1 AN ACT 2 relating to the civil and criminal consequences of engaging in 3 conduct related to the manufacture of methamphetamine and to the distribution and retail sales of certain chemical substances. 4 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS: 5 6 SECTION 1. Section 99.003, Civil Practice and Remedies Code, is amended to read as follows: 7 Sec. 99.003. STRICT LIABILITY AND MINIMUM DAMAGES FOR 8 9 EXPOSURE. A person who manufactures methamphetamine is strictly liable for any exposure by an individual to the manufacturing 10 11 process, including exposure to the methamphetamine itself or any of the byproducts or waste products incident to the manufacture, for 12 the greater of: 13 14 (1) actual damages for personal injury, death, or property damage as a result of the exposure; or 15 \$20,000 [\$10,000] for each incident of exposure. 16 (2) SECTION 2. Section 262.104, Family Code, is amended to read 17 18 as follows: Sec. 262.104. TAKING POSSESSION OF A CHILD IN EMERGENCY 19 WITHOUT A COURT ORDER. (a) If there is no time to obtain a 20 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 Protective [and Regulatory] Services, a law enforcement officer, or 24

H.B. No. 164 1 a juvenile probation officer may take possession of a child without 2 a court order under the following conditions, only:

3 (1) on personal knowledge of facts that would lead a 4 person of ordinary prudence and caution to believe that there is an 5 immediate danger to the physical health or safety of the child;

6 (2) on information furnished by another that has been 7 corroborated by personal knowledge of facts and all of which taken 8 together would lead a person of ordinary prudence and caution to 9 believe that there is an immediate danger to the physical health or 10 safety of the child;

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

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

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

(b) An authorized representative of the Department of
 Family and Protective Services, a law enforcement officer, or a
 juvenile probation officer may take possession of a child under

	H.B. No. 164
1	Subsection (a) on personal knowledge or information furnished by
2	another, that has been corroborated by personal knowledge, that
3	would lead a person of ordinary prudence and caution to believe that
4	the parent or person who has possession of the child has permitted
5	the child to remain on premises used for the manufacture of
6	methamphetamine.
7	SECTION 3. (a) The heading to Subchapter I, Chapter 431,
8	Health and Safety Code, is amended to read as follows:
9	SUBCHAPTER I. WHOLESALE [DRUG] DISTRIBUTORS
10	OF NONPRESCRIPTION DRUGS
11	(b) Section 431.201, Health and Safety Code, is amended to
12	read as follows:
13	Sec. 431.201. DEFINITIONS. In this subchapter:
14	(1) "Nonprescription drug" means any drug that is not
15	a prescription drug as defined by Section 431.401.
16	(2) "Place of business" means each location at which a
17	drug for wholesale distribution is located.
18	(3) "Wholesale distribution" means distribution to a
19	person other than a consumer or patient, and includes distribution
20	by a manufacturer, <u>repackager</u> [repacker], own label distributor,
21	<u>broker,</u> jobber, <u>warehouse,</u> or wholesaler.
22	[(2) "Place of business" means each location at which
23	a drug for wholesale distribution is located.]
24	(c) Subchapter I, Chapter 431, Health and Safety Code, is
25	amended by adding Section 431.2011 to read as follows:
26	Sec. 431.2011. APPLICABILITY OF SUBCHAPTER. This
27	subchapter applies only to the wholesale distribution of

1 nonprescription drugs.

2 (d) Section 431.202, Health and Safety Code, is amended to3 read as follows:

Sec. 431.202. LICENSE [STATEMENT] REQUIRED. (a) A person
may not engage in wholesale distribution of <u>nonprescription</u> drugs
in this state unless the person <u>holds a wholesale drug distribution</u>
<u>license issued by the department under this subchapter or</u>
<u>Subchapter N</u> [has filed with the commissioner a signed and verified
<u>license statement on a form furnished by the commissioner</u>].

10 (b) <u>An applicant for a license under this subchapter must</u> 11 <u>submit an application to the department on the form prescribed by</u> 12 <u>the department or electronically on the TexasOnline Internet</u> 13 <u>website</u> [The license statement must be filed annually].

14 (c) A license issued under this subchapter expires on the 15 second anniversary of the date of issuance.

16 (e) Section 431.204, Health and Safety Code, is amended to 17 read as follows:

18 Sec. 431.204. FEES. (a) The <u>department</u> [board] shall
19 collect fees for:

20

a license that is filed or renewed;

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

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

(b) The <u>executive commissioner of the Health and Human</u>
 27 <u>Services Commission</u> [board may charge annual fees.

1 [(c) The board] by rule shall set the fees in amounts that 2 allow the department to recover [at least 50 percent of] the 3 <u>biennial</u> [annual] expenditures of state funds by the department in:

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- 5

reviewing and acting on a license;

6

(2) amending and renewing a license;

(3) inspecting a licensed facility; and

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

10 (c) [(d)] Fees collected under this section shall be 11 deposited to the credit of the food and drug registration fee 12 account of the general revenue fund and [may be] appropriated to the 13 department [only] to carry out the administration and enforcement 14 of this chapter.

15 (f) Sections 431.206 and 431.207, Health and Safety Code, 16 are amended to read as follows:

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

22 (b) The notice shall include the address of the new 23 location, and the name and residence address of the individual in 24 charge of the business at the new location.

25 <u>(c)</u> Not more than 10 days after the completion of the change 26 of location, the licensee shall notify the <u>department</u> [commissioner 27 or the commissioner's designee] in writing to confirm the

1 completion of [verify] the change of location and provide 2 verification of the information previously provided or correct and confirm any information that has changed since providing the notice 3 of intent[, the address of the new location, and the name and 4 5 residence address of the individual in charge of the business at the 6 new address]. (d) The notice and confirmation required by this section are 7 8 [Notice will be] deemed adequate if the licensee sends [provides] the [intent and verification] notices [to the commissioner or the 9 commissioner's designee] by certified mail, return receipt 10 requested, [mailed] to the central office of the department or 11 submits them electronically through the TexasOnline Internet 12 13 website. Sec. 431.207. REFUSAL TO LICENSE; SUSPENSION OR REVOCATION 14 15 OF LICENSE. (a) The commissioner of state health services may refuse an application for a license or may suspend or revoke a 16 17 license if the applicant or licensee: (1) has been convicted of a felony or misdemeanor that 18 involves moral turpitude; 19 (2) is an association, partnership, or corporation and 20 21 the managing officer has been convicted of a felony or misdemeanor that involves moral turpitude; 22 (3) has been convicted in a state or federal court of 23 24 the illegal use, sale, or transportation of intoxicating liquors, narcotic drugs, barbiturates, amphetamines, desoxyephedrine, their 25 26 compounds or derivatives, or any other dangerous or habit-forming

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drugs;

H.B. No. 164 (4) is an association, partnership, or corporation and 1 the managing officer has been convicted in a state or federal court 2 3 of the illegal use, sale, or transportation of intoxicating 4 narcotic drugs, barbiturates, amphetamines, liquors, desoxyephedrine, their compounds or derivatives, or any other 5 6 dangerous or habit-forming drugs; [or] 7 (5) has not complied with this chapter or the [board's] 8 rules implementing this chapter; 9 (6) has violated Section 431.021(1)(3), relating to the counterfeiting of a drug or the sale or holding for sale of a 10 11 counterfeit drug; 12 (7) has violated Chapter 481 or 483; (8) has violated the rules of the director of the 13 Department of Public Safety, including being responsible for a 14 15 significant discrepancy in the records that state law requires the applicant or licensee to maintain; or 16 17 (9) fails to complete a license application or submits an application that contains false, misleading, or incorrect 18 19 information or contains information that cannot be verified by the department. 20 21 (b) The <u>executive</u> commissioner <u>of the Health and Human</u> Services Commission by rule shall establish minimum standards 22 required for the issuance or renewal of a license under this 23 24 subchapter [may refuse an application for a license or may suspend 25 or revoke a license if the commissioner determines from evidence presented during a hearing that the applicant or licensee: 26 [(1) has violated Section 431.021(1)(3), relating to 27

