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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 1022 Session of 2005

INTRODUCED BY BOYD, DeWEESE, STERN, KOTIK, RUBLEY, TRUE, DALLY, TIGUE, HERSHEY, CALTAGIRONE, SHANER, PICKETT, LEH, R. MILLER, ROSS, HENNESSEY, FREEMAN, WALKO, GEIST, REICHLEY, DENLINGER, CAWLEY, BALDWIN, LEACH, E. Z. TAYLOR, MANDERINO, JAMES, SOLOBAY, GINGRICH, HICKERNELL, HARPER, GOODMAN, WILT, O'NEILL, NICKOL, YOUNGBLOOD, DeLUCA, ROHRER, ARMSTRONG, FABRIZIO, MACKERETH, SAYLOR, STETLER, B. SMITH, WATSON AND KILLION, MARCH 16, 2005

AS REPORTED FROM COMMITTEE ON HEALTH AND HUMAN SERVICES, HOUSE OF REPRESENTATIVES, AS AMENDED, JANUARY 24, 2006

AN ACT

Providing for long-term care patient access to pharmaceuticals; and conferring powers and duties on the State Board of Pharmacy AND THE LEGISLATIVE BUDGET AND FINANCE COMMITTEE. <—

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, 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; and

(ii) repackage and relabel those drugs so they may be dispensed in unit doses 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.

(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

(B) repackage and relabel those drugs so that the patient may receive them in a unit dose.

(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~~ SOURCES 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.

"DISPENSE." AS RELATED TO A DRUG, TO PREPARE THE DRUG FOR SUBSEQUENT ADMINISTRATION TO A PATIENT. THE TERM INCLUDES: <—

(1) THE ACT OF SCREENING THE DRUG FOR POTENTIAL DRUG THERAPY PROBLEMS, INCLUDING REVIEWING POSSIBLE DRUG INTERACTIONS, REVIEWING THE DOSAGE AND DURATION OF DRUG THERAPY, REVIEWING CONTRAINDICATIONS OF THE DRUG, REVIEWING INFORMATION REGARDING THE PATIENT AND PHARMACEUTICAL COVERAGE AND COMPOUNDING AND MIXING THE DRUG; AND

(2) ANY OTHER ACTIVITY ASSOCIATED WITH REVIEW OF THE DRUG WHICH IS DESIGNED TO ENSURE THE SAFETY OF THE DRUG.

"DRUG." MEDICATION WHICH HAS BEEN APPROVED BY THE FOOD AND DRUG ADMINISTRATION. THE TERM DOES NOT INCLUDE MEDICATION WHICH IS PROVIDED UNDER TITLE XVIII PT. D OF THE SOCIAL SECURITY ACT (49 STAT. 620, 42 U.S.C. § 1395W-101 ET SEQ.).

"Drug ~~source facility." A facility where~~ SOURCE." A FACILITY WHERE OR A PROGRAM UNDER WHICH drugs are lawfully manufactured, dispensed or distributed. The term includes a pharmacy, an entity and a Federal or State agency or instrumentality. THE TERM DOES NOT INCLUDE A LONG-TERM CARE 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.

"LONG-TERM CARE PHARMACY." ANY OF THE FOLLOWING: <—

(1) A PHARMACY WITHIN A LONG-TERM CARE FACILITY.

(2) A PHARMACIST EMPLOYED BY A LONG-TERM CARE FACILITY WHO FILLS PRESCRIPTIONS FOR PATIENTS OF A LONG-TERM CARE FACILITY.

(3) A PHARMACIST WHO CONTRACTS WITH A LONG-TERM CARE FACILITY TO FILL PRESCRIPTIONS FOR PATIENTS OF A LONG-TERM CARE FACILITY.

(4) A PHARMACEUTICAL PROVIDER THAT CONTRACTS WITH A LONG-TERM CARE FACILITY TO FILL PRESCRIPTIONS FOR PATIENTS OF A LONG-TERM CARE FACILITY.

"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) (relating to third-party drugs in long-term care facilities).~~ <—

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

(1) WITHIN 90 DAYS OF THE EFFECTIVE DATE OF THIS PARAGRAPH, DEVELOP THE FORM REQUIRED BY SECTION 5(C)(1)(III) AND (2)(III) AND (E). <—

(2) DISTRIBUTE THE FORM, UPON REQUEST, TO LONG-TERM CARE FACILITIES, PHYSICIANS, LONG-TERM CARE PHARMACIES, PHARMACISTS AND THE PUBLIC.

