VANDERBILT UNIVERSITY



MEDICAL CENTER

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TENNESSEE LAW ON OPIOID PRESCRIBING

current as of 7.1.2019

(Disclaimer: the following is an interpretation of the Tennessee code and may be subject to updates and/or clarification)

THE CONTROLLED SUBSTANCE MONITORING DATABASE (CSMD)

When do I need to check the CSMD? Prior to what prescriptions do I need to check the CSMD? When do I NOT need to check the CSMD? Can I delegate someone to check the CSMD for me?

ACUTE PAIN (UP TO 3 DAYS)

What are the requirements for prescribing an opioid for acute pain? My patient had a bad allergic reaction to the 3-day opioid prescription. Can I prescribe a different opioid? What if my patient needs another prescription after 3 days?

MODERATE PAIN (>3 DAYS AND UP TO 10 DAYS)

What am I required to do in order to prescribe for >3 days (but not for surgery)?

PROLONGED PAIN (UP TO 30 DAYS)

What am I required to do in order to prescribe prolonged opioids for a pain condition after I've tried everything else available?

POST OP PAIN (UP TO 30 DAYS)

What am I required to do in order to prescribe opioids after surgery?

EXEMPT CONDITIONS

What conditions are exempt from the TN controlled substance prescribing law requirements? How do I prescribe an opioid for a patient with an EXEMPT condition?

INFORMED CONSENT, CONTRACTS, and AGREEMENTS FOR OPIOID PRESCRIPTIONS

What are the requirements for informed consent for opioid prescribing?

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What is the difference between an informed consent, a contract, and an agreement? How long are these documents good for?

MORPHINE MILLIGRAM EQUIVALENT DOSE

What is a morphine milligram equivalent and how do I calculate it?

OPIOIDS APPROVED FOR TREATMENT OF UPPER RESPIRATORY SYMPTOMS OR COUGH

How can I prescribe a cough medicine with opioids?

OPIOID RENEWAL

What are the laws regarding opioid refills or renewals?

WHAT SHOULD I DO IF I GET A LETTER FROM THE STATE ABOUT MY OPIOID PRESCRIBING?

TN identifies the top 50 prescribers in the state each year and sends out letters. How should I respond if I receive a letter?

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THE CSMD

When do I need to check the CSMD?

- prior to prescribing a controlled substance at the beginning of a new episode of treatment, and
- prior to each new prescription for the first 90 days
- at least every 6 months while prescribing controlled substances
- before prescribing anytime abuse is suspected

Tenn. Code Ann. § 53-10-310

(e)

(1) When prescribing a controlled substance, all healthcare practitioners, unless otherwise exempted under this part, shall check the controlled substance database prior to prescribing one (1) of the controlled substances identified in subdivision (e)(4) to a human patient at the beginning of a new episode of treatment, prior to the issuance of each new prescription for the controlled substance for the first ninety (90) days of a new episode of treatment, and shall check the controlled substance database for that human patient at least every six (6) months when that prescribed controlled substance database on behalf of the healthcare practitioner. A "new episode of treatment" means a prescription for a controlled substance that has not been prescribed by that healthcare practitioner within the previous six (6) months.

(3) Before prescribing or dispensing, a healthcare practitioner shall have the professional responsibility to check the database or have a healthcare practitioner delegate check the database if the healthcare practitioner is aware or reasonably certain that a person is attempting to obtain a Schedule II-V controlled substance, identified by the committee or commissioner as demonstrating a potential for abuse for fraudulent, illegal, or medically inappropriate purposes, in violation of § 53-11-402.

Prior to what prescriptions do I need to check the CSMD?

- opioids
- benzodiazepines
- additional controlled substances identified by the committee or commissioner (gabapentin, pregabalin, some stimulants)

Tenn. Code Ann. § 53-10-310

(4) The controlled substances that trigger a check of the controlled substance database pursuant to subdivisions (e)(1) and (2) include, but are not limited to, all opioids and benzodiazepines. By rule, the commissioner, pursuant to § 53-10-311, may require a check of the database for additional Schedule II-V controlled substances that are identified by the committee or commissioner as demonstrating a potential for abuse.

When do I NOT need to check the CSMD?

- for hospice patients
- for prescriptions 3 days or less

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• for care in a hospital or nursing home

Tenn. Code Ann. § 53-10-310

(6) Healthcare practitioners are not required to check the controlled substance database before prescribing or dispensing one (1) of the controlled substances identified in subdivision (e)(4) or added to that list by the committee or commissioner if one (1) or more of the following conditions are met:

(A) The controlled substance is prescribed or dispensed for a patient who is currently receiving hospice care;

(B) [Deleted by 2018 amendment.]

(C) The quantity of the controlled substance which is prescribed or dispensed does not exceed an amount which is adequate for a single, three-day treatment period and does not allow a refill; or

(D) The controlled substance is prescribed for administration directly to a patient during the course of inpatient or residential treatment in a hospital or nursing home licensed under title 68.

Can I delegate someone to check the CSMD for me?

