

Amendment No. 4 to HB1264

Ramsey
Signature of Sponsor

AMEND Senate Bill No. 676*

House Bill No. 1264

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

SECTION 1. This act shall be known and may be cited as the "Addison Sharp Prescription Regulatory Act of 2013."

SECTION 2. Tennessee Code Annotated, Title 63, Chapter 1, is amended by adding a new part 4 as follows:

63-1-401.

(a) As used in this part:

(1) "Commissioner" means the commissioner of the department of health; and

(2) "Treatment guidelines" means systematically developed statements to assist health care providers in making patient decisions concerning appropriate medical care for specific clinical circumstances.

(b) By January 1, 2014, the commissioner shall develop recommended treatment guidelines for prescribing of opioids, benzodiazepines, barbiturates, and carisoprodol that can be used by prescribers in the state as a guide for caring for patients. This subsection shall not apply to veterinarians.

(c) The commissioner shall review and update the guidelines by September 30th of each year, and shall cause them to be posted on the department's website.

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(d) The treatment guidelines shall be submitted to each prescribing board that licenses health professionals who can legally prescribe controlled substances and to the board of pharmacy. Each board shall be charged with review of the treatment guidelines and determining how the guidelines are to be used by its licensees.

(e) Each board shall notify all of its licensees through routine bulletins or newsletters of the existence of the guidelines.

63-1-402.

(a) On or after July 1, 2014, all prescribers who hold a current federal drug enforcement administration (DEA) license and who prescribe controlled substances shall be required to complete a minimum of two (2) hours of continuing education related to controlled substance prescribing biennially to count toward the licensees' mandatory continuing education.

(b) The continuing education must include instruction in the department's treatment guidelines on opioids, benzodiazepines, barbiturates, and carisoprodol, and may include such other topics as medicine addiction, risk management tools, and other topics as approved by the respective licensing boards.

(c) This section shall not apply to veterinarians, providers practicing at a registered pain management clinic as defined in § 63-1-301 or to medical doctors or osteopathic physicians board certified by the

American Board of Medical Specialties (ABMS) or American Osteopathic Association (AOA) in one or more of the following specialties or subspecialties:

- (1) Pain management;
- (2) Anesthesiology;
- (3) Physical medicine and rehabilitation;
- (4) Neurology; or
- (5) Rheumatology.

SECTION 3. Tennessee Code Annotated, Section 53-10-302(10), is deleted in its entirety and replaced with the following language:

(10) "Healthcare practitioner extender" means any registered or licensed healthcare professional, and up to two (2) unlicensed persons per prescriber or dispenser designated by the prescriber or dispenser to act as agents of such prescriber or dispenser. A prescriber shall have the ability to authorize a healthcare practitioner extender to check the controlled substance database as stipulated in § 53-10- 310(e) for other prescribers in the authorizing prescriber's practice. Notwithstanding the provisions of Section 28 of Chapter 880 of the Public Acts of 2012, any one-time costs required to be made to effectuate the provisions of this act specific to system modifications required by changes in this subdivision shall be shared on a pro-rata basis, excluding the pharmacy board, by the appropriate prescribing boards as enumerated in title 53, chapter 10, part 3. The prescriber or dispenser shall be responsible for actions taken by their agents pursuant to this part;

SECTION 4. Tennessee Code Annotated, Section 53-11-308, is amended by adding the following language as new subsections at the end of the current section:

(e) No prescription for a schedule II-IV controlled substance may be dispensed in quantities greater than a thirty (30) day supply.

(f)

(1) No opioids, benzodiazepines, barbiturates, or carisoprodol may be dispensed directly by a registered pain management clinic as defined in § 63-1-301.

(2) 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 title 53, chapter 10, part 3.

(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 chronic, long-term drug therapy for ninety (90) days or longer shall consider mandatory urine drug testing. This subsection shall not supercede any rules promulgated by the commissioner for urine drug testing by registered pain management clinics.

SECTION 5. Tennessee Code Annotated, Section 53-10-302, is hereby amended by adding the following new language as new subsections at the end of the current section:

() “Manufacturer” means any person, except a pharmacist compounding in the normal course of professional practice, engaged in the commercial production, preparation, propagation, conversion, or processing of a drug, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis, or both, and includes any packaging or repackaging of a drug or the labeling or relabeling of its container and the promotion and marketing of such drugs or devices;

() “Wholesaler” means a person whose principal business is buying or otherwise acquiring drugs or devices for resale or distribution to persons other than consumers.

SECTION 6. Tennessee Code Annotated, Title 53, Chapter 10, Part 3, is amended by adding the following language as new section.

53-10-312.

