By Senator Bean

	4-00674-14 2014836
1	A bill to be entitled
2	An act relating to medical gas; creating part III of
3	ch. 499, F.S., entitled "Medical Gas"; creating s.
4	499.81, F.S.; defining terms; creating s. 499.82,
5	F.S.; requiring a person or establishment located
6	inside or outside the state which intends to
7	distribute medical gas within or into this state to
8	obtain an applicable permit before operating; listing
9	the people or entities that are legally authorized to
10	receive medical gas; establishing categories of
11	permits and setting requirements for each; creating s.
12	499.821, F.S.; requiring the Department of Business
13	and Professional Regulation to establish the form and
14	content of an application; stating that an applicant
15	who is denied a permit has a right of review pursuant
16	to ch. 120, F.S.; requiring the department to ensure
17	that information obtained during the application
18	process identified as trade secret is maintained and
19	remains confidential; authorizing the department to
20	set fees within certain parameters; creating s.
21	499.822, F.S.; requiring a permit to expire 2 years
22	after the last day of the month in which the permit
23	was issued; providing requirements for the renewal of
24	a permit; requiring the department to adopt rules for
25	the renewal of permits; creating s. 499.823, F.S.;
26	authorizing the department to consider certain factors
27	in determining the eligibility of an applicant;
28	creating s. 499.824, F.S.; authorizing the department
29	to approve certain permitholder changes; authorizing

# Page 1 of 69

4-00674-14 2014836 30 the department to revoke the permit of a person that 31 fails to comply with this section; creating s. 499.83, 32 F.S.; requiring an applicant for or a holder of a permit as a wholesale distributor of medical gas or as 33 34 a medical oxygen retailer to designate a registered 35 agent; 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.; requiring a wholesale 38 distributor of medical gas to implement measures to 39 secure the location from unauthorized entry; setting 40 facility requirements for security purposes; 41 authorizing a vehicle used for on-call delivery of 42 oxygen USP and oxygen-related equipment to be parked at a place of residence; requiring the department to 43 44 adopt rules governing the wholesale distribution of prescription medical oxygen; creating s. 499.86, F.S.; 45 46 requiring a wholesale distributor of medical gases to 47 visually examine an immediate container upon receipt for identity and to determine if the medical gas 48 49 container has been damaged or is otherwise unfit for 50 distribution; requiring a medical gas container that 51 is damaged or otherwise unfit for distribution to be 52 quarantined; requiring outgoing shipments to be inspected; requiring wholesale distributors to review 53 54 certain records; creating s. 499.87, F.S.; authorizing the return of medical gas that has left the control of 55 56 the wholesale distributor; requiring that medical gas 57 that is damaged, misbranded, or adulterated be 58 quarantined from other medical gases until it is

#### Page 2 of 69

	4-00674-14 2014836
59	destroyed or returned to the manufacturer or wholesale
60	distributor from which it was acquired; creating s.
61	499.88, F.S.; requiring a wholesale distributor to
62	obtain certain information before the initial
63	acquisition of the medical gas; providing certain
64	exemptions; creating s. 499.89, F.S.; requiring a
65	wholesale distributor to establish and maintain
66	transactional records; providing a retention period
67	for certain records and requiring that the records be
68	available for inspection during that period; creating
69	s. 499.90, F.S.; requiring a wholesale distributor to
70	establish, maintain, and adhere to certain written
71	policies and procedures; creating s. 499.91, F.S.;
72	prohibiting certain acts; creating s. 499.92, F.S.;
73	establishing criminal penalties; authorizing property
74	or assets subject to forfeiture to be seized pursuant
75	to a warrant; creating s. 499.93, F.S.; authorizing
76	the department to require a facility that engages in
77	wholesale distribution to undergo an inspection;
78	authorizing the department to authorize a third party
79	to inspect wholesale distributors; requiring the
80	department to ensure that information obtained during
81	the inspection process identified as trade secret is
82	maintained and remains confidential; creating s.
83	499.94, F.S.; requiring fees collected pursuant to
84	this part to be deposited into the Professional
85	Regulation Trust Fund; creating s. 499.95, F.S.;
86	authorizing the department for the purpose of
87	initiating an investigation or proceeding under this

# Page 3 of 69

	4-00674-14 2014836
88	 part to administer oaths, take depositions, issue and
89	serve subpoenas, and compel attendance of witnesses
90	and the production of books, papers, documents or
91	other evidence; requiring an attorney to whom the
92	department reports a violation of this part to timely
93	institute proceedings in the court of competent
94	jurisdiction; exempting minor violations from
95	reporting requirements at the department's discretion;
96	providing that this part is cumulative and does not
97	repeal or affect the power, duty, or authority of the
98	department; amending ss. 409.9201, 460.403, 465.0265;
99	conforming provisions to changes made by the act;
100	amending s. 499.001, F.S.; conforming a provision to
101	changes made by the act; amending s. 499.003, F.S.;
102	conforming terminology, deleting a definition, and
103	defining the term "medical gas"; amending ss. 499.01
104	and 499.0121, F.S.; conforming provisions to changes
105	made by the act; amending s. 499.01211, F.S.; changing
106	the membership of the Drug Wholesale Distributor
107	Advisory Council; requiring the Compressed Gas
108	Association to appoint one person to the council;
109	amending ss. 499.01212, 499.015, 499.024, 499.041,
110	499.05, 499.051, 499.066, 499.0661, and 499.067, F.S.;
111	conforming provisions to changes made by the act;
112	providing an effective date.
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114	Be It Enacted by the Legislature of the State of Florida:
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116	Section 1. Part III of chapter 499, Florida Statutes,

# Page 4 of 69

	4-00674-14 2014836
117	consisting of ss. 499.81-499.95, Florida Statutes, is created
118	and is entitled "Medical Gas."
119	Section 2. Section 499.81, Florida Statutes, is created to
120	read:
121	499.81 DefinitionsAs used in this part, the term:
122	(1) "Adulterated" with respect to medical gas means medical
123	gas that:
124	(a) Consists, in whole or in part, of impurities or
125	deleterious substances that exceed normal specifications;
126	(b) Has been produced, prepared, packed, or held under
127	conditions whereby the gas may have been contaminated, causing
128	it to be rendered injurious to health; or was manufactured,
129	processed, packed, or held using methods, facilities, or
130	controls that do not conform to or are not operated or
131	administered in conformity with current good manufacturing
132	practices;
133	(c) Has a container interior that is composed, in whole or
134	in part, of a poisonous or deleterious substance that may render
135	the container contents injurious to health; or
136	(d) Has a strength that differs from, or that is of a
137	quality or purity that fails to meet, the standards established
138	in the USP-NF, if the gas is purported to be, or is represented
139	as, medical gas as recognized in the USP-NF. Such a
140	determination as to strength, quality, or purity must be made in
141	accordance with the tests or methods of assay set forth in the
142	USP-NF or a validated equivalent, or, in the absence or
143	inadequacy of these tests or methods of assay, those prescribed
144	under the authority of the federal act shall be used. However, a
145	gas that is purported to be, or is represented as, medical gas

# Page 5 of 69

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SB 836

	4-00674-14 2014836
146	as recognized in the USP-NF but that differs in strength,
147	quality, or purity from the standards established in the USP-NF
148	may not be deemed adulterated for purposes of this paragraph if
149	the difference is plainly stated on its label.
150	(2) "Department" means the Department of Business and
151	Professional Regulation.
152	(3) "Distribute" or "distribution" means to sell or offer
153	to sell, deliver or offer to deliver, broker, give away, or
154	transfer medical gas, by passage of title or by physical
155	movement. The term does not include:
156	(a) Dispensing or administering medical gas;
157	(b) Delivering or offering to deliver medical gas by a
158	common carrier in its usual course of business; or
159	(c) A sales activity that takes place in an establishment
160	that is owned or controlled by a person or business entity
161	authorized to distribute medical gas within or into this state
162	or staffed by persons employed by such person, if the location
163	where the sales activity takes place does not physically store
164	or transport medical gas.
165	(4) "Emergency use oxygen" means oxygen USP that is
166	administered without a prescription for an emergency situation
167	concerning oxygen deficiency or resuscitation and that is in a
168	container labeled in accordance with FDA standards.
169	(5) "FDA" means the federal Food and Drug Administration.
170	(6) "Federal act" means the federal Food, Drug, and
171	Cosmetic Act, 21 U.S.C. ss. 301 et seq.
172	(7) "Health care entity" means a person, including an
173	organization business entity, which provides diagnostic,
174	medical, surgical, or dental treatment or rehabilitative care.
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# Page 6 of 69

175The term includes a home respiratory care provider or a person176or entity authorized to administer emergency use oxygen, but177does not include a retail pharmacy or wholesale distributor.178(8) "Immediate container" means a compressed gas cylinder179or liquid container that contains medical gas. The term does not180include a large-bulk liquid or high pressure container, such asa storage tank, vehicle-mounted vessel, trailer, or railcar.182(9) "Intracompany transaction" means a transaction between183divisions, subsidiaries, parents, or affiliated or relatedcompanies under the common ownership and control of a singlecorporate entity.186(10) "Label" means a display of a written, printed, orgraphic matter upon an immediate container. The term does notinclude the letters, numbers, or symbols stamped onto acontainer as required by the United States Department ofTransportation.191(11) "Manufacturer" means a person or entity thatmanufactures medical gas in bulk or that transfers the gas orliquefied gas product from one container to another.(12) "Medical gas" is defined in accordance with thefederal act and means a liquefied or vaporized gas that is aprescription drug, regardless of whether it is alone or combinedwith other gases.(13) "Medical gas-related equipment" means a device used asan accessory or component part to contain or control flow,delivery, or pressure during the administration of medical gas.		4-00674-14 2014836
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199 an accessory or component part to contain or control flow,	197	with other gases.
	198	(13) "Medical gas-related equipment" means a device used as
200 delivery, or pressure during the administration of medical gas,	199	an accessory or component part to contain or control flow,
	200	delivery, or pressure during the administration of medical gas,
201 such as liquid-oxygen base and portable units, pressure	201	such as liquid-oxygen base and portable units, pressure
202 regulators, flow meters, and oxygen concentrators.	202	regulators, flow meters, and oxygen concentrators.
203 (14) "Misbranded" means medical gas that has a label that	203	(14) "Misbranded" means medical gas that has a label that

# Page 7 of 69

	4-00674-14 2014836
204	is false or misleading or a label that does not:
205	(a) Display the name and address of the manufacturer,
206	packer, or distributor;
207	(b) Provide an accurate statement of the quantity of active
208	ingredients or show an accurate monograph for the medical gas;
209	or
210	(c) In the case of mixtures of designated medical gases,
211	identify the component percentages of each designated medical
212	gas used to make the mixture.
213	(15) "Prescription medical oxygen" means oxygen USP, a drug
214	that may be sold only by the order or prescription of a licensed
215	practitioner authorized by law to prescribe.
216	(16) "USP-NF" or "USP" means the standards published in the
217	official book, "The United States Pharmacopeia and the National
218	Formulary."
219	(17) "Wholesale distribution" means the distribution of
220	medical gas by a wholesale distributor of medical gas to a
221	person other than a consumer or patient. The term does not
222	include:
223	(a) The sale, purchase, or trade of a medical gas, an offer
224	to sell, purchase, or trade a prescription drug or device, or
225	the dispensing of medical gas pursuant to a prescription;
226	(b) The sale, purchase, or trade of a medical gas or an
227	offer to sell, purchase, or trade medical gas for an emergency
228	medical reason that includes, but is not limited to:
229	1. A transfer of a medical gas between wholesale
230	distributors or between a wholesale distributor and a retail
231	pharmacy or health care entity to alleviate a temporary shortage
232	of medical gas resulting from a delay in or an interruption of a
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# Page 8 of 69

	4-00674-14 2014836
233	regular distribution schedule;
234	2. Sales to a licensed emergency medical service provider,
235	such as an ambulance company, a firefighting organization, or a
236	licensed practitioner authorized to prescribe medical gases;
237	3. Provision of minimal emergency supplies of medical gas
238	to a nursing home for use in an emergency or during the hours of
239	the day when necessary medical gas cannot be obtained; or
240	4. Transfers of medical gases to alleviate a temporary
241	shortage between retail pharmacies;
242	(c) An intracompany transaction;
243	(d) The sale, purchase, or trade of medical gas or an offer
244	to sell, purchase, or trade medical gas among hospitals,
245	pharmacies, or other health care entities that are under common
246	<pre>control;</pre>
247	(e) The sale, purchase, or trade of medical gas, or the
248	offer to sell, purchase, or trade medical gas by a charitable
249	organization that has been granted an exemption under s.
250	501(c)(3) of the Internal Revenue Code to a nonprofit affiliate
251	of the organization, to the extent otherwise permitted by law;
252	(f) The purchase or other acquisition of medical gas by a
253	hospital or other similar health care entity that is a member of
254	a group purchasing organization, for the hospital's or the
255	health care entity's own use, from the group purchasing
256	organization or from another hospital or similar health care
257	entity that is a member of such organization;
258	(g) The return of residual medical gas that may be
259	reprocessed in accordance with the manufacturer's procedures or
260	the return of recalled, expired, damaged, or otherwise
261	nonsalable medical gas, when returned by a hospital, health care

# Page 9 of 69

CODING: Words stricken are deletions; words underlined are additions.

