

By: Berman, Flynn, Phillips, Madden, Driver,
et al.

H.B. No. 164

Substitute the following for H.B. No. 164:

By: Driver

C.S.H.B. No. 164

A BILL TO BE ENTITLED

AN ACT

1
2 relating to the civil and criminal consequences of engaging in
3 certain conduct related to the manufacture of methamphetamine and
4 to the distribution and retail sales of pseudoephedrine; providing
5 penalties.

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

7 ARTICLE 1. CIVIL AND CRIMINAL CONSEQUENCES OF
8 ENGAGING IN CERTAIN CONDUCT RELATED TO
9 THE MANUFACTURE OF METHAMPHETAMINE

10 SECTION 1.01. Section 481.124(b), Health and Safety Code,
11 is amended to read as follows:

12 (b) For purposes of this section, an intent to unlawfully
13 manufacture the controlled substance methamphetamine is presumed
14 if the actor possesses or transports:

15 (1) anhydrous ammonia in a container or receptacle
16 that is not designed and manufactured to lawfully hold or transport
17 anhydrous ammonia;

18 (2) lithium metal removed from a battery and immersed
19 in kerosene, mineral spirits, or similar liquid that prevents or
20 retards hydration; or

21 (3) in one container, vehicle, or building,
22 phenylacetic acid, or more than nine grams, three containers
23 packaged for retail sale, or 300 tablets or capsules of a product
24 containing ephedrine or pseudoephedrine, and:

1 (A) anhydrous ammonia;

2 (B) at least three of the following categories of
3 substances commonly used in the manufacture of methamphetamine:

4 (i) lithium or sodium metal or red
5 phosphorus, iodine, or iodine crystals;

6 (ii) lye, sulfuric acid, hydrochloric acid,
7 or muriatic acid;

8 (iii) an organic solvent, including ethyl
9 ether, alcohol, or acetone;

10 (iv) a petroleum distillate, including
11 naphtha, paint thinner, or charcoal lighter fluid; or

12 (v) aquarium, rock, or table salt; or

13 (C) at least three of the following items:

14 (i) an item of equipment subject to
15 regulation under Section 481.080, if the person is not registered
16 under Section 481.063; or

17 (ii) glassware, a plastic or metal
18 container, tubing, a hose, or another item specially designed,
19 assembled, or adapted for use in the manufacture, processing,
20 analyzing, storing, or concealing of methamphetamine.

21 SECTION 1.02. Section 481.136(a), Health and Safety Code,
22 is amended to read as follows:

23 (a) A person commits an offense if the person sells,
24 transfers, furnishes, or receives a chemical precursor subject to
25 Section 481.077(a) and the person:

26 (1) does not hold a chemical precursor transfer permit
27 as required by Section 481.078 at the time of the transaction;

- 1 (2) does not comply with Section 481.077 or 481.0771;
- 2 (3) knowingly makes a false statement in a report or
- 3 record required by Section 481.077, 481.0771, or 481.078; or
- 4 (4) knowingly violates a rule adopted under Section
- 5 481.077, 481.0771, or 481.078.

6 SECTION 1.03. Section 99.003, Civil Practice and Remedies

7 Code, is amended to read as follows:

8 Sec. 99.003. STRICT LIABILITY AND MINIMUM DAMAGES FOR

9 EXPOSURE. A person who manufactures methamphetamine is strictly

10 liable for any exposure by an individual to the manufacturing

11 process, including exposure to the methamphetamine itself or any of

12 the by-products or waste products incident to the manufacture, for

13 the greater of:

- 14 (1) actual damages for personal injury, death, or
- 15 property damage as a result of the exposure; or
- 16 (2) \$20,000 [~~\$10,000~~] for each incident of exposure.

