CHAPTER 440

S.B. No. 564

AN ACT

relating to the licensing of wholesale device distributors under the Texas Food, Drug, and Cosmetic Act; providing civil and administrative penalties.

Be it enacted by the Legislature of the State of Texas:

SECTION 1. 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 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) 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 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 without first registering with the department 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 2. Section 431.111, Health and Safety Code, is amended to read as follows:

Sec. 431.111. ADULTERATED DRUG OR DEVICE. A drug or device shall be deemed to be adulterated:

(a)(1) if it consists in whole or in part of any filthy, putrid, or decomposed substance; or

(2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or

(B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; or

(3) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(4) if it:

(A) bears or contains, for purposes of coloring only, a color additive that is unsafe under Section 431.161(a); or

(B) is a color additive, the intended use of which in or on drugs or devices is for purposes of coloring only, and is unsafe under Section 431.161(a); or

(5) if it is a new animal drug that is unsafe under Section 512 of the federal Act;

(b) if it purports to be or is represented as a drug, the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standards set forth in such compendium. Such determination as to strength, quality or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, or in the absence of or inadequacy of such tests or methods of assay, those prescribed under the authority of the federal Act. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standards of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standards is plainly stated on its label. Whenever a drug is recognized in the United States Pharmacopoeia National Formulary, it shall be subject to the requirements of the United States Pharmacopoeia National Formulary;

(c) if it is not subject to the provision of Paragraph (b) and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess;

(d) if it is a drug and any substance has been:

(1) mixed or packed therewith so as to reduce its quality or strength; or

(2) substituted wholly or in part therefor;

(e) if it is, or purports to be or is represented as, a device that is subject to a performance standard established under Section 514 of the federal Act, unless the device is in all respects in conformity with the standard;

(f)*(1) if it is a class III device:*

(A)(i) that is required by a regulation adopted under Section 515(b) of the federal Act to have an approval under that section of an application for premarket approval and that is not exempt from Section 515 as provided by Section 520(g) of the federal Act; and

(ii)(I) for which an application for premarket approval or a notice of completion of a product development protocol was not filed with the United States Food and Drug Administration by the 90th day after the date of adoption of the regulation; or

(II) for which that application was filed and approval was denied or withdrawn, for which that notice was filed and was declared incomplete, or for which approval of the device under the protocol was withdrawn;

(B) that was classified under Section 513(f) of the federal Act into class III, which under Section 515(a) of the federal Act is required to have in effect an approved application for premarket approval, that is not exempt from Section 515 as provided by Section 520(g) of the federal Act, and that does not have the application in effect; or

(C) that was classified under Section 520(l) of the federal Act into class III, which under that section is required to have in effect an approved application under Section 515 of the federal Act, and that does not have the application in effect, except that:

(2)(A) in the case of a device classified under Section 513(f) of the federal Act into class III and intended solely for investigational use, Subdivision (1)(B) does not apply to the device during the period ending on the 90th day after the date of adoption of the regulations prescribing the procedures and conditions required by Section 520(g)(2) of the federal Act; and

(B) in the case of a device subject to a regulation adopted under Section 515(b) of the federal Act, Subdivision (1) does not apply to the device during the period ending on whichever of the following dates occurs later:

(i) the last day of the 30-day calendar month beginning after the month in which the classification of the device into class III became effective under Section 513 of the federal Act; or

(ii) the 90th day after the date of adoption of the regulation;

(g) if it is a banned device;

(h) [~~(g)~~] if it is a device and the methods used in, or the facilities or controls used for its manufacture, packing, storage, or installations are not in conformity with applicable requirements under Section 520(f)(1) of the federal Act or an applicable condition as prescribed by an order under Section 520(f)(2) of the federal Act; or

(i) [~~(h)~~] if it is a device for which an exemption has been granted under Section 520(g) of the federal Act for investigational use and the person who was granted the exemption or any investigator who uses the device under the exemption fails to comply with a requirement prescribed by or under that section.

SECTION 3. Chapter 431, Health and Safety Code, is amended by adding Subchapter L to read as follows:

SUBCHAPTER L. WHOLESALE DEVICE DISTRIBUTORS

Sec. 431.271. DEFINITIONS. In this subchapter:

(1) "Importer" means any person who initially distributes a device imported into the United States.

(2) "Wholesale distribution" means distribution to a person other than a consumer or patient and includes distribution by a manufacturer, repacker, own label distributor, jobber, importer, or wholesaler.

(3) "Place of business" means each location at which a device for wholesale distribution is located.

Sec. 431.272. LICENSE REQUIRED; MINIMUM STANDARDS. (a) Except as provided by Section 431.273, a person may not engage in the wholesale distribution of devices in this state unless the person has a license from the commissioner for each place of business.

(b) A wholesale distributor of devices in this state must comply with the minimum requirements specified in the federal Act and in this chapter.

Sec. 431.273. EXEMPTION FROM LICENSING. (a) A person is exempt from licensing under this subchapter if the person engages only in the following types of wholesale device distribution:

(1) intracompany sales; or

(2) the sale, purchase, or trade of a distressed or reconditioned device by a salvage broker or a salvage operator licensed under Chapter 432 (Texas Food, Drug, Device, and Cosmetic Salvage Act).

(b) An exemption from the licensing requirements under this section does not constitute an exemption from the other provisions of this chapter or the rules adopted by the board to administer and enforce this chapter.