SB 836

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	287	without a prescription, locations with automated external
289 to be used with such machines, or companies that need medical	288	defibrillation machines where emergency use oxygen is intended
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290 gas in the installation and refurbishment of piping and	290	gas in the installation and refurbishment of piping and

# Page 10 of 69

	4-00674-14 2014836
291	equipment used to contain or administer medical gas.
292	(3) An applicant who is a natural person must be at least
293	18 years of age or an applicant must be managed, controlled, or
294	overseen, directly or indirectly, by a natural person who is at
295	least 18 years of age.
296	(4) An out-of-state wholesale distributor that provides
297	services in this state must be legally authorized as a wholesale
298	distributor in the state in which it resides or is incorporated.
299	(5) A wholesale distributor may not operate from a place of
300	residence, and a place of residence may not be granted a permit
301	or operate under this part, except for the on-call delivery of
302	home care oxygen by a home respiratory care technician.
303	(6) If wholesale distribution is conducted at more than one
304	location within this state or more than one location
305	distributing into this state, each location must be permitted by
306	the department.
307	(7) The following permits are established:
308	(a) Medical gas wholesale distributor permit.—A medical gas
309	wholesale distributor permit is required for wholesale
310	distribution within or into this state.
311	1. Such permit does not authorize distribution to a
312	consumer or patient.
313	2. The medical gas must be in the container that was
314	obtained by that wholesale distributor without further
315	manufacturing operations being performed.
316	3. A wholesale distributor may not possess or engage in the
317	wholesale distribution of any prescription drug other than
318	medical gas.
319	(b) Medical gas manufacturer permitA medical gas
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# Page 11 of 69

	4-00674-14 2014836
320	manufacturer permit is required for a person who engages in the
321	manufacture of medical gas by physical air separation, chemical
322	action, purification, or filling containers using a liquid-to-
323	liquid, liquid-to-gas, or gas-to-gas process and distributes
324	such medical gas within or into this state. A medical gas
325	manufacturer:
326	1. May not manufacture or possess a prescription drug other
327	than medical gas unless the appropriate permit is obtained.
328	2. May engage in the wholesale distribution of medical gas
329	that is manufactured at the permitted establishment without
330	obtaining a medical gas wholesale distributor permit, but shall
331	comply with this part and applicable rules.
332	3. Shall comply with all appropriate state and federal good
333	manufacturing practices.
334	(c) Medical oxygen retail establishment permit.—A medical
335	oxygen retail establishment permit is required for a person who
336	sells prescription medical oxygen directly to patients. Such
337	sales must be based upon an order or prescription from a
338	licensed practitioner authorized by law to prescribe. A pharmacy
339	licensed under chapter 465 is exempt from this paragraph. A
340	medical oxygen retail establishment:
341	1. May not possess, purchase, sell, or trade a prescription
342	drug other than medical oxygen unless other appropriate permits
343	are obtained.
344	2. May refill a prescription medical oxygen container for a
345	patient based on an order or prescription from a licensed
346	practitioner authorized by law to prescribe. A medical oxygen
347	retail establishment that refills prescription medical oxygen
348	shall comply with all appropriate state and federal good
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# Page 12 of 69

	4-00674-14 2014836
349	manufacturing practices.
350	3. Shall comply with the storage and handling requirements
351	<u>under s. 499.84.</u>
352	4. May not receive back into its inventory any prescription
353	medical oxygen that it sold pursuant to a licensed
354	practitioner's order.
355	Section 4. Section 499.821, Florida Statutes, is created to
356	read:
357	499.821 Permit application
358	(1) The department shall establish by rule the form and
359	content of an application to obtain a permit listed under s.
360	<u>499.82.</u>
361	(a) An application for a permit must be filed with the
362	department and must include the following information:
363	1. The trade or business names, including fictitious names,
364	currently and formerly used by the applicant, which may not be
365	identical to a name used by an unrelated wholesale distributor
366	authorized in this state to purchase medical gas.
367	2. The name or names of the owner and operator of the
368	permittee, if not the same person or entity. The application
369	must also include the following if the applicant is:
370	a. An individual: the applicant's business address and date
371	of birth.
372	b. A sole proprietorship: the business address of the sole
373	proprietor and the name and federal employer identification
374	number of the business entity.
375	c. A partnership: the business address and date of birth of
376	each partner and the name and federal employer identification
377	number of the partnership.

# Page 13 of 69

	4-00674-14 2014836
378	d. A limited liability company: the business address and
379	title of each company officer, the name and federal employer
380	identification number of the limited liability company, and the
381	state of incorporation.
382	e. A corporation: the business address and title of each
383	corporate officer and director; the name, state of
384	incorporation, and federal employer identification number of the
385	corporation; and the name and business address of any parent
386	company.
387	3. A list of disciplinary actions pertinent to wholesale
388	distributors of prescription drugs or controlled substances by a
389	state or federal agency against the applicant seeking to
390	distribute into this state and against a principal, owner,
391	director, or officer.
392	4. An address and description of each facility or
393	warehouse, including a description of the security system for
394	any location used for medical gas storage or wholesale
395	distribution.
396	(b) The applicant shall attest in writing that the
397	information contained in the application is complete and
398	accurate, that the applicant has not been convicted of or
399	disciplined for a criminal or prohibited act, and that the
400	application contains complete disclosure of any past criminal
401	convictions or violations of state or federal law relating to
402	medical gases.
403	(2) An applicant that is denied a permit has the right to
404	review of the department's decision pursuant to chapter 120.
405	(3) Information submitted to the department by an applicant
406	for the purposes of this section which the applicant identifies
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# Page 14 of 69

	4-00674-14 2014836
407	as trade secret information as defined under s. 812.081 shall be
408	maintained by the department and remain confidential and exempt
409	from s. 119.07(1) and s. 24(a), Art. I of the State Constitution
410	for as long as the information is retained by the department.
411	(4) An applicant must submit a reasonable fee, to be
412	determined by the department, in order to obtain a permit. The
413	fee for a medical gas wholesale distributor permit may not be
414	less than \$200 or more than \$300 annually. The fee for a medical
415	gas manufacturer permit may not be less than \$400 or more than
416	\$500 annually. The fee for a medical oxygen retail establishment
417	permit may not be less than \$200 or more than \$300 annually.
418	Section 5. Section 499.822, Florida Statutes, is created to
419	read:
420	499.822 Expiration and renewal of a permit
421	(1) A permit issued under this part automatically expires 2
422	years after the last day of the month in which the permit was
423	originally issued unless the permit is suspended or revoked
424	before the automatic expiration date.
425	(2) A permit issued under this part may be renewed by
426	submitting an application for renewal on a form furnished by the
427	department and paying the appropriate fee. The application for
428	renewal must contain a statement by the applicant attesting that
429	the information is true and correct. If a renewal application
430	and renewal fee are submitted and postmarked after the
431	expiration date of the permit, the permit may be renewed only
432	upon payment of a late renewal delinquent fee of \$100, plus the
433	required renewal fee, within 60 days after the expiration date.
434	(3) Failure to renew a permit in accordance with this
435	section precludes future renewal. If a permit has expired and

# Page 15 of 69

	4-00674-14 2014836
436	cannot be renewed, the person or establishment must submit an
437	application for a new permit, pay the applicable application
438	fee, the initial permit fee, and all applicable penalties, and
439	be issued a new permit by the department before engaging in an
440	activity that requires a permit under this part.
441	(4) The department shall adopt rules to administer this
442	section, including setting a reasonable fee for a renewal
443	application.
444	Section 6. Section 499.823, Florida Statutes, is created to
445	read:
446	499.823 Minimum qualificationsThe department may deny an
447	application for a permit or refuse to renew a permit based upon:
448	(1) Whether the applicant has violated, or has been
449	disciplined by a regulatory agency in any state for violating, a
450	federal, state, or local law relating to wholesale distribution;
451	(2) The applicant's criminal convictions;
452	(3) The applicant's past experience in manufacturing or
453	distributing medical gas;
454	(4) Any false or fraudulent material contained in an
455	application;
456	(5) Suspension, sanction, or revocation of a permit
457	currently or previously held by the applicant for violations of
458	a state or federal law relating to medical gas;
459	(6) Compliance with previously granted permit requirements;
460	(7) Compliance with the requirements to maintain or make
461	available to the department or permitting authority or to a
462	federal, state, or local law enforcement official records
463	required to be maintained by a wholesale distributor; and
464	(8) Any other factors or qualifications that the department

# Page 16 of 69

	4-00674-14 2014836
465	considers relevant to and consistent with public health and
466	safety.
467	Section 7. Section 499.824, Florida Statutes, is created to
468	read:
469	499.824 Permitholder changes
470	(1) A permit issued by the department is valid only for the
471	person or entity to which it is issued and is not subject to
472	sale, assignment, or other transfer, voluntarily or
473	involuntarily, and is not valid for an establishment other than
474	the establishment for which it was originally issued, except as
475	provided in this part. The department may approve the following
476	changes, and a person or entity may continue to operate in the
477	following manner:
478	(a) Change of locationA person or entity permitted under
479	this part must notify the department before making a change of
480	location. The department shall set a change-of-location fee not
481	to exceed \$100.
482	(b) Change in ownershipIf a majority of the ownership or
483	controlling interest of a permitted establishment is transferred
484	or assigned or if a lessee agrees to undertake or provide
485	services such that legal liability for operation of the
486	establishment will rest with the lessee, an application for a
487	new permit is required. The application for the new permit must
488	be made before the change of ownership. However, if an applicant
489	is a permitholder or is wholly owned by or wholly owns a
490	permitholder under this part, the application for the new permit
491	must be made by the date of the sale, transfer, assignment, or
492	lease. Between the date of the change of ownership and the date
493	of the application approval or denial by the department, an

# Page 17 of 69

	4-00674-14 2014836
494	applicant may distribute under the permit number of the previous
495	owner.
496	(c) Change of nameA permitholder may make a change of
497	name without submitting a new permit application. The
498	permitholder must notify the department before making a change
499	of name. The permitholder may continue to operate the
500	establishment while the notification is being processed.
501	(d) ClosureIf an establishment permitted under this part
502	closes, the owner must notify the department, in writing, before
503	the effective date of the closure and must:
504	1. Return the permit to the department; and
505	2. If the permittee is authorized to distribute medical
506	gas, indicate the disposition of such medical gas, including the
507	name, address, and inventory, and provide the name and address
508	of a person to contact regarding access to the records that are
509	required to be maintained under this part. Transfer of ownership
510	of medical gas may be made only to persons authorized to receive
511	medical gas pursuant to this part.
512	(2) Notwithstanding paragraph (1)(a), a permitholder in
513	good standing may change the type of permit issued by completing
514	a new application for the requested permit, paying the amount of
515	the difference in the permit fees, and meeting the applicable
516	permitting requirements for the new permit type. A refund may
517	not be issued if the fee for the new permit is less than the fee
518	that was paid for the original permit. The new permit expires on
519	the expiration date of the original permit being changed.
520	(3) The department may revoke a permit for failure to
521	comply with this section.
522	Section 8. Section 499.83 Florida Statutes, is created to
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#### Page 18 of 69

