Report to the General Assembly: Controlled Substance Database Report

A Report to the 2011 107th Tennessee General Assembly

Tennessee Department of Health

Controlled Substance Database Advisory Committee Board of Pharmacy

February, 2011

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 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 this reporting mandate.

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 substances dispensed in Tennessee from January 1, 2010 to December 31, 2010. 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. Also included below is some comparative data from 2008 (previously included in the January 2009 report):

	<u>2008</u>	<u>2009</u>	<u>2010</u>
Total # of prescriptions entered into database:	15,415,239	15,265,702	13,734,564
Total # of data uploads:	250	421	730
Total # of individuals with password access:	7,600	10,241	13,182
Total # of dispensers (prescribers and pharmaci who submit data to the database:	sts)	2,253	2,507

Total # of requests for prescription reports:

639,072

903,553

1,200,435*

146,101 pharmacist requests; 4,303 requests from the following agencies:

Department of Health Bureau of Investigations, TennCare Fraud investigators, Office of Inspector General, TBI Medicaid Fraud Control Unit, 131 subpoenas and 187 other requests)

A 2010 monthly analysis tracking the number of individuals or entities, who accessed the database (pharmacists, prescribers, Tennessee Bureau of Investigations Medicaid Fraud Control Unit, TennCare 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>2010</u>	Number Accessed
January	76,307
February	81,739
March	100,776
April	98,225
May	95,725
June	103,850
July	102,869
August	110,700
September	105,925
October	106,834
November	106,487
December	104,416

Additionally, in their effort to continually improve the usefulness of the database, at the July 28, 2010 meeting of the Controlled Substance Monitoring Database Advisory Committee, it was suggested that additional information could be reviewed by the committee members. The database software has the capability to produce reports which show the top prescribers, the types of controlled substances being prescribed, and the prescribers' license category. The software can also produce a listing of the most dispensed controlled substances in Tennessee.

^{*(}comprised mostly of 1,043,111 prescriber requests;

Top 5 Prescribers and the Top 5 drugs they Prescribe

Active #1	License APN		# Rxs	#Pills 4995641	#Patients 1500
Drug Name	Num of Prescriptions	Num of Pills	0713	4993041	1300
OXYCODONE HYDROCHLORIDE TABLETS HYDROCODONE BITARTRATE AND ACETAMINOPHEN	780	89716			
TABLETS METHADONE HYDROCHLORIDE TABLETS	847	87819			
USP	330	92808			
LYRICA CAPSULES MORPHINE SULFATE TABLETS	399	42507			
WIONFILING SOLFATE TABLETS	342	35753			
Active #2	MD		31663	4374348	3303
Drug Name HYDROCODONE BITARTRATE AND ACETAMINOPHEN	Num of Prescriptions	Num of Pills	•		
TABLETS OXYCODONE	5402	866382			
HYDROCHLORIDE TABLETS	4496	840630		•	
CLONAZEPAM TABLETS USP	4484	446163			
METHADONE HYDROCHLORIDE TABLETS OXYCODONE AND	2348	550280			
ACETAMINOPHEN TABLETS	958	155376			
Active #3	MD		1888	3369801	1253
Drug Name	Num of Prescriptions	Num of Pills			
PHENTERMINE 37.5MG (100)					
CAPS CIV HYDROMET SYRUP	94	3247000			
HYDROCODONE AND	314	37190			
HOMATROPINE SYRUP PHENTERMINE	293	34740			
HYDROCHLORIDE TABLETS	254	8567			
CLONAZEPAM TABLETS USP	101	5935			

Active #4	License MD		# Rxs 21605	#Pills 3096314	# Patients 2541
Drug Name	Num of Prescriptions	Num of Pills			
OXYCODONE HYDROCODONE BITARTRATE AND ACETAMINOPHEN	9420	1691626			
TABLETS	1162	206277			
ALPRAZOLAM TABLETS METHADONE	3152	330582			
HYDROCHLORIDE TABLETS MORPHINE SULFATE	448	123685			
EXTENDED RELEASE TABLETS	643	64499			
Active #5	MD		2909	2765088	856
Drug Name	Num of Prescriptions	Num of Pills			
LORAZEPAM TABLETS HYDROCODONE BITARTRATE AND ACETAMINOPHEN	257	14509			
TABLETS	268	13566			
ALPRAZOLAM TABLETS ZOLPIDEM TARTRATE	221	11570			
TABLETS PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN	298	9698			
TABLETS USP	130	9360			

