Opioid Bills

1. Chapter 1039 of the Public Acts of 2018
Senate Bill 2257 (Norris)
House Bill 1831 (Hawk)

Gov. Haslam proposed this bill, which contains numerous provisions designed to deal with the opioid epidemic:

1) A prescriber must submit to the Controlled Substance Database (along with all the other information currently required by law) the ICD-10 Code for any drug which has an ICD-10 Code.

2) The controlled substances which trigger a check of the database by a prescriber are not changed, but the frequency with which the prescriber must check the database is changed by this law. A prescriber must now check the database: (a) at the beginning of a new episode of treatment, (b) prior to the issuance of each new prescription for the controlled substance for the first 90 days of the new episode of treatment, and (c) at least every 6 months when that prescribed controlled substance remains part of the treatment.

3) The controlled substances which trigger a check of the database by a dispenser are not changed, but the frequency with which the dispenser must check the database is changed by the law. A dispenser must now check the database: (a) the first time the patient is dispensed a controlled substance at that practice site and (b) at least every 6 months after the initial dispensing for the duration of time that controlled substance is dispensed to that patient.

4) The exception in the current law that allowed certain medical specialties not to check the database is repealed by this law.

5) The exception in the current law that allowed prescribers not to check the database if the amount prescribed or dispensed is for a single 7-day period is amended by this law to a single 3-day period.

6) This law initially states that a healthcare practitioner shall not treat a patient with more than a 3-day supply of an opioid, and the opioid dosage must not exceed 180 morphine milligram equivalents (mme). The law then allows an exception to the 3-day limit, provided the following conditions are met:

    a) The practitioner conducts a thorough evaluation of the patient;
    b) The practitioner documents consideration of non-opioid and non-pharmacologic pain management strategies and why they failed or were not tried;
    c) The practitioner includes the ICD-10 Code for the primary disease in the patient's chart and on the prescription; and
    d) Obtains written informed consent from the patient (after explanation of the risks, effects, and characteristics of opioids and of reasonable alternatives to opioids).

7) A healthcare practitioner who treats a patient with more than a 3-day supply of an opioid shall not treat the patient with more than a 10-day supply of an opioid with a dosage that does not exceed 500 mme. In "rare" cases when the treatment is "more than minimally invasive," the treatment may include a 20-day supply of an opioid with a dosage that does not exceed 850 mme. When "medical necessity" and "sound medical judgment" require, the treatment may include a 30-day supply of an opioid with a dosage that does not exceed 1,200 mme.

8) A healthcare practitioner shall not treat a patient with an opioid more frequently than once every 10 days. However, if a patient has an adverse reaction to the prescribed opioid, the healthcare practitioner may treat the patient with a different opioid during the 10-day period if the following conditions are met:

   a) The healthcare practitioner is employed by the same practice that initially treated the patient with the opioid that caused the adverse reaction;

   b) The healthcare practitioner personally evaluates the patient, assesses the patient's adverse reaction, and determines a different course of treatment is more medically appropriate;

   c) The healthcare practitioner confirms with the dispenser that the remainder of the initial prescription has been cancelled by the dispenser;

   d) The healthcare practitioner counsels the patient to appropriately destroy any remaining opioids that were previously dispensed to the patient; and

   e) The healthcare practitioner's treatment of the patient conforms to the requirements of this section.

A healthcare practitioner may dispense an opioid in an amount that does not exceed half of the total prescribed amount and then dispense the remainder of the prescription in a subsequent encounter.

9) The restrictions of this law do <u>not</u> apply to any of the following, provided the prescription contains the ICD-10 Code for the primary disease documented in the patient's chart and the word "exempt":

   a) The treatment of patients who are undergoing active or palliative cancer treatment or who are receiving hospice care;

   b) The treatment of patients with a diagnosis of sickle cell disease;
   c) The administration of opioids directly to a patient during the patient's treatment at any facility licensed under title 68, chapter 11, or any hospital licensed under title 33, chapter 2, part 4;

   d) Prescriptions issued by healthcare practitioners who are:

i. Pain management specialists, as that term is defined in §63-1-301, or who are collaborating with a pain management specialist in accordance with §63-1-306(a)(3); provided, that the patient receiving the prescription is personally assessed by the pain management specialist, or by the advanced practice registered nurse or physician assistant collaborating with the pain management specialist; or

ii. Treating patients in an outpatient setting of a hospital exempt under §63-1-302(2) that holds itself out to the public as a pain management clinic;

e) The treatment of patients who have been treated with an opioid daily for ninety (90) days or more during the three hundred sixty-five (365) days prior to April 15, 2018, or those who are subsequently treated for ninety (90) days or more under one of the exceptions listed in subdivision (d)(4) or this subsection (e);

