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THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 1044 Session of 2009

INTRODUCED BY D. WHITE, STOUT, RAFFERTY, O'PAKE, ERICKSON, TARTAGLIONE, FOLMER, WAUGH, FERLO, WARD, BOSCOLA, ARGALL, KITCHEN, ALLOWAY, VANCE, BRUBAKER AND EARLL, JULY 23, 2009

SENATOR GREENLEAF, JUDICIARY, AS AMENDED, JANUARY 26, 2010

AN ACT

~~Providing~~ AMENDING TITLE 61 (PENAL AND CORRECTIONAL INSTITUTIONS) OF THE PENNSYLVANIA CONSOLIDATED STATUTES, PROVIDING for drug redistribution within correctional facilities.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

~~Section 1. Short title.~~

~~This act shall be known and may be cited as the Correctional Facilities Drug Redistribution Act.~~

~~Section 2. Definitions.~~

~~The following words and phrases when used in this act shall have the meanings given to them in this section unless the context clearly indicates otherwise:~~

~~"Correctional facility." A jail, prison, facility, institution, group home, prerelease center, community corrections center, parole center or any facility that houses a a person convicted of a criminal offense, or awaiting trial, sentencing or extradition in a criminal proceeding. The term~~

~~includes an institution, facility or unit operated by or for the Department of Corrections. The term does not include any facility or institution operated, supervised or licensed under the act of June 13, 1967 (P.L.31, No.21), known as the Public Welfare Code.~~

~~"Designated personnel." Correctional facility employees or employees of a vendor for a correctional facility licensed by the State Board of Medicine, State Board of Osteopathic Medicine, State Board of Nursing or State Board of Pharmacy and authorized by their scope of practice to administer drugs.~~

~~"Drug." Any medication prescribed by a licensed practitioner, either patient specific or stock to a patient in a correctional facility.~~

~~"Manufacturer." A company that produces a drug or a Federal Drug Administration certified repacker who packages or repackages a drug product for distribution.~~

~~"Manufacturer identifier." A manufacturer's name or product National Drug Code number.~~

~~"Unit dose package." An individually sealed package that contains a single dose drug with the drug name, strength, manufacturer identifier, lot number and expiration date of the drug on the package.~~

~~"Unit of issue package." A package that includes multiple unit dose packages of the same drug.~~

~~"Vendor pharmacy." A licensed pharmacy that packages, repackages or prepares a manufacturer sealed container, unit dose package or unit of issue package for delivery to a correctional facility.~~

~~Section 3. Return to and redispensing by vendor pharmacy.~~

~~A drug that is issued to a correctional facility and has left~~

~~the control of a pharmacist at a vendor pharmacy may be returned to its vendor pharmacy for the purpose of redispensing that drug to fill other prescriptions for other correctional facilities only if the following requirements are met:~~

~~(1) The drug is not a Schedule I, II, III, IV or V controlled substance as specified in the act of April 14, 1972 (P.L.233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act.~~

~~(2) The drug is returned to its vendor pharmacy in accordance with the vendor pharmacy's written policies and procedures that comply with section 4 and the State Board of Pharmacy's rules and regulations in regard to delivery, storage, labeling and reissuing of the drug.~~

~~(3) The drug is returned to the vendor pharmacy unopened and still sealed in the unit dose package, unit of issue package, bottle or manufacturer's package.~~

~~(4) Each returned unit dose package, unit of issue package or manufacturer's package retains the drug name, strength, manufacturer identifier, lot and expiration date as originally labeled by the pharmacy or manufacturer.~~

~~(5) The drug issued to the facility was at no time in the possession or control of a patient.~~

~~(6) The drug remained in a controlled environment of a secured drug room or secured drug cart under the supervision of designated personnel who are responsible for the drugs in that correctional facility.~~

~~(7) The drug has no fewer than 90 days before its expiration date.~~

~~(8) A pharmacist at the vendor pharmacy determines by visual inspection that the returned products are not~~

adulterated or misbranded.

(9) A pharmacist at the vendor pharmacy using the pharmacist's professional judgment determines that:

(i) The conditions under which the drug has been delivered, stored and handled before and during its return to the pharmacy have preserved proper integrity, stability and labeling of the drug.

(ii) The drug labeling or packaging has not been altered or defaced.

(iii) The drug name, strength, manufacturer identifier, lot and expiration date are retrievable.

Section 4. Vendor pharmacy redispensing.

The vendor pharmacy to which drug products are returned may redispense a drug properly returned under section 3, provided that:

(1) The drugs are returned directly from the correctional facility to the vendor pharmacy.

(2) The drugs returned to the vendor pharmacy are stored separately from the rest of the pharmacy's stock.

