

By the Committees on Health Policy; and Regulated Industries;
and Senator Bean

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1 A bill to be entitled
2 An act relating to medical gas; amending s. 499.001,
3 F.S.; conforming provisions to changes made by this
4 act; amending s. 499.003, F.S.; revising terms;
5 amending ss. 499.01 and 499.0121, F.S.; conforming
6 provisions to changes made by this act; amending s.
7 499.01211, F.S.; adding a member to the Drug Wholesale
8 Distributor Advisory Council; authorizing the
9 Compressed Gas Association to recommend one person to
10 the council for appointment; amending ss. 499.041,
11 499.05, 499.051, 499.066, 499.0661, and 499.067, F.S.;
12 conforming provisions to changes made by this act;
13 creating part III of ch. 499, F.S., entitled "Medical
14 Gas"; creating s. 499.81, F.S.; providing for the
15 administration and enforcement of this part; creating
16 s. 499.82, F.S.; defining terms; creating s. 499.83,
17 F.S.; requiring a person or entity that intends to
18 distribute medical gas within or into this state to
19 obtain an applicable permit before operating;
20 establishing categories of permits and setting
21 requirements for each; creating s. 499.831, F.S.;
22 requiring the Department of Business and Professional
23 Regulation to establish the form and content of an
24 application; authorizing the department to set fees
25 within certain parameters; creating s. 499.832, F.S.;
26 providing that a permit expires 2 years after the last
27 day of the month in which the permit was originally
28 issued; providing requirements for the renewal of a
29 permit; requiring the department to adopt rules for

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30 the renewal of permits; creating s. 499.833, F.S.;

31 authorizing the department to approve certain

32 permitholder changes; creating s. 499.834, F.S.;

33 authorizing the department to consider certain factors

34 in determining the eligibility of an applicant;

35 creating s. 499.84, F.S.; setting the minimum

36 requirements for the storage and handling of medical

37 gas; creating s. 499.85, F.S.; setting facility

38 requirements for security purposes; authorizing a

39 vehicle used for on-call delivery of oxygen USP and

40 oxygen-related equipment to be parked at a place of

41 residence; requiring the department to adopt rules

42 governing the distribution of medical oxygen; creating

43 s. 499.86, F.S.; requiring a wholesale distributor of

44 medical gases to visually examine a medical gas

45 container upon receipt in order to identify the

46 medical gas stored within and to determine if the

47 container has been damaged or is otherwise unfit for

48 distribution; requiring a medical gas container that

49 is damaged or otherwise unfit for distribution to be

50 quarantined; requiring outgoing shipments of medical

51 gas to be inspected; requiring wholesale distributors

52 to review certain records; creating s. 499.87, F.S.;

53 authorizing the return of medical gas that has left

54 the control of a wholesale distributor; requiring that

55 medical gas that is damaged, misbranded, or

56 adulterated be quarantined from other medical gases

57 until it is destroyed or returned to the manufacturer

58 or wholesale distributor from which it was acquired;

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59 creating s. 499.88, F.S.; requiring a wholesale
60 distributor to obtain certain information before the
61 initial acquisition of a medical gas; providing
62 certain exemptions; creating s. 499.89, F.S.;
63 requiring a permitholder under this part to establish
64 and maintain transactional records; providing a
65 retention period for certain records and requiring
66 that such records be available for inspection during
67 that period; creating s. 499.90, F.S.; requiring a
68 wholesale distributor to establish, maintain, and
69 adhere to certain written policies and procedures;
70 creating s. 499.91, F.S.; prohibiting certain acts;
71 creating s. 499.92, F.S.; establishing criminal
72 penalties; authorizing property or assets subject to
73 forfeiture to be seized pursuant to a warrant;
74 creating s. 499.93, F.S.; authorizing the department
75 to require a facility that engages in the manufacture,
76 retail sale, or wholesale distribution of medical gas
77 to undergo an inspection; authorizing the department
78 to authorize a third party to inspect such facilities;
79 creating s. 499.931, F.S.; providing that trade secret
80 information required to be submitted pursuant to this
81 part must be maintained by the department; creating s.
82 499.94, F.S.; requiring fees collected pursuant to
83 this part to be deposited into the Professional
84 Regulation Trust Fund; amending ss. 409.9201, 460.403,
85 465.0265, 499.01212, 499.015, and 499.024, F.S.;
86 conforming cross-references; providing an effective
87 date.

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Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 499.001, Florida Statutes, is amended to read:

499.001 Florida Drug and Cosmetic Act; short title.— Sections 499.001-499.94 ~~499.001-499.081~~ may be cited as the "Florida Drug and Cosmetic Act."

Section 2. Subsections (12) through (32) and subsections (47) through (55) of section 499.003, Florida Statutes, are renumbered as subsections (11) through (31) and subsections (46) through (54), respectively, and present subsections (11), (43), and (46) of that section are amended, to read:

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

(32) ~~(11)~~ "Compressed Medical gas" means any liquefied or vaporized gas that is a prescription drug, whether ~~it is~~ alone or in combination with other gases, and as defined in the federal act.

(43) "Prescription drug" means a prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active pharmaceutical ingredients subject to, defined by, or described by s. 503(b) of the federal ~~Food, Drug, and Cosmetic~~ act or s. 465.003(8), s. 499.007(13), ~~or~~ subsection (32) ~~(11)~~, ~~subsection (46)~~, or subsection (52) ~~(53)~~, except that an active pharmaceutical ingredient is a prescription drug only if substantially all finished dosage forms in which it may be lawfully dispensed or administered in this state are also prescription drugs.

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117 ~~(46) "Prescription medical oxygen" means oxygen USP which~~
118 ~~is a drug that can only be sold on the order or prescription of~~
119 ~~a practitioner authorized by law to prescribe. The label of~~
120 ~~prescription medical oxygen must comply with current labeling~~
121 ~~requirements for oxygen under the Federal Food, Drug, and~~
122 ~~Cosmetic Act.~~

123 Section 3. Subsection (1), paragraphs (a), (c), (g), (m),
124 (n), and (o) of subsection (2), and subsection (5) of section
125 499.01, Florida Statutes, are amended to read:

126 499.01 Permits.—

127 (1) Prior to operating, a permit is required for each
128 person and establishment that intends to operate as:

- 129 (a) A prescription drug manufacturer;
130 (b) A prescription drug repackager;
131 (c) A nonresident prescription drug manufacturer;
132 (d) A prescription drug wholesale distributor;
133 (e) An out-of-state prescription drug wholesale
134 distributor;
135 (f) A retail pharmacy drug wholesale distributor;
136 (g) A restricted prescription drug distributor;
137 (h) A complimentary drug distributor;
138 (i) A freight forwarder;
139 (j) A veterinary prescription drug retail establishment;
140 (k) A veterinary prescription drug wholesale distributor;
141 (l) A limited prescription drug veterinary wholesale
142 distributor;
143 ~~(m) A medical oxygen retail establishment;~~
144 ~~(n) A compressed medical gas wholesale distributor;~~
145 ~~(o) A compressed medical gas manufacturer;~~

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146 (m)~~(p)~~ An over-the-counter drug manufacturer;

147 (n)~~(q)~~ A device manufacturer;

148 (o)~~(r)~~ A cosmetic manufacturer;

149 (p)~~(s)~~ A third party logistics provider; or

150 (q)~~(t)~~ A health care clinic establishment.

151 (2) The following permits are established:

152 (a) *Prescription drug manufacturer permit.*—A prescription
153 drug manufacturer permit is required for any person that is a
154 manufacturer of a prescription drug and that manufactures or
155 distributes such prescription drugs in this state.

156 1. A person that operates an establishment permitted as a
157 prescription drug manufacturer may engage in wholesale
158 distribution of prescription drugs manufactured at that
159 establishment and must comply with all of the provisions of this
160 part, except s. 499.01212, and the rules adopted under this
161 part, except s. 499.01212, which apply to a wholesale
162 distributor.

163 2. A prescription drug manufacturer must comply with all
164 appropriate state and federal good manufacturing practices.

165 3. A blood establishment, as defined in s. 381.06014,
166 operating in a manner consistent with the provisions of 21
167 C.F.R. parts 211 and 600-640, and manufacturing only the
168 prescription drugs described in s. 499.003(53)(d) ~~s.~~
169 ~~499.003(54)(d)~~ is not required to be permitted as a prescription
170 drug manufacturer under this paragraph or to register products
171 under s. 499.015.

172 (c) *Nonresident prescription drug manufacturer permit.*—A
173 nonresident prescription drug manufacturer permit is required
174 for any person that is a manufacturer of prescription drugs,

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175 unless permitted as a third party logistics provider, located
176 outside of this state or outside the United States and that
177 engages in the wholesale distribution in this state of such
178 prescription drugs. Each such manufacturer must be permitted by
179 the department and comply with all of the provisions required of
180 a wholesale distributor under this part, except s. 499.01212.

181 1. A person that distributes prescription drugs for which
182 the person is not the manufacturer must also obtain an out-of-
183 state prescription drug wholesale distributor permit or third
184 party logistics provider permit pursuant to this section to
185 engage in the wholesale distribution of such prescription drugs.
186 This subparagraph does not apply to a manufacturer as defined in
187 s. 499.003(30)(e) ~~s. 499.003(31)(e)~~.

188 2. Any such person must comply with the licensing or
189 permitting requirements of the jurisdiction in which the
190 establishment is located and the federal act, and any product
191 wholesaled into this state must comply with this part. If a
192 person intends to import prescription drugs from a foreign
193 country into this state, the nonresident prescription drug
194 manufacturer must provide to the department a list identifying
195 each prescription drug it intends to import and document
196 approval by the United States Food and Drug Administration for
197 such importation.

