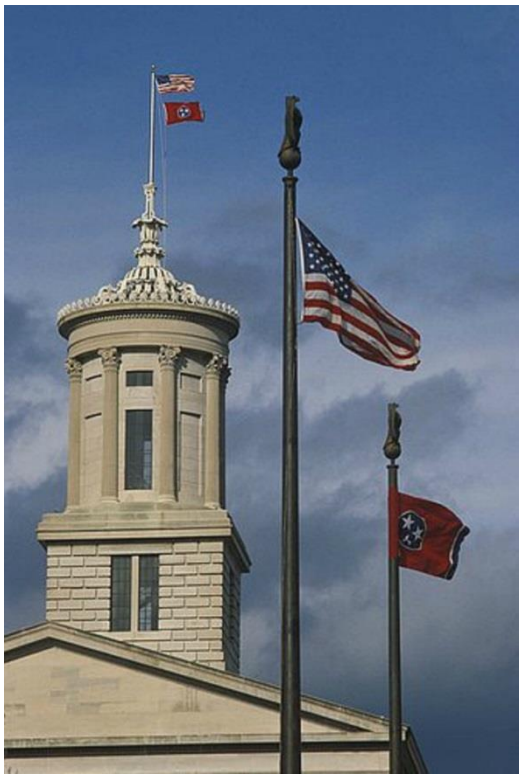
Controlled Substance Monitoring Database

2014 Report to the 108th Tennessee General Assembly



Tennessee Department of Health

Controlled Substance Monitoring Database Committee

February 1, 2014

Executive Summary

Background

This report addresses activities of the Controlled Substance Monitoring Database (CSMD) program. The Controlled Substance Monitoring Database 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 and prevention of diversion of controlled substances and the security measures taken to ensure that only authorized persons or entities access the database.

Data Highlights and Trends

The Prescription Safety Act of 2012 has facilitated a substantial increase in utilization of the CSMD by healthcare practitioners. This year's data indicates:

- The number of registrants increased by 56.8% in 2013 to 34,802;
- There was a 240% increase in the number of patient reports requested in 2013 to 4.49 million;
- There was a 0.7% increase in the overall number of prescriptions reported to the CSMD in 2013;
- There was a 0.4% decrease in the number of opioid prescriptions and a 3.6% decrease in the number of benzodiazepine prescriptions; and
- The number of high-utilization patients ("provider shoppers") identified in the CSMD has steadily decreased.

Innovative Practices and Ongoing/Anticipated Actions

As a measure of satisfaction with improvements to the CSMD, a survey of prescribers was conducted in 2013 with over 900 responding, with the following notable responses:

- 71% of responders have changed a treatment plan after viewing a CSMD report;
- 73% of responders are more likely to discuss substance abuse issues or concerns with a patient;
- 57% of responders are more likely to refer a patient for substance abuse treatment; and
- 79% of respondents feel that the CSMD is useful for decreasing doctor shopping.

In addition to the Prescription Safety Act of 2012, increased usage of the database may also be attributed to the educational efforts of the Committee and Department of Health. In 2013, two separate groups of enhancements were implemented to improve the user experience and the administrative and analytical functions of the database. In 2013, the system experienced only a 0.1% downtime and, in our survey of prescribers, 72% indicated that the system typically provides a patient report less than 10 seconds after submitting a query. CSMD enhancement efforts in 2014 will primarily be focused on:

- Decreasing the time from dispensing of a prescription to appearance in the CSMD by dispensers;
- Furthering the sharing of prescription data with other authorized states (in addition to Virginia, South Carolina and Michigan) to give practitioners a more complete picture of a patient's prescription history;
- Performing analysis of data to help predict inadvertent overdoses, drug abuse and diversion;
- Assisting prescribers with timely information about their patients' prescription histories by incorporating CSMD queries into a practitioner's current workflow; and
- Identifying the outlying prescribers and dispensers, as stipulated by Public Chapter 396 as well as conformance to the requirements of the Prescription Safety Act of 2012.

The Committee and Department of Health will continue to be aggressive in efforts to reduce the likelihood of adverse events, including addiction, overdose, overdose deaths and NAS, related to controlled substance use and help prevent diversion.

Contents

Data and Analysis

To report on the outcome and the efficacy of the program, the Board of Pharmacy staff compiled the following data describing the controlled substances prescriptions reported to the CSMD from January 1, 2013 to December 31, 2013. Tenn. Code Ann. § 53-10-306 (a) (2) allows Board of Pharmacy staff to access database information for the purposes of compiling this report.

A brief statistical overview for 2013 is presented in Table 1, including the number of requests (queries), number of registrants, number of dispensers and number of prescriptions and milligram morphine equivalents reported to the CSMD.

Table 1. 2013 CSMD Statistical Summary

Number of Requests	4,499,804
Number of Registrants	34,802
Number of Dispensers who Reported to CSMD	2,550
Number of Prescriptions Reported	
Opioids	9,227,456
Benzodiazepines	3,913,356
Other	5,433,347
Milligram Morphine Equivalents (MME) Dispensed*	9,898,069,236

*More than 9.8 Billion milligrams of morphine equivalents (MME) were dispensed in Tennessee in 2013. Using MME's allows one to account for the differences in the strength of an opioid relative to morphine, a naturally occurring opioid.

There was a significant increase in utilization of the CSMD in 2013 due to the passage and implementation of the Prescription Safety Act of 2012. To accommodate this expected increase in utilization, the Department of Health collaborated with the software vendor, Optimum Technology, to increase the capacity of the database in 2012. This collaboration was successful, as the system supported a 240% increase in queries over 2012 utilization. The number of registrants also markedly increased in 2013, from 22,192 in 2012 to 34,802 in 2013, an increase of 57%.