• yes, an authorized delegate may check on behalf of the practitioner

Tenn. Code Ann. § 53-10-310

(e)

(1) When prescribing a controlled substance, all healthcare practitioners, unless otherwise exempted under this part, shall check the controlled substance database prior to prescribing one (1) of the controlled substances identified in subdivision (e)(4) to a human patient at the beginning of a new episode of treatment, prior to the issuance of each new prescription for the controlled substance for the first ninety (90) days of a new episode of treatment, and shall check the controlled substance database for that human patient at least every six (6) months when that prescribed controlled substance database on behalf of the healthcare practitioner. A "new episode of treatment" means a prescription for a controlled substance that has not been prescribed by that healthcare practitioner within the previous six (6) months.

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ACUTE PAIN (UP TO 3 DAYS)

What are the requirements for prescribing an opioid for acute pain?

- the prescription must be for 3 days or less
- the total 3-day dose must be 180 MME or less
- the patient must be seen in person, and an H&P with diagnosis completed
- the prescription can be changed if a patient has an adverse reaction, but this must be done in person to document the reaction

Tenn. Code Ann. § 63-1-164

(b) Except as provided in this section, a healthcare practitioner shall not treat a patient with more than a three day supply of an opioid and shall not treat a patient with an opioid dosage that exceeds a total of a one hundred eighty (180) morphine milligram equivalent dose.

PUBLIC CHAPTER NO. 124 - signed April 9, 2019, effective July 1, 2019

SECTION 8. Tennessee Code Annotated, Section 63-1-164(b), is amended by deleting the subsection and substituting the following:

Except as provided in this section, a healthcare practitioner shall not treat a patient with more than a three-day supply of an opioid and shall not treat a patient with an opioid dosage that exceeds a total of one hundred eighty (180) morphine milligram equivalent dose. A healthcare practitioner shall not be required to include an ICD-10 code on any prescription for an opioid of a three-day supply or less and an opioid dosage of less than one hundred eighty (180) morphine milligram equivalent.

My patient had a bad allergic reaction to the 3-day opioid prescription. Can I prescribe a different opioid?

- yes, as long as the person prescribing belongs to the same practice
- the patient must be evaluated again in person to assess the reaction
- must confirm with dispenser that any remainder will not be filled
- must counsel the patient on disposal of the remaining opioid

Tenn. Code Ann. § 63-1-164

(c) (1) A patient shall not be treated with an opioid more frequently than every ten (10) days; provided, however, that if the patient has an adverse reaction to an opioid, a healthcare practitioner may treat a patient with a different opioid within a tenday period under the following circumstances:

(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.

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(2) (A) Notwithstanding subdivision (c)(1), where the treatment provided by a healthcare practitioner is dispensing an opioid, the healthcare practitioner may treat a patient more than once within ten (10) days; provided, that the healthcare practitioner shall not dispense an opioid in an amount that exceeds the greater of:

- (i) A five-day supply per encounter; or
- (ii) Half of the total prescribed amount.
 - (B) The healthcare practitioner may dispense the remainder in a subsequent encounter.
 - **(C)** The partial fill requirements of this subdivision (c)(2) shall not be mandatory prior to January 1, 2019, for a dispenser who has not updated the dispenser's software system.

What if my patient needs another prescription after 3 days?

- A patient must be re-evaluated in person
- Follow the requirements for prolonged pain treatment prescribing >3 days (see below)

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MODERATE PAIN (>3 DAYS AND UP TO 10 DAYS)

What am I required to do in order to prescribe for >3 days (but not for surgery)?

- prescribe only 1 opioid per visit (encounter)
- limit the prescription to 10 days and no more than a total of 500 MME
- evaluate the patient in person
- document what non-opioid and non-medication options you tried, discussed, or reasons why not
- document why you are using an opioid in the chart
- include the ICD-10 code for the primary disease on the prescription and document it in the chart
- get an informed consent for opioid treatment
- for women of childbearing age, an informed consent must be signed that includes information of access to birth control and on neonatal abstinence syndrome (NAS)

Tenn. Code Ann. § 63-1-164

(d) (1) (A) A healthcare practitioner may treat a patient with more than a three-day supply of an opioid if the healthcare practitioner treats the patient with no more than one (1) prescription for an opioid per encounter and:

(i) Personally conducts a thorough evaluation of the patient;

(ii) Documents consideration of non-opioid and non-pharmacologic pain management strategies and why the strategies failed or were not attempted;

(iii) Includes the ICD-10 code for the primary disease in the patient's chart, and on the prescription when a prescription is issued; and

(iv) Obtains informed consent and documents the reason for treating with an opioid in the chart.