198 (g) *Restricted prescription drug distributor permit.*—

199 1. A restricted prescription drug distributor permit is
200 required for:

201 a. Any person located in this state who engages in the
202 distribution of a prescription drug, which distribution is not
203 considered "wholesale distribution" under s. 499.003(53)(a) ~~s.~~

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204 ~~499.003(54)(a).~~

205 b. Any person located in this state who engages in the
206 receipt or distribution of a prescription drug in this state for
207 the purpose of processing its return or its destruction if such
208 person is not the person initiating the return, the prescription
209 drug wholesale supplier of the person initiating the return, or
210 the manufacturer of the drug.

211 c. A blood establishment located in this state which
212 collects blood and blood components only from volunteer donors
213 as defined in s. 381.06014 or pursuant to an authorized
214 practitioner's order for medical treatment or therapy and
215 engages in the wholesale distribution of a prescription drug not
216 described in s. 499.003(53)(d) ~~s. 499.003(54)(d)~~ to a health
217 care entity. A mobile blood unit operated by a blood
218 establishment permitted under this sub-subparagraph is not
219 required to be separately permitted. The health care entity
220 receiving a prescription drug distributed under this sub-
221 subparagraph must be licensed as a closed pharmacy or provide
222 health care services at that establishment. The blood
223 establishment must operate in accordance with s. 381.06014 and
224 may distribute only:

225 (I) Prescription drugs indicated for a bleeding or clotting
226 disorder or anemia;

227 (II) Blood-collection containers approved under s. 505 of
228 the federal act;

229 (III) Drugs that are blood derivatives, or a recombinant or
230 synthetic form of a blood derivative;

231 (IV) Prescription drugs that are identified in rules
232 adopted by the department and that are essential to services

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233 performed or provided by blood establishments and authorized for
234 distribution by blood establishments under federal law; or

235 (V) To the extent authorized by federal law, drugs
236 necessary to collect blood or blood components from volunteer
237 blood donors; for blood establishment personnel to perform
238 therapeutic procedures under the direction and supervision of a
239 licensed physician; and to diagnose, treat, manage, and prevent
240 any reaction of a volunteer blood donor or a patient undergoing
241 a therapeutic procedure performed under the direction and
242 supervision of a licensed physician,

243
244 as long as all of the health care services provided by the blood
245 establishment are related to its activities as a registered
246 blood establishment or the health care services consist of
247 collecting, processing, storing, or administering human
248 hematopoietic stem cells or progenitor cells or performing
249 diagnostic testing of specimens if such specimens are tested
250 together with specimens undergoing routine donor testing. The
251 blood establishment may purchase and possess the drugs described
252 in this sub-subparagraph without a health care clinic
253 establishment permit.

254 2. Storage, handling, and recordkeeping of these
255 distributions by a person required to be permitted as a
256 restricted prescription drug distributor must be in accordance
257 with the requirements for wholesale distributors under s.
258 499.0121, but not those set forth in s. 499.01212 if the
259 distribution occurs pursuant to sub-subparagraph 1.a. or sub-
260 subparagraph 1.b.

261 3. A person who applies for a permit as a restricted

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262 prescription drug distributor, or for the renewal of such a
263 permit, must provide to the department the information required
264 under s. 499.012.

265 4. The department may adopt rules regarding the
266 distribution of prescription drugs by hospitals, health care
267 entities, charitable organizations, other persons not involved
268 in wholesale distribution, and blood establishments, which rules
269 are necessary for the protection of the public health, safety,
270 and welfare.

271 ~~(m) Medical oxygen retail establishment permit. A medical~~
272 ~~oxygen retail establishment permit is required for any person~~
273 ~~that sells medical oxygen to patients only. The sale must be~~
274 ~~based on an order from a practitioner authorized by law to~~
275 ~~prescribe. The term does not include a pharmacy licensed under~~
276 ~~chapter 465.~~

277 1. ~~A medical oxygen retail establishment may not possess,~~
278 ~~purchase, sell, or trade any prescription drug other than~~
279 ~~medical oxygen.~~

280 2. ~~A medical oxygen retail establishment may refill medical~~
281 ~~oxygen for an individual patient based on an order from a~~
282 ~~practitioner authorized by law to prescribe. A medical oxygen~~
283 ~~retail establishment that refills medical oxygen must comply~~
284 ~~with all appropriate state and federal good manufacturing~~
285 ~~practices.~~

286 3. ~~A medical oxygen retail establishment must comply with~~
287 ~~all of the wholesale distribution requirements of s. 499.0121.~~

288 4. ~~Prescription medical oxygen sold by a medical oxygen~~
289 ~~retail establishment pursuant to a practitioner's order may not~~
290 ~~be returned into the retail establishment's inventory.~~

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291 ~~(n) Compressed medical gas wholesale distributor permit. A~~
292 ~~compressed medical gas wholesale distributor is a wholesale~~
293 ~~distributor that is limited to the wholesale distribution of~~
294 ~~compressed medical gases to other than the consumer or patient.~~
295 ~~The compressed medical gas must be in the original sealed~~
296 ~~container that was purchased by that wholesale distributor. A~~
297 ~~compressed medical gas wholesale distributor may not possess or~~
298 ~~engage in the wholesale distribution of any prescription drug~~
299 ~~other than compressed medical gases. The department shall adopt~~
300 ~~rules that govern the wholesale distribution of prescription~~
301 ~~medical oxygen for emergency use. With respect to the emergency~~
302 ~~use of prescription medical oxygen, those rules may not be~~
303 ~~inconsistent with rules and regulations of federal agencies~~
304 ~~unless the Legislature specifically directs otherwise.~~

305 ~~(o) Compressed medical gas manufacturer permit. A~~
306 ~~compressed medical gas manufacturer permit is required for any~~
307 ~~person that engages in the manufacture of compressed medical~~
308 ~~gases or repackages compressed medical gases from one container~~
309 ~~to another.~~

310 ~~1. A compressed medical gas manufacturer may not~~
311 ~~manufacture or possess any prescription drug other than~~
312 ~~compressed medical gases.~~

313 ~~2. A compressed medical gas manufacturer may engage in~~
314 ~~wholesale distribution of compressed medical gases manufactured~~
315 ~~at that establishment and must comply with all the provisions of~~
316 ~~this part and the rules adopted under this part that apply to a~~
317 ~~wholesale distributor.~~

318 ~~3. A compressed medical gas manufacturer must comply with~~
319 ~~all appropriate state and federal good manufacturing practices.~~

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320 (5) A prescription drug repackager permit issued under this
321 part is not required for a restricted prescription drug
322 distributor permitholder that is a health care entity to
323 repackage prescription drugs in this state for its own use or
324 for distribution to hospitals or other health care entities in
325 the state for their own use, pursuant to s. 499.003(53)(a)3. ~~s.~~
326 ~~499.003(54)(a)3.~~, if:

327 (a) The prescription drug distributor notifies the
328 department, in writing, of its intention to engage in
329 repackaging under this exemption, 30 days before engaging in the
330 repackaging of prescription drugs at the permitted
331 establishment;

332 (b) The prescription drug distributor is under common
333 control with the hospitals or other health care entities to
334 which the prescription drug distributor is distributing
335 prescription drugs. As used in this paragraph, "common control"
336 means the power to direct or cause the direction of the
337 management and policies of a person or an organization, whether
338 by ownership of stock, voting rights, contract, or otherwise;

339 (c) The prescription drug distributor repackages the
340 prescription drugs in accordance with current state and federal
341 good manufacturing practices; and

342 (d) The prescription drug distributor labels the
343 prescription drug it repackages in accordance with state and
344 federal laws and rules.

345
346 The prescription drug distributor is exempt from the product
347 registration requirements of s. 499.015 with regard to the
348 prescription drugs that it repackages and distributes under this

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349 subsection.

350 Section 4. Paragraph (b) of subsection (2) of section
351 499.0121, Florida Statutes, is amended to read:

352 499.0121 Storage and handling of prescription drugs;
353 recordkeeping.—The department shall adopt rules to implement
354 this section as necessary to protect the public health, safety,
355 and welfare. Such rules shall include, but not be limited to,
356 requirements for the storage and handling of prescription drugs
357 and for the establishment and maintenance of prescription drug
358 distribution records.

359 (2) SECURITY.—

360 (b) An establishment that is used for wholesale drug
361 distribution must be equipped with:

362 1. An alarm system to detect entry after hours; however,
363 the department may exempt by rule establishments that only hold
364 a permit as prescription drug wholesale distributor-brokers ~~and~~
365 ~~establishments that only handle medical oxygen;~~ and

366 2. A security system that will provide suitable protection
367 against theft and diversion. When appropriate, the security
368 system must provide protection against theft or diversion that
369 is facilitated or hidden by tampering with computers or
370 electronic records.

371 Section 5. Subsections (1) and (2) of section 499.01211,
372 Florida Statutes, are amended to read:

373 499.01211 Drug Wholesale Distributor Advisory Council.—

374 (1) There is created the Drug Wholesale Distributor
375 Advisory Council within the department. The council shall meet
376 at least once each calendar quarter. Staff for the council shall
377 be provided by the department. The council shall consist of 12

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378 ~~11~~ members who shall serve without compensation. The council
379 shall elect a chairperson and a vice chairperson annually.

380 (2) The Secretary of Business and Professional Regulation
381 or his or her designee and the Secretary of Health Care
382 Administration or her or his designee shall be members of the
383 council. The Secretary of Business and Professional Regulation
384 shall appoint 10 ~~nine~~ additional members to the council who
385 shall be appointed to a term of 4 years each, as follows:

386 (a) Three ~~different~~ persons, each of whom is employed by a
387 different prescription drug wholesale distributor permitted
388 ~~licensed~~ under this part which operates nationally and is a
389 primary wholesale distributor, ~~as defined in s. 499.003 s.~~
390 ~~499.003(47).~~

391 (b) One person employed by a prescription drug wholesale
392 distributor permitted ~~licensed~~ under this part which is a
393 secondary wholesale distributor, as defined in s. 499.003 s.
394 ~~499.003(52).~~

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

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

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

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

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

406 (h) One person who is an employee of a permitted medical

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407 gas manufacturer or medical gas wholesale distributor and who
408 has been recommended by the Compressed Gas Association.

