

BILL SUMMARY

***HB 2391 BY *MCCORMICK, MATHENY. (SB 2253 BY *NORRIS, YAGER, CROWE.)**

Drugs, Prescription - As introduced, enacts the "Tennessee Prescription Safety Act of 2012." - Amends TCA Title 53, Chapter 10, Part 3; Title 53, Chapter 11, Part 3; Title 53, Chapter 11, Part 4 and Title 63, Chapter 1, Part 3.

Fiscal Summary

(CORRECTED) Increase State Expenditures - \$281,700/One-Time \$230,300/Recurring \$57,400/Incarceration* Other Fiscal Impact - The one-time costs of \$281,700 will be funded by the Department of Mental Health using the administrative portion of the federal FY12-13 Substance Abuse Prevention and Treatment block grant. Funding in the amount of \$28,300 for incarceration costs is included in the Governors Proposed FY12-13 Budget.

Bill Summary

This bill revises various provisions of present law regarding the controlled substance database.

Generally, present law requires each health care practitioner, or person under the supervision and control of the practitioner, pharmacist or pharmacy that dispenses a schedule II, III, IV, or V controlled substance to submit certain data to the controlled substance database advisory committee for inclusion in the controlled substance database. This bill specifies that such reporting requirement, and present law regarding the database generally, would generally apply to health care practitioners who "prescribe," in addition to "dispense," such controlled substances and to physician extenders, who are

registered or licensed health care professionals designated by a prescriber or a dispenser. This bill requires each prescriber, dispenser, and physician extender in practice in the state for more than three calendar days per year to be registered in the controlled substance database. This bill requires that the data be reported directly to the database instead of to the committee.

This bill requires the committee to review information in the database. If the committee determines that a violation of the law may have occurred, it must notify the appropriate law enforcement personnel or board responsible for licensure, regulation, or discipline of prescribers or dispensers authorized to prescribe or dispense drugs and supply information required by the law enforcement personnel or board of pharmacy for an investigation of the violation of the law that may have occurred.

This bill requires all prescribers and dispensers to check the controlled substance database prior to prescribing or dispensing a controlled substance to a patient at the beginning of a new episode of treatment and to check the controlled substance database for that patient at least every six months of that episode of treatment.

This bill authorizes the commissioner of health to enter into agreements with other states providing for the sharing and dissemination of data and information in the database.

Under present law, the reporting requirement described above does not apply for:

- (1) A drug administered directly to a patient;
- (2) Any drug dispensed by a licensed health care facility that is limited to an amount adequate to treat the patient for up to 48 hours;
- (3) Any drug sample dispensed; or
- (4) Any facility registered by the DEA as a narcotic treatment program and is subject to federal recordkeeping provisions.

This bill removes the exception described above in (2) and adds the following to the above list of items exempt from the reporting requirement:

- (1) Tramadol dispensed by a licensed veterinarian, as long as the amount

dispensed to the animal's owner is limited to an amount equal to the lesser of 600 mgs or a maximum of 96 hours; and
(2) Phenobarbital dispensed by a licensed veterinarian, as long as the amount dispensed to the animal's owner is limited to an amount equal to the lesser of 400 mgs or a maximum of 96 hours.

Present law requires each dispenser, regarding each controlled substance dispensed, to submit to the committee all of the following information within 10 days following the last day of each calendar month:

- (1) Prescriber identifier;
- (2) Dispensing date of controlled substance;
- (3) Patient identifier;
- (4) Controlled substance dispensed identifier;
- (5) Quantity of controlled substance dispensed;
- (6) Strength of controlled substance dispensed;
- (7) Estimated days supply;
- (8) Dispenser identifier; and
- (9) Other relevant information as required by rule.

This bill revises the above requirement to require each prescriber, in addition to each dispenser to submit such information; to require that the information be provided "within 24 hours," instead of "within 10 days following the last day of each calendar month"; to require that the information be sent directly to the database instead of to the committee; and to add the following items to the list of information that must be sent:

- (1) The date the prescription was issued by the prescriber;
- (2) Whether the prescription was new or a refill; and
- (3) The source of payment.

If a prescriber or dispenser provides to the committee a statement in writing indicating why it creates a hardship for them to submit this information within 24 hours as required by this bill, then the prescriber or dispenser may be permitted up to seven days to submit the information. This seven-day extension would be valid for one year from the date the statement is submitted to the committee or for as long as requested in the hardship statement, whichever is shorter, and may be renewed by the committee upon

the written request of the prescriber or dispenser.

Present law requires the committee to allow for waiver of the electronic reporting for individual dispensers for whom it would cause undue hardship. This bill specifies that the waiver would be valid for one year from ratification by the committee and that the committee may authorize a designee to initially approve a waiver subject to ratification by the committee.

