

Wholesale Drug Distribution

This legislation limits the opportunity to introduce counterfeit drugs into the U.S. market via the wholesale transfer process. The legislation accomplishes this by tightening the rules around the licensing of prescription drug wholesalers and establishes pedigree requirements to ensure the authenticity of prescription drugs within the distribution system. The legislation also establishes penalties for violators.

Submitted as:

Idaho

[Session Law Chapter 319 of 2007](#)

Status: Enacted into law in 2007.

Suggested State Legislation

(Title, enacting clause, etc.)

1 Section 1. [*Short Title.*] This Act shall be cited as “The Wholesale Drug Distribution Act.”

2
3 Section 2. [*Definitions.*] As used in this Act:

4 (1) “authentication” means to affirmatively verify before any wholesale distribution
5 of a prescription drug occurs that each transaction listed on the pedigree has occurred;

6 (2) “authorized distributor of record” means a wholesale distributor with whom a
7 manufacturer has established an ongoing relationship to distribute the manufacturer’s prescription
8 drug. An ongoing relationship is deemed to exist between such wholesale distributor and a
9 manufacturer when the wholesale distributor, including any affiliated group of the wholesale
10 distributor, as defined in Section 1504 of the Internal Revenue Code, complies with the following:

11 (a) the wholesale distributor has a written agreement currently in effect with
12 the manufacturer evidencing such ongoing relationship; and

13 (b) the wholesale distributor is listed on the manufacturer’s current list of
14 authorized distributors of record, which is updated by the manufacturer on no less than a monthly
15 basis.

16 (3) “board” means the board as defined under [insert citation];

17 (4) “chain pharmacy warehouse” means a physical location for prescription drugs
18 that acts as a central warehouse and performs intra-company sales or transfers of such drugs to a
19 group of chain pharmacies that have the same common ownership and control;

20 (5) “co-licensed partner or product” means an instance where [two (2)] or more
21 parties have the right to engage in the manufacturing and/or marketing of a prescription drug,
22 consistent with the federal Food and Drug Administration's implementation of the Prescription
23 Drug Marketing Act;

24 (6) “drop shipment” means the sale of a prescription drug to a wholesale distributor
25 or chain pharmacy warehouse by the manufacturer of the prescription drug, or that manufacturer’s
26 co-licensed product partner, that manufacturer’s third party logistics provider or that
27 manufacturer’s exclusive distributor, whereby the wholesale distributor or chain pharmacy
28 warehouse takes title but not physical possession of such prescription drug and the wholesale
29 distributor invoices the pharmacy or chain pharmacy warehouse, or other person authorized by law
30 to dispense or administer such drug to a patient, and the pharmacy or chain pharmacy warehouse
31 or other authorized person receives delivery of the prescription drug directly from the

32 manufacturer, or that manufacturer's third-party logistics provider, or that manufacturer's
33 exclusive distributor;

34 (7) "facility" means a facility of a wholesale distributor where prescription drugs
35 are stored, handled, repackaged or offered for sale;

36 (8) "manufacturer" means a person licensed or approved by the federal Food and
37 Drug Administration to engage in the manufacture of drugs or devices, consistent with the federal
38 Food and Drug Administration definition of "manufacturer" under its regulations and guidance
39 implementing the Prescription Drug Marketing Act;

40 (9) "manufacturer's exclusive distributor" means anyone who contracts with a
41 manufacturer to provide or coordinate warehousing, distribution or other services on behalf of a
42 manufacturer and who takes title to that manufacturer's prescription drug, but who does not have
43 general responsibility to direct the sale or disposition of the manufacturer's prescription drug.

