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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/01/2014	.	
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The Committee on Health Policy (Bean) recommended the following:

Senate Amendment to Amendment (181392)

Delete lines 789 - 1402
and insert:
otherwise authorized under this chapter.

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



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12 state.

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

16 2. A permitted medical gas manufacturer may not distribute
17 a medical gas without obtaining the applicable permit, except
18 that it may engage in wholesale distribution of medical gases
19 that it manufactured without obtaining a medical gas wholesale
20 distributor permit if it complies with this part and the rules
21 adopted under this part that apply to a wholesale distributor.

22 3. A permitted medical gas manufacturer shall comply with
23 all of the requirements applicable to a wholesale distributor
24 under this part and all appropriate state and federal good
25 manufacturing practices.

26 (c) *Medical oxygen retail establishment permit.*—A medical
27 oxygen retail establishment permit is required for an entity
28 that is located in the state and that dispenses medical oxygen
29 directly to patients in this state. The sale and delivery must
30 be based on a prescription or an order from a practitioner
31 authorized by law to prescribe. A pharmacy licensed under
32 chapter 465 does not require a permit as a medical oxygen retail
33 establishment.

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

37 2. A medical oxygen retail establishment may fill and
38 deliver medical oxygen to an individual patient based on an
39 order from a practitioner authorized by law to prescribe. The
40 medical oxygen retail establishment must comply with all



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41 appropriate state and federal good manufacturing practices.
42 Medical oxygen sold or delivered by a medical oxygen retail
43 establishment pursuant to an order from a practitioner may not
44 be returned into the retail establishment's inventory.

45 3. A medical oxygen retail establishment shall comply with
46 all of the requirements applicable to a wholesale distributor
47 under this part, except for those requirements that pertain
48 solely to nitrous oxide.

49 (3) An out-of-state wholesale distributor that engages in
50 wholesale distribution into this state must be legally
51 authorized to engage in the wholesale distribution of medical
52 gases as a wholesale distributor in the state in which it
53 resides or is incorporated and provide proof of registration as
54 set forth in s. 499.93(3), if required.

55 (4) A wholesale distributor may not operate from a place of
56 residence, and a place of residence may not be granted a permit
57 or operate under this part, except for the on-call delivery of
58 home care oxygen for wholesale distributors that also maintain a
59 medical oxygen retail establishment permit.

60 (5) If wholesale distribution is conducted at more than one
61 location within this state or more than one location
62 distributing into this state, each location must be permitted by
63 the department.

64 Section 16. Section 499.831, Florida Statutes, is created
65 to read:

66 499.831 Permit application.—

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



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

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

75 (a) The trade or business name of the applicant, including
76 a fictitious name, which may not be identical to a name used by
77 an unrelated entity permitted in this state to dispense or
78 distribute medical gas.

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

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

84 2. If the applicant is a sole proprietorship, the business
85 address of the sole proprietor and the name and federal employer
86 identification number of the business entity.

87 3. If the applicant is a partnership, the name, business
88 address, date of birth of each partner, the name of the
89 partnership, and the partnership's federal employer
90 identification number.

91 4. If the applicant is a limited liability company, the
92 name, business address, and title of each company officer, the
93 name of the limited liability company and federal employer
94 identification number, and the name of the state in which the
95 limited liability company was organized.

96 5. If the applicant is a corporation, the name, business
97 address, and title of each corporate officer and director, the
98 corporate names, the state of incorporation, the federal



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99 employer identification number, and, if applicable, the name and
100 business address of the parent company.

101 (c) A list of disciplinary actions pertinent to wholesale
102 distributors, manufacturers, and retailers of prescription drugs
103 or controlled substances by a state or federal agency against
104 the applicant seeking to distribute into this state and any such
105 disciplinary actions against such applicant's principals,
106 owners, directors, or officers.

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

109 (e) An address and description of each facility and
110 warehouse, including all locations used for medical gas storage
111 or wholesale distribution including a description of each
112 facility's security system.

113 (4) An applicant shall attest in writing that the
114 information contained in its application is complete and
115 accurate.

116 (5) An applicant must submit a reasonable fee, to be
117 determined by the department, in order to obtain a permit.

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

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

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

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

127 Section 17. Section 499.832, Florida Statutes, is created



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128 to read:

129 499.832 Expiration and renewal of a permit.—

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

133 (2) A permit issued under this part may be renewed by
134 submitting an application for renewal on a form furnished by the
135 department and paying the appropriate fee. The application for
136 renewal must contain a statement by the applicant attesting that
137 the information is true and correct. Upon approval of a renewal
138 application by the department and payment of the required
139 renewal fee, the department shall renew a permit issued under
140 this part pursuant to the rules adopted under this part.

