



General Assembly

Substitute Bill No. 6946

January Session, 2005

* HB06946PH_JUD040405 *

AN ACT ENSURING THE SAFETY OF MEDICINE.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

1 Section 1. (NEW) (*Effective October 1, 2005*) As used in sections 1 to 7,
2 inclusive, of this act:

3 (1) "Authenticate" means to affirmatively verify, before any
4 distribution of a prescription drug occurs, that each transaction listed
5 on the pedigree has occurred.

6 (2) "Commissioner" means the Commissioner of Consumer
7 Protection.

8 (3) "Facility" means a facility of a wholesale distributor where
9 prescription drugs are stored, handled, repackaged or offered for sale.

10 (4) "Immediate family" means a dependent relative who resides in
11 the individual's household or any spouse, child or parent of the
12 individual.

13 (5) "Normal distribution channel" means a chain of custody for a
14 medication that goes from a manufacturer to a wholesaler to a
15 pharmacy to a patient.

16 (6) "Pedigree" means a document or electronic file containing
17 information that records each distribution of any given prescription

18 drug, from sale by a pharmaceutical manufacturer, through acquisition
19 and sale by any wholesale distributor or repackager, until final sale to
20 a pharmacy or other person dispensing or administering the
21 prescription drug.

22 (7) "Prescription drug" means any drug, including any biological
23 product, except for blood and blood components intended for
24 transfusion or biological products that are also medical devices
25 required by federal law or regulations, to be dispensed only by a
26 prescription, including finished dosage forms and bulk drug
27 substances subject to Section 503(b) of the federal Food, Drug and
28 Cosmetic Act.

29 (8) "Repackage" means repackaging or otherwise changing the
30 container, wrapper or labeling to further the distribution of a
31 prescription drug.

32 (9) "Repackager" means a person who repackages.

33 (10) "Wholesale distributor" means any person engaged in the
34 wholesale distribution of prescription drugs, including, but not limited
35 to, manufacturers, unless specified otherwise, repackagers, own-label
36 distributors, private-label distributors, jobbers, brokers, warehouses,
37 including manufacturers' and distributors' warehouses, chain drug
38 warehouses and wholesale drug warehouses, independent wholesale
39 drug traders and retail pharmacies that conduct wholesale
40 distribution.

41 Sec. 2. (NEW) (*Effective October 1, 2005*) Every wholesale distributor
42 that engages in the wholesale distribution of prescription drugs in the
43 state, including nonresident wholesale distributors that ship
44 prescription drugs into the state, shall be licensed by the
45 Commissioner of Consumer Protection, in accordance with the
46 provisions of sections 1 to 7, inclusive, of this act, before engaging in
47 the wholesale distribution of prescription drugs in the state.

48 Sec. 3. (NEW) (*Effective October 1, 2005*) (a) Any person may apply to

49 the Commissioner of Consumer Protection for a wholesale distributor
50 license or for renewal of a wholesale distributor license.

51 (b) The applicant shall disclose on the application (1) the name, full
52 business address and telephone number of the applicant or licensee;
53 (2) all trade or business names used by the applicant or licensee; (3)
54 addresses, telephone numbers and names of contact persons for all
55 facilities used by the applicant or licensee for the storage, handling and
56 distribution of prescription drugs; (4) the type of ownership or
57 operation, including, but not limited to, partnership, corporation or
58 sole proprietorship; (5) the name or names of the owner or operator of
59 the applicant or licensee and related information, including (A) if an
60 individual, the name of the individual, (B) if a partnership, the name of
61 each partner and the name of the partnership, (C) if a corporation, the
62 name and title of each corporate officer and director, the corporate
63 names and the state of incorporation, and (D) if a sole proprietorship,
64 the full name of the sole proprietor and the name of the business
65 entity; (6) a list of all licenses and permits issued to the applicant or
66 licensee by any other state that authorizes the applicant or licensee to
67 purchase or possess prescription drugs; (7) the name of the manager of
68 the facility that is applying for the initial license or to renew the
69 license, the next four highest ranking employees responsible for
70 prescription drug wholesale operations for the facility, and the name
71 of all affiliated parties for the facility, together with the personal
72 information statement required pursuant to subdivision (9) of this
73 subsection; (8) the name of the designated representative of the
74 applicant or licensee for the facility, together with the personal
75 information statement required pursuant to subdivision (9) of this
76 subsection and fingerprints for each such person; and (9) the following
77 information for each person described in subdivisions (7) and (8) of
78 this subsection who is required to provide a personal information
79 statement:

