<BillNo> <Sponsor>

SENATE BILL 2139

By Reeves

AN ACT to amend Tennessee Code Annotated, Title 29; Title 53; Title 56; Title 63; Title 68 and Title 71, relative to dispensing prescription drugs.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 63, Chapter 10, is amended by adding the following new part:

(a) As used in this section:

(1) ''Approved pharmacy'' means a medically integrated pharmacy approved by the department for the purpose of restocking and re-dispensing unopened and unused specialty medications;

(2) ''Department'' means the department of health;

(3) ''Healthcare facility'' means the location where the patient receives treatment from a provider of healthcare services;

(4) ''Medically integrated pharmacy'' means a dispensing pharmacy integrated as a part of a patient's care team, that uses an outcomes-based, collaborative, and comprehensive model that promotes patient-centered care with a multidisciplinary team approach and direct communication with providers of healthcare services and access to electronic medical records;

(5) ''Pharmacist'' has the same meaning as defined in § 63-10-204;

(6) ''Specialty medication'' means a prescription drug that is used to treat:

(A) Cancer or the side effects of cancer;

(B) The side effects of a prescription drug that is used to treat cancer; or

(C) Diseases of blood and blood components; and

(7) "Unopened tamper-evident packaging" has the same meaning as defined in United States Pharmacopeia (USP) General Chapter 659, Packing and Storage Requirements, and includes, but is not limited to, unopened unit-dose, multiple dose, immediate, secondary, and tertiary packaging.

(b) The department shall authorize an approved pharmacy to receive specialty medication for inspection and restock and re-dispense unopened, unused and unexpired specialty medication. The department shall promulgate rules to establish procedures that ensure proper safety and management of specialty medication received and maintained by an approved pharmacy. The rules must be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

(c) A specialty medication that was delivered to a healthcare facility where the patient receives treatment may be returned to an approved pharmacy only if such return is made by a provider at the healthcare facility and the specialty medication has not been in the possession of the patient and has not left the healthcare facility.

(d) A pharmacist in an approved pharmacy shall inspect a specialty medication that has been returned pursuant to subsection (c) before such medication can be restocked or re-dispensed. If the pharmacist determines that the specialty medication:

(1) Has been altered, mislabeled, stored improperly, or if it has expired and is beyond its use date, then the pharmacist shall immediately discard the specialty medication;

(2) Is unused, in its original, unopened tamper-evident packaging, and is not required to be discarded pursuant to subdivision (d)(1), then the pharmacist may restock the specialty medication; and

(3) Is in single-unit dose packaging that is unopened and undisturbed, then the pharmacist may restock the specialty medication.

(e) If specialty medication is eligible to be restocked, then the approved pharmacy shall reimburse or credit the entity that paid for the specialty medication, including TennCare, for such specialty medication returned to the approved pharmacy.

(f) An approved pharmacy shall maintain a record of a credit or reimbursement made pursuant to subsection (e) that contains the following information:

(1) Name and address of the healthcare provider that returned the specialty medication;

(2) Name and address of the healthcare facility from which the specialty medication was received;

(3) Amount of the credit or reimbursement;

(4) Date the credit or reimbursement was issued;

(5) Name of the pharmacist issuing the credit or reimbursement;

(6) Name of the person or entity to whom the credit or reimbursement was issued;

(7) Date the specialty medication was dispensed;

(8) Unique identification number assigned to the specialty medication by the pharmacy; and

(9) Name, strength, and quantity of the specialty medication.

(g) After the approved pharmacy has issued a credit or reimbursement, the approved pharmacy may re-dispense the unopened and unused specialty medication.

(h) A drug manufacturer shall have active commercial general liability insurance to cover claims of injury, death, or loss to a person or property for matters related to the acceptance, restocking, or re-dispensing of a prescription drug manufactured by the

drug manufacturer that is returned under this section, including liability for failure to transfer or communicate product or consumer information or the expiration date of the returned prescription drug.

(i) A person not subject to the requirements of subsection (h), acting reasonably and in good faith pursuant to this section, is immune from civil liability and criminal prosecution for injury to or the death of an individual to whom a returned prescription drug is re-dispensed under this section and is exempt from disciplinary action related to the person's acts or omissions related to the acceptance, restocking, or re-dispensing of a returned prescription drug under this section.

SECTION 2. This act takes effect upon becoming a law, the public welfare requiring it.