

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

REFERRED TO COMMITTEE ON VETERANS AFFAIRS AND EMERGENCY
PREPAREDNESS, MAY 9, 2011

AN ACT

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

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

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

11 CHAPTER 95

12 LONG-TERM CARE PATIENT ACCESS TO PHARMACEUTICALS

13 Sec.

14 9501. Scope of chapter.

15 9502. Declaration of policy.

1 9503. Definitions.
2 9504. State Board of Pharmacy.
3 9505. Third-party drugs in long-term care facilities.
4 9506. Recordkeeping.
5 9507. Fee.
6 9508. Civil liability and unprofessional conduct.
7 § 9501. Scope of chapter.

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

10 § 9502. Declaration of policy.

11 The General Assembly finds and declares as follows:

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

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

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

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

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

29 (i) To provide for the care, protection and
30 treatment of patients in long-term care facilities by

1 allowing them to utilize the drug benefit provided by the
2 Department of Veterans Affairs.

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

6 (A) accept, on behalf of the patient, drugs
7 received directly from the Department of Veterans
8 Affairs; and

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

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

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

21 § 9503. Definitions.

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

25 "Board." The State Board of Pharmacy.

26 "Drug source facility." A facility:

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

29 (2) which is:

30 (i) operated by or under contract with the

Department of Veterans Affairs; or

(ii) approved by the Department of Veterans Affairs.

"Lockbox." A cabinet or safe 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

1 dispense a drug shall repackage, relabel and dispense the drug
2 in a unit dose if all of the following conditions are met:

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

4 (2) There is a prescription for the drug.

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

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

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

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

23 (iii) has immunity from civil liability arising from
24 dispensation of the drug if the person properly
25 repackages and relabels the drug as set forth in section
26 9508 (relating to civil liability and unprofessional
27 conduct)).

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

30 (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 Department of Veterans Affairs provides the drug 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) 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:

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

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

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

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

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

16 § 9506. Recordkeeping.

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

22 § 9507. Fee.

23 A person authorized under section 9505(a) (relating to third-
24 party drugs in long-term care facilities) to dispense a drug may
25 charge no more than the maximum dispensing fee authorized by the
26 Department of Public Welfare regulations under the medical
27 assistance program.

28 § 9508. Civil liability and unprofessional conduct.

29 (a) Repackaging and relabeling.--A person authorized under
30 section 9505(a) (relating to third-party drugs in long-term care

1 facilities) to dispense a drug shall be immune from civil
2 liability arising out of dispensation of the drug if the person
3 properly repackages and relabels a drug based on the information
4 received from the original drug source facility.

5 (b) Administration of drug.--A long-term care facility or an
6 employee or agent of a long-term care facility that properly
7 administers a drug from a person authorized under section
8 9505(a) to dispense the drug shall be immune from civil
9 liability arising out of administration of the drug.

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

16 Section 2. Repeals are as follows:

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

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

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

27 (1) Except as otherwise provided in 51 Pa.C.S. Ch. 95,
28 all activities initiated under the Long-Term Care Patient
29 Access to Pharmaceuticals Act shall continue and remain in
30 full force and effect and may be completed under 51 Pa.C.S.

1 Ch. 95. Orders, regulations, rules and decisions which were
2 made under the Long-Term Care Patient Access to
3 Pharmaceuticals Act and which are in effect on the effective
4 date of section 2 of this act shall remain in full force and
5 effect until revoked, vacated or modified under 51 Pa.C.S.

6 Ch. 95. Contracts, obligations and collective bargaining
7 agreements entered into under the Long-Term Care Patient
8 Access to Pharmaceuticals Act are not affected nor impaired
9 by the repeal of the Long-Term Care Patient Access to
10 Pharmaceuticals Act.

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

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

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

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

24 (iii) Section 9505(b)(7) introductory paragraph,
25 (ii), (iii) and (iv), (8) and (9).

26 Section 4. This act shall take effect as follows:

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

29 (i) Section 3 of this act.

30 (ii) This section.

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