80 (A) The person's places of residence for the past seven years;

81 (B) The person's date and place of birth;

82 (C) The person's occupations, positions of employment and offices
83 held during the past seven years;

84 (D) The principal business and address of any business, corporation
85 or other organization in which each such office of the person was held
86 or in which each such occupation or position of employment was held;

87 (E) Whether the person was, during the past seven years, the subject
88 of any proceeding for the revocation of any license and, if so, the
89 nature and disposition of the proceeding;

90 (F) Whether, during the past seven years, the person was enjoined,
91 either temporarily or permanently, by a court of competent jurisdiction
92 from violating any federal or state law regulating the possession,
93 control or distribution of prescription drugs, together with details
94 concerning any such event;

95 (G) A description of any involvement by the person with any
96 business, including any investments, other than the ownership of stock
97 in a publicly traded company or mutual fund, during the past seven
98 years, that manufactured, administered, prescribed, distributed or
99 stored pharmaceutical products and any lawsuits in which such
100 business was named as a party;

101 (H) A description of any felony criminal offense of which the
102 person, as an adult, was found guilty, regardless of whether
103 adjudication of guilt was withheld or whether the person pled guilty
104 or nolo contendere. If the person indicates that a criminal conviction is
105 under appeal and submits a copy of the notice of appeal of that
106 criminal offense, the applicant or licensee shall, not later than fifteen
107 days after the disposition of the appeal, submit to the state a copy of
108 the final written order of disposition; and

109 (I) A photograph of the person taken not earlier than the thirty-day
110 period preceding submission to the commissioner of the information
111 required by this subsection.

112 (c) The commissioner shall not issue or renew a wholesale
113 distributor license unless the commissioner determines that the
114 applicant's designated representative meets all of the following
115 qualifications: (1) Is at least twenty-one years of age; (2) has been
116 employed full time for at least three years in a pharmacy or with a
117 wholesale distributor in a capacity related to the dispensing and
118 distribution of and recordkeeping relating to prescription drugs; (3)
119 has received a score of seventy-five per cent or more on an
120 examination given by the commissioner regarding federal and state
121 laws governing wholesale distribution of prescription drugs, provided
122 a designated representative who previously served in such capacity
123 retakes the state examination each time a licensee lists the person as
124 the designated representative in an application for license renewal; (4)
125 is employed by the applicant full time in a managerial position; (5) is
126 actively involved in and aware of the actual daily operation of the
127 wholesale distributor; (6) is physically present at the applicant's facility
128 during regular business hours, except when the absence of the
129 designated representative is authorized, including, but not limited to,
130 absences due to sick leave or vacation leave; (7) is serving in the
131 capacity of a designated representative for only one applicant or
132 licensee at a time; (8) does not have any convictions under any federal,
133 state or local laws relating to wholesale or retail prescription drug
134 distribution or distribution of controlled substances; and (9) does not
135 have any felony convictions under federal, state, or local laws.

136 (d) The applicant shall submit to a criminal history records check in
137 accordance with the provisions of section 29-17a of the general
138 statutes.

139 (e) The commissioner shall require each applicant to submit a bond
140 in an amount determined by the commissioner or other equivalent
141 means of security acceptable to the commissioner, such as an
142 irrevocable letter of credit or a deposit in a trust account or financial
143 institution, payable to the drug wholesaler account established
144 pursuant to section 9 of this act. The purpose of the bond is to secure
145 payment of any fines or penalties imposed by the commissioner and

146 any fees or costs incurred by the commissioner regarding a wholesale
147 distributor license under the provisions of sections 1 to 7, inclusive, of
148 this act and which the licensee fails to pay by the date thirty days after
149 the date such fines, penalties, fees or costs become final. The
150 commissioner may make a claim against such bond or security up to
151 one year after the date the licensee's license ceases to be valid.

152 (f) If a wholesale distributor distributes prescription drugs from
153 more than one facility, the wholesale distributor shall obtain a
154 wholesale distributor license for each facility.

155 (g) A wholesale distributor licensed pursuant to the provisions of
156 sections 1 to 7, inclusive, of this act shall notify the commission of any
157 changes to the information required in subsection (b) of this section not
158 later than thirty days after such change.

