HB247

164170-2

By Representatives Todd and Hall

RFD: Health

First Read: 11-MAR-15

ENROLLED, An Act,

Relating to the redispensing under certain conditions of unused prescription drugs by pharmacies operated in or on behalf of HIV clinics; to define HIV clinic; and to provide conditions and protocols for the redispensing of unused prescription drugs by HIV clinic pharmacies.

BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

Section 1. (a) As used in this section, the following terms shall have the following meanings:

(1) CUSTOMIZED PATIENT MEDICATION PACKAGE. A package that is prepared by a pharmacist for a specific patient and that contains two or more prescribed solid oral dosage forms.

(2) HIV CLINIC. Any hospital, nursing home, surgical center, or any other clinic, office, or facility in which medical services are offered or provided to treat individuals infected with human immunodeficiency virus.

(3) REPACKAGING. The process by which the pharmacy prepares a prescription it accepts pursuant to this section in a unit-dose package, unit-of-issue package, or customized patient medication package for immediate dispensing in accordance with a current prescription.

(4) UNIT-DOSE PACKAGE. A package that contains a single-dose drug with the name, strength, control number, and expiration date of that drug on the label.

(5) UNIT-OF-ISSUE PACKAGE. A package that provides multiple doses of the same drug, but each drug is individually separated and includes the name, lot number, and expiration date of the drug.

(b) A pharmacy operated by an HIV clinic or operated by a company under contract with an HIV clinic shall accept, for the purpose of redispensing, a prescription drug that has been dispensed and has left the control of the pharmacy or pharmacist if the prescription drug is being returned by the HIV clinic that has met the requirements of routine on-site inspections by the pharmacy or pharmacist and has a registered professional nurse or a licensed practical nurse who is responsible for the security, handling, and administration of prescription drugs within the HIV clinic and if all of the following conditions are met:

(1) The pharmacy or pharmacist is satisfied that the conditions under which the prescription drug has been delivered, stored, and handled before and during its return were such as to prevent damage, deterioration, or contamination that would adversely affect the identity, strength, quality, purity, stability, integrity, or effectiveness of the prescription drug.

(2) The pharmacist is satisfied that the prescription drug did not leave the control of the registered professional nurse or licensed practical nurse responsible for

the security, handling, and administration of that prescription drug and that the prescription drug did not come into the physical possession of the individual for whom it was prescribed.

(3) The pharmacist is satisfied that the labeling and packaging of the prescription drug are accurate, have not been altered, defaced, or tampered with, and include the identity, strength, expiration date, and lot number of the prescription drug.

(4) The prescription drug was dispensed in a unit-dose package or unit-of-issue package.

(c) A pharmacy operated by an HIV clinic or operated by a company under contract with an HIV clinic shall not accept for return prescription drugs as provided pursuant to this section until the pharmacist in charge develops a written set of protocols for accepting, returning to stock, repackaging, labeling, and redispensing prescription drugs. The written protocols shall be maintained on the premises of any pharmacy dispensing prescriptions for the HIV clinic and shall be readily accessible to each pharmacist on duty. The written protocols shall include, at a minimum, each of the following:

(1) Methods for ensuring that damage, deterioration, or contamination has not occurred during the delivery, handling, storage, or return of the prescription drugs such

that it would adversely affect the identity, strength, quality, purity, stability, integrity, or effectiveness of the prescription drugs or otherwise render the drugs unfit for distribution.

(2) Methods for accepting, returning to stock, repackaging, labeling, and redispensing the prescription drugs returned pursuant to this section.

(3) A uniform system of recording and tracking prescription drugs that are returned to stock, repackaged, labeled, and redistributed pursuant to this section.

(d) If the condition of a prescription drug and its package meets the standards set forth in subsection (c), a prescription drug shall be returned to stock and redistributed as follows:

(1) A prescription drug that was originally dispensed in the manufacturer's unit-dose package or unit-of-issue package that is returned in that same package may be returned to stock, repackaged, and redispensed as needed.

(2) A prescription drug that is repackaged into a unit-dose package or a unit-of-issue package by the pharmacy, dispensed, and returned to that pharmacy in that unit-dose package or unit-of-issue package may be returned to stock, but it shall not be repackaged. A unit-dose package or unit-of-issue package prepared by the pharmacist and returned

to stock shall only be redispensed in that same unit-dose package or unit-of-issue package and shall only be redispensed once. A pharmacist shall not add unit-dose package drugs to a partially used unit-of-issue package.

~~(e) This section does not apply to any of the following:~~

(e) A drug manufacturer may not, in the absence of a finding of gross negligence, be subject to criminal prosecution or liability in tort or other civil action for injury, death, or loss to person or property for matters related to the donation, acceptance, or dispensing of a prescription drug manufactured by the drug manufacturer that is donated by any person under this section, including, but not limited to, liability for failure to transfer or communicate product or consumer information or the expiration date of the donated prescription drug.

(f) This section does not apply to any of the following, which may not be accepted or distributed under the provisions of this section:

(1) A controlled substance.

(2) A prescription drug that is dispensed as part of a customized patient medication package.

(3) A prescription drug that is not dispensed as a unit-dose package or a unit-of-issue package.

(4) A prescription drug that is not properly labeled with the identity, strength, lot number, and expiration date.

(5) A prescription drug that can only be dispensed to a patient registered with the drug's manufacturer in accordance with federal Food and Drug Administration requirements.

Section 2. This act shall become effective on the first day of the third month following its passage and approval by the Governor, or its otherwise becoming law.

Speaker of the House of Representatives

President and Presiding Officer of the Senate

House of Representatives

I hereby certify that the within Act originated in and was passed by the House 19-MAY-15.

Jeff Woodard
Clerk

Senate	04-JUN-15	Amended and Passed
House	04-JUN-15	Concurred in Senate Amendment