

FOR CONSIDERATION By the Committee on Budget

576-02139F-12

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1 A bill to be entitled
2 An act relating to the Department of Business and
3 Professional Regulation; amending s. 20.165, F.S.;
4 creating the Division of Drugs, Devices, and Cosmetics
5 within the Department of Business and Professional
6 Regulation; amending s. 455.116, F.S.; deleting the
7 Florida Drug, Device, and Cosmetic Trust Fund from the
8 list of trust funds placed in the department, to
9 conform; amending ss. 499.003, 499.01211, 499.024,
10 499.065, 499.601, and 499.61, F.S.; conforming
11 provisions to the transfer by s. 27, chapter 2010-161,
12 Laws of Florida, of regulatory authority for ch. 499,
13 F.S., from the Department of Health to the Department
14 of Business and Professional Regulation; repealing s.
15 499.0031, F.S., relating to the Florida Drug, Device,
16 and Cosmetic Trust Fund; terminating the Florida Drug,
17 Device, and Cosmetic Trust Fund; providing for the
18 disposition of balances in and revenues of such trust
19 fund; prescribing procedures for the termination of
20 such trust fund; amending ss. 499.01, 499.028, 499.04,
21 499.057, 499.062, 499.066, 499.62, 499.72, and 499.79,
22 F.S.; conforming provisions; requiring the Department
23 of Business and Professional Regulation to submit a
24 report to the Legislature by a specified date;
25 providing for future expiration; providing effective
26 dates.

27
28 Be It Enacted by the Legislature of the State of Florida:
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30 Section 1. Paragraphs (d) through (k) of subsection (2) of
31 section 20.165, Florida Statutes, are redesignated as paragraphs
32 (e) through (l), respectively, and a new paragraph (d) is added
33 to that subsection to read:

34 20.165 Department of Business and Professional Regulation.—
35 There is created a Department of Business and Professional
36 Regulation.

37 (2) The following divisions of the Department of Business
38 and Professional Regulation are established:

39 (d) Division of Drugs, Devices, and Cosmetics.

40 Section 2. Effective November 1, 2012, subsection (8) of
41 section 455.116, Florida Statutes, is amended to read:

42 455.116 Regulation trust funds.—The following trust funds
43 shall be placed in the department:

44 ~~(8) Florida Drug, Device, and Cosmetic Trust Fund.~~

45 Section 3. Subsection (15) and paragraph (a) of subsection
46 (54) of section 499.003, Florida Statutes, are amended to read:
47 499.003 Definitions of terms used in this part.—As used in
48 this part, the term:

49 (15) "Department" means the Department of Business and
50 Professional Regulation ~~Health~~.

51 (54) "Wholesale distribution" means distribution of
52 prescription drugs to persons other than a consumer or patient,
53 but does not include:

54 (a) Any of the following activities, which is not a
55 violation of s. 499.005(21) if such activity is conducted in
56 accordance with s. 499.01(2)(g):

57 1. The purchase or other acquisition by a hospital or other
58 health care entity that is a member of a group purchasing

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59 organization of a prescription drug for its own use from the
60 group purchasing organization or from other hospitals or health
61 care entities that are members of that organization.

62 2. The sale, purchase, or trade of a prescription drug or
63 an offer to sell, purchase, or trade a prescription drug by a
64 charitable organization described in s. 501(c)(3) of the
65 Internal Revenue Code of 1986, as amended and revised, to a
66 nonprofit affiliate of the organization to the extent otherwise
67 permitted by law.

68 3. The sale, purchase, or trade of a prescription drug or
69 an offer to sell, purchase, or trade a prescription drug among
70 hospitals or other health care entities that are under common
71 control. For purposes of this subparagraph, "common control"
72 means the power to direct or cause the direction of the
73 management and policies of a person or an organization, whether
74 by ownership of stock, by voting rights, by contract, or
75 otherwise.

76 4. The sale, purchase, trade, or other transfer of a
77 prescription drug from or for any federal, state, or local
78 government agency or any entity eligible to purchase
79 prescription drugs at public health services prices pursuant to
80 Pub. L. No. 102-585, s. 602 to a contract provider or its
81 subcontractor for eligible patients of the agency or entity
82 under the following conditions:

83 a. The agency or entity must obtain written authorization
84 for the sale, purchase, trade, or other transfer of a
85 prescription drug under this subparagraph from the Secretary of
86 Business and Professional Regulation ~~State Surgeon General~~ or
87 his or her designee.