44 (a) such manufacturer's exclusive distributor must be licensed as a
45 wholesale distributor under [insert citation], and to be considered part of the normal distribution
46 channel, must also be an authorized distributor of record;

47 (10) "normal distribution channel" means a chain of custody for a prescription drug
48 that goes from a manufacturer of the prescription drug, from that manufacturer to that
49 manufacturer's co-licensed partner, from that manufacturer to that manufacturer's third-party
50 logistics provider or from that manufacturer to that manufacturer's exclusive distributor, either
51 directly or by drop shipment, to:

52 (a) a pharmacy to a patient;

53 (b) other designated people authorized by law to dispense or administer
54 such drug to a patient;

55 (c) a wholesale distributor to a pharmacy to a patient or other designated
56 people authorized by law to dispense or administer such drug to a patient;

57 (d) a wholesale distributor to a chain pharmacy warehouse to that chain
58 pharmacy warehouse's intra-company pharmacy to a patient or other designated people authorized
59 by law to dispense or administer such drug to a patient; or

60 (e) a chain pharmacy warehouse to the chain pharmacy warehouse's intra-
61 company pharmacy to a patient or other designated people authorized by law to dispense or
62 administer such drug to a patient.

63 (11) "pedigree" means a document or electronic file containing information that
64 records each wholesale distribution of any given prescription drug.

65 (12) "prescription drug" means any drug, including any biological product, except
66 for blood and blood components intended for transfusion or biological products that are also
67 medical devices, required by federal law or federal regulation to be dispensed only by a
68 prescription, including finished dosage forms and bulk drug substances, subject to section 503(b)
69 of the federal Food, Drug and Cosmetic Act.

70 (13) "repackage" means repackaging or otherwise changing the container, wrapper
71 or labeling to further the distribution of a prescription drug, excluding that completed by the
72 pharmacist responsible for dispensing product to the patient.

73 (14) "repackager" means a person who repackages.

74 (15) "third-party logistics provider" means anyone who contracts with a
75 prescription drug manufacturer to provide or coordinate warehousing, distribution or other
76 services on behalf of a manufacturer, but does not take title to the prescription drug or have
77 general responsibility to direct the prescription drug's sale or disposition. Such third-party
78 logistics provider must be licensed as a wholesale distributor under [insert citation], and to be
79 considered part of the normal distribution channel, must also be an authorized distributor of
80 record.

81 (16) “wholesale distributor” means anyone engaged in the wholesale distribution of
82 prescription drugs including, but not limited to:

- 83 (a) manufacturers;
- 84 (b) repackagers;
- 85 (c) own-label distributors;
- 86 (d) private-label distributors;
- 87 (e) jobbers;
- 88 (f) brokers;
- 89 (g) warehouses, including manufacturers’ and distributors’ warehouses;
- 90 (h) manufacturer’s exclusive distributors;
- 91 (i) authorized distributors of record;
- 92 (j) drug wholesalers or distributors;
- 93 (k) independent wholesale drug traders;
- 94 (l) specialty wholesale distributors;
- 95 (m) third-party logistics providers;
- 96 (n) retail pharmacies that conduct wholesale distribution;
- 97 (o) chain pharmacy warehouses that conduct wholesale distribution, and
- 98 (p) to be considered part of the normal distribution channel, such wholesale
99 distributor, except for a chain pharmacy warehouse not engaged in wholesale distribution, must
100 also be an authorized distributor of record.

101 (17) “wholesale distribution” means distribution of prescription drugs to people
102 other than a consumer or patient, but does not include:

- 103 (a) intra-company sales of prescription drugs, meaning any transaction or
104 transfer between any division, subsidiary, parent or affiliated or related company under common
105 ownership and control of a corporate entity, or any transaction or transfer between co-licensees of
106 a co-licensed product.
- 107 (b) the sale, purchase, distribution, trade or transfer of a prescription drug or
108 offer to sell, purchase, distribute, trade or transfer a prescription drug for emergency medical
109 reasons.
- 110 (c) the distribution of prescription drug samples by manufacturers’
111 representatives.
- 112 (d) drug returns, when conducted by a hospital, health care entity or
113 charitable institution in accordance with 21 CFR 203.23.
- 114 (e) the sale of minimal quantities of prescription drugs by retail pharmacies
115 to licensed practitioners for office use.
- 116 (f) the sale, purchase or trade of a drug, an offer to sell, purchase or trade a
117 drug, or the dispensing of a drug pursuant to a prescription.
- 118 (g) the sale, transfer, merger or consolidation of all or part of the business of
119 a pharmacy or pharmacies from or with another pharmacy or pharmacies, whether accomplished
120 as a purchase and sale of stock or business assets.
- 121 (h) the sale, purchase, distribution, trade or transfer of a prescription drug
122 from [one (1) authorized distributor of record to one (1) additional authorized distributor of
123 record] when the manufacturer has stated in writing to the receiving authorized distributor of
124 record that the manufacturer is unable to supply such prescription drug and the supplying
125 authorized distributor of record states in writing that the prescription drug being supplied had,
126 until that time, been exclusively in the normal distribution channel.
- 127 (i) the delivery of, or offer to deliver, a prescription drug by a common
128 carrier solely in the common carrier’s usual course of business of transporting prescription drugs,