17 SECTION 1.04. Section 262.104, Family Code, is amended to

18 read as follows:

19 Sec. 262.104. TAKING POSSESSION OF A CHILD IN EMERGENCY

20 WITHOUT A COURT ORDER. (a) If there is no time to obtain a

21 temporary restraining order or attachment before taking possession

22 of a child consistent with the health and safety of that child, an

23 authorized representative of the Department of Family and

24 Protective [~~and Regulatory~~] Services, a law enforcement officer, or

25 a juvenile probation officer may take possession of a child without

26 a court order under the following conditions, only:

- 27 (1) on personal knowledge of facts that would lead a

1 person of ordinary prudence and caution to believe that there is an
2 immediate danger to the physical health or safety of the child;

3 (2) on information furnished by another that has been
4 corroborated by personal knowledge of facts and all of which taken
5 together would lead a person of ordinary prudence and caution to
6 believe that there is an immediate danger to the physical health or
7 safety of the child;

8 (3) on personal knowledge of facts that would lead a
9 person of ordinary prudence and caution to believe that the child
10 has been the victim of sexual abuse;

11 (4) on information furnished by another that has been
12 corroborated by personal knowledge of facts and all of which taken
13 together would lead a person of ordinary prudence and caution to
14 believe that the child has been the victim of sexual abuse; or

15 (5) on information furnished by another that has been
16 corroborated by personal knowledge of facts and all of which taken
17 together would lead a person of ordinary prudence and caution to
18 believe that the parent or person who has possession of the child is
19 currently using a controlled substance as defined by Chapter 481,
20 Health and Safety Code, and the use constitutes an immediate danger
21 to the physical health or safety of the child.

22 (b) An authorized representative of the Department of
23 Family and Protective Services, a law enforcement officer, or a
24 juvenile probation officer may take possession of a child under
25 Subsection (a) on personal knowledge or information furnished by
26 another, that has been corroborated by personal knowledge, that
27 would lead a person of ordinary prudence and caution to believe that

1 the parent or person who has possession of the child has permitted
2 the child to remain on premises used for the manufacture of
3 methamphetamine.

4 SECTION 1.05. Section 22.041, Penal Code, is amended by
5 adding Subsection (c-1) to read as follows:

6 (c-1) For purposes of Subsection (c), it is presumed that a
7 person engaged in conduct that places a child in imminent danger of
8 death, bodily injury, or physical or mental impairment if the
9 person manufactured the controlled substance methamphetamine in
10 the presence of the child.

11 SECTION 1.06. Sections 481.124 and 481.136, Health and
12 Safety Code, as amended by this Act, and Section 22.041(c-1), Penal
13 Code, as added by this Act, apply only to an offense committed on or
14 after September 1, 2005. An offense committed before September 1,
15 2005, is covered by the law in effect when the offense was
16 committed, and the former law is continued in effect for that
17 purpose. For purposes of this section, an offense was committed
18 before September 1, 2005, if any element of the offense was
19 committed before that date.

20 SECTION 1.07. Section 99.003, Civil Practice and Remedies
21 Code, as amended by this Act, applies only to a cause of action that
22 accrues on or after September 1, 2005. An action that accrued
23 before September 1, 2005, is governed by the law applicable to the
24 action immediately before September 1, 2005, and that law is
25 continued in effect for that purpose.

ARTICLE 2. DISTRIBUTION AND RETAIL SALES OF
PSEUDOEPHEDRINE

SECTION 2.01. Subchapter C, Chapter 481, Health and Safety Code, is amended by adding Section 481.0771 to read as follows:

Sec. 481.0771. RECORDS AND REPORTS ON PSEUDOEPHEDRINE. (a)
A wholesaler who sells, transfers, or otherwise furnishes pseudoephedrine to a retailer shall make available to the director all records of the transaction in accordance with department rule.

(b) Not later than five business days after receipt of an order for pseudoephedrine, a wholesaler shall submit to the director in accordance with department rule a report of the order if the order requests delivery of a suspicious quantity of pseudoephedrine as determined by department rule.

(c) A wholesaler who, with reckless disregard for the duty to report under Subsection (b), fails to report as required by that subsection may be subject to disciplinary action in accordance with department rule.

SECTION 2.02. Subtitle C, Title 6, Health and Safety Code, is amended by adding Chapter 486 to read as follows:

CHAPTER 486. PSEUDOEPHEDRINE

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 486.001. DEFINITIONS. (a) In this chapter:

(1) "Commissioner" means the commissioner of state health services.

(2) "Council" means the State Health Services Council.

(3) "Department" means the Department of State Health Services.

