

Report to the General Assembly: Controlled Substance Monitoring Database

A Report to the 2013 108th Tennessee General Assembly

Tennessee Department of Health

**Controlled Substance Monitoring Database Advisory Committee
Board of Pharmacy**

February, 2013

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EXECUTIVE SUMMARY:

Background

This report addresses activities of the Controlled Substance Monitoring Database program. The Controlled Substance Monitoring Database Committee is composed of representatives of each of the prescribing and pharmacy boards and staff from the Division of Health Related Boards. The 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 to include a monthly analysis about tracking the individuals or entities accessing the database and the security measures taken to ensure that only authorized persons or entities access the database.

Data Highlights

The Committee recommends education of health care providers about the benefits of using the database in treating patients and identifying drug-seeking behavior. The 2012 data indicates:

- The number of registrants increased greatly in 2012. There were 22,192 registrants at year's end compared to 15,323 in 2011;
- There was a significant increase in the number of patient history reports requested in 2012. 1,861,485 reports were requested in 2012 compared to 1,487,483 in 2011.
- There was an approximate seven (7) percent increase in the number of dispensers reporting prescriptions to the database, but a much smaller increase in the number of prescriptions reported to the database-approximately one and one-half (1.5) percent; and
- The information in the database is increasingly being used by law enforcement to carry out their tasks related to prescription drug abuse. There were 678 requests for reports from law enforcement in 2011 and 2,565 in 2012. The participation of the Tennessee Department of Health in the meetings of the Tennessee Drug Diversion Task Force have increased other state agencies' awareness and have facilitated a cooperative working relationship between the Department and law enforcement.

New/Anticipated Trends

As various sections of the new law take effect, the passage of the Prescription Safety Act of 2012 is expected to increase the use of the database in 2013. Other changes to database operations and functionality are:

- Dispensers now report information to the database every seven days instead of twice monthly;
- The number of registered users has increased dramatically due to the required registration of prescribers and dispensers of controlled substances as well as the authorized use by healthcare practitioner extenders for the first time following the April 1, 2013 implementation date;
- It is anticipated that there will also be a large increase in the number of requests as a result of required checking of the database by prescribers in certain instances before prescribing an opioid or benzodiazepine;
- Tennessee prescription data will also be shared with other authorized states in 2013 to give practitioners a more complete picture of a patient's prescription history; and
- We also expect to see a continued increasing use of database reports by law enforcement as they carry out their duties.

Innovative Practices

The committee, as part of its duties set forth in T.C.A. § 53-10-303 (h) (1), has begun utilizing the database in innovative ways to help identify possible unusual prescribing and/or dispensing practices,

taking into account the particular specialty, circumstances, patient-type or location of the prescriber or dispenser. As a result:

- Pharmacies are being investigated by the Board of Pharmacy for possible unusual or excessive dispensing practices.
- Reports of prescribers have also been sent to the Health-Related Boards, Office of Investigations for analysis of possible unusual prescribing practices.

Ongoing/Anticipated Actions

The increased and appropriate usage of the database may be partially attributed to the efforts of the Committee and Department of Health to instruct and guide health care providers about the mechanics and the benefits of the database. As a result:

- Increased utilization data from the database suggests that both prescribers and pharmacists are collaborating to help curb prescription drug abuse.
- Through increased funding and resources, the Controlled Substance Monitoring Database Committee and Department of Health will continue to:
 - Explore new, innovative methods to utilize available data to reduce inadvertent overdoses;
 - Identify patients who need substance abuse treatment;
 - Curb prescription drug abuse;
 - Assist prescribers with timely information about their patients' prescription histories; and
 - Identify outlying prescribers and dispensers, as well as conformance to the requirements of Public Chapter 880.

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.

DATA TRACKING:

In attempting to report on the outcome and the efficacy of the program, the Board of Pharmacy staff compiled the following data about controlled substance usage prescribed and dispensed in Tennessee from January 1, 2012 to December 31, 2012. Tenn. Code Ann. § 53-10-306 (a) (2) allows the Board of Pharmacy staff to have access to the database information for the purposes of compiling this report. Figures 1-4 also include comparative data from 2010 and 2011, which was included in the previous year’s report to the General Assembly.