129 and such common carrier does not store, warehouse or take legal ownership of the prescription
130 drug.

131 (j) the sale or transfer from a retail pharmacy or chain pharmacy warehouse
132 of expired, damaged, returned or recalled prescription drugs to the original manufacturer or third-
133 party returns processor, including a reverse distributor.
134

135 Section 3. [*Wholesale Drug Distributor Licensing Requirement – Minimum Requirements*
136 *for Licensure.*]

137 (A) Every wholesale distributor who engages in the wholesale distribution of prescription
138 drugs must be licensed by the [board], and every nonresident wholesale distributor must be
139 licensed by the [board] if it ships prescription drugs into this state in accordance with this Act
140 before engaging in wholesale distributions of wholesale prescription drugs. The [board] shall
141 exempt manufacturers distributing their own federal Food and Drug Administration approved
142 drugs and devices from any licensing and other requirements to the extent not required by federal
143 law or regulation, unless particular requirements are deemed necessary and appropriate following
144 rulemaking.

145 (B) The [board] shall require the following minimum information from each wholesale
146 distributor applying for a license under subsection (A) of this section:

- 147 (1) the name, full business address and telephone number of the licensee;
- 148 (2) all trade or business names used by the licensee;
- 149 (3) addresses, telephone numbers, and the names of contact people for all facilities
150 used by the licensee for the storage, handling, and distribution of prescription drugs;
- 151 (4) the type of ownership or operation, i.e., partnership, corporation, or sole
152 proprietorship;
- 153 (5) the name of each person who is an owner or an operator of the licensee;
- 154 (6) a list of all licenses and permits issued to the applicant by any other state that
155 authorizes the applicant to purchase or possess prescription drugs;
- 156 (7) the name of the applicant's designated representative for the facility, together
157 with the personal information statement and fingerprints, required pursuant to paragraph (8) of this
158 section (3) for such individual;
- 159 (8) each individual required by paragraph (7) of this section (3) to provide a
160 personal information statement and fingerprints shall provide the following information to the
161 [board]:
 - 162 (a) the individual's places of residence for the past [seven (7)] years;
 - 163 (b) the individual's date and place of birth;
 - 164 (c) the individual's occupations, positions of employment and offices held
165 during the past [seven (7)] years;
 - 166 (d) the principal business and address of any business, corporation or other
167 organization in which each such office of the individual was held or in which each such
168 occupation or position of employment was carried on;
 - 169 (e) whether the individual has been, during the past [seven (7)] years, the
170 subject of any proceeding for the revocation of any license or any criminal violation and, if so, the
171 nature of the proceeding and the disposition of the proceeding;
 - 172 (f) whether, during the past [seven (7)] years, the individual has been
173 enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating
174 any federal or state law regulating the possession, control or distribution of prescription drugs or
175 criminal violations, together with details concerning any such event;
 - 176 (g) a description of any involvement by the individual with any business,
177 including any investments, other than the ownership of stock in a publicly traded company or

178 mutual fund, during the past [seven (7) years], which manufactured, administered, prescribed,
179 distributed or stored pharmaceutical products, and any lawsuits in which such businesses were
180 named as a party;

181 (h) a description of any felony criminal offense of which the individual, as
182 an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the
183 individual pled guilty or nolo contendere;

184 (I) if the individual indicates that a criminal conviction is under
185 appeal and submits a copy of the notice of appeal of that criminal offense, the applicant must,
186 within [fifteen (15)] days after the disposition of the appeal, submit to the [board] a copy of the
187 final written order of disposition;

188 (i) a photograph of the individual taken in the previous year.