	4-00674-14 2014836
523	read:
524	499.83 Registered agent.—An applicant for or a holder of a
525	permit as a medical gas wholesale distributor or as a medical
526	oxygen retail establishment shall designate a registered agent
527	in this state for purposes of service of process. If an
528	applicant or a permitted wholesale distributor or medical oxygen
529	retailer fails to designate a registered agent, the Secretary of
530	State shall be deemed the true and lawful attorney of the
531	applicant or the permitted wholesale distributor or medical
532	oxygen retailer, and, in such case, the legal processes in any
533	action or proceeding against an applicant or permitted wholesale
534	distributor or medical oxygen retailer which grows out of or
535	arising from wholesale distribution or retail may be served upon
536	the Secretary of State. A copy of the service of process shall
537	be mailed to the applicant or the permitted wholesale
538	distributor or medical oxygen retailer by the department by
539	certified mail, return receipt requested, postage prepaid, at
540	the address of the applicant or the distributor or retailer as
541	designated on the application for a permit in this state.
542	Section 9. Section 499.84, Florida Statutes, is created to
543	read:
544	499.84 Minimum requirements for the storage and handling of
545	medical gas.—
546	(1) A facility that receives, stores, warehouses, handles,
547	holds, offers, markets, displays, or transports medical gas must
548	avoid any negative effect on the identity, strength, quality, or
549	purity of medical gas by:
550	(a) Being constructed in a way that ensures that medical
551	gas is maintained in accordance with its product labeling

# Page 19 of 69

	4-00674-14 2014836
552	recommendations or in compliance with official compendium
553	standards, such as the USP-NF;
554	(b) Being of a suitable size and construction that
555	facilitates cleaning, maintenance, and proper wholesale
556	distribution;
557	(c) Having an adequate storage area with appropriate
558	lighting, ventilation, space, equipment, and security
559	conditions;
560	(d) Having a quarantine area for the storage of medical gas
561	that is suspected of being misbranded, adulterated, or otherwise
562	unfit for distribution;
563	(e) Being maintained in an orderly condition;
564	(f) Being in a commercial location, except if a personal
565	dwelling location is used for the on-call delivery of oxygen USP
566	for home care use and the person providing on-call delivery is
567	employed by or acting under a written contract with a permittee;
568	(g) Providing for the secure storage of patient
569	information, if applicable, by restricting access and
570	implementing policies and procedures that protect the integrity
571	and confidentiality of patient information; and
572	(h) Providing and maintaining appropriate inventory
573	controls in order to detect and document any theft of nitrous
574	<u>oxide.</u>
575	(2) Medical gas must be stored under appropriate conditions
576	in accordance with the manufacturers' recommendations on product
577	labeling and department rules or, in the absence of rules, in
578	accordance with applicable industry standards. Medical gas must
579	be packaged in accordance with official compendium standards,
580	such as the USP-NF.

# Page 20 of 69

	4-00674-14 2014836
581	Section 10. Section 499.85, Florida Statutes, is created to
582	read:
583	499.85 Security
584	(1) A facility that engages in wholesale distribution shall
585	implement measures to secure its facility from unauthorized
586	entry. Such measures must include the following:
587	(a) Access from outside the premises must be well-
588	controlled and kept to a minimum.
589	(b) The outside perimeter of the premises must be well-
590	lighted.
591	(c) Areas in which medical gas is held must be restricted
592	by a fence or other system that detects or deters entry after
593	hours and limits access only to authorized personnel.
594	(2) A facility that engages in wholesale distribution must
595	have:
596	(a) A security system that provides protection against
597	theft and, if appropriate, theft that is enabled or obscured by
598	tampering with computers or electronic records.
599	(b) A security system that protects the integrity and
600	confidentiality of data and documents.
601	(3) If a wholesale distributor uses electronic distribution
602	records, he or she must employ, train, and document the training
603	of personnel for the proper use of the applicable technology and
604	equipment.
605	(4) A vehicle used for on-call delivery of oxygen USP and
606	oxygen-related equipment for home care use by a home care
607	provider may be parked at a place of residence. Such vehicle
608	while unattended must be locked and equipped with an audible
609	alarm.

# Page 21 of 69

	4-00674-14 2014836
610	(5) The department shall adopt rules that govern the
611	wholesale distribution of prescription medical oxygen for
612	emergency use by persons authorized to receive emergency use
613	oxygen. Unless the laws of this state specifically direct
614	otherwise, such rules must be consistent with federal rules and
615	regulations, including the labeling requirements of oxygen under
616	the federal act.
617	Section 11. Section 499.86, Florida Statutes, is created to
618	read:
619	499.86 Examination of materials
620	(1) A wholesale distributor must visually examine an
621	immediate container upon receipt from the manufacturer in order
622	to identify the medical gas and to determine if the container
623	has been damaged or is otherwise unfit for wholesale
624	distribution. Such examination must occur in a manner that would
625	reveal damage to the container which could suggest possible
626	adulteration or misbranding.
627	(2) A medical gas container that is damaged or otherwise
628	unfit pursuant to subsection (1) must be quarantined from the
629	rest of the stock of medical gas until it is determined that the
630	medical gas in question was not misbranded or adulterated.
631	(3) An outgoing shipment must be inspected for identity and
632	to ensure that medical gas containers that have been damaged in
633	storage or held under improper conditions are not delivered.
634	(4) A wholesale distributor must review records documenting
635	the acquisition of medical gas upon receipt for accuracy and
636	completeness.
637	Section 12. Section 499.87, Florida Statutes, is created to
638	read:

# Page 22 of 69

	4-00674-14 2014836
639	499.87 Returned, damaged, and outdated medical gas
640	(1) Medical gas that has left the control of a wholesale
641	distributor may be returned to the manufacturer or wholesale
642	distributor from which it was acquired.
643	(2) Unless medical gas is reprocessed by a manufacturer
644	employing proper and adequate controls to ensure the identity,
645	strength, quality, and purity of the reprocessed medical gas,
646	the gas may not be resold as a medical gas even if its integrity
647	was maintained.
648	(3) Medical gas that has been subjected to improper
649	conditions, such as a fire, accident, or natural disaster, may
650	not be salvaged or reprocessed.
651	(4) Medical gas, including its container, which is damaged,
652	misbranded, or adulterated must be quarantined from other
653	medical gases until it is destroyed or returned to the
654	manufacturer or wholesale distributor from which it was
655	acquired. External contamination to a medical gas container or
656	closure system which does not impact the integrity of the
657	medical gas is not considered damage or adulteration for
658	purposes of this subsection. If medical gas is adulterated or
659	misbranded or suspected of being adulterated or misbranded,
660	notice shall be provided to the manufacturer or wholesale
661	distributor from which the medical gas was acquired and to the
662	appropriate boards and federal regulatory bodies.
663	(5) A medical gas container that has been opened or used
664	but is not adulterated or misbranded is considered empty and
665	must be quarantined from nonempty medical gas containers and
666	returned to the manufacturer or wholesale distributor from which
667	it was acquired for destruction or reprocessing.

# Page 23 of 69

1	4-00674-14 2014836
668	(6) Medical gas, its container, or its associated
669	documentation or labeling that is suspected of being used in
670	criminal activity must be retained until its disposition is
671	authorized by the department or an applicable law enforcement
672	agency.
673	Section 13. Section 499.88, Florida Statutes, is created to
674	read:
675	499.88 Due diligence
676	(1) A wholesale distributor shall obtain, before the
677	initial acquisition of medical gas, the following information
678	from the supplying wholesale distributor or manufacturer:
679	(a) If a manufacturer is distributing to a wholesale
680	distributor, evidence that the manufacturer is registered and
681	the medical gas is listed with the FDA;
682	(b) If a wholesale distributor is distributing to a
683	wholesale distributor, evidence that the wholesale distributor
684	supplying the medical gas is permitted to distribute medical gas
685	within or into the state;
686	(c) The name of the contact person for the supplying
687	manufacturer or wholesale distributor; and
688	(d) Certification that the manufacturer's or wholesale
689	distributor's policies and procedures comply with this part.
690	(2) A wholesale distributor is exempt from obtaining the
691	information from a manufacturer as required under subsection (1)
692	if the manufacturer is registered with the FDA in accordance
693	with s. 510 of the federal act and provides:
694	(a) Proof of such registration; and
695	(b) Proof of inspection within the past 3 years by the FDA
696	or other regulatory body or proof of conformance with industry

# Page 24 of 69

	4-00674-14 2014836
697	standards or guidelines as identified by the department.
698	(3) A manufacturer or wholesale distributor that
699	distributes to or acquires medical gas from another wholesale
700	distributor shall provide to or obtain from the distributing or
701	acquiring manufacturer or distributor the information required
702	by s. 499.89(1), as applicable.
703	Section 14. Section 499.89, Florida Statutes, is created to
704	read:
705	499.89 Recordkeeping
706	(1) A wholesale distributor shall establish and maintain a
707	record of transactions regarding the receipt and the
708	distribution, or other disposition, of medical gases. Such
709	records constitute an audit trail and must contain information
710	sufficient to perform a recall of medical gas in compliance with
711	21 C.F.R. s. 211.196 and 21 C.F.R. s. 820.160(b). Such records
712	must include all the following information, which need not
713	appear in the same document:
714	(a) The dates of receipt and wholesale distribution, or
715	other disposition, of the medical gas.
716	(b) The name, address, permit number, and permit expiration
717	date for the entity purchasing the medical gas from the
718	wholesale distributor.
719	(c) The name, address, permit number, and permit expiration
720	date for the entity receiving the medical gas from the wholesale
721	distributor, if different from the information required under
722	paragraph (b).
723	(d) Information sufficient to perform a recall of all
724	medical gas received or distributed.
725	(2) From the time of their creation, such records shall be

# Page 25 of 69

1	4-00674-14 2014836
726	kept for 3 years for high pressure medical gas and for 1 year
727	for cryogenic or refrigerated liquid medical gas.
728	(3) During the retention period, such records shall be made
729	available for inspection and photocopying by an authorized
730	official of a state, federal, or local governmental agency. If
731	such records are kept at the inspection site or could be
732	immediately retrieved by electronic means, they shall be made
733	readily available for authorized inspection during the retention
734	period. Records kept at a central location apart from the
735	inspection site and not electronically retrievable shall be made
736	available for inspection within 2 business days of a request.
737	(4) A pedigree paper is not required for the wholesale
738	distribution of medical gas.
739	Section 15. Section 499.90, Florida Statutes, is created to
740	read:
741	499.90 Policies and procedures.—A wholesale distributor
742	shall establish, maintain, and adhere to written policies and
743	procedures for the receipt, security, storage, transport,
744	shipping, and wholesale distribution of medical gas and shall
745	establish, maintain, and adhere to procedures for maintaining
746	inventories; for identifying, recording, and reporting losses or
747	thefts; and for correcting all errors and inaccuracies in
748	inventories associated with nitrous oxide. A wholesale
749	distributor shall include in its written policies and procedures
750	the following:
751	(1) A procedure for handling recalls and withdrawals of
752	medical gas. Such procedure must deal with recalls and
753	withdrawals due to:
754	(a) Action initiated at the request of the FDA or any
I	

# Page 26 of 69

	4-00674-14 2014836
755	federal, state, or local law enforcement or other government
756	agency, including the department; or
757	(b) Voluntary action by the manufacturer of medical gas to
758	remove defective or potentially defective medical gases from the
759	market.
760	(2) A procedure preparing for, protecting against, and
761	handling a crisis that affects the security or operation of a
762	facility in the event of a strike, fire, flood, or other natural
763	disaster or other situations of local, state, or national
764	emergency.
765	(3) A procedure for reporting criminal or suspected
766	criminal activity involving the inventory of nitrous oxide to
767	the department and to applicable law enforcement agencies within
768	3 business days after becoming aware of the criminal or
769	suspected criminal activity.
770	Section 16. Section 499.91, Florida Statutes, is created to
771	read:
772	499.91 Prohibited actsA person may not perform or cause
773	the performance of, or aid and abet in, any of the following
774	acts in this state:
775	(1) The manufacture, sale, or delivery, or the holding or
776	offering for sale, of medical gas that is adulterated,
777	misbranded, or has otherwise been rendered unfit for
778	distribution.
779	(2) The adulteration or misbranding of medical gas.
780	(3) The receipt of medical gas that is adulterated,
781	misbranded, stolen, or obtained by fraud or deceit or the
782	delivery or proffered delivery of such medical gas for pay or
783	otherwise.