159 Sec. 4. (NEW) (*Effective October 1, 2005*) (a) On and after October 1,
160 2005, in any calendar month, a wholesale distributor shall sell,
161 distribute, transfer or otherwise sell at least ninety-five per cent of its
162 total amount of prescription drugs to a pharmacy or other person
163 dispensing or administering the drug, except as may be otherwise
164 required under an agreement between such distributor and the
165 Commissioner of Consumer Protection.

166 (b) A wholesale distributor shall not purchase or otherwise receive a
167 prescription drug from a pharmacy, except that a wholesale distributor
168 may receive a prescription drug from a pharmacy if the prescription
169 drug was originally purchased by the pharmacy from the wholesale
170 distributor.

171 (c) A wholesale distributor that meets the exception in subsection
172 (b) of this section shall not: (1) Receive from a pharmacy an amount or
173 quantity of a prescription drug larger than the amount or quantity that
174 was originally sold by the wholesale distributor to the pharmacy; or (2)
175 pay the pharmacy an amount, either in cash or credit, more than the
176 pharmacy originally paid the wholesale distributor for the prescription
177 drug.

178 (d) A manufacturer or wholesale distributor shall furnish
179 prescription drugs only to a person licensed by the appropriate state
180 licensing authorities. Before furnishing prescription drugs to a person
181 not known to the manufacturer or wholesale distributor, the
182 manufacturer or wholesale distributor shall affirmatively verify the
183 person is legally authorized to receive the prescription drugs by
184 contacting the appropriate state licensing authorities.

185 (e) Prescription drugs furnished by a manufacturer or wholesale
186 distributor shall be delivered only to the premises listed on the license,
187 provided the manufacturer or wholesale distributor may furnish
188 prescription drugs to an authorized person or agent of that person at
189 the premises of the manufacturer or wholesale distributor if: (1) The
190 identity and authorization of the recipient is properly established; and
191 (2) this method of receipt is employed only to meet the immediate
192 needs of a particular patient of the authorized person. Prescription
193 drugs may be furnished to a hospital pharmacy receiving area,
194 provided a pharmacist or authorized receiving personnel signs, at the
195 time of delivery, a receipt stating the type and quantity of such
196 prescription drug or drugs received. Any discrepancy between the
197 receipt and the type and quantity of the prescription drug actually
198 received shall be reported to the delivering manufacturer or wholesale
199 distributor on or before the next business day after delivery to the
200 pharmacy receiving area.

201 (f) A manufacturer or wholesale distributor shall not accept
202 payment for, or allow the use of, a person or entity's credit to establish
203 an account for the purchase of prescription drugs from any person
204 other than the owner or owners of record, the chief executive officer or
205 the chief financial officer listed on the license of a person or entity
206 legally authorized to receive prescription drugs. Any account
207 established for the purchase of prescription drugs shall bear the name
208 of the licensee.

209 Sec. 5. (NEW) (*Effective October 1, 2005*) (a) Each person who is
210 engaged in the wholesale distribution of a prescription drug, including

211 repackagers, but excluding the original manufacturer of the finished
212 form of the prescription drug, shall provide a pedigree or electronic
213 file identifying each sale, trade or transfer of a prescription drug when
214 a prescription drug leaves the normal distribution channel and is sold,
215 traded or transferred to any other person. If a pharmacy sells a drug to
216 any person who is not the final consumer, the pharmacy shall provide
217 to the person acquiring the prescription drug a pedigree identifying
218 each sale, trade or transfer of a prescription drug. This subsection shall
219 not be construed to apply to the sale, trade or transfer of a prescription
220 drug between licensees with a common ownership or to meet
221 emergency needs.

222 (b) Each person who is engaged in the wholesale distribution of a
223 prescription drug, including repackagers, but excluding the original
224 manufacture of the finished form of the prescription drug, who is in
225 possession of a pedigree for a prescription drug and attempts to
226 further distribute such prescription drug, shall affirmatively verify
227 before any distribution of a prescription drug occurs that each
228 transaction listed on the pedigree has occurred.