189 (C) The information required pursuant to subsection (B) of this section shall be provided
190 under oath.

191 (D) The [board] shall not issue a wholesale distributor license to an applicant, unless the
192 [board]:

193 (1) conducts a physical inspection of the facility at the address provided by the
194 applicant as required in subsection (B)(1) of this section; and

195 (2) determines that the designated representative meets the following qualifications:

196 (a) is at least [twenty-one (21)] years of age;

197 (b) has been employed full time for at least [three (3)] years in a pharmacy
198 or with a wholesale distributor in a capacity related to the dispensing and distribution of, and
199 recordkeeping relating to, prescription drugs;

200 (c) is employed by the applicant full time in a managerial level position;

201 (d) is actively involved in and aware of the actual daily operation of the
202 wholesale distributor;

203 (e) is physically present at the facility of the applicant during regular
204 business hours, except when the absence of the designated representative is authorized including,
205 but not limited to, sick leave and vacation leave;

206 (f) is serving in the capacity of a designated representative for only [one (1)]
207 applicant at a time, except where more than [one (1)] licensed wholesale distributor is co-located
208 in the same facility and such wholesale distributors are members of an affiliated group, as defined
209 in Section 1504 of the Internal Revenue Code;

210 (g) does not have any convictions under any federal, state or local law
211 relating to wholesale or retail prescription drug distribution or distribution of controlled
212 substances; and

213 (h) does not have any felony convictions under federal, state or local law.

214 (E) The [board] shall submit the fingerprints provided by a person with a license
215 application for a statewide criminal records check and for forwarding to the Federal Bureau of
216 Investigation for a national criminal records check of the individual.

217 (F) The [board] shall require every wholesale distributor applying for a license to submit a
218 bond of at least [one hundred thousand dollars (\$100,000)], or other equivalent means of security
219 acceptable to the [board], such as an irrevocable letter of credit or a deposit in a trust account or
220 financial institution, payable to a fund established by the [board] pursuant to subsection (G) of this
221 section. Chain pharmacy warehouses that are not engaged in wholesale distribution are exempt
222 from the bond requirement. The purpose of the bond is to secure payment of any fines or penalties
223 imposed by the board and any fees and costs incurred by the board regarding that license, which
224 are authorized under the law of this state and which the licensee fails to pay [thirty (30)] days after
225 the fines, penalties or costs become final. The [board] may make a claim against such bond or

226 security until [one (1)] year after the licensee's license ceases to be valid. A single bond may
227 suffice to cover all facilities operated by the applicant in this state.

228 (G) The [board] shall establish a fund, separate from its other accounts, in which to deposit
229 the wholesale distributor bonds.

230 (H) If a wholesale distributor distributes prescription drugs from more than [one (1)]
231 facility, the wholesale distributor shall obtain a license for each facility.

232 (I) In accordance with each licensure renewal, the [board] shall send to each wholesale
233 distributor licensed under this section a form setting forth the information that the wholesale
234 distributor provided pursuant to subsection (B) of this section. Within [thirty (30)] days of
235 receiving such form, the wholesale distributor must identify and state under oath to the board all
236 changes or corrections to the information that was provided pursuant to subsection (B) of this
237 section. Changes in, or corrections to, any information in subsection (B) of this section shall be
238 submitted to the [board] as required by the [board]. The [board] may suspend or revoke the license
239 of a wholesale distributor if such authority determines that the wholesale distributor no longer
240 qualifies for the license issued under this section.

241 (J) The designated representative identified pursuant to subsection (B)(7) of this section
242 must receive and complete continuing training in applicable federal law and the law of this state
243 governing wholesale distribution of prescription drugs.

