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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 AND WHITE, MARCH 4, 2009

REFERRED TO COMMITTEE ON HEALTH AND HUMAN SERVICES, MARCH 4, 2009

AN ACT

Providing for prescription drug redistribution within health care and governmental 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.