

By Senator Campbell

32-674A-03

1 A bill to be entitled
2 An act relating to the regulation of
3 prescription drugs; providing a short title;
4 providing legislative findings and intent with
5 respect to a report by the Seventeenth
6 Statewide Grand Jury; amending s. 499.003,
7 F.S.; defining additional terms, including the
8 terms "contraband legend drug," "pedigree
9 paper," and "repackager"; amending s. 499.005,
10 F.S.; prohibiting the purchase or sale of
11 prescription drugs in wholesale distribution in
12 exchange for currency; clarifying provisions
13 prohibiting the transfer of legend drugs from
14 or to any person not authorized to possess such
15 drugs; prohibiting additional acts concerning
16 the distribution of prescription drugs;
17 creating s. 499.0051, F.S.; providing that
18 failure to maintain or deliver pedigree papers,
19 failure to authenticate pedigree papers,
20 forgery of pedigree papers, purchase of legend
21 drugs from an unlicensed person, sale of legend
22 drugs to an unlicensed person, possession or
23 sale of contraband legend drugs and possession
24 with intent to sell or deliver contraband
25 legend drugs, and forgery of prescription
26 labels or legend drug labels are felony
27 offenses; providing penalties; creating s.
28 499.0052, F.S.; providing that trafficking in
29 contraband legend drugs is a felony offense;
30 providing penalties; providing enhanced
31 penalties if the defendant is a corporation or

1 not a natural person; creating s. 499.0053,
2 F.S.; providing that the sale or purchase of a
3 contraband legend drug resulting in great
4 bodily harm is a first-degree felony; creating
5 s. 499.0054, F.S.; providing that the sale or
6 purchase of a contraband legend drug resulting
7 in death is a first-degree felony; amending s.
8 499.006, F.S.; providing that a legend drug
9 that is unaccompanied by a proper pedigree
10 paper or that has been in the possession of an
11 unauthorized person is an adulterated drug;
12 amending s. 499.007, F.S.; revising labeling
13 requirements to conform to federal law;
14 amending s. 499.01, F.S.; requiring that
15 prescription drug repackagers, nonresident
16 prescription drug manufacturers, and freight
17 forwarders obtain a permit from the Department
18 of Health in order to do business; requiring
19 that an applicant obtain all necessary
20 occupational licenses; amending s. 499.012,
21 F.S.; excluding the transfer of prescription
22 drugs within a hospital from the definition of
23 wholesale distribution; providing bond
24 requirements for prescription drug wholesalers;
25 deleting provisions authorizing the department
26 to grant out-of-state wholesalers reciprocity;
27 requiring freight forwarders and nonresident
28 prescription drug manufacturers to obtain a
29 permit; providing requirements; providing
30 requirements for the permitting of prescription
31 drug wholesalers, out-of-state prescription

1 drug wholesalers, and retail pharmacy drug
2 wholesalers; requiring prescription drug
3 wholesalers to designate a representative;
4 providing criteria for designation as a
5 representative; amending s. 499.0121, F.S.;
6 requiring pedigree papers for the transfer and
7 sale of legend drugs; providing documentation
8 requirements for the shipment of prescription
9 drugs; providing requirements for wholesale
10 drug distributors with respect to shipping
11 prescription drugs; amending s. 499.013, F.S.;
12 providing requirements for repackagers of
13 drugs, devices, and cosmetics; requiring that a
14 repackager obtain a permit from the department;
15 amending s. 499.014, F.S.; specifying that
16 certain restricted distributors are exempt from
17 the requirements concerning pedigree papers;
18 amending s. 499.041, F.S.; revising the
19 schedule of fees for permits; amending s.
20 499.051, F.S.; extending the authority of the
21 Department of Health to inspect pharmacies and
22 retail pharmacy wholesalers; authorizing the
23 department and the Department of Law
24 Enforcement to inspect certain financial
25 documents and records; amending s. 499.055,
26 F.S.; requiring the Department of Health to
27 establish a website listing all permit holders
28 and pending enforcement actions; creating s.
29 499.065, F.S.; authorizing the department to
30 enter and inspect all permitted facilities at
31 any reasonable time; authorizing the department

1 to seize and destroy prescription drugs
2 representing a threat to public health;
3 authorizing the department to close facilities
4 that represent an imminent danger to public
5 health; amending s. 499.066, F.S.; providing
6 for administrative actions by the department;
7 creating s. 499.0661, F.S.; providing for the
8 department to issue cease and desist orders;
9 providing for the department to order the
10 removal of certain persons from involvement
11 with certain drug wholesalers; amending s.
12 499.067, F.S.; specifying additional grounds
13 for denial of a permit or certification;
14 amending s. 499.069, F.S.; revising certain
15 penalty provisions; creating s. 499.0691, F.S.;
16 providing criminal penalties for violations
17 related to drugs or false advertisement;
18 amending s. 921.0022, F.S., relating to the
19 offense severity ranking chart of the Criminal
20 Punishment Code; conforming provisions to
21 changes made by the act; amending s. 895.02,
22 F.S.; including certain violations of part I of
23 ch. 499, F.S., within the definition of
24 racketeering activity; amending ss. 16.56 and
25 905.34, F.S.; authorizing criminal violations
26 of part I of ch. 499, F.S., to be prosecuted by
27 the Office of Statewide Prosecution and heard
28 by the Statewide Grand Jury; providing for
29 severability; providing an effective date.

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

1 Section 1. This act may be cited as the "Prescription
2 Drug Protection Act."

3 Section 2. Legislative findings and intent.--Based on
4 the report of the Seventeenth Statewide Grand Jury in its
5 First Interim Report the Legislature finds that prescription
6 drugs brought into the state by wholesalers are being
7 reabeled and falsely represented as being of a higher dosage
8 by other wholesalers in order to charge higher prices for
9 those drugs and that counterfeit substances labeled as genuine
10 pharmaceuticals are being distributed, thereby causing an
11 extreme danger that persons eventually receiving the drugs by
12 prescription are receiving ineffective drugs in nontherapeutic
13 doses, or even receiving dangerous or unwholesome substances,
14 with the result that the health and well-being of the public
15 is at risk. The Statewide Grand Jury also found that the lack
16 of an effective pedigree paper requirement has resulted in the
17 inability of prescription drug users to have confidence in the
18 purity and efficacy of the drugs they use. The Statewide Grand
19 Jury further noted that present laws do not allow effective
20 criminal prosecution of persons involved in such false
21 representations. It is the intent of the Legislature that the
22 statutory changes and recommendations outlined in the
23 Statewide Grand Jury's report be implemented as provided by
24 this act.

25 Section 3. Section 499.003, Florida Statutes, is
26 amended to read:

27 499.003 Definitions of terms used in ss.
28 499.001-499.081.--As used in ss. 499.001-499.081, the term:

29 (1) "Advertisement" means any representation
30 disseminated in any manner or by any means, other than by
31 labeling, for the purpose of inducing, or which is likely to

1 induce, directly or indirectly, the purchase of drugs,
2 devices, or cosmetics.

3 (2) "Affiliated party" means:

4 (a) A director, officer, trustee, partner, or
5 committee member of a permittee or applicant or a subsidiary
6 or service corporation of the permittee or applicant;

7 (b) A person who, directly or indirectly, manages,
8 controls, or oversees the operation of a permittee or
9 applicant, regardless of whether such person is a partner,
10 shareholder, manager, member, officer, director, independent
11 contractor, or employee of the permittee or applicant;

12 (c) A person who has filed or is required to file a
13 personal information statement pursuant to s. 499.012(4) or is
14 required to be identified in an application for a permit or to
15 renew a permit pursuant to s. 499.012(3); or

16 (d) The five largest natural shareholders that own at
17 least 5 percent of the permittee or applicant.

18 (3) "Applicant" means a person applying for a permit
19 or certification under ss. 499.001-499.081.

20 (4) "Authenticate" means to affirmatively verify
21 before any distribution of a legend drug occurs that each
22 transaction listed on the pedigree paper has occurred.

23 (5)~~(2)~~ "Certificate of free sale" means a document
24 prepared by the department which certifies a drug, device, or
25 cosmetic, that is registered with the department, as one that
26 can be legally sold in the state.

27 (6)~~(3)~~ "Closed pharmacy" means a pharmacy that is
28 licensed under chapter 465 and purchases prescription drugs
29 for use by a limited patient population and not for wholesale
30 distribution or sale to the public. The term does not include
31 retail pharmacies.

1 ~~(7)(4)~~ "Color" includes black, white, and intermediate
2 grays.

3 ~~(8)(5)~~ "Color additive" means a material that:

4 (a) Is a dye pigment, or other substance, made by a
5 process of synthesis or similar artifice, or extracted,
6 isolated, or otherwise derived, with or without intermediate
7 or final change of identity from a vegetable, animal, mineral,
8 or other source; or

9 (b) When added or applied to a drug or cosmetic or to
10 the human body, or any part thereof, is capable alone, or
11 through reaction with other substances, of imparting color
12 thereto;

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14 except that the term does not include any material which has
15 been or hereafter is exempt under the federal act.

16 ~~(9)(6)~~ "Compressed medical gas" means any liquefied or
17 vaporized gas that is a prescription drug, whether it is alone
18 or in combination with other gases.

19 (10) "Contraband legend drug" means any adulterated
20 drug, as defined in s. 499.006, any counterfeit drug, as
21 defined in this section, and also means any legend drug for
22 which a pedigree paper does not exist, or for which the
23 pedigree paper in existence has been forged, counterfeited,
24 falsely created, or contains any altered, false, or
25 misrepresented matter.

26 ~~(11)(7)~~ "Cosmetic" means an article that is:

27 (a) Intended to be rubbed, poured, sprinkled, or
28 sprayed on; introduced into; or otherwise applied to the human
29 body or any part thereof for cleansing, beautifying, promoting
30 attractiveness, or altering the appearance; or

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1 (b) Intended for use as a component of any such
2 article;

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4 except that the term does not include soap.

5 (12)~~(8)~~ "Counterfeit drug, counterfeit device, or
6 counterfeit cosmetic" means a drug, device, or cosmetic which,
7 or the container, seal, or labeling of which, without
8 authorization, bears the trademark, trade name, or other
9 identifying mark, imprint, or device, or any likeness thereof,
10 of a drug, device, or cosmetic manufacturer, processor,
11 packer, or distributor other than the person that in fact
12 manufactured, processed, packed, or distributed that drug,
13 device, or cosmetic and which thereby falsely purports or is
14 represented to be the product of, or to have been packed or
15 distributed by, that other drug, device, or cosmetic
16 manufacturer, processor, packer, or distributor.

17 (13)~~(9)~~ "Department" means the Department of Health.

18 (14)~~(10)~~ "Device" means any instrument, apparatus,
19 implement, machine, contrivance, implant, in vitro reagent, or
20 other similar or related article, including its components,
21 parts, or accessories, which is:

22 (a) Recognized in the current edition of the United
23 States Pharmacopoeia and National Formulary, or any supplement
24 thereof,

25 (b) Intended for use in the diagnosis, cure,
26 mitigation, treatment, therapy, or prevention of disease in
27 humans or other animals, or

28 (c) Intended to affect the structure or any function
29 of the body of humans or other animals,
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1 and which does not achieve any of its principal intended
2 purposes through chemical action within or on the body of
3 humans or other animals and which is not dependent upon being
4 metabolized for the achievement of any of its principal
5 intended purposes.

6 (15)~~(11)~~ "Distribute or distribution" means to sell;
7 offer to sell; give away; transfer, whether by passage of
8 title, physical movement, or both; deliver; or offer to
9 deliver. The term does not mean to administer or dispense.

10 (16) "Diverted from the legal channels of distribution
11 for prescription drugs" means an adulterated drug pursuant to
12 s. 499.006(10).

13 (17)~~(12)~~ "Drug" means an article that is:

14 (a) Recognized in the current edition of the United
15 States Pharmacopoeia and National Formulary, official
16 Homeopathic Pharmacopoeia of the United States, or any
17 supplement to any of those publications;

18 (b) Intended for use in the diagnosis, cure,
19 mitigation, treatment, therapy, or prevention of disease in
20 humans or other animals;

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

23 (d) Intended for use as a component of any article
24 specified in paragraph (a), paragraph (b), or paragraph (c),
25 but does not include devices or their components, parts, or
26 accessories.

27 (18)~~(13)~~ "Establishment" means a place of business at
28 one general physical location.

29 (19)~~(14)~~ "Federal act" means the Federal Food, Drug,
30 and Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et
31 seq.

1 (20) "Freight forwarder" means a person who receives
2 legend drugs which are owned by another person and designated
3 by that person for export, and exports those legend drugs.

4 ~~(21)(15)~~ "Health care entity" means a closed pharmacy
5 or any person, organization, or business entity that provides
6 diagnostic, medical, surgical, or dental treatment or care, or
7 chronic or rehabilitative care, but does not include any
8 wholesale distributor or retail pharmacy licensed under state
9 law to deal in prescription drugs.

10 ~~(22)(16)~~ "Immediate container" does not include
11 package liners.

12 ~~(23)(17)~~ "Label" means a display of written, printed,
13 or graphic matter upon the immediate container of any drug,
14 device, or cosmetic. A requirement made by or under authority
15 of ss. 499.001-499.081 or rules adopted under those sections
16 that any word, statement, or other information appear on the
17 label is not complied with unless such word, statement, or
18 other information also appears on the outside container or
19 wrapper, if any, of the retail package of such drug, device,
20 or cosmetic or is easily legible through the outside container
21 or wrapper.

22 ~~(24)(18)~~ "Labeling" means all labels and other
23 written, printed, or graphic matters:

24 (a) Upon a drug, device, or cosmetic, or any of its
25 containers or wrappers; or

26 (b) Accompanying or related to such drug, device, or
27 cosmetic.

28 ~~(25)(19)~~ "Legend drug," "prescription drug," or
29 "medicinal drug" means any drug, including, but not limited
30 to, finished dosage forms, or active ingredients subject to,
31 defined by, or described by s. 503(b) of the Federal Food,

1 Drug, and Cosmetic Act or s. 465.003(8), s. 499.007(12), or s.
2 499.0122(1)(b) or (c).

3 (26) "Legend drug label" means any display of written,
4 printed, or graphic matter upon the immediate container of any
5 legend drug prior to its dispensing to an individual patient
6 pursuant to a prescription of a practitioner authorized by law
7 to prescribe.

8 (27)~~(20)~~ "Manufacture" means the preparation,
9 deriving, compounding, propagation, processing, producing, or
10 fabrication of any drug, device, or cosmetic. ~~The term~~
11 ~~includes repackaging or otherwise changing the container,~~
12 ~~wrapper, or labeling to further the distribution of the drug,~~
13 ~~device, or cosmetic.~~

14 (28)~~(21)~~ "Manufacturer" means a person who prepares,
15 derives, manufactures, or produces a drug, device, or
16 cosmetic. The term excludes pharmacies that are operating in
17 compliance with pharmacy practice standards as defined in
18 chapter 465 and rules adopted under that chapter.

19 (29)~~(22)~~ "New drug" means:

20 (a) Any drug the composition of which is such that the
21 drug is not generally recognized, among experts qualified by
22 scientific training and experience to evaluate the safety and
23 effectiveness of drugs, as safe and effective for use under
24 the conditions prescribed, recommended, or suggested in the
25 labeling of that drug; or

26 (b) Any drug the composition of which is such that the
27 drug, as a result of investigations to determine its safety
28 and effectiveness for use under certain conditions, has been
29 recognized for use under such conditions, but which drug has
30 not, other than in those investigations, been used to a
31 material extent or for a material time under such conditions.

1 ~~(30)(23)~~ "Official compendium" means the current
2 edition of the official United States Pharmacopoeia and
3 National Formulary, or any supplement thereto.

4 (31) "Pedigree paper" means a document in a form
5 approved by the Department of Health and containing
6 information that records each distribution of any given legend
7 drug, from sale by a pharmaceutical manufacturer, through
8 acquisition and sale by any wholesaler or repackager, until
9 final sale to a pharmacy or other person administering or
10 dispensing the drug. The information required to be included
11 on a legend drug's pedigree paper must at least detail the
12 amount of the legend drug, its dosage form and strength, its
13 lot numbers, the name and address of each owner of the legend
14 drug and his or her signature, its shipping information,
15 including the name and address of each person certifying
16 delivery or receipt of the legend drug, and a certification
17 that the recipient has authenticated the pedigree papers. It
18 must also include the name, address, telephone number and, if
19 available, e-mail contact information of each wholesaler
20 involved in the chain of the legend drug's custody. The
21 department shall adopt rules and a form relating to the
22 requirements of this paragraph no later than 90 days after the
23 effective date of this act.

24 ~~(32)(24)~~ "Person" means any individual, child, joint
25 venture, syndicate, fiduciary, partnership, corporation,
26 division of a corporation, firm, trust, business trust,
27 company, estate, public or private institution, association,
28 organization, group, city, county, city and county, political
29 subdivision of this state, other governmental agency within
30 this state, and any representative, agent, or agency of any of
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1 the foregoing, or any other group or combination of the
2 foregoing.

3 (33)~~(25)~~ "Prepackaged drug product" means a drug that
4 originally was in finished packaged form sealed by a
5 manufacturer and that is placed in a properly labeled
6 container by a pharmacy or practitioner authorized to dispense
7 pursuant to chapter 465 for the purpose of dispensing in the
8 establishment in which the prepackaging occurred.

9 (34) "Prescription label" means any display of
10 written, printed, or graphic matter upon the immediate
11 container of any legend drug dispensed pursuant to a
12 prescription of a practitioner authorized by law to prescribe.

13 (35)~~(26)~~ "Prescription medical oxygen" means oxygen
14 USP which is a drug that can only be sold on the order or
15 prescription of a practitioner authorized by law to prescribe.
16 The label of prescription medical oxygen must comply with
17 current labeling requirements for oxygen under the Federal
18 Food, Drug, and Cosmetic Act.

19 (36)~~(27)~~ "Proprietary drug," or "OTC drug," means a
20 patent or over-the-counter drug in its unbroken, original
21 package, which drug is sold to the public by, or under the
22 authority of, the manufacturer or primary distributor thereof,
23 is not misbranded under the provisions of ss. 499.001-499.081,
24 and can be purchased without a prescription.

25 (37) "Repackage" includes repacking or otherwise
26 changing the container, wrapper, or labeling to further the
27 distribution of the drug, device, or cosmetic.

28 (38) "Repackager" means a person who repackages. The
29 term excludes pharmacies that are operating in compliance with
30 pharmacy practice standards as defined in chapter 465 and
31 rules adopted under that chapter.

1 ~~(39)(28)~~ "Veterinary prescription drug" means a legend
2 drug intended solely for veterinary use. The label of the
3 drug must bear the statement, "Caution: Federal law restricts
4 this drug to sale by or on the order of a licensed
5 veterinarian."

6 Section 4. Section 499.005, Florida Statutes, is
7 amended to read:

8 499.005 Prohibited acts.--It is unlawful for a person
9 to perform or cause the performance of any of the following
10 acts in this state:

11 (1) The manufacture, repackaging, sale, delivery, or
12 holding or offering for sale of any drug, device, or cosmetic
13 that is adulterated or misbranded or has otherwise been
14 rendered unfit for human or animal use.

15 (2) The adulteration or misbranding of any drug,
16 device, or cosmetic.

17 (3) The receipt of any drug, device, or cosmetic that
18 is adulterated or misbranded, and the delivery or proffered
19 delivery of such drug, device, or cosmetic, for pay or
20 otherwise.

21 (4) The sale, distribution, purchase, trade, holding,
22 or offering of any drug, device, or cosmetic in violation of
23 ss. 499.001-499.081.

24 (5) The dissemination of any false or misleading
25 advertisement of a drug, device, or cosmetic.

26 (6) The refusal or constructive refusal:

27 (a) To allow the department to enter or inspect an
28 establishment in which drugs, devices, or cosmetics are
29 manufactured, processed, repackaged, sold, brokered, or held;

30 (b) To allow inspection of any record of that
31 establishment;

1 (c) To allow the department to enter and inspect any
2 vehicle that is being used to transport drugs, devices, or
3 cosmetics; or

4 (d) To allow the department to take samples of any
5 drug, device, or cosmetic.

6 (7) The purchase or sale of prescription drugs for
7 wholesale distribution in exchange for currency, as defined in
8 s. 560.103(6).~~The giving of a false guaranty or false~~
9 ~~undertaking with respect to a drug, device, or cosmetic,~~
10 ~~except by a person who relied on a guaranty or undertaking to~~
11 ~~the same effect signed by, and containing the name and address~~
12 ~~of, the person residing in this state from whom she or he~~
13 ~~received in good faith the drug, device, or cosmetic.~~

14 (8) Committing any act that causes a drug, device, or
15 cosmetic to be a counterfeit drug, device, or cosmetic; or
16 selling, dispensing, or holding for sale a counterfeit drug,
17 device, or cosmetic.

