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LEGISLATIVE ACTION

Senate

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House

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Senator Bean moved the following:

Senate Amendment

Delete lines 795 - 1447

and insert:

(b) Sales, purchases, trades, transfers, or use of a medical gas acquired by a medical director or licensed emergency medical services provider for use by the emergency medical services provider and its permitted transport and nontransport vehicles in accordance with the provider's license under part III of chapter 401.

(c) The provision of emergency supplies of medical gases to



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12 nursing homes during the hours of the day when necessary medical
13 gases cannot normally be obtained from the nursing home's
14 regular distributors.

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

17 (5) "Emergency use oxygen" means oxygen USP administered in
18 emergency situations without a prescription for oxygen
19 deficiency and resuscitation. The container must be labeled in
20 accordance with requirements of the United States Food and Drug
21 Administration.

22 (6) "Federal act" means the Federal Food, Drug, and
23 Cosmetic Act.

24 (7) "Medical gas" means a liquefied or vaporized gas that
25 is a prescription drug, whether alone or in combination with
26 other gases, and as defined in the federal act.

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

32 (9) "Misbranded" means having a label that is false or
33 misleading; a label without the name and address of the
34 manufacturer, packer, or distributor and without an accurate
35 statement of the quantities of active ingredients; or a label
36 without an accurate monograph for the medical gas, except in the
37 case of mixtures of designated medical gases where the label
38 identifies the component percentages of each designated medical
39 gas used to make the mixture.

40 (10) "Medical oxygen" means oxygen USP which must be



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41 labeled in compliance with labeling requirements for oxygen
42 under the federal act.

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

48 (12) "USP" means the United States Pharmacopeia.

49 (13) "USP-NF" means the United States Pharmacopeia-National
50 Formulary.

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

53 Wholesale distribution of medical gases does not include:

54 (a) The sale, purchase, or trade of a medical gas; an offer
55 to sell, purchase, or trade a medical gas; or the dispensing of
56 a medical gas pursuant to a prescription;

57 (b) Activities exempt from the definition of wholesale
58 distribution in s. 499.003;

59 (c) The sale, purchase, or trade of a medical gas or an
60 offer to sell, purchase, or trade a medical gas for emergency
61 medical reasons; or

62 (d) Other transactions excluded from the definition of
63 wholesale distribution under the federal act or regulations
64 implemented under the federal act related to medical gas.

65 (15) "Wholesale distributor" means any person or entity
66 engaged in wholesale distribution of medical gas within or into
67 this state, including, but not limited to, manufacturers; own-
68 label distributors; private-label distributors; warehouses,
69 including manufacturers' and distributors' warehouses; and



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70 wholesale medical gas warehouses.

71 Section 15. Section 499.83, Florida Statutes, is created to
72 read:

73 499.83 Permits.-

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

77 (a) A medical gas wholesale distributor;

78 (b) A medical gas manufacturer; or

79 (c) A medical oxygen retail establishment.

80 (2) The following permits are established:

81 (a) Medical gas wholesale distributor permit.-A medical gas
82 wholesale distributor permit is required for wholesale
83 distribution, whether within or into this state. A medical gas
84 must remain in the original container obtained by the wholesale
85 distributor and the wholesale distributor may not engage in
86 further manufacturing operations unless it possesses a medical
87 gas manufacturer permit. A medical gas wholesale distributor may
88 not possess or engage in the wholesale distribution of a
89 prescription drug that is not a medical gas or distribute a
90 medical gas other than by wholesale distribution unless
91 otherwise authorized under this chapter.

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



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

102 2. A permitted medical gas manufacturer may not distribute
103 a medical gas without obtaining the applicable permit, except
104 that it may engage in wholesale distribution of medical gases
105 that it manufactured without obtaining a medical gas wholesale
106 distributor permit if it complies with this part and the rules
107 adopted under this part that apply to a wholesale distributor.

108 3. A permitted medical gas manufacturer shall comply with
109 all of the requirements applicable to a wholesale distributor
110 under this part and all appropriate state and federal good
111 manufacturing practices.

112 (c) Medical oxygen retail establishment permit.—A medical
113 oxygen retail establishment permit is required for an entity
114 that is located in the state and that sells or delivers medical
115 oxygen directly to patients in this state. The sale and delivery
116 must be based on a prescription or an order from a practitioner
117 authorized by law to prescribe. A pharmacy licensed under
118 chapter 465 does not require a permit as a medical oxygen retail
119 establishment.