There was a 0.2% increase in the number of dispensers in 2013. The increase in number of dispensers is responsible for a 0.7% increase in the total number of prescriptions dispensed above 2012 reported prescriptions. However, when considering opioids and benzodiazepines, which were specifically targeted by the Prescription Safety Act of 2012, a decrease is reported of 0.4% and 3.6% respectively (see Table 2 below).

*Table 2. Number of Controlled Substances Prescriptions (by class) Reported to CSMD, 2010 - 2013**						
Year	Opioids	% Change	Benzodiazepines	% Change	Other	% Change
2010	8,150,946	-	3,951,144	-	4,423,662	-
2011	9,018,139	10.6	4,152,587	5.1	5,001,445	13.1
2012	9,265,450	2.7	4,061,418	-2.2	5,125,142	2.5
2013	9,227,456	-0.4	3,913,356	-3.6	5,433,347	6

* Classes of controlled substances were defined based on CDC guidance document.

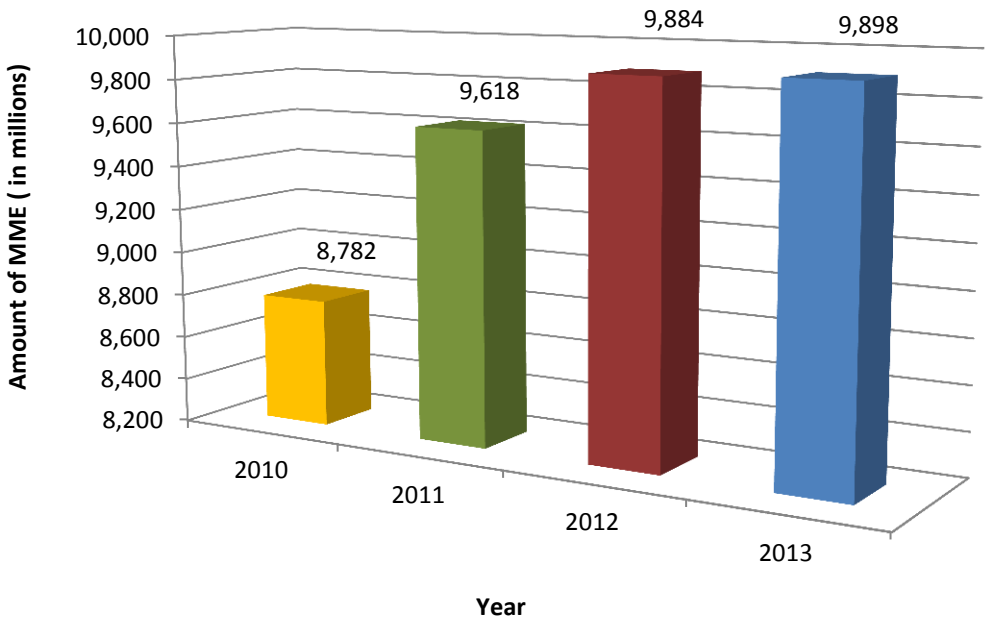
The top 10 most frequently prescribed products remains largely unchanged from 2012 (see Table 3) with the only differences noted being a move up in the number of morphine prescriptions and a move down in the number of buprenorphine prescriptions.

Table 3. Comparison of the 10 most frequently prescribed products in 2012 and 2013 in CSMD		
Rank	2013	2012
1	Hydrocodone products	Hydrocodone products
2	Alprazolam	Alprazolam
3	Oxycodone products	Oxycodone products
4	Zolpidem	Zolpidem
5	Tramadol	Tramadol
6	Clonazepam	Clonazepam
7	Lorazepam	Lorazepam
8	Diazepam	Diazepam
9	Morphine products	Buprenorphine products
10	Buprenorphine products	Morphine products

The number of milligram morphine equivalents (MME) dispensed increased by 0.1% in 2013 (see Figure 1 below). The MME is an industry-recognized standard which converts milligrams of different opioids into an equivalent dose of morphine. This standardization affords the practitioner an opportunity to take all opioids into account when formulating a treatment plan, as

risk of overdose increases as total MME per day increases. The increase in total MME dispensed in Tennessee in 2013 can be attributed to the 0.2% increase in dispensers mentioned previously in this report.

Figure 1. Overall Morphine Milligram Equivalent (MME) Dispensed and Reported to CSMD, 2010 -2013



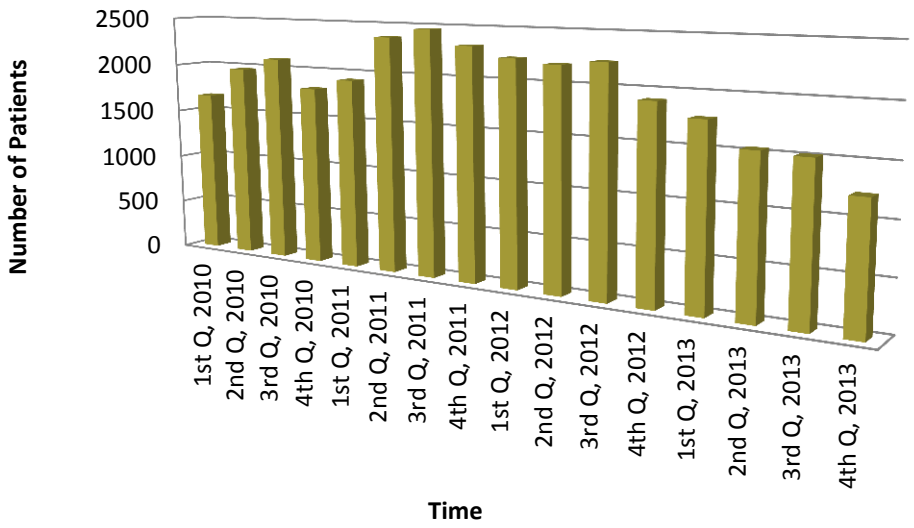
There has been a noticeable decrease in number of high-utilization patients in 2013. A commonly used criterion by the CDC defines a high-utilization patient as a person who utilizes 5 prescribers and 5 pharmacies in a 90 day period. Table 4 and Figure 2 are a representation of those trends taken from the CSMD.

