The Tennessee Prescription Safety Act of 2012, Tenn. Pub. Acts, ch. 880, represents a significant effort by the General Assembly to address the problem of prescription drug abuse. The Act was signed into law by Governor Bill Haslam on May 9.

In accordance with the Controlled Substance Monitoring Act of 2002, the Tennessee Department of Health established a database to monitor the dispensing of Schedule II, III, and IV & V controlled substances. Data collection began for all dispensers on December 1, 2006. The 2012 Act enhances the monitoring capabilities of the database.

All prescribers with DEA numbers who prescribe controlled substances and dispensers *in practice* providing direct care to patients in Tennessee for more than (15) calendar days per year shall be registered in the controlled substance monitoring database by January 1, 2013.

Health care practitioners or persons under the supervision and control of the practitioners, pharmacists or pharmacies who dispense a schedule II, III, IV, or V controlled substance are required to submit certain data to the controlled substance monitoring database.

The law permits practitioners to designate health care extenders. The extenders must act under the supervision of a licensed prescriber or dispenser.

The following *Frequently Asked Questions and Answers* should be of value to you in understanding the law. This is intended to provide an overview of the law; please follow the actual provisions of the law, included at the end of this section in its entirety.

- When do I need to register?
 You must be registered to use the database by January 1, 2013.
- 2. How do I register to access the database?

Go to www.tncsmd.com and click on the word "register" to begin the registration process. Completion of the registration process will require specific identifying elements. Once registration is complete and approved, you will receive an email with your user name and temporary password.

3. What is my password?

Initially the system will send you a temporary password. You will then be required upon first log-in to select a new password. The password requirements are:

- One uppercase alphabet letter
- One lowercase alphabet letter
- One number character
- One special character (EXAMPLE: +, \$, %)

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4. Can someone else in my office, practice or place of business register for me?

Yes, but he/she will need to have access to all the information required.

5. What happens if I forget my password?

The website allows ups to five attempts to enter the correct password and offers reminders about case sensitivity and the combination of characters required. If you are still unable to log in, you may select Forgot/Reset Password and answer security questions you provided at registration. Your password will then be reset and a temporary password will be sent via email. If you have forgotten the answers to your security questions, you will need to send an email to: csml.admin@tn.gov or call 615-253-1305.

6. What happens if I do not have a Tennessee driver's license?

You still register at www.tncsmd.com, but the process will be manual (it is not validated via technology, but the CSMD Administrator will validate your information)

7. I am already registered. Do I need to do anything else?

Yes. Upon login you will be asked to verify/revise your confidential and private email, choose your specialization and enter your driver's license number. Once this is entered, you will continue into the CSMD.

8. How do I register an extender?

As of January 1, 2013 designated extenders can register at www.tncsmd.com and will need specific information from their supervising practitioners.

9. What do I need to do if I relocate or change my email address?

You will need to update your profile with the new information within 30 days. That process may be done online at www.tnscmd.com.

10. Who is required to check the Controlled Substance Monitoring Database?

Any licensed prescriber before prescribing an opioid or benzodiazepine as a new course of treatment <u>lasting more than seven days</u> – and at least annually when said controlled substance remains a part of the treatment.

11. Are there any exceptions for checking the database?

Yes. You do not have to check if:

- a) The drug is administered directly to a patient.
- b) The prescription is for a hospice patient.
- c) The drug is part of a narcotic treatment program (e.g., a methadone treatment program) registered by the United States Drug Enforcement Administration and is subject to the recordkeeping provision of 21 CFR 1304.24.
- d) The drug is dispensed by a licensed healthcare facility, providing the quantity is limited to an amount adequate to treat the patient for a maximum of 48 hours.

- e) It is a sample drug.
- f) The prescription is non-refillable and is for a patient undergoing a surgical procedure at a licensed health care facility.
- g) There is a period of time when use of the controlled substance database is suspended or the Internet is not operational.
- h) The drug is prescribed by a licensed veterinarian, providing the quantity is limited to an amount adequate to treat the non-human patient for a maximum of 48 hours.
- i) The Controlled Substance Database Advisory Committee determines a particular controlled substance presents low potential for abuse.
- 12. When must I start using the database?

We encourage prescribers and dispensers to register and to start as soon as possible. The law, however, specifies some key dates:

- Prescribers who are required by law to <u>register</u> with the database must do so by January 1, 2013 – and must check the database before prescribing any opioid or benzodiazepine after April 1, 2013. Prescribers required to register include those who have a DEA number and provide direct care to patients in Tennessee for more than 15 calendar days per year.
- After January 1, 2013, new prescribers must register within 30 days of notification of licensure.
- After January 1, 2013, dispensers must begin reporting prescriptions to the database every seven days for controlled substance(s) dispensed within the previous seven days.
- 13. How do I navigate between the CSMD and the data collection site?