409 Section 6. Paragraph (e) of subsection (1), paragraph (b)
410 of subsection (2), and paragraph (b) of subsection (3) of
411 section 499.041, Florida Statutes, are amended to read:

412 499.041 Schedule of fees for drug, device, and cosmetic
413 applications and permits, product registrations, and free-sale
414 certificates.—

415 (1) The department shall assess applicants requiring a
416 manufacturing permit an annual fee within the ranges established
417 in this section for the specific type of manufacturer.

418 ~~(e) The fee for a compressed medical gas manufacturer~~
419 ~~permit may not be less than \$400 or more than \$500 annually.~~

420 (2) The department shall assess an applicant that is
421 required to have a wholesaling permit an annual fee within the
422 ranges established in this section for the specific type of
423 wholesaling.

424 ~~(b) The fee for a compressed medical gas wholesale~~
425 ~~distributor permit may not be less than \$200 or more than \$300~~
426 ~~annually.~~

427 (3) The department shall assess an applicant that is
428 required to have a retail establishment permit an annual fee
429 within the ranges established in this section for the specific
430 type of retail establishment.

431 ~~(b) The fee for a medical oxygen retail establishment~~
432 ~~permit may not be less than \$200 or more than \$300 annually.~~

433 Section 7. Section 499.05, Florida Statutes, is amended to
434 read:

435 499.05 Rules.—

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436 (1) The department shall adopt rules to implement and
437 enforce this chapter part with respect to:

438 (a) The definition of terms used in this chapter part, and
439 used in the rules adopted under this chapter part, when the use
440 of the term is not its usual and ordinary meaning.

441 (b) Labeling requirements for drugs, devices, and
442 cosmetics.

443 (c) The establishment of fees authorized in this chapter
444 part.

445 (d) The identification of permits that require an initial
446 application and onsite inspection or other prerequisites for
447 permitting which demonstrate that the establishment and person
448 are in compliance with the requirements of this chapter part.

449 (e) The application processes and forms for product
450 registration.

451 (f) Procedures for requesting and issuing certificates of
452 free sale.

453 (g) Inspections and investigations conducted under s.
454 499.051 or s. 499.93, and the identification of information
455 claimed to be a trade secret and exempt from the public records
456 law as provided in s. 499.051(7).

457 (h) The establishment of a range of penalties, as provided
458 in s. 499.066; requirements for notifying persons of the
459 potential impact of a violation of this chapter part; and a
460 process for the uncontested settlement of alleged violations.

461 (i) Additional conditions that qualify as an emergency
462 medical reason under s. 499.003(53)(b)2. or s. 499.82 s.
463 ~~499.003(54)(b)2.~~

464 (j) Procedures and forms relating to the pedigree paper

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465 requirement of s. 499.01212.

466 (k) The protection of the public health, safety, and
467 welfare regarding good manufacturing practices that
468 manufacturers and repackagers must follow to ensure the safety
469 of the products.

470 (l) Information required from each retail establishment
471 pursuant to s. 499.012(3) or s. 499.83(2)(c), including
472 requirements for prescriptions or orders.

473 (m) The recordkeeping, storage, and handling with respect
474 to each of the distributions of prescription drugs specified in
475 s. 499.003(53)(a)-(d) or s. 499.82(14) ~~s. 499.003(54)(a)-(d)~~.

476 (n) Alternatives to compliance with s. 499.01212 for a
477 prescription drug in the inventory of a permitted prescription
478 drug wholesale distributor as of June 30, 2006, and the return
479 of a prescription drug purchased prior to July 1, 2006. The
480 department may specify time limits for such alternatives.

481 (o) Wholesale distributor reporting requirements of s.
482 499.0121(14).

483 (p) Wholesale distributor credentialing and distribution
484 requirements of s. 499.0121(15).

485 (2) With respect to products in interstate commerce, those
486 rules must not be inconsistent with rules and regulations of
487 federal agencies unless specifically otherwise directed by the
488 Legislature.

489 (3) The department shall adopt rules regulating
490 recordkeeping for and the storage, handling, and distribution of
491 medical devices and over-the-counter drugs to protect the public
492 from adulterated products.

493 Section 8. Subsections (1) through (4) of section 499.051,

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494 Florida Statutes, are amended to read:

495 499.051 Inspections and investigations.—

496 (1) The agents of the department and of the Department of
497 Law Enforcement, after they present proper identification, may
498 inspect, monitor, and investigate any establishment permitted
499 pursuant to this chapter part during business hours for the
500 purpose of enforcing this chapter part, chapters 465, 501, and
501 893, and the rules of the department that protect the public
502 health, safety, and welfare.

503 (2) In addition to the authority set forth in subsection
504 (1), the department and any duly designated officer or employee
505 of the department may enter and inspect any other establishment
506 for the purpose of determining compliance with this chapter part
507 and rules adopted under this chapter part regarding any drug,
508 device, or cosmetic product.

509 (3) Any application for a permit or product registration or
510 for renewal of such permit or registration made pursuant to this
511 chapter part and rules adopted under this chapter part
512 constitutes permission for any entry or inspection of the
513 premises in order to verify compliance with this chapter part
514 and rules; to discover, investigate, and determine the existence
515 of compliance; or to elicit, receive, respond to, and resolve
516 complaints and violations.

517 (4) Any application for a permit made pursuant to s.
518 499.012 or s. 499.831 and rules adopted under those sections
519 ~~that section~~ constitutes permission for agents of the department
520 and the Department of Law Enforcement, after presenting proper
521 identification, to inspect, review, and copy any financial
522 document or record related to the manufacture, repackaging, or

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523 distribution of a drug as is necessary to verify compliance with
524 this chapter part and the rules adopted by the department to
525 administer this chapter part, in order to discover, investigate,
526 and determine the existence of compliance, or to elicit,
527 receive, respond to, and resolve complaints and violations.

528 Section 9. Subsections (1) through (4) of section 499.066,
529 Florida Statutes, are amended to read:

530 499.066 Penalties; remedies.—In addition to other penalties
531 and other enforcement provisions:

532 (1) The department may institute such suits or other legal
533 proceedings as are required to enforce any provision of this
534 chapter part. If it appears that a person has violated any
535 provision of this chapter part for which criminal prosecution is
536 provided, the department may provide the appropriate state
537 attorney or other prosecuting agency having jurisdiction with
538 respect to such prosecution with the relevant information in the
539 department's possession.

540 (2) If any person engaged in any activity covered by this
541 chapter part violates any provision of this chapter part, any
542 rule adopted under this chapter part, or a cease and desist
543 order as provided by this chapter part, the department may
544 obtain an injunction in the circuit court of the county in which
545 the violation occurred or in which the person resides or has its
546 principal place of business, and may apply in that court for
547 such temporary and permanent orders as the department considers
548 necessary to restrain the person from engaging in any such
549 activities until the person complies with this chapter part, the
550 rules adopted under this chapter part, and the orders of the
551 department authorized by this chapter part or to mandate

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552 compliance with this chapter part, the rules adopted under this
553 chapter part, and any order or permit issued by the department
554 under this chapter part.

555 (3) The department may impose an administrative fine, not
556 to exceed \$5,000 per violation per day, for the violation of any
557 provision of this chapter part or rules adopted under this
558 chapter part. Each day a violation continues constitutes a
559 separate violation, and each separate violation is subject to a
560 separate fine. All amounts collected pursuant to this section
561 shall be deposited into the Professional Regulation Trust Fund
562 and are appropriated for the use of the department in
563 administering this chapter part. In determining the amount of
564 the fine to be levied for a violation, the department shall
565 consider:

566 (a) The severity of the violation;

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

569 (c) Any previous violations.

570 (4) The department shall deposit any rewards, fines, or
571 collections that are due the department and which derive from
572 joint enforcement activities with other state and federal
573 agencies which relate to this chapter part, chapter 893, or the
574 federal act, into the Professional Regulation Trust Fund. The
575 proceeds of those rewards, fines, and collections are
576 appropriated for the use of the department in administering this
577 chapter part.

578 Section 10. Paragraph (a) of subsection (1) and paragraph
579 (a) of subsection (2) of section 499.0661, Florida Statutes, are
580 amended to read:

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581 499.0661 Cease and desist orders; removal of certain
582 persons.—

583 (1) CEASE AND DESIST ORDERS.—

584 (a) In addition to any authority otherwise provided in this
585 chapter, the department may issue and serve a complaint stating
586 charges upon a ~~any~~ permittee or upon an ~~any~~ affiliated party,
587 whenever the department has reasonable cause to believe that the
588 person or individual named therein is engaging in or has engaged
589 in conduct that is:

590 1. An act that demonstrates a lack of fitness or
591 trustworthiness to engage in the business authorized under the
592 permit issued pursuant to this chapter ~~part~~, is hazardous to the
593 public health, or constitutes business operations that are a
594 detriment to the public health;

595 2. A violation of a ~~any~~ provision of this chapter ~~part~~;

596 3. A violation of a ~~any~~ rule of the department;

597 4. A violation of an ~~any~~ order of the department; or

598 5. A breach of a ~~any~~ written agreement with the department.

599 (2) REMOVAL OF AFFILIATED PARTIES BY THE DEPARTMENT.—

600 (a) The department may issue and serve a complaint stating
601 charges upon an ~~any~~ affiliated party and upon the permittee
602 involved whenever the department has reason to believe that an
603 affiliated party is engaging in or has engaged in conduct that
604 constitutes:

605 1. An act that demonstrates a lack of fitness or
606 trustworthiness to engage in the business authorized under the
607 permit issued pursuant to this chapter ~~part~~, is hazardous to the
608 public health, or constitutes business operations that are a
609 detriment to the public health;

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610 2. A willful violation of this chapter part; however, if
611 the violation constitutes a misdemeanor, a complaint may not be
612 served as provided in this section until the affiliated party is
613 notified in writing of the matter of the violation and has been
614 afforded a reasonable period of time, as set forth in the
615 notice, to correct the violation and has failed to do so;

616 3. A violation of a any other law involving fraud or moral
617 turpitude which constitutes a felony;

618 4. A willful violation of a any rule of the department;

619 5. A willful violation of an any order of the department;

620 or

621 6. A material misrepresentation of fact, made knowingly and
622 willfully or made with reckless disregard for the truth of the
623 matter.