Sec. 431.274. LICENSE APPLICATION. (a) A person applying for a license under this subchapter shall provide, at a minimum, the following information on a license application form furnished by the commissioner:

(1) the name under which the business is conducted;

(2) the address of each place of business that is licensed;

(3) the name and residence address of:

(A) the proprietor, if the business is a proprietorship;

(B) all partners, if the business is a partnership; or

(C) all principals, if the business is an association;

(4) the date and place of incorporation if the business is a corporation;

(5) the names and residence addresses of the individuals in an administrative capacity showing:

(A) the managing proprietor, if the business is a proprietorship;

(B) the managing partner, if the business is a partnership;

(C) the officers and directors, if the business is a corporation; or

(D) the persons in a managerial capacity, if the business is an association; and

(6) the residence address of an individual in charge of each place of business.

(b) The license application must be signed, verified, and completed in a manner described in the rules adopted by the board.

(c) A person applying for a license under this subchapter must pay a licensing fee for each place of business.

Sec. 431.275. EFFECT OF OPERATIONS IN OTHER JURISDICTIONS; REPORTS. (a) A person who engages in the wholesale distribution of devices outside this state may engage in wholesale distribution of devices in this state if the person holds a license issued by the commissioner.

(b) The commissioner may accept reports from authorities in other jurisdictions to determine the extent of compliance with this chapter. On examination of those reports and the person's compliance history and current compliance record, the commissioner may issue a license to the person if the commissioner determines that the person is in compliance with this subchapter and the board's rules.

(c) The commissioner shall consider each licensing application filed by a person who wishes to engage in wholesale distribution of devices in this state on an individual basis.

Sec. 431.276. FEES. (a) The department shall collect fees for:

(1) a license that is filed or renewed;

(2) a license that is amended, including notification of a change of location of a licensed place of business required under Section 431.278, a change of the name of an association or corporation, or a change in the ownership of the licensee; and

(3) an inspection performed to enforce this subchapter and rules adopted under this subchapter.

(b) The board may charge annual fees.

(c) The board by rule shall set the fees in amounts that allow the department to recover at least 50 percent of the annual expenditures of state funds by the department in:

(1) reviewing and acting on a license or renewal license;

(2) amending a license;

(3) inspecting a licensed facility; and

(4) implementing and enforcing this subchapter, including a rule or order adopted or a license issued under this subchapter.

(d) At least half of the licensing fees collected shall be used to inspect an applicant or licensed place of business.

(e) Fees collected under this section shall be deposited to the credit of the food and drug registration fee account of the general revenue fund and may be appropriated to the department only to carry out this chapter.

Sec. 431.277. LICENSE EXPIRATION. (a) The board by rule may provide that licenses expire on different dates during the year.

(b) If the board changes a license expiration date, the board shall prorate the license fee payable on or before September 1 so that the licensee is required to pay only that portion of the fee that is allocable to the number of months during which the license is valid.

(c) The total renewal license fee is payable when the license is renewed on the new expiration date.

Sec. 431.278. CHANGE OF LOCATION OF PLACE OF BUSINESS. (a) Not fewer than 30 days in advance of the change, the licensee shall notify the commissioner or the commissioner's designee in writing of the licensee's intent to change the location of a licensed place of business. The notice shall include the address of the new location and the name and residence address of the individual in charge of the business at the new location.

(b) Not later than the 10th day after the date of completion of the change of location, the licensee shall notify the commissioner or the commissioner's designee in writing to verify the change of location, the address of the new location, and the name and residence address of the individual in charge of the business at the new address.

(c) Notice is adequate if the licensee provides the intent and verification notices to the commissioner or the commissioner's designee by certified mail, return receipt requested, mailed to the central office of the department.

Sec. 431.279. REFUSAL TO LICENSE; SUSPENSION OR REVOCATION OF LICENSE. (a) The commissioner may refuse an application or may suspend or revoke a license if the applicant or licensee:

(1) has been convicted of a felony or misdemeanor that involves moral turpitude;

(2) is an association, partnership, or corporation and the managing officer has been convicted of a felony or misdemeanor that involves moral turpitude;

(3) has been convicted in a state or federal court of the illegal use, sale, or transportation of intoxicating liquors, narcotic drugs, barbiturates, amphetamines, desoxyephedrine, their compounds or derivatives, or any other dangerous or habit-forming drugs;

(4) is an association, partnership, or corporation and the managing officer has been convicted in a state or federal court of the illegal use, sale, or transportation of intoxicating liquors, narcotic drugs, barbiturates, amphetamines, desoxyephedrine, their compounds or derivatives, or any other dangerous or habit-forming drugs; or

(5) has not complied with this chapter or the board's rules implementing this chapter.

(b) The commissioner may refuse an application for a license or may suspend or revoke a license if the commissioner determines from evidence presented during a hearing that the applicant or licensee:

(1) has violated Section 431.021(l)(3), relating to the counterfeiting of a drug or the sale or holding for sale of a counterfeit drug;

(2) has violated Chapter 481 (Texas Controlled Substances Act) or 483 (Dangerous Drugs); or

(3) has violated the rules of the director of the Department of Public Safety, including being responsible for a significant discrepancy in the records that state law requires the applicant or licensee to maintain.

(c) The refusal to license an applicant or the suspension or revocation of a license by the commissioner and the appeal from that action are governed by the board's formal hearing

procedures and the procedures for a contested case hearing under the Administrative Procedure and Texas Register Act (Article 6252–13a, Vernon's Texas Civil Statutes).

SECTION 4. This Act takes effect September 1, 1993.

SECTION 5. The importance of this legislation and the crowded condition of the calendars in both houses create an emergency and an imperative public necessity that the constitutional rule requiring bills to be read on three several days in each house be suspended, and this rule is hereby suspended.

Passed the Senate on April 21, 1993, by a viva-voce vote; passed the House on May 21, 1993, by a non-record vote.

Approved June 6, 1993.

Effective Sept. 1, 1993.