18 (9) The alteration, mutilation, destruction,
19 obliteration, or removal of the whole or any part of the
20 labeling of a drug, device, or cosmetic, or the doing of any
21 other act with respect to a drug, device, or cosmetic, if the
22 act is done while the drug, device, or cosmetic is held for
23 sale and the act results in the drug, device, or cosmetic
24 being misbranded.

25 (10) Forging; counterfeiting; simulating; falsely
26 representing any drug, device, or cosmetic; or, without the
27 authority of the manufacturer, using any mark, stamp, tag,
28 label, or other identification device authorized or required
29 by rules adopted under ss. 499.001-499.081.

30 (11) The use, on the labeling of any drug or in any
31 advertisement relating to such drug, of any representation or

1 suggestion that an application of the drug is effective when
2 it is not or that the drug complies with ss. 499.001-499.081
3 when it does not.

4 (12) The possession of any drug in violation of ss.
5 499.001-499.081.

6 (13) The sale, delivery, holding, or offering for sale
7 of any self-testing kits designed to tell persons their status
8 concerning human immunodeficiency virus or acquired immune
9 deficiency syndrome or related disorders or conditions. This
10 prohibition shall not apply to home access HIV test kits
11 approved for distribution and sale by the United States Food
12 and Drug Administration.

13 (14) The purchase or receipt of a legend drug from a
14 person that is not authorized under this chapter to distribute
15 legend drugs to that purchaser or recipient.

16 (15) The sale or transfer of a legend drug to a person
17 that is not authorized under the law of the jurisdiction in
18 which the person receives the drug to purchase or possess
19 legend drugs from the person selling or transferring the
20 legend drug.

21 (16) The purchase or receipt of a compressed medical
22 gas from a person that is not authorized under this chapter to
23 distribute compressed medical gases.

24 (17) The sale, purchase, or trade, or the offer to
25 sell, purchase, or trade, a drug sample as defined in s.
26 499.028; the distribution of a drug sample in violation of s.
27 499.028; or the failure to otherwise comply with s. 499.028.

28 (18) Failure to maintain records as required by ss.
29 499.001-499.081 and rules adopted under those sections.

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1 (19) Providing the department with false or fraudulent
2 records, or making false or fraudulent statements, regarding
3 any matter within the provisions of this chapter.

4 (20) The importation of a legend drug except as
5 provided by s. 801(d) of the Federal Food, Drug, and Cosmetic
6 Act.

7 (21) The wholesale distribution of any prescription
8 drug that was:

9 (a) Purchased by a public or private hospital or other
10 health care entity; or

11 (b) Donated or supplied at a reduced price to a
12 charitable organization.

13 (22) Failure to obtain a permit or registration, or
14 operating without a valid permit when a permit or registration
15 is required by ss. 499.001-499.081 for that activity.

16 (23) Obtaining or attempting to obtain a prescription
17 drug or device by fraud, deceit, misrepresentation or
18 subterfuge, or engaging in misrepresentation or fraud in the
19 distribution of a drug or device.

20 (24) The distribution of a legend device to the
21 patient or ultimate consumer without a prescription or order
22 from a practitioner licensed by law to use or prescribe the
23 device.

24 (25) Charging a dispensing fee for dispensing,
25 administering, or distributing a prescription drug sample.

26 (26) Removing a pharmacy's dispensing label from a
27 dispensed prescription drug with the intent to further
28 distribute the prescription drug.

29 (27) Distributing a prescription drug that was
30 previously dispensed by a licensed pharmacy, unless such
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1 distribution was authorized in chapter 465 or the rules
2 adopted under chapter 465.

3 (28) Failure to obtain or pass on a pedigree paper
4 required pursuant to s. 499.0121(6)(d).

5 (29) The receipt of a prescription drug pursuant to a
6 wholesale distribution without first receiving a pedigree
7 paper that was attested to as accurate and complete by the
8 wholesale distributor.

9 Section 5. Section 499.0051, Florida Statutes, is
10 created to read:

11 499.0051 Criminal acts involving contraband or
12 adulterated drugs.--

13 (1) FAILURE TO MAINTAIN OR DELIVER PEDIGREE PAPERS.--

14 (a) A person, other than a manufacturer, engaged in
15 the wholesale distribution of legend drugs who fails to
16 deliver to another person complete and accurate pedigree
17 papers concerning a legend drug or contraband legend drug
18 prior to transferring the legend drug or contraband legend
19 drug to another person commits a felony of the third degree,
20 punishable as provided in s. 775.082, s. 775.083, or s.
21 775.084.

22 (b) A person engaged in the wholesale distribution of
23 legend drugs who fails to acquire complete and accurate
24 pedigree papers concerning a legend drug or contraband legend
25 drug prior to obtaining the legend drug or contraband legend
26 drug from another person commits a felony of the third degree,
27 punishable as provided in s. 775.082, s. 775.083, or s.
28 775.084.

29 (c) Any person who knowingly destroys, alters,
30 conceals, or fails to maintain complete and accurate pedigree
31 papers concerning any legend drug or contraband legend drug in

1 his or her possession commits a felony of the third degree,
2 punishable as provided in s. 775.082, s. 775.083, or s.
3 775.084.

4 (2) FAILURE TO AUTHENTICATE PEDIGREE PAPERS.--

5 (a) A person engaged in the wholesale distribution of
6 legend drugs who is in possession of pedigree papers
7 concerning legend drugs or contraband legend drugs and who
8 fails to authenticate the matters contained in the pedigree
9 papers and who nevertheless attempts to further distribute
10 legend drugs or contraband legend drug commits a felony of the
11 third degree, punishable as provided in s. 775.082, s.
12 775.083, or s. 775.084.

13 (b) A person in possession of pedigree papers
14 concerning legend drugs or contraband legend drugs who falsely
15 swears or certifies that he or she has authenticated the
16 matters contained in the pedigree papers commits a felony of
17 the third degree, punishable as provided in s. 775.082, s.
18 775.083, or s. 775.084.

19 (3) FORGERY OF PEDIGREE PAPERS.--A person who
20 knowingly forges, counterfeits, or falsely creates any
21 pedigree paper; who falsely represents any factual matter
22 contained on any pedigree paper; or who knowingly omits to
23 record material information required to be recorded in a
24 pedigree paper, commits a felony of the second degree,
25 punishable as provided in s. 775.082, s. 775.083, or s.
26 775.084.

27 (4) PURCHASE OR RECEIPT OF LEGEND DRUG FROM
28 UNAUTHORIZED PERSON.--A person who knowingly purchases or
29 receives from a person not authorized to distribute legend
30 drugs under this chapter a legend drug in a wholesale
31 distribution transaction commits a felony of the second

1 degree, punishable as provided in s. 775.082, s. 775.083, or
2 s. 775.084.

3 (5) SALE OR TRANSFER OF LEGEND DRUG TO UNAUTHORIZED
4 PERSON.--A person who knowingly sells or transfers to a person
5 not authorized to purchase or possess legend drugs, under the
6 law of the jurisdiction in which the person receives the drug,
7 a legend drug in a wholesale distribution transaction commits
8 a felony of the second degree, punishable as provided in s.
9 775.082, s. 775.083, or s. 775.084.

10 (6) SALE OR DELIVERY, OR POSSESSION WITH INTENT TO
11 SELL, CONTRABAND LEGEND DRUGS.--A person who is knowingly in
12 actual or constructive possession of any amount of contraband
13 legend drugs, who knowingly sells or delivers, or who
14 possesses with intent to sell or deliver any amount of
15 contraband legend drugs, commits a felony of the second
16 degree, punishable as provided in s. 775.082, s. 775.083, or
17 s. 775.084.

18 (7) FORGERY OF PRESCRIPTION OR LEGEND DRUG LABELS.--A
19 person who knowingly forges, counterfeits, or falsely creates
20 any prescription label or legend drug label, or who falsely
21 represents any factual matter contained on any prescription
22 label or legend drug label, commits a felony of the first
23 degree, punishable as provided in s. 775.082, s. 775.083, or
24 s. 775.084.

25 Section 6. Section 499.0052, Florida Statutes, is
26 created to read:

27 499.0052 Trafficking in contraband legend drugs.--A
28 person who knowingly sells, purchases, manufactures, delivers,
29 or brings into this state, or who is knowingly in actual or
30 constructive possession of any amount of contraband legend
31 drugs valued at \$1,000 or more commits a felony of the first

1 degree, punishable as provided in s. 775.082, s. 775.083, or
2 s. 775.084. Upon conviction, each defendant shall be ordered
3 to pay a mandatory fine according to the following schedule:

4 (1) If the value of contraband legend drugs involved
5 is \$1,000 or more, but less than \$10,000, the defendant shall
6 pay a mandatory fine of \$25,000. If the defendant is a
7 corporation or other person that is not a natural person, it
8 shall pay a mandatory fine of \$75,000.

9 (2) If the value of contraband legend drugs involved
10 is \$10,000 or more, but less than \$100,000, the defendant
11 shall pay a mandatory fine of \$100,000. If the defendant is a
12 corporation or other person that is not a natural person, it
13 shall pay a mandatory fine of \$300,000.

14 (3) If the value of contraband legend drugs involved
15 is \$100,000 or more, the defendant shall pay a mandatory fine
16 of \$200,000. If the defendant is a corporation or other person
17 that is not a natural person, it shall pay a mandatory fine of
18 \$600,000.

19
20 As used in this section, the term "value" means the market
21 value of the property at the time and place of the offense or,
22 if such cannot be satisfactorily ascertained, the cost of
23 replacement of the property within a reasonable time after the
24 offense. Amounts of value of separate contraband legend drugs
25 involved in distinct transactions for the distribution of the
26 contraband legend drugs committed pursuant to one scheme or
27 course of conduct, whether involving the same person or
28 several persons, may be aggregated in determining the
29 punishment of the offense.

30 Section 7. Section 499.0053, Florida Statutes, is
31 created, to read:

1 499.0053 Sale or purchase of contraband legend drugs
2 resulting in great bodily harm.--A person who knowingly sells,
3 purchases, manufactures, delivers, or brings into this state,
4 or who is knowingly in actual or constructive possession of
5 any amount of contraband legend drugs, and whose acts in
6 violation of this section result in great bodily harm to a
7 person, commits a felony of the first degree, as provided in
8 s. 775.082, s. 775.083, or s. 775.084.

9 Section 8. Section 499.0054, Florida Statutes, is
10 created to read:

11 499.0054 Sale or purchase of contraband legend drugs
12 resulting in death.--A person who knowingly manufactures,
13 sells, purchases, delivers, or brings into this state, or who
14 is knowingly in actual or constructive possession of any
15 amount of contraband legend drugs, and whose acts in violation
16 of this section result in the death of a person, commits a
17 felony of the first degree, punishable by a term of years not
18 exceeding life, as provided in s. 775.082, s. 775.083, or s.
19 775.084.

20 Section 9. Section 499.006, Florida Statutes, is
21 amended to read:

22 499.006 Adulterated drug or device.--A drug or device
23 is adulterated:

24 (1) If it consists in whole or in part of any filthy,
25 putrid, or decomposed substance;

26 (2) If it has been produced, prepared, packed, or held
27 under conditions whereby it could have been contaminated with
28 filth or rendered injurious to health;

29 (3) If it is a drug and the methods used in, or the
30 facilities or controls used for, its manufacture, processing,
31 packing, or holding do not conform to, or are not operated or

1 administered in conformity with, current good manufacturing
2 practices to assure that the drug meets the requirements of
3 ss. 499.001-499.081 and that the drug has the identity and
4 strength, and meets the standard of quality and purity, which
5 it purports or is represented to possess;

6 (4) If it is a drug and its container is composed, in
7 whole or in part, of any poisonous or deleterious substance
8 which could render the contents injurious to health;

9 (5) If it is a drug and it bears or contains, for the
10 purpose of coloring only, a color additive that is unsafe
11 within the meaning of the federal act; or, if it is a color
12 additive, the intended use of which in or on drugs is for the
13 purpose of coloring only, and it is unsafe within the meaning
14 of the federal act;

15 (6) If it purports to be, or is represented as, a drug
16 the name of which is recognized in the official compendium,
17 and its strength differs from, or its quality or purity falls
18 below, the standard set forth in such compendium. The
19 determination as to strength, quality, or purity must be made
20 in accordance with the tests or methods of assay set forth in
21 such compendium, or, when such tests or methods of assay are
22 absent or inadequate, in accordance with those tests or
23 methods of assay prescribed under authority of the federal
24 act. A drug defined in the official compendium is not
25 adulterated under this subsection merely because it differs
26 from the standard of strength, quality, or purity set forth
27 for that drug in such compendium if its difference in
28 strength, quality, or purity from such standard is plainly
29 stated on its label;

30 (7) If it is not subject to subsection (6) and its
31 strength differs from, or its purity or quality falls below

1 the standard of, that which it purports or is represented to
2 possess; ~~or~~

3 (8) If it is a drug:

4 (a) With which any substance has been mixed or packed
5 so as to reduce the quality or strength of the drug; or

6 (b) For which any substance has been substituted
7 wholly or in part;~~or~~

8 (9) If it is a drug or device for which the expiration
9 date has passed; ~~or~~

10 (10) If it is a legend drug for which the required
11 pedigree paper is nonexistent, fraudulent, or incomplete under
12 the requirements of ss. 499.001-499.081 or applicable rules,
13 or that has been purchased, held, sold, or distributed at any
14 time by a person not authorized under federal or state law to
15 do so.

16 Section 10. Subsection (2) of section 499.007, Florida
17 Statutes, is amended to read:

18 499.007 Misbranded drug or device.--A drug or device
19 is misbranded:

20 (2) Unless, if in package form, it bears a label
21 containing:

22 (a) The name and place of business of the
23 manufacturer, repackager, or distributor; ~~in addition, for a~~
24 ~~medicinal drug, as defined in s. 499.003, the label must~~
25 ~~contain the name and place of business of the manufacturer of~~
26 the finished dosage form of the drug. For the purpose of this
27 paragraph, the finished dosage form of a medicinal drug is
28 that form of the drug which is, or is intended to be,
29 dispensed or administered to the patient and requires no
30 further manufacturing or processing other than packaging,
31 reconstitution, and labeling; and

1 (b) An accurate statement of the quantity of the
2 contents in terms of weight, measure, or numerical count;
3 however, under this section, reasonable variations are
4 permitted, and the department shall establish by rule
5 exemptions for small packages.

6 Section 11. Subsections (1) and (3) of section 499.01,
7 Florida Statutes, are amended to read:

8 499.01 Permits; applications; renewal; general
9 requirements.--

10 (1) Any person that is required under ss.
11 499.001-499.081 to have a permit must apply to the department
12 on forms furnished by the department.

13 (a) A permit issued pursuant to ss. 499.001-499.081
14 may be issued only to a natural person ~~an individual~~ who is at
15 least 18 years of age or to an applicant that is not a natural
16 person if each person who, directly or indirectly, manages,
17 controls, or oversees the operation of that applicant a
18 ~~corporation that is registered pursuant to chapter 607 or~~
19 ~~chapter 617 and each officer of which~~ is at least 18 years of
20 age.

21 (b) An establishment that is a place of residence may
22 not receive a permit and may not operate under ss.
23 499.001-499.081.

24 (c) A person that applies for or renews a permit to
25 manufacture or distribute legend drugs may not use a name
26 identical to the name used by any other establishment or
27 licensed person authorized to purchase prescription drugs in
28 this state, except that a restricted drug distributor permit
29 issued to a health care entity will be issued in the name in
30 which the institutional pharmacy permit is issued and a retail
31

1 pharmacy drug wholesaler will be issued a permit in the name
2 of its retail pharmacy permit.

3 (d) A permit is required for each establishment that
4 operates as a:

- 5 1. Prescription drug manufacturer;
- 6 2. Over-the-counter drug manufacturer;
- 7 3. Compressed medical gas manufacturer;
- 8 4. Device manufacturer;
- 9 5. Cosmetic manufacturer;
- 10 6. Prescription drug wholesaler;
- 11 7. Compressed medical gas wholesaler;
- 12 8. Out-of-state prescription drug wholesaler;
- 13 9. Retail pharmacy drug wholesaler;
- 14 10. Veterinary legend drug retail establishment;
- 15 11. Medical oxygen retail establishment;
- 16 12. Complimentary drug distributor; or
- 17 13. Restricted prescription drug distributor.

18 (e) A permit for a prescription drug manufacturer,
19 prescription drug wholesaler, or retail pharmacy wholesaler
20 may not be issued to the address of a health care entity or to
21 a pharmacy licensed under chapter 465, except as provided in
22 this paragraph. The department may issue a prescription drug
23 manufacturer permit to an applicant at the same address as a
24 licensed nuclear pharmacy, which is a health care entity, for
25 the purpose of manufacturing prescription drugs used in
26 positron emission tomography or other radiopharmaceuticals, as
27 listed in a rule adopted by the department pursuant to this
28 paragraph. The purpose of this exemption is to assure
29 availability of state-of-the-art pharmaceuticals that would
30 pose a significant danger to the public health if manufactured
31 at a separate establishment address from the nuclear pharmacy

1 from which the prescription drugs are dispensed. The
2 department may also issue a retail pharmacy wholesaler permit
3 to the address of a community pharmacy licensed under chapter
4 465 which does not meet the definition of a closed pharmacy in
5 s. 499.003.

6 (f) The department may not issue a permit required by
7 this part unless the applicant has first obtained all
8 occupational licenses and other permits or licenses, if any,
9 required by the county and local government where the
10 applicant's establishment is located. Notwithstanding any
11 other law to the contrary, a county or local government may
12 not require the applicant to first obtain a permit under this
13 part as a condition to issuing the permits or licenses
14 required by county and local laws or ordinances.

15 (g)~~(f)~~ Notwithstanding subsection (4), a permitted
16 person in good standing may change the type of permit issued
17 to that person by completing a new application for the
18 requested permit, paying the amount of the difference in the
19 permit fees if the fee for the new permit is more than the fee
20 for the original permit, and meeting the applicable permitting
21 conditions for the new permit type. The new permit expires on
22 the expiration date of the original permit being changed;
23 however, a new permit for a prescription drug wholesaler, an
24 out-of-state prescription drug wholesaler, or a retail
25 pharmacy drug wholesaler shall expire on the expiration date
26 of the original permit or 1 year after the date of issuance of
27 the new permit, whichever is earlier. A refund may not be
28 issued if the ~~biennial~~ fee for the new permit is less than the
29 fee that was paid original permit for which a fee was paid.

30 (3) The department shall adopt rules for the biennial
31 renewal of permits.

1 (a) The department shall renew a permit upon receipt
2 of the renewal application and renewal fee if the applicant
3 meets the requirements established under ss. 499.001-499.081
4 and the rules adopted under those sections.

5 (b) A permit, unless sooner suspended or revoked,
6 automatically expires 2 years after the last day of the
7 anniversary month in which the permit was originally issued;
8 except that a prescription drug wholesaler permit, an
9 out-of-state prescription drug wholesaler permit, and a retail
10 pharmacy wholesaler permit issued from July 1, 2003 through
11 December 31, 2003, shall expire 1 year after the last day of
12 the anniversary month in which the permit was issued. Any
13 valid permit issued by the department on or before June 30,
14 2003, with an expiration date between January 1, 2005, and
15 June 30, 2005, shall automatically expire 1 year prior to the
16 expiration date stated on the permit. A permittee that submits
17 a renewal application for a permit with a stated expiration
18 date between January 1, 2005, and June 30, 2005, shall receive
19 a credit of one-half of the permit fee paid when the
20 application for the expiring permit was submitted. Any valid
21 permit issued by the department on or before June 30, 2003,
22 with an expiration date between July 1, 2004, and December 31,
23 2004, shall automatically expire 6 months prior to the
24 expiration date stated on the permit. A permittee that submits
25 a renewal application for a permit with a stated expiration
26 date between July 1, 2004, and December 31, 2004, shall
27 receive a credit of one-fourth of the permit fee paid when the
28 application for the expiring permit was submitted. A permittee
29 whose permit expiration date was accelerated in this paragraph
30 may request a pro rata refund equivalent to the credit
31 available for submission of a renewal application if the

1 permittee does not submit a renewal application.A permit
2 issued under ss. 499.001-499.081 ~~may~~ must be renewed by making
3 application for renewal on forms furnished by the department
4 and paying the appropriate fees. If a renewal application and
5 fee are ~~not~~ submitted and postmarked after ~~by~~ the expiration
6 date of the permit, the permit may be renewed ~~reinstated~~ only
7 upon payment of a late renewal delinquent fee of \$100, plus
8 the required renewal fee, not later than ~~within~~ 60 days after
9 the expiration date.