*Table 4. Number of High Utilization Patients by Quarter in CSMD, 2010-2013**

Year	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
2010	1,668	1,971	2,096	1,811
2011	1,922	2,373	2,465	2,322
2012	2,224	2,185	2,229	1,908
2013	1,776	1,540	1,518	1,228

*Patients filled prescriptions from 5 or more prescribers at 5 or more dispensers within 90 days.

Figure 2. Trend of Number of High Utilization Patients by Quarter in CSMD, 2010-2013



Additional tables and figures are included in Appendix A.

Findings and Recommendations

The marked increases of the number of both authorized users and patient history reports requested from 2012 to 2013 indicate an increased use of the database by prescribers and dispensers. Much of this increase in utilization of the CSMD can be attributed to passage and implementation of the Prescription Safety Act of 2012. The data as a whole indicates that health care providers are using the database for its intended purpose-tailoring patient treatment plans, relative to cumulative controlled substance usage. It also indicates that dispensers are increasingly relying on the database as a tool used to detect the abuse and misuse of controlled substances and also as a tool to better treat the patient in providing competent, quality care.

In 2013, CSMD staff conducted a brief survey of database users with over 900 responses after implementation of the Prescription Safety Act. A summary of the results is included below:

- 71% of respondents have changed a treatment plan after viewing a CSMD report;
- 73% of respondents are more likely to discuss substance abuse issues or concerns with a patient;
- 57% of respondents are more likely to refer a patient for substance abuse treatment;
- 79% of respondents feel that the CSMD is useful for decreasing doctor shopping; and
- 72% of respondents noted that it takes, on average, less than 10 seconds for the CSMD to return a patient report after submitting a query.

As discussed previously, the number of high-utilization patients is decreasing. However, focus should remain on those patients who continue to utilize multiple providers, as they are at an increased risk of overdose or are more likely to divert controlled substances. Providers may use the database information to either refuse to prescribe or dispense a duplication of drug therapy or they may alter the patient's treatment plan accordingly.

The new data indicates that a much greater number of practitioners registered to use the database in 2013 (an increase of 12,610 users.) Work will continue with all stakeholder licensing boards to ensure all healthcare providers who should be registered users of the CSMD take advantage of this valuable tool. There was a corresponding increase in the number of patient reports requested (4,512,763 vs. 1,861,485 in 2012). The Department is pursuing options to make utilization of the CSMD more convenient by incorporating the query into the workflow of healthcare practitioners. New in 2013, there were 14,897 of the total patient requests from out-of-state providers through interstate data sharing hubs. The Department of Health and CSMD Committee are currently pursuing additional states to share data with in 2014 and it is believed that this will decrease the number of doctor shoppers who seek medications across multiple jurisdictions.

The number of prescriptions reported to the CSMD increased from 18,452,512 in 2012 to 18,674,671 in 2013 and the number of dispensers also increased from 2012 to 2013. As new dispensers are added, the potential exists to notice an increase in the total number of prescriptions reported to the CSMD. We will continue to strive to ensure that all dispensers are able to report to the CSMD to help protect patient safety and prevent diversion of controlled substances. To help measure effectiveness, additional focus will be placed on analysis of MME per patient and prescription as these measures may normalize the variability introduced when merely analyzing the total number of prescriptions reported to the CSMD.

The increased and appropriate usage of the database may be partially attributed to the efforts of the Department of Health to instruct and guide health care providers about the operations and the benefits of the CSMD. The Director of the CSMD has presented to professional organizations, to medical practice groups and to pharmacists state-wide through continuing education programs. The Department of Health's Medical Director of Special Projects has been throughout the medical community and has travelled throughout the state speaking to addiction and rehabilitation centers, various state medical associations, Colleges of Medicine and Nursing, community drug coalitions, and law enforcement groups.

In January 2013, the Department welcomed a new epidemiologist dedicated to the statistical evaluation of data found in the database. The epidemiologist has assisted with the Top 50 analysis required by Public Chapter 396 and has performed numerous analysis projects for internal and external stakeholders. The epidemiologist will help establish a statistical framework to further enhance analysis of prescribing habits and educational efforts of the advisory committee and contributed to the data and analysis found in this year's annual report.

The Controlled Substance Monitoring Database Committee and Department of Health are dedicated to using the database in innovative ways. Some areas of consideration are correlation of overdose data with CSMD data and correlation of overdose death data with CSMD data. The purpose is to attempt to develop predictors of prescription overdose and overdose deaths for educational purposes. The committee is also dedicated to analyzing data for overprescribing and over dispensing and continues to look for new ways to identify and evaluate those practices. The Committee will also continue to refer those who are identified as outliers to the appropriate board for disciplinary consideration as well as seek out opportunities to enhance the database and optimize staffing to increase its utility as an educational and regulatory tool.

Additionally, there were approximately 10 successful enhancements to the CSMD in 2013 in two phases. The purpose of the enhancements was to enhance the user experience, increase patient safety, and add administrator features that improve customer support activities. Most notably, the CSMD patient report was enhanced to include the patient's current milligram morphine equivalent (MME). This feature of the patient report is a quantification of MME for all opioid prescriptions which are "active" (based on fill date and day supply) standardized to an equivalent dose of morphine. This standardization of opioid dose aids in determining opioid exposure and shaping the clinical decision-making process. Another enhancement facilitates a single user looking up multiple patients in one queue as a time-saving feature, which was a frequent request by CSMD users in practice. Further enhancements scheduled for 2014 include: enhanced interstate data sharing by adding more states, push notifications to providers indicating the patients who are at potential risk of adverse events, enhanced audit capabilities for supervising prescribers and incorporation of CSMD querying into a provider's clinical workflow.

