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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 1500 Session of 2011

INTRODUCED BY BEAR, BARRAR, SANTONI, BENNINGHOFF, AUMENT, BAKER, BOBACK, BOYD, CALTAGIRONE, CAUSER, COHEN, D. COSTA, COX, CREIGHTON, CUTLER, DAVIS, DELOZIER, DENLINGER, DeWEESE, DONATUCCI, EMRICK, EVERETT, FARRY, FLECK, GEIST, GEORGE, GIBBONS, GILLEN, GINGRICH, GOODMAN, GRELL, GROVE, HACKETT, HARRIS, HEFFLEY, HENNESSEY, HICKERNELL, HUTCHINSON, KILLION, KORTZ, MAJOR, MARSHALL, METCALFE, MICCARELLI, MICOZZIE, MILLARD, MILLER, MILNE, MOUL, MURT, O'NEILL, PERRY, PETRI, PICKETT, PYLE, RAPP, READSHAW, REED, ROCK, SAYLOR, SCAVELLO, STEPHENS, SWANGER, TALLMAN, TAYLOR, VULAKOVICH AND WATSON, MAY 9, 2011

AS REPORTED FROM COMMITTEE ON VETERANS AFFAIRS AND EMERGENCY PREPAREDNESS, HOUSE OF REPRESENTATIVES, AS AMENDED, JUNE 15, 2011

AN ACT

Amending Title 51 (Military Affairs) of the Pennsylvania Consolidated Statutes, consolidating the Long-Term Care Patient Access to Pharmaceuticals Act; further providing for declaration of policy, for definitions and for third-party drugs in long-term care facilities; and making a related repeal.

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

Section 1. Title 51 of the Pennsylvania Consolidated Statutes is amended by adding a chapter to read:

CHAPTER 95

LONG-TERM CARE PATIENT ACCESS TO PHARMACEUTICALS

Sec.

9502. Declaration of policy.
9503. Definitions.
9504. State Board of Pharmacy.
9505. Third-party drugs in long-term care facilities.
9506. Recordkeeping.
9507. Fee.
9508. Civil liability and unprofessional conduct.

§ 9501. Scope of chapter.

This chapter relates to long-term care patient access to pharmaceuticals.

§ 9502. Declaration of policy.

The General Assembly finds and declares as follows:

(1) A mechanism is to be provided through which patients who have the ability to acquire lower cost drugs through the UNITED STATES Department of Veterans Affairs have access to those drugs if they reside in a long-term care facility. ←

(2) The mechanism is to be provided by permitting the pharmacy within the long-term care facility or which has a contract with the long-term care facility to:

(i) receive the lower cost drugs directly from the UNITED STATES Department of Veterans Affairs drug benefit program in the patient's name; and ←

(ii) repackage and relabel those drugs so they may be dispensed in unit doses to patients in a long-term care facility in compliance with the Food and Drug Administration, the United States Pharmacopeia and the long-term care facility's policies and procedures.

(3) This chapter shall be interpreted and construed to effectuate the following purposes:

(i) To provide for the care, protection and

treatment of patients in long-term care facilities by allowing them to utilize the drug benefit provided by the UNITED STATES Department of Veterans Affairs.

(ii) Consistent with the care, protection and treatment of patients in long-term care facilities, to provide a means by which a long-term care pharmacy may:

(A) accept, on behalf of the patient, drugs received directly from the UNITED STATES Department of Veterans Affairs; and

(B) repackage and relabel those drugs so that the patient may receive them in a unit dose in compliance with the Food and Drug Administration, the United States Pharmacopeia and the long-term care facility's policies and procedures.

(iii) To provide a means through which this chapter is executed and enforced and in which long-term care facilities, pharmacists, drug source facilities and pharmaceutical providers may implement this chapter.

(4) Only individuals eligible for benefits provided by the UNITED STATES Department of Veterans Affairs are eligible for the program under this chapter.

§ 9503. Definitions.

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

"Board." The State Board of Pharmacy.

