

Amendment No.

CHAMBER ACTION

Senate

House

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1 The Conference Committee on HB 5511 offered the following:

2
3 **Conference Committee Amendment (with title amendment)**

4 Remove everything after the enacting clause and insert:

5 Section 1. Paragraphs (d) through (k) of subsection (2) of
6 section 20.165, Florida Statutes, are redesignated as paragraphs
7 (e) through (l), respectively, and a new paragraph (d) is added
8 to that subsection to read:

9 20.165 Department of Business and Professional
10 Regulation.—There is created a Department of Business and
11 Professional Regulation.

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

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

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

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17 455.116 Regulation trust funds.—The following trust funds
18 shall be placed in the department:

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

20 Section 3. Subsection (15) and paragraph (a) of subsection
21 (54) of section 499.003, Florida Statutes, are amended to read:

22 499.003 Definitions of terms used in this part.—As used in
23 this part, the term:

24 (15) "Department" means the Department of Business and
25 Professional Regulation Health.

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

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

32 1. The purchase or other acquisition by a hospital or
33 other health care entity that is a member of a group purchasing
34 organization of a prescription drug for its own use from the
35 group purchasing organization or from other hospitals or health
36 care entities that are members of that organization.

37 2. The sale, purchase, or trade of a prescription drug or
38 an offer to sell, purchase, or trade a prescription drug by a
39 charitable organization described in s. 501(c)(3) of the
40 Internal Revenue Code of 1986, as amended and revised, to a
41 nonprofit affiliate of the organization to the extent otherwise
42 permitted by law.

43 3. The sale, purchase, or trade of a prescription drug or
44 an offer to sell, purchase, or trade a prescription drug among
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45 hospitals or other health care entities that are under common
46 control. For purposes of this subparagraph, "common control"
47 means the power to direct or cause the direction of the
48 management and policies of a person or an organization, whether
49 by ownership of stock, by voting rights, by contract, or
50 otherwise.

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

58 a. The agency or entity must obtain written authorization
59 for the sale, purchase, trade, or other transfer of a
60 prescription drug under this subparagraph from the Secretary of
61 Business and Professional Regulation ~~State Surgeon General~~ or
62 his or her designee.

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

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

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

70 e. The contract provider and subcontractor must maintain
71 and produce immediately for inspection all records of movement
72 or transfer of all the prescription drugs belonging to the

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73 agency or entity, including, but not limited to, the records of
74 receipt and disposition of prescription drugs. Each contractor
75 and subcontractor dispensing or administering these drugs must
76 maintain and produce records documenting the dispensing or
77 administration. Records that are required to be maintained
78 include, but are not limited to, a perpetual inventory itemizing
79 drugs received and drugs dispensed by prescription number or
80 administered by patient identifier, which must be submitted to
81 the agency or entity quarterly.

82 f. The contract provider or subcontractor may administer
83 or dispense the prescription drugs only to the eligible patients
84 of the agency or entity or must return the prescription drugs
85 for or to the agency or entity. The contract provider or
86 subcontractor must require proof from each person seeking to
87 fill a prescription or obtain treatment that the person is an
88 eligible patient of the agency or entity and must, at a minimum,
89 maintain a copy of this proof as part of the records of the
90 contractor or subcontractor required under sub-subparagraph e.

91 g. In addition to the departmental inspection authority
92 set forth in s. 499.051, the establishment of the contract
93 provider and subcontractor and all records pertaining to
94 prescription drugs subject to this subparagraph shall be subject
95 to inspection by the agency or entity. All records relating to
96 prescription drugs of a manufacturer under this subparagraph
97 shall be subject to audit by the manufacturer of those drugs,
98 without identifying individual patient information.

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

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499.01211 Drug Wholesale Distributor Advisory Council.—

(2) The Secretary of Business and Professional Regulation ~~State Surgeon General~~, or his or her designee, and the Secretary of Health Care Administration, or her or his designee, shall be members of the council. The Secretary of Business and Professional Regulation ~~State Surgeon General~~ shall appoint nine additional members to the council who shall be appointed to a 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).