	II.D. NO. 104
1	the counterfeiting of a drug or the sale or holding for sale of a
2	counterfeit drug;
3	[(2) has violated Chapter 481 (Texas Controlled
4	Substances Act) or 483 (Dangerous Drugs); or
5	[(3) has violated the rules of the director of the
6	Department of Public Safety, including being responsible for a
7	significant discrepancy in the records that state law requires the
8	applicant or licensee to maintain].
9	(c) The refusal to license an applicant or the suspension or
10	revocation of a license by the <u>department</u> [commissioner] and the
11	appeal from that action are governed by [the board's formal hearing
12	procedures and] the procedures for a contested case hearing under
13	Chapter 2001, Government Code.
14	(g) Chapter 431, Health and Safety Code, is amended by
15	adding Subchapter N to read as follows:
16	SUBCHAPTER N. WHOLESALE DISTRIBUTORS OF PRESCRIPTION DRUGS
17	Sec. 431.401. DEFINITIONS. In this subchapter:
18	(1) "Authentication" means to affirmatively verify
19	before any wholesale distribution of a prescription drug occurs
20	that each transaction listed on the pedigree for the drug has
21	occurred.
22	(2) "Authorized distributor of record" means a
23	distributor with whom a manufacturer has established an ongoing
24	relationship to distribute the manufacturer's products in
25	accordance with Section 431.4011.
26	(3) "Chain pharmacy warehouse" means a location for
27	which a person holds a wholesale drug distribution license under

1	this subchapter, that serves primarily as a central warehouse for
2	drugs or devices, and from which intracompany sales or transfers of
3	drugs or devices are made to a group of pharmacies under common
4	ownership and control.
5	(4) "Logistics provider" means a person that receives
6	prescription drugs only from the original manufacturer, delivers
7	the prescription drugs at the direction of that manufacturer, and
8	does not purchase, sell, trade, or take title to any prescription
9	drug.
10	(5) "Normal distribution chain" means a chain of
11	custody for a drug from:
12	(A) a manufacturer to an authorized distributor
13	of record or to a wholesale distributor licensed under this
14	subchapter to a pharmacy or practitioner to a patient;
15	(B) a manufacturer to an authorized distributor
16	of record to one other authorized distributor of record to a
17	pharmacy or practitioner to a patient; or
18	(C) a manufacturer to an authorized distributor
19	of record to a chain pharmacy warehouse to a pharmacy or
20	practitioner to a patient.
21	(6) "Pedigree" means a document or electronic file
22	containing information that records each wholesale distribution of
23	a prescription drug, from sale by a manufacturer, through
24	acquisition and sale by any wholesale distributor or repackager,
25	until final sale to a pharmacy or other person dispensing or
26	administering the prescription drug.
27	(7) "Place of business" means each location at which a

1	drug for wholesale distribution is located.
2	(8) "Prescription drug" has the meaning assigned by 21
3	C.F.R. Section 203.3.
4	(9) "Repackage" means repackaging or otherwise
5	changing the container, wrapper, or labeling of a drug to further
6	the distribution of a prescription drug. The term does not include
7	repackaging by a pharmacist to dispense a drug to a patient.
8	(10) "Repackager" means a person who engages in
9	repackaging.
10	(11) "Wholesale distribution" means distribution to a
11	person other than a consumer or patient, and includes distribution
12	by a manufacturer, repackager, own label distributor, broker,
13	jobber, warehouse, retail pharmacy that conducts wholesale
14	distribution, or wholesaler. The term does not include:
15	(A) intracompany sales of prescription drugs,
16	which means transactions or transfers of prescription drugs between
17	a division, subsidiary, parent, or affiliated or related company
18	that is under common ownership and control of a corporate entity;
19	(B) the sale, purchase, distribution, trade, or
20	transfer of prescription drugs or the offer to sell, purchase,
21	distribute, trade, or transfer a prescription drug for emergency
22	medical reasons;
23	(C) the distribution of prescription drug
24	samples by a representative of a manufacturer;
25	(D) the return of drugs by a hospital, health
26	care entity, retail pharmacy, chain pharmacy warehouse, or
27	charitable institution in accordance with 21 C.F.R. Section 203.23;

1	or
2	(E) the delivery by a retail pharmacy of a
3	prescription drug to a patient or a patient's agent under the lawful
4	order of a licensed practitioner.
5	Sec. 431.4011. ONGOING RELATIONSHIP. In this subchapter,
6	"ongoing relationship" means an association that exists when a
7	manufacturer and distributor enter into a written agreement under
8	which the distributor is authorized to distribute the
9	manufacturer's products for a period of time or for a number of
10	shipments. If the distributor is not authorized to distribute the
11	manufacturer's entire product line, the agreement must identify the
12	specific drug products that the distributor is authorized to
13	distribute.
14	Sec. 431.4012. APPLICABILITY OF SUBCHAPTER. This
15	subchapter applies only to the wholesale distribution of
16	prescription drugs.
17	Sec. 431.402. LICENSE REQUIRED. (a) A person may not
18	engage in wholesale distribution of prescription drugs in this
19	state unless the person holds a wholesale drug distribution license
20	under this subchapter for each place of business.
21	(b) A license issued under this subchapter expires on the
22	second anniversary of the date of issuance.
23	Sec. 431.403. EXEMPTION FROM LICENSING. (a) A person who
24	engages in wholesale distribution of prescription drugs in this
25	state for use in humans is exempt from this subchapter if the person
26	is exempt under:
27	(1) the Prescription Drug Marketing Act of 1987 (21

1	<u>U.S.C. Section 353(c)(3)(B));</u>
2	(2) the regulations adopted by the secretary to
3	administer and enforce that Act; or
4	(3) the interpretations of that Act set out in the
5	compliance policy manual of the United States Food and Drug
6	Administration.
7	(b) An exemption from the licensing requirements under this
8	section does not constitute an exemption from the other provisions
9	of this chapter or the rules adopted under this chapter to
10	administer and enforce the other provisions of this chapter.
11	Sec. 431.4031. EXEMPTION FROM CERTAIN PROVISIONS FOR
12	CERTAIN WHOLESALE DISTRIBUTORS. A wholesale distributor that
13	distributes prescription drugs that are medical gases or a
14	wholesale distributor that is a logistics provider on behalf of a
15	manufacturer is exempt from Sections 431.404(b) and (c), 431.405,
16	431.407, 431.408, 431.412, and 431.413.
17	Sec. 431.404. LICENSE APPLICATION. (a) An applicant for a
18	license under this subchapter must submit an application to the
19	department on the form prescribed by the department. The
20	application must contain:
21	(1) all trade or business names under which the
22	business is conducted;
23	(2) the address and telephone number of each place of
24	business that is licensed;
25	(3) the type of business and the name and residence
26	address of:
27	(A) the proprietor, if the business is a

H.B. No. 164 1 proprietorship; 2 is a (B) all partners, if the business 3 partnership; or 4 (C) all principals, if the business is an 5 association; 6 (4) the date and place of incorporation, if the business is a corporation; 7 8 (5) the names and business addresses of the 9 individuals in an administrative capacity showing: (A) the managing proprietor, if the business is a 10 11 proprietorship; 12 (B) the managing partner, if the business is a 13 partnership; 14 (C) the officers and directors, if the business 15 is a corporation; or (D) the persons in a managerial capacity, if the 16 17 business is an association; (6) the name, telephone number, and any information 18 19 necessary to complete a criminal history record check on a designated representative of each place of business; 20 21 (7) the state of incorporation, if the business is a 22 corporation; (8) a list of all licenses and permits issued to the 23 24 applicant by any other state under which the applicant is permitted 25 to purchase or possess prescription drugs; and 26 (9) the name of the manager for each place of business. (b) Each person listed in Subsections (a)(6) and (a)(9) 27

