A bill to be entitled 1 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, 499.065, 499.601, and 499.61, F.S.; conforming 10 11 provisions to the transfer by s. 27, ch. 2010-161, Laws of Florida, of regulatory authority for chapter 12 13 499, F.S., from the Department of Health to the 14 Department of Business and Professional Regulation; 15 repealing s. 499.0031, F.S., relating to the Florida 16 Drug, Device, and Cosmetic Trust Fund; terminating the 17 Florida Drug, Device, and Cosmetic Trust Fund; providing for the disposition of balances in and 18 revenues of such trust fund; prescribing procedures 19 for the termination of such trust fund; amending ss. 20 21 499.01, 499.028, 499.04, 499.057, 499.062, 499.066, 22 499.62, 499.72, and 499.79, F.S.; conforming 23 provisions; providing effective dates. 24 25 Be It Enacted by the Legislature of the State of Florida: 26 27 Section 1. Paragraphs (d) through (k) of subsection (2) of 28 section 20.165, Florida Statutes, are redesignated as paragraphs Page 1 of 18

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29	(e) through (l), respectively, and a new paragraph (d) is added
30	to that subsection to read:
31	20.165 Department of Business and Professional
32	RegulationThere is created a Department of Business and
33	Professional Regulation.
34	(2) The following divisions of the Department of Business
35	and Professional Regulation are established:
36	(d) Division of Drugs, Devices, and Cosmetics.
37	Section 2. Effective November 1, 2012, subsection (8) of
38	section 455.116, Florida Statutes, is amended to read:
39	455.116 Regulation trust fundsThe following trust funds
40	shall be placed in the department:
41	(8) Florida Drug, Device, and Cosmetic Trust Fund.
42	Section 3. Subsection (15) and paragraph (a) of subsection
43	(54) of section 499.003, Florida Statutes, are amended to read:
44	499.003 Definitions of terms used in this part.—As used in
45	this part, the term:
46	(15) "Department" means the Department of Business and
47	Professional Regulation Health.
48	(54) "Wholesale distribution" means distribution of
49	prescription drugs to persons other than a consumer or patient,
50	but does not include:
51	(a) Any of the following activities, which is not a
52	violation of s. 499.005(21) if such activity is conducted in
53	accordance with s. 499.01(2)(g):
54	1. The purchase or other acquisition by a hospital or
55	other health care entity that is a member of a group purchasing
56	organization of a prescription drug for its own use from the
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57 group purchasing organization or from other hospitals or health 58 care entities that are members of that organization.

59 2. The sale, purchase, or trade of a prescription drug or 60 an offer to sell, purchase, or trade a prescription drug by a 61 charitable organization described in s. 501(c)(3) of the 62 Internal Revenue Code of 1986, as amended and revised, to a 63 nonprofit affiliate of the organization to the extent otherwise 64 permitted by law.

The sale, purchase, or trade of a prescription drug or 65 3. 66 an offer to sell, purchase, or trade a prescription drug among 67 hospitals or other health care entities that are under common 68 control. For purposes of this subparagraph, "common control" means the power to direct or cause the direction of the 69 70 management and policies of a person or an organization, whether 71 by ownership of stock, by voting rights, by contract, or 72 otherwise.

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

a. The agency or entity must obtain written authorization
for the sale, purchase, trade, or other transfer of a
prescription drug under this subparagraph from the <u>Secretary of</u>
<u>Business and Professional Regulation</u> State Surgeon General or
his or her designee.

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b. The contract provider or subcontractor must be
authorized by law to administer or dispense prescription drugs.
c. In the case of a subcontractor, the agency or entity
must be a party to and execute the subcontract.

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

92 The contract provider and subcontractor must maintain e. 93 and produce immediately for inspection all records of movement 94 or transfer of all the prescription drugs belonging to the agency or entity, including, but not limited to, the records of 95 96 receipt and disposition of prescription drugs. Each contractor and subcontractor dispensing or administering these drugs must 97 98 maintain and produce records documenting the dispensing or administration. Records that are required to be maintained 99 100 include, but are not limited to, a perpetual inventory itemizing 101 drugs received and drugs dispensed by prescription number or 102 administered by patient identifier, which must be submitted to 103 the agency or entity quarterly.