Figure 1. Number of Prescriptions Reported to CSMD, 2010-2012

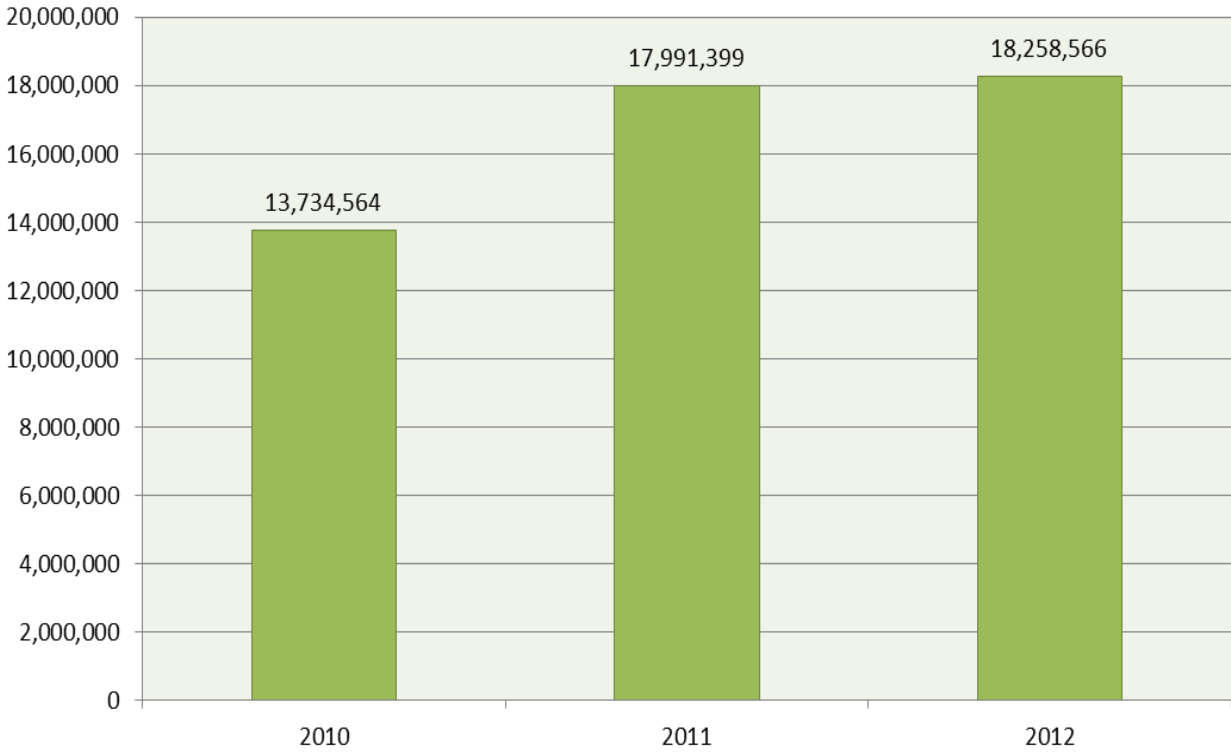


Figure 2. Number of Registered Users of CSMD, 2010-2012

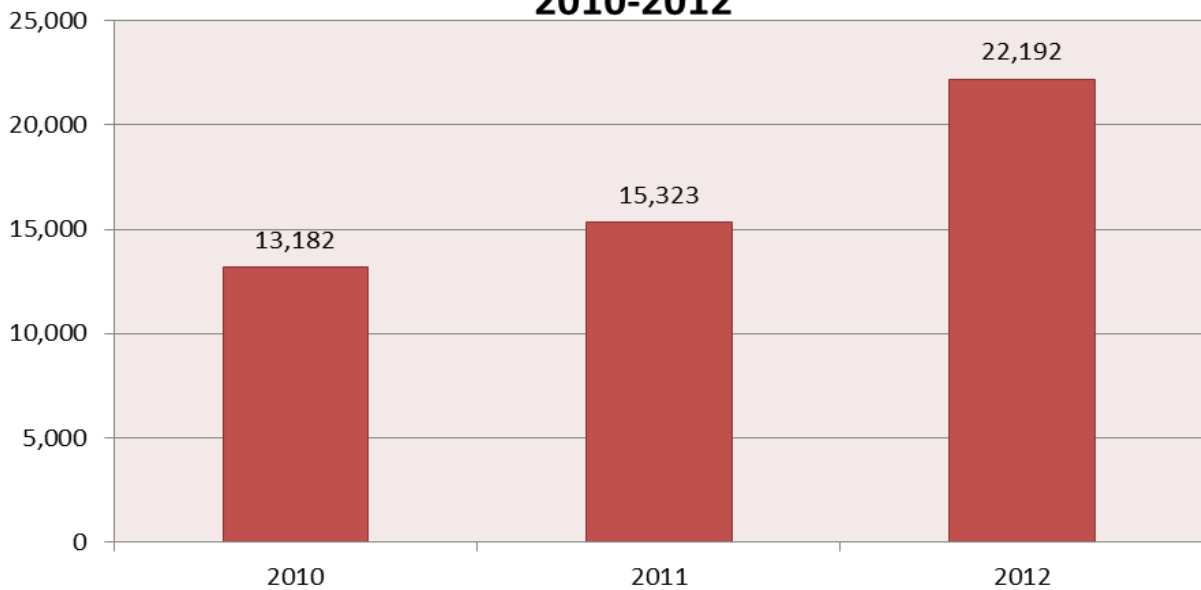