244 (K) The [board] may adopt rules to approve an accreditation body to evaluate a
245 wholesaler's operations to determine compliance with professional standards and any other
246 applicable laws, and to perform inspections of each facility and location where wholesale
247 distribution operations are conducted by the wholesaler.

248 (L) Information provided under this section shall not be disclosed to any person other than
249 a state licensing authority, government board or government agency, provided such licensing
250 authority, government board or agency needs such information for licensing or monitoring
251 purposes.

252
253 Section 4. *[Restrictions on Transactions.]*

254 (A) A wholesale distributor shall receive prescription drug returns or exchanges from a
255 pharmacy or chain pharmacy warehouse pursuant to the terms and conditions of the agreement
256 between the wholesale distributor and the pharmacy or chain pharmacy warehouse. Returns of
257 expired, damaged, recalled or otherwise non-saleable pharmaceutical product shall be distributed
258 by the receiving wholesale distributor only to either the original manufacturer or third party
259 returns processor, including a reverse distributor. The returns or exchanges of prescription drugs,
260 saleable or otherwise, including any redistribution by a receiving wholesaler, shall not be subject
261 to the pedigree requirement of [insert citation], so long as they are exempt from pedigree under the
262 federal Food and Drug Administration's currently applicable Prescription Drug Marketing Act
263 Guidance. Wholesale distributors and pharmacies shall be held accountable for administering their
264 returns process and ensuring that the aspects of this operation are secure and do not permit the
265 entry of adulterated and counterfeit product.

266 (B) A manufacturer or wholesale distributor shall furnish prescription drugs only to a
267 person licensed by the [board] or other appropriate state licensing authorities. Before furnishing
268 prescription drugs to a person not known to the manufacturer or wholesale distributor, the
269 manufacturer or wholesale distributor shall affirmatively verify that the person is legally
270 authorized to receive the prescription drugs by contacting the appropriate state licensing
271 authorities.

272 (C) Prescription drugs furnished by a manufacturer or wholesale distributor shall be
273 delivered only to the premises listed on the license; provided that the manufacturer or wholesale

274 distributor may furnish prescription drugs to an authorized person or agent of that person at the
275 premises of the manufacturer or wholesale distributor if:

276 (1) the identity and authorization of the recipient is properly established; and

277 (2) this method of receipt is employed only to meet the immediate needs of a
278 particular patient of the authorized person.

279 (D) Prescription drugs may be furnished to a hospital pharmacy receiving area provided
280 that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt
281 showing the type and quantity of the prescription drug so received. Any discrepancy between
282 receipt and the type and quantity of the prescription drug actually received shall be reported to the
283 delivering manufacturer or wholesale distributor by the next business day after the delivery to the
284 pharmacy receiving area.

285 (E) A manufacturer or wholesale distributor shall not accept payment for, or allow the use
286 of, a person's credit to establish an account for the purchase of prescription drugs from any person
287 other than the owner(s) of record, the chief executive officer or the chief financial officer listed on
288 the license of a person legally authorized to receive prescription drugs. Any account established
289 for the purchase of prescription drugs must bear the name of the licensee.

290
291 Section 5. [*Pedigree.*]

292 (A) Each person who is engaged in wholesale distribution of prescription drugs, including
293 re-packagers, but excluding the original manufacturer of the finished form of the prescription
294 drug, that leaves, or has ever left, the normal distribution channel shall, before each wholesale
295 distribution of such drug, provide a pedigree to the person who receives such drug.

296 (B) A retail pharmacy or chain pharmacy warehouse shall comply with the requirements of
297 this section only if the pharmacy or chain pharmacy warehouse engages in wholesale distribution
298 of prescription drugs.

299 (C) The [board] shall determine by [July 1, 2009], a targeted implementation date for
300 electronic track and trace pedigree technology. Such a determination shall be based on
301 consultation with manufacturers, distributors and pharmacies responsible for the sale and
302 distribution of prescription drug products in this state. After consultation with interested
303 stakeholders and prior to implementation of the electronic pedigree, the board shall deem that the
304 technology is universally available across the entire prescription pharmaceutical supply chain. The
305 implementation date for the mandated electronic track and trace pedigree technology will be no
306 sooner than [July 1, 2010], and may be extended by the [board] in [one (1)] year increments if it
307 appears the technology is not universally available across the entire prescription pharmaceutical
308 supply chain.