- (B) A healthcare practitioner who is dispensing pursuant to a prescription written by another healthcare practitioner for more than a three-day supply of an opioid is not required to satisfy subdivisions (d)(1)(A)(i)-(iv) when filling a prescription that contains an ICD-10 code; provided, that the healthcare practitioner shall not dispense more than one (1) prescription for an opioid to a patient per encounter.
- (2) If a healthcare practitioner treats a patient with more than a three-day supply of an opioid, the healthcare practitioner may treat the patient with no more than a ten-day supply and with a dosage that does not exceed a total of a five hundred (500) morphine milligram equivalent dose.
- (3) Notwithstanding subdivision (d)(2), in rare cases where the patient has a condition that will be treated by a procedure that is more than minimally invasive 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, a healthcare practitioner may treat a patient with up to a twenty-day supply of an opioid and with a dosage that does not exceed a total of an eight hundred fifty (850) morphine milligram equivalent dose.
 - (4) Notwithstanding subdivision (d)(2), in rare cases after trial and failure of reasonable, appropriate, and available non-opioid treatments for the pain condition or documenting the contraindication, inefficacy, or intolerance of non-opioid treatments, where medical necessity 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, a healthcare practitioner may treat a patient with up to a thirty-day supply of an opioid and with a dosage that does not exceed a total of a one thousand two hundred (1,200) morphine milligram equivalent dose. The healthcare practitioner must include the phrase "medical necessity" on the prescription for any prescription issued pursuant to this subdivision (d)(4).

PUBLIC CHAPTER NO. 124 - signed April 9, 2019, effective July 1, 2019

SECTION 10. Tennessee Code Annotated, Section 63-1-164(d)(3), is amended by deleting the language "twenty-day supply of an opioid and with a dosage that does not exceed a total of an eight hundred fifty (850) morphine milligram equivalent dose" and

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substituting instead the language "thirty-day supply of an opioid and with a dosage that does not exceed a total of a twelve hundred (1200) morphine milligram equivalent dose".

Tenn. Code Ann. § 53-11-308

(h) (1) Prior to prescribing more than a three-day supply of an opioid or an opioid dosage that exceeds a total of a one hundred eighty (180) morphine milligram equivalent dose to a woman of childbearing age, a prescriber shall:

- (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.
- (2) As used in this subsection (h) "a woman of childbearing age" means any woman between the ages of fifteen (15) and forty-four (44).
- (3) This subsection (h) does not apply if:
 - (A) The prescriber has previously taken all actions required by subdivision (h)(1) with respect to the patient within the past three (3) months; or
 - (B) The prescriber reasonably believes that the patient is not capable of becoming pregnant.
- (4) If the patient is under eighteen (18) years of age, the physician may satisfy this subsection (h) by advising, counseling, and providing information to the parent or guardian instead of the patient. This subdivision (h)(4) does not prohibit a physician from advising, counseling, and providing information directly to the patient if not otherwise prohibited by law.
- (5) The department of health shall develop and publish guidance to assist prescribers of opioids in complying with this subsection (h).

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PROLONGED PAIN (UP TO 30 DAYS)

What am I required to do in order to prescribe prolonged opioids for a pain condition after I've tried everything else available?

- prescribe only 1 opioid per visit (encounter)
- limit the prescription to 30 days and no more than a total of 1200 MME
- evaluate the patient in person
- document what non-opioid and non-medication options you tried, discussed, or reasons why not
- document why you are using an opioid in the chart
- include the ICD-10 code for the primary disease on the prescription and document it in the chart
- get an informed consent for opioid treatment
- include "medical necessity" on the prescription
- for women of childbearing age, an informed consent must be signed that includes information of access to birth control and on neonatal abstinence syndrome (NAS)

Tenn. Code Ann. § 63-1-164

(d) (1) (A) A healthcare practitioner may treat a patient with more than a three-day supply of an opioid if the healthcare practitioner treats the patient with no more than one (1) prescription for an opioid per encounter and:

(i) Personally conducts a thorough evaluation of the patient;

(ii) Documents consideration of non-opioid and non-pharmacologic pain management strategies and why the strategies failed or were not attempted;

(iii) Includes the ICD-10 code for the primary disease in the patient's chart, and on the prescription when a prescription is issued; and

(iv) Obtains informed consent and documents the reason for treating with an opioid in the chart.

- (B) A healthcare practitioner who is dispensing pursuant to a prescription written by another healthcare practitioner for more than a three-day supply of an opioid is not required to satisfy subdivisions (d)(1)(A)(i)-(iv) when filling a prescription that contains an ICD-10 code; provided, that the healthcare practitioner shall not dispense more than one (1) prescription for an opioid to a patient per encounter.
- (2) If a healthcare practitioner treats a patient with more than a three-day supply of an opioid, the healthcare practitioner may treat the patient with no more than a ten-day supply and with a dosage that does not exceed a total of a five hundred (500) morphine milligram equivalent dose.
- (3) Notwithstanding subdivision (d)(2), in rare cases where the patient has a condition that will be treated by a procedure that is more than minimally invasive 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, a healthcare practitioner may treat a patient with up to a twenty-day supply of an opioid and with a dosage that does not exceed a total of an eight hundred fifty (850) morphine milligram equivalent dose.
 - (4) Notwithstanding subdivision (d)(2), in rare cases after trial and failure of reasonable, appropriate, and available non-opioid treatments for the pain condition or documenting the contraindication, inefficacy, or intolerance of non-opioid treatments, where medical necessity 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, a healthcare practitioner may treat a patient with up to a thirty-day supply of an opioid and with a dosage that does not exceed a total of a one thousand two hundred (1,200) morphine milligram equivalent dose. The healthcare practitioner must include the phrase "medical necessity" on the prescription for any prescription issued pursuant to this subdivision (d)(4).

