

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

1 ~~Providing~~ AMENDING TITLE 61 (PENAL AND CORRECTIONAL 2 INSTITUTIONS) OF THE PENNSYLVANIA CONSOLIDATED STATUTES, 3 PROVIDING for drug redistribution within correctional 4 facilities. ←

5 The General Assembly of the Commonwealth of Pennsylvania 6 hereby enacts as follows:

7 ~~Section 1. Short title.~~ ←

8 ~~This act shall be known and may be cited as the Correctional 9 Facilities Drug Redistribution Act.~~

10 ~~Section 2. Definitions.~~

11 ~~The following words and phrases when used in this act shall 12 have the meanings given to them in this section unless the 13 context clearly indicates otherwise:~~

14 ~~"Correctional facility." A jail, prison, facility, 15 institution, group home, prerelease center, community 16 corrections center, parole center or any facility that houses a 17 a person convicted of a criminal offense, or awaiting trial, 18 sentencing or extradition in a criminal proceeding. The term~~

~~1 includes an institution, facility or unit operated by or for the  
2 Department of Corrections. The term does not include any  
3 facility or institution operated, supervised or licensed under  
4 the act of June 13, 1967 (P.L.31, No.21), known as the Public  
5 Welfare Code.~~

~~6 "Designated personnel." Correctional facility employees or  
7 employees of a vendor for a correctional facility licensed by  
8 the State Board of Medicine, State Board of Osteopathic  
9 Medicine, State Board of Nursing or State Board of Pharmacy and  
10 authorized by their scope of practice to administer drugs.~~

~~11 "Drug." Any medication prescribed by a licensed  
12 practitioner, either patient specific or stock to a patient in a  
13 correctional facility.~~

~~14 "Manufacturer." A company that produces a drug or a Federal  
15 Drug Administration certified repacker who packages or  
16 repackages a drug product for distribution.~~

~~17 "Manufacturer identifier." A manufacturer's name or product  
18 National Drug Code number.~~

~~19 "Unit dose package." An individually sealed package that  
20 contains a single dose drug with the drug name, strength,  
21 manufacturer identifier, lot number and expiration date of the  
22 drug on the package.~~

~~23 "Unit of issue package." A package that includes multiple  
24 unit dose packages of the same drug.~~

~~25 "Vendor pharmacy." A licensed pharmacy that packages,  
26 repackages or prepares a manufacturer sealed container, unit  
27 dose package or unit of issue package for delivery to a  
28 correctional facility.~~

~~29 Section 3. Return to and redispensing by vendor pharmacy.~~

~~30 A drug that is issued to a correctional facility and has left~~

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

5 ~~(1) The drug is not a Schedule I, II, III, IV or V~~  
6 ~~controlled substance as specified in the act of April 14,~~  
7 ~~1972 (P.L.233, No.64), known as The Controlled Substance,~~  
8 ~~Drug, Device and Cosmetic Act.~~

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

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

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

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

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

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

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

1 ~~adulterated or misbranded.~~

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

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

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

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

12 ~~Section 4. Vendor pharmacy redispensing.~~

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

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

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

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

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

25 ~~(i) The date the drug was received.~~

26 ~~(ii) The quantity of the drug.~~

27 ~~(iii) The lot number of the drug.~~

28 ~~(iv) The expiration date of the drug.~~

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

1       ~~redispensed.~~

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

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

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

13       ~~Section 5. Credit for redispensing.~~

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

18       ~~Section 6. Disposal of unacceptable returned drugs.~~

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

25       ~~Section 7. Unprofessional conduct.~~

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

1 Act.

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

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

8 Section 8. Effective date.

9 This act shall take effect immediately.

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



13 SUBCHAPTER D  
14 DRUG REDISTRIBUTION  
15 SEC.

16 1171. SCOPE.

17 1172. DEFINITIONS.

18 1173. RETURN TO AND REDISPENSING BY VENDOR PHARMACY.

19 1174. VENDOR PHARMACY REDISPENSING.

20 1175. CREDIT FOR REDISPENSING.

21 1176. DISPOSAL OF UNACCEPTABLE RETURNED DRUGS.

22 1177. UNPROFESSIONAL CONDUCT.

23 § 1171. SCOPE.

24 THIS SUBCHAPTER RELATES TO CORRECTIONAL FACILITY DRUG  
25 REDISTRIBUTION.

26 § 1172. DEFINITIONS.

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

30 "CORRECTIONAL FACILITY." A CORRECTIONAL INSTITUTION, GROUP

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

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

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

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

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

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

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

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

30 § 1173. RETURN TO AND REDISPENSING BY VENDOR PHARMACY.

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

6 (1) THE DRUG IS NOT A SCHEDULE I, II, III, IV OR V  
7 CONTROLLED SUBSTANCE AS SPECIFIED IN THE ACT OF APRIL 14,  
8 1972 (P.L.233, NO.64), KNOWN AS THE CONTROLLED SUBSTANCE,  
9 DRUG, DEVICE AND COSMETIC ACT.

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

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

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

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

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

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



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

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

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

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

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

14 § 1174. VENDOR PHARMACY REDISPENSING.

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

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

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

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

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

28           (I) THE DATE THE DRUG WAS RECEIVED.

29           (II) THE QUANTITY OF THE DRUG.

30           (III) THE LOT NUMBER OF THE DRUG.

1           (IV) THE EXPIRATION DATE OF THE DRUG.

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

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

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

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

16 § 1175. CREDIT FOR REDISPENSING.

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

21 § 1176. DISPOSAL OF UNACCEPTABLE RETURNED DRUGS.

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

29 § 1177. UNPROFESSIONAL CONDUCT.

30           (1) A PHARMACIST WHO IS AUTHORIZED UNDER THIS SUBCHAPTER

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

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

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

12 SECTION 2. THIS ACT SHALL TAKE EFFECT IMMEDIATELY.