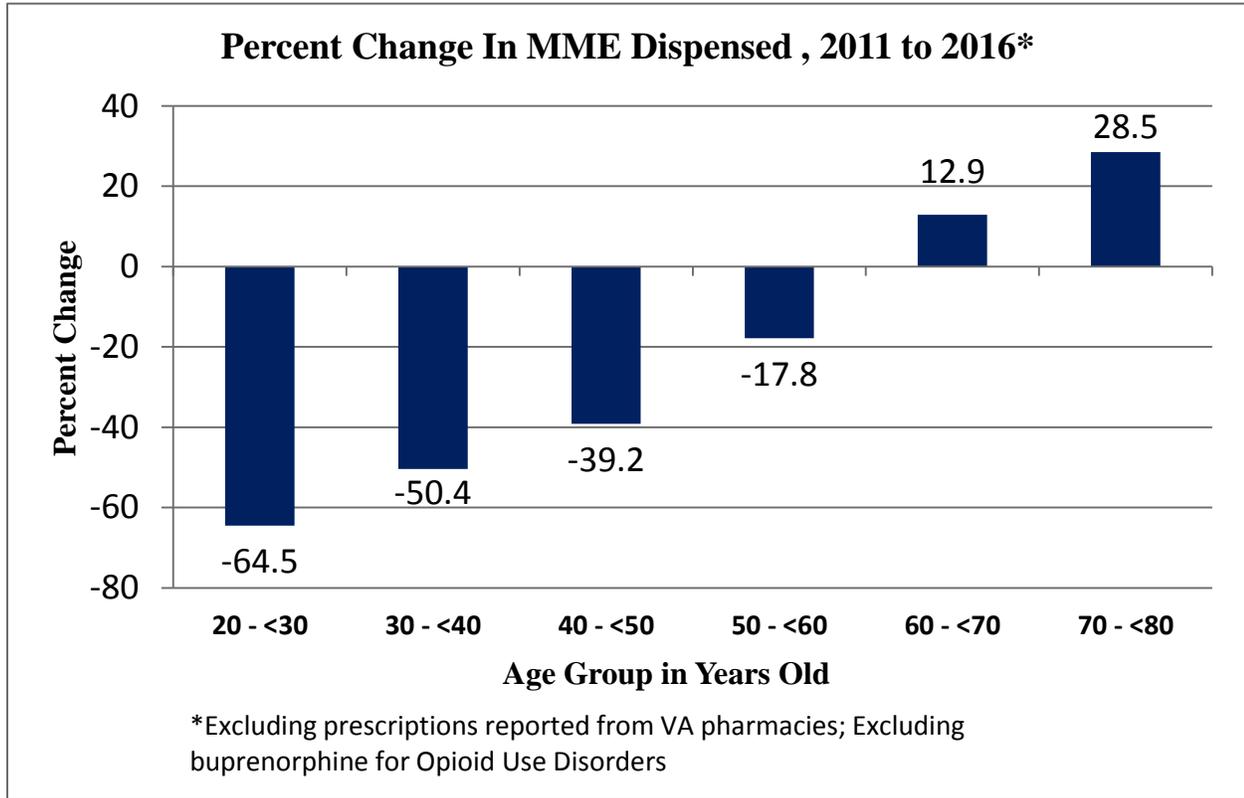
Law enforcement requests to the CSMD continue to be a critical use of the CSMD as TDH works together to address questionable controlled substance use in Tennessee. Of the 7,071,199 requests 1,326 were from law enforcement officers. Effective July 1, 2011, law enforcement officers were granted access to the CSMD. That access was further expanded through the PSA of 2016. During 2016, the TDH received a federal grant that will allow enhancement of the CSMD to provide law enforcement and drug courts improved access to the CSMD.

MME Improvements and Concerns by Age Group

For 2016, the CSMD program provided a more detailed analysis of the MME for trends by age group for Tennessee patients. Encouragingly, there was a decline in MMEs dispensed for the 20 to 59 age ranges compared to 2011 data. These improvements for the younger age groups are an indicator that the TDH’s efforts are preventing a new generation from being overexposed to opioids by the healthcare system.

However, the over 60 age group’s upward trending MME may lead to negative drug related outcomes for this high risk population.

Change in MME for Tennessee Patients, 2011 to 2016



Trends Related to Utilization of Benzodiazepines and Stimulants

Benzodiazepines, such as Xanax and Valium, showed a 4.9% decrease in prescriptions from 2015 to 2016. This class has seen a notable decline in prescribing and dispensing for people between the ages of 20 and 60.