309 (D) Each person who is engaged in the wholesale distribution of a prescription drug,
310 including re-packagers, but excluding the original manufacturer of the finished form of the
311 prescription drug, who is provided a pedigree for a prescription drug and attempts to further
312 distribute that prescription drug, shall affirmatively verify before any wholesale distribution of a
313 prescription drug occurs that each transaction listed on the pedigree has occurred.

314 (E) The pedigree shall include:

315 (1) all necessary identifying information concerning each sale in the chain of
316 distribution of the product from the manufacturer, or the manufacturer's third-party logistics
317 provider, co-licensed product partner, or manufacturer's exclusive distributor, through acquisition
318 and sale by any wholesale distributor or re-packager, until final sale to a pharmacy or other person
319 dispensing or administering the drug;

320 (2) the name, address, telephone number and, if available, the e-mail address, of
321 each owner of the prescription drug, and each wholesale distributor of the prescription drug;

- 322 (3) the name and address of each location from which the product was shipped, if
323 different from the owner's;
324 (4) transaction dates;
325 (5) certification that each recipient has authenticated the pedigree.
326 (6) name of the prescription drug;
327 (7) dosage form and strength of the prescription drug;
328 (8) size of the container;
329 (9) number of containers;
330 (10) lot number and national drug code number of the prescription drug; and
331 (11) name of the manufacturer of the finished dosage form.

332 (F) Each pedigree or electronic file shall be:

333 (1) Notwithstanding the provisions in [insert citation], maintained by the purchaser
334 and the wholesale distributor for not less than [three (3)] years from the date of sale or transfer;
335 and

336 (2) Available for inspection or use within [five (5)] business days upon a request of
337 an authorized officer of the law.

338 (G) The [board] shall adopt rules and a form relating to the requirements of this section no
339 later than [ninety (90)] days after the effective date of this Act.

340
341 Section 6. [*Enforcement - Order to Cease Distribution of a Drug.*]

342 (A) If the [board] finds that there is a reasonable probability that:

343 (1) a wholesale distributor, other than a manufacturer, has violated a provision in
344 this Act or falsified a pedigree, or sold, distributed, transferred, manufactured, repackaged,
345 handled or held a counterfeit prescription drug intended for human use; and

346 (2) the prescription drug at issue as a result of a violation in paragraph (1) of this
347 subsection could cause serious, adverse health consequences or death; and

348 (3) other procedures would result in unreasonable delay;
349 the [board] shall issue an order requiring the appropriate person, including the distributors or
350 retailers of the drug, to immediately cease distribution of the drug within the state.

351 (B) An order under subsection (A) of this section shall provide the person subject to the
352 order with an opportunity for an informal hearing, to be held not later than [ten (10)] days after the
353 date of the issuance of the order, on the actions required by the order. If, after providing an
354 opportunity for such a hearing, the [board] determines that inadequate grounds exist to support the
355 actions required by the order, the [board] shall vacate the order.

356
357 Section 7. [*Discipline -- Grounds -- Penalties.*]

358 (A) Upon a finding that a wholesale distributor is in violation of any provision of this Act,
359 or such rules or standards of conduct and practice as may be adopted by the [board], and in
360 accordance with the provisions of [insert citation], the [board] may impose any [one (1)] or more
361 of the penalties provided for in [insert citation].

362 (B) Imposition of a penalty by the [board] or other action against a wholesale distributor by
363 the [board] as set forth in this Act shall not be construed as barring other civil, administrative or
364 criminal proceedings or prosecutions or entry of any available penalty or sanction as authorized by
365 law.