(3) The redispensing is in compliance with the Food and Drug Administration, the United States Pharmacopeia and the vendor pharmacy's policies and procedures.

(4) The vendor pharmacy records receipt of the drug, including:

(i) The date the drug was received.

(ii) The quantity of the drug.

(iii) The lot number of the drug.

(iv) The expiration date of the drug.

(5) Information recorded under this section is maintained for at least two years from the date the drug is

redispensed.

(6) The unit dose package, unit of issue of originally sealed container stays intact with drug name, strength, manufacturer identifier, lot and expiration date and is not emptied from the returned unit dose, unit of issue or original container for repacking.

(7) The name of any patient for whom the drug was previously prescribed is removed prior to redispensing.

(8) The drug remains in the original container or package and that before redispensing, the label meets the requirements of the State Board of Pharmacy's rules and regulations.

Section 5. Credit for redispensing.

The vendor pharmacy, to which drug products are returned, shall credit the correctional facility for the unused drugs that are permitted to be restocked for redispensing at a rate determined by the vendor pharmacy and the correctional facility.

Section 6. Disposal of unacceptable returned drugs.

Returned drugs that do not meet all the requirements of section 3 shall be deemed unacceptable for redispensing and processed for disposal. Drugs deemed unacceptable for redispensing shall be sent to a destruction agency, reverse distributor, manufacturer, original wholesaler or other approved entity.

Section 7. Unprofessional conduct.

(1) A pharmacist who is authorized under this act to redispense a drug and who properly relabels and repackages the drug shall not be deemed to have engaged in unprofessional conduct under section 5 of the act of September 27, 1961 (P.L.1700, No.699), known as the Pharmacy

~~Act.~~

~~(2) A pharmacist who fails to comply with the provisions of this act may be subject to discipline under the Pharmacy Act.~~

~~(3) A pharmacy that fails to comply with the provisions of this act may be subject to discipline under the Pharmacy Act.~~

~~Section 8. Effective date.~~

~~This act shall take effect immediately.~~

SECTION 1. CHAPTER 11 OF TITLE 61 OF THE PENNSYLVANIA CONSOLIDATED STATUTES, ADDED AUGUST 11, 2009 (P.L.147, NO.33), IS AMENDED BY ADDING A SUBCHAPTER TO READ:

SUBCHAPTER D

DRUG REDISTRIBUTION

SEC.

1171. SCOPE.

1172. DEFINITIONS.

1173. RETURN TO AND REDISPENSING BY VENDOR PHARMACY.

1174. VENDOR PHARMACY REDISPENSING.

1175. CREDIT FOR REDISPENSING.

1176. DISPOSAL OF UNACCEPTABLE RETURNED DRUGS.

1177. UNPROFESSIONAL CONDUCT.

§ 1171. SCOPE.

THIS SUBCHAPTER RELATES TO CORRECTIONAL FACILITY DRUG REDISTRIBUTION.

§ 1172. DEFINITIONS.

THE FOLLOWING WORDS AND PHRASES WHEN USED IN THIS SUBCHAPTER SHALL HAVE THE MEANINGS GIVEN TO THEM IN THIS SECTION UNLESS THE CONTEXT CLEARLY INDICATES OTHERWISE:

"CORRECTIONAL FACILITY." A CORRECTIONAL INSTITUTION, GROUP

HOME, PRERELEASE CENTER, COMMUNITY CORRECTIONS CENTER, PAROLE CENTER OR ANY FACILITY THAT HOUSES A PERSON CONVICTED OF A CRIMINAL OFFENSE, OR AWAITING TRIAL, SENTENCING OR EXTRADITION IN A CRIMINAL PROCEEDING. THE TERM DOES NOT INCLUDE ANY FACILITY OR INSTITUTION OPERATED, SUPERVISED OR LICENSED UNDER THE ACT OF JUNE 13, 1967 (P.L.31, NO.21), KNOWN AS THE PUBLIC WELFARE CODE.

"DESIGNATED PERSONNEL." CORRECTIONAL FACILITY EMPLOYEES OR EMPLOYEES OF A VENDOR FOR A CORRECTIONAL FACILITY LICENSED BY THE STATE BOARD OF MEDICINE, STATE BOARD OF OSTEOPATHIC MEDICINE, STATE BOARD OF NURSING OR STATE BOARD OF PHARMACY AND AUTHORIZED BY THEIR SCOPE OF PRACTICE TO ADMINISTER DRUGS.

"DRUG." ANY MEDICATION PRESCRIBED BY A LICENSED PRACTITIONER, EITHER PATIENT SPECIFIC OR STOCK, TO A PATIENT IN A CORRECTIONAL FACILITY.