1 shall provide the following to the department: 2 (1) the person's places of residence for the past seven 3 years; 4 (2) the person's date and place of birth; 5 (3) the person's occupations, positions of employment, 6 and offices held during the past seven years; 7 (4) the business name and address of any business, corporation, or other organization in which the person held an 8 9 office under Subdivision (3) or in which the person conducted an occupation or held a position of employment; 10 (5) a statement of whether during the preceding seven 11 12 years the person was the subject of a proceeding to revoke a license and the nature and disposition of the proceeding; 13 14 (6) a statement of whether during the preceding seven 15 years the person has been enjoined, either temporarily or permanently, by a court from violating any federal or state law 16 17 regulating the possession, control, or distribution of prescription drugs, including the details concerning the event; 18 19 (7) a written description of any involvement by the person with any business, including any investments, other than the 20 21 ownership of stock in a publicly traded company or mutual fund during the past seven years, that manufactured, administered, 22 prescribed, distributed, or stored pharmaceutical products and any 23 24 lawsuits in which the businesses were named as a party; 25 (8) a description of any felony offense for which the 26 person, as an adult, was found guilty, regardless of whether

H.B. No. 164

adjudication of guilt was withheld or whether the person pled

1	guilty or nolo contendere;
2	(9) a description of any criminal conviction of the
3	person under appeal, a copy of the notice of appeal for that
4	criminal offense, and a copy of the final written order of an appeal
5	not later than the 15th day after the date of the appeal's
6	disposition; and
7	(10) a photograph of the person taken not earlier than
8	30 days before the date the application was submitted.
9	(c) The information submitted under Subsection (b) must be
10	attested to under oath.
11	(d) An applicant or license holder shall file with the
12	department a written notice of any change in the information
13	required under this section.
14	Sec. 431.405. QUALIFICATIONS FOR LICENSE. To qualify for
15	the issuance or renewal of a wholesale distributor license under
16	this subchapter, the designated representative of an applicant or
17	license holder must:
18	(1) be at least 21 years of age;
19	(2) have been employed full-time for at least three
20	years by a pharmacy or a wholesale distributor in a capacity related
21	to the dispensing or distributing of prescription drugs, including
22	recordkeeping for the dispensing or distributing of prescription
23	drugs;
24	(3) be employed by the applicant full-time in a
25	managerial-level position;
26	(4) be actively involved in and aware of the actual
27	daily operation of the wholesale distributor;

(5) be physically present at the applicant's place of 1 2 business during regular business hours, except when the absence of the designated representative is authorized, including sick leave 3 4 and vacation leave; 5 (6) serve as a designated representative for only one 6 applicant at any one time; 7 (7) not have been convicted of a violation of any 8 federal, state, or local laws relating to wholesale or retail 9 prescription drug distribution or the distribution of controlled 10 substances; and (8) not have been convicted of a felony under a 11 12 federal, state, or local law. Sec. 431.406. <u>EFFECT OF OPERATION IN OTHER JURISDICTIONS;</u> 13 14 REPORTS. (a) A person who engages in the wholesale distribution 15 of drugs outside this state may engage in the wholesale distribution of drugs in this state if the person holds a license 16 17 issued by the department. (b) The department may accept reports from authorities in 18 19 other jurisdictions to determine the extent of compliance with this subchapter and the minimum standards adopted under this subchapter. 20 21 (c) The department may issue a license to a person who 22 engages in the wholesale distribution of drugs outside this state to engage in the wholesale distribution of drugs in this state if, 23 24 after an examination of the reports of the person's compliance history and current compliance record, the department determines 25 26 that the person is in compliance with this subchapter and the rules 27 adopted under this subchapter.

(d) The department shall consider each license application 1 2 and any related documents or reports filed by or in connection with a person who wishes to engage in wholesale distribution of drugs in 3 4 this state on an individual basis. 5 Sec. 431.407. CRIMINAL HISTORY RECORD INFORMATION. The 6 department shall submit to the Department of Public Safety the 7 fingerprints provided by a person with an initial or a renewal 8 license application to obtain the person's criminal history record 9 information and may forward the fingerprints to the Federal Bureau of Investigation for a federal criminal history check. 10 Sec. 431.408. BOND. (a) A wholesale distributor applying 11 12 for or renewing a license shall submit payable to this state a bond or other equivalent security acceptable to the department, 13 14 including an irrevocable letter of credit or a deposit in a trust 15 account or financial institution, in the amount of \$100,000 payable 16 to this state. 17 (b) The bond or equivalent security submitted under Subsection (a) shall secure payment of any fines or penalties 18 19 imposed by the department or imposed in connection with an enforcement action by the attorney general, any fees or other 20 21 enforcement costs, including attorney's fees payable to the attorney general, and any other fees and costs incurred by this 22 state related to that license holder, that are authorized under the 23 24 laws of this state and that the license holder fails to pay before 25 the 30th day after the date a fine, penalty, fee, or cost is 26 assessed. (c) The department or this state may make a claim against a 27

1	bond or security submitted under Subsection (a) before the first
2	anniversary of the date a license expires or is revoked under this
3	subchapter.
4	(d) The department shall deposit the bonds and equivalent
5	securities received under this section in a separate account.
6	Sec. 431.409. FEES. (a) The department shall collect fees
7	<u>for:</u>
8	(1) a license that is filed or renewed;
9	(2) a license that is amended, including a
10	notification of a change in the location of a licensed place of
11	business required under Section 431.410; and
12	(3) an inspection performed in enforcing this
13	subchapter and rules adopted under this subchapter.
14	(b) The executive commissioner of the Health and Human
15	Services Commission by rule shall set the fees in amounts that are
16	reasonable and necessary and allow the department to recover the
17	biennial expenditures of state funds by the department in:
18	(1) reviewing and acting on a license;
19	(2) amending and renewing a license;
20	(3) inspecting a licensed facility; and
21	(4) implementing and enforcing this subchapter,
22	including a rule or order adopted or a license issued under this
23	subchapter.
24	(c) Fees collected under this section shall be deposited to
25	the credit of the food and drug registration fee account of the
26	general revenue fund and appropriated to the department to carry
27	out this chapter.

H.B. No. 164 Sec. 431.410. CHANGE OF LOCATION OF PLACE OF BUSINESS. 1 2 (a) Not fewer than 30 days in advance of the change, the license holder shall notify the department in writing of the license 3 4 holder's intent to change the location of a licensed place of 5 business. 6 (b) The notice shall include the address of the new location 7 and the name and residence address of the individual in charge of 8 the business at the new location. 9 (c) Not more than 10 days after the completion of the change of location, the license holder shall notify the department in 10 writing to confirm the completion of the change of location and 11 provide verification of the information previously provided or 12 correct and confirm any information that has changed since 13 14 providing the notice of intent. 15 (d) The notice and confirmation required by this section are considered adequate if the license holder sends the notices by 16 17 certified mail, return receipt requested, to the central office of the department or submits the notices electronically through the 18 19 TexasOnline Internet website. Sec. 431.411. MINIMUM RESTRICTIONS ON TRANSACTIONS. (a) A 20 21 wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy or chain pharmacy warehouse in accordance 22 with the terms and conditions of the agreement between the 23 24 wholesale distributor and the pharmacy or chain pharmacy warehouse. 25 The returns or exchanges received by the wholesale distributor as 26 provided by this subsection are not subject to the pedigree requirement under Section 431.412. In connection with the returned 27

goods process, a wholesale distributor should establish
appropriate business practices and exercise due diligence designed
to prevent the entry of adulterated or counterfeit drugs into the
distribution channel.
(b) A manufacturer or wholesale distributor may distribute
prescription drugs only to a person licensed by the appropriate
state licensing authorities or authorized by federal law to receive
the drug. Before furnishing prescription drugs to a person not
known to the manufacturer or wholesale distributor, the
manufacturer or wholesale distributor must verify that the person
is legally authorized by the appropriate state licensing authority
to receive the prescription drugs or authorized by federal law to
receive the drugs.
(c) Except as otherwise provided by this subsection,
prescription drugs distributed by a manufacturer or wholesale
distributor may be delivered only to the premises listed on the
license. A manufacturer or wholesale distributor may distribute
prescription drugs to an authorized person or agent of that person
at the premises of the manufacturer or wholesale distributor if:
(1) the identity and authorization of the recipient is
properly established; and
(2) delivery is made only to meet the immediate needs
of a particular patient of the authorized person.
(d) Prescription drugs may be distributed to a hospital
pharmacy receiving area if a pharmacist or an authorized receiving
person signs, at the time of delivery, a receipt showing the type
and quantity of the prescription drug received. Any discrepancy