Security Measures

The individuals or entities that had access to the database in 2013 are: authorized committee, board or department of health personnel; pharmacists; prescribers; Office of Inspector General and other authorized Tenncare personnel, and the Medicaid Fraud Control Unit, healthcare extenders and hospital quality improvement committees. Law enforcement personnel engaged in an official investigation and enforcement of state and federal controlled substance laws are allowed to request information from the database pursuant to Tenn. Code Ann. § 53-10-306(a) (8). In order to ensure that only those authorized individuals and entities have access, the Board of Pharmacy employs the following security measures:

- All authorized entities and individuals that have been granted access to the database pursuant to Tenn. Code Ann. § 53-10-306(a) (1-7) are allowed to enter the database through a password obtained from the Board staff.
- Healthcare extenders are granted access to the database pursuant to Tenn. Code Ann. § 53-10-306(a) (9) through a password obtained from the Board staff after approval from their supervising practitioner.
- Before the Office of Inspector General, the Medicaid Fraud Control Unit, and Tenncare personnel are able to access the database, the individuals requesting access must submit a written request on their respective letterheads to the Board office verifying that are in fact employed by the entities that they represent before they are supplied with individual passwords. There are a total of sixteen (16) individuals from the Office of Inspector General and the Medicaid Fraud Control Unit, who have password access to the database.
- Before dispensers are granted access to the database, they must submit a registration request to Board of Pharmacy staff. The Board of Pharmacy staff reviews the request to ensure that the dispenser's license is in good standing in Tennessee or any other states where the individual has a license to dispense controlled substances.
- When the authorized user is granted access, the computer generates a security profile for that user, which, in turn, offers the Board of Pharmacy complete oversight of what data has been accessed, updated or viewed.
- Requests by law enforcement personnel for information sent to, contained in, and reported from the database pursuant to Tenn. Code Ann. § 53-10-306(a) (8) must submit a written request with a case number corresponding to a criminal investigation. The Board of Pharmacy staff verifies that the law enforcement personnel are on the approved list submitted by the TBI director or the district attorney general in the judicial district in which the law enforcement agency or judicial district drug task force has jurisdiction.
- Requests for access by persons other than those individuals outlined in Tenn. Code Ann. § 53-10-306(a) (1-7, 9) were reviewed by Board of Pharmacy staff and Legal Counsel to determine if the person requesting access could be granted access pursuant to applicable laws and rules. Legal staff also reviewed all Court orders to ensure that they were in compliance with Tenn. Code Ann. § 53-10-306 before any information was released.
- The Board of Pharmacy staff monitors requests of database information by the Department of Health's Bureau of Investigations. Tenn. Code Ann. § 53-10-308(a) provides that the committee may release confidential information from the database regarding practitioners, patients, or both, to a manager of any investigations or prosecution unit of a board, committee, or other governing body that licenses practitioners and is engaged in any investigation, an adjudication, or a prosecution of a violation under any state or federal law that involves a controlled substance. In exercising its authority under this statutory section, the Committee voted to allow the Director of the Bureau of Investigations for the Department of Health to obtain a report from the database about a specific practitioner when there is an open complaint against a practitioner and the allegations involve that practitioner's controlled substance prescribing practices. The Bureau of Investigations Director is a licensed attorney and provides the Board staff with a written request for database information containing the practitioner's name, the allegations in the pending complaint against the practitioner, and how the allegations relate to the practitioner's prescribing practices relative to controlled substances.

Background and Summary of the Law

The Controlled Substance Monitoring Act of 2002 was enacted on or about July 3, 2002 in the 2002 Public Acts, Chapter 840, codified in Tenn. Code Ann. § 53-10-301, et seq. for the creation of the controlled substance database ("database") which is administratively attached to the Board of Pharmacy ("Board"). Tenn. Code Ann. § 53-10-304(c) explicitly provides that the purpose of the database is "…to assist in research, statistical analysis, criminal investigations, enforcement of state and federal laws involving controlled substances, and the education of health care practitioners concerning patients who, by virtue of their conduct in acquiring controlled substances, may require counseling or intervention for substance abuse…" Toward that end, dispensers (prescribers and pharmacists) are required to submit data about the controlled substances dispensed (including strength and quantity) along with the patient's name, twice each month to Optimum Technologies who has contracted with the Board of Pharmacy to compile the data for the database. The law also provides that the Board along with the Controlled Substance Database Advisory Committee ("Committee") shall establish, administer, maintain and direct the functioning of the database (Tenn. Code Ann. § 53-10-304(b)).

In addition to those duties, pursuant to Tenn. Code Ann. § 53-10-309, the Committee was required to report 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 and prevention of diversion of controlled substances. Tenn. Code Ann. § 53-10-309 was amended in Public Chapter 498 of the 2007 Public Acts to provide that in addition to the annual reporting requirement recited above, the committee is required to file an annual report with the house and senate general welfare committees starting on or by February 1, 2008 and each year thereafter to include a monthly analysis about tracking the individuals or entities who/that access the database and the security measures taken to ensure that only authorized persons or entities access the database. This report is submitted in compliance with these reporting mandates.

In May of 2012, Public Chapter 880 amended several requirements of Tenn. Code Ann. § 53-10 Part 3. It requires prescribers and dispensers of controlled substances to register in the database. It also requires checking of the database before prescribing over a one week course of benzodiazepines or opioids and once yearly thereafter if continued treatment is warranted. For the first time, a practitioner may designate agents to access the database on their behalf. Healthcare practitioner extenders register for separate password access after designation and approval from their supervising practitioner. Also of importance is the ability to connect with other states and share patient records with other providers who are also treating the patient. Dispensers now must report all prescriptions dispensed every 7 days and submit source of payment with those submissions. Finally, the database capacity was increased in anticipation of more activity from practitioners and staffing of the database office was also increased to support the larger number of users.