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88 b. The contract provider or subcontractor must be
89 authorized by law to administer or dispense prescription drugs.

90 c. In the case of a subcontractor, the agency or entity
91 must be a party to and execute the subcontract.

92 d. A contract provider or subcontractor must maintain
93 separate and apart from other prescription drug inventory any
94 prescription drugs of the agency or entity in its possession.

95 e. The contract provider and subcontractor must maintain
96 and produce immediately for inspection all records of movement
97 or transfer of all the prescription drugs belonging to the
98 agency or entity, including, but not limited to, the records of
99 receipt and disposition of prescription drugs. Each contractor
100 and subcontractor dispensing or administering these drugs must
101 maintain and produce records documenting the dispensing or
102 administration. Records that are required to be maintained
103 include, but are not limited to, a perpetual inventory itemizing
104 drugs received and drugs dispensed by prescription number or
105 administered by patient identifier, which must be submitted to
106 the agency or entity quarterly.

107 f. The contract provider or subcontractor may administer or
108 dispense the prescription drugs only to the eligible patients of
109 the agency or entity or must return the prescription drugs for
110 or to the agency or entity. The contract provider or
111 subcontractor must require proof from each person seeking to
112 fill a prescription or obtain treatment that the person is an
113 eligible patient of the agency or entity and must, at a minimum,
114 maintain a copy of this proof as part of the records of the
115 contractor or subcontractor required under sub-subparagraph e.

116 g. In addition to the departmental inspection authority set

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117 forth in s. 499.051, the establishment of the contract provider
118 and subcontractor and all records pertaining to prescription
119 drugs subject to this subparagraph shall be subject to
120 inspection by the agency or entity. All records relating to
121 prescription drugs of a manufacturer under this subparagraph
122 shall be subject to audit by the manufacturer of those drugs,
123 without identifying individual patient information.

124 Section 4. Subsection (2) of section 499.01211, Florida
125 Statutes, is amended to read:

126 499.01211 Drug Wholesale Distributor Advisory Council.—

127 (2) The Secretary of Business and Professional Regulation
128 ~~State Surgeon General~~, or his or her designee, and the Secretary
129 of Health Care Administration, or her or his designee, shall be
130 members of the council. The Secretary of Business and
131 Professional Regulation ~~State Surgeon General~~ shall appoint nine
132 additional members to the council who shall be appointed to a
133 term of 4 years each, as follows:

134 (a) Three different persons each of whom is employed by a
135 different prescription drug wholesale distributor licensed under
136 this part which operates nationally and is a primary wholesale
137 distributor, as defined in s. 499.003(47).

138 (b) One person employed by a prescription drug wholesale
139 distributor licensed under this part which is a secondary
140 wholesale distributor, as defined in s. 499.003(52).

141 (c) One person employed by a retail pharmacy chain located
142 in this state.

143 (d) One person who is a member of the Board of Pharmacy and
144 is a pharmacist licensed under chapter 465.

145 (e) One person who is a physician licensed pursuant to

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146 chapter 458 or chapter 459.

147 (f) One person who is an employee of a hospital licensed
148 pursuant to chapter 395 and is a pharmacist licensed pursuant to
149 chapter 465.

150 (g) One person who is an employee of a pharmaceutical
151 manufacturer.

152 Section 5. Section 499.024, Florida Statutes, is amended to
153 read:

154 499.024 Drug product classification.—The department ~~State~~
155 ~~Surgeon General~~ shall adopt rules to classify drug products
156 intended for use by humans which the United States Food and Drug
157 Administration has not classified in the federal act or the Code
158 of Federal Regulations.

159 (1) Drug products must be classified as proprietary,
160 prescription, or investigational drugs.

161 (2) If a product is distributed without required labeling,
162 it is misbranded while held for sale.

163 (3) Any product that falls under the definition of drug in
164 s. 499.003(19) may be classified under the authority of this
165 section. This section does not subject portable emergency oxygen
166 inhalators to classification; however, this section does not
167 exempt any person from ss. 499.01 and 499.015.

168 (4) Any product classified under the authority of this
169 section reverts to the federal classification, if different,
170 upon the federal regulation or act becoming effective.

171 (5) The department may by rule reclassify drugs subject to
172 this part when such classification action is necessary to
173 protect the public health.

174 (6) The department may adopt rules that exempt from any

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175 labeling or packaging requirements of this part drugs classified
176 under this section if those requirements are not necessary to
177 protect the public health.