10 (c) Failure to renew a permit in accordance with this
11 section precludes any future renewal of that permit. If a
12 permit issued pursuant to this section has expired and cannot
13 be renewed, before an establishment may engage in activities
14 that require a permit under ss. 499.001-499.081, the
15 establishment must submit an application for a new permit, pay
16 the applicable application fee, the initial permit fee, and
17 all applicable penalties, and be issued a new permit by the
18 department.~~Continuing to engage in activities that require a~~
19 ~~permit under ss. 499.001-499.081 requires a new permit~~
20 ~~application and payment of an application fee, initial permit~~
21 ~~fee, and applicable penalties.~~

22 Section 12. Effective January 1, 2004, section 499.01,
23 Florida Statutes, as amended by this act, is amended to read:

24 499.01 Permits; applications; renewal; general
25 requirements.--

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

28 (a) A prescription drug manufacturer;

29 (b) A prescription drug repackager;

30 (c) An over-the-counter drug manufacturer;

31 (d) A compressed medical gas manufacturer;

- 1 (e) A device manufacturer;
2 (f) A cosmetic manufacturer;
3 (g) A prescription drug wholesaler;
4 (h) A compressed medical gas wholesaler;
5 (i) An out-of-state prescription drug wholesaler;
6 (j) A nonresident prescription drug manufacturer;
7 (k) A freight forwarder;
8 (l) A retail pharmacy drug wholesaler;
9 (m) A veterinary legend drug retail establishment;
10 (n) A medical oxygen retail establishment;
11 (o) A complimentary drug distributor; or
12 (p) A restricted prescription drug distributor.
13 ~~(1) Any person that is required under ss.~~
14 ~~499.001-499.081 to have a permit must apply to the department~~
15 ~~on forms furnished by the department.~~
16 (2)(a) A permit issued pursuant to ss. 499.001-499.081
17 may be issued only to a natural person who is at least 18
18 years of age or to an applicant that is not a natural person
19 if each person who, directly or indirectly, manages, controls,
20 or oversees the operation of that applicant is at least 18
21 years of age.
22 (b) An establishment that is a place of residence may
23 not receive a permit and may not operate under ss.
24 499.001-499.081.
25 (c) A person that applies for or renews a permit to
26 manufacture or distribute legend drugs may not use a name
27 identical to the name used by any other establishment or
28 licensed person authorized to purchase prescription drugs in
29 this state, except that a restricted drug distributor permit
30 issued to a health care entity will be issued in the name in
31 which the institutional pharmacy permit is issued and a retail

1 pharmacy drug wholesaler will be issued a permit in the name
2 of its retail pharmacy permit.

3 ~~(d) A permit is required for each establishment that~~
4 ~~operates as a:~~

- 5 ~~1. Prescription drug manufacturer;~~
- 6 ~~2. Over-the-counter drug manufacturer;~~
- 7 ~~3. Compressed medical gas manufacturer;~~
- 8 ~~4. Device manufacturer;~~
- 9 ~~5. Cosmetic manufacturer;~~
- 10 ~~6. Prescription drug wholesaler;~~
- 11 ~~7. Compressed medical gas wholesaler;~~
- 12 ~~8. Out-of-state prescription drug wholesaler;~~
- 13 ~~9. Retail pharmacy drug wholesaler;~~
- 14 ~~10. Veterinary legend drug retail establishment;~~
- 15 ~~11. Medical oxygen retail establishment;~~
- 16 ~~12. Complimentary drug distributor; or~~
- 17 ~~13. Restricted prescription drug distributor.~~

18 (d)(e) A permit for a prescription drug manufacturer,
19 prescription drug repackager, prescription drug wholesaler, or
20 retail pharmacy wholesaler may not be issued to the address of
21 a health care entity or to a pharmacy licensed under chapter
22 465, except as provided in this paragraph. The department may
23 issue a prescription drug manufacturer permit to an applicant
24 at the same address as a licensed nuclear pharmacy, which is a
25 health care entity, for the purpose of manufacturing
26 prescription drugs used in positron emission tomography or
27 other radiopharmaceuticals, as listed in a rule adopted by the
28 department pursuant to this paragraph. The purpose of this
29 exemption is to assure availability of state-of-the-art
30 pharmaceuticals that would pose a significant danger to the
31 public health if manufactured at a separate establishment

1 address from the nuclear pharmacy from which the prescription
2 drugs are dispensed. The department may also issue a retail
3 pharmacy wholesaler permit to the address of a community
4 pharmacy licensed under chapter 465 which does not meet the
5 definition of a closed pharmacy in s. 499.003.

6 (e)~~(f)~~ The department may not issue a permit required
7 by this part unless the applicant has first obtained all
8 occupational licenses and other permits or licenses, if any,
9 required by the county and local government where the
10 applicant's establishment is located. Notwithstanding any
11 other law to the contrary, a county or local government may
12 not require the applicant to first obtain a permit under this
13 part as a condition to issuing the permits or licenses
14 required by county and local laws or ordinances.

15 (3)~~(g)~~ Notwithstanding subsection (7)~~(4)~~, a permitted
16 person in good standing may change the type of permit issued
17 to that person by completing a new application for the
18 requested permit, paying the amount of the difference in the
19 permit fees if the fee for the new permit is more than the fee
20 for the original permit, and meeting the applicable permitting
21 conditions for the new permit type. The new permit expires on
22 the expiration date of the original permit being changed;
23 however, a new permit for a prescription drug wholesaler, an
24 out-of-state prescription drug wholesaler, or a retail
25 pharmacy drug wholesaler shall expire on the expiration date
26 of the original permit or 1 year after the date of issuance of
27 the new permit, whichever is earlier. A refund may not be
28 issued if the fee for the new permit is less than the fee that
29 was paid original permit.

30 (4)~~(2)~~ A written application for a permit or to renew
31 a permit must be filed with the department on forms furnished

1 by the department.The department shall establish, by rule,
2 the form and content of the application to obtain or renew a
3 permit. The applicant must submit to the department with the
4 application a statement that swears or affirms that the
5 information contained in the application is true and correct.

6 (5)(a) Except for a permit for prescription drug
7 wholesaler, an out-of-state prescription drug wholesaler, or a
8 retail pharmacy drug wholesaler, an application for a permit
9 must include information that an applicant must provide
10 includes, but need not be limited to:

- 11 1. The name, full business address, and telephone
12 number of the applicant;
- 13 2. All trade or business names used by the applicant;
- 14 3. The address, telephone numbers, and the names of
15 contact persons for each facility used by the applicant for
16 the storage, handling, and distribution of prescription drugs;
- 17 4. The type of ownership or operation, such as a
18 partnership, corporation, or sole proprietorship; and
- 19 5. The names of the owner and the operator of the
20 establishment, including:
 - 21 a. If an individual, the name of the individual;
 - 22 b. If a partnership, the name of each partner and the
23 name of the partnership;
 - 24 c. If a corporation, the name and title of each
25 corporate officer and director, the corporate names, and the
26 name of the state of incorporation;
 - 27 d. If a sole proprietorship, the full name of the sole
28 proprietor and the name of the business entity; ~~and~~
 - 29 e. If a limited liability company, the name of each
30 member, the name of each manager, the name of the limited

1 liability company, and the name of the state in which the
2 limited liability company was organized; and

3 f.e. Any other relevant information that the
4 department requires.

5 (b) Upon approval of the application by the department
6 and payment of the required fee, the department shall issue a
7 permit to the applicant, if the applicant meets the
8 requirements of ss. 499.001-499.081 and rules adopted under
9 those sections.

10 (c) Any change in information required under paragraph
11 (a) must be submitted to the department before the change
12 occurs.

13 (d) The department shall consider, at a minimum, the
14 following factors in reviewing the qualifications of persons
15 to be permitted under ss. 499.001-499.081:

16 1. The applicant's having been found guilty,
17 regardless of adjudication, in a court of this state or other
18 jurisdiction, of a violation of a law that directly relates to
19 a drug, device, or cosmetic. A plea of nolo contendere
20 constitutes a finding of guilt for purposes of this
21 subparagraph.

22 2. The applicant's having been disciplined by a
23 regulatory agency in any state for any offense that would
24 constitute a violation of ss. 499.001-499.081.

25 3. Any felony conviction of the applicant under a
26 federal, state, or local law;

27 4. The applicant's past experience in manufacturing or
28 distributing drugs, devices, or cosmetics;

29 5. The furnishing by the applicant of false or
30 fraudulent material in any application made in connection with
31 manufacturing or distributing drugs, devices, or cosmetics;

1 6. Suspension or revocation by a federal, state, or
2 local government of any permit currently or previously held by
3 the applicant for the manufacture or distribution of any
4 drugs, devices, or cosmetics;

5 7. Compliance with permitting requirements under any
6 previously granted permits;

7 8. Compliance with requirements to maintain or make
8 available to the state permitting authority or to federal,
9 state, or local law enforcement officials those records
10 required under this section; and

11 9. Any other factors or qualifications the department
12 considers relevant to and consistent with the public health
13 and safety.

14 (6) Except for permits for prescription drug
15 wholesalers, out-of-state prescription drug wholesalers, and
16 retail pharmacy drug wholesalers:

17 (a)~~(3)~~ The department shall adopt rules for the
18 biennial renewal of permits.

19 (b)~~(a)~~ The department shall renew a permit upon
20 receipt of the renewal application and renewal fee if the
21 applicant meets the requirements established under ss.
22 499.001-499.081 and the rules adopted under those sections.

23 (c)~~(b)~~ A permit, unless sooner suspended or revoked,
24 automatically expires 2 years after the last day of the
25 anniversary month in which the permit was originally issued~~+~~
26 ~~except that a prescription drug wholesaler permit, an~~
27 ~~out-of-state prescription drug wholesaler permit, and a retail~~
28 ~~pharmacy wholesaler permit issued from July 1, 2003 through~~
29 ~~December 31, 2003, shall expire 1 year after the last day of~~
30 ~~the anniversary month in which the permit was issued. Any~~
31 ~~valid permit issued by the department on or before June 30,~~

1 ~~2003, with an expiration date between January 1, 2005, and~~
2 ~~June 30, 2005, shall automatically expire 1 year prior to the~~
3 ~~expiration date stated on the permit. A permittee that submits~~
4 ~~a renewal application for a permit with a stated expiration~~
5 ~~date between January 1, 2005, and June 30, 2005, shall receive~~
6 ~~a credit of one-half of the permit fee paid when the~~
7 ~~application for the expiring permit was submitted. Any valid~~
8 ~~permit issued by the department on or before June 30, 2003,~~
9 ~~with an expiration date between July 1, 2004, and December 31,~~
10 ~~2004, shall automatically expire 6 months prior to the~~
11 ~~expiration date stated on the permit. A permittee that submits~~
12 ~~a renewal application for a permit with a stated expiration~~
13 ~~date between July 1, 2004, and December 31, 2004, shall~~
14 ~~receive a credit of one-fourth of the permit fee paid when the~~
15 ~~application for the expiring permit was submitted. A permittee~~
16 ~~whose permit expiration date was accelerated in this paragraph~~
17 ~~may request a pro rata refund equivalent to the credit~~
18 ~~available for submission of a renewal application if the~~
19 ~~permittee does not submit a renewal application. A permit~~
20 ~~issued under ss. 499.001-499.081 may be renewed by making~~
21 ~~application for renewal on forms furnished by the department~~
22 ~~and paying the appropriate fees. If a renewal application and~~
23 ~~fee are submitted and postmarked after the expiration date of~~
24 ~~the permit, the permit may be renewed only upon payment of a~~
25 ~~late renewal delinquent fee of \$100, plus the required renewal~~
26 ~~fee, not later than 60 days after the expiration date.~~

27 (d)~~(c)~~ Failure to renew a permit in accordance with
28 this section precludes any future renewal of that permit. If a
29 permit issued pursuant to this section has expired and cannot
30 be renewed, before an establishment may engage in activities
31 that require a permit under ss. 499.001-499.081, the

1 establishment must submit an application for a new permit, pay
2 the applicable application fee, the initial permit fee, and
3 all applicable penalties, and be issued a new permit by the
4 department.

5 (7)~~(4)~~ A permit issued by the department is
6 nontransferable. Each permit is valid only for the person or
7 governmental unit to which it is issued and is not subject to
8 sale, assignment, or other transfer, voluntarily or
9 involuntarily; nor is a permit valid for any establishment
10 other than the establishment for which it was originally
11 issued.

12 (a) A person permitted under ss. 499.001-499.081 must
13 notify the department before making a change of address. The
14 department shall set a change of location fee not to exceed
15 \$100.

16 (b)1. An application for a new permit is required when
17 a majority of the ownership or controlling interest of a
18 permitted establishment is transferred or assigned or when a
19 lessee agrees to undertake or provide services to the extent
20 that legal liability for operation of the establishment will
21 rest with the lessee. The application for the new permit must
22 be made before the date of the sale, transfer, assignment, or
23 lease.

24 2. A permittee that is authorized to distribute legend
25 drugs may transfer such drugs to the new owner or lessee under
26 subparagraph 1. only after the new owner or lessee has been
27 approved for a permit to distribute legend drugs.

28 ~~(c) The department shall deny, suspend, or revoke the~~
29 ~~permit of any person or establishment if the assignment, sale,~~
30 ~~transfer, or lease of an establishment permitted under ss.~~

31

1 ~~499.001-499.081 will avoid an administrative penalty, civil~~
2 ~~action, or criminal prosecution.~~

3 (c)(d) If an establishment permitted under ss.
4 499.001-499.081 closes, the owner must notify the department
5 in writing before the effective date of closure and must:

- 6 1. Return the permit to the department;
- 7 2. If the permittee is authorized to distribute legend
8 drugs, indicate the disposition of such drugs, including the
9 name, address, and inventory, and provide the name and address
10 of a person to contact regarding access to records that are
11 required to be maintained under ss. 499.001-499.081. Transfer
12 of ownership of legend drugs may be made only to persons
13 authorized to possess legend drugs under ss. 499.001-499.081.

14
15 The department may revoke the permit of any person that fails
16 to comply with the requirements of this subsection.

17 (8)(5) A permit must be posted in a conspicuous place
18 on the licensed premise.

19 Section 13. Section 499.012, Florida Statutes, is
20 amended to read:

21 499.012 Wholesale distribution; definitions; permits;
22 applications; general requirements.--

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

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

27 1. Any of the following activities, which is not a
28 violation of s. 499.005(21) if such activity is conducted in
29 accordance with s. 499.014:

30 a. The purchase or other acquisition by a hospital or
31 other health care entity that is a member of a group

1 purchasing organization of a prescription drug for its own use
2 from the group purchasing organization or from other hospitals
3 or health care entities that are members of that organization.

4 b. The sale, purchase, or trade of a prescription drug
5 or an offer to sell, purchase, or trade a prescription drug by
6 a charitable organization described in s. 501(c)(3) of the
7 Internal Revenue Code of 1986, as amended and revised, to a
8 nonprofit affiliate of the organization to the extent
9 otherwise permitted by law.

10 c. The sale, purchase, or trade of a prescription drug
11 or an offer to sell, purchase, or trade a prescription drug
12 among hospitals or other health care entities that are under
13 common control. For purposes of this section, "common control"
14 means the power to direct or cause the direction of the
15 management and policies of a person or an organization,
16 whether by ownership of stock, by voting rights, by contract,
17 or otherwise.

18 d. The sale, purchase, trade, or other transfer of a
19 prescription drug from or for any federal, state, or local
20 government agency or any entity eligible to purchase
21 prescription drugs at public health services prices pursuant
22 to Pub. L. No. 102-585, s. 602 to a contract provider or its
23 subcontractor for eligible patients of the agency or entity
24 under the following conditions:

25 (I) The agency or entity must obtain written
26 authorization for the sale, purchase, trade, or other transfer
27 of a prescription drug under this sub-subparagraph from the
28 Secretary of Health or his or her designee.

29 (II) The contract provider or subcontractor must be
30 authorized by law to administer or dispense prescription
31 drugs.

1 (III) In the case of a subcontractor, the agency or
2 entity must be a party to and execute the subcontract.

3 (IV) A contract provider or subcontractor must
4 maintain separate and apart from other prescription drug
5 inventory any prescription drugs of the agency or entity in
6 its possession.

7 (V) The contract provider and subcontractor must
8 maintain and produce immediately for inspection all records of
9 movement or transfer of all the prescription drugs belonging
10 to the agency or entity, including, but not limited to, the
11 records of receipt and disposition of prescription drugs. Each
12 contractor and subcontractor dispensing or administering these
13 drugs must maintain and produce records documenting the
14 dispensing or administration. Records that are required to be
15 maintained include, but are not limited to, a perpetual
16 inventory itemizing drugs received and drugs dispensed by
17 prescription number or administered by patient identifier,
18 which must be submitted to the agency or entity quarterly.

19 (VI) The contract provider or subcontractor may
20 administer or dispense the prescription drugs only to the
21 eligible patients of the agency or entity or must return the
22 prescription drugs for or to the agency or entity. The
23 contract provider or subcontractor must require proof from
24 each person seeking to fill a prescription or obtain treatment
25 that the person is an eligible patient of the agency or entity
26 and must, at a minimum, maintain a copy of this proof as part
27 of the records of the contractor or subcontractor required
28 under sub-sub-subparagraph (V).

29 (VII) In addition to the departmental inspection
30 authority set forth in s. 499.051, the establishment of the
31 contract provider and subcontractor and all records pertaining

1 to prescription drugs subject to this sub-subparagraph shall
2 be subject to inspection by the agency or entity. All records
3 relating to prescription drugs of a manufacturer under this
4 sub-subparagraph shall be subject to audit by the manufacturer
5 of those drugs, without identifying individual patient
6 information.

7 2. Any of the following activities, which is not a
8 violation of s. 499.005(21) if such activity is conducted in
9 accordance with rules established by the department:

10 a. The sale, purchase, or trade of a prescription drug
11 among federal, state, or local government health care entities
12 that are under common control and are authorized to purchase
13 such prescription drug.

14 b. The sale, purchase, or trade of a prescription drug
15 or an offer to sell, purchase, or trade a prescription drug
16 for emergency medical reasons. For purposes of this
17 sub-subparagraph, the term "emergency medical reasons"
18 includes transfers of prescription drugs by a retail pharmacy
19 to another retail pharmacy to alleviate a temporary shortage.

20 c. The transfer of a prescription drug acquired by a
21 medical director on behalf of a licensed emergency medical
22 services provider to that emergency medical services provider
23 and its transport vehicles for use in accordance with the
24 provider's license under chapter 401.

25 d. The revocation of a sale or the return of a
26 prescription drug to the person's prescription drug wholesale
27 supplier.

28 e. The donation of a prescription drug by a health
29 care entity to a charitable organization that has been granted
30 an exemption under s. 501(c)(3) of the Internal Revenue Code
31

1 of 1986, as amended, and that is authorized to possess
2 prescription drugs.

3 f. The transfer of a prescription drug by a person
4 authorized to purchase or receive prescription drugs to a
5 person licensed or permitted to handle reverse distributions
6 or destruction under the laws of the jurisdiction in which the
7 person handling the reverse distribution or destruction
8 receives the drug.

9 g. The transfer of a prescription drug by a hospital
10 or other health care entity to a person licensed under this
11 chapter to repackage prescription drugs for the purpose of
12 repackaging the prescription drug for use by that hospital, or
13 other health care entity and other health care entities that
14 are under common control, if ownership of the prescription
15 drugs remains with the hospital or other health care entity at
16 all times. In addition to the recordkeeping requirements of s.
17 499.0121(6), the hospital or health care entity that transfers
18 prescription drugs pursuant to this sub-subparagraph must
19 reconcile all drugs transferred and returned and resolve any
20 discrepancies in a timely manner.

21 3. The distribution of prescription drug samples by
22 manufacturers' representatives or distributors'
23 representatives conducted in accordance with s. 499.028.

24 4. The sale, purchase, or trade of blood and blood
25 components intended for transfusion. As used in this
26 subparagraph, the term "blood" means whole blood collected
27 from a single donor and processed either for transfusion or
28 further manufacturing, and the term "blood components" means
29 that part of the blood separated by physical or mechanical
30 means.

31

1 5. The lawful dispensing of a prescription drug in
2 accordance with chapter 465.