# Page 27 of 69

	4-00674-14 2014836
784	(4) The alteration, mutilation, destruction, obliteration,
785	or removal of the whole or any part of the product labeling of
786	medical gas or the willful commission of any other act with
787	respect to medical gas that results in it being misbranded.
788	(5) The purchase or receipt of medical gas from a person
789	who is not authorized by permit to distribute wholesale medical
790	gas or who is exempted from permitting requirements to
791	distribute wholesale medical gas to such purchaser or recipient.
792	(6) The knowing and willful sale or transfer of medical gas
793	to a recipient who is not legally authorized to receive medical
794	gas, except for limited distributions of medical oxygen as
795	necessary to protect the health, safety, or welfare of a patient
796	in his or her home.
797	(7) The failure to maintain or provide records required
798	under this part and its implementing regulations.
799	(8) Providing the department or any of its representatives
800	or any state or federal official with false or fraudulent
801	records or making false or fraudulent statements regarding this
802	part and its implementing regulations.
803	(9) The wholesale distribution of medical gas that was:
804	(a) Purchased by a public or private hospital or other
805	health care entity, except for the physical distribution of such
806	medical gas to an authorized recipient at the direction of a
807	hospital or other health care entity;
808	(b) Donated or supplied at a reduced price to a charitable
809	organization; or
810	(c) Stolen or obtained by fraud or deceit.
811	(10) The failure to obtain a permit or operating without a
812	valid permit when a permit is required.

# Page 28 of 69

	4-00674-14 2014836
813	(11) The obtaining of or attempt to obtain medical gas by
814	fraud, deceit, or misrepresentation or engaging in
815	misrepresentation or fraud in the distribution of medical gas.
816	(12) Except for oxygen USP in emergency situations, the
817	distribution of medical gas to a patient without an order or
818	prescription from a licensed practitioner authorized by law to
819	prescribe.
820	(13) The distribution of medical gas that was previously
821	dispensed by a pharmacy or a licensed practitioner authorized by
822	law to prescribe.
823	(14) The distribution of medical gas or medical gas-related
824	equipment to a patient, unless the patient has been provided
825	with the appropriate information and counseling on the use,
826	storage, and disposal of medical gas.
827	(15) The failure to report an act prohibited under this
828	part and its implementing regulations.
829	(16) The failure to exercise due diligence as provided in
830	<u>s. 499.88.</u>
831	Section 17. Section 499.92, Florida Statutes, is created to
832	read:
833	499.92 Criminal acts
834	(1) A person commits a felony of the third degree,
835	punishable as provided in s. 775.082, s. 775.083, or s. 775.084,
836	if he or she:
837	(a) With intent to defraud or deceive adulterates or
838	misbrands medical gas.
839	(b) Engages in the wholesale distribution of, and knowingly
840	purchases or receives, medical gas from a person not legally
841	authorized to distribute medical gas.
I	

# Page 29 of 69

	4-00674-14 2014836
842	(c) Engages in the wholesale distribution of, and knowingly
843	sells, barters, brokers, or transfers, medical gas to a person
844	not legally authorized to purchase medical gas in the
845	jurisdiction in which the person receives the medical gas.
846	(d) Knowingly, falsely creates a label for medical gas or
847	knowingly, falsely represents a factual matter contained in a
848	label for medical gas.
849	(2) A court that has authority over a person who violates
850	this section and that convicts such person shall order him or
851	her to forfeit to the state real or personal property or assets:
852	(a) Used or intended to be used to commit, facilitate, or
853	promote the commission of such violation; and
854	(b) Constituting, derived from, or traceable to the gross
855	proceeds that the defendant obtained as a result of the
856	violation.
857	(3) Property or assets subject to forfeiture under
858	subsection (2) may be seized pursuant to a warrant obtained in
859	the same manner as a search warrant or as otherwise authorized
860	by law and held until the case against the defendant is
861	adjudicated. Moneys ordered to be forfeited or proceeds from the
862	sale of assets ordered to be forfeited shall be equitably
863	divided between the department and agencies involved in the
864	investigation and prosecution that led to the conviction. Other
865	property ordered to be forfeited after conviction of a defendant
866	may, at the discretion of the investigating agencies, be placed
867	into official use by the department or the agencies involved in
868	the investigation and prosecution.
869	Section 18. Section 499.93, Florida Statutes, is created to
870	read:

# Page 30 of 69

	4-00674-14 2014836
871	499.93 Inspections
872	(1) The department may require a facility that engages in
873	the manufacture or wholesale distribution of medical gas to
874	undergo an inspection in accordance with a schedule to be
875	determined by the department.
876	(2) The department may recognize other state inspections of
877	a manufacturer or wholesale distributor in another state if such
878	state's laws are deemed to be substantially equivalent to the
879	laws of this state.
880	(3) A manufacturing facility is exempt from inspection by
881	the department if the facility:
882	(a) Is currently registered with the FDA in accordance with
883	s. 510 of the federal act and can provide proof of such
884	registration, such as a copy of the online verification page;
885	and
886	(b) Can provide proof of inspection within the past 3 years
887	by the FDA or, if the facility is located in another state, by
888	another governmental entity charged with regulation of good
889	manufacturing practices related to medical gas.
890	(4) A wholesale distributor must exhibit or have readily
891	available its state permits and its most recent inspection
892	report administered by the department. The department may
893	authorize a third party to inspect wholesale distributors who
894	distribute within or into this state.
895	(5) The department shall ensure that information obtained
896	during the inspection process which is identified by the
897	establishment being inspected as a trade secret, as defined in
898	s. 812.081, is maintained by the department and remains
899	confidential and exempt from s. 119.07(1) and s. 24(a), Art. I

# Page 31 of 69

	4-00674-14 2014836
900	of the State Constitution for as long as the information is
901	retained by the department.
902	Section 19. Section 499.94, Florida Statutes, is created to
903	read:
904	499.94 FeesA fee collected for a permit under this part
905	shall be deposited into the Professional Regulation Trust Fund.
906	Moneys collected under this part shall be used for administering
907	this part. The department shall maintain a separate account in
908	the trust fund for the Drugs, Devices, and Cosmetics program.
909	Section 20. Section 499.95, Florida Statues, is created to
910	read:
911	499.95 Enforcement and construction of this part
912	(1) For the purpose of initiating an investigation or
913	proceeding under this part, the department may administer oaths,
914	take depositions, issue and serve subpoenas, and compel the
915	attendance of witnesses and the production of books, papers,
916	documents, or other evidence. Challenges to, and enforcement of,
917	a subpoena and an order shall be conducted in accordance with s.
918	120.569.
919	(2) A state, county, or municipal attorney to whom the
920	department or its designated agent reports a violation of this
921	part shall timely institute proceedings in the court of
922	competent jurisdiction and shall prosecute in the manner
923	required by law.
924	(3) The department is not required to report minor
925	violations to a state, county, or municipal attorney if the
926	department determines that the public interest is best served by
927	issuance of a written notice or warning to the violator.
928	(4) This part is cumulative and does not repeal or affect

# Page 32 of 69

	4-00674-14 2014836
929	the power, duty, or authority of the department. However,
930	relating to the regulation of medical gas, if this part
931	conflicts with other law, this part controls.
932	Section 21. Section 499.001, Florida Statutes, is amended
933	to read:
934	499.001 Florida Drug and Cosmetic Act; short title
935	Sections <u>499.001-499.95</u>
936	"Florida Drug and Cosmetic Act."
937	Section 22. Present subsections (11) through (32) and (46)
938	through (55) of section 499.003, Florida Statutes, are amended,
939	and a new subsection (32) is added to that section, to read:
940	499.003 Definitions of terms used in this part.—As used in
941	this part, the term:
942	(11) "Compressed medical gas" means any liquefied or
943	vaporized gas that is a prescription drug, whether it is alone
944	or in combination with other gases.
945	(11) (12) "Contraband prescription drug" means any
946	adulterated drug, <del>as defined in s. 499.006,</del> any counterfeit
947	drug, <del>as defined in this section,</del> and <del>also means</del> any
948	prescription drug for which a pedigree paper does not exist $_{m{ au}}$ or
949	for which the pedigree paper in existence has been forged,
950	counterfeited, falsely created, or contains any altered, false,
951	or misrepresented matter.
952	(12) <del>(13)</del> "Cosmetic" means an article, with the exception of
953	soap, that is:
954	(a) Intended to be rubbed, poured, sprinkled, or sprayed
955	on; introduced into; or otherwise applied to the human body or
956	any part thereof for cleansing, beautifying, promoting
957	attractiveness, or altering the appearance; or

# Page 33 of 69

4-00674-14 2014836 958 (b) Intended for use as a component of any such article. 959 (13) (14) "Counterfeit drug," "counterfeit device," or "counterfeit cosmetic" means a drug, device, or cosmetic which, 960 961 or the container, seal, or labeling of which, without 962 authorization, bears the trademark, trade name, or other 963 identifying mark, imprint, or device, or any likeness thereof, 964 of a drug, device, or cosmetic manufacturer, processor, packer, 965 or distributor other than the person that in fact manufactured, 966 processed, packed, or distributed that drug, device, or cosmetic 967 and which thereby falsely purports or is represented to be the 968 product of, or to have been packed or distributed by, that other 969 drug, device, or cosmetic manufacturer, processor, packer, or 970 distributor. 971 (14) (15) "Department" means the Department of Business and 972 Professional Regulation. 973 (15) (16) "Device" means any instrument, apparatus, 974 implement, machine, contrivance, implant, in vitro reagent, or 975 other similar or related article, including its components, 976 parts, or accessories, which is: 977 (a) Recognized in the current edition of the United States 978 Pharmacopoeia and National Formulary, or any supplement 979 thereof; -980 (b) Intended for use in the diagnosis, cure, mitigation, 981 treatment, therapy, or prevention of disease in humans or other 982 animals; - or 983 (c) Intended to affect the structure or any function of the 984 body of humans or other animals, 985 and that does not achieve any of its principal intended purposes 986

#### Page 34 of 69

CODING: Words stricken are deletions; words underlined are additions.

SB 836

1011

animals;

4-00674-14 2014836 987 through chemical action within or on the body of humans or other 988 animals and which is not dependent upon being metabolized for 989 the achievement of any of its principal intended purposes. 990 (16) (17) "Distribute" or "distribution" means to sell; 991 offer to sell; give away; transfer, whether by passage of title, 992 physical movement, or both; deliver; or offer to deliver. The 993 term does not mean to administer or dispense and does not 994 include the billing and invoicing activities that commonly 995 follow a wholesale distribution transaction. 996 (17) (18) "Drop shipment" means the sale of a prescription 997 drug from a manufacturer to a wholesale distributor, where the 998 wholesale distributor takes title to, but not possession of, the 999 prescription drug, and the manufacturer of the prescription drug 1000 ships the prescription drug directly to a chain pharmacy 1001 warehouse or a person authorized by law to purchase prescription 1002 drugs for the purpose of administering or dispensing the drug, 1003 as defined in s. 465.003. 1004 (18) (19) "Drug" means an article that is: 1005 (a) Recognized in the current edition of the United States 1006 Pharmacopoeia and National Formulary, official Homeopathic 1007 Pharmacopoeia of the United States, or any supplement to any of 1008 those publications; 1009 (b) Intended for use in the diagnosis, cure, mitigation, 1010 treatment, therapy, or prevention of disease in humans or other

1012 (c) Intended to affect the structure or any function of the 1013 body of humans or other animals; or

1014 (d) Intended for use as a component of any article 1015 specified in paragraph (a), paragraph (b), or paragraph (c), and

#### Page 35 of 69

4-00674-14 2014836 1016 includes active pharmaceutical ingredients, but does not include 1017 devices or their nondrug components, parts, or accessories. For 1018 purposes of this paragraph, an "active pharmaceutical 1019 ingredient" includes any substance or mixture of substances 1020 intended, represented, or labeled for use in drug manufacturing 1021 that furnishes or is intended to furnish, in a finished dosage 1022 form, any pharmacological activity or other direct effect in the 1023 diagnosis, cure, mitigation, treatment, therapy, or prevention 1024 of disease in humans or other animals, or to affect the 1025 structure or any function of the body of humans or other 1026 animals. 1027 (19) (20) "Establishment" means a place of business which is

1028 at one general physical location and may extend to one or more 1029 contiguous suites, units, floors, or buildings operated and 1030 controlled exclusively by entities under common operation and 1031 control. Where multiple buildings are under common exclusive 1032 ownership, operation, and control, an intervening thoroughfare 1033 does not affect the contiguous nature of the buildings. For 1034 purposes of permitting, each suite, unit, floor, or building 1035 must be identified in the most recent permit application.

1036(20) (21)"Federal act" means the Federal Food, Drug, and1037Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.

1038 <u>(21) (22)</u> "Freight forwarder" means a person who receives 1039 prescription drugs which are owned by another person and 1040 designated by that person for export, and exports those 1041 prescription drugs.