Figure 3. Number of Dispensers Reporting Prescriptions to CSMD, 2010-2012

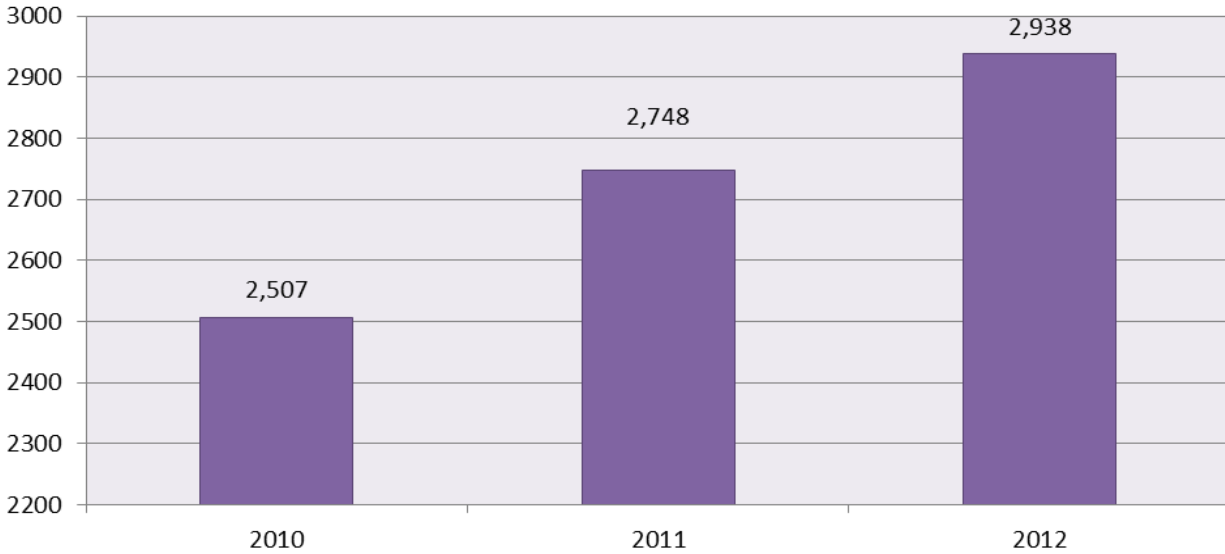
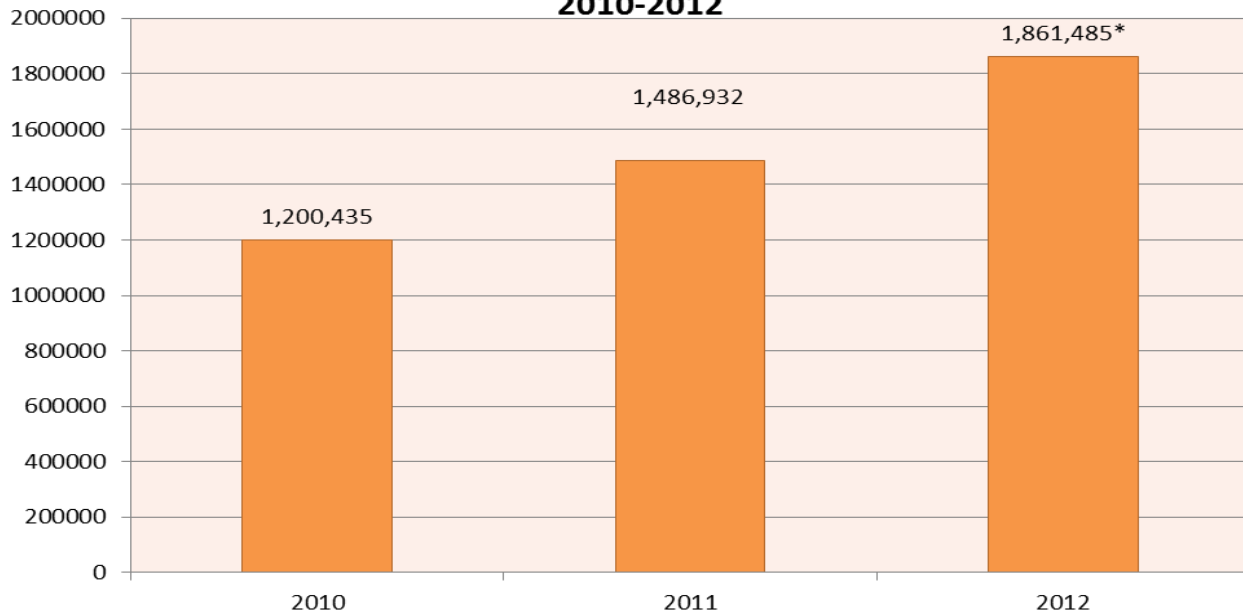


Figure 4. Total Number of Patient Requests from CSMD Pursuant to T.C.A. 53-10-306 (a) (1-5) 2010-2012