There is a button on the right side of the menu bar that allows you to move easily from CSMD to data collection site.

- 14. Beyond a prescriber or dispenser, who else in an office can access the database?

 A licensed or registered health care professional designated by the prescriber or dispenser and up to two (2) non-licensed staff members can access the database.
- 15. What happens if a prescriber or dispenser does not have electronic access to the database?

The law requires that each person or entity operating a practice site where a controlled substance is prescribed or dispensed to a human patient shall provide for electronic access to the database at all times when a prescriber or dispenser provides healthcare services to a human patient potentially receiving a controlled substance. A violation of this requirement is punishable by a civil penalty not to exceed one hundred dollars per day assessed against the person or entity operating the practice site; the penalty shall only be imposed when there is a continued pattern or practice of not providing electronic access to the database.

16. How do I report that the system appears to be down?

Send an email to CSMD.admin@tn.gov.

- 17. Who serves on the Controlled Substance Monitoring Database Advisory Committee?

 The committee members include:
 - The Executive Director of the Tennessee Board of Pharmacy
 - The Director of Health Related Boards for the Tennessee Department of
 - The Executive Director of the Tennessee Board of Medical Examiners
 - One of the governor-appointed and licensed members of each of the following health care professional licensure boards or committees: medical examiners, osteopathic examination, dentistry, podiatric medical examiners, optometry, veterinary medical examiners, nursing, medical examiners' committee for physician assistants, pharmacy.
 - One member of the Board of Pharmacy and one member of the Board of Medical Examiners who were appointed to those boards to represent the general public.
- 18. I am a prescriber. Can I see every prescription that has been dispensed against my DEA number?

Yes. We encourage every practitioner to run a Practitioner Report monthly and check for any abuse of your DEA number. Run the report just like you run a patient report, except choose PRACTITIONER instead of PATIENT at the top. Then input your DEA number and click SUBMIT. Check the printout carefully. If you suspect someone is abusing your DEA number, report that to local law enforcement immediately.

19. How do I run a report to view the controlled substance history of a patient?

Once you are logged into the <u>Controlled Substance Monitoring Database</u>, click on REQUESTS on the top navigation bar. Then choose "New Request" and a page will appear that defaults to a PATIENT report. Fill in the patient's LAST NAME, FIRST NAME, and DOB (date of birth). Scroll down the page and locate the Date Range. It defaults to the past year, but you can change that by clicking on the check mark in the box and entering the dates correctly (mm/dd/yyyy). You can search from 1/1/2010 until present. If you need information from the database from 01/01/2007 through 12/31/2009 please send an email request to CSMD.Admin@tn.gov. You must click on the AUTHORIZE paragraph, and then choose the type of report you want, either .PDF or .XLS. Then click SUBMIT at the very bottom of the page.

The system will show you a green task bar while it is searching the database. Once that disappears, a screen will come up with the Patient_Rx_History_Report link in the middle of the page. Click on that link and the file can be Opened or Saved.

20. Are there required steps of action if I suspect a patient is doctor shopping, based on a review of his or her records?

Yes, any physician, dentist, optometrist, veterinarian, pharmacist, 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 a controlled substance must report that information within five (5) business days to the local law enforcement agency. A reporting form is available at:

http://health.state.tn.us/Downloads/Report_to_Law_Enforcement.pdf. Please call your nearest law enforcement agency and/or the Meth and Pharmaceutical Task Force at 423-752-1479 to obtain the appropriate fax number.

21. What is required of prescribers who work in pain management practices under the new laws?

The Prescription Safety Act provides that any practitioner providing services at a registered pain management clinic who prescribes controlled substances for the treatment of chronic nonmalignant pain must document in the patient's record the reason for prescribing or dispensing the quantity. Other requirements for pain management practices are included in the laws relating to pain management clinics. We suggest pain management practitioners review those provisions. Information regarding pain management clinics is on the Department's website:

http://health.state.tn.us/Boards/PainClinicRegistry.shtml

22. Does the new legislation affect veterinarians?

The Act provides that licensed veterinarians who never prescribe a controlled substance in an amount intended to treat a non-human patient for more than forty-eight (48) hours are not required to register in the database.

23. Who monitors the prescription drug database and how is that monitoring conducted?

The monitoring is conducted by the Tennessee Department of Health staff and overseen by the Controlled Substance Monitoring Database Advisory Committee. The committee seeks to identify unusual patterns of prescribing and dispensing controlled substances that appear to be higher than normal, taking into account the particular specialty, circumstances, patient-type or location of the prescriber or dispenser.