624 Section 11. Section 499.067, Florida Statutes, is amended
625 to read:

626 499.067 Denial, suspension, or revocation of permit,
627 certification, or registration.—

628 (1)(a) The department may deny, suspend, or revoke a permit
629 if it finds that there has been a substantial failure to comply
630 with this chapter part or chapter 465, chapter 501, or chapter
631 893, the rules adopted under ~~this part~~ or those chapters, any
632 final order of the department, or applicable federal laws or
633 regulations or other state laws or rules governing drugs,
634 devices, or cosmetics.

635 (b) The department may deny an application for a permit or
636 certification, or suspend or revoke a permit or certification,
637 if the department finds that:

638 1. The applicant is not of good moral character or that it

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639 would be a danger or not in the best interest of the public
640 health, safety, and welfare if the applicant were issued a
641 permit or certification.

642 2. The applicant has not met the requirements for the
643 permit or certification.

644 3. The applicant is not eligible for a permit or
645 certification for any of the reasons enumerated in s. 499.012.

646 4. The applicant, permittee, or person certified under s.
647 499.012(16) demonstrates any of the conditions enumerated in s.
648 499.012.

649 5. The applicant, permittee, or person certified under s.
650 499.012(16) has committed any violation of this chapter ~~ss.~~
651 ~~499.005-499.0054~~.

652 (2) The department may deny, suspend, or revoke any
653 registration required by ~~the provisions of this chapter part~~ for
654 the violation of any provision of this chapter part or of any
655 rules adopted under this chapter part.

656 (3) The department may revoke or suspend a permit:

657 (a) If the permit was obtained by misrepresentation or
658 fraud or through a mistake of the department;

659 (b) If the permit was procured, or attempted to be
660 procured, for any other person by making or causing to be made
661 any false representation; or

662 (c) If the permittee has violated ~~any provision of this~~
663 chapter part or rules adopted under this chapter part.

664 (4) If a ~~any~~ permit issued under this chapter part is
665 revoked or suspended, the owner, manager, operator, or
666 proprietor of the establishment shall cease to operate as the
667 permit authorized, from the effective date of the suspension or

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668 revocation until the person is again registered with the
669 department and possesses the required permit. If a permit is
670 revoked or suspended, the owner, manager, or proprietor shall
671 remove all signs and symbols that identify the operation as
672 premises permitted as a drug wholesaling establishment; drug,
673 device, or cosmetic manufacturing establishment; or retail
674 establishment. The department shall determine the length of time
675 for which the permit is to be suspended. If a permit is revoked,
676 the person that owns or operates the establishment may not apply
677 for a any permit under this chapter part for a period of 1 year
678 after the date of the revocation. A revocation of a permit may
679 be permanent if the department considers that to be in the best
680 interest of the public health.

681 (5) The department may deny, suspend, or revoke a permit
682 issued under this chapter part which authorizes the permittee to
683 purchase prescription drugs if an any owner, officer, employee,
684 or other person who participates in administering or operating
685 the establishment has been found guilty of a any violation of
686 this chapter part or chapter 465, chapter 501, or chapter 893,
687 any rules adopted under ~~this part~~ or those chapters, or any
688 federal or state drug law, regardless of whether the person has
689 been pardoned, had her or his civil rights restored, or had
690 adjudication withheld.

691 (6) The department shall deny, suspend, or revoke the
692 permit of a any person or establishment if the assignment, sale,
693 transfer, or lease of an establishment permitted under this
694 chapter part will avoid an administrative penalty, civil action,
695 or criminal prosecution.

696 (7) Notwithstanding s. 120.60(5), if a permittee fails to

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697 comply with s. 499.012(6) or s. 499.833, as applicable, the
698 department may revoke the permit of the permittee and shall
699 provide notice of the intended agency action by posting a notice
700 at the department's headquarters and by mailing a copy of the
701 notice of intended agency action by certified mail to the most
702 recent mailing address on record with the department and, if the
703 permittee is not a natural person, to the permittee's registered
704 agent on file with the Department of State.

705 (8) The department may deny, suspend, or revoke a permit
706 under this part if it finds the permittee has not complied with
707 the credentialing requirements of s. 499.0121(15).

708 (9) The department may deny, suspend, or revoke a permit
709 under this part if it finds the permittee has not complied with
710 the reporting requirements of, or knowingly made a false
711 statement in a report required by, s. 499.0121(14).

712 Section 12. Part III of chapter 499, Florida Statutes,
713 consisting of ss. 499.81-499.94, Florida Statutes, is created
714 and entitled "Medical Gas."

715 Section 13. Section 499.81, Florida Statutes, is created to
716 read:

717 499.81 Administration and enforcement.-

718 (1) This part is cumulative and shall be construed and
719 applied as being in addition to, and not in substitution for or
720 limiting any powers, duties, or authority of the department
721 under any other law of this state; except that, with respect to
722 the regulation of medical gas, this part controls over any
723 conflicting provisions.

724 (2) The department shall administer and enforce this part
725 to prevent fraud, adulteration, misbranding, or false

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726 advertising in the manufacture and distribution of medical
727 gases.

728 (3) For the purpose of an investigation or proceeding
729 conducted by the department under this part, the department may
730 administer oaths, take depositions, subpoena witnesses, and
731 compel the production of books, papers, documents, or other
732 records. Challenges to, and enforcement of, subpoenas and orders
733 shall be handled as provided in s. 120.569.

734 (4) Each state attorney, county attorney, or municipal
735 attorney to whom the department or its designated agent reports
736 a violation of this part shall cause appropriate proceedings to
737 be instituted in the proper courts without delay and prosecuted
738 as required by law.

739 (5) This part does not require the department to report,
740 for the purpose of instituting proceedings under this part,
741 minor violations of this part when the department believes that
742 the public interest will be adequately served by a written
743 notice or warning.

744 Section 14. Section 499.82, Florida Statutes, is created to
745 read:

746 499.82 Definitions.—As used in this part, the term:

747 (1) "Adulterated," means a medical gas that:

748 (a) Consists, in whole or in part, of impurities or
749 deleterious substances exceeding normal specifications;

750 (b) Is produced, prepared, packed, or held under conditions
751 whereby the medical gas may have been contaminated causing it to
752 be rendered injurious to health; or if the methods used in, or
753 the facilities or controls used for, its manufacture,
754 processing, packing, or holding do not conform to or are not

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755 operated or administered in conformity with current good
756 manufacturing practices to ensure that the medical gas meets the
757 requirements of this part as to safety and has the identity and
758 strength and meets the quality and purity characteristics that
759 the medical gas is represented to possess;

760 (c) Is held in a container with an interior that is
761 composed in whole or in part of a poisonous or deleterious
762 substance that may render the contents injurious to health; or

763 (d) Is represented as having a strength differing from, or
764 quality or purity falling below, the standard set forth in the
765 USP-NF. A medical gas defined in USP-NF may not be deemed to be
766 adulterated under this paragraph merely because it differs from
767 the standard of strength, quality, or purity set forth in the
768 USP-NF if its difference in strength, quality, or purity from
769 that standard is plainly stated on its label. The determination
770 as to strength, quality, or purity shall be made:

771 1. In accordance with the tests or methods of assay in the
772 USP-NF or its validated equivalent; or

773 2. In the absence or inadequacy of such tests or methods of
774 assay, in accordance with the tests or methods of assay
775 prescribed under the federal act.

776 (2) "Department" means the Department of Business and
777 Professional Regulation.

778 (3) "Distribute" or "distribution" means to sell; offer to
779 sell; deliver; offer to deliver; transfer by either the passage
780 of title, physical movement, or both; broker; or give away a
781 medical gas. The term does not include:

782 (a) The dispensing or administration of a medical gas;

783 (b) The delivery of, or an offer to deliver, a medical gas

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784 by a common carrier in its usual course of business; or

785 (c) Sales activities taking place in a location owned,
786 controlled, or staffed by persons employed by a person or entity
787 permitted in this state to distribute a medical gas, if that
788 location is not used to physically store or move a medical gas.

789 (4) "Emergency medical reasons" include:

790 (a) Transfers between wholesale distributors or between a
791 wholesale distributor and a retail pharmacy or health care
792 entity to alleviate a temporary shortage of a medical gas
793 arising from a long-term delay or interruption of regular
794 distribution schedules.

795 (b) Sales or transfers to licensed emergency medical
796 services in this state, including ambulance companies and
797 firefighting organizations.

798 (c) The provision of emergency supplies of medical gases to
799 nursing homes during the hours of the day when necessary medical
800 gases cannot normally be obtained from the nursing home's
801 regular distributors.

802 (d) The transfer of medical gases between retail pharmacies
803 to alleviate a temporary shortage.

804 (5) "Emergency use oxygen" means oxygen USP administered in
805 emergency situations without a prescription for oxygen
806 deficiency and resuscitation. The container must be labeled in
807 accordance with requirements of the United States Food and Drug
808 Administration.

809 (6) "Federal act" means the Federal Food, Drug, and
810 Cosmetic Act.

811 (7) "Medical gas" means a liquefied or vaporized gas that
812 is a prescription drug, whether alone or in combination with

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813 other gases, and as defined in the federal act.

814 (8) "Medical gas-related equipment" means a device used as
815 a component part or accessory used to contain or control the
816 flow, delivery, or pressure during the administration of a
817 medical gas, such as liquid oxygen base and portable units,
818 pressure regulators and flow meters, and oxygen concentrators.

819 (9) "Misbranded" means having a label that is false or
820 misleading; a label without the name and address of the
821 manufacturer, repackager, or distributor and without an accurate
822 statement of the quantities of active ingredients; or a label
823 without an accurate monograph for the medical gas, except in the
824 case of mixtures of designated medical gases where the label
825 identifies the component percentages of each designated medical
826 gas used to make the mixture.