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

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

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

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

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

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129 499.024 Drug product classification.—The department ~~State~~
130 ~~Surgeon General~~ shall adopt rules to classify drug products
131 intended for use by humans which the United States Food and Drug
132 Administration has not classified in the federal act or the Code
133 of Federal Regulations.

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

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

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

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

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

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

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

155 499.065 Inspections; imminent danger.—

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156 (2) To protect the public from prescription drugs that are
157 adulterated or otherwise unfit for human or animal consumption,
158 the department may examine, sample, seize, and stop the sale or
159 use of prescription drugs to determine the condition of those
160 drugs. The department may immediately seize and remove any
161 prescription drugs if the Secretary of Business and Professional
162 Regulation ~~State Surgeon General~~ or his or her designee
163 determines that the prescription drugs represent a threat to the
164 public health. The owner of any property seized under this
165 section may, within 10 days after the seizure, apply to a court
166 of competent jurisdiction for whatever relief is appropriate. At
167 any time after 10 days, the department may destroy the drugs as
168 contraband.

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

171 499.601 Legislative intent; construction.—

172 (2) The provisions of this part are cumulative and shall
173 not be construed as repealing or affecting any powers, duties,
174 or authority of the department ~~of Health~~ under any other law of
175 this state; except that, with respect to the regulation of ether
176 as herein provided, in instances in which the provisions of this
177 part may conflict with any other such law, the provisions of
178 this part shall control.

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

181 499.61 Definitions.—As used in this part:

182 (2) "Department" means the Department of Business and
183 Professional Regulation ~~Health~~.

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184 Section 9. Effective November 1, 2012, section 499.0031,
185 Florida Statutes, is repealed.

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

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

192 (3) The Department of Business and Professional Regulation
193 shall pay any outstanding debts or obligations of the Florida
194 Drug, Device, and Cosmetic Trust Fund as soon as practicable,
195 and the Chief Financial Officer shall close out and remove the
196 terminated fund from the various state accounting systems using
197 generally accepted accounting principles concerning warrants
198 outstanding, assets, and liabilities.

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

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

202 499.01 Permits.—

203 (2) The following permits are established:

204 (d) Prescription drug wholesale distributor permit.—A
205 prescription drug wholesale distributor is a wholesale
206 distributor that may engage in the wholesale distribution of
207 prescription drugs. A prescription drug wholesale distributor
208 that applies to the department for a new permit or the renewal
209 of a permit must submit a bond of \$100,000, or other equivalent
210 means of security acceptable to the department, such as an
211 irrevocable letter of credit or a deposit in a trust account or
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212 financial institution, payable to the Professional Regulation
213 ~~Florida Drug, Device, and Cosmetic~~ Trust Fund. The purpose of
214 the bond is to secure payment of any administrative penalties
215 imposed by the department and any fees and costs incurred by the
216 department regarding that permit which are authorized under
217 state law and which the permittee fails to pay 30 days after the
218 fine or costs become final. The department may make a claim
219 against such bond or security until 1 year after the permittee's
220 license ceases to be valid or until 60 days after any
221 administrative or legal proceeding authorized in this part which
222 involves the permittee is concluded, including any appeal,
223 whichever occurs later. The department may adopt rules for
224 issuing a prescription drug wholesale distributor-broker permit
225 to a person who engages in the wholesale distribution of
226 prescription drugs and does not take physical possession of any
227 prescription drugs.