1042 (22) (23) "Health care entity" means a closed pharmacy or 1043 any person, organization, or business entity that provides 1044 diagnostic, medical, surgical, or dental treatment or care, or

#### Page 36 of 69

	4-00674-14 2014836
1045	chronic or rehabilitative care, but does not include any
1046	wholesale distributor or retail pharmacy licensed under state
1047	law to deal in prescription drugs. However, a blood
1048	establishment is a health care entity that may engage in the
1049	wholesale distribution of prescription drugs under s.
1050	499.01(2)(g)1.c.
1051	<u>(23)</u> (24) "Health care facility" means a health care
1052	facility licensed under chapter 395.
1053	(24) (25) "Hospice" means a corporation licensed under part
1054	IV of chapter 400.
1055	<u>(25)</u> "Hospital" means a facility as defined in s.
1056	395.002 and licensed under chapter 395.
1057	<u>(26)</u> "Immediate container" does not include package
1058	liners.
1059	<u>(27)</u> "Label" means a display of written, printed, or
1060	graphic matter upon the immediate container of any drug, device,
1061	or cosmetic. A requirement made by or under authority of this
1062	part or rules adopted under this part that any word, statement,
1063	or other information appear on the label is not complied with
1064	unless such word, statement, or other information also appears
1065	on the outside container or wrapper, if any, of the retail
1066	package of such drug, device, or cosmetic or is easily legible
1067	through the outside container or wrapper.
1068	(28) <del>(29)</del> "Labeling" means all labels and other written,
1069	printed, or graphic matters:
1070	(a) Upon a drug, device, or cosmetic, or any of its
1071	containers or wrappers; or
1072	(b) Accompanying or related to such drug, device, or
1073	cosmetic.

# Page 37 of 69

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4-00674-14 2014836 1074 (29) (30) "Manufacture" means the preparation, deriving, 1075 compounding, propagation, processing, producing, or fabrication 1076 of any drug, device, or cosmetic. 1077 (30) (31) "Manufacturer" means: 1078 (a) A person who prepares, derives, manufactures, or 1079 produces a drug, device, or cosmetic; 1080 (b) The holder or holders of a New Drug Application (NDA), 1081 an Abbreviated New Drug Application (ANDA), a Biologics License 1082 Application (BLA), or a New Animal Drug Application (NADA), 1083 provided such application has become effective or is otherwise 1084 approved consistent with s. 499.023; 1085 (c) A private label distributor for whom the private label 1086 distributor's prescription drugs are originally manufactured and 1087 labeled for the distributor and have not been repackaged; 1088 (d) A person registered under the federal act as a manufacturer of a prescription drug, who is described in 1089 1090 paragraph (a), paragraph (b), or paragraph (c), who has entered 1091 into a written agreement with another prescription drug 1092 manufacturer that authorizes either manufacturer to distribute 1093 the prescription drug identified in the agreement as the 1094 manufacturer of that drug consistent with the federal act and 1095 its implementing regulations; 1096 (e) A member of an affiliated group that includes, but is 1097 not limited to, persons described in paragraph (a), paragraph 1098 (b), paragraph (c), or paragraph (d), which member distributes 1099 prescription drugs, whether or not obtaining title to the drugs, only for the manufacturer of the drugs who is also a member of 1100 1101 the affiliated group. As used in this paragraph, the term "affiliated group" means an affiliated group as defined in s. 1102

### Page 38 of 69

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4-00674-14 2014836 1103 1504 of the Internal Revenue Code of 1986, as amended. The manufacturer must disclose the names of all of its affiliated 1104 1105 group members to the department; or (f) A person permitted as a third party logistics provider, 1106 1107 only while providing warehousing, distribution, or other 1108 logistics services on behalf of a person described in paragraph 1109 (a), paragraph (b), paragraph (c), paragraph (d), or paragraph 1110 (e). 1111 The term does not include a pharmacy that is operating in 1112 1113 compliance with pharmacy practice standards as defined in 1114 chapter 465 and rules adopted under that chapter. 1115 (31) (32) "Medical convenience kit" means packages or units 1116 that contain combination products as defined in 21 C.F.R. s. 1117 3.2(e)(2). (32) "Medical gas" is defined in accordance with the 1118 1119 federal act and means a liquefied or vaporized gas that is a 1120 prescription drug, regardless of whether it is alone or combined 1121 with other gases. 1122 (46) "Prescription medical oxygen" means oxygen USP which is a drug that can only be sold on the order or prescription of 1123 1124 a practitioner authorized by law to prescribe. The label of prescription medical oxygen must comply with current labeling 1125 1126 requirements for oxygen under the Federal Food, Drug, and Cosmetic Act. 1127 1128 (47) "Primary wholesale distributor" means any wholesale 1129 distributor that: 1130 (a) Purchased 90 percent or more of the total dollar volume 1131 of its purchases of prescription drugs directly from

### Page 39 of 69

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4-00674-14 2014836 1132 manufacturers in the previous year; and 1133 (b)1. Directly purchased prescription drugs from not fewer 1134 than 50 different prescription drug manufacturers in the 1135 previous year; or 1136 2. Has, or the affiliated group, as defined in s. 1504 of 1137 the Internal Revenue Code, of which the wholesale distributor is a member has, not fewer than 250 employees. 1138 1139 (c) For purposes of this subsection, "directly from manufacturers" means: 1140 1141 1. Purchases made by the wholesale distributor directly 1142 from the manufacturer of prescription drugs; and 1143 2. Transfers from a member of an affiliated group, as 1144 defined in s. 1504 of the Internal Revenue Code, of which the wholesale distributor is a member, if: 1145 1146 a. The affiliated group purchases 90 percent or more of the total dollar volume of its purchases of prescription drugs from 1147 1148 the manufacturer in the previous year; and 1149 b. The wholesale distributor discloses to the department 1150 the names of all members of the affiliated group of which the 1151 wholesale distributor is a member and the affiliated group 1152 agrees in writing to provide records on prescription drug 1153 purchases by the members of the affiliated group not later than 1154 48 hours after the department requests access to such records, 1155 regardless of the location where the records are stored. (47) (48) "Proprietary drug," or "OTC drug," means a patent 1156 1157 or over-the-counter drug in its unbroken, original package, which drug is sold to the public by, or under the authority of, 1158 1159 the manufacturer or primary distributor thereof, is not 1160 misbranded under the provisions of this part, and can be

### Page 40 of 69

4-00674-14 2014836 purchased without a prescription. (48) (49) "Repackage" includes repacking or otherwise changing the container, wrapper, or labeling to further the distribution of the drug, device, or cosmetic. (49) (50) "Repackager" means a person who repackages. The term excludes pharmacies that are operating in compliance with pharmacy practice standards as defined in chapter 465 and rules adopted under that chapter. (50) (51) "Retail pharmacy" means a community pharmacy licensed under chapter 465 that purchases prescription drugs at fair market prices and provides prescription services to the public. (51) (52) "Secondary wholesale distributor" means a wholesale distributor that is not a primary wholesale distributor. (52) (53) "Veterinary prescription drug" means a prescription drug intended solely for veterinary use. The label of the drug must bear the statement, "Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian." (53) (54) "Wholesale distribution" means distribution of 1181 prescription drugs to persons other than a consumer or patient, 1182 1183 but does not include: 1184 (a) Any of the following activities, which is not a 1185 violation of s. 499.005(21) if such activity is conducted in accordance with s. 499.01(2)(g): 1186 1. The purchase or other acquisition by a hospital or other 1187

health care entity that is a member of a group purchasing 1188 1189 organization of a prescription drug for its own use from the

#### Page 41 of 69

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4-00674-14 2014836 1190 group purchasing organization or from other hospitals or health 1191 care entities that are members of that organization. 1192 2. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug by a 1193 1194 charitable organization described in s. 501(c)(3) of the 1195 Internal Revenue Code of 1986, as amended and revised, to a 1196 nonprofit affiliate of the organization to the extent otherwise 1197 permitted by law. 3. The sale, purchase, or trade of a prescription drug or 1198 1199 an offer to sell, purchase, or trade a prescription drug among 1200 hospitals or other health care entities that are under common 1201 control. For purposes of this subparagraph, "common control" 1202 means the power to direct or cause the direction of the 1203 management and policies of a person or an organization, whether 1204 by ownership of stock, by voting rights, by contract, or 1205 otherwise. 1206 4. The sale, purchase, trade, or other transfer of a 1207 prescription drug from or for any federal, state, or local 1208 government agency or any entity eligible to purchase 1209 prescription drugs at public health services prices pursuant to Pub. L. No. 102-585, s. 602 to a contract provider or its 1210 1211 subcontractor for eligible patients of the agency or entity

1212 under the following conditions:

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

b. The contract provider or subcontractor must beauthorized by law to administer or dispense prescription drugs.

#### Page 42 of 69

4-00674-14 2014836 1219 c. In the case of a subcontractor, the agency or entity 1220 must be a party to and execute the subcontract. 1221 d. The contract provider and subcontractor must maintain 1222 and produce immediately for inspection all records of movement 1223 or transfer of all the prescription drugs belonging to the 1224 agency or entity, including, but not limited to, the records of 1225 receipt and disposition of prescription drugs. Each contractor 1226 and subcontractor dispensing or administering these drugs must maintain and produce records documenting the dispensing or 1227 1228 administration. Records that are required to be maintained include, but are not limited to, a perpetual inventory itemizing 1229 drugs received and drugs dispensed by prescription number or 1230 1231 administered by patient identifier, which must be submitted to 1232 the agency or entity guarterly. 1233 e. The contract provider or subcontractor may administer or 1234 dispense the prescription drugs only to the eligible patients of 1235 the agency or entity or must return the prescription drugs for 1236 or to the agency or entity. The contract provider or

1237 subcontractor must require proof from each person seeking to 1238 fill a prescription or obtain treatment that the person is an 1239 eligible patient of the agency or entity and must, at a minimum, 1240 maintain a copy of this proof as part of the records of the 1241 contractor or subcontractor required under sub-subparagraph d.

1242 f. In addition to the departmental inspection authority 1243 <u>described</u> <del>set forth</del> in s. 499.051, the establishment of the 1244 contract provider and subcontractor and all records pertaining 1245 to prescription drugs subject to this subparagraph shall be 1246 subject to inspection by the agency or entity. All records 1247 relating to prescription drugs of a manufacturer under this

#### Page 43 of 69

4-00674-14 2014836 1248 subparagraph shall be subject to audit by the manufacturer of 1249 those drugs, without identifying individual patient information. 1250 (b) Any of the following activities, which is not a 1251 violation of s. 499.005(21) if such activity is conducted in 1252 accordance with rules established by the department: 1253 1. The sale, purchase, or trade of a prescription drug 1254 among federal, state, or local government health care entities 1255 that are under common control and are authorized to purchase 1256 such prescription drug. 1257 2. The sale, purchase, or trade of a prescription drug or 1258 an offer to sell, purchase, or trade a prescription drug for 1259 emergency medical reasons. For purposes of this subparagraph, 1260 the term "emergency medical reasons" includes transfers of 1261 prescription drugs by a retail pharmacy to another retail 1262 pharmacy to alleviate a temporary shortage. 1263 3. The transfer of a prescription drug acquired by a 1264 medical director on behalf of a licensed emergency medical 1265 services provider to that emergency medical services provider 1266 and its transport vehicles for use in accordance with the 1267 provider's license under chapter 401. 1268 4. The revocation of a sale or the return of a prescription 1269 drug to the person's prescription drug wholesale supplier. 1270 5. The donation of a prescription drug by a health care 1271 entity to a charitable organization that has been granted an 1272 exemption under s. 501(c)(3) of the Internal Revenue Code of 1273 1986, as amended, and that is authorized to possess prescription 1274 drugs.

1275 6. The transfer of a prescription drug by a person1276 authorized to purchase or receive prescription drugs to a person

### Page 44 of 69

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4-00674-14 2014836 1277 licensed or permitted to handle reverse distributions or 1278 destruction under the laws of the jurisdiction in which the 1279 person handling the reverse distribution or destruction receives 1280 the drug. 1281 7. The transfer of a prescription drug by a hospital or 1282 other health care entity to a person licensed under this part to 1283 repackage prescription drugs for the purpose of repackaging the 1284 prescription drug for use by that hospital, or other health care 1285 entity and other health care entities that are under common 1286 control, if ownership of the prescription drugs remains with the 1287 hospital or other health care entity at all times. In addition 1288 to the recordkeeping requirements of s. 499.0121(6), the 1289 hospital or health care entity that transfers prescription drugs 1290 pursuant to this subparagraph must reconcile all drugs 1291 transferred and returned and resolve any discrepancies in a 1292 timely manner. 1293 (c) The distribution of prescription drug samples by

1293 (c) The distribution of prescription drug samples by 1294 manufacturers' representatives or distributors' representatives 1295 conducted in accordance with s. 499.028.