827 (10) "Medical oxygen" means oxygen USP which must be
828 labeled in compliance with labeling requirements for oxygen
829 under the federal act.

830 (11) "Product labeling" means the labels and other written,
831 printed, or graphic matter upon an article, or the containers or
832 wrappers that accompany an article, except for letters, numbers,
833 and symbols stamped into the container as required by the
834 federal Department of Transportation.

835 (12) "USP" means United States Pharmacopeial Convention.

836 (13) "USP-NF" means United States Pharmacopeia-National
837 Formulary.

838 (14) "Wholesale distribution" means the distribution of
839 medical gas to a person other than a consumer or patient.

840 Wholesale distribution of medical gases does not include:

841 (a) The sale, purchase, or trade of a medical gas; an offer

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842 to sell, purchase, or trade a medical gas; or the dispensing of
843 a medical gas pursuant to a prescription;

844 (b) Activities exempt from the definition of wholesale
845 distribution in s. 499.003; or

846 (c) Other transactions excluded from the definition of
847 wholesale distribution under the federal act or regulations
848 implemented under the federal act related to medical gas.

849 (15) "Wholesale distributor" means any person or entity
850 engaged in wholesale distribution of medical gas within or into
851 this state, including, but not limited to, manufacturers; own-
852 label distributors; private-label distributors; warehouses,
853 including manufacturers' and distributors' warehouses; and
854 wholesale medical gas warehouses.

855 Section 15. Section 499.83, Florida Statutes, is created to
856 read:

857 499.83 Permits.—

858 (1) A person or entity that intends to distribute medical
859 gas within or into this state, unless exempted under this part,
860 must obtain the applicable permit before operating as:

861 (a) A medical gas wholesale distributor;

862 (b) A medical gas manufacturer; or

863 (c) A medical oxygen retail establishment.

864 (2) The following permits are established:

865 (a) Medical gas wholesale distributor permit.—A medical gas
866 wholesale distributor permit is required for wholesale
867 distribution, whether within or into this state. A medical gas
868 must remain in the original container obtained by the wholesale
869 distributor and the wholesale distributor may not engage in
870 further manufacturing operations unless it possesses a medical

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871 gas manufacturer permit. A medical gas wholesale distributor may
872 not possess or engage in the wholesale distribution of a
873 prescription drug that is not a medical gas or distribute a
874 medical gas other than by wholesale distribution unless
875 otherwise authorized under this chapter.

876 (b) Medical gas manufacturer permit.—A medical gas
877 manufacturer permit is required for a person or entity located
878 in this state which engages in the manufacture of medical gases
879 by physical air separation, chemical action, purification, or
880 filling containers by a liquid-to-liquid, liquid-to-gas, or gas-
881 to-gas process and distributes those medical gases within this
882 state.

883 1. A permitted medical gas manufacturer may not manufacture
884 or possess a prescription drug other than a medical gas, unless
885 otherwise authorized under this chapter.

886 2. A permitted medical gas manufacturer may not distribute
887 a medical gas without obtaining the applicable permit, except
888 that it may engage in wholesale distribution of medical gases
889 that it manufactured without obtaining a medical gas wholesale
890 distributor permit if it complies with this part and the rules
891 adopted under this part that apply to a wholesale distributor.

892 3. A permitted medical gas manufacturer shall comply with
893 all of the requirements applicable to a wholesale distributor
894 under this part and all appropriate state and federal good
895 manufacturing practices.

896 (c) Medical oxygen retail establishment permit.—A medical
897 oxygen retail establishment permit is required for an entity
898 that is located in the state and that dispenses medical oxygen
899 directly to patients in this state. The sale and delivery must

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900 be based on a prescription or an order from a practitioner
901 authorized by law to prescribe. A pharmacy licensed under
902 chapter 465 does not require a permit as a medical oxygen retail
903 establishment.

904 1. A medical oxygen retail establishment may not possess,
905 purchase, sell, or trade a medical gas other than medical
906 oxygen, unless otherwise authorized under this chapter.

907 2. A medical oxygen retail establishment may fill and
908 deliver medical oxygen to an individual patient based on an
909 order from a practitioner authorized by law to prescribe. The
910 medical oxygen retail establishment must comply with all
911 appropriate state and federal good manufacturing practices.
912 Medical oxygen sold or delivered by a medical oxygen retail
913 establishment pursuant to an order from a practitioner may not
914 be returned into the retail establishment's inventory.

915 3. A medical oxygen retail establishment shall comply with
916 all of the requirements applicable to a wholesale distributor
917 under this part, except for those requirements that pertain
918 solely to nitrous oxide.

919 (3) An out-of-state wholesale distributor that engages in
920 wholesale distribution into this state must be legally
921 authorized to engage in the wholesale distribution of medical
922 gases as a wholesale distributor in the state in which it
923 resides and provide proof of registration as set forth in s.
924 499.93(3), if required.

925 (4) A wholesale distributor may not operate from a place of
926 residence, and a place of residence may not be granted a permit
927 or operate under this part, except for the on-call delivery of
928 home care oxygen for wholesale distributors that also maintain a

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929 medical oxygen retail establishment permit.

930 (5) If wholesale distribution is conducted at more than one
931 location within this state or more than one location
932 distributing into this state, each location must be permitted by
933 the department.

934 Section 16. Section 499.831, Florida Statutes, is created
935 to read:

936 499.831 Permit application.-

937 (1) The department shall adopt rules to establish the form
938 and content of the application to obtain a permit and to renew a
939 permit listed under this part.

940 (2) An applicant must be at least 18 years of age or be
941 managed, controlled, or overseen, directly or indirectly, by a
942 natural person who is at least 18 years of age.

943 (3) An application for a permit must be filed with the
944 department and must include all of the following information:

945 (a) The trade or business name of the applicant, including
946 current and former fictitious names, which may not be identical
947 to a name used by an unrelated entity permitted in this state to
948 dispense or distribute medical gas.

949 (b) The name or names of the owner and operator of the
950 applicant, if not the same person or entity. The application
951 must also include:

952 1. If the applicant is an individual, the applicant's name,
953 business address, and date of birth.

954 2. If the applicant is a sole proprietorship, the business
955 address of the sole proprietor and the name and federal employer
956 identification number of the business entity.

957 3. If the applicant is a partnership, the name, business

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958 address, date of birth of each partner, the name of the
959 partnership, and the partnership's federal employer
960 identification number.

961 4. If the applicant is a limited liability company, the
962 name, business address, and title of each company officer, the
963 name of the limited liability company and federal employer
964 identification number, and the name of the state in which the
965 limited liability company was organized.

966 5. If the applicant is a corporation, the name, business
967 address, and title of each corporate officer and director, the
968 corporate names, the state of incorporation, the federal
969 employer identification number, and, if applicable, the name and
970 business address of the parent company.

971 (c) A list of disciplinary actions pertinent to wholesale
972 distributors, manufacturers, and retailers of prescription drugs
973 or controlled substances by a state or federal agency against
974 the applicant seeking to distribute into this state and any such
975 disciplinary actions against such applicant's principals,
976 owners, directors, or officers.

977 (d) A complete disclosure of all of the applicant's past
978 felony convictions.

979 (e) An address and description of each facility and
980 warehouse, including all locations used for medical gas storage
981 or wholesale distribution including a description of each
982 facility's security system.

983 (4) An applicant shall attest in writing that the
984 information contained in its application is complete and
985 accurate.

986 (5) An applicant must submit a reasonable fee, to be

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987 determined by the department, in order to obtain a permit.

988 (a) The fee for a medical gas wholesale distributor permit
989 may not be less than \$200 or more than \$300 annually.

990 (b) The fee for a medical gas manufacturer permit may not
991 be less than \$400 or more than \$500 annually.

992 (c) The fee for a medical oxygen retail establishment
993 permit may not be less than \$200 or more than \$300 annually.

994 (6) Upon approval of the application by the department and
995 payment of the required fee, the department shall issue a permit
996 to the applicant pursuant to the rules adopted under this part.

997 Section 17. Section 499.832, Florida Statutes, is created
998 to read:

999 499.832 Expiration and renewal of a permit.—

1000 (1) A permit issued under this part automatically expires 2
1001 years after the last day of the month in which the permit was
1002 originally issued.

1003 (2) A permit issued under this part may be renewed by
1004 submitting an application for renewal on a form furnished by the
1005 department and paying the appropriate fee. The application for
1006 renewal must contain a statement by the applicant attesting that
1007 the information is true and correct. Upon approval of a renewal
1008 application by the department and payment of the required
1009 renewal fee, the department shall renew a permit issued under
1010 this part pursuant to the rules adopted under this part.

1011 (3) A renewal application may be accepted up to 60 days
1012 after the expiration date of the permit if, along with the
1013 permit renewal fee, the applicant submits an additional renewal
1014 delinquent fee of \$100. A permit that expired more than 60 days
1015 before a renewal application was submitted or postmarked may not

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1016 be renewed.

1017 (4) Failure to renew a permit in accordance with this
1018 section precludes future renewal. If a permit has expired and
1019 cannot be renewed, the person, entity, or establishment holding
1020 the permit must cease all permit related activities. In order to
1021 engage such activities, the person, entity, or establishment
1022 must submit an application for a new permit, pay the applicable
1023 application fee, the initial permit fee, and all applicable
1024 penalties, and be issued a new permit by the department before
1025 engaging in an activity that requires a permit under this part.

1026 (5) The department shall adopt rules to administer this
1027 section, including setting a reasonable fee for a renewal
1028 application.

1029 Section 18. Section 499.833, Florida Statutes, is created
1030 to read:

1031 499.833 Permitholder changes.—

1032 (1) A permit issued under this part is valid only for the
1033 person or entity to which it is issued and is not subject to
1034 sale, assignment, or other transfer, voluntarily or
1035 involuntarily.