3 (b) "Wholesale distributor" means any person engaged
4 in wholesale distribution of prescription drugs in or into
5 this state, including, but not limited to, manufacturers;
6 repackagers ~~repackers~~; own-label distributors; jobbers;
7 private-label distributors; brokers; warehouses, including
8 manufacturers' and distributors' warehouses, chain drug
9 warehouses, and wholesale drug warehouses; independent
10 wholesale drug traders; exporters; retail pharmacies; and the
11 agents thereof that conduct wholesale distributions.

12 (c) "Retail pharmacy" means a community pharmacy
13 licensed under chapter 465 that purchases prescription drugs
14 at fair market prices and provides prescription services to
15 the public.

16 (2) The following types of wholesaler permits are
17 established:

18 (a) A prescription drug wholesaler's permit. A
19 prescription drug wholesaler is a wholesale distributor that
20 may engage in the wholesale distribution of prescription
21 drugs. A prescription drug wholesaler that applies to the
22 department for a new permit or the renewal of a permit after
23 July 1, 2003 ~~January 1, 1993~~, must submit a bond of \$100,000,
24 or other equivalent means of security acceptable to the
25 department, such as an irrevocable letter of credit or a
26 deposit in a trust account or financial institution ~~\$200~~,
27 payable to the Florida Drug, Device, and Cosmetic Trust Fund.
28 The purpose of the bond is to secure payment of any
29 administrative penalties imposed by the department and any
30 fees and costs incurred by the department regarding that
31 permit which are authorized under state law and which the

1 permittee fails to pay 30 days after the fine or costs become
2 final. The department may make a claim against such bond or
3 security until 1 year after the permittee's license ceases to
4 be valid or until 60 days after any administrative or legal
5 proceeding authorized in ss. 499.001-499.081 which involves
6 the permittee is concluded, including any appeal, whichever
7 occurs later.~~This bond will be refunded to the permittee when~~
8 ~~the permit is returned to the department and the permittee~~
9 ~~ceases to function as a business. A permittee that fails to~~
10 ~~notify the department before changing the address of the~~
11 ~~business, fails to notify the department before closing the~~
12 ~~business, or fails to notify the department before a change of~~
13 ~~ownership forfeits its bond.~~The department may adopt rules
14 for issuing a prescription drug wholesaler-broker permit to a
15 person who engages in the wholesale distribution of
16 prescription drugs and does not take physical possession of
17 any prescription drugs.

18 (b) A compressed medical gas wholesaler's permit. A
19 compressed medical gas wholesaler is a wholesale distributor
20 that is limited to the wholesale distribution of compressed
21 medical gases to other than the consumer or patient. The
22 compressed medical gas must be in the original sealed
23 container that was purchased by that wholesaler. A compressed
24 medical gas wholesaler may not possess or engage in the
25 wholesale distribution of any prescription drug other than
26 compressed medical gases. The department shall adopt rules
27 that govern the wholesale distribution of prescription medical
28 oxygen for emergency use. With respect to the emergency use of
29 prescription medical oxygen, those rules may not be
30 inconsistent with rules and regulations of federal agencies
31 unless the Legislature specifically directs otherwise.

1 (c) An out-of-state prescription drug wholesaler's
2 permit. An out-of-state prescription drug wholesaler is a
3 wholesale distributor located outside this state which engages
4 in the wholesale distribution of prescription drugs into this
5 state and which must be permitted by the department and comply
6 with all the provisions required of a wholesale distributor
7 under ss. 499.001-499.081. An out-of-state prescription drug
8 wholesaler that applies to the department for a new permit or
9 the renewal of a permit after July 1, 2003, must submit a bond
10 of \$100,000, or other equivalent means of security acceptable
11 to the department, such as an irrevocable letter of credit or
12 a deposit in a trust account or financial institution, payable
13 to the Florida Drug, Device, and Cosmetic Trust Fund. The
14 purpose of the bond is to secure payment of any administrative
15 penalties imposed by the department and any fees and costs
16 incurred by the department regarding that permit which are
17 authorized under state law and which the permittee fails to
18 pay 30 days after the fine or costs become final. The
19 department may make a claim against such bond or security
20 until 1 year after the permittee's license ceases to be valid
21 or until 60 days after any administrative or legal proceeding
22 authorized in ss. 499.001-499.081 which involves the permittee
23 is concluded, including any appeal, whichever occurs later.

24 1. The out-of-state drug wholesaler must maintain at
25 all times a license or permit to engage in the wholesale
26 distribution of prescription drugs in compliance with laws of
27 the state in which it is a resident.

28 2. An out-of-state prescription drug wholesaler's
29 permit is not required for an intracompany sale or transfer of
30 a prescription drug from an out-of-state establishment that is
31 duly licensed as a prescription drug wholesaler, in its state

1 of residence, to a licensed prescription drug wholesaler in
2 this state, if both wholesalers conduct wholesale
3 distributions of prescription drugs under the same business
4 name ~~are under common control~~. The recordkeeping requirements
5 of s. 499.0121(6) must be followed for this transaction.

6 ~~3. The department may adopt rules that allow~~
7 ~~out-of-state wholesalers to obtain a drug wholesale~~
8 ~~permit on the basis of reciprocity to the extent that an~~
9 ~~out-of-state drug wholesaler:~~

10 ~~a. Possesses a valid permit granted by another state~~
11 ~~that has requirements comparable to those that a drug~~
12 ~~wholesaler in this state must meet as prerequisites to~~
13 ~~obtaining a permit under the laws of this state.~~

14 ~~b. Can show that the other state from which the~~
15 ~~wholesaler holds a permit would extend reciprocal treatment~~
16 ~~under its own laws to a drug wholesaler of this state.~~

17 (d) A retail pharmacy wholesaler's permit. A retail
18 pharmacy wholesaler is a retail pharmacy engaged in wholesale
19 distribution of prescription drugs within this state under the
20 following conditions:

21 1. The pharmacy must obtain a retail pharmacy
22 wholesaler's permit pursuant to ss. 499.001-499.081 and the
23 rules adopted under those sections.

24 2. The wholesale distribution activity does not exceed
25 30 percent of the total annual purchases of prescription
26 drugs. If the wholesale distribution activity exceeds the
27 30-percent maximum, the pharmacy must obtain a prescription
28 drug wholesaler's permit.

29 3. The transfer of prescription drugs that appear in
30 any schedule contained in chapter 893 is subject to chapter
31

1 893 and the federal Comprehensive Drug Abuse Prevention and
2 Control Act of 1970.

3 4. The transfer is between a retail pharmacy and
4 another retail pharmacy, or a Modified Class II institutional
5 pharmacy, or a health care practitioner licensed in this state
6 and authorized by law to dispense or prescribe prescription
7 drugs.

8 5. All records of sales of prescription drugs subject
9 to this section must be maintained separate and distinct from
10 other records and comply with the recordkeeping requirements
11 of ss. 499.001-499.081.

12 (3) A person that engages in wholesale distribution of
13 prescription drugs in this state must have a wholesale
14 distributor's permit issued by the department, except as noted
15 in this section. Each establishment must be separately
16 permitted except as noted in this subsection.

17 (a) A separate establishment permit is not required
18 when a permitted prescription drug wholesaler consigns a
19 prescription drug to a pharmacy that is permitted under
20 chapter 465 and located in this state, provided that:

21 1. The consignor wholesaler notifies the department in
22 writing of the contract to consign prescription drugs to a
23 pharmacy along with the identity and location of each
24 consignee pharmacy;

25 2. The pharmacy maintains its permit under chapter
26 465;

27 3. The consignor wholesaler, which has no legal
28 authority to dispense prescription drugs, complies with all
29 wholesale distribution requirements of s. 499.0121 with
30 respect to the consigned drugs and maintains records
31

1 | documenting the transfer of title or other completion of the
2 | wholesale distribution of the consigned prescription drugs;

3 | 4. The distribution of the prescription drug is
4 | otherwise lawful under this chapter and other applicable law;

5 | 5. Open packages containing prescription drugs within
6 | a pharmacy are the responsibility of the pharmacy, regardless
7 | of how the drugs are titled; and

8 | 6. The pharmacy dispenses the consigned prescription
9 | drug in accordance with the limitations of its permit under
10 | chapter 465 or returns the consigned prescription drug to the
11 | consignor wholesaler. In addition, a person who holds title to
12 | prescription drugs may transfer the drugs to a person
13 | permitted or licensed to handle the reverse distribution or
14 | destruction of drugs. Any other distribution by and means of
15 | the consigned prescription drug by any person, not limited to
16 | the consignor wholesaler or consignee pharmacy, to any other
17 | person is prohibited.

18 | (b) A wholesale distributor's permit is not required
19 | for the one-time transfer of title of a pharmacy's lawfully
20 | acquired prescription drug inventory by a pharmacy with a
21 | valid permit issued under chapter 465 to a consignor
22 | prescription drug wholesaler, permitted under this chapter, in
23 | accordance with a written consignment agreement between the
24 | pharmacy and that wholesaler if: the permitted pharmacy and
25 | the permitted prescription drug wholesaler comply with all of
26 | the provisions of paragraph (a) and the prescription drugs
27 | continue to be within the permitted pharmacy's inventory for
28 | dispensing in accordance with the limitations of the pharmacy
29 | permit under chapter 465. A consignor drug wholesaler may not
30 | use the pharmacy as a wholesale distributor through which it
31 | distributes the legend drugs to other pharmacies. Nothing in

1 this section is intended to prevent a wholesale drug
2 distributor from obtaining this inventory in the event of
3 nonpayment by the pharmacy.

4 (c) The department shall require information from each
5 wholesale distributor as part of the permit and renewal of
6 such permit, as required under s. 499.01.

7 (4) Personnel employed in wholesale distribution must
8 have appropriate education and experience to enable them to
9 perform their duties in compliance with state permitting
10 requirements.

11 (5) The department may adopt rules governing the
12 recordkeeping, storage, and handling with respect to each of
13 the distributions of prescription drugs specified in
14 subparagraphs (1)(a)1.-4.

15 Section 14. Effective January 1, 2004, section
16 499.012, Florida Statutes, as amended by this act, is amended
17 to read:

18 499.012 Wholesale distribution; definitions; permits;
19 applications; general requirements.--

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

21 (a) "Wholesale distribution" means distribution of
22 prescription drugs to persons other than a consumer or
23 patient, but does not include:

24 1. Any of the following activities, which is not a
25 violation of s. 499.005(21) if such activity is conducted in
26 accordance with s. 499.014:

27 a. The purchase or other acquisition by a hospital or
28 other health care entity that is a member of a group
29 purchasing organization of a prescription drug for its own use
30 from the group purchasing organization or from other hospitals
31 or health care entities that are members of that organization.

1 b. The sale, purchase, or trade of a prescription drug
2 or an offer to sell, purchase, or trade a prescription drug by
3 a charitable organization described in s. 501(c)(3) of the
4 Internal Revenue Code of 1986, as amended and revised, to a
5 nonprofit affiliate of the organization to the extent
6 otherwise permitted by law.

7 c. The sale, purchase, or trade of a prescription drug
8 or an offer to sell, purchase, or trade a prescription drug
9 among hospitals or other health care entities that are under
10 common control. For purposes of this section, "common control"
11 means the power to direct or cause the direction of the
12 management and policies of a person or an organization,
13 whether by ownership of stock, by voting rights, by contract,
14 or otherwise.

15 d. The sale, purchase, trade, or other transfer of a
16 prescription drug from or for any federal, state, or local
17 government agency or any entity eligible to purchase
18 prescription drugs at public health services prices pursuant
19 to Pub. L. No. 102-585, s. 602 to a contract provider or its
20 subcontractor for eligible patients of the agency or entity
21 under the following conditions:

22 (I) The agency or entity must obtain written
23 authorization for the sale, purchase, trade, or other transfer
24 of a prescription drug under this sub-subparagraph from the
25 Secretary of Health or his or her designee.

26 (II) The contract provider or subcontractor must be
27 authorized by law to administer or dispense prescription
28 drugs.

29 (III) In the case of a subcontractor, the agency or
30 entity must be a party to and execute the subcontract.

31

1 (IV) A contract provider or subcontractor must
2 maintain separate and apart from other prescription drug
3 inventory any prescription drugs of the agency or entity in
4 its possession.

5 (V) The contract provider and subcontractor must
6 maintain and produce immediately for inspection all records of
7 movement or transfer of all the prescription drugs belonging
8 to the agency or entity, including, but not limited to, the
9 records of receipt and disposition of prescription drugs. Each
10 contractor and subcontractor dispensing or administering these
11 drugs must maintain and produce records documenting the
12 dispensing or administration. Records that are required to be
13 maintained include, but are not limited to, a perpetual
14 inventory itemizing drugs received and drugs dispensed by
15 prescription number or administered by patient identifier,
16 which must be submitted to the agency or entity quarterly.

17 (VI) The contract provider or subcontractor may
18 administer or dispense the prescription drugs only to the
19 eligible patients of the agency or entity or must return the
20 prescription drugs for or to the agency or entity. The
21 contract provider or subcontractor must require proof from
22 each person seeking to fill a prescription or obtain treatment
23 that the person is an eligible patient of the agency or entity
24 and must, at a minimum, maintain a copy of this proof as part
25 of the records of the contractor or subcontractor required
26 under sub-sub-subparagraph (V).

27 (VII) In addition to the departmental inspection
28 authority set forth in s. 499.051, the establishment of the
29 contract provider and subcontractor and all records pertaining
30 to prescription drugs subject to this sub-subparagraph shall
31 be subject to inspection by the agency or entity. All records

1 relating to prescription drugs of a manufacturer under this
2 sub-subparagraph shall be subject to audit by the manufacturer
3 of those drugs, without identifying individual patient
4 information.

5 2. Any of the following activities, which is not a
6 violation of s. 499.005(21) if such activity is conducted in
7 accordance with rules established by the department:

8 a. The sale, purchase, or trade of a prescription drug
9 among federal, state, or local government health care entities
10 that are under common control and are authorized to purchase
11 such prescription drug.

12 b. The sale, purchase, or trade of a prescription drug
13 or an offer to sell, purchase, or trade a prescription drug
14 for emergency medical reasons. For purposes of this
15 sub-subparagraph, the term "emergency medical reasons"
16 includes transfers of prescription drugs by a retail pharmacy
17 to another retail pharmacy to alleviate a temporary shortage.

18 c. The transfer of a prescription drug acquired by a
19 medical director on behalf of a licensed emergency medical
20 services provider to that emergency medical services provider
21 and its transport vehicles for use in accordance with the
22 provider's license under chapter 401.

23 d. The revocation of a sale or the return of a
24 prescription drug to the person's prescription drug wholesale
25 supplier.

26 e. The donation of a prescription drug by a health
27 care entity to a charitable organization that has been granted
28 an exemption under s. 501(c)(3) of the Internal Revenue Code
29 of 1986, as amended, and that is authorized to possess
30 prescription drugs.

31

1 f. The transfer of a prescription drug by a person
2 authorized to purchase or receive prescription drugs to a
3 person licensed or permitted to handle reverse distributions
4 or destruction under the laws of the jurisdiction in which the
5 person handling the reverse distribution or destruction
6 receives the drug.

7 g. The transfer of a prescription drug by a hospital
8 or other health care entity to a person licensed under this
9 chapter to repackage prescription drugs for the purpose of
10 repackaging the prescription drug for use by that hospital, or
11 other health care entity and other health care entities that
12 are under common control, if ownership of the prescription
13 drugs remains with the hospital or other health care entity at
14 all times. In addition to the recordkeeping requirements of s.
15 499.0121(7), the hospital or health care entity that transfers
16 prescription drugs pursuant to this sub-subparagraph must
17 reconcile all drugs transferred and returned and resolve any
18 discrepancies in a timely manner.

19 3. The distribution of prescription drug samples by
20 manufacturers' representatives or distributors'
21 representatives conducted in accordance with s. 499.028.

22 4. The sale, purchase, or trade of blood and blood
23 components intended for transfusion. As used in this
24 subparagraph, the term "blood" means whole blood collected
25 from a single donor and processed either for transfusion or
26 further manufacturing, and the term "blood components" means
27 that part of the blood separated by physical or mechanical
28 means.

29 5. The lawful dispensing of a prescription drug in
30 accordance with chapter 465.

31

1 (b) "Wholesale distributor" means any person engaged
2 in wholesale distribution of prescription drugs in or into
3 this state, including, but not limited to, manufacturers;
4 repackagers; own-label distributors; jobbers; private-label
5 distributors; brokers; warehouses, including manufacturers'
6 and distributors' warehouses, chain drug warehouses, and
7 wholesale drug warehouses; independent wholesale drug traders;
8 exporters; retail pharmacies; and the agents thereof that
9 conduct wholesale distributions.

10 (c) "Retail pharmacy" means a community pharmacy
11 licensed under chapter 465 that purchases prescription drugs
12 at fair market prices and provides prescription services to
13 the public.

14 (2) The following types of wholesaler permits are
15 established:

16 (a) A prescription drug wholesaler's permit. A
17 prescription drug wholesaler is a wholesale distributor that
18 may engage in the wholesale distribution of prescription
19 drugs. A prescription drug wholesaler that applies to the
20 department for a new permit or the renewal of a permit ~~after~~
21 ~~July 1, 2003~~, must submit a bond of \$100,000, or other
22 equivalent means of security acceptable to the department,
23 such as an irrevocable letter of credit or a deposit in a
24 trust account or financial institution, payable to the Florida
25 Drug, Device, and Cosmetic Trust Fund. The purpose of the bond
26 is to secure payment of any administrative penalties imposed
27 by the department and any fees and costs incurred by the
28 department regarding that permit which are authorized under
29 state law and which the permittee fails to pay 30 days after
30 the fine or costs become final. The department may make a
31 claim against such bond or security until 1 year after the

1 | permittee's license ceases to be valid or until 60 days after
2 | any administrative or legal proceeding authorized in ss.
3 | 499.001-499.081 which involves the permittee is concluded,
4 | including any appeal, whichever occurs later. The department
5 | may adopt rules for issuing a prescription drug
6 | wholesaler-broker permit to a person who engages in the
7 | wholesale distribution of prescription drugs and does not take
8 | physical possession of any prescription drugs.

9 | (b) A compressed medical gas wholesaler's permit. A
10 | compressed medical gas wholesaler is a wholesale distributor
11 | that is limited to the wholesale distribution of compressed
12 | medical gases to other than the consumer or patient. The
13 | compressed medical gas must be in the original sealed
14 | container that was purchased by that wholesaler. A compressed
15 | medical gas wholesaler may not possess or engage in the
16 | wholesale distribution of any prescription drug other than
17 | compressed medical gases. The department shall adopt rules
18 | that govern the wholesale distribution of prescription medical
19 | oxygen for emergency use. With respect to the emergency use of
20 | prescription medical oxygen, those rules may not be
21 | inconsistent with rules and regulations of federal agencies
22 | unless the Legislature specifically directs otherwise.

23 | (c) An out-of-state prescription drug wholesaler's
24 | permit. An out-of-state prescription drug wholesaler is a
25 | wholesale distributor located outside this state which engages
26 | in the wholesale distribution of prescription drugs into this
27 | state and which must be permitted by the department and comply
28 | with all the provisions required of a wholesale distributor
29 | under ss. 499.001-499.081. An out-of-state prescription drug
30 | wholesaler that applies to the department for a new permit or
31 | the renewal of a permit ~~after July 1, 2003~~, must submit a bond

1 of \$100,000, or other equivalent means of security acceptable
2 to the department, such as an irrevocable letter of credit or
3 a deposit in a trust account or financial institution, payable
4 to the Florida Drug, Device, and Cosmetic Trust Fund. The
5 purpose of the bond is to secure payment of any administrative
6 penalties imposed by the department and any fees and costs
7 incurred by the department regarding that permit which are
8 authorized under state law and which the permittee fails to
9 pay 30 days after the fine or costs become final. The
10 department may make a claim against such bond or security
11 until 1 year after the permittee's license ceases to be valid
12 or until 60 days after any administrative or legal proceeding
13 authorized in ss. 499.001-499.081 which involves the permittee
14 is concluded, including any appeal, whichever occurs later.

15 1. The out-of-state drug wholesaler must maintain at
16 all times a license or permit to engage in the wholesale
17 distribution of prescription drugs in compliance with laws of
18 the state in which it is a resident.

19 2. An out-of-state prescription drug wholesaler's
20 permit is not required for an intracompany sale or transfer of
21 a prescription drug from an out-of-state establishment that is
22 duly licensed as a prescription drug wholesaler, in its state
23 of residence, to a licensed prescription drug wholesaler in
24 this state, if both wholesalers conduct wholesale
25 distributions of prescription drugs under the same business
26 name. The recordkeeping requirements of s. 499.0121(6) must be
27 followed for this transaction.