141 (3) A renewal application may be accepted up to 60 days
142 after the expiration date of the permit if, along with the
143 permit renewal fee, the applicant submits an additional renewal
144 delinquent fee of \$100. A permit that expired more than 60 days
145 before a renewal application was submitted or postmarked may not
146 be renewed.

147 (4) Failure to renew a permit in accordance with this
148 section precludes future renewal. If a permit has expired and
149 cannot be renewed, the person, entity, or establishment holding
150 the permit must cease all permit related activities. In order to
151 engage in activities that require a permit the person, entity,
152 or establishment must submit an application for a new permit,
153 pay the applicable application fee, the initial permit fee, and
154 all applicable penalties, and be issued a new permit by the
155 department before engaging in an activity that requires a permit
156 under this part.



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157 (5) The department shall adopt rules to administer this
158 section, including setting a reasonable fee for a renewal
159 application.

160 Section 18. Section 499.833, Florida Statutes, is created
161 to read:

162 499.833 Permitholder changes.—

163 (1) A permit issued under this part is valid only for the
164 person or entity to which it is issued and is not subject to
165 sale, assignment, or other transfer, voluntarily or
166 involuntarily.

167 (2) A permit issued under this part is not valid for an
168 establishment other than the establishment for which it was
169 originally issued.

170 (3) The department may approve the following permit
171 changes:

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

176 (b) Change in ownership.—If a majority of the ownership or
177 controlling interest of a permitted establishment is transferred
178 or assigned or if a lessee agrees to undertake or provide
179 services such that legal liability for operation of the
180 establishment will rest with the lessee, an application for a
181 new permit is required. Such application must be submitted and
182 approved by the department before the change of ownership takes
183 place. However, if a permitted wholesale distributor or
184 manufacturer is changing ownership and the new owner has held
185 another permit that allows the wholesale distribution of medical



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186 gas under this chapter for the preceding 18 months without
187 having been found in violation of the provisions of this chapter
188 relating to medical gases, then the new owner may operate under
189 the permit of the acquired entity if the new owner submits the
190 application for a new permit by the first business day after
191 ownership is transferred or assigned. A new owner operating
192 under the original permit is responsible for compliance with all
193 laws and regulations governing medical gas. If the application
194 is denied, the new owner shall immediately cease operation at
195 the establishment until a permit is issued to the new owner.

196 (c) *Change of name.*—A permitholder may make a change of
197 business name without submitting a new permit application.
198 However, the permitholder must notify the department before
199 making the name change.

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

- 203 1. Return the permit to the department; and
204 2. Indicate the disposition of any medical gas authorized
205 to be distributed or dispensed under the permit, including the
206 name, address, and inventory, and provide the name and address
207 of a person to contact regarding access to the records that are
208 required to be maintained under this part. Transfer of ownership
209 of medical gas may be made only to persons authorized to receive
210 medical gas pursuant to this part.

211 (e) *Change in information.*—Any change in the information
212 required under this part, other than the changes in paragraphs
213 (a)-(d), shall be submitted to the department within 30 days
214 after such change occurs.



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215 (4) A permitholder in good standing may change the type of
216 permit issued by completing a new application for the requested
217 permit, meeting the applicable permitting requirements for the
218 new permit type, and paying any difference between the permit
219 fees. A refund may not be issued if the fee for the new permit
220 is less than the fee that was paid for the original permit. The
221 new permit retains the expiration date of the original permit.

222 Section 19. Section 499.834, Florida Statutes, is created
223 to read:

224 499.834 Minimum qualifications.—The department shall
225 consider all of the following factors in determining eligibility
226 for, and renewal of, a permit for a person or entity under this
227 part:

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

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

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

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

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

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



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244 (7) Compliance with the requirements that distributors or
245 retailers of medical gases maintain records and make records
246 available to the department licensing authority or federal,
247 state, or local law enforcement officials.

248 (8) Other factors or qualifications the department
249 considers relevant to and consistent with the public health and
250 safety.

251 Section 20. Section 499.84, Florida Statutes, is created to
252 read:

253 499.84 Minimum requirements for the storage and handling of
254 medical gases.-

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

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

262 (b) Be of suitable size and construction to facilitate
263 cleaning, maintenance, and proper permitted operations;

264 (c) Have adequate storage areas with appropriate lighting,
265 ventilation, space, equipment, and security conditions.

