

# Tennessee's New Prescribing Laws and Old Habits: Effectively Caring for Patients Using Controlled Substances

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## Introduction

The Robert Wood Johnson Foundation identified substance abuse as this nation's number one health problem in 2004.<sup>1</sup> Substance abuse, particularly abuse of controlled prescription drugs, is closely interwoven with pain management. Physicians have the unique opportunity to identify substance misuse and abuse. Physicians can intervene early for patients at risk. Proper prescribing of controlled prescription drugs (CPD) is essential to patient care and appropriate pain management. Many medications used in pain management have potential for creating dependence and/or abuse and relapse. Physicians' use of screening and monitoring techniques can be useful in identifying and reducing misuse and abuse. Over the past three years, the state of Tennessee has enacted new laws to tighten regulations of controlled prescription drugs (CPDs) in an effort to reduce the CPD problem in Tennessee. The overall purpose of the new Tennessee laws is to help reduce negative outcomes, diversion and misuse/abuse of CPDs for all patients. This paper reviews new Tennessee state laws around proper prescribing and offers suggestions for proper prescribing practices.

## Current Legislation

The current legislation (T.C.A. § 53-11-308) "is part of a statewide effort to reduce problems associated with misuse of these powerful drugs," according to the Tennessee Department of Health's Chief Medical Officer, David Reagan, M.D., Ph.D.

Two recent changes include the 2012 Prescription Safety Act (T.C.A. §53-10-300) and the 2011-12 pain clinic regulations (T.C.A. § 63-1-300). Beginning in April 2013, Tennessee law requires health care professionals to check the Controlled Substance Monitoring Database (CSMD) before prescribing a controlled substance to a patient in a majority of cases and as a routine for those on chronic CPD management.<sup>2</sup>

Effective October 1, 2013, a new Tennessee law (T.C.A. § 53-11-308) sets a limit on the amount of Schedule II and III drugs being prescribed or dispensed to a 30-day supply. This regulation will also require practitioners to assess patients for substance misuse by conducting urine drug testing at least every thirty days if they prescribe Schedule II or III drugs alone or in combination beyond a thirty day period. Within this law, any Tennessee licensed pharmacist, receiving prescriptions written from either in or outside of Tennessee, cannot dispense more than a 30-day supply of any Schedule II or III drug regardless of the amount prescribed by the practitioner.

While the time frame for which a physician may prescribe opioids and benzodiazepines has been limited, the number of pills a physician may prescribe has not been limited, as long as that number falls within the range of a 30-day supply for a patient based on the morphine dose equivalent.

Aetna, Blue Cross Blue Shield of Tennessee, and Cigna insurance providers plan to honor the new law and any prescription written for 90 days will only be filled for 30 days. Separate co-pay will apply for each refill of the prescription.<sup>3</sup>

### **Previously Enacted Legislation**

Effective April 1, 2013, all practitioners in Tennessee are required to use tamper-resistant paper for all prescriptions written or printed (T.C.A. § 53-10-400). Each prescriber should be aware of the requirements specific to their practice.<sup>4</sup>

Effective July 1, 2013, physicians supervising physician assistants must follow additional specific guidelines for prescribing Schedule II substances (T.C.A. § 63-19-107).

Also, effective July 1, 2013, dispensing of controlled substances by pain management clinics is prohibited (T.C.A. § 63-1-313). Pharmacists are required to use their professional judgment to make every reasonable effort to prevent abuse of drugs he or she dispenses (T.C.A. § 53-10-112). All of these new laws enacted in 2013 serve the purpose of limiting or preventing the abuse of prescription drugs in Tennessee.

### **Implications of New Legislation**

While the goal of this law is to decrease abuse of opioids and benzodiazepines by patients, it is likely that the law will have secondary effects for physicians and their office practices, patients and pharmacists (T.C.A. § 53-11-308). Such secondary effects include more frequent patient encounters, more time with patients, and changes within the office infrastructure.