28 (d) A retail pharmacy wholesaler's permit. A retail
29 pharmacy wholesaler is a retail pharmacy engaged in wholesale
30 distribution of prescription drugs within this state under the
31 following conditions:

1 1. The pharmacy must obtain a retail pharmacy
2 wholesaler's permit pursuant to ss. 499.001-499.081 and the
3 rules adopted under those sections.

4 2. The wholesale distribution activity does not exceed
5 30 percent of the total annual purchases of prescription
6 drugs. If the wholesale distribution activity exceeds the
7 30-percent maximum, the pharmacy must obtain a prescription
8 drug wholesaler's permit.

9 3. The transfer of prescription drugs that appear in
10 any schedule contained in chapter 893 is subject to chapter
11 893 and the federal Comprehensive Drug Abuse Prevention and
12 Control Act of 1970.

13 4. The transfer is between a retail pharmacy and
14 another retail pharmacy, or a Modified Class II institutional
15 pharmacy, or a health care practitioner licensed in this state
16 and authorized by law to dispense or prescribe prescription
17 drugs.

18 5. All records of sales of prescription drugs subject
19 to this section must be maintained separate and distinct from
20 other records and comply with the recordkeeping requirements
21 of ss. 499.001-499.081.

22 (e) A nonresident prescription drug manufacturer
23 permit is required for any person that is a manufacturer of
24 prescription drugs, or the distribution point for a
25 manufacturer of prescription drugs, and located outside of
26 this state, or that is an an entity to whom an approved new
27 drug application has been issued by the United States Food and
28 Drug Administration, or the contracted manufacturer of the
29 approved new drug application holder, and located outside the
30 United States, which engages in the wholesale distribution in
31 this state of the prescription drugs it manufactures or is

1 responsible for manufacturing. Each such manufacturer or
2 entity must be permitted by the department and comply with all
3 the provisions required of a wholesale distributor under ss.
4 499.001-499.081, except 499.0121(6)(d).

5 1. A person that distributes prescription drugs that
6 it did not manufacture must also obtain an out-of-state
7 prescription drug wholesaler permit pursuant this section to
8 engage in the wholesale distribution of the prescription drugs
9 manufactured by another person and comply with the
10 requirements of an out-of-state prescription drug wholesaler.

11 2. Any such person must comply with the licensing or
12 permitting requirements of the jurisdiction in which the
13 establishment is located and the federal act, and any product
14 wholesaled into this state must comply with ss.

15 499.001-499.081. If a person intends to import prescription
16 drugs from a foreign country into this state, the nonresident
17 prescription drug manufacturer must provide to the department
18 a list identifying each prescription drug it intends to import
19 and document approval by the United States Food and Drug
20 Administration for such importation.

21 (f) A freight forwarder permit is required for any
22 person that engages in the distribution of a legend drug as a
23 freight forwarder unless the person is a common carrier. The
24 storage, handling, and recordkeeping of such distributions
25 must comply with the requirements for wholesale distributors
26 under s. 499.0121, except those set forth in s.

27 499.0121(6)(d). A freight forwarder must provide the source of
28 the legend drugs with a validated airway bill, bill of lading,
29 or other appropriate documentation to evidence the exportation
30 of the product.

31

1 (3) An application for a permit or to renew a permit
2 for a prescription drug wholesaler, an out-of-state
3 prescription drug wholesaler, or a retail pharmacy drug
4 wholesaler submitted to the department must include:

5 (a) The name, full business address, and telephone
6 number of the applicant.

7 (b) All trade or business names used by the applicant.

8 (c) The address, telephone numbers, and the names of
9 contact persons for each facility used by the applicant for
10 the storage, handling, and distribution of prescription drugs.

11 (d) The type of ownership or operation, such as a
12 partnership, corporation, or sole proprietorship.

13 (e) The names of the owner and the operator of the
14 establishment, including:

15 1. If an individual, the name of the individual.

16 2. If a partnership, the name of each partner and the
17 name of the partnership.

18 3. If a corporation:

19 a. The name, address, and title of each corporate
20 officer and director.

21 b. The name and address of the corporation, resident
22 agent of the corporation, the resident agent's address, and
23 the corporation's state of incorporation.

24 c. The name and address of each shareholder of the
25 corporation that owns 5 percent or more of the outstanding
26 stock of the corporation.

27 4. If a sole proprietorship, the full name of the sole
28 proprietor and the name of the business entity.

29 5. If a limited liability company:

30 a. The name and address of each member.

31 b. The name and address of each manager.

1 c. The name and address of the limited liability
2 company, the resident agent of the limited liability company,
3 and the name of the state in which the limited liability
4 company was organized.

5 (f) If applicable, the name and address of each member
6 of the affiliated group of which the applicant is a member.

7 (g)1. For an application for a new permit, the
8 estimated annual dollar volume of prescription drug sales of
9 the applicant, the estimated annual percentage of the
10 applicant's total company sales that are prescription drugs,
11 the applicant's estimated annual total dollar volume of
12 purchases of prescription drugs, and the applicant's estimated
13 annual total dollar volume of prescription drug purchases
14 directly from manufacturers.

15 2. For an application to renew a permit, the total
16 dollar volume of prescription drug sales in the previous year,
17 the total dollar volume of prescription drug sales made in the
18 previous 6 months, the percentage of total company sales that
19 were prescription drugs in the previous year, the total dollar
20 volume of purchases of prescription drugs in the previous
21 year, and the total dollar volume of prescription drug
22 purchases directly from manufacturers in the previous year.

23
24 Such portions of the information required pursuant to this
25 paragraph that is a trade secret, as defined in s. 812.081,
26 shall be maintained by the department in accordance with s.
27 815.045.

28 (h) The tax year of the applicant.

29 (i) A copy of the deed for the property on which
30 applicant's establishment is located, if the establishment is
31 owned by the applicant, or a copy of the applicant's lease for

1 the property on which applicant's establishment is located
2 that has an original term of not less than 1 calendar year, if
3 the establishment is not owned by the applicant.

4 (j) A list of all licenses and permits issued to the
5 applicant by any other state which authorize the applicant to
6 purchase or possess prescription drugs.

7 (k) The name of the manager of the establishment that
8 is applying for the permit or to renew the permit, the next
9 four highest ranking employees responsible for prescription
10 drug wholesale operations for the establishment, and the name
11 of all affiliated parties for the establishment, together with
12 the personal information statement and fingerprints required
13 pursuant to subsection (4) for each of such persons.

14 (l) The name of each of the applicant's designated
15 representatives as required by subsection (11), together with
16 the personal information statement and fingerprints, required
17 pursuant to subsection (4) for each such person.

18 (m) If any of the five largest shareholders of the
19 corporation seeking the permit is a corporation, the name,
20 address, and title of each corporate officer and director of
21 each such corporation; the name and address of such
22 corporation; the name of such corporation's resident agent,
23 such corporation's resident agent's address, and such
24 corporation's state of its incorporation; and the name and
25 address of each shareholder of such corporation that owns 5
26 percent or more of the stock of such corporation.

27 (n) The name and address of all financial institutions
28 in which the applicant has an account which is used to pay for
29 the operation of the establishment or to pay for drugs
30 purchased for the establishment, together with the names of
31 all persons that are authorized signatories on such accounts.

1 The portions of the information required pursuant to this
2 subparagraph which are a trade secret, as defined in s.
3 812.081, shall be maintained by the department in accordance
4 with s. 815.045.

5 (o) The sources of all funds and the amounts of such
6 funds used to purchase or finance purchases of prescription
7 drugs or to finance the premises on which the establishment is
8 to be located. If any of the funds identified in response to
9 this paragraph were borrowed, copies of all promissory notes
10 or loans used to obtain such funds.

11 (p) Any other relevant information that the department
12 requires.

13 (4)(a) Each person required by subsection (3) to
14 provide a personal information statement and fingerprints
15 shall provide the following information to the department on
16 forms prescribed by the department:

17 1. The person's places of residence for the past 7
18 years.

19 2. The person's date and place of birth.

20 3. Whether the person has been, during the past 7
21 years, the subject of any proceeding for the revocation of any
22 license and, if so, the nature of the proceeding and the
23 disposition of the proceeding.

24 4. Whether, during the past 7 years, the person has
25 been enjoined, either temporarily or permanently, by a court
26 of competent jurisdiction from violating any federal or state
27 law regulating the possession, control, or distribution of
28 prescription drugs, together with details concerning any such
29 event.

30 5. A description of any involvement by the person with
31 any business, including any investments, other than the

1 ownership of stock in a publicly traded company or mutual
2 fund, during the past 7 years, which manufactured,
3 administered, prescribed, distributed, or stored
4 pharmaceutical products and any lawsuits in which such
5 businesses were named as a party.

6 6. A description of any felony criminal offense of
7 which the person, as an adult, was found guilty, regardless of
8 whether adjudication of guilt was withheld or whether the
9 person pled guilty or nolo contendere. A criminal offense
10 committed in another jurisdiction which would have been a
11 felony in this state must be reported. If the person indicates
12 that a criminal conviction is under appeal and submits a copy
13 of the notice of appeal of that criminal offense, the
14 applicant must, within 15 days after the disposition of the
15 appeal, submit to the department a copy of the final written
16 order of disposition.

17 7. A set of fingerprints for the person on a form and
18 under procedures specified by the department, together with
19 payment of an amount equal to the costs incurred by the
20 department for the criminal record check of the person.

21 8. The name, address, occupation, and date and place
22 of birth for each member of the person's immediate family who
23 is 18 years of age or older and a description of any felony
24 criminal offense committed as an adult by any such person
25 during the past 7 years, regardless of whether adjudication of
26 guilt was withheld or whether the person pled guilty or nolo
27 contendere. A criminal offense committed in another
28 jurisdiction which would have been a felony in this state must
29 be reported. As used in this subparagraph, the term "member of
30 the person's immediate family" includes the person's spouse,
31

1 children, parents, siblings, the spouses of the person's
2 children, and the spouses of the person's siblings.

3 9. Any other relevant information that the department
4 requires.

5 (b) The information required pursuant to paragraph (a)
6 shall be provided under oath.

7 (c) The department shall submit the fingerprints
8 provided by a person for initial licensure to the Department
9 of Law Enforcement for a statewide criminal record check and
10 for forwarding to the Federal Bureau of Investigation for a
11 national criminal record check of the person. The department
12 shall submit the fingerprints provided by a person as a part
13 of a renewal application to the Department of Law Enforcement
14 for a statewide criminal record check, and for forwarding to
15 the Federal Bureau of Investigation for a national criminal
16 record check, for the initial renewal of a permit after
17 January 1, 2004; for any subsequent renewal of a permit, the
18 department shall submit the required information for a
19 statewide and national criminal record check of the person.
20 Any person who as a part of an initial permit application or
21 initial permit renewal after January 1, 2004, submits to the
22 department a set of fingerprints required for the criminal
23 record check required in this paragraph shall not be required
24 to provide a subsequent set of fingerprints for a criminal
25 record check to the department, if the person has undergone a
26 criminal record check as a condition of the the issuance of
27 an initial permit or the initial renewal of a permit of an
28 applicant after January 1, 2004.

29 (5) The department may deny an application for a
30 permit or refuse to renew a permit for a prescription drug
31

1 wholesaler, an out-of-state prescription drug wholesaler, or a
2 retail pharmacy wholesaler if the department finds:

3 (a) The applicant has not met the requirements for the
4 permit.

5 (b) The management, officers, or directors of the
6 applicant or any affiliated party are found by the department
7 to be incompetent or untrustworthy.

8 (c) The applicant is so lacking in experience in
9 managing a wholesale distributor as to make the issuance of
10 the proposed permit hazardous to the public health.

11 (d) The applicant is so lacking in experience in
12 managing a wholesale distributor as to jeopardize the
13 reasonable promise of successful operation of the wholesale
14 distributor.

15 (e) The applicant is lacking in experience in the
16 distribution of prescription drugs.

17 (f) The applicant's past experience in manufacturing
18 or distributing prescription drugs indicates that the
19 applicant poses a public health risk.

20 (g) The applicant is affiliated directly or indirectly
21 through ownership, control, or other business relations, with
22 any person or persons whose business operations are or have
23 been detrimental to the public health.

24 (h) The applicant, or any affiliated party, has been
25 found guilty of or has pleaded guilty or nolo contendere to
26 any felony or crime punishable by imprisonment for 1 year or
27 more under the laws of the United States, any state, or any
28 other country, regardless of whether adjudication of guilt was
29 withheld.

30 (i) The applicant or any affiliated party has been
31 charged with a felony in a state or federal court and the

1 disposition of that charge is pending during the application
2 review or renewal review period.

3 (j) The applicant has furnished false or fraudulent
4 information or material in any application made in this state
5 or any other state in connection with obtaining a permit or
6 license to manufacture or distribute drugs, devices, or
7 cosmetics.

8 (k) That a federal, state, or local government permit
9 currently or previously held by the applicant, or any
10 affiliated party, for the manufacture or distribution of any
11 drugs, devices, or cosmetics has been disciplined, suspended,
12 or revoked and has not been reinstated.

13 (l) The applicant does not possess the financial or
14 physical resources to operate in compliance with the permit
15 being sought, this chapter, and the rules adopted under this
16 chapter.

17 (m) The applicant or any affiliated party receives,
18 directly or indirectly, financial support and assistance from
19 a person who was an affiliated party of a permittee whose
20 permit was subject to discipline or was suspended or revoked,
21 other than through the ownership of stock in a publicly traded
22 company or a mutual fund.

23 (n) The applicant or any affiliated party receives,
24 directly or indirectly, financial support and assistance from
25 a person who has been found guilty of any violation of ss.
26 499.001-499.081 or chapter 465, chapter 501, or chapter 893,
27 any rules adopted under any of those sections or chapters, any
28 federal or state drug law, or any felony where the underlying
29 facts related to drugs, regardless of whether the person has
30 been pardoned, had her or his civil rights restored, or had
31

1 adjudication withheld, other than through the ownership of
2 stock in a publicly traded company or a mutual fund.

3 (o) The applicant for renewal of a permit under
4 paragraph (2)(a) or paragraph (2)(c) has not actively engaged
5 in the wholesale distribution of prescription drugs, as
6 demonstrated by the regular and systematic distribution of
7 prescription drugs throughout the year as evidenced by not
8 fewer than 12 wholesale distributions in the previous year and
9 not fewer than three wholesale distributions in the previous 6
10 months.

11 (p) Information obtained in response to paragraph
12 (2)(a) or paragraph (2)(c) demonstrates it would not be in the
13 best interest of the public health, safety, and welfare to
14 issue a permit.

15 (q) The applicant does not possess the financial
16 standing and business experience for the successful operation
17 of the applicant.

18 (r) The applicant or any affiliated party has failed
19 to comply with the requirements for manufacturing or
20 distributing prescription drugs under ss. 499.001-499.081,
21 similar federal laws, similar laws in other states, or the
22 rules adopted under such laws.

23 (6) Upon approval of the application by the department
24 and payment of the required fee, the department shall issue or
25 renew a prescription drug wholesaler, an out-of-state
26 prescription drug wholesaler, or a retail pharmacy drug
27 wholesaler permit to the applicant.

28 (7) For permits for prescription drug wholesalers,
29 out-of-state prescription drug wholesalers, and retail
30 pharmacy drug wholesalers:

31

1 (a) The department shall adopt rules for the annual
2 renewal of permits. At least 90 days before the expiration of
3 a permit, the department shall forward a permit renewal
4 notification and renewal application to the prescription drug
5 wholesaler, out-of-state prescription drug wholesaler, or
6 retail pharmacy drug wholesaler at the mailing address of the
7 permitted establishment on file with the department. The
8 permit renewal notification must state conspicuously the date
9 on which the permit for the establishment will expire and that
10 the establishment may not operate unless the permit for the
11 establishment is renewed timely.

12 (b) A permit, unless sooner suspended or revoked,
13 automatically expires 1 year after the last day of the
14 anniversary month in which the permit was originally issued. A
15 permit may be renewed by making application for renewal on
16 forms furnished by the department and paying the appropriate
17 fees. If a renewal application and fee are submitted and
18 postmarked after 45 days prior to the expiration date of the
19 permit, the permit may be renewed only upon payment of a late
20 renewal fee of \$100, plus the required renewal fee. A
21 permittee that has submitted a renewal application in
22 accordance with this paragraph may continue to operate under
23 its permit, unless the permit is suspended or revoked, until
24 final disposition of the renewal application.

25 (c) Failure to renew a permit in accordance with this
26 section precludes any future renewal of that permit. If a
27 permit issued pursuant to this section has expired and cannot
28 be renewed, before an establishment may engage in activities
29 that require a permit under ss. 499.001-499.081, the
30 establishment must submit an application for a new permit; pay
31 the applicable application fee, initial permit fee, and all

1 applicable penalties; and be issued a new permit by the
2 department.

3 (8)~~(3)~~ A person that engages in wholesale distribution
4 of prescription drugs in this state must have a wholesale
5 distributor's permit issued by the department, except as noted
6 in this section. Each establishment must be separately
7 permitted except as noted in this subsection.

8 (a) A separate establishment permit is not required
9 when a permitted prescription drug wholesaler consigns a
10 prescription drug to a pharmacy that is permitted under
11 chapter 465 and located in this state, provided that:

12 1. The consignor wholesaler notifies the department in
13 writing of the contract to consign prescription drugs to a
14 pharmacy along with the identity and location of each
15 consignee pharmacy;

16 2. The pharmacy maintains its permit under chapter
17 465;

18 3. The consignor wholesaler, which has no legal
19 authority to dispense prescription drugs, complies with all
20 wholesale distribution requirements of s. 499.0121 with
21 respect to the consigned drugs and maintains records
22 documenting the transfer of title or other completion of the
23 wholesale distribution of the consigned prescription drugs;

24 4. The distribution of the prescription drug is
25 otherwise lawful under this chapter and other applicable law;

26 5. Open packages containing prescription drugs within
27 a pharmacy are the responsibility of the pharmacy, regardless
28 of how the drugs are titled; and

29 6. The pharmacy dispenses the consigned prescription
30 drug in accordance with the limitations of its permit under
31 chapter 465 or returns the consigned prescription drug to the

1 consignor wholesaler. In addition, a person who holds title to
2 prescription drugs may transfer the drugs to a person
3 permitted or licensed to handle the reverse distribution or
4 destruction of drugs. Any other distribution by and means of
5 the consigned prescription drug by any person, not limited to
6 the consignor wholesaler or consignee pharmacy, to any other
7 person is prohibited.

8 (b) A wholesale distributor's permit is not required
9 for the one-time transfer of title of a pharmacy's lawfully
10 acquired prescription drug inventory by a pharmacy with a
11 valid permit issued under chapter 465 to a consignor
12 prescription drug wholesaler, permitted under this chapter, in
13 accordance with a written consignment agreement between the
14 pharmacy and that wholesaler if: the permitted pharmacy and
15 the permitted prescription drug wholesaler comply with all of
16 the provisions of paragraph (a) and the prescription drugs
17 continue to be within the permitted pharmacy's inventory for
18 dispensing in accordance with the limitations of the pharmacy
19 permit under chapter 465. A consignor drug wholesaler may not
20 use the pharmacy as a wholesale distributor through which it
21 distributes the legend drugs to other pharmacies. Nothing in
22 this section is intended to prevent a wholesale drug
23 distributor from obtaining this inventory in the event of
24 nonpayment by the pharmacy.

25 (c) The department shall require information from each
26 wholesale distributor as part of the permit and renewal of
27 such permit, as required under s. 499.01 or s. 499.012.

28 (9)~~(4)~~ Personnel employed in wholesale distribution
29 must have appropriate education and experience to enable them
30 to perform their duties in compliance with state permitting
31 requirements.

1 (10) The name of a permittee or establishment on a
2 prescription drug wholesaler permit or an out-of-state
3 prescription drug wholesaler permit may not include any
4 indicia of attainment of any educational degree, any indicia
5 that the permittee or establishment possesses a professional
6 license, or any name or abbreviation that the department
7 determines is likely to cause confusion or mistake or that the
8 department determines is deceptive, including that of any
9 other entity authorized to purchase prescription drugs.

10 (11)(a) Each establishment that is issued an initial
11 or renewal permit as a prescription drug wholesaler or an
12 out-of-state prescription drug wholesaler must designate in
13 writing to the department at least one natural person to serve
14 as the designated representative of the wholesaler. Such
15 person must have an active certification as a designated
16 representative from the department.