Appendix A.

Supplementary Tables and Figures

Additional information concerning the number of registrants and number of CSMD requests is included in Tables 5 and 6.

Table 5. Number of Registrants in CSMD, 2010 - 2013

Year	Registrants	Change (%)
2010	13,182	-
2011	15,323	16.2
2012	22,192	44.8
2013	34,802	56.8

Table 6. Number of Patient Requests from CSMD, 2010 - 2013

Year	Healthcare Providers	Law Enforcement
2010	1,200,435	N/A
2011	1,486,932	551
2012	1,861,485	2,565
2013	4,497,866	1,938

Table 7. Number of Requests by Month from CSMD users and Law Enforcement, 2013

Month	Number of Requests-Tenn. Code Ann. § 53-10-306(a)(1-7, 9)	Number of Law Enforcement Requests-Tenn. Code Ann. § 53-10-306(a)(8)
January	249,187	196
February	242,324	202
March	266,809	151
April	480,719	199
May	432,445	147
June	379,677	159
July	400,330	143
August	395,718	130
September	410,150	179
October	533,145	190
November	348,746	150
December	358,616	92

Additional information concerning the number of dispensers reporting to the CSMD and the number of prescriptions reported is incorporated into Table 8 and Figures 3 and 4.

Table 8. Number of Prescriptions Reported to CSMD, 2010 - 2013

Year	Prescriptions	Change (%)
2010	16,525,752	-
2011	18,172,171	10
2012	18,452,010	1.5
2013	18,574,159	0.7

Figure 3. Number of Dispensers Reporting Prescriptions to CSMD, 2010-2013

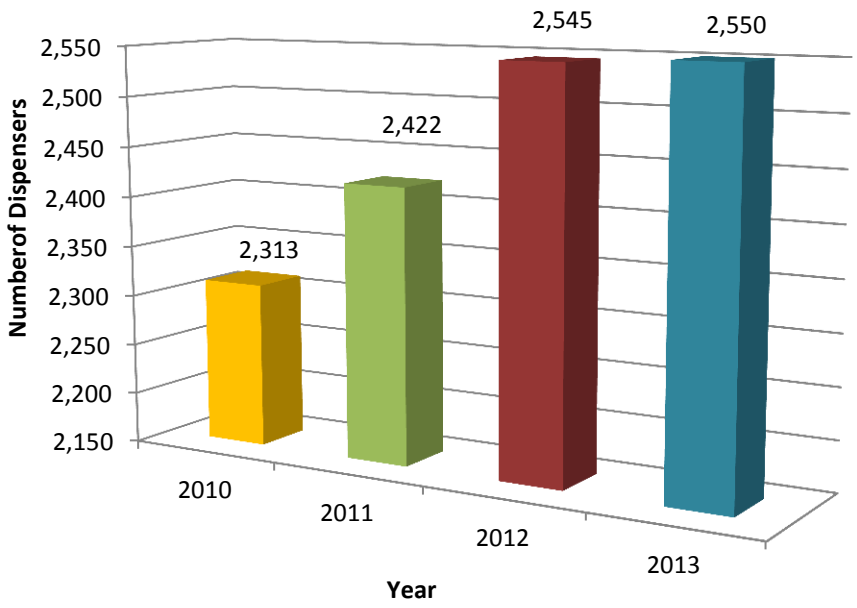
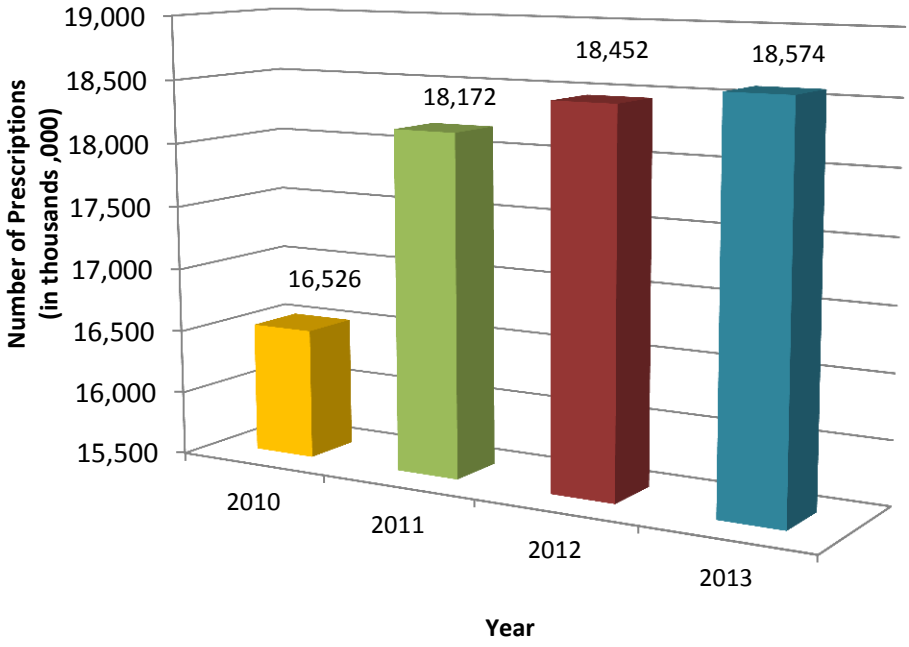


Figure 4. Number of Prescriptions Reported to CSMD, 2010-2013



Figures 5, 6 and 7 present additional information pertaining to the breakdown of prescriptions reported to the CSMD by drug type or class.