104 f. The contract provider or subcontractor may administer 105 or dispense the prescription drugs only to the eligible patients 106 of the agency or entity or must return the prescription drugs 107 for or to the agency or entity. The contract provider or subcontractor must require proof from each person seeking to 108 fill a prescription or obtain treatment that the person is an 109 eligible patient of the agency or entity and must, at a minimum, 110 maintain a copy of this proof as part of the records of the 111 contractor or subcontractor required under sub-subparagraph e. 112

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113 In addition to the departmental inspection authority q. 114 set forth in s. 499.051, the establishment of the contract 115 provider and subcontractor and all records pertaining to 116 prescription drugs subject to this subparagraph shall be subject 117 to inspection by the agency or entity. All records relating to prescription drugs of a manufacturer under this subparagraph 118 119 shall be subject to audit by the manufacturer of those drugs, without identifying individual patient information. 120

Section 4. Subsection (2) of section 499.01211, FloridaStatutes, is amended to read:

123

499.01211 Drug Wholesale Distributor Advisory Council.-

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

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

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

138 (c) One person employed by a retail pharmacy chain located139 in this state.

140 (d) One person who is a member of the Board of Pharmacy Page 5 of 18

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141 and is a pharmacist licensed under chapter 465.

(e) One person who is a physician licensed pursuant tochapter 458 or chapter 459.

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

147 (g) One person who is an employee of a pharmaceutical 148 manufacturer.

149 Section 5. Section 499.024, Florida Statutes, is amended 150 to read:

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

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

158 (2) If a product is distributed without required labeling,159 it is misbranded while held for sale.

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

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

(5) The department may by rule reclassify drugs subject to Page 6 of 18

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169 this part when such classification action is necessary to 170 protect the public health.

171 (6) The department may adopt rules that exempt from any 172 labeling or packaging requirements of this part drugs classified 173 under this section if those requirements are not necessary to 174 protect the public health.

Section 6. Subsection (2) of section 499.065, FloridaStatutes, is amended to read:

177

499.065 Inspections; imminent danger.-

178 To protect the public from prescription drugs that are (2)179 adulterated or otherwise unfit for human or animal consumption, 180 the department may examine, sample, seize, and stop the sale or use of prescription drugs to determine the condition of those 181 182 drugs. The department may immediately seize and remove any 183 prescription drugs if the Secretary of Business and Professional 184 Regulation State Surgeon General or his or her designee 185 determines that the prescription drugs represent a threat to the 186 public health. The owner of any property seized under this 187 section may, within 10 days after the seizure, apply to a court of competent jurisdiction for whatever relief is appropriate. At 188 189 any time after 10 days, the department may destroy the drugs as 190 contraband.

Section 7. Subsection (2) of section 499.601, FloridaStatutes, is amended to read:

193

499.601 Legislative intent; construction.-

(2) The provisions of this part are cumulative and shall
 not be construed as repealing or affecting any powers, duties,
 or authority of the department of Health under any other law of