228 (e) Out-of-state prescription drug wholesale distributor
229 permit.—An out-of-state prescription drug wholesale distributor
230 is a wholesale distributor located outside this state which
231 engages in the wholesale distribution of prescription drugs into
232 this state and which must be permitted by the department and
233 comply with all the provisions required of a wholesale
234 distributor under this part. An out-of-state prescription drug
235 wholesale distributor that applies to the department for a new
236 permit or the renewal of a permit must submit a bond of
237 \$100,000, or other equivalent means of security acceptable to
238 the department, such as an irrevocable letter of credit or a
239 deposit in a trust account or financial institution, payable to
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240 the Professional Regulation Florida Drug, Device, and Cosmetic
241 Trust Fund. The purpose of the bond is to secure payment of any
242 administrative penalties imposed by the department and any fees
243 and costs incurred by the department regarding that permit which
244 are authorized under state law and which the permittee fails to
245 pay 30 days after the fine or costs become final. The department
246 may make a claim against such bond or security until 1 year
247 after the permittee's license ceases to be valid or until 60
248 days after any administrative or legal proceeding authorized in
249 this part which involves the permittee is concluded, including
250 any appeal, whichever occurs later.

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

255 2. An out-of-state prescription drug wholesale distributor
256 permit is not required for an intracompany sale or transfer of a
257 prescription drug from an out-of-state establishment that is
258 duly licensed as a prescription drug wholesale distributor, in
259 its state of residence, to a licensed prescription drug
260 wholesale distributor in this state, if both wholesale
261 distributors conduct wholesale distributions of prescription
262 drugs under the same business name. The recordkeeping
263 requirements of ss. 499.0121(6) and 499.01212 must be followed
264 for this transaction.

265 (1) Limited prescription drug veterinary wholesale
266 distributor permit.—Unless engaging in the activities of and
267 permitted as a prescription drug manufacturer, nonresident
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268 prescription drug manufacturer, prescription drug wholesale
269 distributor, or out-of-state prescription drug wholesale
270 distributor, a limited prescription drug veterinary wholesale
271 distributor permit is required for any person that engages in
272 the distribution in or into this state of veterinary
273 prescription drugs and prescription drugs subject to, defined
274 by, or described by s. 503(b) of the Federal Food, Drug, and
275 Cosmetic Act under the following conditions:

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

278 a. Licensed as veterinarians practicing on a full-time
279 basis;

280 b. Regularly and lawfully engaged in instruction in
281 veterinary medicine;

282 c. Regularly and lawfully engaged in law enforcement
283 activities;

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

285 e. For use in chemical analysis or physical testing or for
286 purposes of instruction in law enforcement activities, research,
287 or testing.

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

292 3. The person does not distribute in any jurisdiction
293 prescription drugs subject to, defined by, or described by s.
294 503(b) of the Federal Food, Drug, and Cosmetic Act to any person

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

297 4. A limited prescription drug veterinary wholesale
298 distributor that applies to the department for a new permit or
299 the renewal of a permit must submit a bond of \$20,000, or other
300 equivalent means of security acceptable to the department, such
301 as an irrevocable letter of credit or a deposit in a trust
302 account or financial institution, payable to the Professional
303 Regulation ~~Florida Drug, Device, and Cosmetic~~ Trust Fund. The
304 purpose of the bond is to secure payment of any administrative
305 penalties imposed by the department and any fees and costs
306 incurred by the department regarding that permit which are
307 authorized under state law and which the permittee fails to pay
308 30 days after the fine or costs become final. The department may
309 make a claim against such bond or security until 1 year after
310 the permittee's license ceases to be valid or until 60 days
311 after any administrative or legal proceeding authorized in this
312 part which involves the permittee is concluded, including any
313 appeal, whichever occurs later.

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

318 6. A limited prescription drug veterinary wholesale
319 distributor must comply with the requirements for wholesale
320 distributors under ss. 499.0121 and 499.01212, except that a
321 limited prescription drug veterinary wholesale distributor is
322 not required to provide a pedigree paper as required by s.
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323 499.01212 upon the wholesale distribution of a prescription drug
324 to a veterinarian.

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

330 8. A limited prescription drug veterinary wholesale
331 distributor permit is not required for an intracompany sale or
332 transfer of a prescription drug from an out-of-state
333 establishment that is duly licensed to engage in the wholesale
334 distribution of prescription drugs in its state of residence to
335 a licensed limited prescription drug veterinary wholesale
336 distributor in this state if both wholesale distributors conduct
337 wholesale distributions of prescription drugs under the same
338 business name. The recordkeeping requirements of ss. 499.0121(6)
339 and 499.01212 must be followed for this transaction.

