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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 540 Session of 2013

INTRODUCED BY KORTZ, DAVIS, STURLA, CALTAGIRONE, MUNDY, DELUCA, V. BROWN, COHEN, HESS, HARKINS AND MCGEEHAN, FEBRUARY 6, 2013

REFERRED TO COMMITEE ON HEALTH, FEBRUARY 6, 2013

AN ACT

Providing for the collection and disposal of leftover and expired medicines and for penalties.

The General Assembly finds and declares that:

(1) Pennsylvania citizens benefit from the authorized use of prescription and nonprescription medicines. The proper use of medicines helps to cure, treat and prevent diseases and to prolong life.

(2) Failure to properly dispose of leftover and expired medicines can lead to the illegal possession and abuse of medicines by children and others, possibly causing addiction, poisonings, overdoses and other harmful health effects.

(3) Disposing of medicines by flushing them down the toilet or placing them in the garbage can lead to the contamination of groundwater and other bodies of water, contributing to degradation of the environment and harm to humans, animals and aquatic life.

(4) Pennsylvania residents need a safe method for disposal of medicines through programs that provide

environmentally sound disposal of medicines with effective controls against diversion.

(5) The costs of properly collecting and disposing of leftover and expired medicines should be included in the manufacturer's business costs and the manufacturers of the medicines are best positioned to efficiently develop and operate programs for the safe and convenient collection and disposal of unused medicines.

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 Pharmaceutical Stewardship 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:

"Controlled substance." A drug, substance or immediate precursor included in Schedules I through V of the act of April 14, 1972 (P.L.233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act.

"Covered drug." As follows:

(1) A lawfully obtained prescription drug and nonprescription drug. The term includes both brand name and generic drugs permitted to be accepted in accordance with Federal and State law.

(2) The term does not include:

(i) Herbal-based remedies and homeopathic drugs, products or remedies.

(ii) Cosmetics, shampoos, sunscreens, toothpaste,

lip balm, antiperspirants or other personal care products that are regulated as both cosmetics and proprietary drugs under the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040, 21 U.S.C. § 301 et seq.).

(iii) Drugs for which a manufacturer provides a take-back program as part of the managed risk evaluation and mitigation strategy under 21 U.S.C. § 355-1 (relating to risk evaluation and mitigation strategies).

(iv) Drugs that are biological products as defined in 21 CFR 600.3(h) (relating to definitions) as it exists on the effective date of this section if the manufacturer already provides a take-back program.

(v) Pet pesticides contained in pet collars, powders or shampoos.

"Department." The Department of Health of the Commonwealth.

"Drug." Any of the following:

(1) Substances recognized in the official United States Pharmacopeia, or official National Formulary, or any supplement to either of them.

(2) Substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals.

(3) Substances, other than food, intended to affect the structure or any function of the human body or other animal body.

(4) Substances intended for use as a component of any article specified under paragraphs (1), (2) and (3).

"Generic drug." A drug that is chemically identical or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance

characteristics and intended use, though inactive ingredients may vary.

"Mail-back program." A system whereby residential sources of unwanted covered drugs obtain prepaid and preaddressed mailing envelopes for shipment to an entity that will dispose of them safely and legally.

"Manufacture." As follows:

(1) Any of the following:

(i) The production, preparation, propagation, compounding, conversion or processing of a drug or controlled substance.

(ii) The packaging or repackaging of a substance under subparagraph (i).

(iii) The labeling or relabeling of the commercial container of a substance under subparagraph (i).

(2) The term does not include the activities of a practitioner who, as an incident to his administration or dispensing the substance in the course of his professional practice, prepares, compounds, packages or labels the substance.

"Manufacturer." A person lawfully authorized to manufacture a drug or controlled substance.

"Nonproprietary drug." A drug or controlled substance required by any applicable Federal or State law to be dispensed only by prescription.

"Pharmaceutical stewardship program." A program operated by a manufacturer, group of manufacturers or an association for the collection, transportation and disposal of unwanted covered drugs from residential sources that is financed by the manufacturers of those products.

"Proprietary drug." Nonprescription, nonnarcotic medicines or drugs which may be sold without a prescription and which are prepackaged for use by the consumer and labeled in accordance with Federal and State requirements.

"Residential sources." As follows:

(1) Single and multiple-family residences and locations where household drugs are unused, unwanted, disposed or abandoned.

(2) The term does not include drugs from hospitals, clinics, pharmacies, airport security, drug seizures by law enforcement, businesses or other nonresidential or business sources.