1	between the receipt and the type and quantity of the prescription
2	drug actually received shall be reported to the delivering
3	manufacturer or wholesale distributor not later than the next
4	business day after the date of delivery to the pharmacy receiving
5	area.
6	Sec. 431.412. PEDIGREE REQUIRED. (a) A person who is
7	engaged in the wholesale distribution of a prescription drug,
8	including a repackager but excluding the original manufacturer and
9	the original labeler of a prescription drug, shall provide a
10	pedigree for each prescription drug that is not distributed through
11	the normal distribution chain and is sold, traded, or transferred
12	to any other person.
13	(b) A pharmacy that sells a drug to a person other than the
14	final consumer shall provide a pedigree to the person acquiring the
15	prescription drug. The sale of a reasonable quantity of a drug to a
16	practitioner for office use is not subject to this subsection.
17	(c) The sale, trade, or transfer of a prescription drug
18	between license holders with common ownership or for an emergency
19	is not subject to this section.
20	(d) A person who is engaged in the wholesale distribution of
21	a prescription drug, including a repackager, and who is in
22	possession of a pedigree for a prescription drug must verify before
23	distributing the prescription drug that each transaction listed on
24	the pedigree has occurred.
25	Sec. 431.413. PEDIGREE CONTENTS. (a) A pedigree must
26	include all necessary identifying information concerning each sale
27	in the product's chain of distribution from the manufacturer,

1	through acquisition and sale by a wholesale distributor or
2	repackager, until final sale to a pharmacy or other person
3	dispensing or administering the drug. At a minimum, the chain of
4	distribution information must include:
5	(1) the name, address, telephone number, and, if
6	available, the e-mail address of each person who owns or possesses
7	the prescription drug, except common carriers and logistics
8	providers;
9	(2) the signature of each owner of the prescription
10	drug;
11	(3) the name and address of each location from which
12	the product was shipped, if different from the owner's name and
13	address;
14	(4) the transaction dates; and
15	(5) certification that each recipient has
16	authenticated the pedigree.
17	(b) The pedigree must include, at a minimum, the:
18	(1) name of the prescription drug;
19	(2) dosage form and strength of the prescription drug;
20	(3) size of the container;
21	(4) number of containers;
22	(5) lot number of the prescription drug; and
23	(6) name of the manufacturer of the finished dosage
24	form.
25	(c) Each pedigree statement must be:
26	(1) maintained by the purchaser and the wholesale
27	distributor for at least three years; and

	H.B. No. 164
1	(2) available for inspection and photocopying on a
2	request by the department or a peace officer in this state.
3	(d) The executive commissioner of the Health and Human
4	Services Commission shall adopt rules to implement this section.
5	(e) The department shall:
6	(1) conduct a study on the implementation of
7	electronic pedigrees;
8	(2) in conducting the study under Subdivision (1),
9	consult with manufacturers, distributors, and pharmacies
10	responsible for the sale and distribution of prescription drugs in
11	this state; and
12	(3) based on the results of the study, establish an
13	implementation date, which may not be earlier than December 31,
14	2007, for electronic pedigrees.
15	(f) Subsection (e) and this subsection expire January 1,
16	<u>2009.</u>
17	Sec. 431.414. REFUSAL TO LICENSE; SUSPENSION OR REVOCATION
18	OF LICENSE. (a) The commissioner of state health services may
19	refuse an application for a license or may suspend or revoke a
20	license if the applicant or license holder:
21	(1) has been convicted of a felony or misdemeanor that
22	involves moral turpitude;
23	(2) is an association, partnership, or corporation and
24	the managing officer has been convicted of a felony or misdemeanor
25	that involves moral turpitude;
26	(3) has been convicted in a state or federal court of
27	the illegal use, sale, or transportation of intoxicating liquors,

	H.B. No. 164
1	narcotic drugs, barbiturates, amphetamines, desoxyephedrine, their
2	compounds or derivatives, or any other dangerous or habit-forming
3	drugs;
4	(4) is an association, partnership, or corporation and
5	the managing officer has been convicted in a state or federal court
6	of the illegal use, sale, or transportation of intoxicating
7	liquors, narcotic drugs, barbiturates, amphetamines,
8	desoxyephedrine, their compounds or derivatives, or any other
9	dangerous or habit-forming drugs;
10	(5) has not complied with this subchapter or the rules
11	implementing this subchapter;
12	(6) has violated Section 431.021(1)(3), relating to
13	the counterfeiting of a drug or the sale or holding for sale of a
14	<u>counterfeit drug;</u>
15	(7) has violated Chapter 481 or 483; or
16	(8) has violated the rules of the director of the
17	Department of Public Safety, including being responsible for a
18	significant discrepancy in the records that state law requires the
19	applicant or license holder to maintain.
20	(b) The executive commissioner of the Health and Human
21	Services Commission by rule shall establish minimum standards
22	required for the issuance or renewal of a license under this
23	subchapter.
24	(c) The department shall deny a license application that is
25	incomplete, contains false, misleading, or incorrect information,
26	or contains information that cannot be verified by the department.
27	(d) The refusal to license an applicant or the suspension or

1	revocation of a license by the department and the appeal from that
2	action are governed by the procedures for a contested case hearing
3	under Chapter 2001, Government Code.
4	Sec. 431.415. ORDER TO CEASE DISTRIBUTION. (a) The
5	commissioner of state health services shall issue an order
6	requiring a person, including a manufacturer, distributor, or
7	retailer of a prescription drug, to immediately cease distribution
8	of the drug if the commissioner determines there is a reasonable
9	probability that:
10	(1) a wholesale distributor has:
11	(A) violated this subchapter;
12	(B) falsified a pedigree; or
13	(C) sold, distributed, transferred,
14	manufactured, repackaged, handled, or held a counterfeit
15	prescription drug intended for human use that could cause serious
16	adverse health consequences or death; and
17	(2) other procedures would result in unreasonable
18	delay.
19	(b) An order under Subsection (a) must provide the person
20	subject to the order with an opportunity for an informal hearing on
21	the actions required by the order to be held not later than the 10th
22	day after the date of issuance of the order.
23	(c) If, after providing an opportunity for a hearing, the
24	commissioner of state health services determines that inadequate
25	grounds exist to support the actions required by the order, the
26	commissioner shall vacate the order.
27	(h) Section 431.059, Health and Safety Code, is amended by

H.B. No. 164 1 amending Subsection (a) and adding Subsections (a-1) and (a-2) to 2 read as follows:

A person commits an offense if the person violates any 3 (a) of the provisions of Section 431.021 relating to unlawful or 4 5 prohibited acts. A first offense under this subsection is a Class A 6 misdemeanor unless it is shown on the trial of an offense under this subsection that the defendant was previously convicted of an 7 offense under this subsection, in which event the offense is a state 8 jail felony. In a criminal proceeding under this section, it is not 9 necessary to prove intent, knowledge, recklessness, or criminal 10 negligence of the defendant beyond the degree of culpability, if 11 any, stated in Subsection (a-2) or Section 431.021, as applicable, 12 to establish criminal responsibility for the violation. 13

14 (a-1) A person commits an offense if the person engages in
 15 the wholesale distribution of prescription drugs in violation of
 16 Subchapter N. An offense under this subsection is punishable by a
 17 fine not to exceed \$50,000.