PUBLIC CHAPTER NO. 124 - signed April 9, 2019, effective July 1, 2019

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SECTION 10. Tennessee Code Annotated, Section 63-1-164(d)(3), is amended by deleting the language "twenty-day supply of an opioid and with a dosage that does not exceed a total of an eight hundred fifty (850) morphine milligram equivalent dose" and substituting instead the language "thirty-day supply of an opioid and with a dosage that does not exceed a total of a twelve hundred (1200) morphine milligram equivalent dose".

Tenn. Code Ann. § 53-11-308

(h) (1) Prior to prescribing more than a three-day supply of an opioid or an opioid dosage that exceeds a total of a one hundred

- eighty (180) morphine milligram equivalent dose to a woman of childbearing age, a prescriber shall: (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.
- (2) As used in this subsection (h) "a woman of childbearing age" means any woman between the ages of fifteen (15) and forty-four (44).
- (3) This subsection (h) does not apply if:
 - (A) The prescriber has previously taken all actions required by subdivision (h)(1) with respect to the patient within the past three (3) months; or
 - (B) The prescriber reasonably believes that the patient is not capable of becoming pregnant.
- (4) If the patient is under eighteen (18) years of age, the physician may satisfy this subsection (h) by advising, counseling, and providing information to the parent or guardian instead of the patient. This subdivision (h)(4) does not prohibit a physician from advising, counseling, and providing information directly to the patient if not otherwise prohibited by law.
- (5) The department of health shall develop and publish guidance to assist prescribers of opioids in complying with this subsection (h).

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POST OP PAIN (UP TO 30 DAYS)

What am I required to do in order to prescribe opioids after surgery?

- prescribe only 1 opioid per visit (encounter)
- limit the prescription to 30 days and no more than a total of 1200 MME
- evaluate the patient in person
- document what non-opioid and non-medication options you tried, discussed, or reasons why not
- document why you are using an opioid in the chart
- include the ICD-10 code for the primary disease on the prescription and document it in the chart
- get an informed consent for opioid treatment
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(iii) Includes the ICD-10 code for the primary disease in the patient's chart, and on the prescription when a prescription is issued; and

(iv) Obtains informed consent and documents the reason for treating with an opioid in the chart.

- (B) A healthcare practitioner who is dispensing pursuant to a prescription written by another healthcare practitioner for more than a three-day supply of an opioid is not required to satisfy subdivisions (d)(1)(A)(i)-(iv) when filling a prescription that contains an ICD-10 code; provided, that the healthcare practitioner shall not dispense more than one (1) prescription for an opioid to a patient per encounter.
- (2) If a healthcare practitioner treats a patient with more than a three-day supply of an opioid, the healthcare practitioner may treat the patient with no more than a ten-day supply and with a dosage that does not exceed a total of a five hundred (500) morphine milligram equivalent dose.
- (3) Notwithstanding subdivision (d)(2), in rare cases where the patient has a condition that will be treated by a procedure that is more than minimally invasive 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, a healthcare practitioner may treat a patient with up to a twenty day supply of an opioid and with a dosage that does not exceed a total of an eight hundred fifty (850) morphine milligram equivalent dose.
 - (4) Notwithstanding subdivision (d)(2), in rare cases after trial and failure of reasonable, appropriate, and available non-opioid treatments for the pain condition or documenting the contraindication, inefficacy, or intolerance of non-opioid treatments, where medical necessity 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, a healthcare practitioner may treat a patient with up to a thirty-day supply of an opioid and with a dosage that does not exceed a total of a one thousand two hundred (1,200) morphine milligram equivalent dose. The healthcare practitioner must include the phrase "medical necessity" on the prescription for any prescription issued pursuant to this subdivision (d)(4).

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substituting instead the language "thirty-day supply of an opioid and with a dosage that does not exceed a total of a twelve hundred (1200) morphine milligram equivalent dose".

Tenn. Code Ann. § 53-11-308

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- (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.
- (2) As used in this subsection (h) "a woman of childbearing age" means any woman between the ages of fifteen (15) and forty-four (44).
- (3) This subsection (h) does not apply if:
 - (A) The prescriber has previously taken all actions required by subdivision (h)(1) with respect to the patient within the past three (3) months; or
 - (B) The prescriber reasonably believes that the patient is not capable of becoming pregnant.
- (4) If the patient is under eighteen (18) years of age, the physician may satisfy this subsection (h) by advising, counseling, and providing information to the parent or guardian instead of the patient. This subdivision (h)(4) does not prohibit a physician from advising, counseling, and providing information directly to the patient if not otherwise prohibited by law.
- (5) The department of health shall develop and publish guidance to assist prescribers of opioids in complying with this subsection (h).

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EXEMPT CONDITIONS

What conditions are exempt from the TN controlled substance prescribing law requirements?

- active cancer treatment
- palliative care treatment
- hospice care treatment
- sickle cell disease
- inpatients in the hospital
- prescriptions issued by pain management specialists or under the collaborative direction of a pain management specialist after that specialist or their APRN or PA have seen the patient
- patients who have been treated with daily opioids already for 90 days or more
- methadone, or other products approved for treatment of opioid use disorder
- treatment with an opioid antagonist
- severe burn
- major physical trauma

Tenn. Code Ann. § 63-1-164

(e) The restrictions of this section do not apply to the following; provided, that where a prescription is issued pursuant to this subsection (e), the prescription contains the ICD-10 code for the primary disease documented in the patient's chart and the word "exempt":

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

(2) The treatment of patients with a diagnosis of sickle cell disease;

(3) 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;

(4) Prescriptions issued by healthcare practitioners who are:

(A) 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

(B) 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.