The number of prescriptions for stimulants has continued to increase, growing by 48.9% for patients in Tennessee from 2010 to 2016.

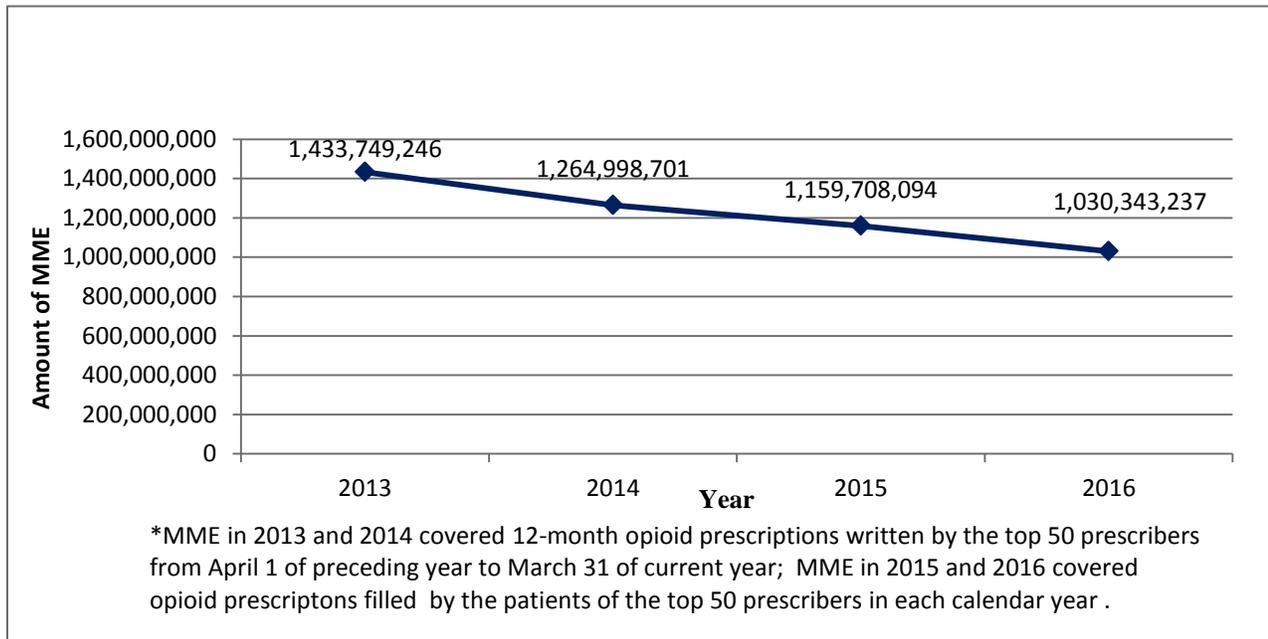
Increased Buprenorphine for Opioid Use Disorders

There has been a 119% increase in MMEs between 2010 and 2016 of buprenorphine for opioid use disorders dispensed among Tennessee patients. This may indicate that many patients have been successful in getting treatment for opioid use disorder but it should be noted that these drugs can be associated with overdoses and NAS.

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

Public Chapter 476 (passed during 2015) required the CSMD to continue to identify the top 50 prescribers in Tennessee and added a new requirement for the CSMD program to identify the top 10 prescribers from all of the combined counties having populations of fewer than 50,000 residents to the top prescriber annual identification process. After four years of experience with the top 50 prescriber analysis, the MMEs prescribed by this group have declined 28% since 2013 as noted in the line graph below.