18 <u>(a-2) A person commits an offense if the person knowingly</u> 19 <u>engages in the wholesale distribution of prescription drugs in</u> 20 <u>violation of Subchapter N. An offense under this subsection is</u> 21 <u>punishable by imprisonment for not more than 15 years, a fine not to</u> 22 <u>exceed \$500,000, or both imprisonment and a fine.</u>

23 (i) Section 431.021, Health and Safety Code, is amended to 24 read as follows:

25 Sec. 431.021. PROHIBITED ACTS. The following acts and the 26 causing of the following acts within this state are unlawful and 27 prohibited:

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

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

6 (c) the receipt in commerce of any food, drug, device, 7 or cosmetic that is adulterated or misbranded, and the delivery or 8 proffered delivery thereof for pay or otherwise;

9 (d) the distribution in commerce of a consumer 10 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 11 provisions of this chapter and of rules adopted under the authority 12 of this chapter; provided, however, that this prohibition shall not 13 14 apply to persons engaged in business as wholesale or retail 15 distributors of consumer commodities except to the extent that such 16 persons:

17 (1) are engaged in the packaging or labeling of18 such commodities; or

19 (2) prescribe or specify by any means the manner20 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;

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

7 (i) the giving of a guaranty or undertaking referred 8 to in Section 431.059, which guaranty or undertaking is false, except by a person who relied on a guaranty or undertaking to the 9 same effect signed by, and containing the name and address of the 10 person residing in this state from whom the person received in good 11 faith the food, drug, device, or cosmetic; or the giving of a 12 guaranty or undertaking referred to in Section 431.059, which 13 14 guaranty or undertaking is false;

15 (j) the use, removal, or disposal of a detained or 16 embargoed article in violation of Section 431.048;

17 (k) the alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling 18 of, or the doing of any other act with respect to a food, drug, 19 device, or cosmetic, if such act is done while such article is held 20 21 for sale after shipment in commerce and results in such article being adulterated or misbranded; 22

(1)(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;

making, selling, disposing of, or keeping in 1 (2) 2 possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, 3 imprint, or reproduce the trademark, trade name, or other identifying mark, 4 imprint, or device of another or any likeness of any of the 5 6 foregoing on any drug or container or labeling thereof so as to 7 render such drug a counterfeit drug;

8 (3) the doing of any act that causes a drug to be 9 a counterfeit drug, or the sale or dispensing, or the holding for 10 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;

1 (p) in the case of a prescription drug distributed or 2 offered for sale in this state, the failure of the manufacturer, 3 packer, or distributor of the drug to maintain for transmittal, or 4 to transmit, to any practitioner licensed by applicable law to 5 administer such drug who makes written request for information as 6 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 7 8 distributed or sold, or such other printed matter as is approved 9 under the federal Act. Nothing in this subsection shall be 10 construed to exempt any person from any labeling requirement imposed by or under other provisions of this chapter; 11

(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 16 17 to be sold, dispensed, or disposed of, or concealing or keeping in possession, control, or custody, with intent to sell, dispense, or 18 dispose of, any drug, device, or any container of any drug or 19 device, with knowledge that the trade name or other identifying 20 21 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 22 23 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

1 reproduce the trademark, trade name, or other identifying mark, 2 imprint, or device of another or any likeness of any of the 3 foregoing on any drug or container or labeling of any drug or 4 container so as to render such drug a counterfeit drug;

H.B. No. 164

5 (r) dispensing or causing to be dispensed a different 6 drug in place of the drug ordered or prescribed without the express 7 permission in each case of the person ordering or prescribing;

8 (s) the failure to register in accordance with Section 9 510 of the federal Act, the failure to provide any information 10 required by Section 510(j) or (k) of the federal Act, or the failure 11 to provide a notice required by Section 510(j)(2) of the federal 12 Act;

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

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

16 (B) furnish any notification or other 17 material or information required by or under Section 519 or 520(g) 18 of the federal Act;

19 (2) with respect to any device, the submission of
20 any report that is required by or under this chapter that is false
21 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

H.B. No. 164
H.B. No. 164
H.B. vo. 164
H.B. prescribed under Section 412(d)(2) of the federal Act;

3 (w) except as provided under Subchapter M of this 4 chapter and Section 562.1085, Occupations Code, the acceptance by a 5 person of an unused prescription or drug, in whole or in part, for 6 the purpose of resale, after the prescription or drug has been 7 originally dispensed, or sold;

8 (x) engaging in the wholesale distribution of drugs or 9 operating as a distributor or manufacturer of devices in this state 10 without <u>obtaining a license issued by the department under</u> 11 <u>Subchapter I, L, or N</u> [filing a licensing statement with the 12 commissioner as required by Section 431.202 or having a license as 13 required by Section 431.272], as applicable;

(y) engaging in the manufacture of food in this state or operating as a warehouse operator in this state without having a license as required by Section 431.222 or operating as a food wholesaler in this state without having a license under Section 431.222 or being registered under Section 431.2211, as appropriate;

(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; [or]

(aa) making a false statement or false representation
in an application for a license or in a statement, report, or other
instrument to be filed with <u>or requested by the department</u> [the

1	board, the commissioner, or the department] under this chapter <u>;</u>
2	(bb) failing to comply with a requirement or request
3	to provide information or failing to submit an application,
4	statement, report, or other instrument required by the department;
5	(cc) performing, causing the performance of, or aiding
6	and abetting the performance of an act described by Subdivision
7	<u>(x);</u>
8	(dd) purchasing or otherwise receiving a prescription
9	drug from a pharmacy in violation of Section 431.411(a);
10	(ee) selling, distributing, or transferring a
11	prescription drug to a person who is not authorized under state or
12	federal law to receive the prescription drug in violation of
13	Section 431.411(b);
14	(ff) failing to deliver prescription drugs to
15	specified premises as required by Section 431.411(c);
16	(gg) failing to maintain or provide pedigrees as
17	required by Section 431.412 or 431.413;
18	(hh) failing to obtain, pass, or authenticate a
19	pedigree as required by Section 431.412 or 431.413; or
20	(ii) the introduction or delivery for introduction
21	into commerce of a drug or prescription device at a flea market.
22	(j) Section 411.110, Government Code, is amended to read as
23	follows:
24	Sec. 411.110. ACCESS TO CRIMINAL HISTORY RECORD
25	INFORMATION: [TEXAS] DEPARTMENT OF STATE HEALTH SERVICES.
26	(a) The [Texas] Department of <u>State</u> Health <u>Services</u> is entitled to
27	obtain from the department criminal history record information

1 maintained by the department that relates to:

(1) a person who is:

2

3 <u>(A)</u> [(1)] an applicant for a license or 4 certificate under the Emergency Medical Services Act (Chapter 773, 5 Health and Safety Code);

6 (B) [(2)] an owner or manager of an applicant for
7 an emergency medical services provider license under that Act; or

8 (C) [(3)] the holder of a license or certificate 9 under that Act; or

10 (2) an applicant for a license or a license holder
 11 under Subchapter N, Chapter 431, Health and Safety Code.