1036 (2) A permit issued under this part is not valid for an
1037 establishment other than the establishment for which it was
1038 originally issued.

1039 (3) The department may approve the following permit
1040 changes:

1041 (a) Change of location.—A person or entity permitted under
1042 this part must notify and receive approval from the department
1043 before changing location. The department shall set a change-of-
1044 location fee not to exceed \$100.

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1045 (b) Change in ownership.—If a majority of the ownership or
1046 controlling interest of a permitted establishment is transferred
1047 or assigned or if a lessee agrees to undertake or provide
1048 services such that legal liability for operation of the
1049 establishment will rest with the lessee, an application for a
1050 new permit is required. Such application must be submitted and
1051 approved by the department before the change of ownership takes
1052 place. However, if a permitted wholesale distributor or
1053 manufacturer is changing ownership and the new owner has held
1054 another permit that allows the wholesale distribution of medical
1055 gas under this chapter for the preceding 18 months without
1056 having been found in violation of the provisions of this chapter
1057 relating to medical gases, then the new owner may operate under
1058 the permit of the acquired entity if the new owner submits the
1059 application for a new permit by the first business day after
1060 ownership is transferred or assigned. A new owner operating
1061 under the original permit is responsible for compliance with all
1062 laws and regulations governing medical gas. If the application
1063 is denied, the new owner shall immediately cease operation at
1064 the establishment until a permit is issued to the new owner.

1065 (c) Change of name.—A permitholder may make a change of
1066 business name without submitting a new permit application.
1067 However, the permitholder must notify the department before
1068 making the name change.

1069 (d) Closure.—If an establishment permitted under this part
1070 closes, the owner must notify the department, in writing, before
1071 the effective date of the closure and must:

- 1072 1. Return the permit to the department; and
- 1073 2. Indicate the disposition of any medical gas authorized

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1074 to be distributed or dispensed under the permit, including the
1075 name, address, and inventory, and provide the name and address
1076 of a person to contact regarding access to the records that are
1077 required to be maintained under this part. Transfer of ownership
1078 of medical gas may be made only to persons authorized to receive
1079 medical gas pursuant to this part.

1080 (e) Change in information.—Any change in the information
1081 required under this part, other than the changes in paragraphs
1082 (a)-(d), shall be submitted to the department within 30 days
1083 after such change occurs.

1084 (4) A permit holder in good standing may change the type of
1085 permit issued by completing a new application for the requested
1086 permit, meeting the applicable permitting requirements for the
1087 new permit type, and paying any difference between the permit
1088 fees. A refund may not be issued if the fee for the new permit
1089 is less than the fee that was paid for the original permit. The
1090 new permit retains the expiration date of the original permit.

1091 Section 19. Section 499.834, Florida Statutes, is created
1092 to read:

1093 499.834 Minimum qualifications.—The department shall
1094 consider all of the following factors in determining eligibility
1095 for, and renewal of, a permit for a person or entity under this
1096 part:

1097 (1) A finding by the department that the applicant has
1098 violated or been disciplined by a regulatory agency in any state
1099 for violating a federal, state, or local law relating to
1100 prescription drugs.

1101 (2) Felony convictions of the applicant under a federal,
1102 state, or local law.

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1103 (3) The applicant's past experience in the manufacture,
1104 retail, or distribution of medical gases.

1105 (4) False or fraudulent material provided by the applicant
1106 in an application made in connection with the manufacturing,
1107 retailing, or distribution of prescription drugs.

1108 (5) Any suspension, sanction, or revocation by a federal,
1109 state, or local government against a license or permit currently
1110 or previously held by the applicant or its owners for violations
1111 of a federal, state, or local law regarding prescription drugs.

1112 (6) Compliance with previously granted licenses or permits.

1113 (7) Compliance with the requirements that distributors or
1114 retailers of medical gases maintain records and make records
1115 available to the department licensing authority or federal,
1116 state, or local law enforcement officials.

1117 (8) Other factors or qualifications the department
1118 considers relevant to and consistent with the public health and
1119 safety.

1120 Section 20. Section 499.84, Florida Statutes, is created to
1121 read:

1122 499.84 Minimum requirements for the storage and handling of
1123 medical gases.—

1124 (1) A facility where a medical gas is received, stored,
1125 warehoused, handled, held, offered, marketed, displayed, or
1126 transported, to avoid any negative effect on the identity,
1127 strength, quality, or purity of the medical gas, must:

1128 (a) Be of suitable construction to ensure that medical
1129 gases are maintained in accordance with the product labeling of
1130 the medical gas or in compliance with the USP-NF;

1131 (b) Be of suitable size and construction to facilitate

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1132 cleaning, maintenance, and proper permitted operations;

1133 (c) Have adequate storage areas with appropriate lighting,
1134 ventilation, space, equipment, and security conditions;

1135 (d) Have a quarantined area for storage of medical gases
1136 that are suspected of being misbranded, adulterated, or
1137 otherwise unfit for distribution;

1138 (e) Be maintained in an orderly condition;

1139 (f) Be located in a commercial location and not in a
1140 personal dwelling or residence location, except that a personal
1141 dwelling location used for on-call delivery of oxygen USP for
1142 homecare use if the person providing on-call delivery is
1143 employed by or acting under a written contract with an entity
1144 that holds a medical oxygen retailer permit;

1145 (g) Provide for the secure and confidential storage of
1146 patient information, if applicable, with restricted access and
1147 policies and procedures to protect the integrity and
1148 confidentiality of patient information; and

1149 (h) Provide and maintain appropriate inventory controls to
1150 detect and document any theft of nitrous oxide.

1151 (2) Medical gas shall be stored under appropriate
1152 conditions in accordance with the manufacturer's recommendations
1153 on product labeling and department rules or, in the absence of
1154 rules, in accordance with applicable industry standards.

1155 (3) Medical gas shall be packaged in accordance with
1156 official compendium standards, such as the USP-NF.

1157 Section 21. Section 499.85, Florida Statutes, is created to
1158 read:

1159 499.85 Security.-

1160 (1) A permitholder that has a facility used for the

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1161 distribution or retailing of medical gases shall protect such
1162 gases from unauthorized access by implementing all of the
1163 following security measures:

1164 (a) Keeping access from outside the premises well-
1165 controlled and to a minimum.

1166 (b) Ensuring the outside perimeter of the premises is well
1167 lit.

1168 (c) Limiting access into areas where medical gases are held
1169 to authorized personnel.

1170 (d) Equipping all facilities with a fence or other system
1171 to detect or deter entry after hours.

1172 (2) A facility used for distributing or retailing medical
1173 gases shall be equipped with a system that provides suitable
1174 protection against theft, including if appropriate, protection
1175 against theft of computers or electronic records and the
1176 protection of the integrity and confidentiality of data and
1177 documents.

1178 (3) A facility used for wholesale distribution of medical
1179 gases shall be equipped with inventory management and control
1180 systems that protect against, detect, and document any instances
1181 of theft of nitrous oxide.

1182 (4) If a wholesale distributor uses electronic distribution
1183 records, the wholesale distributor shall employ, train, and
1184 document the training of personnel in the proper use of such
1185 technology and equipment.

1186 (5) Vehicles used for on-call delivery of oxygen USP and
1187 oxygen-related equipment for home care use by home care
1188 providers may be parked at a place of residence and must be
1189 locked and equipped with an audible alarm when not attended.

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1190 (6) The department shall adopt rules that govern the
1191 distribution of medical oxygen for emergency use by persons
1192 authorized to receive emergency use oxygen. Unless the laws of
1193 this state specifically direct otherwise, such rules must be
1194 consistent with federal regulations, including the labeling
1195 requirements of oxygen under the federal act.

1196 Section 22. Section 499.86, Florida Statutes, is created to
1197 read:

1198 499.86 Examination of materials.-

1199 (1) A wholesale distributor must visually examine a medical
1200 gas container upon receipt from the manufacturer in order to
1201 identify the medical gas stored within and to determine if the
1202 container has been damaged or is otherwise unfit for
1203 distribution. Such examination must occur in a manner that would
1204 reveal damage to the container which could suggest possible
1205 adulteration or misbranding.

1206 (2) A medical gas container that is found to be damaged or
1207 otherwise unfit pursuant to subsection (1) must be quarantined
1208 from the stock of medical gas until a determination is made that
1209 the medical gas in question is not misbranded or adulterated.

1210 (3) An outgoing shipment must be inspected to identify the
1211 medical gases in the shipment to ensure that medical gas
1212 containers that have been damaged in storage or held under
1213 improper conditions are not distributed or dispensed.

1214 (4) A wholesale distributor must review records documenting
1215 the acquisition of medical gas upon receipt for accuracy and
1216 completeness.

1217 Section 23. Section 499.87, Florida Statutes, is created to
1218 read:

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- 1219 499.87 Returned, damaged, and outdated medical gas.-
1220 (1) A medical gas that has left the control of the
1221 wholesale distributor may be returned to the wholesale
1222 distributor or manufacturer from which it was acquired, but may
1223 not be resold as a medical gas unless it is reprocessed by a
1224 manufacturer using proper and adequate controls to ensure the
1225 identity, strength, quality, and purity of the reprocessed
1226 medical gas.
- 1227 (2) A medical gas that has been subjected to improper
1228 conditions, such as a fire, accident, or natural disaster, may
1229 not be salvaged or reprocessed.
- 1230 (3) A medical gas, including its container, which is
1231 damaged, misbranded, or adulterated must be quarantined from
1232 other medical gases until it is destroyed or returned to the
1233 manufacturer or wholesale distributor from which it was
1234 acquired. External contamination of a medical gas container or
1235 closure system which does not impact the integrity of the
1236 medical gas is not considered damaged or adulterated for
1237 purposes of this subsection. If a medical gas is adulterated or
1238 misbranded or suspected of being adulterated or misbranded,
1239 notice shall be provided to the manufacturer or wholesale
1240 distributor from which the medical gas was acquired and to the
1241 appropriate boards and federal regulatory bodies.
- 1242 (4) A medical gas container that has been opened or used
1243 but is not adulterated or misbranded is considered empty and
1244 must be quarantined from nonempty medical gas containers and
1245 returned to the manufacturer or wholesale distributor from which
1246 it was acquired for destruction or reprocessing.
- 1247 (5) A medical gas, its container, or its associated

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1248 documentation or labeling that is suspected of being used in
1249 criminal activity must be retained until its disposition is
1250 authorized by the department or an applicable law enforcement
1251 agency.

