Amendment No._____

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Signature of Sponsor

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Comm. Amdt. _____
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AMEND Senate Bill No. 2257 House Bill No. 1831*

by deleting all language after the enacting clause and substituting instead the following:

SECTION 1. Tennessee Code Annotated, Section 53-10-303(f), is amended by deleting the subsection in its entirety and substituting the following:

(f) Pursuant to § 53-10-311 and the Uniform Administrative Procedures Act, compiled in title 4, chapter 5, the commissioner shall have the authority to promulgate rules as necessary for implementation of this part regarding:

(1) Establishing, maintaining, and operating the database;

(2) Access to the database and how access is obtained;

(3) Control and dissemination of data and information in the database;

(4) The control, sharing, and dissemination of data and information in the database with other states or other entities acting on behalf of a state; and

(5) Establishing the morphine milligram equivalent calculation for an opioid drug contained in Schedules II-V for purposes of SECTION 6 of this act; provided, that if no such rule is promulgated for an opioid drug, the morphine milligram equivalent calculation established by the federal centers for disease control and prevention for that drug shall be used.

SECTION 2. Tennessee Code Annotated, Section 53-10-305(b)(1), is amended by redesignating the existing subdivision (b)(1)(L) as (b)(1)(N) and adding the following language as new subdivisions (b)(1)(L) and (M):

(L) The ICD-10 code for any prescription that contains an ICD-10 code; provided, that this shall not be mandatory prior to January 1, 2019, for a dispenser who has not updated the dispenser's software system to enable submission of ICD-10 codes;

(M) A value signifying opioid treatment is occurring pursuant to a medical necessity under SECTION 6 for any prescription containing the words "medical necessity." The value will be determined by the committee and published through the committee's website;

SECTION 3. Tennessee Code Annotated, Section 53-10-310, is amended by deleting subdivisions (e)(1) and (e)(2) in their entireties and substituting the following:

(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 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.

SECTION 4. Tennessee Code Annotated, Section 53-10-310, is amended by deleting subdivision (e)(6)(B) in its entirety.

SECTION 5. Tennessee Code Annotated, Section 53-10-310(e)(6)(C), is amended by deleting the language "seven-day treatment period" and substituting instead "three-day treatment period".

SECTION 6. Tennessee Code Annotated, Title 63, Chapter 1, Part 1, is amended by adding the following language as a new, appropriately designated section:

(a) As used in this section:

(1) "Encounter" means a single visit where an opioid is administered or an opioid prescription is issued or dispensed;

(2) "Healthcare practitioner" means a person licensed under this title who has the authority to prescribe or dispense controlled substances in the course of professional practice;

(3) "ICD-10 code" means the code established in the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) adopted by the federal centers for medicare and medicaid services, or the code used in any successor classification system adopted by the federal centers for medicare and medicaid services, that corresponds to the diagnosis of the condition being treated;

(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);

(B) Nothing in subdivision (a)(4)(A) limits other requirements imposed on healthcare practitioners by law or applicable licensing authority;

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

(6) "Treat" means prescribe, dispense, or administer.

(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 twenty (120) morphine milligram equivalent dose.

(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 ten-day 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.

(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.

(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 four hundred (400) 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 a one thousand two hundred (1,200) 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).

(5)

(A) If a healthcare practitioner treats a patient with an opioid pursuant to subdivision (d)(4) and that healthcare practitioner's licensing board or agency finds that the healthcare practitioner engaged in a gross deviation or pattern of deviation from sound medical judgment, the minimum disciplinary action that a healthcare practitioner's licensing board or committee must take shall be established and promulgated by rule by a task force composed of representatives from:

(i) The board of medical examiners;

(ii) The board of osteopathic examination;

(iii) The board of dentistry;

(iv) The board of podiatric medical examiners;

(v) The board of optometry;

(vi) The board of nursing; and

(vii) The board of medical examiners' committee on physician assistants.

(B) The task force must create a uniform minimum disciplinary action pursuant to this section, which shall be binding on each board and committee listed in subdivision (d)(5)(A).

(C) The task force is authorized to establish minimum disciplinary actions pursuant to this subdivision (d)(5) by emergency rule in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5. The rule promulgated by the task force shall be codified and published by the secretary of state in each of the chapters for the boards and committee listed in subdivision (d)(5)(A).

(D)

(i) Each board and committee listed in subdivision (d)(5)(A) must select and appoint by majority vote one (1) member of their respective board or committee to serve on the task force.

(ii) The task force shall select and appoint a member to serve as chair of the task force.

(iii) A majority of that task force shall constitute a quorum, and a majority vote of the task force members present is required for any action.

(iv) Notwithstanding any provision of the Uniform Administrative Procedures Act, to the contrary, the task force shall hear public comment at any required hearing on behalf of all boards listed in subdivision (d)(5)(A) when a hearing is required. The task force is authorized to vote to promulgate the rule to establish the uniform minimum disciplinary action for each board and committee listed in subdivision (d)(5)(A).

(E) However, in the event that the task force has not promulgated uniform minimum disciplinary actions by July 1, 2019, then the minimum disciplinary action that a healthcare practitioner's licensing board or agency must take is a removal of the healthcare practitioner's right to prescribe controlled substances for no less than five (5) years.

(F) The task force shall terminate upon the later of July 1, 2019, or the effective date of a permanent rule establishing the uniform minimum disciplinary action pursuant to this section. The procedures of this subdivision (d)(5) must be followed to amend, repeal, or otherwise revise the uniform minimum disciplinary action established pursuant to this section. In such case, the task force may be reconvened by the commissioner of health or a majority of the boards and committee listed in subdivision (d)(5)(A).

(G) Nothing in this part shall be construed to prohibit the licensing boards and committee listed in subdivision (d)(5)(A) from promulgating rules regarding other minimum disciplinary actions that will be taken against their licensees.

(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 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.

(e) The commissioner of health, in consultation with the regulatory boards created pursuant to this title that license healthcare practitioners, shall study and analyze the impact and effects of the restrictions and limitations set forth in this section. No later than November 1, 2021, the commissioner shall issue a report relative to the impact and effects of the restrictions and limitations to the governor, the health and welfare committee of the senate, and the health committee of the house of representatives. The report may include recommendations for revisions to the restrictions on the prescription of opioids.

(f) This section applies only to the treatment of human patients.

SECTION 7. Tennessee Code Annotated, Title 63, Chapter 10, Part 2, is amended by adding the following as a new section:

(a) The general assembly finds that patient access to information about controlled substances is crucial to combating the deadly opioid epidemic in this state and that any obstacle to patients' receiving information about controlled substances is a serious threat to public health.

(b) Any agreement purporting to limit the ability of a pharmacist to discuss any issue related to the dispensing of a controlled substance with a patient is contrary to the public policy of this state and is void and unenforceable. This includes, but is not limited to, information about the risks, effects, and characteristics of the controlled substance; what to expect when taking the controlled substance and how the controlled substance should be used; reasonable alternatives to the prescribed controlled substance; and any applicable cost sharing for a controlled substance or any amount an individual would pay for a controlled substance if that individual were paying cash.

SECTION 8. If any provision of this act or the application of any provision of this act to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the act that can be given effect without the invalid provision or application, and to that end, the provisions of this act are declared to be severable.

SECTION 9. Sections 1 and 6 of this act shall terminate on July 1, 2023, and the law in effect prior to this act's effective date shall be restored.

SECTION 10. For rulemaking purposes, this act shall take effect immediately, the public welfare requiring it. For all other purposes, this act shall take effect July 1, 2018, the public welfare requiring it.