(5) 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 (1) of the exceptions listed in subdivision (d)(4) or this subsection (e);

(6) 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);

(7) 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);

(8) The treatment of a patient with a product that is an opioid antagonist and does not

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contain an opioid agonist; or

(9) 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.

PUBLIC CHAPTER NO. 124 – signed April 9, 2019, effective July 1, 2019

SECTION 11. Tennessee Code Annotated, Section 63-1-164(e)(1), is amended by deleting the subdivision and substituting the following: The treatment of patients who are undergoing active cancer treatment, undergoing palliative care treatment, or are receiving hospice care;

PUBLIC CHAPTER NO. 124 - signed April 9, 2019, effective July 1, 2019

SECTION 7. Tennessee Code Annotated, Section 63-1-164(a), is amended by adding the following as a new subdivision: () "Palliative care" means specialized treatment for patients facing serious illness, which focuses on providing relief of suffering through a multidisciplinary approach in order to maximize quality of life for the patient. As used in this subdivision (aX), "serious illness" means a health condition that carries a high risk of mortality and negatively impacts a patient's daily bodily functions;

PUBLIC CHAPTER NO. 124 – signed April 9, 2019, effective July 1, 2019

SECTION 12. Tennessee Code Annotated, Section 63-1-164(e)(9), is amended by deleting the subdivision and substituting the following: (9) The treatment of a patient who has suffered a severe burn or major physical trauma and for whom 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. As used in this subdivision (eX9), "severe burn" means an injury sustained from thermal or chemical causes resulting in second degree or third degree burns. As used in this subdivision (eX9), "major physical trauma" means a serious injury sustained due to blunt or penetrating force which results in serious blood loss, fracture, significant temporary or permanent impairment, or disability.

How do I prescribe an opioid for a patient with an EXEMPT condition?

- include the word "exempt" and the reason for exemption on the prescription
- include the ICD-10 code for the primary disease on the prescription
- for women of childbearing age, an informed consent must be signed that includes information of access to birth control and on neonatal abstinence syndrome (NAS)

Tenn. Code Ann. § 63-1-164

(e) The restrictions of this section do not apply to the following; provided, that where a prescription is issued pursuant to this subsection (e), the prescription contains the ICD-10 code for the primary disease documented in the patient's chart and the word "exempt":

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

(2) The treatment of patients with a diagnosis of sickle cell disease;

(3) 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;

(4) Prescriptions issued by healthcare practitioners who are:

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(A) 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

(B) 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.

(5) 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 (1) of the exceptions listed in subdivision (d)(4) or this subsection (e);

(6) 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);

(7) 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);

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

(9) 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.

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Tenn. Code Ann. § 53-11-308

- (h) (1) Prior to prescribing more than a three-day supply of an opioid or an opioid dosage that exceeds a total of a one hundred eighty (180) morphine milligram equivalent dose to a woman of childbearing age, a prescriber shall:
 - (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.
 - (2) As used in this subsection (h) "a woman of childbearing age" means any woman between the ages of fifteen (15) and forty-four (44).
 - (3) This subsection (h) does not apply if:
 - (A) The prescriber has previously taken all actions required by subdivision (h)(1) with respect to the patient within the past three (3) months; or
 - (B) The prescriber reasonably believes that the patient is not capable of becoming pregnant.
 - (4) If the patient is under eighteen (18) years of age, the physician may satisfy this subsection (h) by advising, counseling, and providing information to the parent or guardian instead of the patient. This subdivision (h)(4) does not prohibit a physician from advising, counseling, and providing information directly to the patient if not otherwise prohibited by law.
 - (5) The department of health shall develop and publish guidance to assist prescribers of opioids in complying with this subsection (h).

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INFORMED CONSENT, CONTRACTS, and AGREEMENTS FOR OPIOID PRESCRIPTIONS

What are the requirements for informed consent for opioid prescribing?

- the prescriber must explain and disclose at a minimum the risk, effects, characteristics of opioids, including the risk for dependency, addiction, misuse, diversion; must explain what to expect and how to use the opioids; must discuss reasonable alternatives and their risks and benefits
- the consent form must be signed by the patient or their legal representative
- there must be a reasonable opportunity for questions
- there should be a discussion and consideration of whether the patient should take an opioid
- if the patient is a woman of childbearing age and ability, must provide information on neonatal abstinence syndrome and specific information on how to access contraceptive services in the community

Tenn. Code Ann. § 63-1-164

(4) (A) "Informed consent" means consent voluntarily given in writing by the patient or the patient's legal representative after sufficient explanation and disclosure by the healthcare practitioner of the subject matter involved to enable the person whose consent is sought to make a knowing and willful decision. This explanation and disclosure by the healthcare practitioner to the patient or the patient's legal representative before consent may be obtained must include, at a minimum:

