

Amendment No. 1 to SB0097

Crowe  
Signature of Sponsor

**AMEND Senate Bill No. 97\***

**House Bill No. 86**

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

SECTION 1. Tennessee Code Annotated, Section 53-11-302, is amended by deleting subsections (a), (b), and (d) and substituting instead the following:

(a) Every person who manufactures, distributes, dispenses, or is a third-party logistics provider for any controlled substance pursuant to § 53-11-301 within this state or who proposes to engage in the manufacture, distribution, dispensing, warehousing, or providing logistics services for any controlled substance within this state, shall annually obtain a registration issued by the board of pharmacy and the appropriate occupational or professional licensing board governing persons who may legally dispense controlled substances in accordance with the licensing board's rules.

(b) Persons registered by the board of pharmacy and the appropriate occupational or professional licensing board governing persons who may legally dispense controlled substances under this part, part 4 of this chapter, and title 39, chapter 17, part 4, to manufacture, distribute, dispense, warehouse, or provide logistics services for controlled substances may possess, manufacture, warehouse, distribute, or dispense those substances to the extent authorized by their registration and in conformity with this section.

(d) The board of pharmacy and the appropriate occupational or professional licensing board governing persons who may legally dispense controlled substances may waive by rule the requirement for registration of certain manufacturers, distributors,

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dispensers, or entities providing warehousing or logistics services if they find it consistent with the public health and safety.

SECTION 2. Tennessee Code Annotated, Section 53-11-304(a), is amended by deleting the language:

(a) A registration under § 53-11-302 to manufacture, distribute or dispense a controlled substance may be suspended or revoked by the board of pharmacy and the appropriate occupational or professional licensing board governing persons who may legally dispense controlled substances upon a finding that the registrant has:

and substituting instead the following:

(a) A registration under § 53-11-302 to manufacture, warehouse, distribute, dispense, or provide logistics services for a controlled substance may be suspended or revoked by the board of pharmacy and the appropriate occupational or professional licensing board governing persons who may legally dispense controlled substances upon a finding that the registrant has:

SECTION 3. Tennessee Code Annotated, Section 63-10-204, is amended by deleting subdivisions (15) and (45) and substituting instead the following:

(15) "Distribute" or "distribution" means the sale, purchase, trade, delivery, handling, storage, or receipt of a product or the arrangement of the sale, purchase, trade, delivery, handling, storage, or receipt of a product through third parties; provided, that "distribute" or "distribution" does not include dispensing or administering a product pursuant to a prescription, medical order, or an over-the-counter order. For the

purposes of this part, transfers and sales of drugs or devices from one licensed pharmacy to another shall not constitute distribution of drugs or devices;

(45) “Wholesaler” or “wholesale distributor” means a person primarily engaged in the wholesale distribution of drugs or devices; provided, that “wholesaler” or “wholesale distributor” does not include licensed third-party logistics providers. For the purposes of this part, transfers and sales of drugs or devices from one licensed pharmacy to another shall not constitute wholesale distribution of drugs or devices.

SECTION 4. Tennessee Code Annotated, Section 63-10-204, is further amended by inserting the following language as new, appropriately designated subdivisions:

( ) “Distributor” means a person engaged in the distribution of drugs or devices; provided, that “distributor” does not include licensed wholesale distributors or licensed third-party logistics providers;

( ) “Outsourcing facility” means a facility engaged in the compounding of sterile drugs that has elected to register as an outsourcing facility with the U.S. food and drug administration and that complies with all relevant federal laws and regulations;

( ) “Third-party logistics provider” means a person who provides or coordinates warehousing or other logistics services of a drug or device on behalf of a manufacturer, wholesale distributor, or dispenser of the drug or device, but does not take ownership of the drug or device, nor has responsibility to direct the sale or disposition of the drug or device;

( ) “Wholesale distribution” means the distribution of a drug or device to persons other than the patient or consumer, or the receipt of a drug or device by persons other than the patient or consumer; provided, that “wholesale distribution” does not include the distribution or receipt of products, transactions, or services that are exempted from this definition by rule. For the purposes of this part, transfers and sales of drugs or devices

from one licensed pharmacy to another shall not constitute wholesale distribution of drugs or devices;

SECTION 5. Tennessee Code Annotated, Section 63-10-306, is amended by deleting subsection (f) and substituting instead the following:

(f) The board has the authority to license and register pharmacists, pharmacies, wholesalers, distributors, pharmacy technicians, manufacturers, third-party logistics providers, and such other persons as the board may be required to license under federal or state law upon requirements established by the board's rules. This subsection (f) shall not be construed to include manufacturers' representatives, unless otherwise required by federal or state law.

SECTION 6. Tennessee Code Annotated, Section 53-11-301, is amended by deleting the language:

the manufacture, distribution and dispensing of controlled substances within this state and by substituting instead the language:

the manufacture, distribution, dispensing, warehousing of, and the provision of logistics services for controlled substances within this state

SECTION 7. This act shall take effect upon becoming a law, the public welfare requiring it.