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

123 2. A medical oxygen retail establishment may fill and
124 deliver medical oxygen to an individual patient based on an
125 order from a practitioner authorized by law to prescribe. The
126 medical oxygen retail establishment must comply with all
127 appropriate state and federal good manufacturing practices.



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128 Medical oxygen sold or delivered by a medical oxygen retail
129 establishment pursuant to an order from a practitioner may not
130 be returned into the retail establishment's inventory.

131 3. A medical oxygen retail establishment shall comply with
132 all of the requirements applicable to a wholesale distributor
133 under this part, except for those requirements that pertain
134 solely to nitrous oxide.

135 (3) An out-of-state wholesale distributor that engages in
136 wholesale distribution into this state must be legally
137 authorized to engage in the wholesale distribution of medical
138 gases as a wholesale distributor in the state in which it
139 resides and provide proof of registration as set forth in s.
140 499.93(3), if required.

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

146 (5) If wholesale distribution is conducted at more than one
147 location within this state or more than one location
148 distributing into this state, each location must be permitted by
149 the department.

150 Section 16. Section 499.831, Florida Statutes, is created
151 to read:

152 499.831 Permit application.-

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

156 (2) An applicant must be at least 18 years of age or be



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157 managed, controlled, or overseen, directly or indirectly, by a
158 natural person who is at least 18 years of age.

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

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

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

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

170 2. If the applicant is a sole proprietorship, the business
171 address of the sole proprietor and the name and federal employer
172 identification number of the business entity.

173 3. If the applicant is a partnership, the name, business
174 address, date of birth of each partner, the name of the
175 partnership, and the partnership's federal employer
176 identification number.

177 4. If the applicant is a limited liability company, the
178 name, business address, and title of each company officer, the
179 name of the limited liability company and federal employer
180 identification number, and the name of the state in which the
181 limited liability company was organized.

182 5. If the applicant is a corporation, the name, business
183 address, and title of each corporate officer and director, the
184 corporate names, the state of incorporation, the federal
185 employer identification number, and, if applicable, the name and



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186 business address of the parent company.

187 (c) A list of disciplinary actions pertinent to wholesale
188 distributors, manufacturers, and retailers of prescription drugs
189 or controlled substances by a state or federal agency against
190 the applicant seeking to distribute into this state and any such
191 disciplinary actions against such applicant's principals,
192 owners, directors, or officers.

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

195 (e) An address and description of each facility and
196 warehouse, including all locations used for medical gas storage
197 or wholesale distribution including a description of each
198 facility's security system.

199 (4) An applicant shall attest in writing that the
200 information contained in its application is complete and
201 accurate.

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

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

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

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

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

213 Section 17. Section 499.832, Florida Statutes, is created
214 to read:



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215 499.832 Expiration and renewal of a permit.-

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

219 (2) A permit issued under this part may be renewed by
220 submitting an application for renewal on a form furnished by the
221 department and paying the appropriate fee. The application for
222 renewal must contain a statement by the applicant attesting that
223 the information is true and correct. Upon approval of a renewal
224 application by the department and payment of the required
225 renewal fee, the department shall renew a permit issued under
226 this part pursuant to the rules adopted under this part.

227 (3) A renewal application may be accepted up to 60 days
228 after the expiration date of the permit if, along with the
229 permit renewal fee, the applicant submits an additional renewal
230 delinquent fee of \$100. A permit that expired more than 60 days
231 before a renewal application was submitted or postmarked may not
232 be renewed.

233 (4) Failure to renew a permit in accordance with this
234 section precludes future renewal. If a permit has expired and
235 cannot be renewed, the person, entity, or establishment holding
236 the permit must cease all permit related activities. In order to
237 engage in such activities, the person, entity, or establishment
238 must submit an application for a new permit, pay the applicable
239 application fee, the initial permit fee, and all applicable
240 penalties, and be issued a new permit by the department before
241 engaging in an activity that requires a permit under this part.

242 (5) The department shall adopt rules to administer this
243 section, including setting a reasonable fee for a renewal



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244 application.

245 Section 18. Section 499.833, Florida Statutes, is created
246 to read:

247 499.833 Permitholder changes.—

248 (1) A permit issued under this part is valid only for the
249 person or entity to which it is issued and is not subject to
250 sale, assignment, or other transfer, voluntarily or
251 involuntarily.

252 (2) A permit issued under this part is not valid for an
253 establishment other than the establishment for which it was
254 originally issued.