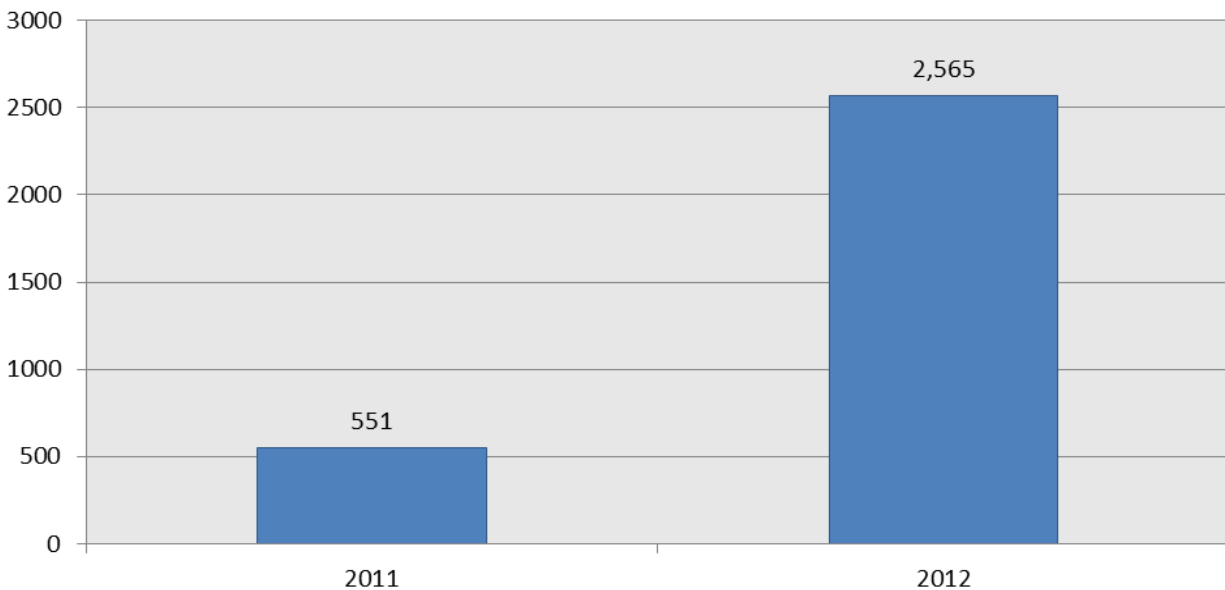
*(comprised of 1,568,351 prescriber requests; 285,196 pharmacist requests; 4,501 requests from the following agencies: Department of Health Bureau of Investigations, TennCare Fraud investigators, Office of Inspector General)

A 2012 monthly analysis tracking the number of individuals or entities, who accessed the database (pharmacists, prescribers, Tennessee Bureau of Investigations, Medicaid Fraud Control Unit, Office of Inspector General, Department of Health, Bureau of Health Licensure and Regulation, Division of Investigations, and Court orders) as required by Tenn. Code Ann. § 53-10-309 is as follows:

<u>2012</u>	<u>Number of Reports Accessed</u>
January	150,811
February	145,604
March	72,857
April	140,538
May	155,289
June	157,427
July	161,514
August	183,197
September	158,682
October	191,705
November	173,723
December	170,138

There has been an increased use of the information contained in the database by law enforcement as a result of Public Chapter 310 in 2011. Figure 5 contains data reporting on the number of requests as a direct result of Public Chapter 310.

Figure 5. Total Number of Requests for Reports from CSMD Pursuant to TCA 53-10-306 (a)(6) 2011-2012



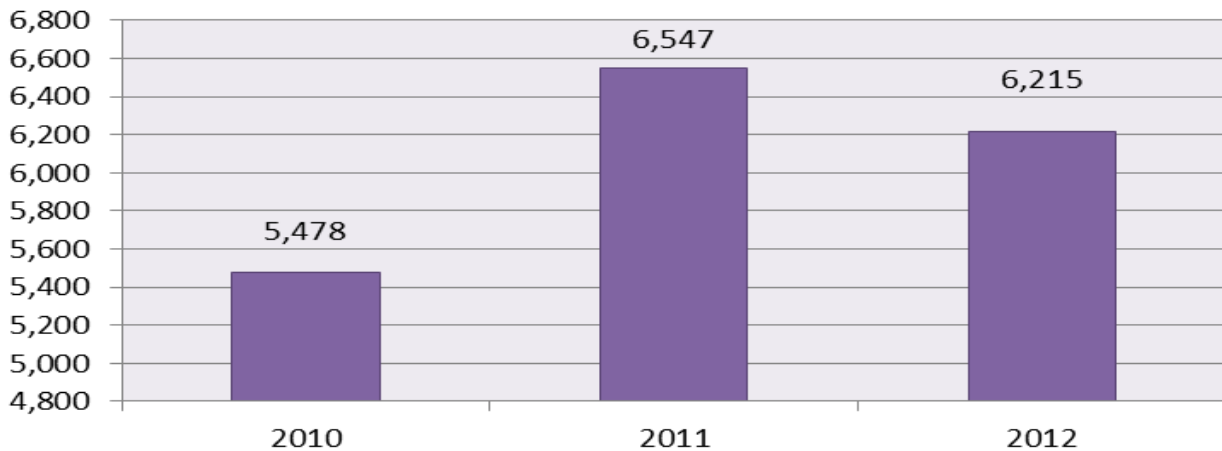
A 2012 monthly analysis tracking the number of law enforcement reports requested from the database pursuant to Tenn. Code Ann. § 53-10-306(a)(6) is as follows:

<u>2012</u>	<u>Reports Requested</u>
January	353
February	135
March	219
April	146
May	329
June	166
July	195
August	249
September	201
October	218
November	212
December	142

Analysis of the top prescribers for 2012 indicates that 52 providers prescribed over 1 million dosage units. 61 practitioners prescribed from 750,000 to 999,999 dosage units and 180 practitioners prescribed from 500,000 to 749,999 dosage units.