178 Section 6. Subsection (2) of section 499.065, Florida
179 Statutes, is amended to read:

180 499.065 Inspections; imminent danger.—

181 (2) To protect the public from prescription drugs that are
182 adulterated or otherwise unfit for human or animal consumption,
183 the department may examine, sample, seize, and stop the sale or
184 use of prescription drugs to determine the condition of those
185 drugs. The department may immediately seize and remove any
186 prescription drugs if the Secretary of Business and Professional
187 Regulation ~~State Surgeon General~~ or his or her designee
188 determines that the prescription drugs represent a threat to the
189 public health. The owner of any property seized under this
190 section may, within 10 days after the seizure, apply to a court
191 of competent jurisdiction for whatever relief is appropriate. At
192 any time after 10 days, the department may destroy the drugs as
193 contraband.

194 Section 7. Subsection (2) of section 499.601, Florida
195 Statutes, is amended to read:

196 499.601 Legislative intent; construction.—

197 (2) The provisions of this part are cumulative and shall
198 not be construed as repealing or affecting any powers, duties,
199 or authority of the department ~~of Health~~ under any other law of
200 this state; except that, with respect to the regulation of ether
201 as herein provided, in instances in which the provisions of this
202 part may conflict with any other such law, the provisions of
203 this part shall control.

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204 Section 8. Subsection (2) of section 499.61, Florida
205 Statutes, is amended to read:

206 499.61 Definitions.—As used in this part:

207 (2) "Department" means the Department of Business and
208 Professional Regulation ~~Health~~.

209 Section 9. Effective November 1, 2012, section 499.0031,
210 Florida Statutes, is repealed.

211 Section 10. (1) The Florida Drug, Device, and Cosmetic
212 Trust Fund within the Department of Business and Professional
213 Regulation, FLAIR number 20-2-173005, is terminated.

214 (2) The current balance remaining in, and all revenues of,
215 the Florida Drug, Device, and Cosmetic Trust Fund shall be
216 transferred to the Professional Regulation Trust Fund.

217 (3) The Department of Business and Professional Regulation
218 shall pay any outstanding debts or obligations of the Florida
219 Drug, Device, and Cosmetic Trust Fund as soon as practicable,
220 and the Chief Financial Officer shall close out and remove the
221 terminated fund from the various state accounting systems using
222 generally accepted accounting principles concerning warrants
223 outstanding, assets, and liabilities.

224 (4) This section shall take effect November 1, 2012.

225 Section 11. Paragraphs (d), (e), and (l) of subsection (2)
226 of section 499.01, Florida Statutes, are amended to read:

227 499.01 Permits.—

228 (2) The following permits are established:

229 (d) *Prescription drug wholesale distributor permit.*—A
230 prescription drug wholesale distributor is a wholesale
231 distributor that may engage in the wholesale distribution of
232 prescription drugs. A prescription drug wholesale distributor

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233 that applies to the department for a new permit or the renewal
234 of a permit must submit a bond of \$100,000, or other equivalent
235 means of security acceptable to the department, such as an
236 irrevocable letter of credit or a deposit in a trust account or
237 financial institution, payable to the Professional Regulation
238 ~~Florida Drug, Device, and Cosmetic~~ Trust Fund. The purpose of
239 the bond is to secure payment of any administrative penalties
240 imposed by the department and any fees and costs incurred by the
241 department regarding that permit which are authorized under
242 state law and which the permittee fails to pay 30 days after the
243 fine or costs become final. The department may make a claim
244 against such bond or security until 1 year after the permittee's
245 license ceases to be valid or until 60 days after any
246 administrative or legal proceeding authorized in this part which
247 involves the permittee is concluded, including any appeal,
248 whichever occurs later. The department may adopt rules for
249 issuing a prescription drug wholesale distributor-broker permit
250 to a person who engages in the wholesale distribution of
251 prescription drugs and does not take physical possession of any
252 prescription drugs.

253 (e) *Out-of-state prescription drug wholesale distributor*
254 *permit.*-An out-of-state prescription drug wholesale distributor
255 is a wholesale distributor located outside this state which
256 engages in the wholesale distribution of prescription drugs into
257 this state and which must be permitted by the department and
258 comply with all the provisions required of a wholesale
259 distributor under this part. An out-of-state prescription drug
260 wholesale distributor that applies to the department for a new
261 permit or the renewal of a permit must submit a bond of

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262 \$100,000, or other equivalent means of security acceptable to
263 the department, such as an irrevocable letter of credit or a
264 deposit in a trust account or financial institution, payable to
265 the Professional Regulation ~~Florida Drug, Device, and Cosmetic~~
266 Trust Fund. The purpose of the bond is to secure payment of any
267 administrative penalties imposed by the department and any fees
268 and costs incurred by the department regarding that permit which
269 are authorized under state law and which the permittee fails to
270 pay 30 days after the fine or costs become final. The department
271 may make a claim against such bond or security until 1 year
272 after the permittee's license ceases to be valid or until 60
273 days after any administrative or legal proceeding authorized in
274 this part which involves the permittee is concluded, including
275 any appeal, whichever occurs later.