(d) The sale, purchase, or trade of blood and blood components intended for transfusion. As used in this paragraph, the term "blood" means whole blood collected from a single donor and processed for transfusion or further manufacturing, and the term "blood components" means that part of the blood separated by physical or mechanical means.

(e) The lawful dispensing of a prescription drug inaccordance with chapter 465.

1304(f) The sale, purchase, or trade of a prescription drug1305between pharmacies as a result of a sale, transfer, merger, or

### Page 45 of 69

	4-00674-14 2014836
1306	consolidation of all or part of the business of the pharmacies
1307	from or with another pharmacy, whether accomplished as a
1308	purchase and sale of stock or of business assets.
1309	(54) <del>(55)</del> "Wholesale distributor" means any person engaged
1310	in wholesale distribution of prescription drugs in or into this
1311	state, including, but not limited to, manufacturers;
1312	repackagers; own-label distributors; jobbers; private-label
1313	distributors; brokers; warehouses, including manufacturers' and
1314	distributors' warehouses, chain drug warehouses, and wholesale
1315	drug warehouses; independent wholesale drug traders; exporters;
1316	retail pharmacies; and the agents thereof that conduct wholesale
1317	distributions.
1318	Section 23. Paragraph (a) of subsection (1) of section
1319	409.9201, Florida Statutes, is amended to read:
1320	409.9201 Medicaid fraud
1321	(1) As used in this section, the term:
1322	(a) "Prescription drug" means any drug, including, but not
1323	limited to, finished dosage forms or active ingredients that are
1324	subject to, defined in <del>by</del> , or described in <del>by</del> s. 503(b) of the
1325	Federal Food, Drug, and Cosmetic Act or <u>in</u> <del>by</del> s. 465.003(8), <u>s.</u>
1326	<u>499.003(52),</u> <del>s. 499.003(46) or (53)</del> or s. 499.007(13).
1327	
1328	The value of individual items of the legend drugs or goods or
1329	services involved in distinct transactions committed during a
1330	single scheme or course of conduct, whether involving a single
1331	person or several persons, may be aggregated when determining
1332	the punishment for the offense.
1333	Section 24. Paragraph (c) of subsection (9) of section
1334	460.403, Florida Statutes, is amended to read:

# Page 46 of 69

4-00674-14 2014836 1335 460.403 Definitions.-As used in this chapter, the term: 1336 (9) 1337 (c)1. Chiropractic physicians may adjust, manipulate, or treat the human body by manual, mechanical, electrical, or 1338 1339 natural methods; by the use of physical means or physiotherapy, 1340 including light, heat, water, or exercise; by the use of 1341 acupuncture; or by the administration of foods, food concentrates, food extracts, and items for which a prescription 1342 is not required and may apply first aid and hygiene, but 1343 1344 chiropractic physicians are expressly prohibited from 1345 prescribing or administering to any person any legend drug 1346 except as authorized under subparagraph 2., from performing any 1347 surgery except as stated herein, or from practicing obstetrics. 1348 2. Notwithstanding the prohibition against prescribing and 1349 administering legend drugs under subparagraph 1. or s. 1350 499.82(7)(c) s. 499.01(2)(m), pursuant to board rule 1351 chiropractic physicians may order, store, and administer, for 1352 emergency purposes only at the chiropractic physician's office 1353 or place of business, prescription medical oxygen and may also 1354 order, store, and administer the following topical anesthetics 1355 in aerosol form: 1356 a. Any solution consisting of 25 percent ethylchloride and 1357 75 percent dichlorodifluoromethane. 1358 b. Any solution consisting of 15 percent 1359 dichlorodifluoromethane and 85 percent 1360 trichloromonofluoromethane. 1361 1362 However, this paragraph does not authorize a chiropractic 1363 physician to prescribe medical oxygen as defined in chapter 499.

### Page 47 of 69

·	4-00674-14 2014836
1364	Section 25. Subsection (3) of section 465.0265, Florida
1365	Statutes, is amended to read:
1366	465.0265 Centralized prescription filling
1367	(3) The filling, delivery, and return of a prescription by
1368	one pharmacy for another pursuant to this section <u>may</u> shall not
1369	be construed as the filling of a transferred prescription as
1370	<u>described</u> <del>set forth</del> in s. 465.026 or as a wholesale distribution
1371	as <u>defined</u> <del>set forth</del> in <u>s. 499.003</u> <del>s. 499.003(54)</del> .
1372	Section 26. Subsection (1), paragraphs (a), (c), (g), (m),
1373	(n), and (o) of subsection (2), and subsection (5) of section
1374	499.01, Florida Statutes, are amended to read:
1375	499.01 Permits
1376	(1) <u>Before</u> <del>Prior to</del> operating, a permit is required for
1377	each person and establishment that intends to operate as:
1378	(a) A prescription drug manufacturer;
1379	(b) A prescription drug repackager;
1380	(c) A nonresident prescription drug manufacturer;
1381	(d) A prescription drug wholesale distributor;
1382	(e) An out-of-state prescription drug wholesale
1383	distributor;
1384	(f) A retail pharmacy drug wholesale distributor;
1385	(g) A restricted prescription drug distributor;
1386	(h) A complimentary drug distributor;
1387	(i) A freight forwarder;
1388	(j) A veterinary prescription drug retail establishment;
1389	(k) A veterinary prescription drug wholesale distributor;
1390	(1) A limited prescription drug veterinary wholesale
1391	distributor;
1392	(m) A medical oxygen retail establishment;
I	

# Page 48 of 69

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	4-00674-14 2014836
1393	(n) A compressed medical gas wholesale distributor;
1394	(o) A compressed medical gas manufacturer;
1395	(m) (p) An over-the-counter drug manufacturer;
1396	(n) (q) A device manufacturer;
1397	(o) (r) A cosmetic manufacturer;
1398	(p)(s) A third party logistics provider; or
1399	(q)(t) A health care clinic establishment.
1400	(2) The following permits are established:
1401	(a) Prescription drug manufacturer permitA prescription
1402	drug manufacturer permit is required for any person that is a
1403	manufacturer of a prescription drug and that manufactures or
1404	distributes such prescription drugs in this state.
1405	1. A person that operates an establishment permitted as a
1406	prescription drug manufacturer may engage in wholesale
1407	distribution of prescription drugs manufactured at that
1408	establishment and must comply with all of the provisions of this
1409	part, except s. 499.01212, and the rules adopted under this
1410	part, except s. 499.01212, which apply to a wholesale
1411	distributor.
1412	2. A prescription drug manufacturer must comply with all
1413	appropriate state and federal good manufacturing practices.
1414	3. A blood establishment, as defined in s. 381.06014,
1415	operating in a manner consistent with the provisions of 21
1416	C.F.R. parts 211 and 600-640, and manufacturing only the
1417	prescription drugs described in <u>s. 499.003(53)(d)</u> <del>s.</del>
1418	499.003(54)(d) is not required to be permitted as a prescription
1419	drug manufacturer under this paragraph or to register products
1420	under s. 499.015.
1421	(c) Nonresident prescription drug manufacturer permit.—A

# Page 49 of 69

4-00674-14 2014836 1422 nonresident prescription drug manufacturer permit is required 1423 for any person that is a manufacturer of prescription drugs, 1424 unless permitted as a third party logistics provider, located 1425 outside of this state or outside the United States and that 1426 engages in the wholesale distribution in this state of such 1427 prescription drugs. Each such manufacturer must be permitted by 1428 the department and comply with all of the provisions required of 1429 a wholesale distributor under this part, except s. 499.01212. 1. A person that distributes prescription drugs for which 1430 1431 the person is not the manufacturer must also obtain an out-of-1432 state prescription drug wholesale distributor permit or third 1433 party logistics provider permit pursuant to this section to 1434 engage in the wholesale distribution of such prescription drugs. 1435 This subparagraph does not apply to a manufacturer as defined in 1436 s. 499.003(30)(e) <del>s. 499.003(31)(e)</del>. 1437 2. Any such person must comply with the licensing or 1438 permitting requirements of the jurisdiction in which the 1439 establishment is located and the federal act, and any product 1440 wholesaled into this state must comply with this part. If a 1441 person intends to import prescription drugs from a foreign 1442 country into this state, the nonresident prescription drug 1443 manufacturer must provide to the department a list identifying 1444 each prescription drug it intends to import and document 1445 approval by the United States Food and Drug Administration for such importation. 1446 (q) Restricted prescription drug distributor permit.-1447

1448 1. A restricted prescription drug distributor permit is 1449 required for:

1450

a. Any person located in this state who engages in the

#### Page 50 of 69

4-00674-14 2014836 1451 distribution of a prescription drug, which distribution is not 1452 considered "wholesale distribution" under s. 499.003(53)(a) s. 1453 499.003(54)(a). 1454 b. Any person located in this state who engages in the 1455 receipt or distribution of a prescription drug in this state for 1456 the purpose of processing its return or its destruction if such 1457 person is not the person initiating the return, the prescription 1458 drug wholesale supplier of the person initiating the return, or 1459 the manufacturer of the drug. 1460 c. A blood establishment located in this state which 1461 collects blood and blood components only from volunteer donors 1462 as defined in s. 381.06014 or pursuant to an authorized 1463 practitioner's order for medical treatment or therapy and 1464 engages in the wholesale distribution of a prescription drug not described in s. 499.003(53)(d) s. 499.003(54)(d) to a health 1465 1466 care entity. A mobile blood unit operated by a blood 1467 establishment permitted under this sub-subparagraph is not 1468 required to be separately permitted. The health care entity 1469 receiving a prescription drug distributed under this sub-1470 subparagraph must be licensed as a closed pharmacy or provide 1471 health care services at that establishment. The blood

1472 establishment must operate in accordance with s. 381.06014 and 1473 may distribute only:

1474 (I) Prescription drugs indicated for a bleeding or clotting1475 disorder or anemia;

1476 (II) Blood-collection containers approved under s. 505 of 1477 the federal act;

1478 (III) Drugs that are blood derivatives, or a recombinant or 1479 synthetic form of a blood derivative;

#### Page 51 of 69

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I	4-00674-14 2014836
1480	(IV) Prescription drugs that are identified in rules
1481	adopted by the department and that are essential to services
1482	performed or provided by blood establishments and authorized for
1483	distribution by blood establishments under federal law; or
1484	(V) To the extent authorized by federal law, drugs
1485	necessary to collect blood or blood components from volunteer
1486	blood donors; for blood establishment personnel to perform
1487	therapeutic procedures under the direction and supervision of a
1488	licensed physician; and to diagnose, treat, manage, and prevent
1489	any reaction of a volunteer blood donor or a patient undergoing
1490	a therapeutic procedure performed under the direction and
1491	supervision of a licensed physician,
1492	
1493	as long as all of the health care services provided by the blood
1494	establishment are related to its activities as a registered
1495	blood establishment or the health care services consist of
1496	collecting, processing, storing, or administering human
1497	hematopoietic stem cells or progenitor cells or performing
1498	diagnostic testing of specimens if such specimens are tested
1499	together with specimens undergoing routine donor testing. The
1500	blood establishment may purchase and possess the drugs described
1501	in this sub-subparagraph without a health care clinic
1502	establishment permit.
1503	2. Storage, handling, and recordkeeping of these
1504	distributions by a person required to be permitted as a

distributions by a person required to be permitted as a restricted prescription drug distributor must be in accordance with the requirements for wholesale distributors under s. 499.0121, but not those <u>described</u> set forth in s. 499.01212 if the distribution occurs pursuant to sub-subparagraph 1.a. or