255 (3) The department may approve the following permit
256 changes:

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

261 (b) Change in ownership.—If a majority of the ownership or
262 controlling interest of a permitted establishment is transferred
263 or assigned or if a lessee agrees to undertake or provide
264 services such that legal liability for operation of the
265 establishment will rest with the lessee, an application for a
266 new permit is required. Such application must be submitted and
267 approved by the department before the change of ownership takes
268 place. However, if a permitted wholesale distributor or
269 manufacturer is changing ownership and the new owner has held
270 another permit that allows the wholesale distribution of medical
271 gas under this chapter for the preceding 18 months without
272 having been found in violation of the provisions of this chapter



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273 relating to medical gases, then the new owner may operate under
274 the permit of the acquired entity if the new owner submits the
275 application for a new permit by the first business day after
276 ownership is transferred or assigned. A new owner operating
277 under the original permit is responsible for compliance with all
278 laws and regulations governing medical gas. If the application
279 is denied, the new owner shall immediately cease operation at
280 the establishment until a permit is issued to the new owner.

281 (c) *Change of name.*—A permitholder may make a change of
282 business name without submitting a new permit application.
283 However, the permitholder must notify the department before
284 making the name change.

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

- 288 1. Return the permit to the department; and
289 2. Indicate the disposition of any medical gas authorized
290 to be distributed or dispensed under the permit, including the
291 name, address, and inventory, and provide the name and address
292 of a person to contact regarding access to the records that are
293 required to be maintained under this part. Transfer of ownership
294 of medical gas may be made only to persons authorized to receive
295 medical gas pursuant to this part.

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

300 (4) A permitholder in good standing may change the type of
301 permit issued by completing a new application for the requested



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302 permit, meeting the applicable permitting requirements for the
303 new permit type, and paying any difference between the permit
304 fees. A refund may not be issued if the fee for the new permit
305 is less than the fee that was paid for the original permit. The
306 new permit retains the expiration date of the original permit.

307 Section 19. Section 499.834, Florida Statutes, is created
308 to read:

309 499.834 Minimum qualifications.—The department shall
310 consider all of the following factors in determining eligibility
311 for, and renewal of, a permit for a person or entity under this
312 part:

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

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

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

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

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

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

329 (7) Compliance with the requirements that distributors or
330 retailers of medical gases maintain records and make records



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331 available to the department licensing authority or federal,
332 state, or local law enforcement officials.

333 (8) Other factors or qualifications the department has
334 established in rule that are relevant to and consistent with the
335 public health and safety.

336 Section 20. Section 499.84, Florida Statutes, is created to
337 read:

338 499.84 Minimum requirements for the storage and handling of
339 medical gases.—

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

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

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

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

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

354 (e) Be maintained in an orderly condition;

355 (f) Be located in a commercial location and not in a
356 personal dwelling or residence location, except that a personal
357 dwelling location used for on-call delivery of oxygen USP for
358 homecare use if the person providing on-call delivery is
359 employed by or acting under a written contract with an entity



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360 that holds a medical oxygen retailer permit;

361 (g) Provide for the secure and confidential storage of
362 patient information, if applicable, with restricted access and
363 policies and procedures to protect the integrity and
364 confidentiality of patient information; and

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

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

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

373 Section 21. Section 499.85, Florida Statutes, is created to
374 read:

375 499.85 Security.-

376 (1) A permitholder that has a facility used for the
377 distribution or retailing of medical gases shall protect such
378 gases from unauthorized access by implementing all of the
379 following security measures:

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

382 (b) Ensuring the outside perimeter of the premises is well
383 lit.

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

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

388 (2) A facility used for distributing or retailing medical



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389 gases shall be equipped with a system that provides suitable
390 protection against theft, including if appropriate, protection
391 against theft of computers or electronic records and the
392 protection of the integrity and confidentiality of data and
393 documents.

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

398 (4) If a wholesale distributor uses electronic distribution
399 records, the wholesale distributor shall employ, train, and
400 document the training of personnel in the proper use of such
401 technology and equipment.

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

406 (6) The department shall adopt rules that govern the
407 distribution of medical oxygen for emergency use by persons
408 authorized to receive emergency use oxygen. Unless the laws of
409 this state specifically direct otherwise, such rules must be
410 consistent with federal regulations, including the labeling
411 requirements of oxygen under the federal act. Such rules may not
412 be inconsistent with part III of chapter 401 or rules adopted
413 thereunder.

414 Section 22. Section 499.86, Florida Statutes, is created to
415 read:

416 499.86 Examination of materials.-

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



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418 gas container upon receipt from the manufacturer in order to
419 identify the medical gas stored within and to determine if the
420 container has been damaged or is otherwise unfit for
421 distribution. Such examination must occur in a manner that would
422 reveal damage to the container which could suggest possible
423 adulteration or misbranding.