"Drug source facility." A facility:

(1) where drugs are lawfully manufactured, dispensed or distributed; and

(2) which is:

(i) operated by or under contract with the UNITED STATES Department of Veterans Affairs; or

(ii) approved by the UNITED STATES Department of Veterans Affairs.

"Lockbox." A cabinet ~~or safe~~, SAFE, CONTAINER OR OTHER STRUCTURE to contain medications that shall be securely locked, substantially constructed and accessible only to the pharmacist or his representative as authorized by the regulations of the State Board of Pharmacy.

"Long-term care facility." A long-term care nursing facility as defined in section 802.1 of the act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities Act.

"Means." The placement of a lockbox at a ~~secure drop-off~~ location at the long-term care facility.

"Pharmaceutical provider." An entity that employs a pharmacist.

§ 9504. State Board of Pharmacy.

The board has the following powers and duties:

(1) Develop the form required by section 9505(b)(3) and (4) (relating to third-party drugs in long-term care facilities).

(2) Publish a notice in the Pennsylvania Bulletin that the form has been developed.

§ 9505. Third-party drugs in long-term care facilities.

(a) Authority.--Notwithstanding any other provision of law, all of the following may dispense a drug acquired from a drug source facility outside the long-term care facility to a patient of a long-term care facility:

(1) A pharmacist employed by a long-term care facility.

(2) A pharmacy that contracts with a long-term care

facility to fill prescriptions for patients of the long-term care facility.

(b) Unit dose.--A person authorized under subsection (a) to dispense a drug shall repackage, relabel and dispense the drug in a unit dose if all of the following conditions are met:

(1) The drug is obtained from a drug source facility.

(2) There is a prescription for the drug.

(3) The prescriber has signed a form authorizing the long-term care facility to administer a drug from a drug source facility outside the long-term care facility.

(4) The patient has signed a form authorizing the long-term care facility to administer a drug from a drug source facility outside the long-term care facility and provided payment information for payment of the related fees to the pharmacy. In the case of a minor or a patient who is unable to sign the form, a parent, a guardian, an agent acting under a power of attorney or a family member is authorized to sign the form. The form must explain that a person authorized under subsection (a) to dispense a drug from a drug source facility outside the long-term care facility:

(i) is required to go through the process of repackaging and relabeling the drug;

(ii) may charge a fee for repackaging and relabeling the drug, including the amount of the fee and the frequency of its assessment; and

(iii) has immunity from civil liability arising from dispensation of the drug if the person properly repackages and relabels the drug as set forth in section 9508 (relating to civil liability and unprofessional conduct).

(5) The nursing facility attending physician has issued an order continuing the patient's medical regime.

(6) The repackaging is in compliance with the Food and Drug Administration, the United States Pharmacopeia and the long-term care facility's policies and procedures.

(7) The UNITED STATES Department of Veterans Affairs provides the drug ~~by mailing it to a lockbox located at~~ DIRECTLY TO THE PHARMACY IN the long-term care facility in the patient's name OR BY MAILING IT TO A LOCKBOX LOCATED AT THE LONG-TERM CARE FACILITY IN THE PATIENT'S NAME and with the following information in preparation for the repackaging and relabeling:

(i) The name and address of the dispensing pharmacy.

(ii) (Reserved).

(iii) (Reserved).

(iv) A copy of the original prescription upon request.

(v) The date the drug was dispensed.

(vi) Directions for use, contraindications and other materials required by law to be provided to the patient.

~~(8) A pharmacist shall be held responsible for his activity or activity performed under his supervision or authorization.~~

~~(9)~~ (8) The pharmacist manager of the long-term care pharmacy responsible for access to the lockbox shall be responsible for the following:

(i) Reviewing and approving written policies and procedures for lockbox operation, safety, security, accuracy, access and patient confidentiality.

(ii) Ensuring that medications received at the

lockbox are inspected for expiration date, misbranding and physical integrity and ensuring that the lockbox is inspected for security and accountability every month.

