

Amend CSSB 943 (committee printing) as follows:

(1) In SECTION 1 of the bill, strike the recital (page 1, lines 13 through 16) and substitute the following:

Section 431.401, Health and Safety Code, is amended by amending Subdivisions (3), (5), and (11) and adding Subdivisions (3-a), (3-b), (4-a), (4-b), (10-a), and (12) to read as follows:

(3) "Pharmacy [~~Chain pharmacy~~] warehouse" means a location for which a person holds a wholesale drug distribution license under this subchapter, that serves [~~primarily~~] as a central warehouse for drugs or devices, and from which intracompany sales or transfers of drugs or devices are made to a group of pharmacies under common ownership and control.

(2) In SECTION 1 of the bill, in proposed Paragraphs (B) and (C), Subdivision (3-b), Section 431.401, Health and Safety Code (page 1, lines 31 and 33), strike "chain" each place it occurs.

(3) In SECTION 1 of the bill, in proposed Subdivision (4-a), Section 431.401, Health and Safety Code (page 1, line 42), insert the following after the period:

The term does not include a pharmacist engaged in compounding that is done within the practice of pharmacy and pursuant to a prescription drug order or initiative from a practitioner for a patient or prepackaging that is done in accordance with Section 562.154, Occupations Code.

(4) In SECTION 1 of the bill, strike amended Subdivision (5), Section 431.401, Health and Safety Code (page 1, line 52, through page 2, line 17), and substitute the following:

(5) "Normal distribution channel [~~chain~~]" means a chain of custody for a prescription drug, either directly or by drop shipment, from the manufacturer of the prescription drug, the manufacturer to the manufacturer's co-licensed product partner, the manufacturer to the manufacturer's third-party logistics provider, or the manufacturer to the manufacturer's exclusive distributor, to:

(A) [~~a manufacturer to an authorized distributor of record or to a wholesale distributor licensed under this subchapter to~~] a pharmacy [~~or practitioner~~] to:

(i) a patient; or

(ii) another designated person authorized by law to dispense or administer the drug to a patient;

(B) an authorized distributor of record to:

(i) a pharmacy to a patient; or

(ii) another designated person authorized by law to dispense or administer the drug to a patient;

(C) [~~a manufacturer to~~] an authorized distributor of record to a pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy or another designated person authorized by law to dispense or administer the drug [~~one other authorized distributor of record to a pharmacy or practitioner~~] to a patient; [~~or~~]

(D) [~~(C) a manufacturer to an authorized distributor of record to~~] a [~~chain~~] pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy or another designated person authorized by law to dispense or administer the drug [~~a pharmacy or practitioner~~] to a patient; or

(E) a person authorized by law to prescribe a prescription drug that by law may be administered only under the supervision of the prescriber.

(5) In SECTION 1 of the bill, strike amended Paragraph (A), Subdivision (11), Section 431.401, Health and Safety Code (page 2, lines 33 through 38), and substitute the following:

(A) intracompany sales of prescription drugs, which means transactions or transfers of prescription drugs between a division, subsidiary, parent, or affiliated or related company that is under common ownership and control, or any transaction or transfer between co-license holders of a co-licensed product [~~of a corporate entity~~];

(6) In SECTION 1 of the bill, in proposed Paragraph (J), Subdivision (11), Section 431.401, Health and Safety Code (page 3, line 6), strike "chain".

(7) In SECTION 1 of the bill, strike proposed Subdivision (12), Section 431.401, Health and Safety Code (page 3, lines 9 through 20), and substitute the following:

(12) "Wholesale distributor" means a person engaged in the wholesale distribution of prescription drugs, including a

manufacturer, repackager, own-label distributor, private-label distributor, jobber, broker, manufacturer warehouse, distributor warehouse, or other warehouse, manufacturer's exclusive distributor, authorized distributor of record, drug wholesaler or distributor, independent wholesale drug trader, specialty wholesale distributor, third-party logistics provider, retail pharmacy that conducts wholesale distribution, and pharmacy warehouse that conducts wholesale distribution.