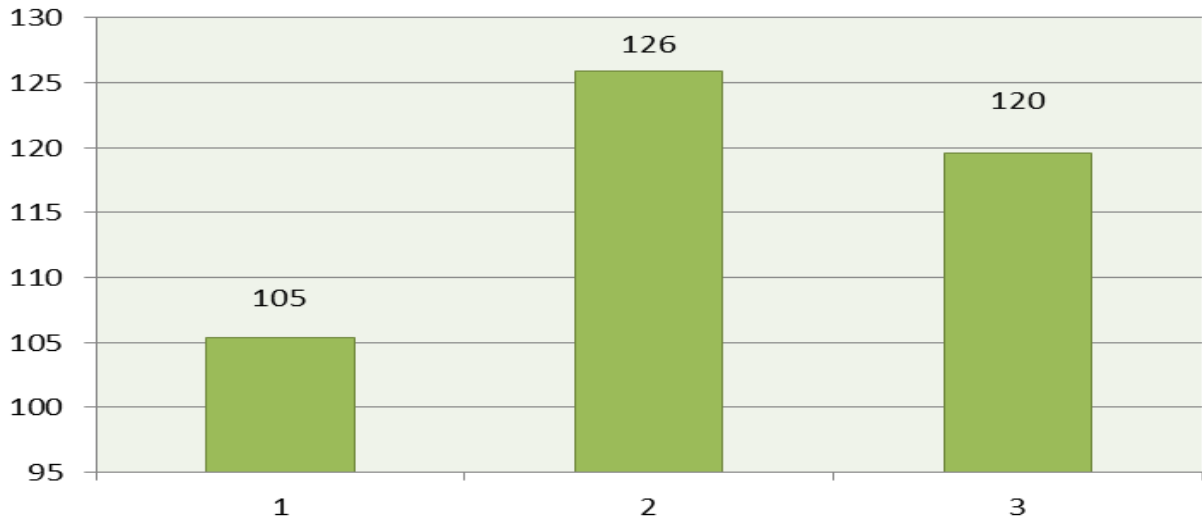
Analysis of dispensing patterns for 2012 indicates dispensers filled fewer prescriptions per facility in 2012 compared to the previous 2 years. Figure 6 is the average number of controlled substance prescriptions dispensed per year by reporting dispenser. Figure 7 is the average number of controlled substance prescriptions dispensed per dispenser, per week.

Figure 6. Average Number of Prescriptions per Dispenser* per Year Reported to CSMD 2010-2012



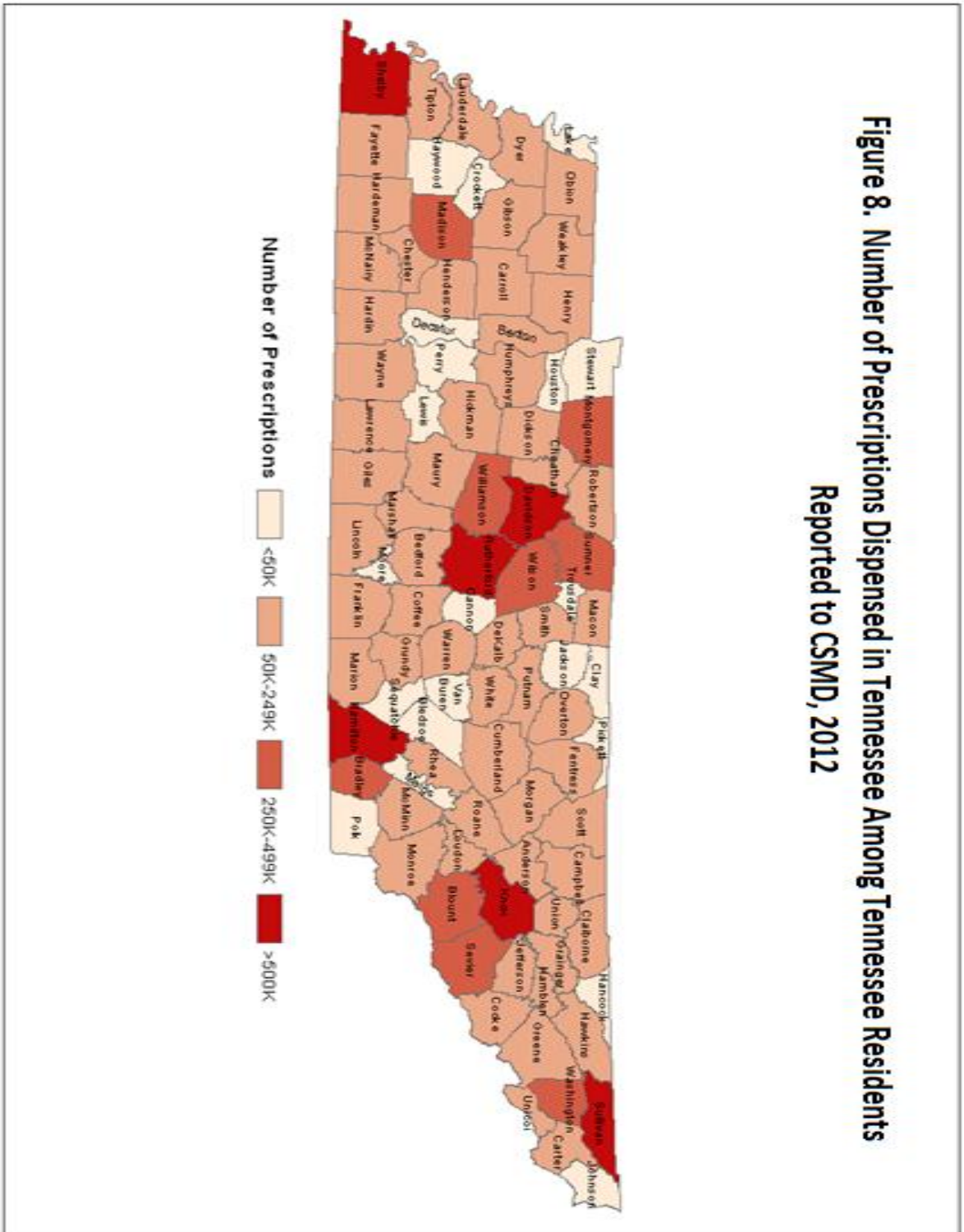
***Dispenser includes pharmacies and dispensing prescribers**