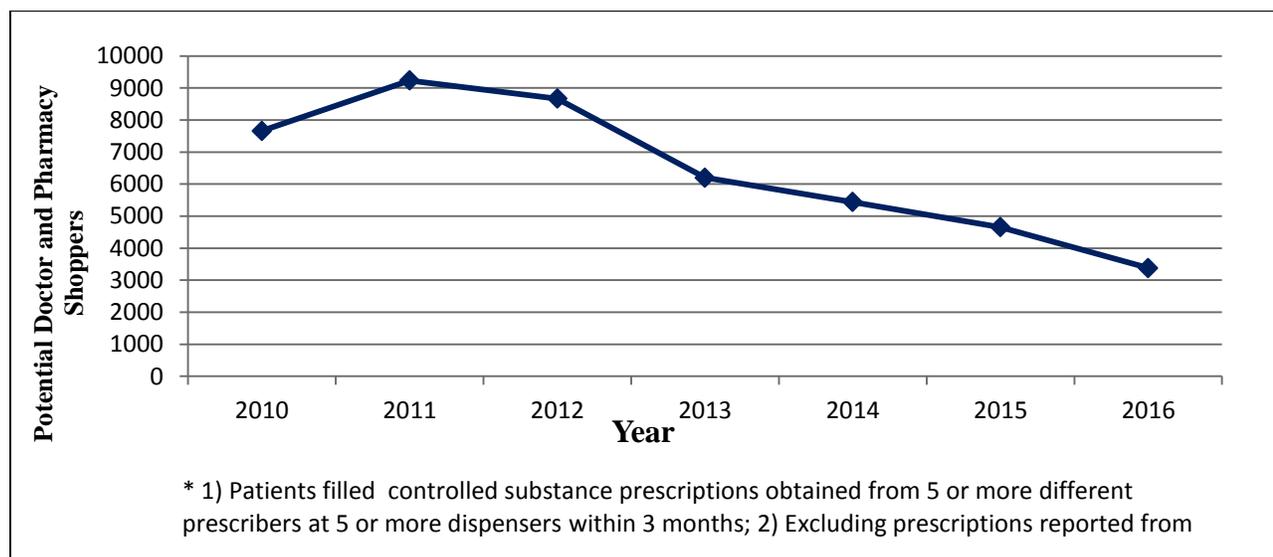
MMEs Prescribed by Top 50 Prescribers and Dispensed in 2013 – 2016*



Decline in Potential Doctor-Pharmacy Shopping

The TDH defines 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 63% decrease of potential doctor and pharmacy shopping patients from 2011 to 2016.

Potential Doctor and Pharmacy Shoppers Identified in the CSMD, 2010-2016*



User Satisfaction & Perception of the CSMD

The 2016 CSMD survey was the third for prescribers and the second for dispensers. Highlights of the 2016 survey are listed below.

2016 Prescriber User Survey

As a measure of satisfaction with improvements to the CSMD, a survey of prescribers was conducted in 2016 with greater than 2,800 prescribers responding:

- 73% use the CSMD at least monthly;
- 70% of responders have changed a treatment plan after viewing a CSMD report;
- 72% report discussing the CSMD report with their patients and 44% do so somewhat to very often;
- 28% of responders are more likely to refer a patient for substance abuse treatment;
- 87% of respondents report that the CSMD is useful for decreasing doctor shopping; and
- 43% report that they are less likely to prescribe controlled substances after checking the CSMD.

2016 Dispensers User Survey

A survey of dispensers was conducted in 2016 with greater than 950 responding:

- 91% use the CSMD at least monthly;
- 69% of responders communicate with the prescriber after viewing a CSMD report;
- 71% report discussing the CSMD report with their patients and 34% do so somewhat to very often;
- 58% of responders are more likely to communicate with the prescriber regarding a patient with potential for referral to substance abuse treatment;

- 91% of respondents report that the CSMD is useful for decreasing doctor shopping; and
- 84% report that they are less likely to fill a prescription as written after checking the CSMD.

Database Performance

In 2016, the CSMD system was up and functional 99.9% of the year. Much of the down time occurred in the first half of 2016. The CSMD team worked with its vendor to improve stability and the system stabilized by the last quarter of 2016.

Increased Interstate Data Sharing

The PSAs of 2012 and 2016 permit data sharing with other states. One of the areas of focus for 2016 was to enhance the sharing of prescription data with other authorized states. The CSMD program shared data with Kentucky, Virginia, South Carolina, Mississippi, Arkansas, North Dakota, Louisiana, West Virginia, Minnesota, and Michigan practitioners to give them a more complete picture of patients' controlled substance prescription history. The CSMD program has been in communication with Alabama, Georgia, North Carolina, Oklahoma and Rhode Island to share data. Each state has unique regulations and requirements that need to be addressed to share data.

Security Measures

In 2016, the CSMD program improved its operations and security by moving its data storage to an Amazon Web Services (AWS) center. CSMD data, now housed at the AWS center, is encrypted both at rest and in transmission. Additional security, previously unavailable due to on-site storage, has been gained by restricting encryption key access in such a way that the data cannot be unencrypted at the AWS data center where it resides.

TDH Provides Significant Educational Outreach

Over 55 presentations were made live across the state to approximately 3,000 attendees to educate on regulatory changes related to the best practices of controlled substance prescribing, dispensing, and monitoring as well as the Chronic Pain Guidelines and requirements related to pain clinics and pain specialists. The audiences consisted of consumers, health care providers, law enforcement officers, drug enforcement officials, and attorneys.

Ten of these events were accredited courses complying with the education requirement in TCA § 63-1-402 and provided in partnership with East Tennessee State University (ETSU) and Vanderbilt University. Programming included live audiences, live streaming, and archived efforts to reach all health care providers. The streaming and archived programs reached additional health care providers. Each of these educational opportunities allowed health care providers to earn Continuing Medical Education (CME) or other Continuing Education (CE) credits.