(iii) Inspecting medications received at the lockbox to determine if:

(A) the original contents have deteriorated significantly due to heat, cold fermentation or prolonged agitation; or

(B) the sensors indicate the integrity of the drug was compromised if the drugs were shipped in a manner that would preserve the integrity of the drug, such as cold packs or other temperature control devices.

(iv) Assigning, discontinuing or changing authorized personnel access to the lockbox.

(v) Ensuring that an accountability record is maintained in accordance with the written policies and procedures of operation.

(vi) Ensuring compliance with the applicable provisions of Federal and State law.

§ 9506. Recordkeeping.

For each drug dispensed in accordance with section 9505(a) (relating to third-party drugs in long-term care facilities), the person authorized to dispense the drug and the long-term care facility shall maintain a record for at least two years of all of the items specified in section 9505(b)(7).

§ 9507. Fee.

A person authorized under section 9505(a) (relating to third-party drugs in long-term care facilities) to dispense a drug may charge no more than the maximum dispensing fee authorized by the

Department of Public Welfare regulations under the medical assistance program.

§ 9508. Civil liability and unprofessional conduct.

(a) Repackaging and relabeling.--A person authorized under section 9505(a) (relating to third-party drugs in long-term care facilities) to dispense a drug shall be immune from civil liability arising out of dispensation of the drug if the person properly repackages and relabels a drug based on the information received from the original drug source facility.

(b) Administration of drug.--A long-term care facility or an employee or agent of a long-term care facility that properly administers a drug from a person authorized under section 9505(a) to dispense the drug shall be immune from civil liability arising out of administration of the drug.

(c) Unprofessional conduct.--A pharmacist authorized under section 9505(a) to dispense a drug who properly relabels and repackages the drug shall not be deemed to have engaged in unprofessional conduct under section 5(9) of the act of September 27, 1961 (P.L.1700, No.699), known as the Pharmacy Act.

Section 2. Repeals are as follows:

(1) The General Assembly declares that the repeal under paragraph (2) is necessary to effectuate the addition of 51 Pa.C.S. Ch. 95.

(2) The act of October 9, 2008 (P.L.1413, No.114), known as the Long-Term Care Patient Access to Pharmaceuticals Act, is repealed.

Section 3. The addition of 51 Pa.C.S. Ch. 95 is a continuation of the act of October 9, 2008 (P.L.1413, No.114), known as the Long-Term Care Patient Access to Pharmaceuticals

Act. The following apply:

(1) Except as otherwise provided in 51 Pa.C.S. Ch. 95, all activities initiated under the Long-Term Care Patient Access to Pharmaceuticals Act shall continue and remain in full force and effect and may be completed under 51 Pa.C.S. Ch. 95. Orders, regulations, rules and decisions which were made under the Long-Term Care Patient Access to Pharmaceuticals Act and which are in effect on the effective date of section 2 of this act shall remain in full force and effect until revoked, vacated or modified under 51 Pa.C.S. Ch. 95. Contracts, obligations and collective bargaining agreements entered into under the Long-Term Care Patient Access to Pharmaceuticals Act are not affected nor impaired by the repeal of the Long-Term Care Patient Access to Pharmaceuticals Act.

(2) Except as set forth in paragraph (3), any difference in language between 51 Pa.C.S. Ch. 95 and the Long-Term Care Patient Access to Pharmaceuticals Act is intended only to conform to the style of the Pennsylvania Consolidated Statutes and is not intended to change or affect the legislative intent, judicial construction or administration and implementation of the Long-Term Care Patient Access to Pharmaceuticals Act.

(3) Paragraph (2) does not apply to the addition of the following provisions of Title 51:

(i) Section 9502(3)(ii).

(ii) The definitions of "lockbox" and "means" in section 9503.

(iii) Section 9505(b)(7) introductory paragraph, (ii), (iii) and (iv)~~, (8) and (9)~~ AND (8). ←

Section 4. This act shall take effect as follows:

(1) The following provisions shall shall take effect immediately:

(i) Section 3 of this act.

(ii) This section.

(2) The remainder of this act shall take effect in 60 days.