17 (b) To be certified as a designated representative, a
18 natural person must:

19 1. Submit an application on a form furnished by the
20 department and pay the appropriate fees;

21 2. Be at least 18 years of age;

22 3. Have not less than 2 years of verifiable full-time
23 work experience in a pharmacy licensed in this state or
24 another state, where the person's responsibilities included,
25 but were not limited to, recordkeeping for prescription drugs,
26 or have not less than 2 years of verifiable full-time
27 managerial experience with a prescription drug wholesaler
28 licensed in this state or in another state;

29 4. Receive a passing score of at least 75 percent on
30 an examination given by the department regarding federal laws
31 governing distribution of prescription drugs and ss.

1 499.001-499.081 and the rules adopted by the department
2 governing the wholesale distribution of prescription drugs.
3 This requirement shall be effective 1 year after the results
4 of the initial examination are mailed to the persons that took
5 the examination. The department shall offer such examinations
6 at least four times each calendar year; and

7 5. Provide the department with a personal information
8 statement and fingerprints pursuant to subsection (4).

9 (c) The department may deny an application for
10 certification as a designated representative or may suspend or
11 revoke a certification of a designated representative pursuant
12 to s. 499.067.

13 (d) A designated representative:

14 1. Must be actively involved in and aware of the
15 actual daily operation of the wholesale distributor.

16 2. Must be employed full time in a managerial position
17 by the wholesale distributor.

18 3. Must be physically present at the establishment
19 during normal business hours, except for time periods when
20 absent due to illness, family illness or death, scheduled
21 vacation, or other authorized absence.

22 4. May serve as a designated representative for only
23 one wholesale distributor at any one time.

24 (e) A wholesale distributor must notify the department
25 when a designated representative leaves the employ of the
26 wholesale distributor. Such notice must be provided to the
27 department within 10 business days after the last day of
28 designated representative's employment with the wholesale
29 distributor.

30 (f) A wholesale distributor may not operate under a
31 prescription drug wholesaler permit or an out-of-state

1 prescription drug wholesaler permit for more than 10 business
2 days after the designated representative leaves the employ of
3 the wholesale distributor, unless the wholesale distributor
4 employs another designated representative and notifies the
5 department within 10 business days of the identity of the new
6 designated representative.

7 (12)~~(5)~~ The department may adopt rules governing the
8 recordkeeping, storage, and handling with respect to each of
9 the distributions of prescription drugs specified in
10 subparagraphs (1)(a)1.-4.

11 Section 15. Subsections (4), (6), (7), and (8) of
12 section 499.0121, Florida Statutes, are amended, and
13 subsection (11) is added to that section, to read:

14 499.0121 Storage and handling of prescription drugs;
15 recordkeeping.--The department shall adopt rules to implement
16 this section as necessary to protect the public health,
17 safety, and welfare. Such rules shall include, but not be
18 limited to, requirements for the storage and handling of
19 prescription drugs and for the establishment and maintenance
20 of prescription drug distribution records.

21 (4) EXAMINATION OF MATERIALS AND RECORDS.--

22 (a) Upon receipt, each outside shipping container must
23 be visually examined for identity and to prevent the
24 acceptance of contaminated prescription drugs that are
25 otherwise unfit for distribution. This examination must be
26 adequate to reveal container damage that would suggest
27 possible contamination or other damage to the contents.

28 (b) Each outgoing shipment must be carefully inspected
29 for identity of the prescription drug products and to ensure
30 that there is no delivery of prescription drugs that have
31

1 expired or been damaged in storage or held under improper
2 conditions.

3 (c) The recordkeeping requirements in subsection (6)
4 must be followed for all incoming and outgoing prescription
5 drugs.

6 (d) Upon receipt, a wholesaler must review records
7 required under this section for the acquisition of
8 prescription drugs for accuracy and completeness, considering
9 the total facts and circumstances surrounding the transactions
10 and the wholesale distributors involved. This includes
11 authenticating each transaction listed on a pedigree paper in
12 paragraph (6)(d).

13 (6) RECORDKEEPING.--The department shall adopt rules
14 that require keeping such records of prescription drugs as are
15 necessary for the protection of the public health.

16 (a) Wholesale drug distributors must establish and
17 maintain inventories and records of all transactions regarding
18 the receipt and distribution or other disposition of
19 prescription drugs. These records must provide a complete
20 audit trail from receipt to sale or other disposition, be
21 readily retrievable for inspection, and include, at a minimum,
22 the following information:

23 1. The source of the drugs, including the name and
24 principal address of the seller or transferor, and the address
25 of the location from which the drugs were shipped;

26 2. The name, principal address, and state license
27 permit or registration number of the person authorized to
28 purchase prescription drugs;

29 3. The name, strength, dosage form, and quantity of
30 the drugs received and distributed or disposed of; ~~and~~

31

1 4. The dates of receipt and distribution or other
2 disposition of the drugs; and-

3 5. Any financial documentation supporting the
4 transaction.

5 (b) Inventories and records must be made available for
6 inspection and photocopying by authorized federal, state, or
7 local officials for a period of 2 years following disposition
8 of the drugs or 3 years after the creation of the records,
9 whichever period is longer.

10 (c) Records described in this section that are kept at
11 the inspection site or that can be immediately retrieved by
12 computer or other electronic means must be readily available
13 for authorized inspection during the retention period.

14 Records that are kept at a central location outside of this
15 state and that are not electronically retrievable must be made
16 available for inspection within 2 working days after a request
17 by an authorized official of a federal, state, or local law
18 enforcement agency. Records that are maintained at a central
19 location within this state must be maintained at an
20 establishment that is permitted pursuant to ss.
21 499.001-499.081 and must be readily available.

22 (d)1. Each person who is engaged in the wholesale
23 distribution of a prescription drug, and who is not the
24 manufacturer of that drug must, before each wholesale
25 distribution of such drug, provide to the person who receives
26 the drug a pedigree paper as defined in s. 499.003(31).

27 2. A repackager must comply with this paragraph.

28 3. The department may by rule exempt compressed
29 medical gases and veterinary prescription drugs from the
30 pedigree paper requirements in this paragraph.~~an authorized~~
31 ~~distributor of record of such drug, must provide to each~~

1 ~~wholesale distributor of such drug, before the sale is made to~~
2 ~~such wholesale distributor, a written statement identifying~~
3 ~~each previous sale of the drug. The written statement~~
4 ~~identifying all sales of such drug must accompany the drug for~~
5 ~~each subsequent wholesale distribution of the drug to a~~
6 ~~wholesale distributor. The department shall adopt rules~~
7 ~~relating to the requirements of this written statement.~~

8 4.2. Each wholesale distributor of prescription drugs
9 must maintain separate and distinct from other required
10 records all statements that are required under subparagraph 1.

11 5.3. In order to verify compliance with subparagraph
12 1., each manufacturer of a prescription drug sold in this
13 state must maintain at its corporate offices a current list of
14 authorized distributors and must make such list available to
15 the department upon request distribution documentation related
16 to its sales of prescription drugs regardless of whether the
17 prescription drug was sold directly by the manufacturer to a
18 person in this state.

19
20 ~~For the purposes of this subsection, the term "authorized~~
21 ~~distributors of record" means those distributors with whom a~~
22 ~~manufacturer has established an ongoing relationship to~~
23 ~~distribute the manufacturer's products.~~

24 (e) Each wholesale distributor, except for a
25 manufacturer, shall annually provide the department with a
26 written list of all wholesale distributors and manufacturers
27 from whom the wholesale distributor purchases prescription
28 drugs. A wholesale distributor, except a manufacturer, shall
29 notify the department not later than 10 days after any change
30 to either list. Such portions of the information required
31 pursuant to this paragraph which are a trade secret, as

1 defined in s. 812.081, shall be maintained by the department
2 in accordance with s. 815.045.

3 (7) WRITTEN POLICIES AND PROCEDURES.--Wholesale drug
4 distributors must establish, maintain, and adhere to written
5 policies and procedures, which must be followed for the
6 receipt, security, storage, inventory, and distribution of
7 prescription drugs, including policies and procedures for
8 identifying, recording, and reporting losses or thefts, and
9 for correcting all errors and inaccuracies in inventories.
10 Wholesale drug distributors must include in their written
11 policies and procedures:

12 (a) A procedure whereby the oldest approved stock of a
13 prescription drug product is distributed first. The procedure
14 may permit deviation from this requirement, if the deviation
15 is temporary and appropriate.

16 (b) A procedure to be followed for handling recalls
17 and withdrawals of prescription drugs. Such procedure must be
18 adequate to deal with recalls and withdrawals due to:

19 1. Any action initiated at the request of the Food and
20 Drug Administration or any other federal, state, or local law
21 enforcement or other government agency, including the
22 department.

23 2. Any voluntary action by the manufacturer or
24 repackager to remove defective or potentially defective drugs
25 from the market; or

26 3. Any action undertaken to promote public health and
27 safety by replacing existing merchandise with an improved
28 product or new package design.

29 (c) A procedure to ensure that wholesale drug
30 distributors prepare for, protect against, and handle any
31 crisis that affects security or operation of any facility if a

1 strike, fire, flood, or other natural disaster, or a local,
2 state, or national emergency, occurs.

3 (d) A procedure to ensure that any outdated
4 prescription drugs are segregated from other drugs and either
5 returned to the manufacturer or repackager or destroyed. This
6 procedure must provide for written documentation of the
7 disposition of outdated prescription drugs. This documentation
8 must be maintained for 2 years after disposition of the
9 outdated drugs.

10 (8) RESPONSIBLE PERSONS.--Wholesale drug distributors
11 must establish and maintain lists of officers, directors,
12 managers, designated representatives, and other persons in
13 charge of wholesale drug distribution, storage, and handling,
14 including a description of their duties and a summary of their
15 qualifications.

16 (11) SHIPPING AND TRANSPORTATION.--The person
17 responsible for shipment and transportation of a prescription
18 drug in a wholesale distribution may use a common carrier; its
19 own vehicle or employee acting within the scope of employment
20 if authorized under s. 499.03 for the possession of
21 prescription drugs in this state; or, in the case of a
22 prescription drug intended for domestic distribution, an
23 independent contractor who must be the agent of the authorized
24 seller or recipient responsible for shipping and
25 transportation as set forth in a written contract between the
26 parties. A person selling a prescription drug for export must
27 obtain documentation, such as a validated airway bill, bill of
28 lading, or other appropriate documentation that the
29 prescription drug was exported. A person responsible for
30 shipping or transporting prescription drugs is not required to
31 maintain documentation from a common carrier that the

1 designated recipient received the prescription drugs; however,
2 the person must obtain such documentation from the common
3 carrier and make it available to the department upon request
4 of the department.

5 Section 16. Effective January 1, 2004, section
6 499.013, Florida Statutes, is amended to read:

7 499.013 Manufacturers and repackagers of drugs,
8 devices, and cosmetics; definitions, permits, and general
9 requirements.--

10 (1) As used in this section, the terms term
11 "manufacture" and "repackage" have has the meaning as in
12 assigned to it under s. 499.003. A pharmacy is exempt from
13 these definitions this definition if it is operating in
14 compliance with pharmacy practice standards as defined in
15 chapter 465 and the rules adopted under that chapter.

16 (2) Any person that engages in the manufacture or
17 repackaging of drugs, devices, or cosmetics in this state must
18 first obtain one of the following permits and may engage only
19 in the activity allowed under that permit:

20 (a) A prescription drug manufacturer's permit is
21 required for any person that manufactures a prescription drug
22 in this state. A prescription drug repackager's permit is
23 required for any person that repackages a prescription drug in
24 this state.

25 1. A person that operates an establishment permitted
26 as a prescription drug manufacturer or prescription drug
27 repackager may engage in wholesale distribution of
28 prescription drugs manufactured or repackaged at that
29 establishment and must comply with all the provisions of ss.
30 499.001-499.081 and the rules adopted under those sections
31 that apply to a wholesale distributor.

1 2. A prescription drug manufacturer permittee or
2 prescription drug repackager must comply with all appropriate
3 state and federal good manufacturing practices.

4 (b) An over-the-counter drug manufacturer's permit is
5 required for any person that engages in the manufacture or
6 repackaging of an over-the-counter drug.

7 1. An over-the-counter drug manufacturer permittee may
8 not possess or purchase prescription drugs.

9 2. A pharmacy is exempt from obtaining an
10 over-the-counter drug manufacturer's permit if it is operating
11 in compliance with pharmacy practice standards as defined in
12 chapter 465 and the rules adopted under that chapter.

13 3. An over-the-counter drug manufacturer permittee
14 must comply with all appropriate state and federal good
15 manufacturing practices.

16 (c) A compressed medical gas manufacturer's permit is
17 required for any person that engages in the manufacture of
18 compressed medical gases or repackages compressed medical
19 gases from one container to another.

20 1. A compressed medical gas manufacturer permittee may
21 not manufacture or possess any prescription drug other than
22 compressed medical gases.

23 2. A compressed medical gas manufacturer permittee may
24 engage in wholesale distribution of compressed medical gases
25 manufactured at that establishment and must comply with all
26 the provisions of ss. 499.001-499.081 and the rules adopted
27 under those sections that apply to a wholesale distributor.

28 3. A compressed medical gas manufacturer permittee
29 must comply with all appropriate state and federal good
30 manufacturing practices.

31

1 (d) A device manufacturer's permit is required for any
2 person that engages in the manufacture, repackaging, or
3 assembly of medical devices for human use in this state,
4 except that a permit is not required if the person is engaged
5 only in manufacturing, repackaging, or assembling a medical
6 device pursuant to a practitioner's order for a specific
7 patient.

8 1. A manufacturer or repackager of medical devices in
9 this state must comply with all appropriate state and federal
10 good manufacturing practices and quality system rules.

11 2. The department shall adopt rules related to
12 storage, handling, and recordkeeping requirements for
13 manufacturers of medical devices for human use.

14 (e) A cosmetic manufacturer's permit is required for
15 any person that manufactures or repackages cosmetics in this
16 state. A person that only labels or changes the labeling of a
17 cosmetic but does not open the container sealed by the
18 manufacturer of the product is exempt from obtaining a permit
19 under this paragraph.

20 (3) The department may adopt such rules as are
21 necessary for the protection of the public health, safety, and
22 welfare regarding good manufacturing practices that
23 manufacturers and repackagers must follow to ensure the safety
24 of the products.

25 (4) Each manufacturer or repackager of medical
26 devices, over-the-counter drugs, or cosmetics must maintain
27 records that include the name and principal address of the
28 seller or transferor of the product, the address of the
29 location from which the product was shipped, the date of the
30 transaction, the name and quantity of the product involved,
31

1 and the name and principal address of the person who purchased
2 the product.

3 Section 17. Subsection (3) of section 499.014, Florida
4 Statutes, is amended to read:

5 499.014 Distribution of legend drugs by hospitals,
6 health care entities, charitable organizations, and return or
7 destruction companies; permits, general requirements.--

8 (3) Storage and handling, and recordkeeping of these
9 distributions must comply with the requirements for wholesale
10 distributors under s. 499.0121, except those set forth in s.
11 499.0121(6)d.

12 Section 18. Section 499.041, Florida Statutes, is
13 amended to read:

14 499.041 Schedule of fees for drug, device, and
15 cosmetic applications and permits, product registrations, and
16 free-sale certificates.--

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

21 (a) The fee for a prescription drug manufacturer's
22 permit may not be less than \$500 or more than \$750~~\$600~~
23 annually.

24 (b) The fee for a device manufacturer's permit may not
25 be less than \$500 or more than \$600 annually.

26 (c) The fee for a cosmetic manufacturer's permit may
27 not be less than \$250 or more than \$400 annually.

28 (d) The fee for an over-the-counter drug
29 manufacturer's permit may not be less than \$300 or more than
30 \$400 annually.

31

1 (e) The fee for a compressed medical gas
2 manufacturer's permit may not be less than \$400 or more than
3 \$500 annually.

4 (f) The fee for a prescription drug repackager's
5 permit may not be less than \$500 or more than \$750 annually.

6 (g)~~(f)~~ A manufacturer may not be required to pay more
7 than one fee per establishment to obtain an additional
8 manufacturing permit, but each manufacturer must pay the
9 highest fee applicable to his or her operation in each
10 establishment.

11 (2) The department shall assess an applicant that is
12 required to have a wholesaling permit an annual fee within the
13 ranges established in this section for the specific type of
14 wholesaling.

15 (a) The fee for a prescription drug wholesaler's
16 permit may not be less than \$300 or more than ~~\$800~~\$400
17 annually.~~†~~

18 (b) The fee for a compressed medical gas wholesaler's
19 permit may not be less than \$200 or more than \$300 annually.~~†~~

20 (c) The fee for an out-of-state prescription drug
21 wholesaler's permit may not be less than ~~\$300~~\$200 or more
22 than ~~\$800~~\$300 annually.~~†~~

23 (d) The fee for a nonresident prescription drug
24 manufacturer's permit may not be less than \$300 or more than
25 \$500 annually.

26 (e)~~(d)~~ The fee for a retail pharmacy wholesaler's
27 permit may not be less than \$35 or more than \$50 annually.

28 (f) The fee for a freight forwarder's permit may not
29 be less than \$200 or more than \$300 annually.

30 (3) The department shall assess an applicant that is
31 required to have a retail establishment permit an annual fee

1 within the ranges established in this section for the specific
2 type of retail establishment.

3 (a) The fee for a veterinary legend drug retail
4 establishment permit may not be less than \$200 or more than
5 \$300 annually.

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

8 (4) The department shall assess an applicant that is
9 required to have a restricted prescription drug distributor's
10 permit an annual fee of not less than \$200 or more than \$300.

11 (5) In addition to the fee charged for a permit
12 required by ss. 499.001-499.081, ~~beginning January 1, 1993,~~
13 the department shall assess applicants an initial application
14 fee of \$150 for each new permit issued by the department which
15 requires an onsite inspection.

16 (6) A person that is required to register drugs,
17 devices, or cosmetic products under s. 499.015 shall pay an
18 annual product registration fee of not less than \$5 or more
19 than \$15 for each separate and distinct product in package
20 form. The registration fee is in addition to the fee charged
21 for a free-sale certificate.

22 (7) The department shall assess an applicant that
23 requests a free-sale certificate a fee of \$25. A fee of \$2
24 will be charged for each signature copy of a free-sale
25 certificate that is obtained at the same time the free-sale
26 certificate is issued.

27 (8) The department shall assess an out-of-state
28 prescription drug wholesaler applicant or permittee an on-site
29 inspection fee of not less than \$1,000 or more than \$3,000
30 annually, to be based on the actual cost of the inspection if
31

1 an on-site inspection is performed by agents of the
2 department.

3 (9) The department shall assess each person applying
4 for certification as a designated representative a fee of
5 \$150, plus the cost of processing the criminal history record
6 check.

7 (10)~~(8)~~ The department shall assess other fees as
8 provided in ss. 499.001-499.081.

9 Section 19. Subsection (2) and present subsection (5)
10 of section 499.051, Florida Statutes, are amended, present
11 subsections (4) and (5) of that section are redesignated as
12 subsections (6) and (7), respectively, and new subsections (4)
13 and (5) are added to that section, to read:

14 499.051 Inspections and investigations.--

15 (2) In addition to the authority set forth in
16 subsection (1), the department and any duly designated officer
17 or employee of the department may enter and inspect any other
18 establishment for the purpose of determining compliance with
19 ss. 499.001-499.081 and rules adopted under those sections
20 regarding any drug, device, or cosmetic product. ~~The authority~~
21 ~~to enter and inspect does not extend to the practice of the~~
22 ~~profession of pharmacy, as defined in chapter 465 and the~~
23 ~~rules adopted under that chapter, in a pharmacy permitted~~
24 ~~under chapter 465. The Department of Business and Professional~~
25 ~~Regulation shall conduct routine inspections of retail~~
26 ~~pharmacy wholesalers at the time of the regular pharmacy~~
27 ~~permit inspection and shall send the inspection report~~
28 ~~regarding drug wholesale activity to the Department of Health.~~

29 (4) Any application for a permit made pursuant to ss.
30 499.01 and 499.012 and rules adopted under those sections
31 constitutes permission for agents of the Department of Health

1 and the Department of Law Enforcement, after presenting proper
2 identification, to inspect, review, and copy any financial
3 document or record related to the manufacture, repackaging, or
4 distribution of a drug as is necessary to verify compliance
5 with ss. 499.001-499.081 and the rules adopted by the
6 department to administer those sections, in order to discover,
7 investigate, and determine the existence of compliance, or to
8 elicit, receive, respond to, and resolve complaints and
9 violations.

10 (5) The authority to inspect under this section
11 includes the authority to access, review, and copy any and all
12 financial documents related to the activity of manufacturing,
13 repackaging, or distributing prescription drugs.