Under present law, if any practitioner providing services at a pain management clinic dispenses or prescribes more than a 72-hour dose of controlled substances for the treatment of chronic nonmalignant pain, the practitioner must document in the patient's record the reason for prescribing or dispensing that quantity. This bill revises this provision to require such practitioner to document in the patient's record the reason for prescribing or dispensing that quantity of controlled substances at any time that the practitioner dispenses or prescribes a controlled substance, instead of only when the practitioner dispenses or prescribes more than a 72-hour dose of controlled substances.

CONFIDENTIALITY AND USE OF INFORMATION

Under present law, information sent to, contained in, and reported from the database is confidential, is not subject to present law regarding public records, is not subject to subpoena from any court, and may be made available only to certain persons, including the following:

- (1) A licensed health care practitioner having authority to prescribe or dispense controlled substances, to the extent the information relates specifically to a current or bona fide prospective patient of the practitioner, to whom the practitioner has prescribed or dispensed or is prescribing or dispensing any controlled substance; and
- (2) A licensed pharmacist having authority to dispense controlled substances to the extent the information relates specifically to a current patient to whom that pharmacist has dispensed, is dispensing or considering dispensing any controlled substance.

This bill adds the following to the list of person who may receive such

information:

- (1) A prescriber conducting medication history reviews who is actively involved in the care of the patient or a prescriber or supervising physician of the prescriber conducting a review of all medications dispensed by prescription attributed to that prescriber;
- (2) A dispenser conducting drug utilization or medication history reviews who is actively involved in the care of the patient; and
- (3) A physician extender, who is acting under the direction and supervision of a prescriber or dispenser, but only to the extent the information relates specifically to a current patient to whom the prescriber or dispenser has prescribed or dispensed, is prescribing or dispensing, or considering prescribing or dispensing any controlled substance.

This bill requires that each user described above have a separate identifiable authentication for access to such information.

Present law authorizes the committee to release confidential information from the database regarding practitioners, patients, or both, to a manager of any investigations or prosecution unit of a body that licenses practitioners and is engaged in any investigation, adjudication, or prosecution of a violation under any state or federal law that involves a controlled substance. This bill additionally authorizes the committee to release such information to law enforcement personnel. This bill requires the committee or its designee to release information from the database when ordered by a court to do so upon the court's finding that disclosure is necessary for the conduct of proceedings before the court regarding the investigation, adjudication, or prosecution of a violation under any state or federal law that involves controlled substances and after an appropriate protective order is issued regarding the information to be released to the court.

Under present law, information may not be released as described above until the committee, including a member of the committee who is licensed in the same profession as the prescribing or dispensing practitioner identified by the data, has reviewed the information and has certified that further investigation or prosecution is warranted and that release of the information is necessary to that continued investigation or prosecution. This bill removes the requirement that "a member of the committee who is licensed in the

same profession as the prescribing or dispensing practitioner identified by the data" review and certify the information and instead only requires that the committee review and certify such information.

CIVIL PENALTIES, CIVIL IMMUNITY, AND CRIMINAL OFFENSES

Present law requires each practice site where a controlled substance is dispensed to provide for electronic access to the database at all times when the dispenser provides health care services to a human patient potentially receiving a controlled substance. A violation of this requirement is punishable by a civil penalty of up to \$100 a day assessed against the prescriber or the pharmacy, if there is a continued pattern or practice of not providing electronic access to the database. This bill clarifies that the above requirement would apply to practice sites where a controlled substance is "prescribed," in addition to "dispensed".

Under present law, any dispenser, individual or entity is not subject to a suit for civil damages or is civilly liable for the failure to check the database or for actions taken after reasonable reliance on information in the database. This bill revises this provision to instead specify that any prescriber, dispenser, individual or entity authorized to access the database would not be subject to a suit for civil damages or held civilly liable for the failure to register in, report to, or check the database, for actions taken after reasonable reliance on information in the database, or accessing the database to determine whether or not the prescriber or dispenser's professional medical credentials are being inappropriately used or for reporting the same to the appropriate authorities.

Under present law, it is a Class A misdemeanor for a person to knowingly or intentionally deceive or fail to disclose to a health care provider from whom the person obtains a controlled substance or a prescription for a controlled substance that the person has received either the same, or a prescription for the same, controlled substance or a controlled substance of similar therapeutic use or a prescription for a controlled substance of similar therapeutic use from another practitioner within the previous 30 days. Any physician, dentist, optometrist, podiatrist, veterinarian, advanced practice nurse with a certificate of fitness or physician assistant who has actual knowledge that a person has knowingly, willfully and with intent to deceive,

obtained or attempted to obtain controlled substances in such manner must cause a report to be submitted regarding such activity within five business days of obtaining such knowledge.

This bill specifies that a violation of the above offense would be a Class E felony, instead of a Class A misdemeanor, if the offense involves more than 250 units of a controlled substance. This bill additionally requires any pharmacist who has actual knowledge that a person has knowingly, willfully and with intent to deceive, obtained or attempted to obtain controlled substances as described above to cause a report to be submitted regarding such activity within five business days of obtaining such knowledge.

This bill would take effect on October 1, 2012.