Figure 5. Number of Prescription by Class of Controlled Substances Reported to CSMD, 2010-2013

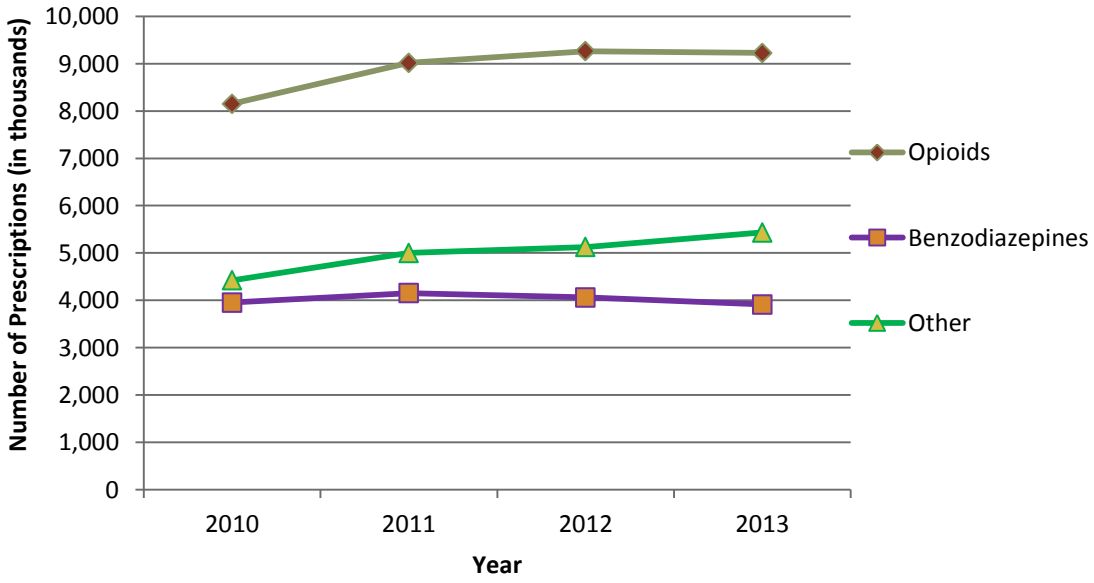


Figure 6. Distribution of Number of Prescriptions by Product Reported to CSMD, 2013