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197	this state; except that, with respect to the regulation of ether
198	as herein provided, in instances in which the provisions of this
199	part may conflict with any other such law, the provisions of
200	this part shall control.
201	Section 8. Subsection (2) of section 499.61, Florida
202	Statutes, is amended to read:
203	499.61 Definitions.—As used in this part:
204	(2) "Department" means the Department of Business and
205	Professional Regulation Health.
206	Section 9. Effective November 1, 2012, section 499.0031,
207	Florida Statutes, is repealed.
208	Section 10. (1) The Florida Drug, Device, and Cosmetic
209	Trust Fund within the Department of Business and Professional
210	Regulation, FLAIR number 20-2-173005, is terminated.
211	(2) The current balance remaining in, and all revenues of,
212	the Florida Drug, Device, and Cosmetic Trust Fund shall be
213	transferred to the Professional Regulation Trust Fund.
214	(3) The Department of Business and Professional Regulation
215	shall pay any outstanding debts or obligations of the Florida
216	Drug, Device, and Cosmetic Trust Fund as soon as practicable,
217	and the Chief Financial Officer shall close out and remove the
218	terminated fund from the various state accounting systems using
219	generally accepted accounting principles concerning warrants
220	outstanding, assets, and liabilities.
221	(4) This section shall take effect November 1, 2012.
222	Section 11. Paragraphs (d), (e), and (l) of subsection (2)
223	of section 499.01, Florida Statutes, are amended to read:
224	499.01 Permits
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225 (2)The following permits are established: 226 (d) Prescription drug wholesale distributor permit.-A 227 prescription drug wholesale distributor is a wholesale 228 distributor that may engage in the wholesale distribution of 229 prescription drugs. A prescription drug wholesale distributor 230 that applies to the department for a new permit or the renewal 231 of a permit must submit a bond of \$100,000, or other equivalent 232 means of security acceptable to the department, such as an 233 irrevocable letter of credit or a deposit in a trust account or 234 financial institution, payable to the Professional Regulation 235 Florida Drug, Device, and Cosmetic Trust Fund. The purpose of 236 the bond is to secure payment of any administrative penalties 237 imposed by the department and any fees and costs incurred by the 238 department regarding that permit which are authorized under 239 state law and which the permittee fails to pay 30 days after the 240 fine or costs become final. The department may make a claim 241 against such bond or security until 1 year after the permittee's 242 license ceases to be valid or until 60 days after any 243 administrative or legal proceeding authorized in this part which 244 involves the permittee is concluded, including any appeal, 245 whichever occurs later. The department may adopt rules for 246 issuing a prescription drug wholesale distributor-broker permit 247 to a person who engages in the wholesale distribution of 248 prescription drugs and does not take physical possession of any 249 prescription drugs. Out-of-state prescription drug wholesale distributor 250 (e)

251 permit.—An out-of-state prescription drug wholesale distributor 252 is a wholesale distributor located outside this state which

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253 engages in the wholesale distribution of prescription drugs into 254 this state and which must be permitted by the department and 255 comply with all the provisions required of a wholesale 256 distributor under this part. An out-of-state prescription drug 257 wholesale distributor that applies to the department for a new 258 permit or the renewal of a permit must submit a bond of 259 \$100,000, or other equivalent means of security acceptable to 260 the department, such as an irrevocable letter of credit or a 261 deposit in a trust account or financial institution, payable to 262 the Professional Regulation Florida Drug, Device, and Cosmetic 263 Trust Fund. The purpose of the bond is to secure payment of any 264 administrative penalties imposed by the department and any fees and costs incurred by the department regarding that permit which 265 266 are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department 267 268 may make a claim against such bond or security until 1 year 269 after the permittee's license ceases to be valid or until 60 270 days after any administrative or legal proceeding authorized in 271 this part which involves the permittee is concluded, including 272 any appeal, whichever occurs later.

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

277 2. An out-of-state prescription drug wholesale distributor 278 permit is not required for an intracompany sale or transfer of a 279 prescription drug from an out-of-state establishment that is 280 duly licensed as a prescription drug wholesale distributor, in

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its state of residence, to a licensed prescription drug wholesale distributor in this state, if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of ss. 499.0121(6) and 499.01212 must be followed for this transaction.

287 (1) Limited prescription drug veterinary wholesale 288 distributor permit.-Unless engaging in the activities of and 289 permitted as a prescription drug manufacturer, nonresident prescription drug manufacturer, prescription drug wholesale 290 distributor, or out-of-state prescription drug wholesale 291 292 distributor, a limited prescription drug veterinary wholesale 293 distributor permit is required for any person that engages in 294 the distribution in or into this state of veterinary 295 prescription drugs and prescription drugs subject to, defined 296 by, or described by s. 503(b) of the Federal Food, Drug, and 297 Cosmetic Act under the following conditions:

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

300 a. Licensed as veterinarians practicing on a full-time301 basis;

302 b. Regularly and lawfully engaged in instruction in 303 veterinary medicine;

304 c. Regularly and lawfully engaged in law enforcement 305 activities;

306 d. For use in research not involving clinical use; or
 307 e. For use in chemical analysis or physical testing or for
 308 purposes of instruction in law enforcement activities, research,

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309 or testing.