1 (4) "Pseudoephedrine" means any compound, mixture, or
2 preparation containing any detectable amount of pseudoephedrine,
3 including its salts, optical isomers, and salts of optical isomers.
4 The term does not include any compounds, mixtures, or preparations
5 that are in liquid, liquid capsule, or gel capsule form and in which
6 pseudoephedrine is not the only active ingredient.

7 (5) "Sale" includes a conveyance, exchange, barter, or
8 trade.

9 (b) A term that is used in this chapter but is not defined by
10 Subsection (a) has the meaning assigned by Section 481.002.

11 Sec. 486.002. APPLICABILITY. This chapter does not apply
12 to the sale of any product dispensed or delivered by a pharmacist
13 according to a prescription issued by a practitioner for a valid
14 medical purpose and in the course of professional practice.

15 Sec. 486.003. RULES. The council shall adopt rules
16 necessary to implement and enforce this chapter.

17 Sec. 486.004. FEES. (a) The department shall collect fees
18 for:

19 (1) the issuance of a certificate of authority under
20 this chapter; and

21 (2) an inspection performed in enforcing this chapter
22 and rules adopted under this chapter.

23 (b) The commissioner by rule shall set the fees in amounts
24 that allow the department to recover the biennial expenditures of
25 state funds by the department in:

26 (1) reviewing applications for the issuance of a
27 certificate of authority under this chapter;

1 (2) issuing certificates of authority under this
2 chapter;

3 (3) inspecting and auditing a business establishment
4 that is issued a certificate of authority under this chapter; and

5 (4) otherwise implementing and enforcing this
6 chapter.

7 (c) Fees collected under this section shall be deposited to
8 the credit of a special account in the general revenue fund and
9 appropriated to the department to implement and enforce this
10 chapter.

11 [Sections 486.005-486.010 reserved for expansion]

12 SUBCHAPTER B. OVER-THE-COUNTER SALES OF PSEUDOEPHEDRINE

13 Sec. 486.011. SALES BY PHARMACIES. A business
14 establishment that operates a pharmacy licensed by the Texas State
15 Board of Pharmacy may engage in over-the-counter sales of
16 pseudoephedrine.

17 Sec. 486.012. SALES BY ESTABLISHMENTS OTHER THAN
18 PHARMACIES; CERTIFICATE OF AUTHORITY. (a) A business
19 establishment that does not operate a pharmacy licensed by the
20 Texas State Board of Pharmacy may engage in over-the-counter sales
21 of pseudoephedrine only if the establishment holds a certificate of
22 authority issued under this section.

23 (b) The department may issue a certificate of authority to
24 engage in over-the-counter sales of pseudoephedrine to a business
25 establishment that does not operate a pharmacy licensed by the
26 Texas State Board of Pharmacy if the establishment:

27 (1) applies to the department for the certificate in

1 accordance with department rule; and

2 (2) complies with the requirements established by the
3 department for issuance of a certificate.

4 (c) The department by rule shall establish requirements for
5 the issuance of a certificate of authority under this section. The
6 rules must include a consideration by the department of whether the
7 establishment:

8 (1) complies with the requirements of the Texas State
9 Board of Pharmacy for the issuance of a license to operate a
10 pharmacy;

11 (2) sells a wide variety of pharmaceutical products;
12 and

13 (3) employs sales techniques and other measures
14 designed to deter the theft of products containing pseudoephedrine
15 and other items used in the manufacture of methamphetamine.

16 (d) The department may inspect or audit a business
17 establishment that is issued a certificate of authority under this
18 section at any time the department determines necessary.

19 Sec. 486.013. RESTRICTION OF ACCESS TO PSEUDOEPHEDRINE. A
20 business establishment that engages in over-the-counter sales of
21 pseudoephedrine shall display the pseudoephedrine in a manner that
22 makes the pseudoephedrine accessible to a patron of the business
23 establishment only with the assistance of an employee of the
24 establishment.