"MANUFACTURER." A COMPANY THAT PRODUCES A DRUG OR A FEDERAL DRUG ADMINISTRATION CERTIFIED REPACKER WHO PACKAGES OR REPACKAGES A DRUG PRODUCT FOR DISTRIBUTION.

"MANUFACTURER IDENTIFIER." A MANUFACTURER'S NAME OR PRODUCT NATIONAL DRUG CODE NUMBER.

"UNIT DOSE PACKAGE." AN INDIVIDUALLY SEALED PACKAGE THAT CONTAINS A SINGLE DOSE DRUG WITH THE DRUG NAME, STRENGTH, MANUFACTURER IDENTIFIER, LOT NUMBER AND EXPIRATION DATE OF THE DRUG ON THE PACKAGE.

"UNIT OF ISSUE PACKAGE." A PACKAGE THAT INCLUDES MULTIPLE UNIT DOSE PACKAGES OF THE SAME DRUG.

"VENDOR PHARMACY." A LICENSED PHARMACY THAT PACKAGES, REPACKAGES OR PREPARES A MANUFACTURER-SEALED CONTAINER, UNIT DOSE PACKAGE OR UNIT OF ISSUE PACKAGE FOR DELIVERY TO A CORRECTIONAL FACILITY.

§ 1173. RETURN TO AND REDISPENSING BY VENDOR PHARMACY.

A DRUG THAT IS ISSUED TO A CORRECTIONAL FACILITY AND HAS LEFT THE CONTROL OF A PHARMACIST AT A VENDOR PHARMACY MAY BE RETURNED TO ITS VENDOR PHARMACY FOR THE PURPOSE OF REDISPENSING THAT DRUG TO FILL OTHER PRESCRIPTIONS FOR OTHER CORRECTIONAL FACILITIES ONLY IF THE FOLLOWING REQUIREMENTS ARE MET:

(1) THE DRUG IS NOT A SCHEDULE I, II, III, IV OR V CONTROLLED SUBSTANCE AS SPECIFIED IN THE ACT OF APRIL 14, 1972 (P.L.233, NO.64), KNOWN AS THE CONTROLLED SUBSTANCE, DRUG, DEVICE AND COSMETIC ACT.

(2) THE DRUG IS RETURNED TO ITS VENDOR PHARMACY IN ACCORDANCE WITH THE VENDOR PHARMACY'S WRITTEN POLICIES AND PROCEDURES THAT COMPLY WITH SECTION 1174 (RELATING TO VENDOR PHARMACY REDISPENSING) AND THE STATE BOARD OF PHARMACY'S RULES AND REGULATIONS IN REGARD TO DELIVERY, STORAGE, LABELING AND REISSUING OF THE DRUG.

(3) THE DRUG IS RETURNED TO THE VENDOR PHARMACY UNOPENED AND STILL SEALED IN THE UNIT DOSE PACKAGE, UNIT OF ISSUE PACKAGE, BOTTLE OR MANUFACTURER'S PACKAGE.

(4) EACH RETURNED UNIT DOSE PACKAGE, UNIT OF ISSUE PACKAGE, BOTTLE OR MANUFACTURER'S PACKAGE RETAINS THE DRUG NAME, STRENGTH, MANUFACTURER IDENTIFIER, LOT AND EXPIRATION DATE AS ORIGINALLY LABELED BY THE PHARMACY OR MANUFACTURER.

(5) THE DRUG ISSUED TO THE FACILITY WAS AT NO TIME IN THE POSSESSION OR CONTROL OF A PATIENT.

(6) THE DRUG REMAINED IN A CONTROLLED ENVIRONMENT OF A SECURED DRUG ROOM OR SECURED DRUG CART UNDER THE SUPERVISION OF DESIGNATED PERSONNEL WHO ARE RESPONSIBLE FOR THE DRUGS IN THAT CORRECTIONAL FACILITY.

(7) THE DRUG HAS NO FEWER THAN 90 DAYS BEFORE ITS EXPIRATION DATE.

(8) A PHARMACIST AT THE VENDOR PHARMACY DETERMINES BY VISUAL INSPECTION THAT THE RETURNED PRODUCTS ARE NOT ADULTERATED OR MISBRANDED.

(9) A PHARMACIST AT THE VENDOR PHARMACY USING THE PHARMACIST'S PROFESSIONAL JUDGMENT DETERMINES THAT:

(I) THE CONDITIONS UNDER WHICH THE DRUG HAS BEEN DELIVERED, STORED AND HANDLED BEFORE AND DURING ITS RETURN TO THE PHARMACY HAVE PRESERVED PROPER INTEGRITY, STABILITY AND LABELING OF THE DRUG.

(II) THE DRUG LABELING OR PACKAGING HAS NOT BEEN ALTERED OR DEFACED.

(III) THE DRUG NAME, STRENGTH, MANUFACTURER IDENTIFIER, LOT AND EXPIRATION DATE ARE RETRIEVABLE.