14 (7)(5) The complaint and all information obtained
15 pursuant to the investigation by the department are
16 confidential and exempt from the provisions of s. 119.07(1)
17 and s. 24(a), Art. I of the State Constitution until the
18 investigation and the enforcement action are completed.
19 However, trade secret information ~~contained therein~~ as defined
20 by s. 812.081(1)(c), contained therein or as otherwise
21 required to be provided to the department under ss.
22 499.001-499.081, shall remain confidential and exempt from the
23 provisions of s. 119.07(1) and s. 24(a), Art. I of the State
24 Constitution, as long as the information is retained by the
25 department. This subsection does not prohibit the department
26 from using such information for regulatory or enforcement
27 proceedings under this chapter or from providing such
28 information to any law enforcement agency or any other
29 regulatory agency. However, the receiving agency shall keep
30 such records confidential and exempt as provided in this
31 subsection. In addition, this subsection is not intended to

1 prevent compliance with the provisions of s. 499.0121(6)(d),
2 and the pedigree papers required in that subsection shall not
3 be deemed a trade secret.

4 Section 20. Subsection (4) is added to section
5 499.055, Florida Statutes, to read:

6 499.055 Reports and dissemination of information by
7 department.--

8 (4) The department shall publish on the department's
9 website and update at least monthly:

10 (a) A list of the prescription drug wholesalers,
11 out-of-state prescription drug wholesalers, and retail
12 pharmacy drug wholesalers against whom the department has
13 initiated enforcement action pursuant to 499.001-499.081 to
14 suspend or revoke a permit, seek an injunction, or otherwise
15 file an administrative complaint and the permit number of each
16 such wholesaler.

17 (b) A list of the prescription drug wholesalers,
18 out-of-state prescription drug wholesalers, and retail
19 pharmacy drug wholesalers to which the department has issued a
20 permit, including the date on which each permit will expire.

21 (c) A list of the prescription drug wholesalers,
22 out-of-state prescription drug wholesalers, and retail
23 pharmacy drug wholesalers' permits that have been returned to
24 the department, were suspended, were revoked, have expired, or
25 were not renewed in the previous year.

26 Section 21. Section 499.065, Florida Statutes, is
27 created to read:

28 499.065 Imminent danger.--

29 (1) Notwithstanding s. 499.051, the department shall
30 inspect each prescription drug wholesale establishment,
31 prescription drug repackager establishment, and retail

1 pharmacy drug wholesaler establishment that is required to be
2 permitted under this chapter as often as necessary to ensure
3 compliance with applicable laws and rules. The department
4 shall have the right of entry and access to these facilities
5 at any reasonable time.

6 (2) To protect the public from prescription drugs that
7 are adulterated or otherwise unfit for human consumption, the
8 department may examine, sample, seize, and stop the sale or
9 use of prescription drugs to determine the condition of those
10 drugs. The department may immediately seize and remove any
11 prescription drugs if the Secretary of Health or his or her
12 designee determines that such prescription drugs represent a
13 threat to the public health. The owner of any property seized
14 under this section may, within 10 days after the seizure,
15 apply to a court of competent jurisdiction for whatever relief
16 is appropriate. At any time after 10 days, the department may
17 destroy the drugs as contraband.

18 (3) The department may determine that a prescription
19 drug wholesale establishment, prescription drug repackager
20 establishment, or retail pharmacy drug wholesaler
21 establishment that is required to be permitted under this
22 chapter is an imminent danger to the public health and require
23 its immediate closure if such establishment fails to comply
24 with applicable laws and rules and, because of such failure,
25 presents an imminent threat to the public's health, safety, or
26 welfare. Any establishment so deemed and closed shall remain
27 closed until allowed by the department or by judicial order to
28 reopen.

29
30 For purposes of this section, a refusal to allow entry to the
31 department for inspection at reasonable times, or a failure or

1 refusal to provide the department with required documentation
2 for purposes of inspection, constitutes an imminent danger to
3 the public health.

4 Section 22. Subsection (1) of section 499.066, Florida
5 Statutes, is amended, and subsection (7) is added to that
6 section, to read:

7 499.066 Penalties; remedies.--In addition to other
8 penalties and other enforcement provisions:

9 (1) The department may institute such suits or other
10 legal proceedings as are required to enforce any provision of
11 ss. 499.001-499.081. If it appears that a person has violated
12 any provision of ss. 499.001-499.081 for which criminal
13 prosecution is provided, the department may provide the
14 appropriate state attorney or other prosecuting agency having
15 jurisdiction with respect to such prosecution with the
16 relevant information in the department's possession.~~When the~~
17 ~~department believes that any person has violated ss.~~
18 ~~499.001-499.081 or any rules adopted pursuant to those~~
19 ~~sections, it may issue and deliver an order to cease and~~
20 ~~desist from such violation.~~

21 (7) Resignation or termination of an affiliated party
22 does not affect the department's jurisdiction or discretion to
23 proceed with action to suspend or revoke a permit or to impose
24 other penalties or enforcement actions authorized by law.

25 Section 23. Section 499.0661, Florida Statutes, is
26 created to read:

27 499.0661 Cease and desist orders; removal of certain
28 persons.--

29 (1) DEFINITION.--As used in this section, the term
30 "permittee" means any person holding a permit issued pursuant
31 to s. 499.012.

1 (2) CEASE AND DESIST ORDERS.--

2 (a) In addition to any authority otherwise provided in
3 this chapter, the department may issue and serve a complaint
4 stating charges upon any permittee or upon any affiliated
5 party, whenever the department has reasonable cause to believe
6 that the person or individual named therein is engaging in or
7 has engaged in conduct that is:

8 1. An act that demonstrates a lack of fitness or
9 trustworthiness to engage in the business authorized under the
10 permit issued pursuant to ss. 499.001-499.081, is hazardous to
11 the public health, or constitutes business operations that are
12 a detriment to the public health;

13 2. A violation of any provision of ss.
14 499.001-499.081;

15 3. A violation of any rule of the department;

16 4. A violation of any order of the department; or

17 5. A breach of any written agreement with the
18 department.

19 (b) The complaint must contain a statement of facts
20 and notice of opportunity for a hearing pursuant to ss.
21 120.569 and 120.57.

22 (c) If a hearing is not requested within the time
23 allowed by ss. 120.569 and 120.57, or if a hearing is held and
24 the department finds that any of the charges are proven, the
25 department may enter an order directing the permittee or the
26 affiliated party named in the complaint to cease and desist
27 from engaging in the conduct complained of and take corrective
28 action to remedy the effects of past improper conduct and
29 assure future compliance.

30 (d) A contested or default cease and desist order is
31 effective when reduced to writing and served upon the

1 permittee or affiliated party named therein. An uncontested
2 cease and desist order is effective as agreed.

3 (e) Whenever the department finds that conduct
4 described in paragraph (a) is likely to cause an immediate
5 threat to the public health, it may issue an emergency cease
6 and desist order requiring the permittee or any affiliated
7 party to immediately cease and desist from engaging in the
8 conduct complained of and to take corrective and remedial
9 action. The emergency order is effective immediately upon
10 service of a copy of the order upon the permittee or
11 affiliated party named therein and remains effective for 90
12 days. If the department begins nonemergency cease and desist
13 proceedings under this subsection, the emergency order remains
14 effective until the conclusion of the proceedings under ss.
15 120.569 and 120.57.

16 (3) REMOVAL OF AFFILIATED PARTIES BY THE DEPARTMENT.--

17 (a) The department may issue and serve a complaint
18 stating charges upon any affiliated party and upon the
19 permittee involved whenever the department has reason to
20 believe that an affiliated party is engaging in or has engaged
21 in conduct that constitutes:

22 1. An act that demonstrates a lack of fitness or
23 trustworthiness to engage in the business authorized under the
24 permit issued pursuant to ss. 499.001-499.081, is hazardous to
25 the public health, or constitutes business operations that are
26 a detriment to the public health;

27 2. A willful violation of ss. 499.001-499.081;
28 however, if the violation constitutes a misdemeanor, a
29 complaint may not be served as provided in this section until
30 the affiliated party is notified in writing of the matter of
31 the violation and has been afforded a reasonable period of

1 time, as set forth in the notice, to correct the violation and
2 has failed to do so;

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

5 4. A willful violation of any rule of the department;

6 5. A willful violation of any order of the department;

7 or

8 6. A material misrepresentation of fact, made
9 knowingly and willfully or made with reckless disregard for
10 the truth of the matter.

11 (b) The complaint must contain a statement of facts
12 and notice of opportunity for a hearing pursuant to ss.
13 120.569 and 120.57.

14 (c) If a hearing is not requested within the time
15 allotted by ss. 120.569 and 120.57, or if a hearing is held
16 and the department finds that any of the charges in the
17 complaint are proven true, the department may enter an order
18 removing the affiliated party or restricting or prohibiting
19 participation by the person in the affairs of that permittee
20 or of any other permittee.

21 (d) A contested or default order of removal,
22 restriction, or prohibition is effective when reduced to
23 writing and served on the permittee and the affiliated party.
24 An uncontested order of removal, restriction, or prohibition
25 is effective as agreed.

26 (e)1. The chief executive officer, designated
27 representative, or the person holding the equivalent office,
28 of a permittee shall promptly notify the department if she or
29 he has actual knowledge that any affiliated party is charged
30 with a felony in a state or federal court.

31

1 2. Whenever any affiliated party is charged with a
2 felony in a state or federal court or with the equivalent of a
3 felony in the courts of any foreign country with which the
4 United States maintains diplomatic relations, and the charge
5 alleges violation of any law involving prescription drugs,
6 pharmaceuticals, fraud, theft, or moral turpitude, the
7 department may enter an emergency order suspending the
8 affiliated party or restricting or prohibiting participation
9 by the affiliated party in the affairs of the particular
10 permittee or of any other permittee upon service of the order
11 upon the permittee and the affiliated party charged. The order
12 must contain notice of opportunity for a hearing pursuant to
13 ss. 120.569 and 120.57, where the affiliated party may request
14 a postsuspension hearing to show that continued service to or
15 participation in the affairs of the permittee does not pose a
16 threat to the public health or the interests of the permittee
17 and does not threaten to impair public confidence in the
18 permittee. In accordance with applicable departmental rules,
19 the department shall notify the affiliated party whether the
20 order suspending or prohibiting the person from participation
21 in the affairs of a permittee will be rescinded or otherwise
22 modified. The emergency order remains in effect, unless
23 otherwise modified by the department, until the criminal
24 charge is disposed of. The acquittal of the person charged, or
25 the final, unappealed dismissal of all charges against the
26 person, dissolves the emergency order, but does not prohibit
27 the department from instituting proceedings under paragraph
28 (a). If the person charged is convicted or pleads guilty or
29 nolo contendere, whether or not an adjudication of guilt is
30 entered by the court, the emergency order shall become final.
31

1 (f) Any affiliated party removed pursuant to this
2 section is not eligible for reemployment by the permittee or
3 to be an affiliated party of any permittee except upon the
4 written consent of the department. Any affiliated party who is
5 removed, restricted, or prohibited from participating in the
6 affairs of a permittee pursuant to this section may petition
7 the department for modification or termination of the removal,
8 restriction, or prohibition.

9 Section 24. Effective January 1, 2004, section
10 499.067, Florida Statutes, is amended to read:

11 499.067 Denial, suspension, or revocation of permit,
12 certification, or registration.--

13 (1)(a) The department may deny, suspend, or revoke a
14 permit if it finds that there has been a substantial failure
15 to comply with ss. 499.001-499.081 or chapter 465, chapter
16 501, or chapter 893, the rules adopted under any of those
17 sections or chapters, any final order of the department, or
18 applicable federal laws or regulations or other state laws or
19 rules governing drugs, devices, or cosmetics.

20 (b) The department may deny an application for a
21 permit or certification, or suspend or revoke a permit or
22 certification, if the department finds it is shown that:

23 1. The applicant is not of good moral character or
24 that it would be a danger or not in the best interest of the
25 public health, safety, and welfare if the applicant were
26 issued a permit or certification.

27 2. The applicant has not met the requirements for the
28 permit or certification.

29 3. The applicant is not eligible for a permit or
30 certification for any of the reasons enumerated in s. 499.01
31 or s. 499.012(5).

1 4. The applicant, permittee, or person certified under
2 s. 499.012(11) demonstrates any of the conditions enumerated
3 in s. 499.01 or s. 499.012(5).

4 5. The applicant, permittee, or person certified under
5 s. 499.012(11) has committed any violation of ss.
6 499.005-499.0054.

7 (2) The department may deny, suspend, or revoke any
8 registration required by the provisions of ss. 499.001-499.081
9 for the violation of any provision of ss. 499.001-499.081 or
10 of any rules adopted under those sections.

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

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

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

17 (c) If the permittee has violated any provision of ss.
18 499.001-499.081 or rules adopted under those sections.

19 (4) If any permit issued under ss. 499.001-499.081 is
20 revoked or suspended, the owner, manager, operator, or
21 proprietor of the establishment shall cease to operate as the
22 permit authorized, from the effective date of the suspension
23 or revocation until the person is again registered with the
24 department and possesses the required permit. If a permit is
25 revoked or suspended, the owner, manager, or proprietor shall
26 remove all signs and symbols that identify the operation as
27 premises permitted as a drug wholesaling establishment; drug,
28 device, or cosmetic manufacturing establishment; or retail
29 establishment. The department shall determine the length of
30 time for which the permit is to be suspended. If a permit is
31 revoked, the person that owns or operates the establishment

1 may not apply for any permit under ss. 499.001-499.081 for a
2 period of 1 year after the date of the revocation. A
3 revocation of a permit may be permanent if the department
4 considers that to be in the best interest of the public
5 health.

6 (5) The department may deny, suspend, or revoke a
7 permit issued under ss. 499.001-499.081 which authorizes the
8 permittee to purchase prescription drugs, if any owner,
9 officer, employee, or other person who participates in
10 administering or operating the establishment has been found
11 guilty of any violation of ss. 499.001-499.081 or chapter 465,
12 chapter 501, or chapter 893, any rules adopted under any of
13 those sections or chapters, or any federal or state drug law,
14 regardless of whether the person has been pardoned, had her or
15 his civil rights restored, or had adjudication withheld.

16 (6) The department shall deny, suspend, or revoke the
17 permit of any person or establishment if the assignment, sale,
18 transfer, or lease of an establishment permitted under ss.
19 499.001-499.081 will avoid an administrative penalty, civil
20 action, or criminal prosecution.

21 (7) Notwithstanding s. 120.60(5), if a permittee fails
22 to comply with s. 499.01(7), the department may revoke the
23 permit of the permittee and shall provide notice of the
24 intended agency action by posting a notice at the department's
25 headquarters and by mailing a copy of the notice of intended
26 agency action by certified mail to the most recent mailing
27 address on record with the department and, if the permittee is
28 not a natural person, to the permittee's registered agent on
29 file with the Department of State.

30 Section 25. Section 499.069, Florida Statutes, is
31 amended to read:

1 499.069 Criminal punishment for violations of s.
2 499.005 related to devices and cosmetics; dissemination of
3 false advertisement.--

4 (1) Any person who violates any of the provisions of
5 s. 499.005 with respect to a device or cosmetic commits is
6 ~~guilty of~~ a misdemeanor of the second degree, punishable as
7 provided in s. 775.082 or s. 775.083; but, if the violation is
8 committed after a conviction of such person under this section
9 has become final, such person is guilty of a misdemeanor of
10 the first degree, punishable as provided in s. 775.082 or s.
11 775.083 or as otherwise provided in ss. 499.001-499.081,
12 except that any person who violates subsection (8), or
13 ~~subsection (10), subsection (14), subsection (15), or~~
14 ~~subsection (17)~~of s. 499.005 with respect to a device or
15 cosmetic commits is guilty of a felony of the third degree,
16 punishable as provided in s. 775.082, s. 775.083, or s.
17 775.084, or as otherwise provided in ss. 499.001-499.081.

18 ~~(2) A person is not subject to the penalties of~~
19 ~~subsection (1) for having violated any of the provisions of s.~~
20 ~~499.005 if he or she establishes a guaranty or undertaking,~~
21 ~~which guaranty or undertaking is signed by and contains the~~
22 ~~name and address of the person residing in the state, or the~~
23 ~~manufacturer, from whom he or she received the article in good~~
24 ~~faith, to the effect that such article is not adulterated or~~
25 ~~misbranded within the meaning of ss. 499.001-499.081, citing~~
26 ~~such sections.~~

27 (2)~~(3)~~ A publisher, radio broadcast licensee, or
28 agency or medium for the dissemination of an advertisement,
29 except the manufacturer, wholesaler, or seller of the article
30 to which a false advertisement relates, is not liable under
31 this section by reason of the dissemination by him or her of

1 such false advertisement, unless he or she has refused, on the
2 request of the department, to furnish to the department the
3 name and post office address of the manufacturer, wholesaler,
4 seller, or advertising agency that asked him or her to
5 disseminate such advertisement.

6 Section 26. Section 499.0691, Florida Statutes, is
7 created to read:

8 499.0691 Criminal punishment for violations related to
9 drugs; dissemination of false advertisement.--

10 (1) Any person who violates any of the following
11 provisions commits a misdemeanor of the second degree,
12 punishable as provided in s. 775.082 or s. 775.083; but, if
13 the violation is committed after a conviction of such person
14 under this section has become final, such person commits a
15 misdemeanor of the first degree, punishable as provided in s.
16 775.082 or s. 775.083, or as otherwise provided in ss.
17 499.001-499.081:

18 (a) The manufacture, repackaging, sale, delivery, or
19 holding or offering for sale of any drug that is adulterated
20 or misbranded or has otherwise been rendered unfit for human
21 or animal use.

22 (b) The adulteration or misbranding of any drug
23 intended for further distribution.

24 (c) The receipt of any drug that is adulterated or
25 misbranded, and the delivery or proffered delivery of such
26 drug, for pay or otherwise.

27 (d) The dissemination of any false or misleading
28 advertisement of a drug.

29 (e) The use, on the labeling of any drug or in any
30 advertisement relating to such drug, of any representation or
31 suggestion that an application of the drug is effective when

1 it is not or that the drug complies with ss. 499.001-499.081
2 when it does not.

3 (f) The purchase or receipt of a compressed medical
4 gas from a person that is not authorized under this chapter to
5 distribute compressed medical gases.

6 (g) Charging a dispensing fee for dispensing,
7 administering, or distributing a prescription drug sample.

8 (h) The failure to maintain records related to a drug
9 as required by ss. 499.001-499.081 and rules adopted under
10 those sections, except for pedigree papers, invoices, or
11 shipping documents related to legend drugs.

12 (i) The possession of any drug in violation of ss.
13 499.001-499.081, except if the violation relates to a
14 deficiency in pedigree papers.

15 (2) Any person who violates any of the following
16 provisions commits a felony of the third degree, punishable as
17 provided in s. 775.082, s. 775.083, or s. 775.084, or as
18 otherwise provided in ss. 499.001-499.081.

19 (a) The refusal or constructive refusal to allow:
20 1. The department to enter or inspect an establishment
21 in which drugs are manufactured, processed, repackaged, sold,
22 brokered, or held;

23 2. Inspection of any record of that establishment;

24 3. The department to enter and inspect any vehicle
25 that is being used to transport drugs; or

26 4. The department to take samples of any drug.

27 (b) The sale, purchase, or trade, or the offer to
28 sell, purchase, or trade, a drug sample as defined in s.
29 499.028; the distribution of a drug sample in violation of s.
30 499.028; or the failure to otherwise comply with s. 499.028.

31

1 (c) Providing the department with false or fraudulent
2 records, or making false or fraudulent statements, regarding
3 any matter within the provisions of this chapter related to a
4 drug.

5 (d) The failure to receive, maintain, or provide
6 invoices and shipping documents, other than pedigree papers,
7 if applicable, related to the distribution of a legend drug.

8 (e) The importation of a legend drug for wholesale
9 distribution, except as provided by s. 801(d) of the Federal
10 Food, Drug, and Cosmetic Act.

11 (f) The wholesale distribution of any prescription
12 drug that was:

13 1. Purchased by a public or private hospital or other
14 health care entity; or

15 2. Donated or supplied at a reduced price to a
16 charitable organization.

17 (g) The failure to obtain a permit as a prescription
18 drug wholesaler when a permit is required by ss.
19 499.001-499.081 for that activity.

20 (h) Knowingly possessing any adulterated or misbranded
21 legend drug outside of a designated quarantine area.

22 (i) The purchase or sale of prescription drugs for
23 wholesale distribution in exchange for currency, as defined in
24 s. 560.103(6).

25 (3) Any person who violates any of the following
26 provisions commits a felony of the second degree, punishable
27 as provided in s. 775.082, s. 775.083, or s. 775.084, or as
28 otherwise provided in ss. 499.001-499.081.