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

342 499.028 Drug samples or complimentary drugs; starter
343 packs; permits to distribute.—

344 (13) The department may, pursuant to chapter 120, impose
345 an administrative fine, not to exceed \$5,000 per violation per
346 day, for the violation of this section or rules adopted under
347 this section. Each day such violation continues constitutes a
348 separate violation, and each such separate violation is subject
349 to a separate fine. All amounts collected under this section
350 shall be deposited into the Professional Regulation Drug,

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351 ~~Device, and Cosmetic~~ Trust Fund. In determining the amount of
352 fine to be levied for a violation, the following factors must be
353 considered:

354 (a) The severity of the violation.

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

357 (c) Any previous violations.

358 Section 13. Section 499.04, Florida Statutes, is amended
359 to read:

360 499.04 Fee authority.—The department may collect fees for
361 all drug, device, and cosmetic applications, permits, product
362 registrations, and free-sale certificates. The total amount of
363 fees collected from all permits, applications, product
364 registrations, and free-sale certificates must be adequate to
365 fund the expenses incurred by the department in carrying out
366 this part. The department shall, by rule, establish a schedule
367 of fees that are within the ranges provided in this section and
368 shall adjust those fees from time to time based on the costs
369 associated with administering this part. The fees are payable to
370 the department to be deposited into the Professional Regulation
371 ~~Florida Drug, Device, and Cosmetic~~ Trust Fund for the sole
372 purpose of carrying out ~~the provisions of~~ this part.

373 Section 14. Section 499.057, Florida Statutes, is amended
374 to read:

375 499.057 Expenses and salaries.—Except as otherwise
376 provided in the General Appropriations Act, all expenses and
377 salaries shall be paid out of the Professional Regulation Trust
378 Fund. ~~special fund hereby created in the office of the Chief~~

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379 ~~Financial Officer, which fund is to be known as the "Florida~~
380 ~~Drug, Device, and Cosmetic Trust Fund."~~

381 Section 15. Paragraph (a) of subsection (2) of section
382 499.062, Florida Statutes, is amended to read:

383 499.062 Seizure and condemnation of drugs, devices, or
384 cosmetics.—

385 (2) Whenever a duly authorized officer or employee of the
386 department finds cause, or has probable cause to believe that
387 cause exists, for the seizure of any drug, device, or cosmetic,
388 as set out in this part, he or she shall affix to the article a
389 tag, stamp, or other appropriate marking, giving notice that the
390 article is, or is suspected of being, subject to seizure under
391 this part and that the article has been detained and seized by
392 the department. Such officer or employee shall also warn all
393 persons not to remove or dispose of the article, by sale or
394 otherwise, until permission is given by the department or the
395 court. Any person who violates this subsection is guilty of a
396 felony of the second degree, punishable as provided in s.
397 775.082, s. 775.083, or s. 775.084.

398 (a) When any article detained or seized under this
399 subsection has been found by the department to be subject to
400 seizure and condemnation, the department shall petition the
401 court for an order of condemnation or sale, as the court
402 directs. The proceeds of the sale of drugs, devices, and
403 cosmetics, less the legal costs and charges, shall be deposited
404 into the Professional Regulation ~~Florida Drug, Device, and~~
405 ~~Cosmetic~~ Trust Fund.

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

408 499.066 Penalties; remedies.—In addition to other
409 penalties and other enforcement provisions:

410 (3) The department may impose an administrative fine, not
411 to exceed \$5,000 per violation per day, for the violation of any
412 provision of this part or rules adopted under this part. Each
413 day a violation continues constitutes a separate violation, and
414 each separate violation is subject to a separate fine. All
415 amounts collected pursuant to this section shall be deposited
416 into the Professional Regulation ~~Florida Drug, Device, and~~
417 ~~Cosmetic~~ Trust Fund and are appropriated for the use of the
418 department in administering this part. In determining the amount
419 of the fine to be levied for a violation, the department shall
420 consider:

421 (a) The severity of the violation;

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

424 (c) Any previous violations.