Figure 7. Average Number of Prescriptions per Dispenser* per Week Reported to CSMD 2010-2012



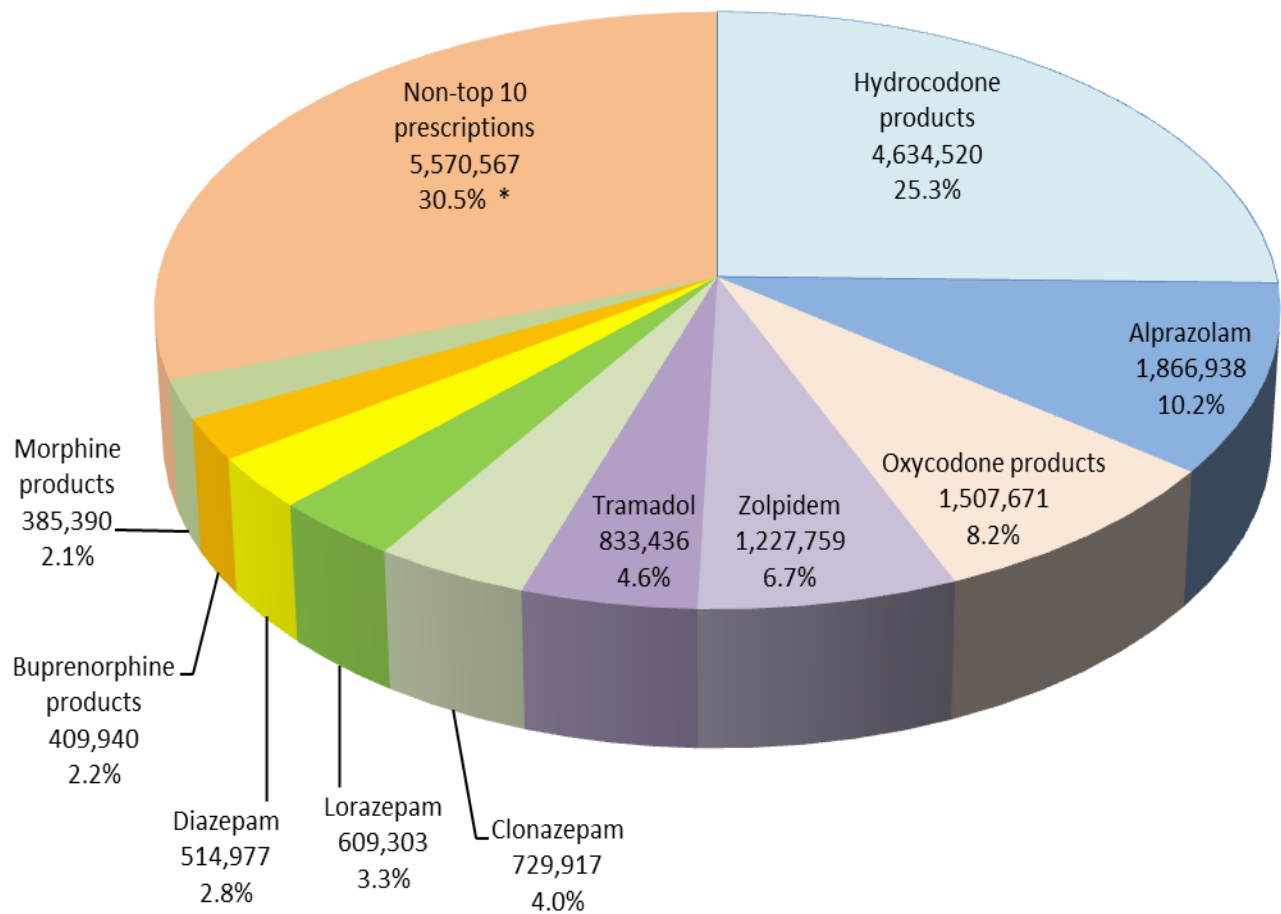
***Dispenser includes pharmacies and dispensing prescribers**

There were approximately 18,258,566 controlled substance prescriptions reported to the database in 2012. Figure 8 is a mapping of the raw number of prescriptions dispensed by patient's county of residence reported to the CSMD.