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

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

432 (4) A wholesale distributor must review records documenting
433 the acquisition of medical gas upon receipt for accuracy and
434 completeness.

435 Section 23. Section 499.87, Florida Statutes, is created to
436 read:

437 499.87 Returned, damaged, and outdated medical gas.—

438 (1) A medical gas that has left the control of the
439 wholesale distributor may be returned to the wholesale
440 distributor or manufacturer from which it was acquired, but may
441 not be resold as a medical gas unless it is reprocessed by a
442 manufacturer using proper and adequate controls to ensure the
443 identity, strength, quality, and purity of the reprocessed
444 medical gas.

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



447 not be salvaged or reprocessed.

448 (3) A medical gas, including its container, which is
449 damaged, misbranded, or adulterated must be quarantined from
450 other medical gases until it is destroyed or returned to the
451 manufacturer or wholesale distributor from which it was
452 acquired. External contamination of a medical gas container or
453 closure system which does not impact the integrity of the
454 medical gas is not considered damaged or adulterated for
455 purposes of this subsection. If a medical gas is adulterated or
456 misbranded or suspected of being adulterated or misbranded,
457 notice shall be provided to the manufacturer or wholesale
458 distributor from which the medical gas was acquired and to the
459 appropriate boards and federal regulatory bodies.

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

465 (5) A medical gas, its container, or its associated
466 documentation or labeling that is suspected of being used in
467 criminal activity must be retained until its disposition is
468 authorized by the department or an applicable law enforcement
469 agency.

470 Section 24. Section 499.88, Florida Statutes, is created to
471 read:

472 499.88 Due diligence.—

473 (1) A wholesale distributor shall obtain, before the
474 initial acquisition of medical gas, the following information
475 from the supplying wholesale distributor or manufacturer:



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476 (a) If a manufacturer is distributing to a wholesale
477 distributor, evidence that the manufacturer is registered and
478 the medical gas is listed with the United States Food and Drug
479 Administration;

480 (b) If a wholesale distributor is distributing to a
481 wholesale distributor, evidence that the wholesale distributor
482 supplying the medical gas is legally authorized to distribute
483 medical gas within or into the state;

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

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

488 (2) A wholesale distributor is exempt from obtaining the
489 information from a manufacturer, as required under subsection
490 (1), if the manufacturer is registered with the United States
491 Food and Drug Administration in accordance with s. 510 of the
492 federal act and the manufacturer provides:

493 (a) Proof of such registration; and

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

498 (3) A manufacturer or wholesale distributor that
499 distributes to or acquires medical gas from another wholesale
500 distributor shall provide to or obtain from the distributing or
501 acquiring manufacturer or distributor the information required
502 by s. 499.89(1), as applicable.

503 Section 25. Section 499.89, Florida Statutes, is created to
504 read:



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505 499.89 Recordkeeping.-

506 (1) A permitholder under this part shall establish and
507 maintain a record of transactions regarding the receipt and the
508 distribution, or other disposition, of medical gases, as
509 applicable. Such records constitute an audit trail and must
510 contain information sufficient to perform a recall of medical
511 gas in compliance with 21 C.F.R. s. 211.196 and 21 C.F.R. s.
512 820.160(b). Such records must include all of the following
513 information, which may be kept in two separate documents one
514 related to the distribution of medical gas and the other related
515 to the receipt of medical gas:

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

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

521 (c) The name, address, license or permit number and its
522 expiration date for the person or entity receiving the medical
523 gas, if different from the information required under paragraph
524 (b).

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

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

530 (a) Three years following the distribution date of high
531 pressure medical gases.

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



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534 (3) Records kept at the inspection site or that can be
535 immediately retrieved by computer or other electronic means
536 shall be readily available for authorized inspection during the
537 retention period. Records kept at a central location apart from
538 the inspection site and not electronically retrievable shall be
539 made available for inspection within 2 working days of a request
540 by an authorized official of any state or federal governmental
541 agency charged with enforcement of these rules.

