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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 721 Session of 2009

INTRODUCED BY SOLOBAY, BELFANTI, BRENNAN, CARROLL, CREIGHTON, FABRIZIO, GOODMAN, GRUCELA, HORNAMAN, KULA, LONGIETTI, MAHONEY, MANN, McILVAINE SMITH, M. O'BRIEN, PALLONE, PICKETT, READSHAW, SIPTROTH, STABACK, VULAKOVICH, WATSON, WHITE, YOUNGBLOOD, KORTZ, MURT, SEIP AND MIRABITO, MARCH 4, 2009

AS AMENDED ON SECOND CONSIDERATION, HOUSE OF REPRESENTATIVES, AUGUST 5, 2009

AN ACT

~~Providing for prescription drug redistribution within health care and governmental correctional facilities.~~

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 Prescription 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:~~

~~"Crediting fee." The fee imposed by a licensed pharmacist for accepting any portion of an unused, returned prescription, which shall be approved by the Pennsylvania Fair Drug Pricing Board. The crediting fee shall be not less than $3.50 and not~~

more than $7.50 for any prescription.

"FDA." The Federal Food and Drug Administration.

"Health care facility." Any of the following, regardless of whether the facility is for profit, nonprofit or governmental:

(1) A general or specific hospital, including State centers for the mentally retarded and psychiatric hospitals.

(2) Skilled nursing facilities.

(3) Intermediate care facilities.

(4) Personal care homes.

"Hospital." An institution licensed or regulated as a hospital by the Department of Health or the Department of Public Welfare or a facility owned or operated by the Federal Government and accredited by the Joint Commission on Accreditation of Hospitals as a hospital.

"Vendor pharmacy." The licensed pharmacy of origin.

Section 3. Return to and repackaging by vendor pharmacy.

(a) General.--Each health care facility or governmental correctional facility shall return to the vendor pharmacy, for initial repackaging by that vendor pharmacy and redistribution to that health care facility or governmental correctional facility, drug products which are:

(1) prescription drug products that are not controlled substances;

(2) sealed in individually packaged units;

(3) returned to the vendor pharmacy at least 90 days prior to the expiration of the recommended period of shelf life for the purpose of redispensing such drug products; and

(4) oral and parenteral medication in single-dose sealed containers approved by the FDA, topical or inhalant drug products in units of use containers approved by the FDA or

~~parenteral medications in multiple-dose sealed containers approved by the FDA from which no doses have been withdrawn.~~

~~(b) Return to vendor.--Each health care facility or governmental correctional facility shall return to the vendor pharmacy, for subsequent repackaging and redistribution by that vendor pharmacy to that health care facility or governmental correctional facility, drug products that have already been repackaged and redistributed pursuant to subsection (a) if:~~

~~(1) such drug products meet all of the requirements for initial repackaging found in subsection (a);~~

~~(2) the date on which the drug product was last repackaged, the drug product's lot number and the drug product's expiration date are indicated clearly on the package of such repackaged drug;~~

~~(3) 90 days or fewer have elapsed from the date of initial repackaging of such drug product; and~~

~~(4) a repackaging log is maintained by the pharmacy in the case of drug products repackaged in advance of immediate needs.~~

~~(c) Exception.--No drug products dispensed in a bulk-dispensing container, including bottles, may be returned to vendor pharmacy for redistribution.~~

~~(d) Consent not required.--The consent of the individual for whom the unused drugs were originally prescribed shall not be required for reuse and redistribution.~~

~~(e) Rebate.--Nothing in this section shall require a pharmaceutical manufacturer to provide a rebate based on the reuse and redistribution of any unused drug as authorized in subsections (a) and (b).~~

~~(f) Department action.--The appropriate department shall~~

~~implement policies to provide reimbursement for the return of unused drug products to the vendor pharmacy from which such drug products were purchased.~~

~~(g) Fees.--A fee of not more than 15% of the maximum wholesale price plus a crediting fee shall be provided to the vendor pharmacy by the health care facility receiving prepackaged drugs for the return of unused drug products.~~

~~(h) Limitation of liability.--No pharmaceutical manufacturers shall be held liable for any claim or injury arising from the transfer of any prescription drug pursuant to the provisions of this section, including, but not limited to, liability for failure to transfer or communicate product or consumer information regarding the transferred drug, as well as the expiration date of the transferred drug.~~

~~(i) Regulations.--The Department of Health, the Department of Corrections and the State Board of Pharmacy shall promulgate regulations to carry out the provisions of this act, including governing:~~

~~(1) the repackaging and labeling of drug products returned pursuant to subsections (a) and (b); and~~

~~(2) procedures for the return of unused products to the vendor pharmacy from which such drug products were purchased.~~

~~(j) Federal law.--All provisions of this act shall be in compliance with section 1171(4) of the Social Security Act (49 Stat. 620, 42 U.S.C. § 1320d(4)).~~

~~Section 4. Effective date.~~

~~This act shall take effect in 60 days.~~

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 PERSON CONVICTED OF A CRIMINAL OFFENSE OR A PERSON AWAITING TRIAL, SENTENCING OR EXTRADITION IN A CRIMINAL PROCEEDING. EXCEPT FOR AN INSTITUTION, FACILITY OR UNIT OPERATED BY OR FOR THE DEPARTMENT OF CORRECTIONS, THE TERM SHALL NOT INCLUDE A 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." A CORRECTIONAL FACILITY EMPLOYEE OR AN EMPLOYEE OF A VENDOR FOR A CORRECTIONAL FACILITY THAT IS AUTHORIZED BY THE SCOPE OF PRACTICE TO ADMINISTER DRUGS AND IS LICENSED BY THE STATE BOARD OF MEDICINE, STATE BOARD OF OSTEOPATHIC MEDICINE, STATE BOARD OF NURSING OR STATE BOARD OF PHARMACY.

"DRUG." A 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 THAT 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 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 UNIT DOSE PACKAGE, UNIT OF ISSUE PACKAGE OR MANUFACTURER'S PACKAGE RETURNED 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 NEVER 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 LESS 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 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 AND THAT THE DRUG LABELING OR PACKAGING HAS NOT BEEN ALTERED OR DEFACED AND 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, IF ALL OF THE FOLLOWING APPLY:

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

(2) THE DRUGS RETURNED TO THE VENDOR PHARMACY MUST BE 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 ALL OF THE FOLLOWING:

(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 SHALL BE 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 MUST REMAIN IN THE ORIGINAL CONTAINER OR PACKAGE. BEFORE REDISPENSING, THE VENDOR PHARMACY SHALL ENSURE THAT 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 IN 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 AUTHORIZED UNDER THIS ACT TO REDISPENSE A DRUG, 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 20. EFFECTIVE DATE.

THIS ACT SHALL TAKE EFFECT IMMEDIATELY.