1252 Section 24. Section 499.88, Florida Statutes, is created to
1253 read:

1254 499.88 Due diligence.-

1255 (1) A wholesale distributor shall obtain, before the
1256 initial acquisition of medical gas, the following information
1257 from the supplying wholesale distributor or manufacturer:

1258 (a) If a manufacturer is distributing to a wholesale
1259 distributor, evidence that the manufacturer is registered and
1260 the medical gas is listed with the United States Food and Drug
1261 Administration;

1262 (b) If a wholesale distributor is distributing to a
1263 wholesale distributor, evidence that the wholesale distributor
1264 supplying the medical gas is legally authorized to distribute
1265 medical gas within or into the state;

1266 (c) The name of the responsible facility contact person for
1267 the supplying manufacturer or wholesale distributor; and

1268 (d) Certification that the manufacturer's or wholesale
1269 distributor's policies and procedures comply with this part.

1270 (2) A wholesale distributor is exempt from obtaining the
1271 information from a manufacturer, as required under subsection
1272 (1), if the manufacturer is registered with the United States
1273 Food and Drug Administration in accordance with s. 510 of the
1274 federal act and the manufacturer provides:

1275 (a) Proof of such registration; and

1276 (b) Proof of inspection by the United States Food and Drug

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1277 Administration or other regulatory body within the past 3 years
1278 demonstrating substantial compliance with current good
1279 manufacturing practices applicable to medical gases.

1280 (3) A manufacturer or wholesale distributor that
1281 distributes to or acquires medical gas from another wholesale
1282 distributor shall provide to or obtain from the distributing or
1283 acquiring manufacturer or distributor the information required
1284 by s. 499.89(1), as applicable.

1285 Section 25. Section 499.89, Florida Statutes, is created to
1286 read:

1287 499.89 Recordkeeping.-

1288 (1) A permit holder under this part shall establish and
1289 maintain a record of transactions regarding the receipt and the
1290 distribution, or other disposition, of medical gases, as
1291 applicable. Such records constitute an audit trail and must
1292 contain information sufficient to perform a recall of medical
1293 gas in compliance with 21 C.F.R. s. 211.196 and 21 C.F.R. s.
1294 820.160(b). Such records must include all of the following
1295 information, which may be kept in two separate documents one
1296 related to the distribution of medical gas and the other related
1297 to the receipt of medical gas:

1298 (a) The dates of receipt and distribution or other
1299 disposition of the medical gas.

1300 (b) The name, address, license or permit number and its
1301 expiration date for the person or entity purchasing the medical
1302 gas from the wholesale distributor.

1303 (c) The name, address, license or permit number and its
1304 expiration date for the person or entity receiving the medical
1305 gas, if different from the information required under paragraph

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1306 (b).

1307 (d) Information sufficient to perform a recall of all
1308 medical gas received, distributed, or dispensed.

1309 (2) Such records shall be made available for inspection and
1310 copying by an authorized official of any federal, state, or
1311 local governmental agency for a period of:

1312 (a) Three years following the distribution date of high
1313 pressure medical gases.

1314 (b) Two years following the distribution date for cryogenic
1315 or refrigerated liquid medical gases.

1316 (3) Records kept at the inspection site or that can be
1317 immediately retrieved by computer or other electronic means
1318 shall be readily available for authorized inspection during the
1319 retention period. Records kept at a central location apart from
1320 the inspection site and not electronically retrievable shall be
1321 made available for inspection within 2 working days of a request
1322 by an authorized official of any state or federal governmental
1323 agency charged with enforcement of these rules.

1324 (4) A pedigree paper is not required for distributing or
1325 dispensing medical gas.

1326 (5) A wholesale distributor shall maintain records
1327 sufficient to aid in the mandatory reporting of any theft,
1328 suspected theft, or other significant loss of nitrous oxide to
1329 the department and other appropriate law enforcement agencies.

1330 Section 26. Section 499.90, Florida Statutes, is created to
1331 read:

1332 499.90 Policies and procedures.—A wholesale distributor
1333 shall establish, maintain, and adhere to written policies and
1334 procedures for the receipt, security, storage, transport,

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1335 shipping, and distribution of medical gases and shall establish,
1336 maintain, and adhere to procedures for maintaining inventories;
1337 for identifying, recording, and reporting losses or thefts; and
1338 for correcting all errors and inaccuracies in inventories
1339 associated with nitrous oxide. A wholesale distributor shall
1340 include in its written policies and procedures all of the
1341 following:

1342 (1) A procedure for handling recalls and withdrawals of
1343 medical gas. Such procedure must deal with recalls and
1344 withdrawals due to:

1345 (a) Action initiated at the request of the United States
1346 Food and Drug Administration or any federal, state, or local law
1347 enforcement or other government agency, including the
1348 department; or

1349 (b) Voluntary action by a manufacturer of medical gases to
1350 remove defective or potentially defective medical gases from the
1351 market.

1352 (2) A procedure that includes preparation for, protection
1353 against, and responding to a crisis that affects the security or
1354 operation of a facility that stores medical gases in the event
1355 of a strike; a fire, flood, or other natural disaster; or other
1356 local, state, or national emergency.

1357 (3) A procedure for reporting criminal or suspected
1358 criminal activity involving the inventory of nitrous oxide to
1359 the department and to applicable law enforcement agencies within
1360 3 business days after becoming aware of the criminal or
1361 suspected criminal activity.

1362 Section 27. Section 499.91, Florida Statutes, is created to
1363 read:

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1364 499.91 Prohibited acts.—A person may not perform or cause
1365 the performance of, or aid and abet in, any of the following
1366 acts:

1367 (1) The manufacture, sale, or delivery, or the holding or
1368 offering for sale, of a medical gas that is adulterated,
1369 misbranded, or is otherwise unfit for distribution.

1370 (2) The adulteration or misbranding of a medical gas.

1371 (3) The receipt of a medical gas that is adulterated,
1372 misbranded, stolen, or obtained by fraud or deceit, and the
1373 delivery or proffered delivery of such medical gas for pay or
1374 otherwise.

1375 (4) The alteration, mutilation, destruction, obliteration,
1376 or removal of all or any part of the product labeling of a
1377 medical gas, or the willful commission of any other act with
1378 respect to a medical gas that results in it being misbranded.

1379 (5) The purchase or receipt of a medical gas from a person
1380 not authorized to distribute or dispense medical gas or who is
1381 not exempted from permitting requirements to wholesale
1382 distribute medical gas to such purchaser or recipient.

1383 (6) The knowing and willful sale or transfer of a medical
1384 gas to a recipient who is not legally authorized to receive a
1385 medical gas, except that a violation does not exist if a
1386 permitted wholesale distributor provides oxygen to a permitted
1387 medical oxygen retail establishment that is out of compliance
1388 with the notice of location change requirements of s. 499.834,
1389 provided that the wholesale distributor with knowledge of the
1390 violation notifies the department of the transaction by the next
1391 business day.

1392 (7) The failure to maintain or provide records required

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1393 under this part and the rules adopted under this part.

1394 (8) Providing the department or any of its representatives
1395 or any state or federal official with false or fraudulent
1396 records or making false or fraudulent statements regarding this
1397 part or the rules adopted under this part.

1398 (9) The distribution of a medical gas that was:

1399 (a) Purchased by a public or private hospital or other
1400 health care entity, except for the physical distribution of such
1401 medical gas to an authorized recipient at the direction of a
1402 hospital or other health care entity;

1403 (b) Donated or supplied at a reduced price to a charitable
1404 organization; or

1405 (c) Stolen or obtained by fraud or deceit.

1406 (10) The failure to obtain a license or permit or operating
1407 without a valid license or permit, if one is required.

1408 (11) The obtaining of, or attempt to obtain, a medical gas
1409 by fraud, deceit, or misrepresentation or engaging in
1410 misrepresentation or fraud in the distribution of a medical gas.

1411 (12) Except for emergency use oxygen, the distribution of a
1412 medical gas to a patient without a prescription from a
1413 practitioner authorized by law to prescribe a medical gas.

1414 (13) The distribution or dispensing of a medical gas that
1415 was previously dispensed by a pharmacy or a practitioner
1416 authorized by law to prescribe.

1417 (14) The distribution or dispensing of a medical gas or
1418 medical gas-related equipment to a patient, unless the patient
1419 has been provided with the appropriate information and
1420 counseling on the use, storage, and disposal of the medical gas.

1421 (15) Failure to report an act prohibited under this part or

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1422 the rules adopted under this part.

1423 (16) Failure to exercise due diligence as provided in s.
1424 499.88.

1425 Section 28. Section 499.92, Florida Statutes, is created to
1426 read:

1427 499.92 Criminal acts.—

1428 (1) A person commits a felony of the third degree,
1429 punishable as provided in s. 775.082, s. 775.083, or s. 775.084,
1430 if he or she:

1431 (a) Adulterates or misbrands a medical gas with intent to
1432 defraud or deceive;

1433 (b) Knowingly purchases or receives a medical gas from a
1434 person not legally authorized to distribute or dispense medical
1435 gas;

1436 (c) Knowingly engages in the wholesale distribution of, or
1437 sells, barter, brokers, or transfers, a medical gas to a person
1438 not legally authorized to purchase or receive medical gas in the
1439 jurisdiction in which the person receives the medical gas. A
1440 permitted wholesale distributor that provides oxygen to a
1441 permitted medical oxygen retail establishment that is out of
1442 compliance with only the change of location notice requirement
1443 under s. 499.834, does not commit a violation of this paragraph
1444 if the wholesale distributor notifies the department of the
1445 transaction no later than the next business day; or

1446 (d) Knowingly falsely creates a label for a medical gas or
1447 knowingly falsely misrepresents a factual matter contained in a
1448 label for a medical gas.