24. What happens if the Controlled Substance Monitoring Database Committee suspects irregularities?

Please note the provisions for prescribers and dispensers:

<u>For prescribers:</u> If the committee determines a prescriber has a difficult to understand or an unusually high pattern of prescribing/dispensing controlled substances, taking into account the particular specialty, circumstances, patient-type or location of the prescriber, the committee will request more information to better understand the facts in the context of the prescriber's clinical practice. After receiving the information, if the committee's concerns are resolved, then the issue will be deemed closed. However, in some instances, a formal investigation by health licensure and regulation staff may be warranted. An investigation itself does not imply any violation or wrongdoing, only that additional diligence is required to resolve or advance the question.

<u>For dispensers:</u> If the committee has questions about dispensing patterns of a pharmacy, it will notify the chief investigator for the Board of Pharmacy. The chief

investigator may initiate fact finding or a formal investigation as needed, looking at dispensing patterns of the pharmacist or pharmacists conducting business at that pharmacy. Similarly, prescribers who also dispense controlled substances will be subject to the same process through the appropriate regulatory board.

- 25. Do all dispensing reports have to be filed electronically?
 - No. If filing reports electronically presents an undue hardship, the committee may waive electronic reporting requirements for a period of up to two years. Click here to access the Request for Waiver Form http://health.state.tn.us/boards/Controlledsubstance/PDFs/PH-4138.pdf. However manual reporting is still required.
- 26. If I have general questions or technical issues with the database, how do I resolve those?

 Contact the CSMD Administrator at 615-253-1305 or email the CSMD Administrator at CSMD.ADMIN@TN.GOV
- 27. What if a prescriber or dispenser chooses to ignore the requirements of the law? Failure to comply with the requirements of the Controlled Substance Monitoring Database laws may subject a licensee to discipline by the licensing board.
- 28. Will prescribers and dispensers be able to find out what controlled substances might have been previously dispensed by out-of-state dispensers?
 - The Commissioner of the Tennessee Department of Health is authorized to enter into agreements with other states or other entities acting on behalf of a state for the purposes of sharing and dissemination of data and information in the database beginning January 1, 2013. As agreements are finalized users will have the option to view other states data.
- 29. Does Veterans Administration or military prescribers have to check the database?

 Under current interpretation of federal law, prescribers employed or contracted by the federal government may not be permitted to check the database. However, if a prescriber providing services at a federal facility holds a Tennessee license, state law does require the prescriber to register with the database. Such registration will be evidence of compliance with the Tennessee law until such time as federal permission is granted.

PHARMACY DATA COLLECTION:

1. Why am I sometimes directed to call Optimum Technology?

Optimum Technology takes care of all prescription data uploads, so if you are a Pharmacy or a doctor who dispenses controlled substances from your practice, you must upload your prescription information. If your problems deal with uploading data, please call Optimum Technology at Phone: 1-866-683-9771 or Email: tnrxreport@otech.com. The upload center is at https://tnrxreport.com

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- 2. If I am having trouble uploading my prescription data what should I do?
 - Optimum Technology is under contract to provide customer support to help you resolve any technical issues with your prescription uploading. Contact Optimum Technology at Phone: 1-866-683-9771 or Email: tnrxreport@otech.com.
- 3. How can I be sure my file was uploaded successfully and accepted into the Tennessee Data Collection Portal?
 - You can receive automated notifications via email after your file has been processed. To activate this, you will need to visit your My Account page in the Data Collection Portal and set your notification method to Email and provide your email address. After your file is processed, you'll receive an email providing information about your file upload and a link to the Data Collection Portal so you can correct any errors that have occurred.
- 4. If I don't want to provide an email or fax number for notification, how can I be sure my file was uploaded successfully and accepted into the Tennessee Data Collection Portal?
 - You can check the status of your file at any time by logging into the Data Collection Portal and selecting Data Center/File Upload. This page will list your uploaded files along with the file status and number of errors. To correct the errors, you can click on the file name which will load the File Upload Errors page. Once the File Upload Errors page has loaded, you can click on the error description and you will be allowed to correct the data online. You can repeat this data correction scenario for each error.

NOTE: The above frequently asked questions and answers do not supersede the terms of the law governing the Controlled Substance Monitoring Database, but are merely provided as guidance for purposes of implementation and enforcement. They are a good faith effort by the Tennessee Department of Health (TDH) to be as transparent as possible in carrying out its regulatory role. The questions are informational in nature and do not constitute legal advice. Moreover, the questions and answers are subject to change. Those who are or may be subject to these laws are strongly urged to review the applicable laws and rules and seek their own legal counsel if necessary. Neither the TDH nor health-related boards are bound by this guidance in their interpretation of the law because each situation is unique. Medical and public health professionals were consulted in creating these FAQs, and the department thanks them for their role while acknowledging its sole responsibility for the FAQs.

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