425 (4) The department shall deposit any rewards, fines, or
426 collections that are due the department and which derive from
427 joint enforcement activities with other state and federal
428 agencies which relate to this part, chapter 893, or the federal
429 act, into the Professional Regulation ~~Florida Drug, Device, and~~
430 ~~Cosmetic~~ Trust Fund. The proceeds of those rewards, fines, and
431 collections are appropriated for the use of the department in
432 administering this part.

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

435 499.62 License or permit required of manufacturer,
436 distributor, dealer, or purchaser of ether.-

437 (7) A licensed or permitted facility shall renew its
438 license or permit prior to its expiration date. If a renewal
439 application and fee are not filed by the expiration date of any
440 year, the permit may be reinstated only upon payment of a
441 delinquent fee of \$50, plus the required renewal fee, within 30
442 days after the date of expiration. If any person who is subject
443 to the requirements of this part fails to comply with the
444 renewal, the department shall have the authority to seize all
445 ether products and dispose of them as of November 1 of the year
446 the license or permit expires. Any funds collected from the
447 disposal shall be placed in the Professional Regulation Florida
448 ~~Drug, Device, and Cosmetic~~ Trust Fund.

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

451 499.72 Administrative fines.-

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

456 Section 19. Section 499.79, Florida Statutes, is amended
457 to read:

458 499.79 Deposit of fees.-All fees collected for licenses
459 and permits required by this part shall be deposited in the
460 Professional Regulation Florida ~~Drug, Device, and Cosmetic~~ Trust

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461 Fund ~~created by s. 499.057,~~ and all moneys collected under ~~the~~
462 ~~provisions of~~ this part and deposited in the such trust fund
463 shall be used by ~~are hereby appropriated for the use of~~ the
464 department in the administration of this part. The Department of
465 Business and Professional Regulation shall maintain a separate
466 account in the Professional Regulation Trust Fund for the Drugs,
467 Devices, and Cosmetics program.

468 Section 20. Section 548.061, Florida Statutes, is
469 repealed.

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

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T I T L E A M E N D M E N T

475 Remove the entire title and insert:

476 A bill to be entitled
477
478 An act relating to the Department of Business and
479 Professional Regulation; amending s. 20.165, F.S.;
480 creating the Division of Drugs, Devices, and Cosmetics
481 within the Department of Business and Professional
482 Regulation; amending s. 455.116, F.S.; deleting the
483 Florida Drug, Device, and Cosmetic Trust Fund from the
484 list of trust funds placed in the department, to
485 conform; amending ss. 499.003, 499.01211, 499.024,
486 499.065, 499.601, and 499.61, F.S.; conforming
487 provisions to the transfer by s. 27, ch. 2010-161,
488 Laws of Florida, of regulatory authority for chapter

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489 499, F.S., from the Department of Health to the
490 Department of Business and Professional Regulation;
491 repealing s. 499.0031, F.S., relating to the Florida
492 Drug, Device, and Cosmetic Trust Fund; terminating the
493 Florida Drug, Device, and Cosmetic Trust Fund;
494 providing for the disposition of balances in and
495 revenues of such trust fund; prescribing procedures
496 for the termination of such trust fund; amending ss.
497 499.01, 499.028, 499.04, 499.057, 499.062, 499.066,
498 499.62, and 499.72; conforming provisions; amending s.
499 499.79, F.S.; conforming provisions; requiring the
500 department to maintain a separate account in the
501 Professional Regulation Trust Fund for the Drugs,
502 Devices, and Cosmetics program; repealing s. 548.061,
503 F.S., relating to report and tax requirements for each
504 person or club that holds or shows pugilistic matches
505 on a closed circuit telecast viewed within the state;
506 providing effective dates.