(3) MAKE THE FORM AVAILABLE ELECTRONICALLY VIA THE INTERNET.

~~(3)~~ (4) Provide a written report every ~~90~~ 30 days regarding the steps taken by the board to implement <—

paragraphs (1) and ~~(2)~~ (3), 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.

~~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 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. 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 8 (relating to civil liability and unprofessional conduct).~~

SECTION 5. AUTHORIZATION TO ADMINISTER AND DISPENSE DRUGS OBTAINED OUTSIDE OF LONG-TERM CARE PHARMACY. <——

(A) LONG-TERM CARE FACILITIES.--NOTWITHSTANDING ANY OTHER PROVISION OF LAW TO THE CONTRARY, A LONG-TERM CARE FACILITY MAY ADMINISTER A DRUG ACQUIRED FROM A DRUG SOURCE TO A PATIENT OF A LONG-TERM CARE FACILITY.

(B) LONG-TERM CARE PHARMACIES.--NOTWITHSTANDING ANY OTHER PROVISION OF LAW TO THE CONTRARY, A LONG-TERM CARE PHARMACY MAY DISPENSE A DRUG ACQUIRED FROM A DRUG SOURCE FOR ADMINISTRATION TO A PATIENT OF A LONG-TERM CARE FACILITY.

(C) PROVISION OF DRUG TO PATIENT.--

(1) A LONG-TERM CARE FACILITY SHALL ADMINISTER A DRUG ACQUIRED FROM A DRUG SOURCE TO A PATIENT OF A LONG-TERM CARE

FACILITY IF ALL OF THE FOLLOWING CONDITIONS ARE MET:

(I) THE DRUG IS ACQUIRED FROM A DRUG SOURCE.

(II) THERE IS A PRESCRIPTION FOR THE DRUG.

(III) THE PATIENT HAS SIGNED A FORM UNDER SUBSECTION (E) AUTHORIZING THE LONG-TERM CARE FACILITY TO ADMINISTER A DRUG ACQUIRED FROM A DRUG SOURCE. IN THE CASE OF A MINOR OR PATIENT WHO IS UNABLE TO SIGN THE FORM, A PARENT, GUARDIAN, AN AGENT ACTING UNDER A POWER OF ATTORNEY OR A FAMILY MEMBER IS AUTHORIZED TO SIGN THE FORM.

(2) A LONG-TERM CARE PHARMACY SHALL DISPENSE A DRUG ACQUIRED FROM A DRUG SOURCE TO A PATIENT OF A LONG-TERM CARE FACILITY IF ALL OF THE FOLLOWING CONDITIONS ARE MET:

(I) THE DRUG IS ACQUIRED FROM A DRUG SOURCE.

(II) THERE IS A PRESCRIPTION FOR THE DRUG.

(III) THE PATIENT HAS SIGNED A FORM UNDER SUBSECTION (E) AUTHORIZING THE LONG-TERM CARE PHARMACY TO DISPENSE A DRUG ACQUIRED FROM A DRUG SOURCE. IN THE CASE OF A MINOR OR PATIENT WHO IS UNABLE TO SIGN THE FORM, A PARENT, GUARDIAN, AN AGENT ACTING UNDER A POWER OF ATTORNEY OR A FAMILY MEMBER IS AUTHORIZED TO SIGN THE FORM.

(D) UNIT DOSE.--A LONG-TERM CARE PHARMACY SHALL REPACKAGE, RELABEL AND DISPENSE A DRUG ACQUIRED FROM A DRUG SOURCE IN UNIT DOSES OR SUCH OTHER FORMS AS TO ENABLE A LONG-TERM CARE FACILITY TO ADMINISTER THE DRUG TO A PATIENT SAFELY AND IN A MANNER AND FORM THAT CONFORM WITH THE LONG-TERM CARE FACILITY'S DRUG ADMINISTRATION PROCEDURES AND QUALITY ASSURANCE STANDARDS.