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

269 (e) Be maintained in an orderly condition;

270 (f) Be located in a commercial location and not in a
271 personal dwelling or residence location, except that a personal
272 dwelling location used for on-call delivery of oxygen USP for



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273 homecare use if the person providing on-call delivery is
274 employed by or acting under a written contract with an entity
275 that holds a medical oxygen retailer permit;

276 (g) Provide for the secure and confidential storage of
277 patient information, if applicable, with restricted access and
278 policies and procedures to protect the integrity and
279 confidentiality of patient information; and

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

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

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

288 Section 21. Section 499.85, Florida Statutes, is created to
289 read:

290 499.85 Security.-

291 (1) A permitholder that has a facility used for the
292 distribution or retailing of medical gases shall protect such
293 gases from unauthorized access by implementing all of the
294 following security measures:

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

297 (b) Ensuring the outside perimeter of the premises is well
298 lit.

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

301 (d) Equipping all facilities with a fence or other system



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302 to detect or deter entry after hours.

303 (2) A facility used for distributing or retailing medical
304 gases shall be equipped with a system that provides suitable
305 protection against theft, including if appropriate, protection
306 against theft of computers or electronic records and the
307 protection of the integrity and confidentiality of data and
308 documents.

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

313 (4) If a wholesale distributor uses electronic distribution
314 records, the wholesale distributor shall employ, train, and
315 document the training of personnel in the proper use of such
316 technology and equipment.

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

321 (6) The department shall adopt rules that govern the
322 distribution of medical oxygen for emergency use by persons
323 authorized to receive emergency use oxygen. Unless the laws of
324 this state specifically direct otherwise, such rules must be
325 consistent with federal regulations, including the labeling
326 requirements of oxygen under the federal act.

327 Section 22. Section 499.86, Florida Statutes, is created to
328 read:

329 499.86 Examination of materials.-

330 (1) A wholesale distributor must visually examine a medical



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331 gas container upon receipt from the manufacturer in order to
332 identify the medical gas stored within and to determine if the
333 container has been damaged or is otherwise unfit for
334 distribution. Such examination must occur in a manner that would
335 reveal damage to the container which could suggest possible
336 adulteration or misbranding.

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

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

345 (4) A wholesale distributor must review records documenting
346 the acquisition of medical gas upon receipt for accuracy and
347 completeness.

348 Section 23. Section 499.87, Florida Statutes, is created to
349 read:

350 499.87 Returned, damaged, and outdated medical gas.—

351 (1) A medical gas that has left the control of the
352 wholesale distributor may be returned to the wholesale
353 distributor or manufacturer from which it was acquired, but may
354 not be resold as a medical gas unless it is reprocessed by a
355 manufacturer using proper and adequate controls to ensure the
356 identity, strength, quality, and purity of the reprocessed
357 medical gas.

358 (2) A medical gas that has been subjected to improper
359 conditions, such as a fire, accident, or natural disaster, may



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360 not be salvaged or reprocessed.

361 (3) A medical gas, including its container, which is
362 damaged, misbranded, or adulterated must be quarantined from
363 other medical gases until it is destroyed or returned to the
364 manufacturer or wholesale distributor from which it was
365 acquired. External contamination of a medical gas container or
366 closure system which does not impact the integrity of the
367 medical gas is not considered damaged or adulterated for
368 purposes of this subsection. If a medical gas is adulterated or
369 misbranded or suspected of being adulterated or misbranded,
370 notice shall be provided to the manufacturer or wholesale
371 distributor from which the medical gas was acquired and to the
372 appropriate boards and federal regulatory bodies.

373 (4) A medical gas container that has been opened or used
374 but is not adulterated or misbranded is considered empty and
375 must be quarantined from nonempty medical gas containers and
376 returned to the manufacturer or wholesale distributor from which
377 it was acquired for destruction or reprocessing.

378 (5) A medical gas, its container, or its associated
379 documentation or labeling that is suspected of being used in
380 criminal activity must be retained until its disposition is
381 authorized by the department or an applicable law enforcement
382 agency.