12 (b) Criminal history record information obtained by the 13 [Texas] Department of <u>State</u> Health <u>Services</u> under Subsection (a) 14 may not be released or disclosed to any person except on court 15 order, with the written consent of the person or entity that is the 16 subject of the criminal history record information, or as provided 17 by Subsection (e).

(c) After an entity is licensed or certified, the [Texas]
 Department of <u>State</u> Health <u>Services</u> shall destroy the criminal
 history record information that relates to that entity.

(d) The <u>Department of State Health Services</u> [Texas Board of
 Health] shall destroy criminal history record information that
 relates to an applicant that is not certified.

(e) The <u>Department of State Health Services</u> [Texas Board of
Health] is not prohibited from disclosing criminal history record
information obtained under Subsection (a) in a criminal proceeding
or in a hearing conducted by the [Texas] Department of <u>State</u> Health

1 <u>Services</u>.

2 (k) Sections 431.2021 and 431.205, Health and Safety Code,
3 are repealed.

4 (1)Not later than January 1, 2006, the executive 5 commissioner of the Health and Human Services Commission shall adopt the rules necessary to implement the changes in law made by 6 7 this section by amending Subchapter I, Chapter 431, Health and Safety Code, and adding Subchapter N, Chapter 431, Health and 8 Safety Code. 9

(m) Not later than January 1, 2006, the Department of State Health Services shall prescribe the forms required to implement the changes in law made by this section by the amendment of Subchapter I, Chapter 431, Health and Safety Code, and the addition of Subchapter N, Chapter 431, Health and Safety Code.

(n) The change in law made by this section applies only to an offense committed on or after March 1, 2006. An offense committed before that date is covered by the law in effect when the offense was committed, and the former law is continued in effect for that purpose. For purposes of this subsection, an offense was committed before March 1, 2006, if any element of the offense was committed before that date.

(o) Except as provided by Subsection (p) of this section,
this section takes effect September 1, 2005.

(p) Subsections (a) through (i) of this section take effectMarch 1, 2006.

26 SECTION 4. Section 481.077(1), Health and Safety Code, is 27 amended to read as follows:

	H.B. No. 164
1	(l) This section does not apply to the sale or transfer of
2	any compound, mixture, or preparation containing [a nonnarcotic
3	product that:
4	[(1) includes:
5	[(A)] ephedrine <u>/</u> [+
6	[(B)] pseudoephedrine <u>, or</u> [;
7	[(C)] norpseudoephedrine <u>that is in liquid</u> ,
8	liquid capsule, or liquid gel capsule form[; or
9	[(D) phenylpropanolamine; and
10	[(2) is sold with a prescription or over the counter in
11	accordance with a federal statute or rule].
12	SECTION 5. Subchapter C, Chapter 481, Health and Safety
13	Code, is amended by adding Section 481.0771 to read as follows:
14	Sec. 481.0771. RECORDS AND REPORTS ON PSEUDOEPHEDRINE.
15	(a) A wholesaler who sells, transfers, or otherwise furnishes a
16	product containing ephedrine, pseudoephedrine, or
17	norpseudoephedrine to a retailer shall:
18	(1) before delivering the product, obtain from the
19	retailer the retailer's address, area code, and telephone number;
20	and
21	(2) make an accurate and legible record of the
22	transaction and maintain the record for at least two years after the
23	date of the transaction.
24	(b) The wholesaler shall make all records available to the
25	director in accordance with department rule, including:
26	(1) the information required by Subsection (a)(1);
27	(2) the amount of the product containing ephedrine,

NI. 161 ם דד

1	pseudoephedrine, or norpseudoephedrine delivered; and
2	(3) any other information required by the director.
3	(c) Not later than 10 business days after receipt of an
4	order for a product containing ephedrine, pseudoephedrine, or
5	norpseudoephedrine that requests delivery of a suspicious quantity
6	of the product as determined by department rule, a wholesaler shall
7	submit to the director a report of the order in accordance with
8	department rule.
9	(d) A wholesaler who, with reckless disregard for the duty
10	to report, fails to report as required by Subsection (c) may be
11	subject to disciplinary action in accordance with department rule.
12	SECTION 6. Section 481.124(b), Health and Safety Code, is
13	amended to read as follows:
14	(b) For purposes of this section, an intent to unlawfully
15	manufacture the controlled substance methamphetamine is presumed
16	if the actor possesses or transports:
17	(1) anhydrous ammonia in a container or receptacle
18	that is not designed and manufactured to lawfully hold or transport
19	anhydrous ammonia;
20	(2) lithium metal removed from a battery and immersed
21	in kerosene, mineral spirits, or similar liquid that prevents or
22	retards hydration; or
23	(3) in one container, vehicle, or building,
24	phenylacetic acid, or more than nine grams, three containers
25	packaged for retail sale, or 300 tablets or capsules of a product
26	containing ephedrine or pseudoephedrine, and:
27	(A) anhydrous ammonia;

H.B. No. 164 1 (B) at least three of the following categories of 2 substances commonly used in the manufacture of methamphetamine: 3 (i) lithium or sodium metal or red 4 phosphorus, iodine, or iodine crystals; 5 (ii) lye, sulfuric acid, hydrochloric acid, 6 or muriatic acid; 7 (iii) an organic solvent, including ethyl 8 ether, alcohol, or acetone; 9 (iv) a petroleum distillate, including 10 naphtha, paint thinner, or charcoal lighter fluid; or (v) aquarium, rock, or table salt; or 11 at least three of the following items: 12 (C) (i) an item of equipment subject 13 to regulation under Section 481.080, if the person is not registered 14 15 under Section 481.063; or (ii) glassware, a plastic or metal 16 17 container, tubing, a hose, or other item specially designed, assembled, or adapted for use in the manufacture, processing, 18 19 analyzing, storing, or concealing of methamphetamine. SECTION 7. Subchapter D, Chapter 481, Health and Safety 20 21 Code, is amended by adding Section 481.1245 to read as follows: Sec. 481.1245. OFFENSE: POSSESSION OR TRANSPORT OF 22 ANHYDROUS AMMONIA; USE OF OR TAMPERING WITH EQUIPMENT. (a) 23 А 24 person commits an offense if the person: 25 (1) possesses or transports anhydrous ammonia in a 26 container or receptacle that is not designed or manufactured to 27 hold or transport anhydrous ammonia;

1	(2) uses, transfers, or sells a container or
2	receptacle that is designed or manufactured to hold anhydrous
3	ammonia without the express consent of the owner of the container or
4	receptacle; or
5	(3) tampers with equipment that is manufactured or
6	used to hold, apply, or transport anhydrous ammonia without the
7	express consent of the owner of the equipment.
8	(b) An offense under this section is a felony of the third
9	degree.
10	SECTION 8. Section 481.136(a), Health and Safety Code, is
11	amended to read as follows:
12	(a) A person commits an offense if the person sells,
13	transfers, furnishes, or receives a chemical precursor subject to
14	Section 481.077(a) and the person:
15	(1) does not hold a chemical precursor transfer permit
16	as required by Section 481.078 at the time of the transaction;
17	(2) does not comply with Section 481.077 <u>or 481.0771</u> ;
18	(3) knowingly makes a false statement in a report or
19	record required by Section 481.077 <u>, 481.0771,</u> or 481.078; or
20	(4) knowingly violates a rule adopted under Section
21	481.077 <u>, 481.0771,</u> or 481.078.
22	SECTION 9. Subtitle C, Title 6, Health and Safety Code, is
23	amended by adding Chapter 486 to read as follows:
24	CHAPTER 486. OVER-THE-COUNTER SALES OF EPHEDRINE,
25	PSEUDOEPHEDRINE, AND NORPSEUDOEPHEDRINE
26	SUBCHAPTER A. GENERAL PROVISIONS
27	Sec. 486.001. DEFINITIONS. (a) In this chapter:

	H.B. No. 164
1	(1) "Commissioner" means the commissioner of state
2	health services.
3	(2) "Council" means the State Health Services Council.
4	(3) "Department" means the Department of State Health
5	Services.
6	(4) "Ephedrine," "pseudoephedrine," and
7	"norpseudoephedrine" mean any compound, mixture, or preparation
8	containing any detectable amount of that substance, including its
9	salts, optical isomers, and salts of optical isomers. The term does
10	not include any compound, mixture, or preparation that is in
11	liquid, liquid capsule, or liquid gel capsule form.
12	(5) "Sale" includes a conveyance, exchange, barter, or
13	trade.
14	(b) A term that is used in this chapter but is not defined by
15	Subsection (a) has the meaning assigned by Section 481.002.
16	Sec. 486.002. APPLICABILITY. This chapter does not apply
17	to the sale of any product dispensed or delivered by a pharmacist
18	according to a prescription issued by a practitioner for a valid
19	medical purpose and in the course of professional practice.
20	Sec. 486.003. RULES. The council shall adopt rules
21	necessary to implement and enforce this chapter.
22	Sec. 486.004. FEES. (a) The department shall collect fees
23	for:
24	(1) the issuance of a certificate of authority under
25	this chapter; and
26	(2) an inspection performed in enforcing this chapter
27	and rules adopted under this chapter.

	H.B. No. 164
1	(b) The commissioner by rule shall set the fees in amounts
2	that allow the department to recover the biennial expenditures of
3	state funds by the department in:
4	(1) reviewing applications for the issuance of a
5	certificate of authority under this chapter;
6	(2) issuing certificates of authority under this
7	<pre>chapter;</pre>
8	(3) inspecting and auditing a business establishment
9	that is issued a certificate of authority under this chapter; and
10	(4) otherwise implementing enforcing this chapter.
11	(c) Fees collected under this section shall be deposited to
12	the credit of a special account in the general revenue fund and
13	appropriated to the department to implement and enforce this
14	<u>chapter.</u>
15	Sec. 486.005. STATEWIDE APPLICATION AND UNIFORMITY. (a)
16	To ensure uniform and equitable implementation and enforcement
17	throughout this state, this chapter constitutes the whole field of
18	regulation regarding over-the-counter sales of products that
19	contain ephedrine, pseudoephedrine, or norpseudoephedrine.
20	(b) This chapter preempts and supersedes a local ordinance,
21	rule, or regulation adopted by a political subdivision of this
22	state pertaining to over-the-counter sales of products that contain
23	ephedrine, pseudoephedrine, or norpseudoephedrine.
24	(c) This section does not preclude a political subdivision
25	from imposing administrative sanctions on the holder of a business
26	or professional license or permit issued by the political
27	subdivision who engages in conduct that violates this chapter.

1	[Sections 486.006-486.010 reserved for expansion]
2	SUBCHAPTER B. OVER-THE-COUNTER SALES
3	Sec. 486.011. SALES BY PHARMACIES. A business establishment
4	that operates a pharmacy licensed by the Texas State Board of
5	Pharmacy may engage in over-the-counter sales of ephedrine,
6	pseudoephedrine, and norpseudoephedrine.
7	Sec. 486.012. SALES BY ESTABLISHMENTS OTHER THAN
8	PHARMACIES; CERTIFICATE OF AUTHORITY. (a) A business establishment
9	that does not operate a pharmacy licensed by the Texas State Board
10	of Pharmacy may engage in over-the-counter sales of ephedrine,
11	pseudoephedrine, or norpseudoephedrine only if the establishment
12	holds a certificate of authority issued under this section.
13	(b) The department may issue a certificate of authority to
14	engage in over-the-counter sales of ephedrine, pseudoephedrine,
15	and norpseudoephedrine to a business establishment that does not
16	operate a pharmacy licensed by the Texas State Board of Pharmacy if
17	the establishment:
18	(1) applies to the department for the certificate in
19	accordance with department rule; and
20	(2) complies with the requirements established by the
21	department for issuance of a certificate.
22	(c) The department by rule shall establish requirements for
23	the issuance of a certificate of authority under this section. The
24	rules must include a consideration by the department of whether the
25	establishment:
26	(1) complies with the requirements of the Texas State
27	Board of Pharmacy for the issuance of a license to operate a

1	pharmacy;
2	(2) sells a wide variety of healthcare products; and
3	(3) employs sales techniques and other measures
4	designed to deter the theft of products containing ephedrine,
5	pseudoephedrine, or norpseudoephedrine and other items used in the
6	manufacture of methamphetamine.
7	(d) The department may inspect or audit a business
8	establishment that is issued a certificate of authority under this
9	section at any time the department determines necessary.
10	Sec. 486.013. RESTRICTION OF ACCESS TO EPHEDRINE,
11	PSEUDOEPHEDRINE, AND NORPSEUDOEPHEDRINE. A business establishment
12	that engages in over-the-counter sales of products containing
13	ephedrine, pseudoephedrine, or norpseudoephedrine shall:
14	(1) if the establishment operates a pharmacy licensed
15	by the Texas State Board of Pharmacy, maintain those products:
16	(A) behind the pharmacy counter; or
17	(B) in a locked case within 30 feet and in a
18	direct line of sight from a pharmacy counter staffed by an employee
19	of the establishment; or
20	(2) if the establishment does not operate a pharmacy
21	licensed by the Texas State Board of Pharmacy, maintain those
22	products:
23	(A) behind a sales counter; or
24	(B) in a locked case within 30 feet and in a
25	direct line of sight from a sales counter continuously staffed by an
26	employee of the establishment.
27	Sec. 486.014. PREREQUISITES TO SALE. Before completing an

1	over-the-counter sale of a product containing ephedrine,
2	pseudoephedrine, or norpseudoephedrine, a business establishment
3	that engages in those sales shall:
4	(1) require the person making the purchase to:
5	(A) display a driver's license or other form of
6	identification containing the person's photograph and indicating
7	that the person is 16 years of age or older; and
8	(B) sign for the purchase;
9	(2) make a record of the sale, including the name of
10	the person making the purchase, the date of the purchase, and the
11	item and number of grams purchased; and
12	(3) take actions necessary to prevent a person who
13	makes over-the-counter purchases of one or more products containing
14	ephedrine, pseudoephedrine, or norpseudoephedrine from obtaining
15	from the establishment in a single transaction more than:
16	(A) two packages of those products; or
17	(B) six grams of ephedrine, pseudoephedrine,
18	norpseudoephedrine, or a combination of those substances.
19	Sec. 486.015. MAINTENANCE OF RECORDS. The business
20	establishment shall maintain each record made under Section
21	486.014(2) until at least the second anniversary of the date the
22	record is made and shall make each record available on request by
23	the department or the Department of Public Safety.
24	[Sections 486.016-486.020 reserved for expansion]
25	SUBCHAPTER C. ADMINISTRATIVE PENALTY
26	Sec. 486.021. IMPOSITION OF PENALTY. The department may
27	impose an administrative penalty on a person who violates this

1	<u>chapter.</u>
2	Sec. 486.022. AMOUNT OF PENALTY. (a) The amount of the
3	penalty may not exceed \$1,000 for each violation, and each day a
4	violation continues or occurs is a separate violation for purposes
5	of imposing a penalty. The total amount of the penalty assessed for
6	a violation continuing or occurring on separate days under this
7	subsection may not exceed \$20,000.
8	(b) The amount shall be based on:
9	(1) the seriousness of the violation, including the
10	nature, circumstances, extent, and gravity of the violation;
11	(2) the threat to health or safety caused by the
12	violation;
13	(3) the history of previous violations;
14	(4) the amount necessary to deter a future violation;
15	(5) whether the violator demonstrated good faith,
16	including when applicable whether the violator made good faith
17	efforts to correct the violation; and
18	(6) any other matter that justice may require.
19	Sec. 486.023. REPORT AND NOTICE OF VIOLATION AND PENALTY.
20	(a) If the department initially determines that a violation
21	occurred, the department shall give written notice of the report by
22	certified mail to the person.
23	(b) The notice must:
24	(1) include a brief summary of the alleged violation;
25	(2) state the amount of the recommended penalty; and
26	(3) inform the person of the person's right to a
27	hearing on the occurrence of the violation, the amount of the

