

AN ACT

relating to a health care facility's return of certain unused drugs to a pharmacy and to reimbursement or credit under the state's medical assistance program for returned drugs.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subchapter C, Chapter 562, Occupations Code, is amended by adding Sections 562.1085 and 562.1086 to read as follows:

Sec. 562.1085. UNUSED DRUGS RETURNED BY CERTAIN PHARMACISTS. (a) A pharmacist who practices in or serves as a consultant for a health care facility in this state may return to a pharmacy certain unused drugs, other than a controlled substance as defined by Chapter 481, Health and Safety Code, purchased from the pharmacy as provided by board rule. The unused drugs must:

(1) be approved by the federal Food and Drug Administration and be:

(A) sealed in the manufacturer's original unopened tamper-evident packaging and either individually packaged or packaged in unit-dose packaging;

(B) oral or parenteral medications in sealed single-dose containers approved by the federal Food and Drug Administration;

(C) topical or inhalant drugs in sealed units-of-use containers approved by the federal Food and Drug

1 Administration; or

2 (D) parenteral medications in sealed
3 multiple-dose containers approved by the federal Food and Drug
4 Administration from which doses have not been withdrawn; and

5 (2) not be the subject of a mandatory recall by a state
6 or federal agency or a voluntary recall by a drug seller or
7 manufacturer.

8 (b) A pharmacist for the pharmacy shall examine a drug
9 returned under this section to ensure the integrity of the drug
10 product. A health care facility may not return a drug that:

11 (1) has been compounded;

12 (2) appears on inspection to be adulterated;

13 (3) requires refrigeration; or

14 (4) has less than 120 days until the expiration date or
15 end of the shelf life.

16 (c) The pharmacy may restock and redistribute unused drugs
17 returned under this section.

18 (d) The pharmacy shall reimburse or credit the state
19 Medicaid program for an unused drug returned under this section.

20 (e) The board shall adopt the rules, policies, and
21 procedures necessary to administer this section, including rules
22 that require a health care facility to inform the Health and Human
23 Services Commission of drugs returned to a pharmacy under this
24 section.

25 Sec. 562.1086. LIMITATION ON LIABILITY. (a) A pharmacist
26 that returns unused drugs or the health care facility at which the
27 pharmacist practices or serves and a pharmacy that accepts the

1 unused drugs under Section 562.1085 and the employees of the
2 pharmacist, health care facility, or pharmacy are not liable for
3 harm caused by the accepting, dispensing, or administering of drugs
4 returned in strict compliance with Section 562.1085 unless the harm
5 is caused by:

6 (1) wilful or wanton acts of negligence;

7 (2) conscious indifference or reckless disregard for
8 the safety of others; or

9 (3) intentional conduct.

10 (b) This section does not limit, or in any way affect or
11 diminish, the liability of a drug seller or manufacturer under
12 Chapter 82, Civil Practice and Remedies Code.

13 (c) This section does not apply if harm results from the
14 failure to fully and completely comply with the requirements of
15 Section 562.1085.

16 SECTION 2. Section 431.021, Health and Safety Code, is
17 amended to read as follows:

18 Sec. 431.021. PROHIBITED ACTS. The following acts and the
19 causing of the following acts within this state are unlawful and
20 prohibited:

21 (a) the introduction or delivery for introduction into
22 commerce of any food, drug, device, or cosmetic that is adulterated
23 or misbranded;

24 (b) the adulteration or misbranding of any food, drug,
25 device, or cosmetic in commerce;

26 (c) the receipt in commerce of any food, drug, device,
27 or cosmetic that is adulterated or misbranded, and the delivery or

1 proffered delivery thereof for pay or otherwise;

2 (d) the distribution in commerce of a consumer
3 commodity, if such commodity is contained in a package, or if there
4 is affixed to that commodity a label that does not conform to the
5 provisions of this chapter and of rules adopted under the authority
6 of this chapter; provided, however, that this prohibition shall not
7 apply to persons engaged in business as wholesale or retail
8 distributors of consumer commodities except to the extent that such
9 persons:

10 (1) are engaged in the packaging or labeling of
11 such commodities; or

12 (2) prescribe or specify by any means the manner
13 in which such commodities are packaged or labeled;

14 (e) the introduction or delivery for introduction into
15 commerce of any article in violation of Section 431.084, 431.114,
16 or 431.115;

17 (f) the dissemination of any false advertisement;

18 (g) the refusal to permit entry or inspection, or to
19 permit the taking of a sample or to permit access to or copying of
20 any record as authorized by Sections 431.042-431.044; or the
21 failure to establish or maintain any record or make any report
22 required under Section 512(j), (l), or (m) of the federal Act, or
23 the refusal to permit access to or verification or copying of any
24 such required record;