366
367 Section 8. [*Prohibited Acts.*]

368 (A) It shall be unlawful for a person to knowingly perform, or cause the performance of, or
369 aid and abet any of the following acts in this state:

- 370 (1) failure to obtain a license when a license is required by this Act;

- 371 (2) operate as a wholesale distributor without a valid license when a license is
372 required by this act;
- 373 (3) purchase from or otherwise receive, return or exchange a prescription drug from
374 a pharmacy or chain pharmacy warehouse, other than in compliance with section 4(A) of this Act;
- 375 (4) when a state license is required pursuant to section 4(B) of this Act, to sell,
376 distribute, transfer or otherwise furnish a prescription drug to a person who is not authorized under
377 the law of the jurisdiction in which the person received the prescription drug to receive the
378 prescription drug;
- 379 (5) failure to deliver prescription drugs to specified premises, as required by section
380 4(C) of this Act;
- 381 (6) acceptance of payment or credit for the purchase of prescription drugs, other
382 than in compliance with section 4(E) of this Act;
- 383 (7) failure to maintain or provide pedigrees as required by this Act;
- 384 (8) failure to obtain, pass or authenticate a pedigree, as required by this Act;
- 385 (9) provide the [board] or any of its representatives or any federal official with false
386 or fraudulent records or make false or fraudulent statements regarding any matter within the
387 provisions of this Act;
- 388 (10) obtain, or attempt to obtain, a prescription drug by fraud, deceit or
389 misrepresentation or engage in misrepresentation or fraud in the distribution of a prescription
390 drug;
- 391 (11) manufacture, repackage, sell, transfer, deliver, hold or offer for sale any
392 prescription drug that is adulterated, misbranded, counterfeit, suspected of being counterfeit or
393 otherwise has been rendered unfit for distribution;
- 394 (12) adulterate, misbrand or counterfeit any prescription drug;
- 395 (13) receive any prescription drug that is adulterated, misbranded, stolen, obtained
396 by fraud or deceit, counterfeit or suspected of being counterfeit;
- 397 (14) deliver or proffer delivery of, for pay or otherwise, any prescription drug that
398 is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit or suspected of being
399 counterfeit;
- 400 (15) alter, mutilate, destroy, obliterate or remove the whole or any part of the
401 labeling of a prescription drug or commit any other act with respect to a prescription drug that
402 results in the prescription drug being misbranded; or
- 403 (16) sell, deliver, transfer or offer to sell to a person not authorized under law to
404 receive the return or exchange of a prescription drug, a prescription drug that has expired, been
405 damaged or recalled by either the original manufacturer, a third party returns processor or a
406 reverse distributor.

407 (B) The Acts prohibited in subsection (A) of this section do not include a prescription drug
408 manufacturer, or agent of a prescription drug manufacturer, who obtains or attempts to obtain a
409 prescription drug for the sole purpose of testing the prescription drug for authenticity.

410

411 Section 9. [*Penalties.*]

412 (A) Any person who commits any act prohibited by section 8(A)(1) through 8(A)(8) of this
413 Act, is guilty of a [misdemeanor], which is punishable by not more than [one (1) year of
414 imprisonment, or by a fine not exceeding five thousand dollars (\$5,000)], or both.

415 (B) Any person who commits any act prohibited by section 8(A)(9) through 8(A)(16) of
416 this Act, is guilty of a [felony], which is punishable by imprisonment for a term of [not less than
417 five (5) years and not more than twenty (20) years, or by a fine not exceeding five hundred
418 thousand dollars (\$500,000)], or both.

419 (C) Any person who, with the intent to commit any of the acts prohibited by section
420 8(A)(9) through 8(A)(16) of this Act, commits any act prohibited by section 8(A)(1) through
421 8(A)(9) of this Act, is guilty of a [felony], which is punishable by imprisonment for a term of [not
422 less than five (5) years and not more than twenty (20) years, or by a fine not exceeding five
423 hundred thousand dollars (\$500,000)], or both.

424 (D) Any criminal penalty imposed on a person who commits any act prohibited by section
425 8 of this Act, is in addition to, and not in lieu of, any other civil or administrative penalty or
426 sanction authorized by law.

427

428 Section 10. [*Severability.*] [Insert severability clause.]

429

430 Section 11. [*Repealer.*] [Insert repealer clause.]

431

432 Section 12. [*Effective Date.*] [Insert effective date.]