(8) In SECTION 3 of the bill, strike amended Subdivision (10), Subsection (b), Section 431.404, Health and Safety Code (page 4, lines 46 and 47), and substitute the following:

(10) a photograph of the person taken not earlier than 180 [~~30~~] days before the date the application was submitted.

(9) In SECTION 6 of the bill, strike proposed Subsection (a-1), Section 431.408, Health and Safety Code (page 5, lines 28 through 30), and substitute the following:

(a-1) A pharmacy warehouse that is not engaged in wholesale distribution is exempt from the bond requirement under Subsection (a).

(10) In SECTION 8 of the bill, strike proposed Section 431.4101, Health and Safety Code (page 5, lines 47 through 51), and substitute the following:

Sec. 431.4101. CONTINUING TRAINING. Designated representatives identified in Section 431.404(a)(5) shall successfully complete continuing training regarding applicable federal and state laws governing the wholesale distribution of prescription drugs as required by department rule.

(11) In SECTION 9 of the bill, strike the recital (page 5, lines 55 through 57), and substitute the following:

Section 431.411, Health and Safety Code, is amended by amending Subsection (a) and adding Subsections (a-1), (a-2), and (e) to read as follows:

(12) In SECTION 9 of the bill, in amended Subsection (a), Section 431.411, Health and Safety Code (page 5, lines 59 and 61), strike "chain" each place it occurs and substitute "~~chain~~".

(13) In SECTION 9 of the bill, strike proposed Subdivision (3), Subsection (a), Section 431.411, Health and Safety Code (page

6, lines 7 through 9), and substitute the following:

(3) the interpretations of that Act set out in the compliance policy guide of the United States Food and Drug Administration.

(14) In SECTION 9 of the bill, immediately following proposed Subsection (a-1), Section 431.411, Health and Safety Code (page 6, between lines 15 and 16), insert the following:

(a-2) Notwithstanding any provision of state or federal law to the contrary, a person that has not otherwise been required to obtain a wholesale license under this subchapter and that is a pharmacy engaging in the sale or transfer of expired, damaged, returned, or recalled prescription drugs to the originating wholesale distributor or manufacturer and pursuant to federal statute, rules, and regulations, including the United States Food and Drug Administration's applicable guidances implementing the Prescription Drug Marketing Act of 1987 (Pub. L. No. 100-293), is exempt from wholesale licensure requirements under this subchapter.

(15) In SECTION 9 of the bill, in proposed Subsection (e), Section 431.411, Health and Safety Code (page 6, line 23), between "holder" and the underlined period, insert the following:

or the license holder's professional entity, as that term is defined by Section 301.003, Business Organizations Code. This subsection does not prohibit a pharmacy or pharmacy warehouse from receiving prescription drugs where the payment for the prescription drugs is processed through the pharmacy's or pharmacy warehouse's contractual wholesale distributor

(16) In SECTION 10 of the bill, in proposed Subsection (b-1), Section 431.412, Health and Safety Code (page 6, line 34), strike "chain".

(17) In SECTION 11 of the bill, strike proposed Subsection (e-1), Section 431.413, Health and Safety Code (page 7, lines 15 through 24), and substitute the following:

(e-1) If, after consulting with manufacturers, distributors, and pharmacies responsible for the sale and distribution of prescription drugs in this state, the department determines that electronic track and trace pedigree technology is

universally available across the entire prescription pharmaceutical supply chain, the department shall establish a targeted implementation date for electronic track and trace pedigree technology. After the department has established a targeted implementation date, the department may revise the date. The targeted implementation date may not be earlier than July 1, 2010.

(18) In SECTION 14 of the bill, strike proposed Subsection (a), Section 431.417, Health and Safety Code (page 8, lines 42 through 44), and substitute the following:

(a) A person commits an offense if the person knowingly or with criminal negligence engages in the wholesale distribution of prescription drugs in violation of this subchapter.