25 Sec. 486.014. PREREQUISITES TO SALE OF PSEUDOEPHEDRINE.
26 Before completing an over-the-counter sale of pseudoephedrine, a
27 business establishment that engages in those sales shall:

1 (1) require the person purchasing pseudoephedrine to:

2 (A) display a driver's license or other form of
3 identification containing the person's photograph and indicating
4 that the person is 16 years of age or older; and

5 (B) sign for the purchase;

6 (2) make a record of the sale, including the name of
7 the person purchasing pseudoephedrine, the date of purchase, and
8 the number of grams of pseudoephedrine purchased; and

9 (3) take actions necessary to prevent a person who
10 makes over-the-counter purchases of one or more products containing
11 pseudoephedrine from obtaining from the establishment in a single
12 transaction more than:

13 (A) two packages of a product containing
14 pseudoephedrine; or

15 (B) six grams of pseudoephedrine.

16 Sec. 486.015. MAINTENANCE OF RECORDS. A business
17 establishment that engages in over-the-counter sales of
18 pseudoephedrine shall maintain all records made under Section
19 486.014(2) in a secure centralized location. The establishment
20 shall maintain each record until at least the second anniversary of
21 the date the record is made.

22 [Sections 486.016-486.020 reserved for expansion]

23 SUBCHAPTER C. ADMINISTRATIVE PENALTY

24 Sec. 486.021. IMPOSITION OF PENALTY. The department may
25 impose an administrative penalty on a person who violates this
26 chapter.

27 Sec. 486.022. AMOUNT OF PENALTY. (a) The amount of the

1 penalty may not exceed \$1,000 for each violation, and each day a
2 violation continues or occurs is a separate violation for purposes
3 of imposing a penalty. The total amount of the penalty assessed for
4 a violation continuing or occurring on separate days under this
5 subsection may not exceed \$10,000.

6 (b) The amount shall be based on:

7 (1) the seriousness of the violation, including the
8 nature, circumstances, extent, and gravity of the violation;

9 (2) the threat to health or safety caused by the
10 violation;

11 (3) the history of previous violations;

12 (4) the amount necessary to deter a future violation;

13 (5) whether the violator demonstrated good faith,
14 including when applicable whether the violator made good faith
15 efforts to correct the violation; and

16 (6) any other matter that justice may require.

17 Sec. 486.023. REPORT AND NOTICE OF VIOLATION AND PENALTY.

18 (a) If the department initially determines that a violation
19 occurred, the department shall give written notice of the report by
20 certified mail to the person.

21 (b) The notice must:

22 (1) include a brief summary of the alleged violation;

23 (2) state the amount of the recommended penalty; and

24 (3) inform the person of the person's right to a
25 hearing on the occurrence of the violation, the amount of the
26 penalty, or both.

27 Sec. 486.024. PENALTY TO BE PAID OR HEARING REQUESTED. (a)

1 Before the 21st day after the date the person receives notice under
2 Section 486.023, the person in writing may:

3 (1) accept the determination and recommended penalty;

4 or

5 (2) make a request for a hearing on the occurrence of
6 the violation, the amount of the penalty, or both.

7 (b) If the person accepts the determination and recommended
8 penalty or if the person fails to respond to the notice, the
9 commissioner by order shall approve the determination.

10 Sec. 486.025. HEARING. (a) If the person requests a
11 hearing, the commissioner shall refer the matter to the State
12 Office of Administrative Hearings, which shall promptly set a
13 hearing date and give written notice of the time and place of the
14 hearing to the person. An administrative law judge of the State
15 Office of Administrative Hearings shall conduct the hearing.

16 (b) The administrative law judge shall make findings of fact
17 and conclusions of law and promptly issue to the commissioner a
18 proposal for a decision about the occurrence of the violation and
19 the amount of a proposed penalty.

20 Sec. 486.026. DECISION. (a) Based on the findings of fact,
21 conclusions of law, and proposal for a decision, the commissioner
22 by order may:

23 (1) find that a violation occurred and impose a
24 penalty; or

25 (2) find that a violation did not occur.

26 (b) The notice of the commissioner's order under Subsection
27 (a) that is sent to the person in the manner provided by Chapter

1 2001, Government Code, must include a statement of the right of the
2 person to judicial review of the order.

3 Sec. 486.027. OPTIONS FOLLOWING DECISION: PAY OR APPEAL.
4 Before the 31st day after the date the order under Section 486.026
5 that imposes an administrative penalty becomes final, the person
6 shall:

7 (1) pay the penalty; or

8 (2) file a petition for judicial review of the order
9 contesting the occurrence of the violation, the amount of the
10 penalty, or both.