1449 (2) A person found guilty of an offense under this section,
1450 under the authority of the court convicting and sentencing the

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1451 person, shall be ordered to forfeit to the state any real or
1452 personal property:

1453 (a) Used or intended to be used to commit, to facilitate,
1454 or to promote the commission of such offense; and

1455 (b) Constituting, derived from, or traceable to the gross
1456 proceeds that the defendant obtained directly or indirectly as a
1457 result of the offense.

1458 (3) Property or assets subject to forfeiture under
1459 subsection (2) may be seized pursuant to a warrant obtained in
1460 the same manner as a search warrant or as otherwise authorized
1461 by law, and held until the case against a defendant is
1462 adjudicated. Monies ordered forfeited, or proceeds from the sale
1463 of other assets ordered forfeited, shall be equitably divided
1464 between the department and other agencies involved in the
1465 investigation and prosecution that led to the conviction. Other
1466 property ordered forfeited after conviction of a defendant may,
1467 at the discretion of the investigating agencies, be placed into
1468 official use by the department or the agencies involved in the
1469 investigation and prosecution that led to the conviction.

1470 Section 29. Section 499.93, Florida Statutes, is created to
1471 read:

1472 499.93 Inspections.—

1473 (1) The department may require a facility that engages in
1474 the manufacture, retail sale, or wholesale distribution of
1475 medical gas to undergo an inspection in accordance with a
1476 schedule to be determined by the department, including
1477 inspections for initial permitting, permit renewal, and a
1478 permitholder's change of location. The department may recognize
1479 a third party to inspect wholesale distributors in this state or

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1480 other states pursuant to a schedule to be determined by the
1481 department.

1482 (2) The department may recognize another state's
1483 inspections of a manufacturer or wholesale distributor located
1484 in that state if such state's laws are deemed to be
1485 substantially equivalent to the laws of this state by the
1486 department.

1487 (3) A manufacturing facility of medical gases is exempt
1488 from routine inspection by the department if:

1489 (a) The manufacturing facility is currently registered with
1490 the United States Food and Drug Administration under s. 510 of
1491 the federal act and can provide proof of registration, such as a
1492 copy of the Internet verification page; and

1493 (b) The manufacturing facility can provide proof of
1494 inspection by the Food and Drug Administration, or if the
1495 facility is located in another state, inspection by the Food and
1496 Drug Administration or other governmental entity charged with
1497 regulation of good manufacturing practices related to medical
1498 gases in that state within the past 3 years, which demonstrates
1499 substantial compliance with current good manufacturing practices
1500 applicable to medical gases.

1501 (4) A permitholder under this part shall exhibit or have
1502 readily available its state permits and its most recent
1503 inspection report administered by the department.

1504 Section 30. Section 499.931, Florida Statutes, is created
1505 to read:

1506 499.931 Trade secret information.—Information required to
1507 be submitted under this part which is a trade secret as defined
1508 in s. 812.081(1)(c) and designated as a trade secret by an

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1509 applicant or permitholder must be maintained as required under
1510 s. 499.051.

1511 Section 31. Section 499.94, Florida Statutes, is created to
1512 read:

1513 499.94 Fees.—A fee collected for a permit under this part
1514 shall be deposited into the Professional Regulation Trust Fund.
1515 Moneys collected under this part shall be used for administering
1516 this part. The department shall maintain a separate account in
1517 the trust fund for the Drugs, Devices, and Cosmetics program.

1518 Section 32. Paragraph (a) of subsection (1) of section
1519 409.9201, Florida Statutes, is amended to read:

1520 409.9201 Medicaid fraud.—

1521 (1) As used in this section, the term:

1522 (a) "Prescription drug" means any drug, including, but not
1523 limited to, finished dosage forms or active ingredients that are
1524 subject to, defined in ~~by~~, or described in ~~by~~ s. 503(b) of the
1525 Federal Food, Drug, and Cosmetic Act or in ~~by~~ s. 465.003(8), s.
1526 499.003(52), s. 499.003(46) or (53) or s. 499.007(13), or s.
1527 499.82(10).

1528
1529 The value of individual items of the legend drugs or goods or
1530 services involved in distinct transactions committed during a
1531 single scheme or course of conduct, whether involving a single
1532 person or several persons, may be aggregated when determining
1533 the punishment for the offense.

1534 Section 33. Paragraph (c) of subsection (9) of section
1535 460.403, Florida Statutes, is amended to read:

1536 460.403 Definitions.—As used in this chapter, the term:

1537 (9)

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1538 (c)1. Chiropractic physicians may adjust, manipulate, or
1539 treat the human body by manual, mechanical, electrical, or
1540 natural methods; by the use of physical means or physiotherapy,
1541 including light, heat, water, or exercise; by the use of
1542 acupuncture; or by the administration of foods, food
1543 concentrates, food extracts, and items for which a prescription
1544 is not required and may apply first aid and hygiene, but
1545 chiropractic physicians are expressly prohibited from
1546 prescribing or administering to any person any legend drug
1547 except as authorized under subparagraph 2., from performing any
1548 surgery except as stated herein, or from practicing obstetrics.

1549 2. Notwithstanding the prohibition against prescribing and
1550 administering legend drugs under subparagraph 1. or s.
1551 499.83(2)(c) ~~s. 499.01(2)(m)~~, pursuant to board rule
1552 chiropractic physicians may order, store, and administer, for
1553 emergency purposes only at the chiropractic physician's office
1554 or place of business, prescription medical oxygen and may also
1555 order, store, and administer the following topical anesthetics
1556 in aerosol form:

1557 a. Any solution consisting of 25 percent ethylchloride and
1558 75 percent dichlorodifluoromethane.

1559 b. Any solution consisting of 15 percent
1560 dichlorodifluoromethane and 85 percent
1561 trichloromonofluoromethane.

1562
1563 However, this paragraph does not authorize a chiropractic
1564 physician to prescribe medical oxygen as defined in chapter 499.

1565 Section 34. Subsection (3) of section 465.0265, Florida
1566 Statutes, is amended to read:

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1567 465.0265 Centralized prescription filling.—

1568 (3) The filling, delivery, and return of a prescription by
1569 one pharmacy for another pursuant to this section shall not be
1570 construed as the filling of a transferred prescription as
1571 described set forth in s. 465.026 or as a wholesale distribution
1572 as defined set forth in s. 499.003 ~~s. 499.003(54)~~.

1573 Section 35. Paragraph (b) of subsection (2) of section
1574 499.01212, Florida Statutes, is amended to read:

1575 499.01212 Pedigree paper.—

1576 (2) FORMAT.—A pedigree paper must contain the following
1577 information:

1578 (b) For all other wholesale distributions of prescription
1579 drugs:

1580 1. The quantity, dosage form, and strength of the
1581 prescription drugs.

1582 2. The lot numbers of the prescription drugs.

1583 3. The name and address of each owner of the prescription
1584 drug and his or her signature.

1585 4. Shipping information, including the name and address of
1586 each person certifying delivery or receipt of the prescription
1587 drug.

1588 5. An invoice number, a shipping document number, or
1589 another number uniquely identifying the transaction.

1590 6. A certification that the recipient wholesale distributor
1591 has authenticated the pedigree papers.

1592 7. The unique serialization of the prescription drug, if
1593 the manufacturer or repackager has uniquely serialized the
1594 individual prescription drug unit.

1595 8. The name, address, telephone number, and, if available,

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1596 e-mail contact information of each wholesale distributor
1597 involved in the chain of the prescription drug's custody.

1598
1599 When an affiliated group member obtains title to a prescription
1600 drug before distributing the prescription drug as the
1601 manufacturer as defined in s. 499.003(30) (e) ~~under s.~~
1602 ~~499.003(31) (e)~~, information regarding the distribution between
1603 those affiliated group members may be omitted from a pedigree
1604 paper required under this paragraph for subsequent distributions
1605 of that prescription drug.

1606 Section 36. Paragraph (a) of subsection (1) and subsection
1607 (3) of section 499.015, Florida Statutes, are amended to read:

1608 499.015 Registration of drugs, devices, and cosmetics;
1609 issuance of certificates of free sale.-

1610 (1) (a) Except for those persons exempted from the
1611 definition of manufacturer in s. 499.003 ~~s. 499.003(31)~~, any
1612 person who manufactures, packages, repackages, labels, or
1613 relabels a drug, device, or cosmetic in this state must register
1614 such drug, device, or cosmetic biennially with the department;
1615 pay a fee in accordance with the fee schedule provided by s.
1616 499.041; and comply with this section. The registrant must list
1617 each separate and distinct drug, device, or cosmetic at the time
1618 of registration.

1619 (3) Except for those persons exempted from the definition
1620 of manufacturer in s. 499.003 ~~s. 499.003(31)~~, a person may not
1621 sell any product that he or she has failed to register in
1622 conformity with this section. Such failure to register subjects
1623 such drug, device, or cosmetic product to seizure and
1624 condemnation as provided in s. 499.062, and subjects such person

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1625 to the penalties and remedies provided in this part.

1626 Section 37. Subsection (3) of section 499.024, Florida
1627 Statutes, is amended to read:

1628 499.024 Drug product classification.—The department shall
1629 adopt rules to classify drug products intended for use by humans
1630 which the United States Food and Drug Administration has not
1631 classified in the federal act or the Code of Federal
1632 Regulations.

1633 (3) Any product that falls under the definition of drug in
1634 s. 499.003 ~~s. 499.003(19)~~ may be classified under the authority
1635 of this section. This section does not subject portable
1636 emergency oxygen inhalators to classification; however, this
1637 section does not exempt any person from ss. 499.01 and 499.015.

1638 Section 38. This act shall take effect October 1, 2014.