25 (h) the manufacture within this state of any food,
26 drug, device, or cosmetic that is adulterated or misbranded;

27 (i) the giving of a guaranty or undertaking referred

1 to in Section 431.059, which guaranty or undertaking is false,
2 except by a person who relied on a guaranty or undertaking to the
3 same effect signed by, and containing the name and address of the
4 person residing in this state from whom the person received in good
5 faith the food, drug, device, or cosmetic; or the giving of a
6 guaranty or undertaking referred to in Section 431.059, which
7 guaranty or undertaking is false;

8 (j) the use, removal, or disposal of a detained or
9 embargoed article in violation of Section 431.048;

10 (k) the alteration, mutilation, destruction,
11 obliteration, or removal of the whole or any part of the labeling
12 of, or the doing of any other act with respect to a food, drug,
13 device, or cosmetic, if such act is done while such article is held
14 for sale after shipment in commerce and results in such article
15 being adulterated or misbranded;

16 (l)(1) forging, counterfeiting, simulating, or
17 falsely representing, or without proper authority using any mark,
18 stamp, tag, label, or other identification device authorized or
19 required by rules adopted under this chapter or the regulations
20 promulgated under the provisions of the federal Act;

21 (2) making, selling, disposing of, or keeping in
22 possession, control, or custody, or concealing any punch, die,
23 plate, stone, or other thing designed to print, imprint, or
24 reproduce the trademark, trade name, or other identifying mark,
25 imprint, or device of another or any likeness of any of the
26 foregoing on any drug or container or labeling thereof so as to
27 render such drug a counterfeit drug;

1 (3) the doing of any act that causes a drug to be
2 a counterfeit drug, or the sale or dispensing, or the holding for
3 sale or dispensing, of a counterfeit drug;

4 (m) the using by any person to the person's own
5 advantage, or revealing, other than to the commissioner, an
6 authorized agent, a health authority or to the courts when relevant
7 in any judicial proceeding under this chapter, of any information
8 acquired under the authority of this chapter concerning any method
9 or process that as a trade secret is entitled to protection;

10 (n) the using, on the labeling of any drug or device or
11 in any advertising relating to such drug or device, of any
12 representation or suggestion that approval of an application with
13 respect to such drug or device is in effect under Section 431.114 or
14 Section 505, 515, or 520(g) of the federal Act, as the case may be,
15 or that such drug or device complies with the provisions of such
16 sections;

17 (o) the using, in labeling, advertising or other sales
18 promotion of any reference to any report or analysis furnished in
19 compliance with Sections 431.042-431.044 or Section 704 of the
20 federal Act;

21 (p) in the case of a prescription drug distributed or
22 offered for sale in this state, the failure of the manufacturer,
23 packer, or distributor of the drug to maintain for transmittal, or
24 to transmit, to any practitioner licensed by applicable law to
25 administer such drug who makes written request for information as
26 to such drug, true and correct copies of all printed matter that is
27 required to be included in any package in which that drug is

1 distributed or sold, or such other printed matter as is approved
2 under the federal Act. Nothing in this subsection shall be
3 construed to exempt any person from any labeling requirement
4 imposed by or under other provisions of this chapter;

5 (q)(1) placing or causing to be placed on any drug or
6 device or container of any drug or device, with intent to defraud,
7 the trade name or other identifying mark, or imprint of another or
8 any likeness of any of the foregoing;

9 (2) selling, dispensing, disposing of or causing
10 to be sold, dispensed, or disposed of, or concealing or keeping in
11 possession, control, or custody, with intent to sell, dispense, or
12 dispose of, any drug, device, or any container of any drug or
13 device, with knowledge that the trade name or other identifying
14 mark or imprint of another or any likeness of any of the foregoing
15 has been placed thereon in a manner prohibited by Subdivision (1) of
16 this subsection; or

17 (3) making, selling, disposing of, causing to be
18 made, sold, or disposed of, keeping in possession, control, or
19 custody, or concealing with intent to defraud any punch, die,
20 plate, stone, or other thing designed to print, imprint, or
21 reproduce the trademark, trade name, or other identifying mark,
22 imprint, or device of another or any likeness of any of the
23 foregoing on any drug or container or labeling of any drug or
24 container so as to render such drug a counterfeit drug;

25 (r) dispensing or causing to be dispensed a different
26 drug in place of the drug ordered or prescribed without the express
27 permission in each case of the person ordering or prescribing;

1 (s) the failure to register in accordance with Section
2 510 of the federal Act, the failure to provide any information
3 required by Section 510(j) or (k) of the federal Act, or the failure
4 to provide a notice required by Section 510(j)(2) of the federal
5 Act;