Physicians will see patients who are prescribed opioids and benzodiazepines more often. Physicians will have to query the CSMD themselves or delegate the task to other qualified office personnel. The office team must determine the best office plan to implement an efficient and effective monitoring system. According to the CSMD guidelines/rules, each physician can have two designated individuals to query the CSMD. The health care team might consider focus clinic days. For example, set aside days in which patients on chronic CPDs are seen (e.g., Tuesday and Thursday). This type of office plan may support patient compliance and make office practices more efficient. All patients on chronic CPD would return on their assigned day for visits and refills. Training and education may reduce the problem of the on-call physician receiving refill requests on weekends. Checking the CSMD for all patients scheduled for a select day can be completed at the close of the day before or the morning of the appointment. All monitoring (CSMD queries, pill counts and urine drug tests or UDT) can be completed and followed up on selected weekdays.

Patients will certainly be impacted with regards to their lifestyle and finances. Patient return appointments, visits to pick up prescriptions, and lab visits will increase resulting in higher costs for patients, which along with separate co-pays for each refill, may make certain prescriptions prohibitively expensive.

Under the 2012 Prescription Safety Act, dispensers (pharmacists, clinics, etc.) will have an increased work load as the number of monthly prescriptions multiplies. The increased work load includes more patient visits to fill prescriptions, meaning more prescriptions to fill, and more time to upload data into the CSMD (currently set at every seven days).

Under our new laws, collaboration between the physician and pharmacist is valuable and beneficial to both parties. The greatest benefit of a collaborative working relationship between practitioner and pharmacist, however, is better patient care through early identification of patients exhibiting behaviors

consistent with misuse, abuse and/or diversion. This takes a true interprofessional team effort between health care providers, patients and family members.

### Action for Physicians

There are additional measures that can reduce the number of scheduled drugs being diverted while adequately treating pain at the same time. We suggest a five-pronged approach when prescribing CPDs for chronic, non-cancer pains including: 1) using a systematic four-step approach to patient care, 2) screening for potential substance abuse and at-risk behaviors for patients using CPDs, 3) providing informed consent and a written pain agreement for all patients requiring chronic CPDs, 4) monitoring all patients using both the CSMD and UDT and 5) using the 100 mg morphine milligram dose equivalents and referring to specialists if patient requires more pain control. For a thorough review of guidelines for managing chronic non-cancer pain, see the article by Chou et al.<sup>5</sup>

1. Using a systematic four-step approach for all patients reduces the chance of missing critical information. The four-step approach is easy and based on the SOAP note format. **Step 1** – gather subjective and objective data. Take a thorough history and complete a focused physical exam as you always do, but add an emphasis on asking an appropriate screening question for substance use. Ask the patient about their substance use history and history within their family. **Step 2** – implement Screening, Brief Intervention, and Referral to Treatment (SBIRT). If the substance use question in the step above is positive, implement a full SBIRT. (See SBIRT below.) **Step 3** – assessment and plan. Complete your assessment and plan focusing on pain, diagnostic studies needed, results, and treatment plans/goals. **Step 4** – Document. Use any state specific or Federation of State Medical Boards documentation guidelines. For all patients on chronic CPDs, ask and document the four A's (analgesia, activities of daily living, adverse events, and aberrance) on each follow up visit.<sup>5-6</sup>
2. Proper screening for substance abuse and at-risk behaviors is a critical first step in patient care because it identifies a patient at risk and allows for early intervention. There is ample evidence that physicians are not adequately trained in screening and intervening on patients with substance abuse issues.<sup>7</sup> Screening, Brief Intervention, and Referral to Treatment (SBIRT) is a well-researched model for reducing harm related to at risk alcohol use. It reduces risks for patients, emergency department visits, and health care costs.<sup>8</sup> SBIRT has been used for patients on CPDs.<sup>9</sup> To screen patients, physicians can ask, "do you now or have you ever used alcohol, tobacco, controlled prescription drugs, marijuana, cocaine, hallucinogens, street drugs, etc. Ask each question and allow the patient to answer. Determine if their use is normal or misuse, which includes excessive amounts, diversion, and incorrect use due to poor understanding or misinterpretations of the directions. Ask about any at risk behaviors or consequences from substance use such as driving under the influence (DUI), financial problems due to substance use, etc. Ask the same question related to the patient's family. This identifies a potential genetic risk. For at-risk patients or patients whose behaviors are suspicious of misuse, implement an opioid risk assessment tool. For a patient who screens positive, use motivational interviewing to advise them of their risk, assess if they are able to cut down or stop, assist them with treatment options and make arrangements for follow up and when needed, referral to an appropriate substance use program, addiction medicine, pain medicine and/or mental health specialist.
3. Complete an informed consent regarding the risk and benefits of each specific pain medication for every patient who requires CPDs. A written pain agreement should be implemented setting clear