f) The direct administration of, or dispensing of, methadone for the treatment of an opioid use disorder to a patient who is receiving treatment from a healthcare practitioner practicing under 21 U.S.C. §823(g)(1);

g) The treatment of a patient for opioid use disorder with products that are approved by the U.S. food and drug administration for opioid use disorder by a healthcare practitioner under 21 U.S.C. §823(g)(2);

h) The treatment of a patient with a product that is an opioid antagonist and does not contain an opioid agonist; or

i) The treatment of a patient who has suffered a severe burn or major physical trauma, as those terms are defined by the controlled substance database committee by rule and adopted by the licensing boards created pursuant to title 63, and sound medical judgment would determine the risk of adverse effects from the pain exceeds the risk of the development of a substance use disorder or overdose event.

10) This law takes effect on July 1, 2018.

11) The law prohibits any agreement that limits the ability of a pharmacist to discuss with a patient <u>any</u> issue related to the dispensing of a controlled substance.

12) The Commissioner of Health is authorized to establish by rule the mme for all opioid drugs. If no rule is promulgated for a particular opioid drug, the mme established by the federal CDC shall be used.

2. **Chapter 675 of the Public Acts of 2018**
   Senate Bill 2022 (Haile)
   House Bill 2004 (Terry)

This law requires the Tennessee Department of Health to publicize a means of reporting allegations of opioid abuse or diversion and shall refer any such reports to law enforcement or to the appropriate health-related board.

The law requires any entity that prescribes or handles opioids to provide information to its employees about reporting suspected opioid abuse or diversion. This can be done by providing this information to employees in writing or by posting a sign stating:

> NOTICE: PLEASE REPORT ANY SUSPECTED ABUSE OR DIVERSION OF OPIOIDS, OR ANY OTHER IMPROPER BEHAVIOR WITH RESPECT TO OPIOIDS, TO THE DEPARTMENT OF HEALTH'S COMPLAINT INTAKE LINE: [NUMBER OF INTAKE LINE]

The law prohibits the termination of any entity's employee for reporting information in good faith to the Department of Health. The law prohibits adverse licensure actions based solely on reporting information to the Department of Health. The law grants immunity from civil liability to a person who reports information to the Department of Health.

3. **Chapter 901 of the Public Acts of 2018**
   Senate Bill 2674 (Bailey)
   House Bill 2348 (Williams)

This law applies to prescribers who prescribe more than a 3-day supply of an opioid (or an opioid dosage of more than 180 mme) to a woman of childbearing age (between 15 and 44 years old)

The prescriber must:

A) Advise the patient of the risk associated with opioid use during pregnancy;

B) Counsel the patient on appropriate and effective forms of birth control; and

C) Offer information about the availability of free or reduced cost birth control to the patient.

The Department of Health will publish guidance to assist prescribers in complying with this law. The only sanction for violation of this law is a civil penalty assessed by the prescriber's licensing board where there is a pattern of willful failure to comply.

4. **Chapter 864 of the Public Acts of 2018**
   Senate Bill 1227 (Massey)
   House Bill 901 (Kumar)

This law requires the TennCare Bureau to promulgate rules to promote the safe and responsible coverage of opioids and to reduce the development of opioid dependency and addiction. The rules must require providers to submit information regarding pregnancy status and contraceptive use by women of childbearing age when prior authorization is required for an opioid prescription.

5. **Chapter 978 of the Public Acts of 2018**
   Senate Bill 777 (Jackson)
   House Bill 717 (Johnson)

This law does several things:

1) It requires a healthcare practitioner to report the dispensing of buprenorphine products to the Controlled Substance Database, unless reporting such dispensing would conflict with federal law.

2) It prohibits the dispensing of buprenorphine products except by an office-based opiate treatment facility, a substitution-based treatment center for opiate addiction, a pharmacy, or a hospital.

3) Pharmacies and distributors must report to the Department of Health the quantities of buprenorphine they delivered to office-based opiate treatment facilities.

4) Similar to the list of the top 50 prescribers of controlled substances which is currently being compiled, the Department of Health is required to compile a list of the top 20 prescribers with unique DEA numbers of buprenorphine products.

5) The law requires the Comptroller of the Treasury to complete a study of "the incidence of significantly statistically abnormal prescribing patterns by licensed prescribers and the disciplinary response of each licensing board to those prescribers," using information from the Controlled Substance Database. When this study is completed, each licensing board must identify the action taken against each prescriber whose pattern of prescribing controlled substances makes that prescriber a statistical outlier, as well as each top prescriber and each high-risk prescriber.

6) The law requires that a task force composed of representatives from the 7 health-related boards that license prescribers must establish by rule the minimum disciplinary action that a licensed board must take if the board finds that the practitioner "engaged in a significant deviation from sound medical judgment" in treating a patient with an opioid.