383 Section 24. Section 499.88, Florida Statutes, is created to
384 read:

385 499.88 Due diligence.—

386 (1) A wholesale distributor shall obtain, before the
387 initial acquisition of medical gas, the following information
388 from the supplying wholesale distributor or manufacturer:



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389 (a) If a manufacturer is distributing to a wholesale
390 distributor, evidence that the manufacturer is registered and
391 the medical gas is listed with the United States Food and Drug
392 Administration;

393 (b) If a wholesale distributor is distributing to a
394 wholesale distributor, evidence that the wholesale distributor
395 supplying the medical gas is legally authorized to distribute
396 medical gas within or into the state;

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

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

401 (2) A wholesale distributor is exempt from obtaining the
402 information from a manufacturer, as required under subsection
403 (1), if the manufacturer is registered with the United States
404 Food and Drug Administration in accordance with s. 510 of the
405 federal act and the manufacturer provides:

406 (a) Proof of such registration; and

407 (b) Proof of inspection by the United States Food and Drug
408 Administration or other regulatory body within the past 3 years
409 demonstrating substantial compliance with current good
410 manufacturing practices applicable to medical gases.

411 (3) A manufacturer or wholesale distributor that
412 distributes to or acquires medical gas from another wholesale
413 distributor shall provide to or obtain from the distributing or
414 acquiring manufacturer or distributor the information required
415 by s. 499.89(1), as applicable.

416 Section 25. Section 499.89, Florida Statutes, is created to
417 read:



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418 499.89 Recordkeeping.-

419 (1) A permitholder under this part shall establish and
420 maintain a record of transactions regarding the receipt and the
421 distribution, or other disposition, of medical gases, as
422 applicable. Such records constitute an audit trail and must
423 contain information sufficient to perform a recall of medical
424 gas in compliance with 21 C.F.R. s. 211.196 and 21 C.F.R. s.
425 820.160(b). Such records must include all of the following
426 information, which may be kept in two separate documents one
427 related to the distribution of medical gas and the other related
428 to the receipt of medical gas:

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

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

434 (c) The name, address, license or permit number and its
435 expiration date for the person or entity receiving the medical
436 gas, if different from the information required under paragraph
437 (b).

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

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

443 (a) Three years following the distribution date of high
444 pressure medical gases.

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



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447 (3) Records kept at the inspection site or that can be
448 immediately retrieved by computer or other electronic means
449 shall be readily available for authorized inspection during the
450 retention period. Records kept at a central location apart from
451 the inspection site and not electronically retrievable shall be
452 made available for inspection within 2 working days of a request
453 by an authorized official of any state or federal governmental
454 agency charged with enforcement of these rules.

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

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

461 Section 26. Section 499.90, Florida Statutes, is created to
462 read:

463 499.90 Policies and procedures.—A wholesale distributor
464 shall establish, maintain, and adhere to written policies and
465 procedures for the receipt, security, storage, transport,
466 shipping, and distribution of medical gases and shall establish,
467 maintain, and adhere to procedures for maintaining inventories;
468 for identifying, recording, and reporting losses or thefts; and
469 for correcting all errors and inaccuracies in inventories
470 associated with nitrous oxide. A wholesale distributor shall
471 include in its written policies and procedures the following:

472 (1) A procedure for handling recalls and withdrawals of
473 medical gas. Such procedure must deal with recalls and
474 withdrawals due to:

475 (a) Action initiated at the request of the United States



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476 Food and Drug Administration or any federal, state, or local law
477 enforcement or other government agency, including the
478 department; or

479 (b) Voluntary action by a manufacturer of medical gases to
480 remove defective or potentially defective medical gases from the
481 market.

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

487 (3) A procedure for reporting criminal or suspected
488 criminal activity involving the inventory of nitrous oxide to
489 the department and to applicable law enforcement agencies within
490 3 business days after becoming aware of the criminal or
491 suspected criminal activity.

492 Section 27. Section 499.91, Florida Statutes, is created to
493 read:

494 499.91 Prohibited acts.—A person may not perform or cause
495 the performance of, or aid and abet in, any of the following
496 acts:

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

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

501 (3) The receipt of a medical gas that is adulterated,
502 misbranded, stolen, or obtained by fraud or deceit, and the
503 delivery or proffered delivery of such medical gas for pay or
504 otherwise.



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

509 (5) The purchase or receipt of a medical gas from a person
510 not authorized to distribute or dispense medical gas or who is
511 not exempted from permitting requirements to wholesale
512 distribute medical gas to such purchaser or recipient.

513 (6) The knowing and willful sale or transfer of a medical
514 gas to a recipient who is not legally authorized to receive a
515 medical gas, except that a violation does not exist if a
516 permitted wholesale distributor provides oxygen to a permitted
517 medical oxygen retail establishment that is out of compliance
518 with the notice of location change requirements of s. 499.834,
519 provided that the wholesale distributor with knowledge of the
520 violation notifies the department of the transaction by the next
521 business day.