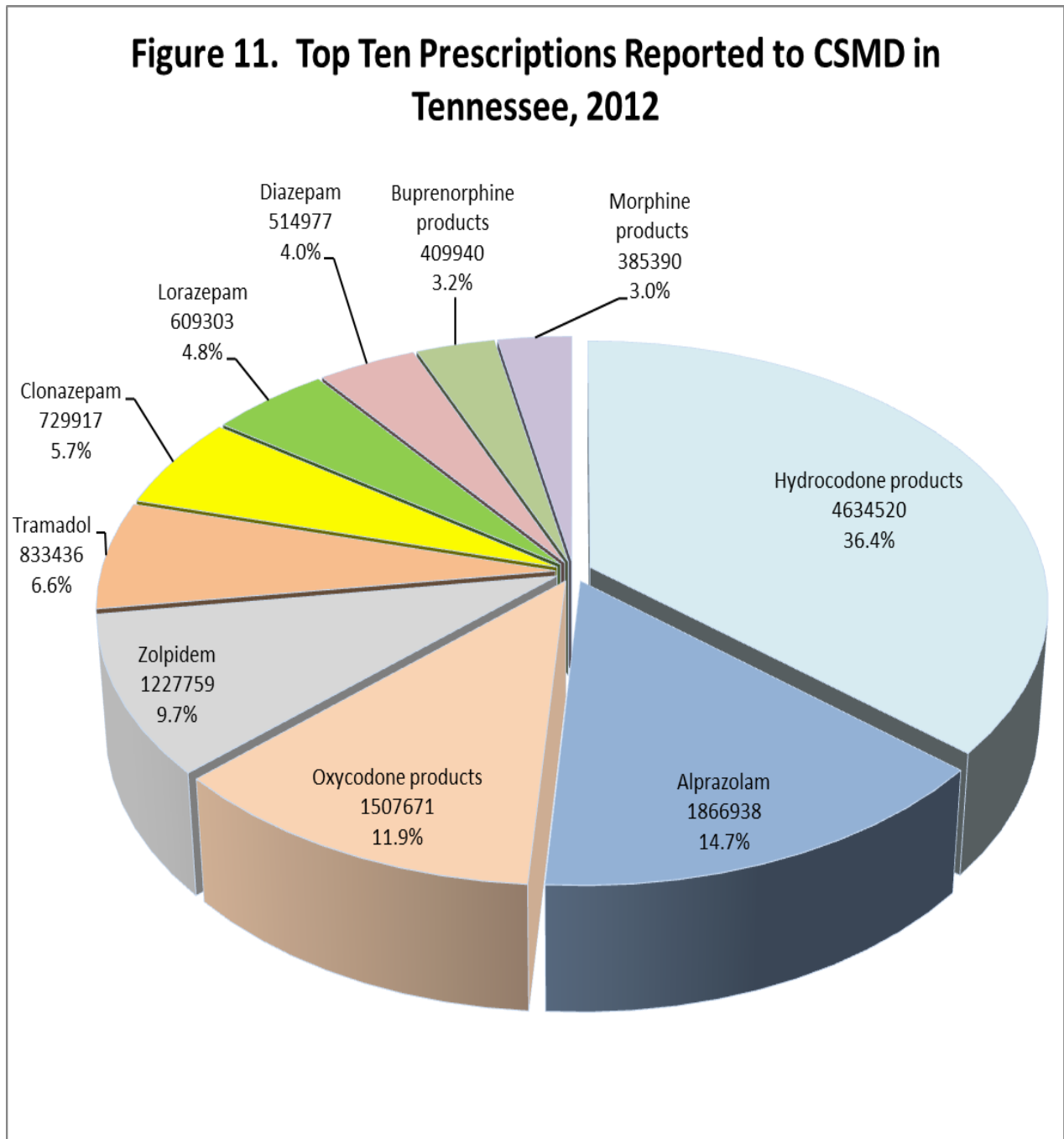
The top ten controlled substances prescriptions filled in 2012 account for 69.5% of all controlled substance prescriptions filled, or approximately 12.7 million prescriptions. Figure 10 illustrates both the number of prescriptions and percentage for the top ten compared to the aggregate of all other controlled substances.

Figure 10. Distribution of Prescriptions Dispensed and Reported to CSMD in TN, 2012



*Include; Carisoprodol, Lisdexamphetamine, Pregabalin, Phentermines, Amphetamines, and other controlled substances.