TDH Grants Update

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

nation's prescription drug overdose (PDO) epidemic. Funding for this initiative, "PDO: Prevention for States" (PFS), was awarded to sixteen states. The grant expanded upon the work already under way through the "PDO: Boost" grant. In 2016, the TDH was awarded additional, supplemental funding to expand use of data and allow for better, complex linkages across data sources. The purpose of the PFS grant is to provide state health departments with additional resources and support needed to advance interventions for preventing prescription drug overdoses within their own jurisdictions.

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

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

TDH Recommends the Following Approaches to the Opioid Epidemic

- **We recommend decreasing the supply of and reliance on opioids for pain**
Specifically, we suggest improving information provided through CSMD to include overdose information from Emergency Departments, proactively reaching out to clinicians with warning signs of patient opioid abuse, improving medication take back programs, and promoting safer, effective non-opioid treatments for pain.
- **We recommend increasing focus on prevention**
Specifically, we suggest developing education, focused on adolescents, to foster resistance to substance abuse, increasing screening for opioid abuse (SBIRT), increasing the availability of SUD treatment (through MHSAS), increasing oversight of clinics offering MAT (through

MHSAS), expanding support for community drug coalitions including their important work to reduce the stigma of substance use disorders, adopting effective safe syringe programs, and increase use of naloxone (estimated to decrease overdose deaths by 10%).

- **We recommend focus on reducing NAS**

Specifically, increasing support for prevention of unintended pregnancy and strategies for prevention of substance abuse, and focusing on medical management of pregnant women at risk of substance use disorder, especially in the third trimester.

- **In summary**

By focusing on reducing the number of people who are nonmedical users we “turn off the faucet” and avoid the difficult and expensive physical, legal and mental health implications of progression to dependence and substance use disorder. By better integrating actions thorough rapid analysis and coordinated responses we can work with communities to address developing problems before they become entrenched in our communities. By working to eliminate the stigma of SUD we can help people who have substance use disorders to get help early, when treatment is easier and more successful. And by working with FDA on new medication approval, we can continue to assure Tennesseans have the safety and efficacy they have rightly come to expect from approved medications.

Conclusion

While much progress has been made, much work remains to be done. This is an urgent situation that is unparalleled in recent state history. Much more should and, thankfully, can be done. TDH is pleased to see improvements in opioid prescribing and dispensing across the state and is maximizing partnerships with other agencies and grant funding to best design a process to more quickly share information and empower CSMD users, law enforcement, drug courts and coalitions to have the best information available to fight the substance abuse crisis. While these are important steps in fighting the prescription drug epidemic, the many partners must continue to take action in order to reverse the overdose death trend in Tennessee and to shrink the number of NAS cases in our state.

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

2017 Members of the CSMD Committee

Member Name	Board
Alan Musil, M.D.	Board of Medical Examiners
Katherine N. Halls, DDS	Board of Dentistry
Brent Earwood, APN, CRNA	Board of Nursing
Brad Lindsay	Board of Optometry
Shant Garabedian, DO	Board of Osteopathy
Debra Wilson, D.Ph.	Board of Pharmacy
David J. Sables, DPM	Board of Podiatry
Kim Johnson, DVM	Board of Veterinary Medical Examiners
Omar Nava, PA-C	Committee on Physician Assistants
Julianne Coles	Public Member Board of Medical Examiners
Lisa Tittle	Public Member Board of Pharmacy

Acronyms

Advanced Practice Registered Nurse	APRN
Amazon Web Services	AWS
Centers for Disease Control and Prevention	CDC
Continuing Education	CE
Continuing Medical Education	CME
Controlled Substance Monitoring Database	CSMD
Controlled Substance Monitoring Database Committee	CSMD Committee
Department of Justice	DOJ
East Tennessee State University	ETSU
Emergency Department	ED
Food and Drug Administration	FDA
Medicated Assisted Treatment	MAT
Morphine Milligram Equivalents	MME
Neonatal Abstinence Syndrome	NAS
Physician Assistant	PA
Prescription Drug Monitoring Program	PDMP
Prescription Drug Overdose	PDO
Prevention for States	PFS
Screening, Brief Intervention and Referral to Treatment	SBIRT
Substance Use Disorder	SUD
Tennessee	TN
Tennessee Bureau of Investigations	TBI
Tennessee Department of Health	TDH
Tennessee Department of Mental Health and Substance	TDMHSAS
Veterans Affairs	VA