- (i) Adequate information to allow the patient or the patient's legal representative to understand:
 - (a) The risks, effects, and characteristics of opioids, including the risks of physical dependency and addiction, misuse, and diversion;
 - (b) What to expect when taking an opioid and how opioids should be used; and
 - (c) Reasonable alternatives to opioids for treating or managing the patient's condition or symptoms and the benefits and risks of the alternative treatments;
- (ii) A reasonable opportunity for questions by the patient or patient's legal representative;

(iii) Discussion and consideration by the patient or the patient's legal representative and the healthcare practitioner of whether the patient should take an opioid medication; and

(iv) If the patient is a woman of childbearing age and ability, information regarding neonatal abstinence syndrome and specific information regarding how to access contraceptive services in the community. For purposes of this section, childbearing age is between the ages of fifteen (15) and forty-four (44);

TN Chronic Pain Guidelines

Informed consent for the use of opioids in treating pain must be obtained prior to initiating treatment. Informed consent documents typically cover: potential risks and anticipated benefits of opioid therapy, potential side effects, likelihood of physical dependence, risk of over-sedation, pregnancy, risk of impaired motor skills, risk of addiction and death.

What is the difference between an informed consent, a contract, and an agreement?

- The purpose of an opioid *informed consent* is to inform and ensure understanding and acceptance of the risks and benefits associated with taking medication. This is not a long-term agreement or contract.
- A patient-provider agreement in this context serves as a contract, and in many instances also incorporates the language of informed consent.

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It is recommended that a patient-provider agreement (contract) be obtained for prescription of opioids
or other controlled substances if intended for prolonged use (e.g. > 90 days), and that an agreement be
maintained by a single clinic.

Tenn. Code Ann. § 63-1-164

(4) (A) "Informed consent" means consent voluntarily given in writing by the patient or the patient's legal representative after sufficient explanation and disclosure by the healthcare practitioner of the subject matter involved to enable the person whose consent is sought to make a knowing and willful decision. This explanation and disclosure by the healthcare practitioner to the patient or the patient's legal representative before consent may be obtained must include, at a minimum:

- (i) Adequate information to allow the patient or the patient's legal representative to understand:
 - (a) The risks, effects, and characteristics of opioids, including the risks of physical dependency and addiction, misuse, and diversion;
 - (b) What to expect when taking an opioid and how opioids should be used; and
 - (c) Reasonable alternatives to opioids for treating or managing the patient's condition or symptoms and the benefits and risks of the alternative treatments;

(ii) A reasonable opportunity for questions by the patient or patient's legal representative;

(iii) Discussion and consideration by the patient or the patient's legal representative and the healthcare practitioner of whether the patient should take an opioid medication; and

(iv) If the patient is a woman of childbearing age and ability, information regarding neonatal abstinence syndrome and specific information regarding how to access contraceptive services in the community. For purposes of this section, childbearing age is between the ages of fifteen (15) and forty-four (44);

TN Chronic Pain Guidelines

Informed consent for the use of opioids in treating pain must be obtained prior to initiating treatment. Informed consent documents typically cover: potential risks and anticipated benefits of opioid therapy, potential side effects, likelihood of physical dependence, risk of over-sedation, pregnancy, risk of impaired motor skills, risk of addiction and death.

A written **treatment agreement** should be used with the patient at the time opioids are first prescribed for chronic pain. Treatment agreements typically cover reasons, for which opioids may be discontinued, the practice policy on early refills, policy on lost prescriptions or medications, expectation for safe storage of medications, use of one pharmacy and expectations about periodic drug testing. The treatment agreement shall include an expectation that a female patient will tell the provider if she wishes to avoid unintended pregnancy and if she becomes pregnant.

1. The provider should discuss a method to prevent unintended pregnancy with every woman of child-bearing age who has reproductive capacity when opioids are initiated. 2. The provider shall advise every woman of child-bearing potential on opioids that she be on a method to prevent unintended pregnancy specifically considering long acting contraceptive methods. 3. The treatment agreement shall include an expectation that a female patient will tell the provider if she becomes pregnant or plans to become pregnant.

How long are these documents good for?

- An opioid informed consent applies for the episode of care for which the opioid is being prescribed by that prescriber. There are no specific laws or guidelines specifying expiration.
- An opioid patient-provider agreement (contract) applies for the duration of care under that provider/practice. Prudence would dictate that this should be renewed periodically and/or with major changes in treatment, although there are no specific laws or guidelines specifying this.

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MORPHINE MILLIGRAM EQUIVALENT DOSE

What is a morphine milligram equivalent and how do I calculate it?