§ 1174. VENDOR PHARMACY REDISPENSING.

THE VENDOR PHARMACY TO WHICH DRUG PRODUCTS ARE RETURNED MAY REDISPENSE A DRUG PROPERLY RETURNED UNDER SECTION 1173 (RELATING TO RETURN TO AND REDISPENSING BY VENDOR PHARMACY), PROVIDED THAT:

(1) THE DRUGS ARE RETURNED DIRECTLY FROM THE CORRECTIONAL FACILITY TO THE VENDOR PHARMACY.

(2) THE DRUGS RETURNED TO THE VENDOR PHARMACY ARE STORED SEPARATELY FROM THE REST OF THE PHARMACY'S STOCK.

(3) THE REDISPENSING IS IN COMPLIANCE WITH THE UNITED STATES PHARMACOPEIA AND THE VENDOR PHARMACY'S POLICIES AND PROCEDURES.

(4) THE VENDOR PHARMACY RECORDS RECEIPT OF THE DRUG, INCLUDING:

(I) THE DATE THE DRUG WAS RECEIVED.

(II) THE QUANTITY OF THE DRUG.

(III) THE LOT NUMBER OF THE DRUG.

(IV) THE EXPIRATION DATE OF THE DRUG.

(5) INFORMATION RECORDED UNDER THIS SECTION IS MAINTAINED FOR AT LEAST TWO YEARS FROM THE DATE THE DRUG IS REDISPENSED.

(6) THE UNIT DOSE PACKAGE, UNIT OF ISSUE OR ORIGINALLY SEALED CONTAINER STAYS INTACT WITH DRUG NAME, STRENGTH, MANUFACTURER IDENTIFIER, LOT AND EXPIRATION DATE AND IS NOT EMPTIED FROM THE RETURNED UNIT DOSE, UNIT OF ISSUE OR ORIGINAL CONTAINER FOR REPACKING.

(7) THE NAME OF ANY PATIENT FOR WHOM THE DRUG WAS PREVIOUSLY PRESCRIBED IS REMOVED PRIOR TO REDISPENSING.

(8) THE DRUG REMAINS IN THE ORIGINAL CONTAINER OR PACKAGE AND BEFORE REDISPENSING, THE VENDOR PHARMACY ENSURES THAT THE LABEL MEETS THE REQUIREMENTS OF THE STATE BOARD OF PHARMACY'S RULES AND REGULATIONS.

§ 1175. CREDIT FOR REDISPENSING.

THE VENDOR PHARMACY, TO WHICH DRUG PRODUCTS ARE RETURNED, SHALL CREDIT THE CORRECTIONAL FACILITY FOR THE UNUSED DRUGS THAT ARE PERMITTED TO BE RESTOCKED FOR REDISPENSING AT A RATE DETERMINED BY THE VENDOR PHARMACY AND THE CORRECTIONAL FACILITY.

§ 1176. DISPOSAL OF UNACCEPTABLE RETURNED DRUGS.

RETURNED DRUGS THAT DO NOT MEET ALL THE REQUIREMENTS OF SECTION 1173 (RELATING TO RETURN TO AND REDISPENSING BY VENDOR PHARMACY) SHALL BE DEEMED UNACCEPTABLE FOR REDISPENSING AND PROCESSED FOR DISPOSAL. DRUGS DEEMED UNACCEPTABLE FOR REDISPENSING SHALL BE SENT TO A DESTRUCTION AGENCY, REVERSE DISTRIBUTOR, MANUFACTURER, ORIGINAL WHOLESALER OR OTHER APPROVED ENTITY.

§ 1177. UNPROFESSIONAL CONDUCT.

(1) A PHARMACIST WHO IS AUTHORIZED UNDER THIS SUBCHAPTER

TO REDISPENSE A DRUG AND WHO PROPERLY RELABELS AND REPACKAGES THE DRUG SHALL NOT BE DEEMED TO HAVE ENGAGED IN UNPROFESSIONAL CONDUCT UNDER SECTION 5 OF THE ACT OF SEPTEMBER 27, 1961 (P.L.1700, NO.699), KNOWN AS THE PHARMACY ACT.

(2) A PHARMACIST WHO FAILS TO COMPLY WITH THE PROVISIONS OF THIS SUBCHAPTER MAY BE SUBJECT TO DISCIPLINE UNDER THE PHARMACY ACT.

(3) A PHARMACY THAT FAILS TO COMPLY WITH THE PROVISIONS OF THIS SUBCHAPTER MAY BE SUBJECT TO DISCIPLINE UNDER THE PHARMACY ACT.

SECTION 2. THIS ACT SHALL TAKE EFFECT IMMEDIATELY.