"Ultimate user." A person who lawfully possesses a drug or controlled substance for his own use or for the use of a member of his household or for administering to an animal in his care.

"Unwanted covered drug." Any covered drug no longer wanted by its ultimate user or that has been abandoned, discarded or is intended to be discarded by its ultimate user.

Section 3. Pharmaceutical stewardship program.

(a) Participation required.--Beginning January 1, 2015, any manufacturer offering a covered drug for sale in this Commonwealth must operate or participate in an approved pharmaceutical stewardship program prior to offering covered drugs for sale in Pennsylvania.

(b) Submittal.--After January 1, 2015, any manufacturer who intends to offer covered drugs for sale in this Commonwealth must have received an approval to operate a pharmaceutical stewardship program plan from the department or provide evidence of having joined an existing pharmaceutical stewardship program to the department at least 45 days prior to the manufacturer's

initial offer of sale of covered drugs.

(c) Program requirements.--A pharmaceutical stewardship program plan must meet or include all of the following:

(1) Implementation of the pharmaceutical stewardship program without charging a line item fee for the cost of the program visible to the consumer at the time of sale of the covered drugs or at the time the unwanted covered drugs are delivered or collected for disposal from residential sources.

(2) A description of a proposed collection system which shall include all of the following:

(i) (A) Except as provided under clause (B), at least one collection site in each county. At least one of the collection sites in each county shall have Federal authorization to collect lawfully obtained controlled substances.

(B) Counties with the following populations based on the most recent Federal decennial census shall have collection sites as follows:

(I) A county with a population of 100,001 to 300,000 shall have at least two collection sites.

(II) A county with a population of 300,001 to 1,000,000 shall have at least three collection sites.

(III) A county with a population in excess of 1,000,000 shall have at least four collection sites.

(C) Except for a county of the first class, a collection site under this subparagraph may not be established in the same municipality as a collection site under subparagraph (ii).

(ii) At least one collection site in every municipality with a population over 50,000 in the most recent Federal decennial census. Collection sites established under subparagraph (i) may not be used to meet the requirements under this subparagraph.

(iii) A mail-back program for unwanted covered drugs. Envelopes for the program must be made available at each collection site and to any pharmacy in the county interested in providing envelopes to their customers.

(3) A handling and disposal system, including:

(i) Identification of and contact information for disposal facilities and other entities to be used by the program to collect and destroy the unwanted covered drugs.

(ii) The policies and procedures to be followed by persons handling and transporting unwanted covered drugs collected under the pharmaceutical stewardship program.

(iii) A description of how the collected unwanted covered drugs are tracked through to final disposal and how safety and security is maintained.

(iv) Final disposal or reuse technologies that provide superior environmental and human health protection compared with current disposal technologies for unwanted covered drugs, if approved by the department upon petition. The department may not approve the use of an alternative proposed technology unless the petitioners have presented clear and convincing evidence that the technology's performance under field conditions provides equivalent protection in each and superior protection in one or more of the following areas:

(A) Monitoring emissions or waste.

(B) Worker health and safety.

(C) Air, water or land emissions contributing to persistent, bioaccumulative and toxic pollution.

(D) Overall impact to the environment and human health.

(v) Separation of unwanted covered drugs from their original containers, if appropriate, prior to disposal.

(4) A list of all entities participating in the collection, handling and disposal proposed in the pharmaceutical stewardship program and the entities' contact information.

(5) Certification that the pharmaceutical stewardship program will accept all unwanted covered drugs, including unwanted covered drugs from other manufacturers.

(6) An education and outreach program that shall include:

(i) A toll-free phone number and a website which shall provide information on the pharmaceutical stewardship program and a list of all collections sites and allow a person to request that a mail-back program envelope be mailed to them.

(ii) Printed brochures and posters describing where and how to return unwanted covered drugs provided at no cost to pharmacies, health care facilities and other interested parties.

(7) Performance goals, including recovery goals expressed as pounds of unwanted covered drugs disposed of per capita and an explanation of how the recovery goals have been set to recover a significant percentage of unwanted covered

drugs relative to the quantity of unwanted covered drugs that may be available for disposal.

(8) Operation of the pharmaceutical stewardship program in accordance with this act and other applicable Federal and State laws.

(9) A specific date for implementation.

(d) Secure and Responsible Drug Disposal Act of 2010.--Within 180 days after promulgation of Federal regulations authorized under the Secure and Responsible Drug Disposal Act of 2010 (P.L. 111-273), each pharmaceutical stewardship program shall submit an updated plan reflecting any necessary changes required by the Federal regulations.