310 2. No more than 30 percent of total annual prescription 311 drug sales may be prescription drugs approved for human use 312 which are subject to, defined by, or described by s. 503(b) of 313 the Federal Food, Drug, and Cosmetic Act.

314 3. The person does not distribute in any jurisdiction 315 prescription drugs subject to, defined by, or described by s. 316 503(b) of the Federal Food, Drug, and Cosmetic Act to any person 317 who is authorized to sell, distribute, purchase, trade, or use 318 these drugs on or for humans.

A limited prescription drug veterinary wholesale 319 4. distributor that applies to the department for a new permit or 320 the renewal of a permit must submit a bond of \$20,000, or other 321 322 equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust 323 324 account or financial institution, payable to the Professional 325 Regulation Florida Drug, Device, and Cosmetic Trust Fund. The 326 purpose of the bond is to secure payment of any administrative 327 penalties imposed by the department and any fees and costs 328 incurred by the department regarding that permit which are 329 authorized under state law and which the permittee fails to pay 330 30 days after the fine or costs become final. The department may 331 make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days 332 after any administrative or legal proceeding authorized in this 333 part which involves the permittee is concluded, including any 334 335 appeal, whichever occurs later.

336

5. A limited prescription drug veterinary wholesale Page 12 of 18

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337 distributor must maintain at all times a license or permit to 338 engage in the wholesale distribution of prescription drugs in 339 compliance with laws of the state in which it is a resident.

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

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

352 8. A limited prescription drug veterinary wholesale 353 distributor permit is not required for an intracompany sale or 354 transfer of a prescription drug from an out-of-state 355 establishment that is duly licensed to engage in the wholesale 356 distribution of prescription drugs in its state of residence to 357 a licensed limited prescription drug veterinary wholesale distributor in this state if both wholesale distributors conduct 358 359 wholesale distributions of prescription drugs under the same 360 business name. The recordkeeping requirements of ss. 499.0121(6) and 499.01212 must be followed for this transaction. 361

362 Section 12. Subsection (13) of section 499.028, Florida 363 Statutes, is amended to read:

364 499.028 Drug samples or complimentary drugs; starter

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365 packs; permits to distribute.-

366 (13)The department may, pursuant to chapter 120, impose 367 an administrative fine, not to exceed \$5,000 per violation per 368 day, for the violation of this section or rules adopted under 369 this section. Each day such violation continues constitutes a 370 separate violation, and each such separate violation is subject 371 to a separate fine. All amounts collected under this section 372 shall be deposited into the Professional Regulation Drug, 373 Device, and Cosmetic Trust Fund. In determining the amount of 374 fine to be levied for a violation, the following factors must be considered: 375

376

(a) The severity of the violation.

377 (b) Any actions taken by the permittee to correct the378 violation or to remedy complaints.

379

(c) Any previous violations.

380 Section 13. Section 499.04, Florida Statutes, is amended 381 to read:

382 Fee authority.-The department may collect fees for 499.04 383 all drug, device, and cosmetic applications, permits, product 384 registrations, and free-sale certificates. The total amount of 385 fees collected from all permits, applications, product 386 registrations, and free-sale certificates must be adequate to 387 fund the expenses incurred by the department in carrying out 388 this part. The department shall, by rule, establish a schedule of fees that are within the ranges provided in this section and 389 shall adjust those fees from time to time based on the costs 390 391 associated with administering this part. The fees are payable to 392 the department to be deposited into the Professional Regulation

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393 Florida Drug, Device, and Cosmetic Trust Fund for the sole 394 purpose of carrying out the provisions of this part.

395 Section 14. Section 499.057, Florida Statutes, is amended 396 to read:

397 499.057 Expenses and salaries.—<u>Except as otherwise</u> 398 provided in the General Appropriations Act, all expenses and 399 salaries shall be paid out of the <u>Professional Regulation Trust</u> 400 <u>Fund.</u> special fund hereby created in the office of the Chief 401 Financial Officer, which fund is to be known as the "Florida 402 Drug, Device, and Cosmetic Trust Fund."