boundaries regarding refills, lost or stolen medication, and the expectation for routine and random drug screens. The screens are useful to both verify that the medication is in fact being consumed by the patient and if other medications and/or street drugs are being used. Women of childbearing ages will need full informed consent regarding pregnancy prevention and risk to the fetus. Read the DEA Practitioner's Manual for important information on proper prescribing practices. The DEA remains committed to the 2001 balanced policy of promoting pain relief and preventing abuse of pain medications.<sup>10</sup>

4. Implement monitoring for patients using chronic CPDs for more than thirty days continuously. The Tennessee Prescription Safety Act (TN-PSA) of 2012 requires that physicians check the CSMD on all patients prescribed CPDs for more than seven days and at least annually if patients are maintained on the CPD long term. One trial using a combination of opioid agreements & compliance monitoring (CSMD + UDT) was prospectively associated with a 50% reduction in opioid abuse in a chronic pain population.<sup>11</sup> Emergency department physicians should also check the CSMD for patients with suspected overdoses.<sup>12</sup> The TN-PSA stipulates that the CSMD need not be checked in the following four circumstances: 1) if the amount prescribed is less than a single, seven day, non-refillable treatment plan; 2) in particular medical specialties with a low potential for abuse by patients in that specialty; 3) if the CPD is prescribed by certain interventionists or proceduralists as a non-refillable prescription as part of treatment for a surgical procedure in a licensed healthcare facility; or 4) if the patient is enrolled in hospice care. The Tennessee physician should document the results of the CSMD query without placing the document in the medical record. Physicians should periodically query the database assessing their own DEA number to assure there is no misuse of their DEA number. Physicians living near a state border should register for that state's monitoring database and query it when appropriate. It is not uncommon for physicians to discover prescriptions that they did not write. Other methods for monitoring patients on chronic CPDs includes pill counts (know what the pills should look like) and urine drug testing (UDT). When implementing UDT, make sure the urine received is from the patient being tested. With readily available 'clean urine' samples for purchase over the internet, patients can easily trick the practitioner. Make sure to observe sampling or implement a double void policy; meaning the patient must void twice during the clinic visit to obtain two appropriate urine samples.
5. Side effects and accidental overdoses due to CPDs increase over the 100 mg morphine dose equivalent level. In Tennessee, the CSMD calculates the morphine dose equivalent for you. You may also use on-line or printed tables estimating the 100 mg morphine milligram dose equivalent. When appropriate, reduce the dose for those who exceed this level. If patients require more pain control, refer them to a pain medicine specialist. Several available on-line tools exist to help the practitioner with calculations or adjustments.

## Summary

There are major important changes for Tennessee prescribers. Each physician is responsible for understanding and abiding by the rules and laws that govern prescribing practices. The state medical board expects physicians to be aware of and follow these new practice and prescribing guidelines. Our hope is that you practice smart, treat pain appropriately, consult and refer as needed, and document appropriately so that patient care is improved. Patients greatly benefit from a health care team that works together to help reduce misuse, abuse and diversion of CPDs. Below is a list of our

recommendations to help improve your comfort and knowledge around proper prescribing of controlled prescription drugs.

### **Recommendations:**

1. Familiarize yourself with the new TN prescribing laws and identify office practices that need to be adjusted.
2. Read the DEA Practitioner's Manual and comply with their prescribing guidelines. (<http://www.deadiversion.usdoj.gov/pubs/manuals/pract/index.html>)
3. Follow a systematic four-step approach and implement office changes as needed.
4. Screen all patients to assess risk using SBIRT.
5. Take a course on SBIRT, either online or in person.
6. Query the CSMD for all patients requiring CPDs for more than seven days and at least annually if on chronic treatment.
7. Implement random urine drug testing for patients on chronic CPD treatment.
8. Query your own name in the CSMD.
9. Identify treatment resources in your area by going to the SAMSHA website and looking at their treatment finder. (<http://findtreatment.samhsa.gov/>)
10. Work collaboratively with other health care professionals including pharmacists, nurses, psychiatry, pain, and addiction medicine specialists.

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