276 1. The out-of-state prescription drug wholesale distributor
277 must maintain at all times a license or permit to engage in the
278 wholesale distribution of prescription drugs in compliance with
279 laws of the state in which it is a resident.

280 2. An out-of-state prescription drug wholesale distributor
281 permit is not required for an intracompany sale or transfer of a
282 prescription drug from an out-of-state establishment that is
283 duly licensed as a prescription drug wholesale distributor, in
284 its state of residence, to a licensed prescription drug
285 wholesale distributor in this state, if both wholesale
286 distributors conduct wholesale distributions of prescription
287 drugs under the same business name. The recordkeeping
288 requirements of ss. 499.0121(6) and 499.01212 must be followed
289 for this transaction.

290 (1) *Limited prescription drug veterinary wholesale*

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291 *distributor permit.*—Unless engaging in the activities of and
292 permitted as a prescription drug manufacturer, nonresident
293 prescription drug manufacturer, prescription drug wholesale
294 distributor, or out-of-state prescription drug wholesale
295 distributor, a limited prescription drug veterinary wholesale
296 distributor permit is required for any person that engages in
297 the distribution in or into this state of veterinary
298 prescription drugs and prescription drugs subject to, defined
299 by, or described by s. 503(b) of the Federal Food, Drug, and
300 Cosmetic Act under the following conditions:

301 1. The person is engaged in the business of wholesaling
302 prescription and veterinary prescription drugs to persons:

303 a. Licensed as veterinarians practicing on a full-time
304 basis;

305 b. Regularly and lawfully engaged in instruction in
306 veterinary medicine;

307 c. Regularly and lawfully engaged in law enforcement
308 activities;

309 d. For use in research not involving clinical use; or

310 e. For use in chemical analysis or physical testing or for
311 purposes of instruction in law enforcement activities, research,
312 or testing.

313 2. No more than 30 percent of total annual prescription
314 drug sales may be prescription drugs approved for human use
315 which are subject to, defined by, or described by s. 503(b) of
316 the Federal Food, Drug, and Cosmetic Act.

317 3. The person does not distribute in any jurisdiction
318 prescription drugs subject to, defined by, or described by s.
319 503(b) of the Federal Food, Drug, and Cosmetic Act to any person

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320 who is authorized to sell, distribute, purchase, trade, or use
321 these drugs on or for humans.

322 4. A limited prescription drug veterinary wholesale
323 distributor that applies to the department for a new permit or
324 the renewal of a permit must submit a bond of \$20,000, or other
325 equivalent means of security acceptable to the department, such
326 as an irrevocable letter of credit or a deposit in a trust
327 account or financial institution, payable to the Professional
328 Regulation ~~Florida Drug, Device, and Cosmetic~~ Trust Fund. The
329 purpose of the bond is to secure payment of any administrative
330 penalties imposed by the department and any fees and costs
331 incurred by the department regarding that permit which are
332 authorized under state law and which the permittee fails to pay
333 30 days after the fine or costs become final. The department may
334 make a claim against such bond or security until 1 year after
335 the permittee's license ceases to be valid or until 60 days
336 after any administrative or legal proceeding authorized in this
337 part which involves the permittee is concluded, including any
338 appeal, whichever occurs later.

339 5. A limited prescription drug veterinary wholesale
340 distributor must maintain at all times a license or permit to
341 engage in the wholesale distribution of prescription drugs in
342 compliance with laws of the state in which it is a resident.

343 6. A limited prescription drug veterinary wholesale
344 distributor must comply with the requirements for wholesale
345 distributors under ss. 499.0121 and 499.01212, except that a
346 limited prescription drug veterinary wholesale distributor is
347 not required to provide a pedigree paper as required by s.
348 499.01212 upon the wholesale distribution of a prescription drug

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349 to a veterinarian.