229 (c) The Commissioner of Consumer Protection shall establish a list
230 of prescription drugs for which a pedigree is required. Such list shall
231 be based on priorities established by the commissioner including, but
232 not limited to, public health preparedness, pharmacoterrorism
233 prevention or response, medication integrity and economic integrity
234 and shall be issued twice yearly, indicating each time whether any or
235 no changes have been made to such list. Each pedigree shall:

236 (1) Include all necessary identifying information concerning each
237 sale in the chain of distribution of the product from the manufacture,
238 through acquisition and sale by any wholesale distributor or
239 repackager, until final sale to a pharmacy or other person dispensing
240 or administering the drug. The necessary chain of distribution
241 information shall include, but shall not be limited to: (A) The name,
242 address, telephone number and, if available, the electronic mail
243 address, of each owner of the prescription drug and each wholesale

244 distributor who does not take title to the prescription drug; (B) the
245 signature of each owner of the prescription drug and each wholesale
246 distributor who does not take title to the prescription drug; (C) the
247 name and address of each location from which the product was
248 shipped, if different from the owner's; (D) the transaction dates; and
249 (E) certification that each recipient has authenticated the pedigree.

250 (2) The pedigree shall also include, but shall not be limited to: (A)
251 The name of the prescription drug; (B) dosage form and strength of the
252 prescription drug; (C) size of the container; (D) number of containers;
253 (E) lot number of the prescription drug; and (F) name of the
254 manufacturer of the finished dosage form.

255 (d) Each pedigree shall be: (1) Maintained by the purchaser and the
256 wholesale distributor for three years; and (2) available for inspection or
257 removal upon request of an authorized officer of the law. Wholesale
258 distributors that distribute certain prescription drugs identified by the
259 commissioner shall report inventory levels and distribution
260 information including, but not limited to, the name, address, town and
261 state of the distributor or manufacturer, the prescription drug, the
262 drug quantity and the date of transfer of the drug and the name,
263 address, town and state of the distributor or receiving entity. Such
264 information shall be reported at such time and in such form as
265 required by the commissioner. The information provided under this
266 subsection shall not be subject to disclosure under the Freedom of
267 Information Act, as defined in section 1-200 of the general statutes, and
268 shall be available only to the Departments of Consumer Protection and
269 Public Health, the Office of Emergency Management and such other
270 agency as the commissioner determines, after request by such agency,
271 has need for the information for purposes of public health
272 preparedness, pharmacoterrorism prevention or response, medication
273 integrity or such other purpose deemed appropriate by the
274 commissioner.

275 (e) The Commissioner of Consumer Protection, with the advice and
276 assistance of the Commission of Pharmacy, shall adopt regulations, in

277 accordance with chapter 54 of the general statutes, to carry out the
278 provisions of this section.

279 Sec. 6. (NEW) (*Effective October 1, 2005*) (a) If the state finds that
280 there is a reasonable probability that: (1) A wholesale distributor has:
281 (A) Knowingly violated a provision of sections 1 to 7, inclusive, of this
282 act; or (B) falsified a pedigree, or knowingly sold, distributed,
283 transferred, manufactured, repackaged, handled or held a counterfeit
284 prescription drug intended for human use; (2) the prescription drug
285 that is alleged to be in violation of subdivision (1) of this subsection
286 could cause serious adverse health consequences or death; and (3)
287 other procedures would result in unreasonable delay, the state shall
288 issue an order requiring the appropriate person, including the
289 manufacturers, distributors or retailers of the drug, to immediately
290 cease distribution of the drug.

291 (b) An order issued under subdivision (3) of subsection (a) of this
292 section shall provide the person subject to the order with an
293 opportunity for an informal hearing, to be held not later than ten days
294 after the date of the issuance of the order, on the actions required by
295 the order. If, after providing an opportunity for such a hearing, the
296 state determines that inadequate grounds exist to support the actions
297 required by the order, the state shall vacate the order.