- morphine milligram equivalent (MME) is the standard used to compare opioid prescription potencies
- MME is calculated by adding the daily amount of prescribed opioid and multiplying it by the number of days prescribed
- for example, oxycodone is 1.5x as potent as morphine so oxycodone 10mg = morphine 15mg (15 MME). If oxycodone 10mg is prescribed 8hrs daily for 30 days, the MME calculation would be as follows:

oxycodone 5mg q8hr x 30 days

- oxycodone 15mg total in 1 day * 1.5 = 22.5mg morphine equivalents in 1 day
- 22.5mg * 30 days = 675 MME total for a 30-day prescription

Tenn. Code Ann. § 63-1-164

(5) "Morphine milligram equivalent dose" means the morphine milligram equivalent calculation for the amount of a prescribed opioid, multiplied by the days of treatment

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OPIOIDS APPROVED FOR TREATMENT OF UPPER RESPIRATORY SYMPTOMS OR COUGH

How can I prescribe a cough medicine with opioids?

 cough and upper respiratory approved medications with opioids can be prescribed for a maximum of 14 days

PUBLIC CHAPTER NO. 124 - signed April 9, 2019, effective July 1, 2019

SECTION 13. Tennessee Code Annotated, Section 63-1-164, is amended by adding the following as a new subsection: This section does not apply to opioids approved by the food and drug administration to treat upper respiratory symptoms or cough. However, a healthcare practitioner shall not treat a patient with more than a fourteen-day supply of such an opioid.

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FUTURE CHANGES IN TENNESSEE PRESCRIBING LAW

Jan 1, 2021

- controlled substance prescriptions must be sent electronically
- prescriptions issued by an APRN or PA must include the collaborating physician's name, address, and telephone number

PUBLIC CHAPTER NO. 124 - signed April 9, 2019, effective July 1, 2019

SECTION 4. Tennessee Code Annotated, Section 63-1-160, is amended by deleting subsection (c) and substituting the following: (c) Subject to subsection (d), on or after January 1,2021, any prescription for a Schedule II, III, IV, or V controlled substance issued by a prescriber who is authorized by law to prescribe the drug must be issued as an electronic prescription from the person issuing the prescription to a pharmacy. The name, address, and telephone number of the collaborating physician of an advanced practice registered nurse or physician assistant must be included on electronic prescriptions issued by an advance practice registered nurse or physician assistant.

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OPIOID RENEWALS

What are the laws regarding opioid refills or renewals?

- First time opioid prescriptions must follow the laws noted above
- Automatic refills are prohibited
- After a new 3-day prescription for acute pain, renewals can occur by following the requirements for prescriptions >3 days, which includes an in-person visit (as clarified in the TN FAQs: <u>link</u>)
- After new prescriptions for 10+ days, where the required steps have been taken, renewals must occur in-person at each new encounter (visit)
- Patients that meet Exempt conditions may have prescriptions renewed after an in-person visit, after a patient requests by phone or electronic means, or with a prescription signed on the date issued to be dispensed on a future specified date (see <u>link</u>)

Tenn. Code Ann. § 53-11-308

(a) Except when dispensed directly by a health care prescriber other than a pharmacy to an ultimate user, no controlled substance in Schedule II may be dispensed without the electronic prescription of a health care prescriber, unless authorized by § 63-1-160. To the extent federal law does not permit an electronic prescription, a written prescription from a health care prescriber is required.

(b) In emergency situations, **Schedule II drugs** may be dispensed upon oral prescription of a health care prescriber, reduced promptly to writing or to electronic form, as appropriate, and filed by the pharmacy. Prescriptions shall be retained in conformity with the requirements of § 53-11-306. No prescription for a Schedule II substance may be refilled.

(c) Except when dispensed directly by a practitioner other than a pharmacy to an ultimate user, a controlled substance included in **Schedule III or IV** that is a prescription drug shall not be dispensed without a written or oral prescription of a practitioner. The prescription shall not be filled or refilled more than six (6) months after the date of the written or oral prescription or be refilled more than five (5) times, unless renewed by the practitioner.

(d) A controlled substance included in Schedule V shall not be distributed or dispensed other than for a medical purpose.

(e) No prescription for any opioids or benzodiazepines may be <u>dispensed</u> in quantities greater than a thirty-day supply.

(f) If a prescriber dispenses any opioids, benzodiazepines, barbiturates, or carisoprodol, then the prescriber shall submit the transaction to the controlled substances monitoring database operated under chapter 10, part 3 of this title.

(g) Any prescribers of opioids, benzodiazepines, barbiturates or carisoprodol, either alone, concurrently, or sequentially with any other opioids, benzodiazepines, barbiturates, or carisoprodol to patients who are in chronic, long-term drug therapy for ninety (90) days or longer shall consider mandatory urine drug testing. This subsection (g) shall not supercede any rules promulgated by the commissioner for urine drug testing by registered pain management clinics.

Tenn. Code Ann. § 53-11-308

(e)

(1) When prescribing a controlled substance, all healthcare practitioners, unless otherwise exempted under this part, shall check the controlled substance database prior to prescribing one (1) of the controlled substances identified in subdivision (e)(4)

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to a human patient at the beginning of a new episode of treatment, prior to the issuance of each new prescription for the controlled substance for the first ninety (90) days of a new episode of treatment, and shall check the controlled substance database for that human patient at least every six (6) months when that prescribed controlled substance remains part of the treatment. An authorized healthcare practitioner's delegate may check the controlled substance database on behalf of the healthcare practitioner. A "new episode of treatment" means a prescription for a controlled substance that has not been prescribed by that healthcare practitioner within the previous six (6) months.

