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THE GENERAL ASSEMBLY OF PENNSYLVANIA

# SENATE BILL

## No. 808 Session of 2005

INTRODUCED BY ARMSTRONG, FERLO, BROWNE, M. WHITE, TARTAGLIONE, PIPPY, WOZNIAK, RAFFERTY AND LEMMOND, JUNE 28, 2005

SENATOR CORMAN, PUBLIC HEALTH AND WELFARE, AS AMENDED, JUNE 20, 2006

AN ACT

Providing for long-term care patient access to pharmaceuticals; and conferring powers and duties on the State Board of Pharmacy.

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 Long-Term Care Patient Access to Pharmaceuticals Act.

Section 2. Legislative intent.

The General Assembly finds and declares as follows:

(1) A mechanism is to be provided whereby patients who have the ability to acquire lower cost drugs through ~~a~~ <—
~~Federal or State program, any insurance benefit program or provider or another entity,~~ THE VETERANS' ADMINISTRATION 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 ~~from the Federal or State program, insurance program or provider or other entity~~ DIRECTLY FROM THE VETERANS' ADMINISTRATION DRUG BENEFIT PROGRAM IN PATIENT'S NAME; and

(ii) repackage and relabel those drugs so they may be dispensed in unit doses IN COMPLIANCE WITH THE FOOD AND DRUG ADMINISTRATION, THE UNITED STATES PHARMACOPEIA AND THE LONG-TERM CARE FACILITY'S POLICIES AND PROCEDURES to patients in a long-term care facility.

(3) This act 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 ~~Federal Government or State government, any insurance program or provider or any other entity.~~ VETERANS' ADMINISTRATION.

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

(A) accept, on behalf of the patient, drugs ~~received from a Federal or State program, any insurance program or provider or another entity; and~~ RECEIVED DIRECTLY FROM THE VETERANS' ADMINISTRATION; 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 the provisions of this act are executed and enforced and in which long-term care facilities, pharmacists, drug source facilities and pharmaceutical providers may implement the provisions of this act.

Section 3. 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:

"Board." The State Board of Pharmacy.

"Drug source facility." A facility where drugs are lawfully manufactured, dispensed or distributed. The term includes a pharmacy, an entity and a Federal or State agency or instrumentality.

"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.

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

Section 4. State Board of Pharmacy.

The board has the following powers and duties:

(1) Develop the form required by section 5(b)(3) and (4).

~~(2) Promulgate regulations to set the fee under section 7. Included in this rulemaking, the board shall make a statement that the forms under paragraph (1) have been developed.~~ <—

~~(3) Provide a written report every 90 days regarding the steps taken by the board to implement paragraphs (1) and (2), to all of the following:~~

~~(i) The Consumer Protection and Professional Licensure Committee of the Senate.~~

~~(ii) The Professional Licensure Committee of the House of Representatives.~~

~~(iii) The Commissioner of the Bureau of Professional and Occupational Affairs.~~

~~(iv) The Secretary of the Commonwealth.~~

(2) PUBLISH A NOTICE IN THE PENNSYLVANIA BULLETIN THAT THE FORM HAS BEEN DEVELOPED. <——

Section 5. 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 ~~pharmacist~~ PHARMACY who contracts with a long-term care facility to fill prescriptions for patients of the long-term care facility. <——

~~(3) A pharmaceutical provider 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 NOT TO EXCEED $20 FOR UP TO 90 UNITS PER DRUG, $10 ADDITIONAL FOR HALF TABLETS AND $10 FOR EACH ADDITIONAL 90 UNITS; 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 8.

(5) THE NURSING FACILITY ATTENDING PHYSICIAN HAS ISSUED AN ORDER CONTINUING THE PATIENT'S MEDICAL REGIME.

(6) THE DRUG IS NOT A CONTROLLED SUBSTANCE.

(7) 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.

(8) THE VETERANS' ADMINISTRATION PROVIDES THE DRUG

DIRECTLY TO THE LONG-TERM CARE PHARMACY 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) THE NAME OF THE DISPENSING PHARMACIST.

(III) THE LOT NUMBER OF THE DRUG.

(IV) A COPY OF THE ORIGINAL PRESCRIPTION.

(V) THE DATE THE DRUG WAS DISPENSED.

(VI) DIRECTIONS FOR USE, CONTRAINDICATIONS AND OTHER MATERIALS REQUIRED BY LAW TO BE PROVIDED TO THE PATIENT.

Section 6. Recordkeeping.

For each drug dispensed in accordance with section 5(a), 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 ~~following~~ ITEMS SPECIFIED IN SECTION 5(B)(8): <—

(1) The name and quantity of the drug prescribed, including whether the prescription is a controlled substance or if it was written PRN or ad lib refill.

(2) The name and address of the patient to whom it was dispensed.

(3) The name and address or other identifier of the prescriber.

(4) The date the prescription was issued and the date the drug was dispensed.

(5) Directions for use, including cautions communicated to the patient by auxiliary labels or other means when dispensed.

(6) The date the prescription was compounded or dispensed.

(7) The name and address of the dispensing pharmacist.

(8) The drug source facility which provided the drug.

Section 7. Fee.

A person authorized under 5(a) to dispense a drug may charge a reasonable fee~~, set by the board,~~ to repackage and relabel the drug. <—

Section 8. Civil liability and unprofessional conduct.

(a) Repackaging and relabeling.--A person authorized under section 5(a) 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 5(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 5(a)(3) to dispense 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.

Section 40. Effective date.

~~This act shall take effect as follows:~~ <—

~~(1) The following provisions shall take effect upon publication of the rulemaking in the Pennsylvania Bulletin under section 4(2):~~

~~(i) Section 5.~~

~~(ii) Section 7.~~

~~(2) The remainder of this act shall take effect immediately.~~

THIS ACT SHALL TAKE EFFECT 90 DAYS FOLLOWING THE PUBLICATION <—
OF THE RULEMAKING IN THE PENNSYLVANIA BULLETIN UNDER SECTION
4(1).