11 Sec. 486.028. STAY OF ENFORCEMENT OF PENALTY. (a) Within
12 the period prescribed by Section 486.027, a person who files a
13 petition for judicial review may:

14 (1) stay enforcement of the penalty by:

15 (A) paying the penalty to the court for placement
16 in an escrow account; or

17 (B) giving the court a supersedeas bond approved
18 by the court that:

19 (i) is for the amount of the penalty; and

20 (ii) is effective until all judicial review
21 of the order is final; or

22 (2) request the court to stay enforcement of the
23 penalty by:

24 (A) filing with the court a sworn affidavit of
25 the person stating that the person is financially unable to pay the
26 penalty and is financially unable to give the supersedeas bond; and

27 (B) sending a copy of the affidavit to the

1 commissioner by certified mail.

2 (b) Following receipt of a copy of an affidavit under
3 Subsection (a)(2), the commissioner may file with the court, before
4 the sixth day after the date of receipt, a contest to the affidavit.
5 The court shall hold a hearing on the facts alleged in the affidavit
6 as soon as practicable and shall stay the enforcement of the penalty
7 on finding that the alleged facts are true. The person who files an
8 affidavit has the burden of proving that the person is financially
9 unable to pay the penalty or to give a supersedeas bond.

10 Sec. 486.029. COLLECTION OF PENALTY. (a) If the person
11 does not pay the penalty and the enforcement of the penalty is not
12 stayed, the penalty may be collected.

13 (b) The attorney general may sue to collect the penalty.

14 Sec. 486.030. DECISION BY COURT. (a) If the court sustains
15 the finding that a violation occurred, the court may uphold or
16 reduce the amount of the penalty and order the person to pay the
17 full or reduced amount of the penalty.

18 (b) If the court does not sustain the finding that a
19 violation occurred, the court shall order that a penalty is not
20 owed.

21 Sec. 486.031. REMITTANCE OF PENALTY AND INTEREST. (a) If
22 the person paid the penalty and if the amount of the penalty is
23 reduced or the penalty is not upheld by the court, the court shall
24 order, when the court's judgment becomes final, that the
25 appropriate amount plus accrued interest be remitted to the person
26 before the 31st day after the date that the judgment of the court
27 becomes final.

1 SUBCHAPTER I. WHOLESALE [DRUG] DISTRIBUTORS

2 OF NONPRESCRIPTION DRUGS

3 SECTION 3.02. Section 431.201, Health and Safety Code, is
4 amended to read as follows:

5 Sec. 431.201. DEFINITIONS. In this subchapter:

6 (1) "Nonprescription drug" means any drug that is not
7 a prescription drug as defined by Section 431.401.

8 (2) "Place of business" means each location at which a
9 drug for wholesale distribution is located.

10 (3) "Wholesale distribution" means distribution to a
11 person other than a consumer or patient, and includes distribution
12 by a manufacturer, repackager [repacker], own label distributor,
13 broker, jobber, warehouse, or wholesaler.

14 [~~(2) "Place of business" means each location at which~~
15 ~~a drug for wholesale distribution is located.]~~

16 SECTION 3.03. Subchapter I, Chapter 431, Health and Safety
17 Code, is amended by adding Section 431.2011 to read as follows:

18 Sec. 431.2011. APPLICABILITY OF SUBCHAPTER. This
19 subchapter applies only to the wholesale distribution of
20 nonprescription drugs.

21 SECTION 3.04. Section 431.202, Health and Safety Code, is
22 amended to read as follows:

23 Sec. 431.202. LICENSE [~~STATEMENT~~] REQUIRED. (a) A person
24 may not engage in wholesale distribution of nonprescription drugs
25 in this state unless the person holds a wholesale drug distribution
26 license issued by the department under this subchapter or
27 Subchapter N [has filed with the commissioner a signed and verified

1 ~~license statement on a form furnished by the commissioner].~~

2 (b) An applicant for a license under this subchapter must
3 submit an application to the department on the form prescribed by
4 the department or electronically on the TexasOnline Internet
5 website [~~The license statement must be filed annually~~].