(2) When dispensing a controlled substance, all healthcare practitioners, unless otherwise exempted under this part, shall check the controlled substance database prior to dispensing one (1) of the controlled substances identified in subdivision (e)(4) to a human patient the first time that patient is dispensed a controlled substance at that practice site. The dispenser shall check the controlled substance database again at least once every six (6) months for that human patient after the initial dispensing for the duration of time the controlled substance is dispensed to that patient. The initial dispensing check fulfills the check requirement for the first six-month period. An authorized healthcare practitioner's delegate may check the controlled substance database on behalf of the healthcare practitioner.

(3) Before prescribing or dispensing, a healthcare practitioner shall have the professional responsibility to check the database or have a healthcare practitioner delegate check the database if the healthcare practitioner is aware or reasonably certain that a person is attempting to obtain a Schedule II-V controlled substance, identified by the committee or commissioner as demonstrating a potential for abuse for fraudulent, illegal, or medically inappropriate purposes, in violation of § 53-11-402.
(4) The controlled substances that trigger a check of the controlled substance database pursuant to subdivisions (e)(1) and (2) include, but are not limited to, all opioids and benzodiazepines. By rule, the commissioner, pursuant to § 53-10-311, may require a check of the database for additional Schedule II-V controlled substances that are identified by the committee or

commissioner as demonstrating a potential for abuse.

(5) The commissioner, pursuant to § 53-10-311, shall adopt rules in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5, that establish standards and procedures to be followed by a healthcare practitioner regarding the review of patient information available through the database.

(6) Healthcare practitioners are not required to check the controlled substance database before prescribing or dispensing one (1) of the controlled substances identified in subdivision (e)(4) or added to that list by the committee or commissioner if one (1) or more of the following conditions are met:

(A) The controlled substance is prescribed or dispensed for a patient who is currently receiving hospice care;

(B) [Deleted by 2018 amendment.]

(C) The quantity of the controlled substance which is prescribed or dispensed does not exceed an amount which is adequate for a single, three-day treatment period and does not allow a **refill**; or

(D) The controlled substance is prescribed for administration directly to a patient during the course of inpatient or residential treatment in a hospital or nursing home licensed under title 68.

Tenn. Code Ann. § 63-1-160

63-1-160. Prescription for Schedule II controlled substance -- Electronic prescription for Schedule II, III, IV, or V controlled substance -- Exceptions.

(a) As used in this section, "electronic prescription" means a written prescription that is generated on an electronic application and is transmitted in accordance with 21 CFR Part 1311.

(b) All written, printed, or electronic prescription orders for a Schedule II controlled substance must contain all information otherwise required by law. The healthcare prescriber must sign the written, printed, or electronic prescription order on the day it is issued. Nothing in this section prevents a healthcare prescriber from issuing a verbal prescription order.

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WHAT SHOULD I DO IF I GET A LETTER FROM THE STATE ABOUT MY OPIOID PRESCRIBING?

TN identifies the top 50 prescribers in the state each year and sends out letters. How should I respond if I receive a letter?

STEP 1: Email the Vanderbilt Committee on Opioid Monitoring & Stewardship (VCOMS) at <u>opioidinfo@vumc.org</u> to inform that you received a letter for being a top 50 prescriber.

STEP 2: Login to the CSMD and review your prescriptions for the past year to ensure there are no obvious pharmacy errors or prescriptions that do not seem to be from you.

VCOMS will work with you to draft a response letter to the Department of Health showing why your prescribing is appropriate or where assistance is being provided for appropriate prescribing.

Tenn. Code Ann. § 68-1-128

(a) No later than July 31, 2013, and at least annually thereafter but more often at the discretion of the commissioner, the department of health shall:

(1)

(A) Identify the top fifty (50) prescribers who have unique DEA numbers of controlled substances, other than buprenorphine formulations that have not received approval for pain applications from the federal food and drug administration, in the previous calendar year, or if implemented more frequently for the relevant time period as determined by the department, from the data available in the controlled substances database established pursuant to title 53, chapter 10, part 3;

(B) Identify the top twenty (20) prescribers who have unique DEA numbers of buprenorphine products or equivalent products in the previous calendar year, or if implemented more frequently for the relevant time period as determined by the department, from the data available in the controlled substances database established pursuant to title 53, chapter 10, part 3. The department may organize the list of prescribers required by this subdivision (a)(1)(B) in any manner as may be appropriate to reflect levels of service, training, or other relevant factors by a healthcare provider. These factors may include, but not be limited to, whether the provider is board-certified;

(2) Send a letter through registered mail to each prescriber identified in subdivision (a)(1), and to the collaborating physician as found on the provider's profile established in title 63, chapter 32 of each advanced practice registered nurse and each physician assistant identified in subdivision (a)(1) that notifies the prescribers and, where appropriate, the collaborating physician that the prescriber has been identified pursuant to subdivision (a)(1) and includes the following information:

(A) The significant controlled substances prescribed by the prescriber;

(B) The number of patients prescribed these controlled substances by the prescriber;

(C) The total milligrams in morphine equivalents of controlled substances prescribed during the relevant period of time; and

(D) Any other relevant information sought by the department; and

(3) If there is an active investigation against the prescriber or, where appropriate the collaborating physician on the lists of prescribers identified in (a)(1), the department is authorized to withhold any communication required under this section until such time as charges are brought or the investigation is closed.

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