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

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

548 Section 26. Section 499.90, Florida Statutes, is created to
549 read:

550 499.90 Policies and procedures.—A wholesale distributor
551 shall establish, maintain, and adhere to written policies and
552 procedures for the receipt, security, storage, transport,
553 shipping, and distribution of medical gases and shall establish,
554 maintain, and adhere to procedures for maintaining inventories;
555 for identifying, recording, and reporting losses or thefts; and
556 for correcting all errors and inaccuracies in inventories
557 associated with nitrous oxide. A wholesale distributor shall
558 include in its written policies and procedures all of the
559 following:

560 (1) A procedure for handling recalls and withdrawals of
561 medical gas. Such procedure must deal with recalls and
562 withdrawals due to:



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563 (a) Action initiated at the request of the United States
564 Food and Drug Administration or any federal, state, or local law
565 enforcement or other government agency, including the
566 department; or

567 (b) Voluntary action by a manufacturer of medical gases to
568 remove defective or potentially defective medical gases from the
569 market.

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

575 (3) A procedure for reporting criminal or suspected
576 criminal activity involving the inventory of nitrous oxide to
577 the department and to applicable law enforcement agencies within
578 3 business days after becoming aware of the criminal or
579 suspected criminal activity.

580 Section 27. Section 499.91, Florida Statutes, is created to
581 read:

582 499.91 Prohibited acts.—A person may not perform or cause
583 the performance of, or aid and abet in, any of the following
584 acts:

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

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

589 (3) The receipt of a medical gas that is adulterated,
590 misbranded, stolen, or obtained by fraud or deceit, and the
591 delivery or proffered delivery of such medical gas for pay or



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592 otherwise.

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

597 (5) The purchase or receipt of a medical gas from a person
598 not authorized to distribute or dispense medical gas or who is
599 not exempted from permitting requirements to wholesale
600 distribute medical gas to such purchaser or recipient.

601 (6) The knowing and willful sale or transfer of a medical
602 gas to a recipient who is not legally authorized to receive a
603 medical gas, except that a violation does not exist if a
604 permitted wholesale distributor provides oxygen to a permitted
605 medical oxygen retail establishment that is out of compliance
606 with the notice of location change requirements of s. 499.834,
607 provided that the wholesale distributor with knowledge of the
608 violation notifies the department of the transaction by the next
609 business day.

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

612 (8) Providing the department or any of its representatives
613 or any state or federal official with false or fraudulent
614 records or making false or fraudulent statements regarding this
615 part or the rules adopted under this part.

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

617 (a) Purchased by a public or private hospital or other
618 health care entity, except for the physical distribution of such
619 medical gas to an authorized recipient at the direction of a
620 hospital or other health care entity;



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621 (b) Donated or supplied at a reduced price to a charitable
622 organization; or
623 (c) Stolen or obtained by fraud or deceit.
624 (10) The failure to obtain a license or permit or operating
625 without a valid license or permit, if one is required.
626 (11) The obtaining of, or attempt to obtain, a medical gas
627 by fraud, deceit, or misrepresentation or engaging in
628 misrepresentation or fraud in the distribution of a medical gas.
629 (12) Except for emergency use oxygen, the distribution of a
630 medical gas to a patient without a prescription from a
631 practitioner authorized by law to prescribe a medical gas.
632 (13) The distribution or dispensing of a medical gas that
633 was previously dispensed by a pharmacy or a practitioner
634 authorized by law to prescribe.
635 (14) The distribution or dispensing of a medical gas or
636 medical gas-related equipment to a patient, unless the patient
637 has been provided with the appropriate information and
638 counseling on the use, storage, and disposal of the medical gas.
639 (15) Failure to report an act prohibited under this part or
640 the rules adopted under this part.
641 (16) Failure to exercise due diligence as provided in s.
642 499.88.
643 Section 28. Section 499.92, Florida Statutes, is created to
644 read:
645 499.92 Criminal acts.-
646 (1) A person commits a felony of the third degree,
647 punishable as provided in s. 775.082, s. 775.083, or s. 775.084,
648 if he or she:
649 (a) Adulterates or misbrands a medical gas with intent to



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650 defraud or deceive;

651 (b) Knowingly purchases or receives a medical gas from a
652 person not legally authorized to distribute or dispense medical
653 gas;

654 (c) Knowingly engages in the wholesale distribution of, or
655 sells, barterers, brokers, or transfers, a medical gas to a person
656 not legally authorized to purchase or receive medical gas in the
657 jurisdiction in which the person receives the medical gas. A
658 permitted wholesale distributor that provides oxygen to a
659 permitted medical oxygen retail establishment that is out of
660 compliance with only the change of location notice requirement
661 under s. 499.834, does not commit a violation of this paragraph
662 if the wholesale distributor notifies the department of the
663 transaction no later than the next business day; or

664 (d) Knowingly falsely creates a label for a medical gas or
665 knowingly misrepresents a factual matter contained in a