6 (c) A license issued under this subchapter expires on the
7 second anniversary of the date of issuance.

8 SECTION 3.05. Section 431.204, Health and Safety Code, is
9 amended to read as follows:

10 Sec. 431.204. FEES. (a) The department [~~board~~] shall
11 collect fees for:

12 (1) a license that is filed or renewed;

13 (2) a license that is amended, including a
14 notification of a change in the location of a licensed place of
15 business required under Section 431.206; and

16 (3) an inspection performed in enforcing this
17 subchapter and rules adopted under this subchapter.

18 (b) The executive commissioner of the Health and Human
19 Services Commission [~~board may charge annual fees.~~

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

23 (1) reviewing and acting on a license;

24 (2) amending and renewing a license;

25 (3) inspecting a licensed facility; and

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

1 subchapter.

2 (c) [~~(d)~~] Fees collected under this section shall be
3 deposited to the credit of the food and drug registration fee
4 account of the general revenue fund and [~~may be~~] appropriated to the
5 department [~~only~~] to carry out the administration and enforcement
6 of this chapter.

7 SECTION 3.06. Sections 431.206 and 431.207, Health and
8 Safety Code, are amended to read as follows:

9 Sec. 431.206. CHANGE OF LOCATION OF PLACE OF BUSINESS. (a)
10 Not fewer than 30 days in advance of the change, the licensee shall
11 notify the department [~~commissioner or the commissioner's~~
12 ~~designee~~] in writing of the licensee's intent to change the
13 location of a licensed place of business.

14 (b) The notice shall include the address of the new
15 location, and the name and residence address of the individual in
16 charge of the business at the new location.

17 (c) Not more than 10 days after the completion of the change
18 of location, the licensee shall notify the department [~~commissioner~~
19 ~~or the commissioner's designee~~] in writing to confirm the
20 completion of [~~verify~~] the change of location and provide
21 verification of the information previously provided or correct and
22 confirm any information that has changed since providing the notice
23 of intent [~~, the address of the new location, and the name and~~
24 ~~residence address of the individual in charge of the business at the~~
25 ~~new address~~].

26 (d) The notice and confirmation required by this section are
27 [~~Notice will be~~] deemed adequate if the licensee sends [~~provides~~]

1 the [~~intent and verification~~] notices [~~to the commissioner or the~~
2 ~~commissioner's designee~~] by certified mail, return receipt
3 requested, [~~mailed~~] to the central office of the department or
4 submits them electronically through the TexasOnline Internet
5 website.

6 Sec. 431.207. REFUSAL TO LICENSE; SUSPENSION OR REVOCATION
7 OF LICENSE. (a) The commissioner of state health services may
8 refuse an application for a license or may suspend or revoke a
9 license if the applicant or licensee:

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

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

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

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

26 (5) has not complied with this chapter or the [~~board's~~]
27 rules implementing this chapter;

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

4 (7) has violated Chapter 481 (Texas Controlled
5 Substances Act) or 483 (Texas Dangerous Drugs Act);

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

10 (9) fails to complete a license application or submits
11 an application that contains false, misleading, or incorrect
12 information or contains information that cannot be verified by the
13 department.

14 (b) The executive commissioner of the Health and Human
15 Services Commission by rule shall establish minimum standards
16 required for the issuance or renewal of a license under this
17 subchapter [~~may refuse an application for a license or may suspend~~
18 ~~or revoke a license if the commissioner determines from evidence~~
19 ~~presented during a hearing that the applicant or licensee:~~

20 ~~[(1) has violated Section 431.021(1)(3), relating to~~
21 ~~the counterfeiting of a drug or the sale or holding for sale of a~~
22 ~~counterfeit drug;~~

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

25 ~~[(3) has violated the rules of the director of the~~
26 ~~Department of Public Safety, including being responsible for a~~
27 ~~significant discrepancy in the records that state law requires the~~

1 ~~applicant or licensee to maintain].~~

2 (c) The refusal to license an applicant or the suspension or
3 revocation of a license by the department ~~[commissioner]~~ and the
4 appeal from that action are governed by ~~[the board's formal hearing~~
5 ~~procedures and]~~ the procedures for a contested case hearing under
6 Chapter 2001, Government Code.