The top ten prescriptions reported to the database in 2012 were hydrocodone, alprazolam, oxycodone, zolpidem, tramadol, clonazepam, lorazepam, diazepam, buprenorphine, and morphine. Figure 11 illustrates the number of prescriptions filled and percentage of the top ten prescriptions for each drug.



SECURITY MEASURES:

The individuals or entities that had access to the database in 2012 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. 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)(6). In order to ensure that only those authorized individuals and entities have access, the Board of Pharmacy employs the following security measures:

(1). All authorized entities and individuals that have been granted access to the database pursuant to Tenn. Code Ann. § 53-10-306(a)(1) through (5) are allowed to enter the database through a password obtained from the Board staff.

(2). 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 they 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.

(3). 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.

(4). 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.

(5). 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) (6) 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.

(6). Requests for access by persons other than a dispenser or those individuals outlined in Tenn. Code Ann. § 53-10-306(a)(1) through (6) 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.

(7). The Board of Pharmacy staff receives and monitors written requests to access the database 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.

FINDINGS AND RECOMMENDATIONS:

The new data indicates that a much greater number of practitioners registered to use the database in 2012 (an increase of 6,869 users.) There is also a corresponding increase in the number of patient reports requested (1,861,485 vs. 1,487,483 in 2011.)

On April 7, 2011, tramadol, carisoprodol and all products containing tramadol or carisoprodol became Schedule IV controlled substances in the State of Tennessee pursuant to Tenn. Comp. R. & Regs. Rule 0940-06-01.04, as authorized under Tenn. Code Ann. § 39-17-403. In 2012, there was a slight increase in the total number of prescriptions reported (18,165,988) compared to 2011 (17,991,399.) This increase can, in part, be attributed to a full twelve months of reporting carisoprodol and tramadol to the database.

The marked increases of the number of both authorized users and patient history reports requested from 2011 to 2012 would indicate an increased use of the database by prescribers and dispensers. 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.

The marked increase in the number of law enforcement requests indicate that information in the database is increasingly being used by law enforcement to carry out their tasks related to prescription drug abuse. There were 678 requests for reports from law enforcement in 2011 and 2,565 in 2012.

In addition to empirical data collected by Board staff about the effect of the database on the distribution and abuse of controlled substances, the Board receives anecdotal evidence from health care providers indicating that database information has allowed them to determine if a patient is seeing various doctors at the same time and obtaining the same or therapeutically equivalent 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. Prescribers and pharmacists have also stated that the database information has allowed them to communicate with other health care providers who may be treating or have treated the same patient in an effort to exchange information about the patient's condition and the appropriate future treatment regimen for the patient. This anecdotal evidence suggests that through greater usage of the database from health care providers, the database is affecting the distribution of controlled substances such that those health care providers who are accessing the database are attempting to appropriately prescribe and dispense controlled substances to patients. This also suggests that both prescribers and pharmacists are working together to help curb prescription drug abuse.

The committee, as part of its duties set forth in T.C.A. § 53-10-303 (h) (1), has begun utilizing the database to help identify possible unusual prescribing and/or dispensing practices, taking into account the particular specialty, circumstances, patient-type or location of the prescriber or dispenser. As a result, pharmacies are being investigated by the Board of Pharmacy for possible unusual or excessive dispensing practices. Reports of prescribers have also been sent to the Health-Related Boards, Office of Investigations for analysis of possible unusual prescribing practices. There have been multiple disciplinary actions taken against over-prescribers of controlled substances as a result of information contained in the database.

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 mechanics and the benefits of the database. Board of Pharmacy staff has made presentations to the Tennessee Pharmacists Association, various colleges of pharmacy, and to pharmacists state-wide through continuing education updates about the database. Department of Health personnel have also traveled throughout the state speaking to various groups about the benefits of using the database to prevent prescription drug abuse. The Department has hired a Medical Director of Special Projects, who has been well-received by the medical community. The Director has travelled throughout the state educating and informing healthcare providers throughout the state through various seminars and symposia. In January 2013, the Department welcomed a new Epidemiologist dedicated to the statistical evaluation of data found in the database. The epidemiologist will help establish a statistical framework to further enhance analysis of prescribing habits and educational efforts of the advisory committee.

The participation of the Tennessee Department of Health in the meetings of the Tennessee Drug Diversion Task Force have increased other state agencies' awareness and have facilitated a cooperative working relationship between the agency and law enforcement. The task force develops educational programs aimed at helping prescribers, dispensers, and law enforcement improve prescribing practices and teach health care professionals and law enforcement how to effectively use the database to identify and prohibit controlled substance abuse and diversion.

The Committee recommends education for health care providers about the benefits of using the database in treating patients and identifying drug-seeking behavior. The Committee authorized pursuing a grant to develop a multi-media educational webinar to educate providers about database usage and practice resources related to addiction and diversion. This webinar is currently under development and will be deployed soon.

The Committee is dedicated to using the database in innovative ways. Some areas of consideration are: Neonatal Abstinence Syndrome, analysis of death rates from possible overprescribing, and development of predictors of prescription overdose and overdose deaths. The committee is also dedicated to the charge to analyze 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. The Committee will also seek out opportunities to enhance the database and optimize staffing to increase its utility as a healthcare and regulatory tool.

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.