350 7. A limited prescription drug veterinary wholesale
351 distributor may not return to inventory for subsequent wholesale
352 distribution any prescription drug subject to, defined by, or
353 described by s. 503(b) of the Federal Food, Drug, and Cosmetic
354 Act which has been returned by a veterinarian.

355 8. A limited prescription drug veterinary wholesale
356 distributor permit is not required for an intracompany sale or
357 transfer of a prescription drug from an out-of-state
358 establishment that is duly licensed to engage in the wholesale
359 distribution of prescription drugs in its state of residence to
360 a licensed limited prescription drug veterinary wholesale
361 distributor in this state if both wholesale distributors conduct
362 wholesale distributions of prescription drugs under the same
363 business name. The recordkeeping requirements of ss. 499.0121(6)
364 and 499.01212 must be followed for this transaction.

365 Section 12. Subsection (13) of section 499.028, Florida
366 Statutes, is amended to read:

367 499.028 Drug samples or complimentary drugs; starter packs;
368 permits to distribute.-

369 (13) The department may, pursuant to chapter 120, impose an
370 administrative fine, not to exceed \$5,000 per violation per day,
371 for the violation of this section or rules adopted under this
372 section. Each day such violation continues constitutes a
373 separate violation, and each such separate violation is subject
374 to a separate fine. All amounts collected under this section
375 shall be deposited into the Professional Regulation Drug,
376 ~~Device, and Cosmetic~~ Trust Fund. In determining the amount of
377 fine to be levied for a violation, the following factors must be

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378 considered:

379 (a) The severity of the violation.

380 (b) Any actions taken by the permittee to correct the
381 violation or to remedy complaints.

382 (c) Any previous violations.

383 Section 13. Section 499.04, Florida Statutes, is amended to
384 read:

385 499.04 Fee authority.—The department may collect fees for
386 all drug, device, and cosmetic applications, permits, product
387 registrations, and free-sale certificates. The total amount of
388 fees collected from all permits, applications, product
389 registrations, and free-sale certificates must be adequate to
390 fund the expenses incurred by the department in carrying out
391 this part. The department shall, by rule, establish a schedule
392 of fees that are within the ranges provided in this section and
393 shall adjust those fees from time to time based on the costs
394 associated with administering this part. The fees are payable to
395 the department to be deposited into the Professional Regulation
396 ~~Florida Drug, Device, and Cosmetic~~ Trust Fund for the sole
397 purpose of carrying out ~~the provisions of~~ this part.

398 Section 14. Section 499.057, Florida Statutes, is amended
399 to read:

400 499.057 Expenses and salaries.—Except as otherwise provided
401 in the General Appropriations Act, all expenses and salaries
402 shall be paid out of the Professional Regulation Trust Fund.
403 ~~special fund hereby created in the office of the Chief Financial~~
404 ~~Officer, which fund is to be known as the "Florida Drug, Device,~~
405 ~~and Cosmetic Trust Fund."~~

406 Section 15. Paragraph (a) of subsection (2) of section

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407 499.062, Florida Statutes, is amended to read:

408 499.062 Seizure and condemnation of drugs, devices, or
409 cosmetics.—

410 (2) Whenever a duly authorized officer or employee of the
411 department finds cause, or has probable cause to believe that
412 cause exists, for the seizure of any drug, device, or cosmetic,
413 as set out in this part, he or she shall affix to the article a
414 tag, stamp, or other appropriate marking, giving notice that the
415 article is, or is suspected of being, subject to seizure under
416 this part and that the article has been detained and seized by
417 the department. Such officer or employee shall also warn all
418 persons not to remove or dispose of the article, by sale or
419 otherwise, until permission is given by the department or the
420 court. Any person who violates this subsection is guilty of a
421 felony of the second degree, punishable as provided in s.
422 775.082, s. 775.083, or s. 775.084.

423 (a) When any article detained or seized under this
424 subsection has been found by the department to be subject to
425 seizure and condemnation, the department shall petition the
426 court for an order of condemnation or sale, as the court
427 directs. The proceeds of the sale of drugs, devices, and
428 cosmetics, less the legal costs and charges, shall be deposited
429 into the Professional Regulation ~~Florida Drug, Device, and~~
430 ~~Cosmetic~~ Trust Fund.