7 SECTION 3.07. Section 431.021, Health and Safety Code, is
8 amended to read as follows:

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

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

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

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

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

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

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

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

8 (f) the dissemination of any false advertisement;

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

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

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

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

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

7 (1)(1) forging, counterfeiting, simulating, or
8 falsely representing, or without proper authority using any mark,
9 stamp, tag, label, or other identification device authorized or
10 required by rules adopted under this chapter or the regulations
11 promulgated under the provisions of the federal Act;

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

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

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

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

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

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

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

27 (2) selling, dispensing, disposing of or causing

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

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

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

19 (s) the failure to register in accordance with Section
20 510 of the federal Act, the failure to provide any information
21 required by Section 510(j) or (k) of the federal Act, or the failure
22 to provide a notice required by Section 510(j)(2) of the federal
23 Act;

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

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

27 (B) furnish any notification or other

1 material or information required by or under Section 519 or 520(g)
2 of the federal Act;

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

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

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

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

19 (x) engaging in the wholesale distribution of drugs or
20 operating as a distributor or manufacturer of devices in this state
21 without obtaining a license issued by the department under
22 Subchapter I, L, or N [~~filing a licensing statement with the~~
23 ~~commissioner as required by Section 431.202 or having a license as~~
24 ~~required by Section 431.272~~], as applicable;

25 (y) engaging in the manufacture of food in this state
26 or operating as a warehouse operator in this state without having a
27 license as required by Section 431.222 or operating as a food

1 wholesaler in this state without having a license under Section
2 431.222 or being registered under Section 431.2211, as appropriate;

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

9 (aa) making a false statement or false representation
10 in an application for a license or in a statement, report, or other
11 instrument to be filed with or requested by the department [~~the~~
12 ~~board, the commissioner, or the department~~] under this chapter;

13 (bb) failing to comply with a requirement or request
14 to provide information or failing to submit an application,
15 statement, report, or other instrument required by the department;
16 or

17 (cc) performing, causing the performance of, or aiding
18 and abetting the performance of an act described by Subdivision
19 (x).

20 SECTION 3.08. Sections 431.2021 and 431.205, Health and
21 Safety Code, are repealed.

22 SECTION 3.09. Not later than January 1, 2006, the executive
23 commissioner of the Health and Human Services Commission shall
24 adopt the rules necessary to implement the changes in law made by
25 this article by amending Subchapter I, Chapter 431, Health and
26 Safety Code.

27 SECTION 3.10. Not later than January 1, 2006, the

1 Department of State Health Services shall prescribe the forms
2 required to implement the changes in law made by this article by the
3 amendment of Subchapter I, Chapter 431, Health and Safety Code.

4 SECTION 3.11. The change in law made by this article applies
5 only to an offense committed on or after March 1, 2006. An offense
6 committed before that date is covered by the law in effect when the
7 offense was committed, and the former law is continued in effect for
8 that purpose. For purposes of this section, an offense was
9 committed before March 1, 2006, if any element of the offense was
10 committed before that date.

11 SECTION 3.12. (a) Subject to Subsection (b) of this
12 section, this article takes effect on the date designated by
13 Section 4.01 of this Act, except that Sections 3.01-3.07 of this
14 article take effect March 1, 2006.

15 (b) This article takes effect only if Senate Bill 1685 or
16 another similar bill of the Regular Session of the 79th Legislature
17 adding Subchapter N, Chapter 431, Health and Safety Code,
18 regulating wholesale prescription drug distributors is enacted and
19 becomes law. If Senate Bill 1685 or another similar bill of the
20 Regular Session of the 79th Legislature adding Subchapter N,
21 Chapter 431, Health and Safety Code, regulating wholesale
22 prescription drug distributors does not become law, this article
23 does not take effect.

24 ARTICLE 4. EFFECTIVE DATE

25 SECTION 4.01. This Act takes effect on June 1, 2005, if it
26 receives a vote of two-thirds of all the members elected to each
27 house, as provided by Section 39, Article III, Texas Constitution.

C.S.H.B. No. 164

1 If this Act does not receive the vote necessary to take effect on
2 that date, this Act takes effect September 1, 2005.