403 Section 15. Paragraph (a) of subsection (2) of section 404 499.062, Florida Statutes, is amended to read:

405 499.062 Seizure and condemnation of drugs, devices, or 406 cosmetics.-

407 (2) Whenever a duly authorized officer or employee of the 408 department finds cause, or has probable cause to believe that 409 cause exists, for the seizure of any drug, device, or cosmetic, 410 as set out in this part, he or she shall affix to the article a 411 tag, stamp, or other appropriate marking, giving notice that the 412 article is, or is suspected of being, subject to seizure under 413 this part and that the article has been detained and seized by 414 the department. Such officer or employee shall also warn all 415 persons not to remove or dispose of the article, by sale or 416 otherwise, until permission is given by the department or the court. Any person who violates this subsection is guilty of a 417 felony of the second degree, punishable as provided in s. 418 775.082, s. 775.083, or s. 775.084. 419

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(a) When any article detained or seized under this

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421 subsection has been found by the department to be subject to 422 seizure and condemnation, the department shall petition the 423 court for an order of condemnation or sale, as the court 424 directs. The proceeds of the sale of drugs, devices, and 425 cosmetics, less the legal costs and charges, shall be deposited 426 into the <u>Professional Regulation</u> Florida Drug, Device, and 427 Cosmetic Trust Fund.

428 Section 16. Subsections (3) and (4) of section 499.066, 429 Florida Statutes, are amended to read:

430 499.066 Penalties; remedies.—In addition to other431 penalties and other enforcement provisions:

432 The department may impose an administrative fine, not (3) to exceed \$5,000 per violation per day, for the violation of any 433 434 provision of this part or rules adopted under this part. Each 435 day a violation continues constitutes a separate violation, and 436 each separate violation is subject to a separate fine. All 437 amounts collected pursuant to this section shall be deposited 438 into the Professional Regulation Florida Drug, Device, and 439 Cosmetic Trust Fund and are appropriated for the use of the 440 department in administering this part. In determining the amount 441 of the fine to be levied for a violation, the department shall 442 consider:

443

(a) The severity of the violation;

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

446 (c) Any previous violations.

(4) The department shall deposit any rewards, fines, orcollections that are due the department and which derive from

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449 joint enforcement activities with other state and federal 450 agencies which relate to this part, chapter 893, or the federal 451 act, into the <u>Professional Regulation</u> Florida Drug, Device, and 452 Cosmetic Trust Fund. The proceeds of those rewards, fines, and 453 collections are appropriated for the use of the department in 454 administering this part.

455 Section 17. Subsection (7) of section 499.62, Florida 456 Statutes, is amended to read:

457 499.62 License or permit required of manufacturer,
458 distributor, dealer, or purchaser of ether.-

459 A licensed or permitted facility shall renew its (7) 460 license or permit prior to its expiration date. If a renewal application and fee are not filed by the expiration date of any 461 462 year, the permit may be reinstated only upon payment of a delinquent fee of \$50, plus the required renewal fee, within 30 463 464 days after the date of expiration. If any person who is subject 465 to the requirements of this part fails to comply with the 466 renewal, the department shall have the authority to seize all 467 ether products and dispose of them as of November 1 of the year 468 the license or permit expires. Any funds collected from the 469 disposal shall be placed in the Professional Regulation Florida 470 Drug, Device, and Cosmetic Trust Fund.

471 Section 18. Subsection (2) of section 499.72, Florida472 Statutes, is amended to read:

473

499.72 Administrative fines.-

474 (2) All such fines, monetary penalties, and costs received
475 by the department in connection with this part shall be
476 deposited in the <u>Professional Regulation</u> Florida Drug, Device,

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477 and Cosmetic Trust Fund.

478 Section 19. Section 499.79, Florida Statutes, is amended 479 to read: 499.79 Deposit of fees.-All fees collected for licenses 480 481 and permits required by this part shall be deposited in the 482 Professional Regulation Florida Drug, Device, and Cosmetic Trust 483 Fund created by s. 499.057, and all moneys collected under the 484 provisions of this part and deposited in the such trust fund 485 shall be used by are hereby appropriated for the use of the 486 department in the administration of this part. Section 20. Except as otherwise expressly provided in this 487 488 act, this act shall take effect July 1, 2012.

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