(E) CONTENTS OF FORM.--AN AUTHORIZATION UNDER SUBSECTION (C)(1)(III) AND (2)(III) MUST EXPLAIN THAT A LONG-TERM CARE PHARMACY:

(1) IS REQUIRED TO GO THROUGH THE PROCESS OF DISPENSING, REPACKAGING AND RELABELING THE DRUG SO THAT THE DRUG MAY BE ADMINISTERED SAFELY AND IN A MANNER AND FORM THAT CONFORM TO THE LONG-TERM CARE FACILITY'S DRUG ADMINISTRATION PROCEDURES AND QUALITY ASSURANCE STANDARDS;

(2) MAY CHARGE A REASONABLE FEE WHICH MAY NOT EXCEED THE LIMIT SET FORTH IN SECTION 7(C) WHICH MAY BE CHARGED TO THE PATIENT FOR COSTS ASSOCIATED WITH DISPENSING, REPACKAGING AND RELABELING THE DRUG;

(3) IS REQUIRED TO DISCLOSE THE AMOUNT OF THE FEE, AND THAT THE FEE MAY BE CHARGED FOR EACH DRUG DISPENSED; AND

(4) IS IMMUNE FROM CIVIL LIABILITY ARISING FROM HARM CAUSED BY THE DRUG DUE TO ACTS OR OMISSIONS OF OTHER PERSONS OUTSIDE OF THE LONG-TERM CARE PHARMACY IF THE LONG-TERM CARE PHARMACY PROPERLY DISPENSES, REPACKAGES AND RELABELS THE DRUG.

(F) TEMPORARY FORM.--A LONG-TERM CARE FACILITY MAY DEVELOP THE FORM REQUIRED UNDER SUBSECTIONS (C)(1)(III) AND (2)(III) AND (E) AND USE THE FORM UNTIL THE BOARD DEVELOPS A FORM UNDER SECTION 4.

Section 6. Recordkeeping.

~~For each drug dispensed in accordance with section 5(a) (relating to third-party drugs in long-term care facilities), the person authorized to dispense the drug and the long-term~~ <—

FOR EACH DRUG DISPENSED BY A LONG-TERM CARE PHARMACY UNDER SECTION 5(B) AND (C)(2), THE LONG-TERM CARE PHARMACY AND THE LONG-TERM care facility shall maintain a record for at least two years of all of the following: <—

(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) (relating to third-party drugs in long-term care facilities) 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) (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.~~

~~(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.~~

SECTION 7. FEE. <—

(A) FEE AUTHORIZED.--A LONG-TERM CARE PHARMACY AUTHORIZED UNDER SECTION 5 TO DISPENSE A DRUG ACQUIRED FROM A DRUG SOURCE MAY CHARGE A REASONABLE FEE FOR EACH DRUG AS SET FORTH IN SUBSECTION (C) TO THE PATIENT OF A LONG-TERM CARE FACILITY.

(B) REPORT TO THE BOARD.--THE LONG-TERM CARE PHARMACY SHALL REPORT THE AMOUNT OF THE FEE TO THE BOARD. A CHANGE IN THE FEE SHALL BE REPORTED TO THE BOARD WITHIN TEN BUSINESS DAYS.

(C) DETERMINATION OF FEE.--A FEE IS REASONABLE IF THE FEE DOES NOT EXCEED AN AMOUNT WHICH IS FOUR TIMES THE SPECIFIC DOLLAR AMOUNT OF THE PROGRAM PAYMENT UNDER SECTION 509(6)(III) OF THE ACT OF AUGUST 26, 1971 (P.L.351, NO.91), KNOWN AS THE STATE LOTTERY LAW.

SECTION 8. IMMUNITY AND UNPROFESSIONAL CONDUCT.

(A) LONG-TERM CARE PHARMACIES.--A LONG-TERM CARE PHARMACY AUTHORIZED UNDER SECTION 5 TO DISPENSE A DRUG ACQUIRED FROM A

DRUG SOURCE SHALL BE IMMUNE FROM CIVIL LIABILITY ARISING FROM HARM CAUSED BY THE DRUG DUE TO ACTS OR OMISSIONS OF OTHER PERSONS OUTSIDE OF THE LONG-TERM CARE PHARMACY IF THE LONG-TERM CARE PHARMACY PROPERLY DISPENSES, REPACKAGES AND RELABELS THE DRUG.