TOP 10 DRUGS DISPENSED:

Drug	# pills
Hydrocodone	275,496,939
Alprazolam.	116,622,992
Oxycodone	113,451,297
Codeine	47,860,451
Clonazepam	38,855,248
Zolpidem/AMBIEN	36,219,403
Lorazepam	29,641,346
Diazepam	28,042,841
Propoxyphene	25,525,314
Lyrica	22,613,717

SECURITY MEASURES:

The individuals or entities that have access to the database are: personnel of the committee; authorized committee, board or department of health personnel; pharmacists; prescribers; Tennessee Bureau of Investigations Medicaid Fraud Control Unit; TennCare Office of Inspector General and other authorized TennCare personnel. Access is also granted through a criminal or circuit court order upon the proper application by a District Attorney General (Tenn. Code Ann. §53-10-306). In order to ensure that only those authorized individuals and entities have access, the Board of Pharmacy employs the following security measures:

- (1). All of the authorized entities and individuals who have access to the database pursuant to Tenn. Code Ann. §53-10-306 are allowed to enter the database through a password obtained from the Board staff.
- (2). Before TennCare Office of Inspector General, Tennessee Bureau of Investigations 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 twelve (12) individuals from the TennCare Office of Inspector General and the Tennessee Bureau of Investigations Medicaid Fraud Control Unit, who have password access to the database.
- (3). Before the 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 control over what data has been accessed, updated or viewed.
- (5). Requests for access by persons other than a dispenser or those individuals outlined in Tenn. Code Ann. §53-10-306(5) are reviewed by Board of Pharmacy staff and Legal Counsel to determine if the person requesting access can be granted access pursuant to applicable laws and rules. Legal staff also reviews all Court orders to ensure that they are in compliance with Tenn. Code Ann. §53-10-306(b) before any information is released.

(6). 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 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 she 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 practitioners prescribing practices relative to controlled substances.

FINDINGS AND RECOMMENDATIONS:

The 2010 data indicates that the database is being accessed by a significantly greater number of prescribers and pharmacists in 2010 than in 2009 (an increase from 10,241 to 13,182). There is also a corresponding increase (from 903,553 in 2009 to 1,200,435 in 2010) in the number of patient history reports being pulled. Another significant piece of data is the continued decrease in controlled substance prescriptions being dispensed (from approximately 15.4 million in 2008, 15.2 million in 2009, to 13.7 million in 2010). While it may be difficult to directly attribute all of the prescription decrease to the database, with such a marked discrepancy between the 2008 and 2010 prescription numbers, the committee hopes the substantial increase of users and increased usage of the database contributed to this decrease. All of the data taken 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 healthcare tool to detect the abuse and misuse of controlled substances in order to better treat the patient by providing competent, quality care.

In addition to the empirical data collected by Board staff about the effect of the database on the distribution and abuse of controlled substances, the Board continuously 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 in drug therapy or they may alter the patient's treatment plan accordingly. Physicians 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 health care providers and pharmacists are working together to help curb prescription drug abuse.

The increased and appropriate usage of the database in 2010 appears to be attributed to the Board's and the Department of Health's educational efforts in instructing and guiding health care providers about the

mechanics and the benefits of the database. Board of Pharmacy staff members have made presentations to various groups and to pharmacists state-wide, through continuing education updates about the database. The participation of the Tennessee Department of Health (Board of Pharmacy and Health Related Boards), Tennessee Medical Association, Tennessee Pharmacist Association, Drug Enforcement Agency, Federal Bureau of Investigation, District Attorneys, and other federal and state law enforcement agencies in the Tennessee Drug Diversion Task Force have increased other state agencies' awareness and have facilitated a cooperative working relationship between health care providers and law enforcement. The task force continues to develop educational programs aimed at helping prescribers, dispensers, and law enforcement to better understand prescribing practices and teaching health care professionals and law enforcement how to effectively use the database to identify and prohibit controlled substance abuse and diversion.

In consideration of the data extracted from the database, the Committee recommends greater education for health care providers about the benefits of using the database in treating patients and identifying drug-seeking behavior. The Committee also recommends greater education for health care providers and law enforcement demonstrating how the two can work cooperatively toward the same goal. The committee's next step is to look into the possibility of identifying top prescribers and notifying them via mailings in order to encourage education of controlled substance abuse.