Section 4. Department review and approval.

(a) Approval required.--No manufacturer or other entity may collect unwanted covered drugs until it has received written approval or renewal of its pharmaceutical stewardship program plan from the department.

(b) Compliance.--Within 90 days after receipt of a pharmaceutical stewardship program plan, the department shall determine whether it complies with this act. If it is deemed in compliance with this act, the department shall notify the applicant of its approval in writing. If the pharmaceutical stewardship program plan is rejected, the department shall notify the applicant in writing of its reasons for rejection.

(c) Review.--

(1) A manufacturer or other entity operating a pharmaceutical stewardship program shall conduct an internal evaluation of its program which shall be submitted to the department as follows:

(i) Two years after implementation of the plan.

(ii) Five years after implementation of the plan, and every five years thereafter.

(2) The department shall review the internal evaluations submitted under this subsection and shall grant or deny approval for the continued operation of the program in accordance with the procedures under subsection (b).

(d) Substantive changes.--Any substantive changes to a pharmaceutical stewardship program plan must be approved by the department in writing.

Section 5. Report.

On or before April 1, 2016, and each April thereafter, a pharmaceutical stewardship program under section 3(b) must prepare and submit an annual report describing the program's activities during the previous calendar year to the department. The report must include all of the following:

(1) A list of manufacturers participating in the pharmaceutical stewardship program.

(2) The amount, by weight, of unwanted covered drugs collected at each site and the total amount by weight collected by a mail-back program.

(3) A list of the collection sites provided in each county, including the location of each collection site and locations where envelopes for a mail-back program are provided.

(4) The name and location of disposal facilities at which unwanted covered drugs were disposed of and the weight of unwanted covered drugs disposed of at each facility.

(5) If packaging was separated from the unwanted covered drugs prior to disposal, the amount and percentage of packaging recycled and the name and location of the material

recovery facility to which it was delivered.

(6) Whether policies and procedures for collecting, transporting and disposing of unwanted covered drugs, as established in the pharmaceutical stewardship program plan, were followed during the reporting period and a description of any noncompliance.

(7) Whether any safety or security problems occurred during collection, transportation or disposal of unwanted covered drugs during the reporting period and, if so, what changes have or will be made to policies, procedures or tracking mechanisms to alleviate the problem and to improve safety and security.

(8) A description of public education and outreach activities implemented during the reporting period, including the methodology used to evaluate the outreach and program activities.

(9) Any other information that the agency may reasonably require.

Section 6. Enforcement.

(a) Penalty for nonimplementation.--If an approved pharmaceutical stewardship program plan is not fully implemented as follows, the department shall assess the following penalties for each calendar day along with written notification to each manufacturer associated with the pharmaceutical stewardship program plan:

(1) If full implementation has not occurred within 30 days of the start date contained in the pharmaceutical stewardship program plan, the department shall assess a penalty of $5,000 against the manufacturer or entity that developed the pharmaceutical stewardship program under

section 3(b).

(2) If full implementation has not occurred within 60 days of the start date contained in the pharmaceutical stewardship program plan, the department shall assess a penalty of $10,000 against the manufacturer or entity that developed the pharmaceutical stewardship program under section 3(b).

(b) Penalty for noncompliance.--If the department finds that a pharmaceutical stewardship program is not in compliance with its approved plan, the department must notify in writing each manufacturer in the pharmaceutical stewardship program of the violation and allow the manufacturer or entity operating the pharmaceutical stewardship program 30 days to correct the noncompliance. After 30 days, the manufacturer or entity operating the pharmaceutical stewardship program under section 3(b) shall be assessed a penalty of $5,000 for the first violation and $10,000 for each subsequent violation. Subsequent violations shall occur after each ten days of noncompliance under this subsection.

(c) Penalty for nonparticipation.--

(1) Upon first determining that a manufacturer is offering a covered drug for sale in this Commonwealth but is not participating in a pharmaceutical stewardship program approved by the agency, the department shall send the manufacturer a written warning that the manufacturer is in violation of this act.

(2) A manufacturer not participating in a pharmaceutical stewardship program approved by the department whose covered drug continues to be sold in this Commonwealth 60 days after receiving a written warning from the department shall be

assessed a penalty of $10,000 for each calendar day that the violation continues.

Section 20. Effective date.

This act shall take effect in 90 days.