(B) LONG-TERM CARE FACILITIES.--

(1) A LONG-TERM CARE FACILITY THAT PROPERLY ADMINISTERS A DRUG PROVIDED BY A LONG-TERM CARE PHARMACY UNDER SECTION 5 SHALL BE IMMUNE FROM CIVIL LIABILITY ARISING FROM HARM CAUSED BY THE DRUG DUE TO ACTS OR OMISSIONS OF OTHER PERSONS OUTSIDE THE LONG-TERM CARE FACILITY.

(2) AN EMPLOYEE OR AGENT OF A LONG-TERM CARE FACILITY WHO PROPERLY ADMINISTERS A DRUG PROVIDED BY A LONG-TERM CARE PHARMACY UNDER SECTION 5 SHALL BE IMMUNE FROM CIVIL LIABILITY ARISING FROM HARM CAUSED BY THE DRUG DUE TO ACTS OR OMISSIONS OF OTHER PERSONS OUTSIDE THE LONG-TERM CARE FACILITY.

(C) UNPROFESSIONAL CONDUCT.--A PHARMACIST WHO PROPERLY DISPENSES, REPACKAGES AND RELABELS A DRUG ACQUIRED FROM A DRUG SOURCE UNDER SECTION 5 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 9. RELATION TO PHARMACY ACT.

(A) PREVENTION OR PROHIBITION.--NOTHING IN THE ACT OF SEPTEMBER 27, 1961 (P.L.1700, NO.699), KNOWN AS THE PHARMACY ACT, SHALL BE CONSTRUED TO PREVENT OR PROHIBIT ANY OF THE FOLLOWING FROM COMPLYING WITH THE PROVISIONS OF THIS ACT:

(1) A PHARMACIST.

(2) A PHARMACY, AS DEFINED IN SECTION 2(12) OF THE PHARMACY ACT.

(B) CONFLICT.--IF THERE IS A CONFLICT BETWEEN A PROVISION OF

THE PHARMACY ACT AND A PROVISION OF THIS ACT, THE PROVISION OF THIS ACT SHALL PREVAIL.

SECTION 10. STUDY BY LEGISLATIVE BUDGET AND FINANCE COMMITTEE.

(A) STUDY COMMISSIONED.--ONE YEAR AFTER THE EFFECTIVE DATE OF THIS SECTION, THE LEGISLATIVE BUDGET AND FINANCE COMMITTEE SHALL COMMENCE A STUDY OF THE FOLLOWING:

(1) THE EFFECTIVENESS OF THIS ACT WITH RESPECT TO PATIENTS IN LONG-TERM CARE FACILITIES RECEIVING LOWER-COST PHARMACEUTICALS.

(2) THE EXPERIENCE OF PATIENTS, LONG-TERM CARE FACILITIES AND LONG-TERM CARE PHARMACIES AUTHORIZED UNDER SECTION 5 TO DISPENSE A DRUG ACQUIRED FROM A DRUG SOURCE, WITH RESPECT TO COMPLYING WITH THE PROVISIONS OF THIS ACT.

(3) THE SUFFICIENCY OF THE RECORDKEEPING REQUIREMENTS SET FORTH IN SECTION 6 WITH RESPECT TO ASSURING PATIENT SAFETY, PREVENTING DIVERSION OF DRUGS AND ASSURING THE QUALITY OF DRUGS.

(B) REPORT AND RECOMMENDATIONS.--THE COMMITTEE SHALL MAKE A REPORT OF ITS FINDINGS AND RECOMMENDATIONS WITHIN TWO YEARS OF THE EFFECTIVE DATE OF THIS SECTION TO THE PRESIDENT PRO TEMPORE OF THE SENATE, THE SPEAKER OF THE HOUSE OF REPRESENTATIVES, THE CONSUMER PROTECTION AND PROFESSIONAL LICENSURE COMMITTEE OF THE SENATE AND THE PROFESSIONAL LICENSURE COMMITTEE OF THE HOUSE OF REPRESENTATIVES.

SECTION 40. EFFECTIVE DATE.

THIS ACT SHALL TAKE EFFECT IN 60 DAYS.