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STATE OF TENNESSEE
DEPARTMENT OF HEALTH
BUREAU OF HEALTH LICENSURE AND REGULATION
DIVISION OF HEALTH RELATED BOARDS
227 French Landing, Suite 300
Heritage Place MetroCenter
Nashville, TN 37243
tennessee.gov/health

MEMORANDUM

TO: Honorable Rusty Crowe
Chairman of the Senate General Welfare, Health & Human
Resources Committee

Honorable Joe Armstrong
Chairman of the House Health and Human Resources Committee

FROM: Kevin K. Eidson, Pharm D 
Chairperson, Controlled Substance Monitoring Database Advisory
Committee

DATE: January 30, 2009

RE: Controlled Substance Monitoring Database Program

Please find enclosed the Controlled Substance Monitoring Database Report as required by Public Chapter 498, Public Acts of 2007.

KKE:ma

Attachments

cc: Tom Sharp, Legislative Liaison
Alison Cleaves, Chief Deputy Counsel
Christy Allen, Assistant Commissioner for Bureau of Health, Licensure and
Regulation
Elizabeth Miller, Director, Health Related Boards
Susan Cooper, Commissioner of Department of Health

Report to the General Assembly: Controlled Substance Database Report

A Report to the 2009 106th Tennessee General Assembly

Tennessee Department of Health

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

February, 2009

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 these reporting mandates.

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, 2008 to December 31, 2008. 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 2007 (previously included in the January 2008 report):

	<u>2007</u>	<u>2008</u>
Total number of prescriptions entered into the database:	17,738,054	14,602,916
Total number of data uploads:	259	250
Total number of individuals with password access:	3,717	7,600
Total number of dispensers (prescribers and pharmacists) who submit data to the database:	2,465	7,600*
*(comprised of 5,310 prescribers and 2, 290 pharmacists)		
Total number of requests for prescription reports:	135,940	2.54 million*
*(comprised of 1,496,626 prescriber requests; 917,925 pharmacist requests; 86 requests from the Department of Health Bureau of Investigations; 35 requests from the TennCare Office of Inspector General; 95 requests from out-of-state pharmacies; and 52 Court orders)		

A 2008 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>2008</u>	<u>Number Accessed</u>
January	257,194
February	265,321
March	302,187
April	310,938
May	350,794
June	291,882
July	297,424
August	378,102
September	370,456
October	250,439
November	172,356
December	292,680

SECURITY MEASURES:

The individuals or entities who have access to the database (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 court orders) are provided in statute, specifically, 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 following entities and individual 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: Licensed pharmacists; licensed prescribers; Committee personnel assigned to conduct analysis and research; Committee, Board, or Department of Health personnel engaged in the analysis of controlled substance prescription information; and personnel from the TennCare Office of Inspector General, the Tennessee Bureau of Investigation, the Medicaid Fraud Control Unit, and TennCare's Chief Medical Officer, Associate Chief Medical Directors, Director of Quality Oversight, and Associate Director of Pharmacy who are actively engaged in analysis of controlled substances related directly to TennCare.

(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 were supplied with individual passwords. There are a total of twenty-one (21) individuals from TennCare Office of Inspector General, 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.

(4). When the dispenser, TennCare Office of Inspector General, Tennessee Bureau of Investigations Medicaid Fraud Control Unit, and TennCare personnel 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:

In the 2008 report to the General Assembly about the database, the Committee was unable to make any recommendations about the effectiveness of the database in preventing the abuse and misuse of controlled substances because 2007 was the first year that the database was functional and the Committee did not have enough data available to draw any conclusions or make any recommendations. The 2008 data indicates that the database is being accessed by a significantly greater number of dispensers (prescribers and pharmacists) in 2008 than in 2007 (an increase from 3,717 to 7,600). There is also a corresponding increase (from 2,465 in 2007 to 7,500 in 2008) in the number of dispensers who are accessing the data in the database about the number of controlled substances dispensed. The data also demonstrates a dramatic increase in the number of prescription reports requested from dispensers, increasing from 135,940 to 2.54 million. Another significant piece of data is the nearly 3 million decrease in controlled substance prescriptions being dispensed in 2008 (from approximately 17 million in 2007 to approximately 14 million in 2008). While it may be difficult to directly attribute all of the prescription decrease to the database, such a marked discrepancy between the 2007 and 2008 prescription numbers indicates that the database has most likely contributed to this decreased number. 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 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 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 therapy or may alter the patient's treatment plan. Physicians and pharmacists have also stated that the database information has allowed them 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 and abuse 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.

The increased and appropriate usage of the database in 2008 appears to be attributed (in part) 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 has made presentations to the Tennessee Medical Association and to all 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 in the Tennessee Drug Diversion Task Force has increased other state agencies' awareness and has 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 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.