### Page 52 of 69

4-00674-14 2014836 1509 sub-subparagraph 1.b. 1510 3. A person who applies for a permit as a restricted 1511 prescription drug distributor, or for the renewal of such a 1512 permit, must provide to the department the information required under s. 499.012. 1513 4. The department may adopt rules regarding the 1514 1515 distribution of prescription drugs by hospitals, health care 1516 entities, charitable organizations, other persons not involved 1517 in wholesale distribution, and blood establishments, which rules 1518 are necessary for the protection of the public health, safety, 1519 and welfare. 1520 (m) Medical oxygen retail establishment permit. A medical 1521 oxygen retail establishment permit is required for any person that sells medical oxygen to patients only. The sale must be 1522 1523 based on an order from a practitioner authorized by law to 1524 prescribe. The term does not include a pharmacy licensed under 1525 chapter 465. 1526 1. A medical oxygen retail establishment may not possess, 1527 purchase, sell, or trade any prescription drug other than 1528 medical oxygen. 1529 2. A medical oxygen retail establishment may refill medical 1530 oxygen for an individual patient based on an order from a 1531 practitioner authorized by law to prescribe. A medical oxygen 1532 retail establishment that refills medical oxygen must comply 1533 with all appropriate state and federal good manufacturing 1534 practices. 1535 3. A medical oxygen retail establishment must comply with all of the wholesale distribution requirements of s. 499.0121. 1536 4. Prescription medical oxygen sold by a medical oxygen 1537

#### Page 53 of 69

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	4-00674-14 2014836
1538	retail establishment pursuant to a practitioner's order may not
1539	be returned into the retail establishment's inventory.
1540	(n) Compressed medical gas wholesale distributor permitA
1541	compressed medical gas wholesale distributor is a wholesale
1542	distributor that is limited to the wholesale distribution of
1543	compressed medical gases to other than the consumer or patient.
1544	The compressed medical gas must be in the original sealed
1545	container that was purchased by that wholesale distributor. A
1546	
	compressed medical gas wholesale distributor may not possess or
1547	engage in the wholesale distribution of any prescription drug
1548	other than compressed medical gases. The department shall adopt
1549	rules that govern the wholesale distribution of prescription
1550	medical oxygen for emergency use. With respect to the emergency
1551	use of prescription medical oxygen, those rules may not be
1552	inconsistent with rules and regulations of federal agencies
1553	unless the Legislature specifically directs otherwise.
1554	(o) Compressed medical gas manufacturer permit.—A
1555	compressed medical gas manufacturer permit is required for any
1556	person that engages in the manufacture of compressed medical
1557	gases or repackages compressed medical gases from one container
1558	to another.
1559	1. A compressed medical gas manufacturer may not
1560	manufacture or possess any prescription drug other than
1561	compressed medical gases.
1562	2. A compressed medical gas manufacturer may engage in
1563	wholesale distribution of compressed medical gases manufactured
1564	at that establishment and must comply with all the provisions of
1565	this part and the rules adopted under this part that apply to a
1566	wholesale distributor.
I	

# Page 54 of 69

	4-00674-14 2014836
1567	
1568	all appropriate state and federal good manufacturing practices.
1569	(5) A prescription drug repackager permit issued under this
1570	part is not required for a restricted prescription drug
1571	distributor permitholder that is a health care entity to
1572	repackage prescription drugs in this state for its own use or
1573	for distribution to hospitals or other health care entities in
1574	the state for their own use, pursuant to <u>s. 499.003(53)(a)3.</u> <del>s.</del>
1575	<del>499.003(54)(a)3.</del> , if:
1576	(a) The prescription drug distributor notifies the
1577	department, in writing, of its intention to engage in
1578	repackaging under this exemption, 30 days before engaging in the
1579	repackaging of prescription drugs at the permitted
1580	establishment;
1581	(b) The prescription drug distributor is under common
1582	control with the hospitals or other health care entities to
1583	which the prescription drug distributor is distributing
1584	prescription drugs. As used in this paragraph, "common control"
1585	means the power to direct or cause the direction of the
1586	management and policies of a person or an organization, whether
1587	by ownership of stock, voting rights, contract, or otherwise;
1588	(c) The prescription drug distributor repackages the
1589	prescription drugs in accordance with current state and federal
1590	good manufacturing practices; and
1591	(d) The prescription drug distributor labels the
1592	prescription drug it repackages in accordance with state and
1593	federal laws and rules.
1594	
1595	The prescription drug distributor is exempt from the product

# Page 55 of 69

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4-00674-14 2014836 1596 registration requirements of s. 499.015 with regard to the 1597 prescription drugs that it repackages and distributes under this 1598 subsection. 1599 Section 27. Paragraph (b) of subsection (2) of section 1600 499.0121, Florida Statutes, is amended to read: 1601 499.0121 Storage and handling of prescription drugs; 1602 recordkeeping.-The department shall adopt rules to implement 1603 this section as necessary to protect the public health, safety, 1604 and welfare. Such rules shall include, but not be limited to, 1605 requirements for the storage and handling of prescription drugs 1606 and for the establishment and maintenance of prescription drug 1607 distribution records. (2) SECURITY.-1608 1609 (b) An establishment that is used for wholesale drug 1610 distribution must be equipped with: 1. An alarm system to detect entry after hours; however, 1611 1612 the department may exempt by rule establishments that only hold 1613 a permit as prescription drug wholesale distributor-brokers and 1614 establishments that only handle medical oxygen; and 1615 2. A security system that will provide suitable protection 1616 against theft and diversion. When appropriate, the security 1617 system must provide protection against theft or diversion that 1618 is facilitated or hidden by tampering with computers or 1619 electronic records. 1620 Section 28. Section 499.01211, Florida Statutes, is amended 1621 to read: 1622 499.01211 Drug Wholesale Distributor Advisory Council.-1623 (1) There is created the Drug Wholesale Distributor

### 1624 Advisory Council within the department. The council shall meet

### Page 56 of 69

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4-00674-14 2014836 1625 at least once each calendar quarter. Staff for the council shall 1626 be provided by the department. The council shall consist of 12 1627 11 members who shall serve without compensation. The council 1628 shall elect a chairperson and a vice chairperson annually. 1629 (2) The Secretary of Business and Professional Regulation 1630 or his or her designee and the Secretary of Health Care 1631 Administration or her or his designee shall be members of the 1632 council. The Secretary of Business and Professional Regulation shall appoint nine additional members to the council who shall 1633 1634 be appointed to a term of 4 years each, as follows: 1635 (a) Three different persons each of whom is employed by a 1636 different prescription drug wholesale distributor licensed under 1637 this part which operates nationally and is a primary wholesale distributor, as defined in s. 499.003 s. 499.003(47). 1638 1639 (b) One person employed by a prescription drug wholesale 1640 distributor licensed under this part which is a secondary 1641 wholesale distributor, as defined in s. 499.003 s. 499.003(52). 1642 (c) One person employed by a retail pharmacy chain located 1643 in this state. 1644 (d) One person who is a member of the Board of Pharmacy and 1645 is a pharmacist licensed under chapter 465. 1646 (e) One person who is a physician licensed pursuant to 1647 chapter 458 or chapter 459. 1648 (f) One person who is an employee of a hospital licensed 1649 pursuant to chapter 395 and is a pharmacist licensed pursuant to 1650 chapter 465. 1651 (q) One person who is an employee of a pharmaceutical 1652 manufacturer. 1653 (3) The Compressed Gas Association shall appoint one person Page 57 of 69

,	4-00674-14 2014836
1654	to the council who is an employee of a permitted medical gas
1655	wholesale distributor or manufacturer.
1656	(4) (3) The council shall review this part and the rules
1657	adopted to administer this part annually, provide input to the
1658	department regarding all proposed rules to administer this part,
1659	make recommendations to the department to improve the protection
1660	of the prescription drugs and public health, make
1661	recommendations to improve coordination with other states'
1662	regulatory agencies and the federal government concerning the
1663	wholesale distribution of drugs, and make recommendations to
1664	minimize the impact of regulation of the wholesale distribution
1665	industry while ensuring protection of the public health.
1666	Section 29. Paragraph (b) of subsection (2) of section
1667	499.01212, Florida Statutes, is amended to read:
1668	499.01212 Pedigree paper
1669	(2) FORMAT.—A pedigree paper must contain the following
1670	information:
1671	(b) For all other wholesale distributions of prescription
1672	drugs:
1673	1. The quantity, dosage form, and strength of the
1674	prescription drugs.
1675	2. The lot numbers of the prescription drugs.
1676	3. The name and address of each owner of the prescription
1677	drug and his or her signature.
1678	4. Shipping information, including the name and address of
1679	each person certifying delivery or receipt of the prescription
1680	drug.
1681	5. An invoice number, a shipping document number, or
1682	another number uniquely identifying the transaction.
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# Page 58 of 69

4-00674-14 2014836 1683 6. A certification that the recipient wholesale distributor 1684 has authenticated the pedigree papers. 1685 7. The unique serialization of the prescription drug, if 1686 the manufacturer or repackager has uniquely serialized the 1687 individual prescription drug unit. 1688 8. The name, address, telephone number, and, if available, 1689 e-mail contact information of each wholesale distributor 1690 involved in the chain of the prescription drug's custody. 1691 1692 When an affiliated group member obtains title to a prescription 1693 drug before distributing the prescription drug as the manufacturer as defined in s. 499.003(30)(e) under s. 1694 1695 499.003(31)(e), information regarding the distribution between 1696 those affiliated group members may be omitted from a pedigree 1697 paper required under this paragraph for subsequent distributions 1698 of that prescription drug. 1699 Section 30. Paragraph (a) of subsection (1) and subsection 1700 (3) of section 499.015, Florida Statutes, are amended to read: 1701 499.015 Registration of drugs, devices, and cosmetics; 1702 issuance of certificates of free sale.-1703 (1) (a) Except for those persons exempted from the 1704 definition of manufacturer in s. 499.003 s. 499.003(31), any person who manufactures, packages, repackages, labels, or 1705 1706 relabels a drug, device, or cosmetic in this state must register 1707 such drug, device, or cosmetic biennially with the department; 1708 pay a fee in accordance with the fee schedule provided by s. 1709 499.041; and comply with this section. The registrant must list 1710 each separate and distinct drug, device, or cosmetic at the time 1711 of registration.

### Page 59 of 69

I	4-00674-14 2014836
1712	(3) Except for those persons exempted from the definition
1713	of manufacturer in <u>s. 499.003</u> <del>s. 499.003(31)</del> , a person may not
1714	sell any product that he or she has failed to register in
1715	conformity with this section. Such failure to register subjects
1716	such drug, device, or cosmetic product to seizure and
1717	condemnation as provided in s. 499.062, and subjects such person
1718	to the penalties and remedies provided in this part.
1719	Section 31. Subsection (3) of section 499.024, Florida
1720	Statutes, is amended to read:
1721	499.024 Drug product classificationThe department shall
1722	adopt rules to classify drug products intended for use by humans
1723	which the United States Food and Drug Administration has not
1724	classified in the federal act or the Code of Federal
1725	Regulations.
1726	(3) Any product that falls under the definition of drug in
1727	<u>s. 499.003</u> <del>s. 499.003(19)</del> may be classified under the authority
1728	of this section. This section does not subject portable
1729	emergency oxygen inhalators to classification; however, this
1730	section does not exempt any person from ss. 499.01 and 499.015.
1731	Section 32. Paragraph (e) of subsection (1), paragraph (b)
1732	of subsection (2), and paragraph (b) of subsection (3) of
1733	section 499.041, Florida Statutes, are amended to read:
1734	499.041 Schedule of fees for drug, device, and cosmetic
1735	applications and permits, product registrations, and free-sale
1736	certificates
1737	(1) The department shall assess applicants requiring a
1738	manufacturing permit an annual fee within the ranges established
1739	in this section for the specific type of manufacturer.
1740	(e) The fee for a compressed medical gas manufacturer

# Page 60 of 69

	4-00674-14 2014836
1741	permit may not be less than \$400 or more than \$500 annually.
1742	(2) The department shall assess an applicant that is
1743	required to have a wholesaling permit an annual fee within the
1744	ranges established in this section for the specific type of
1745	wholesaling.
1746	(b) The fee for a compressed medical gas wholesale
1747	distributor permit may not be less than \$200 or more than \$300
1748	annually.
1749	(3) The department shall assess an applicant that is
1750	required to have a retail establishment permit an annual fee
1751	within the ranges established in this section for the specific
1752	type of retail establishment.
1753	(b) The fee for a medical oxygen retail establishment
1754	permit may not be less than \$200 or more than \$300 annually.
1755	Section 33. Paragraphs (i) and (m) of subsection (1) of
1756	section 499.05, Florida Statutes, are amended to read:
1757	499.05 Rules
1758	(1) The department shall adopt rules to implement and
1759	enforce this <u>chapter</u> <del>part</del> with respect to:
1760	(i) Additional conditions that qualify as an emergency
1761	medical reason under <u>s. 499.003(53)(b)2.</u> <del>s. 499.003(54)(b)2</del> .
1762	(m) The recordkeeping, storage, and handling with respect
1763	to each of the distributions of prescription drugs specified in
1764	<u>s. 499.003(53)(a)-(d)</u> <del>s. 499.003(54)(a)-(d)</del> .
1765	Section 34. Subsections (1) through (4) of section 499.051,
1766	Florida Statutes, are amended to read:
1767	499.051 Inspections and investigations
1768	(1) The agents of the department and of the Department of
1769	Law Enforcement, after they present proper identification, may
I	