6 (t)(1) the failure or refusal to:

7 (A) comply with any requirement prescribed
8 under Section 518 or 520(g) of the federal Act; or

9 (B) furnish any notification or other
10 material or information required by or under Section 519 or 520(g)
11 of the federal Act;

12 (2) with respect to any device, the submission of
13 any report that is required by or under this chapter that is false
14 or misleading in any material respect;

15 (u) the movement of a device in violation of an order
16 under Section 304(g) of the federal Act or the removal or alteration
17 of any mark or label required by the order to identify the device as
18 detained;

19 (v) the failure to provide the notice required by
20 Section 412(b) or 412(c), the failure to make the reports required
21 by Section 412(d)(1)(B), or the failure to meet the requirements
22 prescribed under Section 412(d)(2) of the federal Act;

23 (w) except as provided under Subchapter M of this
24 chapter and Section 562.1085, Occupations Code, the acceptance by a
25 person of an unused prescription or drug, in whole or in part, for
26 the purpose of resale, after the prescription or drug has been
27 originally dispensed, or sold;

1 (x) engaging in the wholesale distribution of drugs or
2 operating as a distributor or manufacturer of devices in this state
3 without filing a licensing statement with the commissioner as
4 required by Section 431.202 or having a license as required by
5 Section 431.272, as applicable;

6 (y) engaging in the manufacture of food in this state
7 or operating as a food wholesaler in this state without having a
8 license as required by Section 431.222; or

9 (z) unless approved by the United States Food and Drug
10 Administration pursuant to the federal Act, the sale, delivery,
11 holding, or offering for sale of a self-testing kit designed to
12 indicate whether a person has a human immunodeficiency virus
13 infection, acquired immune deficiency syndrome, or a related
14 disorder or condition.

15 SECTION 3. Section 32.028, Human Resources Code, is amended
16 by adding Subsections (i), (j), and (k) to read as follows:

17 (i) The Health and Human Services Commission shall adopt
18 rules governing the determination of the amount of reimbursement or
19 credit for restocking drugs under Section 562.1085, Occupations
20 Code, that recognize the costs of processing the drugs, including
21 the cost of:

22 (1) reporting the drug's prescription number and date
23 of original issue;

24 (2) verifying whether the drug's expiration date or
25 the drug's recommended shelf life exceeds 120 days;

26 (3) determining the source of payment; and

27 (4) preparing credit records.

1 (j) The commission shall provide an electronic system for
2 the issuance of credit for returned drugs that complies with the
3 Health Insurance Portability and Accountability Act of 1996 (Pub.
4 L. No. 104-191), as amended. To ensure a cost-effective system,
5 only drugs for which the credit exceeds the cost of the restocking
6 fee by at least 100 percent are eligible for credit.

7 (k) The commission shall establish a task force to develop
8 the rules necessary to implement Subsections (i) and (j). The task
9 force must include representatives of nursing facilities and
10 pharmacies.

11 SECTION 4. If before implementing any provision of this Act
12 a state agency determines that a waiver or authorization from a
13 federal agency is necessary for implementation of that provision,
14 the agency affected by the provision shall request the waiver or
15 authorization and may delay implementing that provision until the
16 waiver or authorization is granted.

17 SECTION 5. The Health and Human Services Commission shall
18 adopt the rules required by Sections 32.028(i) and (j), Human
19 Resources Code, as added by this Act, not later than December 1,
20 2003.

21 SECTION 6. (a) The Texas State Board of Pharmacy shall
22 adopt the rules required by Section 562.1085, Occupations Code, as
23 added by this Act, not later than December 1, 2003.

24 (b) Notwithstanding Section 562.1085, Occupations Code, as
25 added by this Act, a pharmacy is not required to accept unused drugs
26 from a health care facility before January 1, 2004.

27 SECTION 7. This Act takes effect immediately if it receives

H.B. No. 3486

1 a vote of two-thirds of all the members elected to each house, as
2 provided by Section 39, Article III, Texas Constitution. If this
3 Act does not receive the vote necessary for immediate effect, this
4 Act takes effect September 1, 2003.

President of the Senate

Speaker of the House

I certify that H.B. No. 3486 was passed by the House on May 10, 2003, by the following vote: Yeas 131, Nays 0, 1 present, not voting; and that the House concurred in Senate amendments to H.B. No. 3486 on May 30, 2003, by the following vote: Yeas 143, Nays 0, 2 present, not voting.

Chief Clerk of the House

I certify that H.B. No. 3486 was passed by the Senate, with amendments, on May 28, 2003, by the following vote: Yeas 31, Nays 0.

Secretary of the Senate

APPROVED: _____

Date

Governor