522 (7) The failure to maintain or provide records required
523 under this part and the rules adopted under this part.

524 (8) Providing the department or any of its representatives
525 or any state or federal official with false or fraudulent
526 records or making false or fraudulent statements regarding this
527 part or the rules adopted under this part.

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

529 (a) Purchased by a public or private hospital or other
530 health care entity, except for the physical distribution of such
531 medical gas to an authorized recipient at the direction of a
532 hospital or other health care entity;

533 (b) Donated or supplied at a reduced price to a charitable



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534 organization; or
535 (c) Stolen or obtained by fraud or deceit.
536 (10) The failure to obtain a license or permit or operating
537 without a valid license or permit, if one is required.
538 (11) The obtaining of, or attempt to obtain, a medical gas
539 by fraud, deceit, or misrepresentation or engaging in
540 misrepresentation or fraud in the distribution of a medical gas.
541 (12) Except for emergency use oxygen, the distribution of a
542 medical gas to a patient without a prescription from a
543 practitioner authorized by law to prescribe a medical gas.
544 (13) The distribution or dispensing of a medical gas that
545 was previously dispensed by a pharmacy or a practitioner
546 authorized by law to prescribe.
547 (14) The distribution or dispensing of a medical gas or
548 medical gas-related equipment to a patient, unless the patient
549 has been provided with the appropriate information and
550 counseling on the use, storage, and disposal of the medical gas.
551 (15) Failure to report an act prohibited under this part or
552 the rules adopted under this part.
553 (16) Failure to exercise due diligence as provided in s.
554 499.88.
555 Section 28. Section 499.92, Florida Statutes, is created to
556 read:
557 499.92 Criminal acts.—
558 (1) A person commits a felony of the third degree,
559 punishable as provided in s. 775.082, s. 775.083, or s. 775.084,
560 if he or she:
561 (a) Adulterates or misbrands a medical gas with intent to
562 defraud or deceive;



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563 (b) Knowingly purchases or receives a medical gas from a
564 person not legally authorized to distribute or dispense medical
565 gas;

566 (c) Knowingly engages in the wholesale distribution of, or
567 sells, barter, brokers, or transfers, a medical gas to a person
568 not legally authorized to purchase or receive medical gas in the
569 jurisdiction in which the person receives the medical gas. A
570 permitted wholesale distributor that, at its location, provides
571 oxygen to a permitted medical oxygen retail establishment that
572 is out of compliance with only the change of location notice
573 requirement under s. 499.834, does not commit a violation of
574 this subsection if the wholesale distributor notifies the
575 department of the transaction no later than the next business
576 day; or

577 (d) Knowingly falsely creates a label for a medical gas or
578 knowingly falsely misrepresents a factual matter contained in a
579 label for a medical gas.

580 (2) A person found guilty of an offense under this section,
581 under the authority of the court convicting and sentencing the
582 person, shall be ordered to forfeit to the state any real or
583 personal property:

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

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

589 (3) Property or assets subject to forfeiture under
590 subsection (2) may be seized pursuant to a warrant obtained in
591 the same manner as a search warrant or as otherwise authorized



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592 by law, and held until the case against a defendant is
593 adjudicated. Monies ordered forfeited, or proceeds from the sale
594 of other assets ordered forfeited, shall be equitably divided
595 between the department and other agencies involved in the
596 investigation and prosecution that led to the conviction. Other
597 property ordered forfeited after conviction of a defendant may,
598 at the discretion of the investigating agencies, be placed into
599 official use by the department or the agencies involved in the
600 investigation and prosecution that led to the conviction.

601 Section 29. Section 499.93, Florida Statutes, is created to
602 read:

603 499.93 Inspections.—

604 (1) The department may require a facility that engages in
605 the manufacture, retail sale, or wholesale distribution of
606 medical gas to undergo an inspection in accordance with a
607 schedule to be determined by the department, including
608 inspections for initial permitting, permit renewal, and a
609 permitholder's change of location. The department may recognize
610 a third party to inspect wholesale distributors in this state or
611 other states pursuant to a schedule to be determined by the
612 department.

613 (2) The department may recognize another state's
614 inspections of a manufacturer or wholesale distributor located
615 in that state if such state's laws are deemed to be
616 substantially equivalent to the laws of this state by the
617 department.

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