### Page 61 of 69

4-00674-14 2014836 1770 inspect, monitor, and investigate any establishment permitted pursuant to this chapter part during business hours for the 1771 1772 purpose of enforcing this chapter part, chapters 465, 501, and 1773 893, and the rules of the department that protect the public 1774 health, safety, and welfare. 1775 (2) In addition to the authority set forth in subsection 1776 (1), the department and any duly designated officer or employee 1777 of the department may enter and inspect any other establishment for the purpose of determining compliance with this part and 1778 1779 rules adopted under this chapter part regarding any drug, 1780 device, or cosmetic product. 1781 (3) Any application for a permit or product registration or 1782 for renewal of such permit or registration made pursuant to this chapter part and rules adopted under this chapter part 1783 1784 constitutes permission for any entry or inspection of the 1785 premises in order to verify compliance with this chapter part 1786 and rules; to discover, investigate, and determine the existence 1787 of compliance; or to elicit, receive, respond to, and resolve 1788 complaints and violations. 1789 (4) Any application for a permit made pursuant to s. 1790 499.012 or s. 499.821 and rules adopted under those sections 1791 that section constitutes permission for agents of the department 1792 and the Department of Law Enforcement, after presenting proper 1793 identification, to inspect, review, and copy any financial 1794 document or record related to the manufacture, repackaging, or distribution of a drug as is necessary to verify compliance with 1795 1796 this chapter part and the rules adopted by the department to 1797 administer this chapter part, in order to discover, investigate, 1798 and determine the existence of compliance, or to elicit,

#### Page 62 of 69

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4-00674-14
                                                               2014836
      receive, respond to, and resolve complaints and violations.
1799
1800
           Section 35. Section 499.066, Florida Statutes, is amended
1801
      to read:
1802
           499.066 Penalties; remedies.-In addition to other penalties
1803
      and other enforcement provisions:
1804
            (1) The department may institute such suits or other legal
1805
      proceedings as are required to enforce any provision of this
1806
      chapter part. If it appears that a person has violated any
1807
      provision of this chapter part for which criminal prosecution is
1808
      provided, the department may provide the appropriate state
1809
      attorney or other prosecuting agency having jurisdiction with
1810
      respect to such prosecution with the relevant information in the
1811
      department's possession.
1812
            (2) If any person engaged in any activity covered by this
1813
      chapter part violates any provision of this chapter part, any
1814
      rule adopted under this chapter part, or a cease and desist
      order as provided by this chapter part, the department may
1815
1816
      obtain an injunction in the circuit court of the county in which
1817
      the violation occurred or in which the person resides or has its
      principal place of business, and may apply in that court for
1818
1819
      such temporary and permanent orders as the department considers
1820
      necessary to restrain the person from engaging in any such
1821
      activities until the person complies with this chapter part, the
1822
      rules adopted under this chapter part, and the orders of the
1823
      department authorized by this chapter part or to mandate
1824
      compliance with this chapter part, the rules adopted under this
1825
      chapter part, and any order or permit issued by the department
1826
      under this chapter part.
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(3) The department may impose an administrative fine, not

#### Page 63 of 69

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	4-00674-14 2014836
1828	to exceed \$5,000 per violation per day, for the violation of any
1829	provision of this <u>chapter</u> <del>part</del> or rules adopted under this
1830	<u>chapter</u> <del>part</del> . Each day a violation continues constitutes a
1831	separate violation, and each separate violation is subject to a
1832	separate fine. All amounts collected pursuant to this section
1833	shall be deposited into the Professional Regulation Trust Fund
1834	and are appropriated for the use of the department in
1835	administering this <u>chapter</u> <del>part</del> . In determining the amount of
1836	the fine to be levied for a violation, the department shall
1837	consider:
1838	(a) The severity of the violation;
1839	(b) Any actions taken by the person to correct the
1840	violation or to remedy complaints; and
1841	(c) Any previous violations.
1842	(4) The department shall deposit any rewards, fines, or
1843	collections that are due the department and which derive from
1844	joint enforcement activities with other state and federal
1845	agencies which relate to this <u>chapter</u> <del>part</del> , chapter 893, or the
1846	federal act, into the Professional Regulation Trust Fund. The
1847	proceeds of those rewards, fines, and collections are
1848	appropriated for the use of the department in administering this
1849	chapter part.
1850	(5) The department may issue an emergency order immediately
1851	suspending or revoking a permit if it determines that any
1852	condition in the establishment presents a danger to the public
1853	health, safety, and welfare.
1854	(6) The department may issue an emergency order to
1855	immediately remove from commerce and public access any drug,
1856	device, or cosmetic, if the department determines that the drug,

# Page 64 of 69

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	4-00674-14 2014836
1857	device, or cosmetic presents a clear and present danger to the
1858	public health, safety, and welfare.
1859	(7) Resignation or termination of an affiliated party does
1860	not affect the department's jurisdiction or discretion to
1861	proceed with action to suspend or revoke a permit or to impose
1862	other penalties or enforcement actions authorized by law.
1863	Section 36. Paragraph (a) of subsection (1) and paragraph
1864	(a) of subsection (2) of section 499.0661, Florida Statutes, are
1865	amended to read:
1866	499.0661 Cease and desist orders; removal of certain
1867	persons
1868	(1) CEASE AND DESIST ORDERS.—
1869	(a) In addition to any authority otherwise provided in this
1870	chapter, the department may issue and serve a complaint stating
1871	charges upon any permittee or upon any affiliated party,
1872	whenever the department has reasonable cause to believe that the
1873	person or individual named therein is engaging in or has engaged
1874	in conduct that is:
1875	1. An act that demonstrates a lack of fitness or
1876	trustworthiness to engage in the business authorized under the
1877	permit issued pursuant to this <u>chapter</u> part, is hazardous to the
1878	public health, or constitutes business operations that are a
1879	detriment to the public health;
1880	2. A violation of any provision of this <u>chapter</u> <del>part</del> ;
1881	3. A violation of any rule of the department;
1882	4. A violation of any order of the department; or
1883	5. A breach of any written agreement with the department.
1884	(2) REMOVAL OF AFFILIATED PARTIES BY THE DEPARTMENT
1885	(a) The department may issue and serve a complaint stating
I	

# Page 65 of 69

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4-00674-14 2014836 1886 charges upon any affiliated party and upon the permittee 1887 involved whenever the department has reason to believe that an 1888 affiliated party is engaging in or has engaged in conduct that 1889 constitutes: 1890 1. An act that demonstrates a lack of fitness or 1891 trustworthiness to engage in the business authorized under the 1892 permit issued pursuant to this chapter part, is hazardous to the 1893 public health, or constitutes business operations that are a 1894 detriment to the public health; 1895 2. A willful violation of this chapter part; however, if 1896 the violation constitutes a misdemeanor, a complaint may not be 1897 served as provided in this section until the affiliated party is 1898 notified in writing of the matter of the violation and has been 1899 afforded a reasonable period of time, as set forth in the 1900 notice, to correct the violation and has failed to do so; 1901 3. A violation of any other law involving fraud or moral 1902 turpitude which constitutes a felony; 1903 4. A willful violation of any rule of the department; 1904 5. A willful violation of any order of the department; or 1905 6. A material misrepresentation of fact, made knowingly and 1906 willfully or made with reckless disregard for the truth of the 1907 matter. Section 37. Section 499.067, Florida Statutes, is amended 1908 1909 to read: 499.067 Denial, suspension, or revocation of permit, 1910 1911 certification, or registration.-(1) (a) The department may deny, suspend, or revoke a permit 1912 1913 if it finds that there has been a substantial failure to comply 1914 with this chapter part or chapter 465, chapter 501, or chapter

### Page 66 of 69

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	4-00674-14 2014836
1915	
1916	chapters, any final order of the department, or applicable
1917	federal laws or regulations or other state laws or rules
1918	governing drugs, devices, or cosmetics.
1919	(b) The department may deny an application for a permit or
1920	certification, or suspend or revoke a permit or certification,
1921	if the department finds that:
1922	1. The applicant is not of good moral character or that it
1923	would be a danger or not in the best interest of the public
1924	health, safety, and welfare if the applicant were issued a
1925	permit or certification.
1926	2. The applicant has not met the requirements for the
1927	permit or certification.
1928	3. The applicant is not eligible for a permit or
1929	certification for any of the reasons enumerated in s. 499.012.
1930	4. The applicant, permittee, or person certified under s.
1931	499.012(16) demonstrates any of the conditions enumerated in s.
1932	499.012.
1933	5. The applicant, permittee, or person certified under s.
1934	499.012(16) has committed any violation of ss. 499.005-499.0054.
1935	(2) The department may deny, suspend, or revoke any
1936	registration required by the provisions of this <u>chapter</u> <del>part</del> for
1937	the violation of any provision of this <u>chapter</u> <del>part</del> or of any
1938	rules adopted under this <u>chapter</u> <del>part</del> .
1939	(3) The department may revoke or suspend a permit:
1940	(a) If the permit was obtained by misrepresentation or
1941	fraud or through a mistake of the department;
1942	(b) If the permit was procured, or attempted to be
1943	procured, for any other person by making or causing to be made
	Page 67 of 69

### Page 67 of 69

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2014836

4-00674-14

1944 any false representation; or

1945(c) If the permittee has violated any provision of this1946chapter part or rules adopted under this chapter part.

1947 (4) If any permit issued under this chapter part is revoked 1948 or suspended, the owner, manager, operator, or proprietor of the 1949 establishment shall cease to operate as the permit authorized, 1950 from the effective date of the suspension or revocation until 1951 the person is again registered with the department and possesses 1952 the required permit. If a permit is revoked or suspended, the 1953 owner, manager, or proprietor shall remove all signs and symbols 1954 that identify the operation as premises permitted as a drug 1955 wholesaling establishment; drug, device, or cosmetic 1956 manufacturing establishment; or retail establishment. The 1957 department shall determine the length of time for which the 1958 permit is to be suspended. If a permit is revoked, the person 1959 that owns or operates the establishment may not apply for any 1960 permit under this chapter part for a period of 1 year after the 1961 date of the revocation. A revocation of a permit may be 1962 permanent if the department considers that to be in the best 1963 interest of the public health.

1964 (5) The department may deny, suspend, or revoke a permit 1965 issued under this chapter part which authorizes the permittee to 1966 purchase prescription drugs if any owner, officer, employee, or 1967 other person who participates in administering or operating the 1968 establishment has been found guilty of any violation of this 1969 chapter part or chapter 465, chapter 501, or chapter 893, any rules adopted under this chapter part or those chapters, or any 1970 1971 federal or state drug law, regardless of whether the person has 1972 been pardoned, had her or his civil rights restored, or had

#### Page 68 of 69

	4-00674-14 2014836
1973	adjudication withheld.
1974	(6) The department shall deny, suspend, or revoke the
1975	permit of any person or establishment if the assignment, sale,
1976	transfer, or lease of an establishment permitted under this
1977	chapter part will avoid an administrative penalty, civil action,
1978	or criminal prosecution.
1979	(7) Notwithstanding s. 120.60(5), if a permittee fails to
1980	comply with s. 499.012(6) or s. 499.83, as applicable, the
1981	department may revoke the permit of the permittee and shall
1982	provide notice of the intended agency action by posting a notice
1983	at the department's headquarters and by mailing a copy of the
1984	notice of intended agency action by certified mail to the most
1985	recent mailing address on record with the department and, if the
1986	permittee is not a natural person, to the permittee's registered
1987	agent on file with the Department of State.
1988	(8) The department may deny, suspend, or revoke a permit
1989	under this part if it finds the permittee has not complied with
1990	the credentialing requirements of s. 499.0121(15).
1991	(9) The department may deny, suspend, or revoke a permit
1992	under this part if it finds the permittee has not complied with
1993	the reporting requirements of, or knowingly made a false
1994	statement in a report required by, s. 499.0121(14).
1995	Section 38. This act shall take effect October 1, 2014.
1996	

# Page 69 of 69