1	penalty, or both.
2	Sec. 486.024. PENALTY TO BE PAID OR HEARING REQUESTED. (a)
3	Before the 21st day after the date the person receives notice under
4	Section 486.023, the person in writing may:
5	(1) accept the determination and recommended penalty;
6	or
7	(2) make a request for a hearing on the occurrence of
8	the violation, the amount of the penalty, or both.
9	(b) If the person accepts the determination and recommended
10	penalty or if the person fails to respond to the notice, the
11	commissioner by order shall approve the determination.
12	Sec. 486.025. HEARING. (a) If the person requests a
13	hearing, the commissioner shall refer the matter to the State
14	Office of Administrative Hearings, which shall promptly set a
15	hearing date and give written notice of the time and place of the
16	hearing to the person. An administrative law judge of the State
17	Office of Administrative Hearings shall conduct the hearing.
18	(b) The administrative law judge shall make findings of fact
19	and conclusions of law and promptly issue to the commissioner a
20	proposal for a decision about the occurrence of the violation and
21	the amount of a proposed penalty.
22	Sec. 486.026. DECISION. (a) Based on the findings of fact,
23	conclusions of law, and proposal for a decision, the commissioner
24	by order may:
25	(1) find that a violation occurred and impose a
26	penalty; or
27	(2) find that a violation did not occur.

	H.B. No. 164
1	(b) The notice of the commissioner's order under Subsection
2	(a) that is sent to the person in the manner provided by Chapter
3	2001, Government Code, must include a statement of the right of the
4	person to judicial review of the order.
5	Sec. 486.027. OPTIONS FOLLOWING DECISION: PAY OR APPEAL.
6	Before the 31st day after the date the order under Section 486.026
7	that imposes an administrative penalty becomes final, the person
8	shall:
9	(1) pay the penalty; or
10	(2) file a petition for judicial review of the order
11	contesting the occurrence of the violation, the amount of the
12	penalty, or both.
13	Sec. 486.028. STAY OF ENFORCEMENT OF PENALTY. (a) Within
14	the period prescribed by Section 486.027, a person who files a
15	petition for judicial review may:
16	(1) stay enforcement of the penalty by:
17	(A) paying the amount of the penalty to the court
18	for placement in an escrow account; or
19	(B) giving the court a supersedeas bond approved
20	by the court that:
21	(i) is for the amount of the penalty; and
22	(ii) is effective until all judicial review
23	of the order is final; or
24	(2) request the court to stay enforcement of the
25	penalty by:
26	(A) filing with the court an affidavit of the
27	person stating that the person is financially unable to pay the

H.B. No. 164 penalty and is financially unable to give the supersedeas bond; and 1 2 (B) sending a copy of the affidavit to the 3 commissioner by certified mail. 4 (b) Following receipt of a copy of an affidavit under Subsection (a)(2), the commissioner may file with the court, before 5 6 the sixth day after the date of receipt, a contest to the affidavit. The court shall hold a hearing on the facts alleged in the affidavit 7 8 as soon as practicable and shall stay the enforcement of the penalty on finding that the alleged facts are true. The person who files an 9 affidavit has the burden of proving that the person is financially 10 unable to pay the penalty or to give a supersedeas bond. 11 Sec. 486.029. COLLECTION OF PENALTY. (a) If the person 12 does not pay the penalty and the enforcement of the penalty is not 13 14 stayed, the penalty may be collected. 15 (b) The attorney general may sue to collect the penalty. 16 Sec. 486.030. DECISION BY COURT. (a) If the court sustains 17 the finding that a violation occurred, the court may uphold or reduce the amount of the penalty and order the person to pay the 18 19 full or reduced amount of the penalty. (b) If the court does not sustain the finding that a 20 21 violation occurred, the court shall order that a penalty is not 22 owed. Sec. 486.031. REMITTANCE OF PENALTY AND INTEREST. (a) If 23 24 the person paid the penalty and if the amount of the penalty is 25 reduced or the penalty is not upheld by the court, the court shall 26 order, when the court's judgment becomes final, that the

appropriate amount plus accrued interest be remitted to the person

1	before the 31st day after the date that the judgment of the court
2	becomes final.
3	(b) The interest accrues at the rate charged on loans to
4	depository institutions by the New York Federal Reserve Bank.
5	(c) The interest shall be paid for the period beginning on
6	the date the penalty is paid and ending on the date the penalty is
7	remitted.
8	Sec. 486.032. RELEASE OF BOND. (a) If the person gave a
9	supersedeas bond and the penalty is not upheld by the court, the
10	court shall order, when the court's judgment becomes final, the
11	release of the bond.
12	(b) If the person gave a supersedeas bond and the amount of
13	the penalty is reduced, the court shall order the release of the
14	bond after the person pays the reduced amount.
15	Sec. 486.033. ADMINISTRATIVE PROCEDURE. A proceeding to
16	impose the penalty under this subchapter is considered to be a
17	contested case under Chapter 2001, Government Code.
18	SECTION 10. Section 22.041, Penal Code, is amended by
19	adding Subsection (c-1) to read as follows:
20	(c-1) For purposes of Subsection (c), it is presumed that a
21	person engaged in conduct that places a child in imminent danger of
22	death, bodily injury, or physical or mental impairment if the
23	person manufactured the controlled substance methamphetamine in
24	the presence of the child.
25	SECTION 11. Chapter 504, Health and Safety Code, is
26	repealed.
27	SECTION 12. (a) Section 99.003, Civil Practice and

Remedies Code, as amended by this Act, applies only to a cause of action that accrues on or after September 1, 2005. An action that accrued before September 1, 2005, is governed by the law applicable to the action immediately before September 1, 2005, and that law is continued in effect for that purpose.

6 (b) The changes in law made by this Act in amending Section 7 481.124(b), Health and Safety Code, in adding Section 481.1245, Health and Safety Code, and Section 22.041(c-1), Penal Code, and in 8 9 repealing Chapter 504, Health and Safety Code, apply only to an offense committed on or after September 1, 2005. 10 An offense committed before September 1, 2005, is covered by the law in effect 11 when the offense was committed, and the former law is continued in 12 effect for that purpose. For purposes of this section, an offense 13 was committed before September 1, 2005, if any element of the 14 15 offense was committed before that date.

16 (c) The director of the Department of Public Safety of the
17 State of Texas shall adopt any rules necessary to administer and
18 enforce Section 481.0771, Health and Safety Code, as added by this
19 Act, not later than September 1, 2005.

20 SECTION 13. This Act takes effect August 1, 2005, if it 21 receives a vote of two-thirds of all the members elected to each 22 house, as provided by Section 39, Article III, Texas Constitution. 23 If this Act does not receive the vote necessary to take effect on 24 that date, this Act takes effect September 1, 2005.

President of the Senate

Speaker of the House

I certify that H.B. No. 164 was passed by the House on May 13, 2005, by the following vote: Yeas 143, Nays 1, 1 present, not voting; and that the House concurred in Senate amendments to H.B. No. 164 on May 27, 2005, by the following vote: Yeas 136, Nays 0, 2 present, not voting.

Chief Clerk of the House

I certify that H.B. No. 164 was passed by the Senate, with amendments, on May 24, 2005, by the following vote: Yeas 31, Nays O.

Secretary of the Senate

APPROVED: _____

Date

Governor