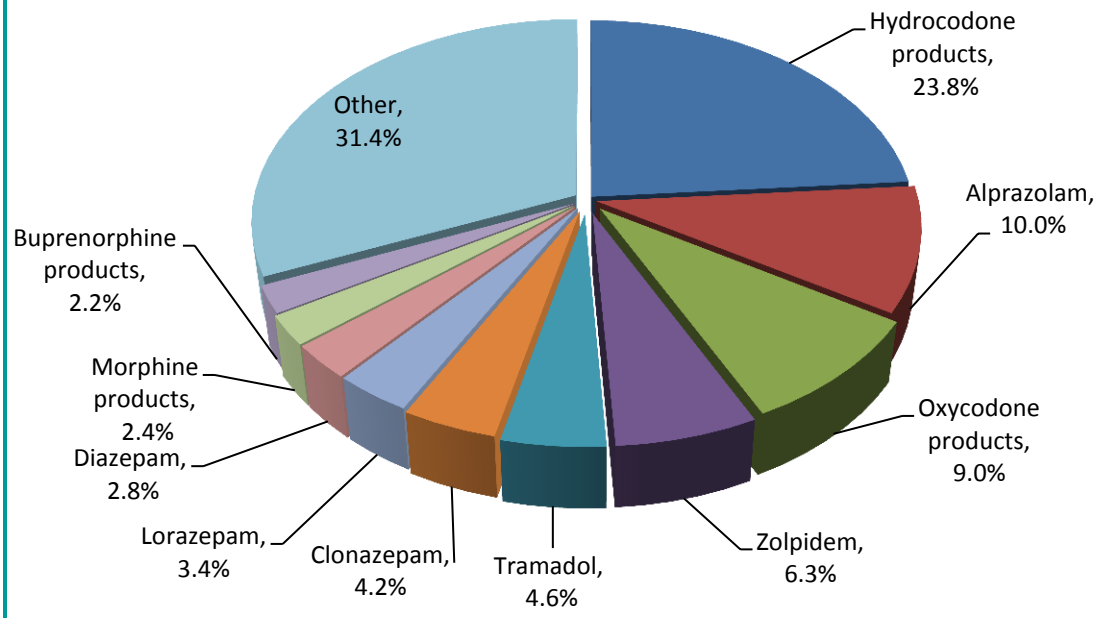


Figure 7. Distribution of the Top 10 Products Reported to CSMD, 2013

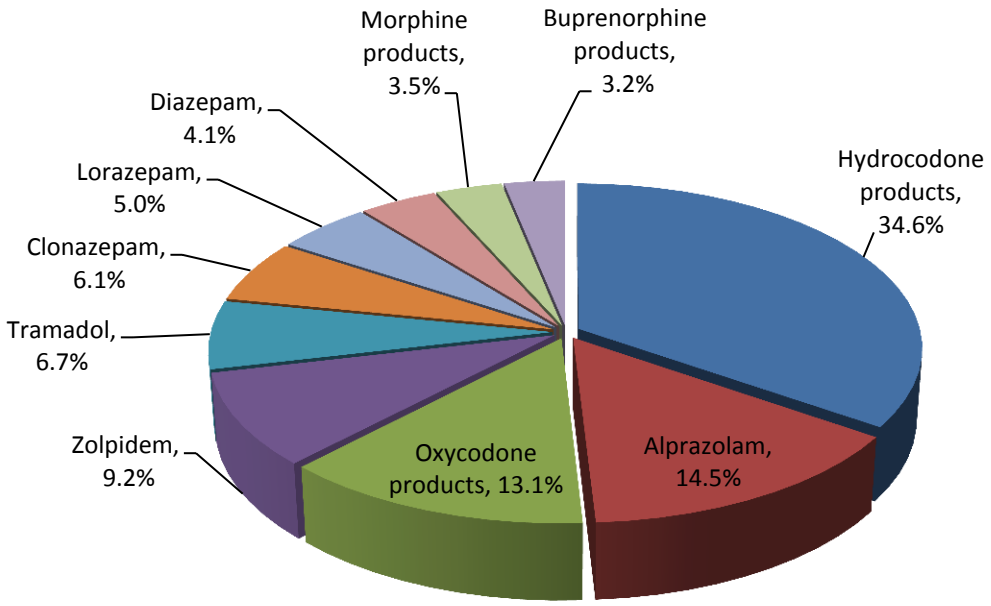


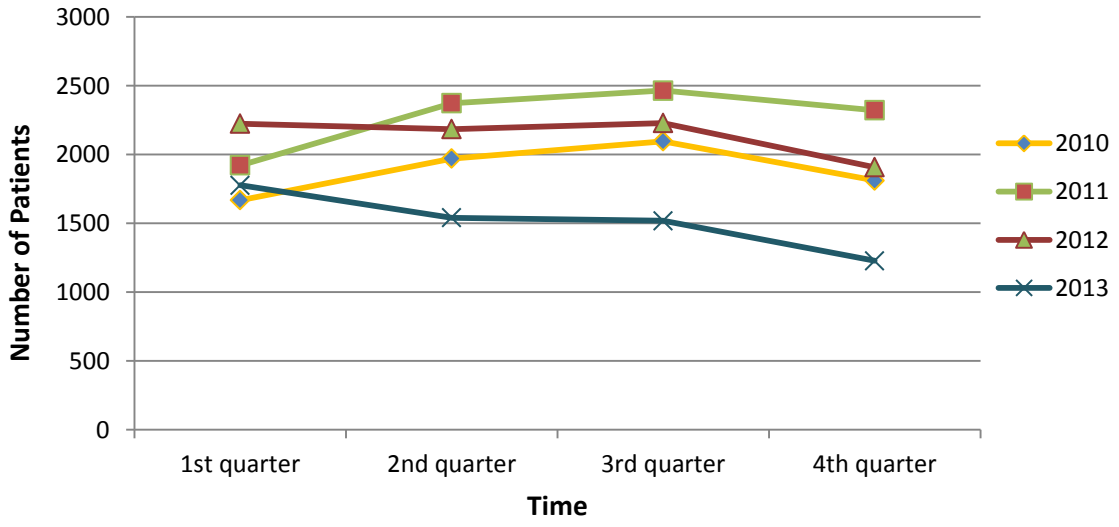
Table 9 presents a comparison of MME dispensed over time.

Table 9. Overall Morphine Milligram Equivalent (MME) Dispensed and Reported to CSMD, 2010-2013

Year	MME	Change (%)
2010	8,782,383,683	-
2011	9,618,319,622	9.5
2012	9,883,615,759	2.8
2013	9,898,069,236	0.1

Figure 8 shows the number of high utilization patients by quarter over time. A high utilization patient was defined as a patient who utilized 5 different prescribers and 5 different dispensers over a 90 day period.

Figure 8. Number of High Utilization Patients by Quarter in CSMD, 2010-2013



The maps on pages 16 and 17 (Figures 9 and 10) depict prescriptions dispensed by county and rate of dispensing per capita when utilizing 2010 census data, respectively.

