By: Delisi, Madden (Senate Sponsor - Deuell) H.B. No. 3486

(In the Senate - Received from the House May 13, 2003; May 14, 2003, read first time and referred to Committee on Health and Human Services; May 23, 2003, reported adversely, with favorable Committee Substitute by the following vote: Yeas 8, Nays 0; May 23, 2003, sent to printer.)

COMMITTEE SUBSTITUTE FOR H.B. No. 3486 By: Deuell

A BILL TO BE ENTITLED
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 Administration; or

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in sealed multiple-dose containers approved by the federal Food and Drug Administration from which doses have not been withdrawn; and

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

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

(1) has been compounded;

(2) appears on inspection to be adulterated;

(3) requires refrigeration; or

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

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

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

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

Sec. 562.1086. LIMITATION ON LIABILITY. (a) A pharmacist that returns unused drugs or the health care facility at which the pharmacist practices or serves and a pharmacy that accepts the unused drugs under Section 562.1085 and the employees of the pharmacist, health care facility, or pharmacy are not liable for harm caused by the accepting, dispensing, or administering of drugs returned in strict compliance with Section 562.1085 unless the harm

is caused by:

(1) wilful or wanton acts of negligence;

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

(3) intentional conduct.

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

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

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

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

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

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

(c) the receipt in commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise;

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

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

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

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

(f) the dissemination of any false advertisement;

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

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

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

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

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

(l)(1) forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by rules adopted under this chapter or the regulations

promulgated under the provisions of the federal Act;

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

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

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

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

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

(p) in the case of a prescription drug distributed or offered for sale in this state, the failure of the manufacturer, packer, or distributor of the drug to maintain for transmittal, or to transmit, to any practitioner licensed by applicable law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter that is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved under the federal Act. Nothing in this subsection shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this chapter;

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

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

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

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

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

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

(A) comply with any requirement prescribed

under Section 518 or 520(g) of the federal Act; or

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

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

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

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

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

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

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

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

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

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

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

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

(3) determining the source of payment; and

(4) preparing credit records.

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

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

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

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

SECTION 6. (a) The Texas State Board of Pharmacy shall adopt the rules required by Section 562.1085, Occupations Code, as

added by this Act, not later than December 1, 2003.

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

SECTION 7. This Act takes effect immediately if it receives a vote of two-thirds of all the members elected to each house, as provided by Section 39, Article III, Texas Constitution. If this Act does not receive the vote necessary for immediate effect, this Act takes effect September 1, 2003.

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