298 Sec. 7. (NEW) (*Effective October 1, 2005*) (a) It shall be unlawful for a
299 person to perform or cause the performance of or aid and abet any of
300 the following acts in this state:

301 (1) Failure to obtain a license in accordance with sections 1 to 7,
302 inclusive, of this act, or operating without a valid license when a
303 license is required by sections 1 to 7, inclusive, of this act;

304 (2) Selling, distributing, transferring or otherwise providing
305 prescription drugs in violation of the five per cent rule established in
306 subsection (a) of section 4 of this act;

307 (3) Purchasing or otherwise receiving a prescription drug from a

308 pharmacy in violation of the provisions of subsection (b) or (c) of
309 section 4 of this act;

310 (4) The sale, distribution or transfer of a prescription drug to a
311 person that is not authorized under the law of the jurisdiction in which
312 the person receives the prescription drug to receive the prescription
313 drug, in violation of subsection (d) of section 4 of this act;

314 (5) Failure to deliver prescription drugs to specified premises, in
315 accordance with the provisions of subsection (e) of section 4 of this act;

316 (6) Accepting payment or credit for the sale of prescription drugs, in
317 violation of subsection (f) of section 4 of this act;

318 (7) Failure to maintain or provide pedigrees, in accordance with the
319 provisions of section 5 of this act;

320 (8) Failure to obtain, pass or authenticate a pedigree, in violation of
321 section 5 of this act;

322 (9) Providing the state or any of its representatives or any federal
323 official with false or fraudulent records or making false or fraudulent
324 statements regarding any matter under the provisions of sections 1 to
325 7, inclusive, of this act;

326 (10) Obtaining or attempting to obtain a prescription drug by fraud,
327 deceit, misrepresentation or engaging in misrepresentation or fraud in
328 the distribution of a prescription drug;

329 (11) The manufacture, repacking, sale, transfer, delivery, holding or
330 offering for sale any prescription drug that is adulterated, misbranded,
331 counterfeit, suspected of being counterfeit or has otherwise been
332 rendered unfit for distribution;

333 (12) The adulteration, misbranding or counterfeiting of any
334 prescription drug;

335 (13) The receipt of any prescription drug that is knowingly

336 adulterated, misbranded, stolen, obtained by fraud or deceit,
337 counterfeit or suspected of being counterfeit and the delivery or
338 proffered delivery of such drug for pay or otherwise; and

339 (14) The alteration, mutilation, destruction, obliteration or removal
340 of the whole or any part of the labeling of a prescription drug or the
341 commission of any other act with respect to a prescription drug that
342 results in the prescription drug being misbranded.

343 (b) Any person who violates the provisions of subsection (a) of this
344 section shall be fined not more than twenty thousand dollars or
345 imprisoned not less than ten years or more than twenty-five years, or
346 both.

347 Sec. 8. (NEW) (*Effective July 1, 2005*) (a) A violation of the provisions
348 of sections 1 to 7, inclusive, of this act constitutes an unfair trade
349 practice under subsection (a) of section 42-110b of the general statutes.

350 (b) Any person who violates any provision of sections 1 to 7,
351 inclusive, of this act shall be fined not more than twenty thousand
352 dollars or be imprisoned not less than ten years or more than twenty
353 years, or both.

354 Sec. 9. (NEW) (*Effective July 1, 2005*) There is established a drug
355 wholesaler account which shall be a separate, nonlapsing account
356 within the General Fund. The account may contain proceeds from the
357 bond prescribed by subsection (e) of section 3 of this act and any other
358 moneys required by law to be deposited in the account, and shall be
359 held in trust separate and apart from all other moneys, funds and
360 accounts. Any balance remaining in the account at the end of any fiscal
361 year shall be carried forward in the account for the fiscal year next
362 succeeding. Investment earnings credited to the account shall become
363 part of the account. Amounts in the account shall be expended only
364 pursuant to appropriations by the General Assembly, for the fiscal
365 year ending June 30, 2006, and each fiscal year thereafter, for the
366 purposes prescribed in subsection (e) of section 3 of this act, provided
367 such amounts so expended shall not supplant any state or federal

368 funds otherwise available for such services.

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|---|------------------------|-------------|
| This act shall take effect as follows and shall amend the following sections: | | |
| Section 1 | <i>October 1, 2005</i> | New section |
| Sec. 2 | <i>October 1, 2005</i> | New section |
| Sec. 3 | <i>October 1, 2005</i> | New section |
| Sec. 4 | <i>October 1, 2005</i> | New section |
| Sec. 5 | <i>October 1, 2005</i> | New section |
| Sec. 6 | <i>October 1, 2005</i> | New section |
| Sec. 7 | <i>October 1, 2005</i> | New section |
| Sec. 8 | <i>July 1, 2005</i> | New section |
| Sec. 9 | <i>July 1, 2005</i> | New section |

PH

Joint Favorable Subst. C/R

JUD