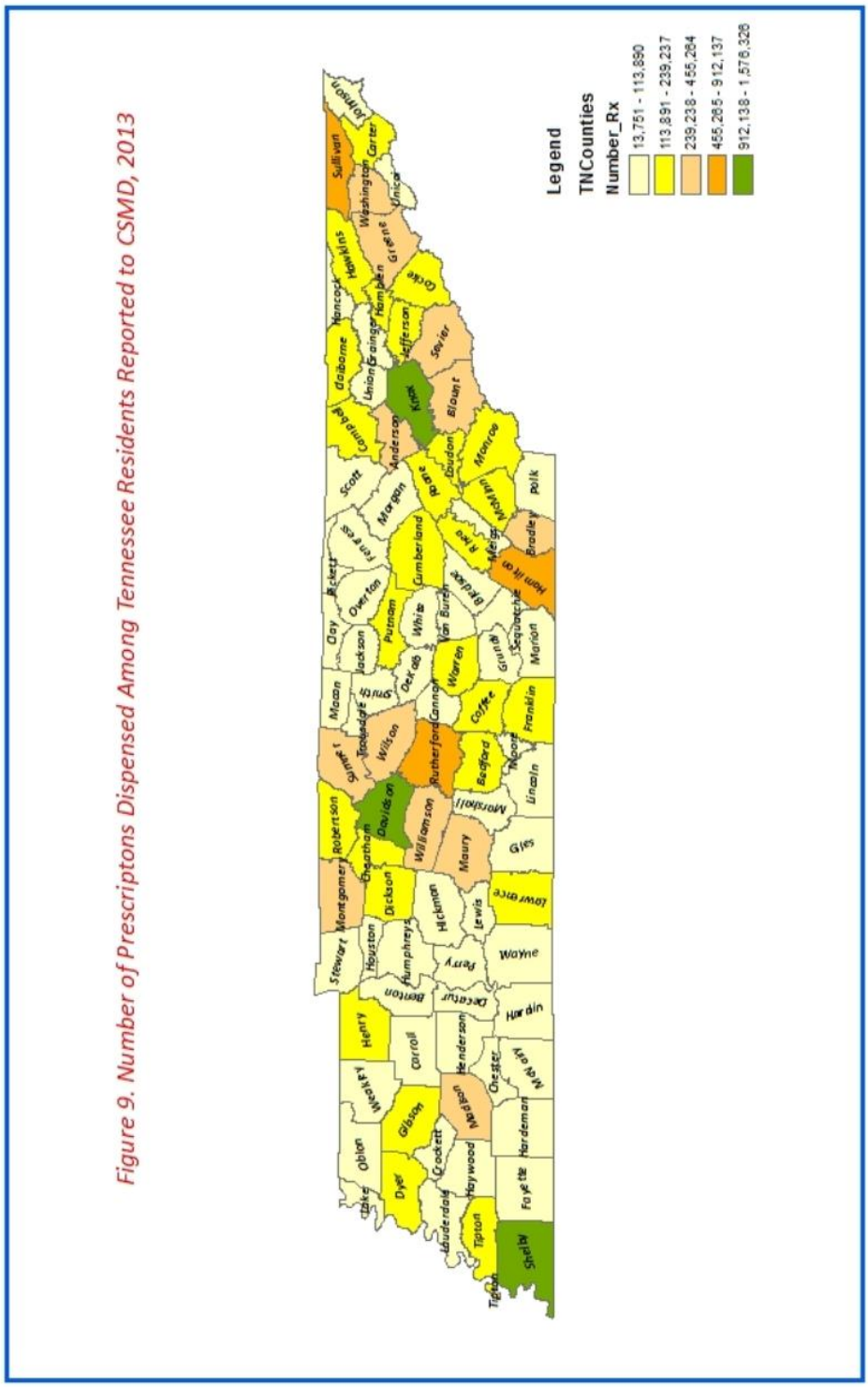


Figure 9. Number of Prescriptons Dispensed Among Tennessee Residents Reported to CSMD, 2013

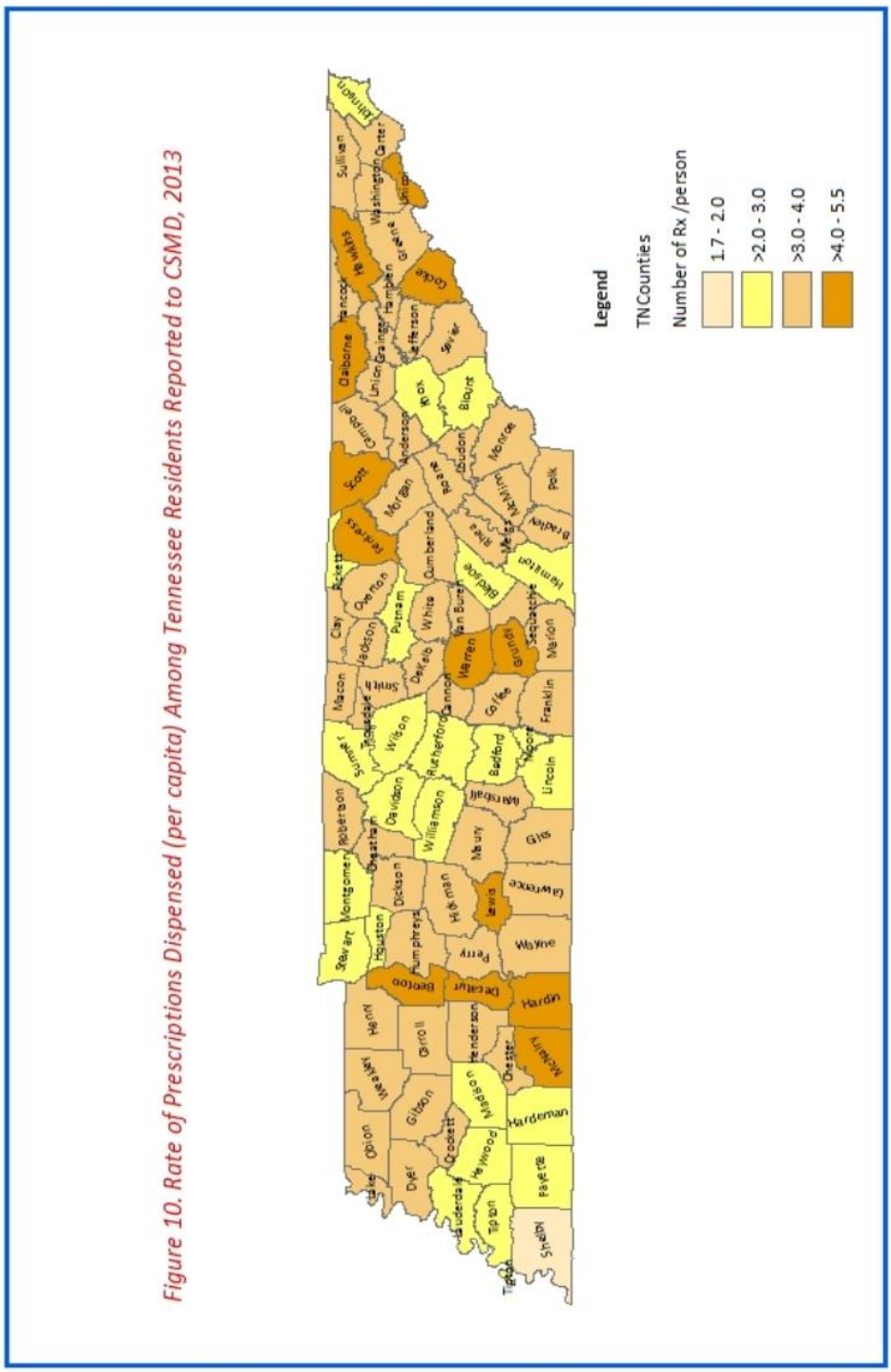


Figure 10. Rate of Prescriptions Dispensed (per capita) Among Tennessee Residents Reported to CSMD, 2013

Statement of compliance with 2012 Tenn. Pub. Acts, ch. 1061 (the "Eligibility Verification for Entitlements Act") as required by Tenn. Code Ann. § 4-57-106(b)

The Tennessee Department of Health, including local health departments, boards and commissions, has implemented protocols and policies to verify that every adult applicant for "public benefits" is an United States citizen or a "qualified alien", within the meaning of Chapter 1061.