(a) Wholesalers and manufacturers, as defined in § 63-10-204, that sell controlled substances at wholesale must at least report the following information to the committee in Automation of Reports and Consolidated Orders System (ARCOS) format or other mutually acceptable format:

(1) Wholesaler or manufacturer with a drug enforcement administration registration number; provided that if this number is not applicable, then another mutually acceptable identifier;

(2) Purchaser’s drug enforcement administration registration number; provided that if this number is not applicable, then another mutually acceptable identifier;

(3) National drug code number of the actual drug sold;

(4) Quantity of the drug sold;

(5) Date of sale; and

(6) Transaction identifier or invoice number.

(b) The department of health will establish such rules are necessary to specify which medications shall be reported, the time frames for such reporting, and other reporting requirements as required.

SECTION 7. Tennessee Code Annotated, Section 63-1-301(5), is amended by deleting subdivision (5) in its entirety and by substituting instead the following:

(5) "Pain management clinic" means a privately-owned facility in which a medical doctor, an osteopathic physician, an advanced practice nurse, a physician assistant, or any other health care provider licensed under title 63 provides pain management services to patients, a majority of whom are issued a prescription for, or are dispensed, opioids, benzodiazepine, barbiturates, or carisoprodol and provides prescriptions for more than ninety (90) days in a twelve-month period. For purposes of determining if a clinic should be registered under this part, patients of health care providers who do not prescribe controlled substances shall be excluded from the count. "Pain management clinic" shall also mean any privately owned clinic, facility, or office which advertises in any medium for any type pain management services and in which one (1) or more employees or contractors prescribe controlled substances; and

SECTION 8. Tennessee Code Annotated, Section 63-1-303(c), is amended by deleting subsection (c) in its entirety and by substituting instead the following:

(c) The rules adopted pursuant to subsection (b) shall address the following topics, among others:

(1) The operation of the clinic, including requirements:

(A) That patients have current and valid government issued identification or current health insurance card issued by either a government or private carrier; and

(B) That providers conduct urine drug screening in accordance with a written drug screening and compliance plan, which may include testing on initial assessment or upon new admission;

(2) Personnel requirements for the clinic;

- (3) Training requirements for clinic providers who are regulated by that board;
- (4) Patient records;
- (5) Standards to ensure quality of patient care;
- (6) Infection control;
- (7) Health and safety requirements;
- (8) Certificate application and renewal procedures and requirements;
- (9) Data collection and reporting requirements;
- (10) Inspections and complaint investigations; and
- (11) Patient billing procedures.

SECTION 9. Tennessee Code Annotated, Section 63-1-309(d), is amended by adding the following language at the end of the subsection:

A medical director shall serve as medical director and provider services for no more than four (4) pain management clinics.

SECTION 10. Tennessee Code Annotated, Section 63-1-310(a), is amended by deleting the subsection in its entirety and by substituting instead the following:

(a) A pain management clinic may accept only a check or credit card in payment for services provided at the clinic, except as provided in subsection (b).

SECTION 11. The department of health, the board of pharmacy or any board operating under Tennessee Code Annotated, Title 63, is authorized to use emergency rules under Tennessee Code Annotated, Section 4-5-208(a)(5), in order to promulgate any rules required by this act.

SECTION 12. Tennessee Code Annotated, Section 63-1-311(b), is amended by deleting the language “an administrative penalty of one thousand dollars (\$1,000) per day,” and by substituting instead the language “an administrative penalty of no less than

one thousand dollars (\$1,000) per day and which shall not exceed five thousand (\$5,000) per day.”

SECTION 13. Tennessee Code Annotated, Section 63-1-311, is amended by adding the following as a new subsection (c):

(c) An owner, co-owner, or operator of an uncertified pain management clinic is subject to an administrative penalty of no less than one thousand dollars (\$1,000) per day and which shall not exceed five thousand dollars (\$5,000) per day, imposed by the department of health, in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5. Before such a penalty may be assessed by the department, the department shall give at least thirty (30) days notice to the owner, co-owner, or operator of the alleged violation of this part.

SECTION 14. Tennessee Code Annotated, Title 63, Chapter 1, Part 3, is amended by adding the following as a new subsection:

63-1-313. The commissioner of health and each appropriate occupational professional licensing board governing licensees who may legally prescribe or dispense controlled substances shall prepare a comprehensive report on actions relative to prescription drug abuse and pain management clinics to the General Assembly no later than January 31st for actions in the prior calendar year. This report shall summarize the number of complaints received, frequent findings, and actions taken.

SECTION 15. This act shall take effect on October 1, 2013, the public welfare requiring it, except for rulemaking purposes for which purposes it shall take effect upon becoming law, the public welfare requiring it.