431 Section 16. Subsections (3) and (4) of section 499.066,
432 Florida Statutes, are amended to read:

433 499.066 Penalties; remedies.—In addition to other penalties
434 and other enforcement provisions:

435 (3) The department may impose an administrative fine, not

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436 to exceed \$5,000 per violation per day, for the violation of any
437 provision of this part or rules adopted under this part. Each
438 day a violation continues constitutes a separate violation, and
439 each separate violation is subject to a separate fine. All
440 amounts collected pursuant to this section shall be deposited
441 into the Professional Regulation ~~Florida Drug, Device, and~~
442 ~~Cosmetic~~ Trust Fund and are appropriated for the use of the
443 department in administering this part. In determining the amount
444 of the fine to be levied for a violation, the department shall
445 consider:

446 (a) The severity of the violation;

447 (b) Any actions taken by the person to correct the
448 violation or to remedy complaints; and

449 (c) Any previous violations.

450 (4) The department shall deposit any rewards, fines, or
451 collections that are due the department and which derive from
452 joint enforcement activities with other state and federal
453 agencies which relate to this part, chapter 893, or the federal
454 act, into the Professional Regulation ~~Florida Drug, Device, and~~
455 ~~Cosmetic~~ Trust Fund. The proceeds of those rewards, fines, and
456 collections are appropriated for the use of the department in
457 administering this part.

458 Section 17. Subsection (7) of section 499.62, Florida
459 Statutes, is amended to read:

460 499.62 License or permit required of manufacturer,
461 distributor, dealer, or purchaser of ether.—

462 (7) A licensed or permitted facility shall renew its
463 license or permit prior to its expiration date. If a renewal
464 application and fee are not filed by the expiration date of any

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465 year, the permit may be reinstated only upon payment of a
466 delinquent fee of \$50, plus the required renewal fee, within 30
467 days after the date of expiration. If any person who is subject
468 to the requirements of this part fails to comply with the
469 renewal, the department shall have the authority to seize all
470 ether products and dispose of them as of November 1 of the year
471 the license or permit expires. Any funds collected from the
472 disposal shall be placed in the Professional Regulation Florida
473 ~~Drug, Device, and Cosmetic~~ Trust Fund.

474 Section 18. Subsection (2) of section 499.72, Florida
475 Statutes, is amended to read:

476 499.72 Administrative fines.—

477 (2) All such fines, monetary penalties, and costs received
478 by the department in connection with this part shall be
479 deposited in the Professional Regulation Florida ~~Drug, Device,~~
480 ~~and Cosmetic~~ Trust Fund.

481 Section 19. Section 499.79, Florida Statutes, is amended to
482 read:

483 499.79 Deposit of fees.—All fees collected for licenses and
484 permits required by this part shall be deposited in the
485 Professional Regulation Florida ~~Drug, Device, and Cosmetic~~ Trust
486 Fund ~~created by s. 499.057~~, and all moneys collected under ~~the~~
487 ~~provisions of~~ this part and deposited in the ~~such~~ trust fund
488 ~~shall be used by~~ ~~are hereby appropriated for the use of~~ the
489 department in the administration of this part.

490 Section 20. (1) (a) The Department of Business and
491 Professional Regulation shall maintain a separate account in the
492 Professional Regulation Trust Fund for the Drugs, Devices, and
493 Cosmetics Program.

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494 (b) The Drugs, Devices, and Cosmetics Program protects the
495 public health, safety, and welfare by preventing fraud,
496 adulteration, misbranding, and false advertising in the
497 manufacture, repackaging, or distribution of drugs, devices, and
498 cosmetics. The program promotes consistency between state and
499 federal laws governing drugs, devices, and cosmetics by
500 licensing manufacturers, repackagers, distributors, and certain
501 retailers as required by federal law, and regulating persons and
502 entities engaged in related activities, including, but not
503 limited to, licensees, practitioners, pharmacies, clinics, and
504 hospitals.

505 (2) By January 15, 2013, the Department of Business and
506 Professional Regulation shall submit a report to the chairs of
507 the Senate Budget Subcommittee on General Government
508 Appropriations, the Senate Committee on Regulated Industries,
509 the House Government Operations Appropriations Subcommittee, and
510 the House of Representatives Subcommittee on Business and
511 Consumer Affairs regarding the operation of the Drugs, Devices,
512 and Cosmetics Program. The report must provide detailed options
513 and recommendations to the Legislature relating to:

514 (a) Eliminating the program's operating deficit through
515 operational changes or improved efficiencies;

516 (b) The cost-efficient alignment of the licensure renewal
517 process under the program with other professions; and

518 (c) Regulating the program under chapter 455, Florida
519 Statutes.

520 (d) This subsection expires July 1, 2013.

521 Section 21. Except as otherwise expressly provided in this
522 act, this act shall take effect July 1, 2012.