29 (a) Knowingly manufacturing, repackaging, selling,
30 delivering, or holding or offering for sale any drug that is
31

1 adulterated or misbranded or has otherwise been rendered unfit
2 for human or animal use.

3 (b) Knowingly adulterating a drug that is intended for
4 further distribution.

5 (c) Knowingly receiving a drug that is adulterated and
6 delivering or proffering delivery of such drug for pay or
7 otherwise.

8 (d) Committing any act that causes a drug to be a
9 counterfeit drug, or selling, dispensing, or knowingly holding
10 for sale a counterfeit drug.

11 (e) Forging, counterfeiting, simulating, or falsely
12 representing any drug, or, without the authority of the
13 manufacturer, using any mark, stamp, tag, label, or other
14 identification device authorized or required by rules adopted
15 under ss. 499.001-499.081.

16 (f) Knowingly obtaining or attempting to obtain a
17 prescription drug for wholesale distribution by fraud, deceit,
18 misrepresentation, or subterfuge, or engaging in
19 misrepresentation or fraud in the distribution of a drug.

20 (g) Removing a pharmacy's dispensing label from a
21 dispensed prescription drug with the intent to further
22 distribute the prescription drug.

23 (h) Knowingly distributing a prescription drug that
24 was previously dispensed by a licensed pharmacy, unless such
25 distribution was authorized in chapter 465 or the rules
26 adopted under chapter 465.

27 (4) A publisher, radio broadcast licensee, or agency
28 or medium for the dissemination of an advertisement, except
29 the manufacturer, repackager, wholesaler, or seller of the
30 article to which a false advertisement relates, is not liable
31 under this section by reason of the dissemination by him or

1 her of such false advertisement, unless he or she has refused,
2 on the request of the department, to furnish to the department
3 the name and post office address of the manufacturer,
4 repackager, wholesaler, seller, or advertising agency that
5 asked him or her to disseminate such advertisement.

6 Section 27. Paragraphs (d), (f), (h), (i), and (j) of
7 subsection (3) of section 921.0022, Florida Statutes, are
8 amended to read:

9 921.0022 Criminal Punishment Code; offense severity
10 ranking chart.--

11 (3) OFFENSE SEVERITY RANKING CHART

12	13 Florida	14 Statute	15 Felony	16 Degree	17 Description
18		316.1935(3)		2nd	(d) LEVEL 4 Driving at high speed or with wanton disregard for safety while fleeing or attempting to elude law enforcement officer who is in a marked patrol vehicle with siren and lights activated.
19		<u>499.0051(1)</u>		<u>3rd</u>	<u>Failure to maintain or deliver</u> <u>pedigree papers.</u>
20		<u>499.0051(2)</u>		<u>3rd</u>	<u>Failure to authenticate pedigree</u> <u>papers.</u>
21		<u>499.0051(6)</u>		<u>2nd</u>	<u>Sale or delivery, or possession</u> <u>with intent to sell, contraband</u> <u>legend drugs.</u>

1	784.07(2)(b)	3rd	Battery of law enforcement
2			officer, firefighter, intake
3			officer, etc.
4	784.074(1)(c)	3rd	Battery of sexually violent
5			predators facility staff.
6	784.075	3rd	Battery on detention or
7			commitment facility staff.
8	784.078	3rd	Battery of facility employee by
9			throwing, tossing, or expelling
10			certain fluids or materials.
11	784.08(2)(c)	3rd	Battery on a person 65 years of
12			age or older.
13	784.081(3)	3rd	Battery on specified official or
14			employee.
15	784.082(3)	3rd	Battery by detained person on
16			visitor or other detainee.
17	784.083(3)	3rd	Battery on code inspector.
18	784.085	3rd	Battery of child by throwing,
19			tossing, projecting, or expelling
20			certain fluids or materials.
21	787.03(1)	3rd	Interference with custody;
22			wrongly takes child from
23			appointed guardian.
24	787.04(2)	3rd	Take, entice, or remove child
25			beyond state limits with criminal
26			intent pending custody
27			proceedings.
28			
29			
30			
31			

1	787.04(3)	3rd	Carrying child beyond state lines
2			with criminal intent to avoid
3			producing child at custody
4			hearing or delivering to
5			designated person.
6	790.115(1)	3rd	Exhibiting firearm or weapon
7			within 1,000 feet of a school.
8	790.115(2)(b)	3rd	Possessing electric weapon or
9			device, destructive device, or
10			other weapon on school property.
11	790.115(2)(c)	3rd	Possessing firearm on school
12			property.
13	800.04(7)(d)	3rd	Lewd or lascivious exhibition;
14			offender less than 18 years.
15	810.02(4)(a)	3rd	Burglary, or attempted burglary,
16			of an unoccupied structure;
17			unarmed; no assault or battery.
18	810.02(4)(b)	3rd	Burglary, or attempted burglary,
19			of an unoccupied conveyance;
20			unarmed; no assault or battery.
21	810.06	3rd	Burglary; possession of tools.
22	810.08(2)(c)	3rd	Trespass on property, armed with
23			firearm or dangerous weapon.
24	812.014(2)(c)3.	3rd	Grand theft, 3rd degree \$10,000
25			or more but less than \$20,000.
26	812.014		
27	(2)(c)4.-10.	3rd	Grand theft, 3rd degree, a will,
28			firearm, motor vehicle,
29			livestock, etc.
30			
31			

1	812.0195(2)	3rd	Dealing in stolen property by use
2			of the Internet; property stolen
3			\$300 or more.
4	817.563(1)	3rd	Sell or deliver substance other
5			than controlled substance agreed
6			upon, excluding s. 893.03(5)
7			drugs.
8	817.568(2)(a)	3rd	Fraudulent use of personal
9			identification information.
10	817.625(2)(a)	3rd	Fraudulent use of scanning device
11			or reencoder.
12	828.125(1)	2nd	Kill, maim, or cause great bodily
13			harm or permanent breeding
14			disability to any registered
15			horse or cattle.
16	837.02(1)	3rd	Perjury in official proceedings.
17	837.021(1)	3rd	Make contradictory statements in
18			official proceedings.
19	839.13(2)(a)	3rd	Falsifying records of an
20			individual in the care and
21			custody of a state agency.
22	839.13(2)(c)	3rd	Falsifying records of the
23			Department of Children and Family
24			Services.
25	843.021	3rd	Possession of a concealed
26			handcuff key by a person in
27			custody.
28	843.025	3rd	Deprive law enforcement,
29			correctional, or correctional
30			probation officer of means of
31			protection or communication.

1	843.15(1)(a)	3rd	Failure to appear while on bail
2			for felony (bond estreature or
3			bond jumping).
4	874.05(1)	3rd	Encouraging or recruiting another
5			to join a criminal street gang.
6	893.13(2)(a)1.	2nd	Purchase of cocaine (or other s.
7			893.03(1)(a), (b), or (d),
8			(2)(a), (2)(b), or (2)(c)4.
9			drugs).
10	914.14(2)	3rd	Witnesses accepting bribes.
11	914.22(1)	3rd	Force, threaten, etc., witness,
12			victim, or informant.
13	914.23(2)	3rd	Retaliation against a witness,
14			victim, or informant, no bodily
15			injury.
16	918.12	3rd	Tampering with jurors.
17	934.215	3rd	Use of two-way communications
18			device to facilitate commission
19			of a crime.
20			(f) LEVEL 6
21	316.027(1)(b)	2nd	Accident involving death, failure
22			to stop; leaving scene.
23	316.193(2)(b)	3rd	Felony DUI, 4th or subsequent
24			conviction.
25	<u>499.0051(3)</u>	<u>2nd</u>	<u>Forgery of pedigree papers.</u>
26	<u>499.0051(4)</u>	<u>2nd</u>	<u>Purchase or receipt of legend</u>
27			<u>drug from unauthorized person.</u>
28	<u>499.0051(5)</u>	<u>2nd</u>	<u>Sale of legend drug to</u>
29			<u>unauthorized person.</u>
30	775.0875(1)	3rd	Taking firearm from law
31			enforcement officer.

1	775.21(10)	3rd	Sexual predators; failure to
2			register; failure to renew
3			driver's license or
4			identification card.
5	784.021(1)(a)	3rd	Aggravated assault; deadly weapon
6			without intent to kill.
7	784.021(1)(b)	3rd	Aggravated assault; intent to
8			commit felony.
9	784.041	3rd	Felony battery.
10	784.048(3)	3rd	Aggravated stalking; credible
11			threat.
12	784.048(5)	3rd	Aggravated stalking of person
13			under 16.
14	784.07(2)(c)	2nd	Aggravated assault on law
15			enforcement officer.
16	784.074(1)(b)	2nd	Aggravated assault on sexually
17			violent predators facility staff.
18	784.08(2)(b)	2nd	Aggravated assault on a person 65
19			years of age or older.
20	784.081(2)	2nd	Aggravated assault on specified
21			official or employee.
22	784.082(2)	2nd	Aggravated assault by detained
23			person on visitor or other
24			detainee.
25	784.083(2)	2nd	Aggravated assault on code
26			inspector.
27	787.02(2)	3rd	False imprisonment; restraining
28			with purpose other than those in
29			s. 787.01.
30	790.115(2)(d)	2nd	Discharging firearm or weapon on
31			school property.

1	790.161(2)	2nd	Make, possess, or throw
2			destructive device with intent to
3			do bodily harm or damage
4			property.
5	790.164(1)	2nd	False report of deadly explosive,
6			weapon of mass destruction, or
7			act of arson or violence to state
8			property.
9	790.19	2nd	Shooting or throwing deadly
10			missiles into dwellings, vessels,
11			or vehicles.
12	794.011(8)(a)	3rd	Solicitation of minor to
13			participate in sexual activity by
14			custodial adult.
15	794.05(1)	2nd	Unlawful sexual activity with
16			specified minor.
17	800.04(5)(d)	3rd	Lewd or lascivious molestation;
18			victim 12 years of age or older
19			but less than 16 years; offender
20			less than 18 years.
21	800.04(6)(b)	2nd	Lewd or lascivious conduct;
22			offender 18 years of age or
23			older.
24	806.031(2)	2nd	Arson resulting in great bodily
25			harm to firefighter or any other
26			person.
27	810.02(3)(c)	2nd	Burglary of occupied structure;
28			unarmed; no assault or battery.
29	812.014(2)(b)1.	2nd	Property stolen \$20,000 or more,
30			but less than \$100,000, grand
31			theft in 2nd degree.

1	812.014(2)(b)2.	2nd	Property stolen; cargo valued at
2			less than \$50,000, grand theft in
3			2nd degree.
4	812.015(9)	2nd	Retail theft; property stolen
5			\$300 or more; second or
6			subsequent conviction.
7	812.13(2)(c)	2nd	Robbery, no firearm or other
8			weapon (strong-arm robbery).
9	817.034(4)(a)1.	1st	Communications fraud, value
10			greater than \$50,000.
11	817.4821(5)	2nd	Possess cloning paraphernalia
12			with intent to create cloned
13			cellular telephones.
14	825.102(1)	3rd	Abuse of an elderly person or
15			disabled adult.
16	825.102(3)(c)	3rd	Neglect of an elderly person or
17			disabled adult.
18	825.1025(3)	3rd	Lewd or lascivious molestation of
19			an elderly person or disabled
20			adult.
21	825.103(2)(c)	3rd	Exploiting an elderly person or
22			disabled adult and property is
23			valued at less than \$20,000.
24	827.03(1)	3rd	Abuse of a child.
25	827.03(3)(c)	3rd	Neglect of a child.
26	827.071(2)&(3)	2nd	Use or induce a child in a sexual
27			performance, or promote or direct
28			such performance.
29	836.05	2nd	Threats; extortion.
30	836.10	2nd	Written threats to kill or do
31			bodily injury.

1	843.12	3rd	Aids or assists person to escape.
2	847.0135(3)	3rd	Solicitation of a child, via a
3			computer service, to commit an
4			unlawful sex act.
5	914.23	2nd	Retaliation against a witness,
6			victim, or informant, with bodily
7			injury.
8	943.0435(9)	3rd	Sex offenders; failure to comply
9			with reporting requirements.
10	944.35(3)(a)2.	3rd	Committing malicious battery upon
11			or inflicting cruel or inhuman
12			treatment on an inmate or
13			offender on community
14			supervision, resulting in great
15			bodily harm.
16	944.40	2nd	Escapes.
17	944.46	3rd	Harboring, concealing, aiding
18			escaped prisoners.
19	944.47(1)(a)5.	2nd	Introduction of contraband
20			(firearm, weapon, or explosive)
21			into correctional facility.
22	951.22(1)	3rd	Intoxicating drug, firearm, or
23			weapon introduced into county
24			facility.
25			(h) LEVEL 8
26	316.193		
27	(3)(c)3.a.	2nd	DUI manslaughter.
28	327.35(3)(c)3.	2nd	Vessel BUI manslaughter.
29	<u>499.0051(7)</u>	<u>1st</u>	<u>Forgery of prescription or legend</u>
30			<u>drug labels.</u>
31			

1	<u>499.0052</u>	<u>1st</u>	<u>Trafficking in contraband legend</u>
2			<u>drugs.</u>
3	560.123(8)(b)2.	2nd	Failure to report currency or
4			payment instruments totaling or
5			exceeding \$20,000, but less than
6			\$100,000 by money transmitter.
7	560.125(5)(b)	2nd	Money transmitter business by
8			unauthorized person, currency or
9			payment instruments totaling or
10			exceeding \$20,000, but less than
11			\$100,000.
12	655.50(10)(b)2.	2nd	Failure to report financial
13			transactions totaling or
14			exceeding \$20,000, but less than
15			\$100,000 by financial
16			institutions.
17	777.03(2)(a)	1st	Accessory after the fact, capital
18			felony.
19	782.04(4)	2nd	Killing of human without design
20			when engaged in act or attempt of
21			any felony other than arson,
22			sexual battery, robbery,
23			burglary, kidnapping, aircraft
24			piracy, or unlawfully discharging
25			bomb.
26	782.051(2)	1st	Attempted felony murder while
27			perpetrating or attempting to
28			perpetrate a felony not
29			enumerated in s. 782.04(3).
30			
31			

1	782.071(1)(b)	1st	Committing vehicular homicide and
2			failing to render aid or give
3			information.
4	782.072(2)	1st	Committing vessel homicide and
5			failing to render aid or give
6			information.
7	790.161(3)	1st	Discharging a destructive device
8			which results in bodily harm or
9			property damage.
10	794.011(5)	2nd	Sexual battery, victim 12 years
11			or over, offender does not use
12			physical force likely to cause
13			serious injury.
14	800.04(4)	2nd	Lewd or lascivious battery.
15	806.01(1)	1st	Maliciously damage dwelling or
16			structure by fire or explosive,
17			believing person in structure.
18	810.02(2)(a)	1st,PBL	Burglary with assault or battery.
19	810.02(2)(b)	1st,PBL	Burglary; armed with explosives
20			or dangerous weapon.
21	810.02(2)(c)	1st	Burglary of a dwelling or
22			structure causing structural
23			damage or \$1,000 or more property
24			damage.
25	812.13(2)(b)	1st	Robbery with a weapon.
26	812.135(2)	1st	Home-invasion robbery.
27	825.102(2)	2nd	Aggravated abuse of an elderly
28			person or disabled adult.
29	825.1025(2)	2nd	Lewd or lascivious battery upon
30			an elderly person or disabled
31			adult.

1	825.103(2)(a)	1st	Exploiting an elderly person or
2			disabled adult and property is
3			valued at \$100,000 or more.
4	837.02(2)	2nd	Perjury in official proceedings
5			relating to prosecution of a
6			capital felony.
7	837.021(2)	2nd	Making contradictory statements
8			in official proceedings relating
9			to prosecution of a capital
10			felony.
11	860.121(2)(c)	1st	Shooting at or throwing any
12			object in path of railroad
13			vehicle resulting in great bodily
14			harm.
15	860.16	1st	Aircraft piracy.
16	893.13(1)(b)	1st	Sell or deliver in excess of 10
17			grams of any substance specified
18			in s. 893.03(1)(a) or (b).
19	893.13(2)(b)	1st	Purchase in excess of 10 grams of
20			any substance specified in s.
21			893.03(1)(a) or (b).
22	893.13(6)(c)	1st	Possess in excess of 10 grams of
23			any substance specified in s.
24			893.03(1)(a) or (b).
25	893.135(1)(a)2.	1st	Trafficking in cannabis, more
26			than 2,000 lbs., less than 10,000
27			lbs.
28	893.135		
29	(1)(b)1.b.	1st	Trafficking in cocaine, more than
30			200 grams, less than 400 grams.
31			

1	893.135		
2	(1)(c)1.b.	1st	Trafficking in illegal drugs,
3			more than 14 grams, less than 28
4			grams.
5	893.135		
6	(1)(d)1.b.	1st	Trafficking in phencyclidine,
7			more than 200 grams, less than
8			400 grams.
9	893.135		
10	(1)(e)1.b.	1st	Trafficking in methaqualone, more
11			than 5 kilograms, less than 25
12			kilograms.
13	893.135		
14	(1)(f)1.b.	1st	Trafficking in amphetamine, more
15			than 28 grams, less than 200
16			grams.
17	893.135		
18	(1)(g)1.b.	1st	Trafficking in flunitrazepam, 14
19			grams or more, less than 28
20			grams.
21	893.135		
22	(1)(h)1.b.	1st	Trafficking in
23			gamma-hydroxybutyric acid (GHB),
24			5 kilograms or more, less than 10
25			kilograms.
26	893.135		
27	(1)(j)1.b.	1st	Trafficking in 1,4-Butanediol, 5
28			kilograms or more, less than 10
29			kilograms.
30			
31			

1	893.135		
2	(1)(k)2.b.	1st	Trafficking in Phenethylamines,
3			200 grams or more, less than 400
4			grams.
5	895.03(1)	1st	Use or invest proceeds derived
6			from pattern of racketeering
7			activity.
8	895.03(2)	1st	Acquire or maintain through
9			racketeering activity any
10			interest in or control of any
11			enterprise or real property.
12	895.03(3)	1st	Conduct or participate in any
13			enterprise through pattern of
14			racketeering activity.
15	896.101(5)(b)	2nd	Money laundering, financial
16			transactions totaling or
17			exceeding \$20,000, but less than
18			\$100,000.
19	896.104(4)(a)2.	2nd	Structuring transactions to evade
20			reporting or registration
21			requirements, financial
22			transactions totaling or
23			exceeding \$20,000 but less than
24			\$100,000.
25			(i) LEVEL 9
26	316.193		
27	(3)(c)3.b.	1st	DUI manslaughter; failing to
28			render aid or give information.
29	327.35(3)(c)3.b.	1st	BUI manslaughter; failing to
30			render aid or give information.
31			

1	<u>499.0053</u>	<u>1st</u>	<u>Sale or purchase of contraband</u>
2			<u>legend drugs resulting in great</u>
3			<u>bodily harm.</u>
4	560.123(8)(b)3.	1st	Failure to report currency or
5			payment instruments totaling or
6			exceeding \$100,000 by money
7			transmitter.
8	560.125(5)(c)	1st	Money transmitter business by
9			unauthorized person, currency, or
10			payment instruments totaling or
11			exceeding \$100,000.
12	655.50(10)(b)3.	1st	Failure to report financial
13			transactions totaling or
14			exceeding \$100,000 by financial
15			institution.
16	775.0844	1st	Aggravated white collar crime.
17	782.04(1)	1st	Attempt, conspire, or solicit to
18			commit premeditated murder.
19	782.04(3)	1st,PBL	Accomplice to murder in
20			connection with arson, sexual
21			battery, robbery, burglary, and
22			other specified felonies.
23	782.051(1)	1st	Attempted felony murder while
24			perpetrating or attempting to
25			perpetrate a felony enumerated in
26			s. 782.04(3).
27	782.07(2)	1st	Aggravated manslaughter of an
28			elderly person or disabled adult.
29	787.01(1)(a)1.	1st,PBL	Kidnapping; hold for ransom or
30			reward or as a shield or hostage.
31			

1	787.01(1)(a)2.	1st,PBL	Kidnapping with intent to commit
2			or facilitate commission of any
3			felony.
4	787.01(1)(a)4.	1st,PBL	Kidnapping with intent to
5			interfere with performance of any
6			governmental or political
7			function.
8	787.02(3)(a)	1st	False imprisonment; child under
9			age 13; perpetrator also commits
10			aggravated child abuse, sexual
11			battery, or lewd or lascivious
12			battery, molestation, conduct, or
13			exhibition.
14	790.161	1st	Attempted capital destructive
15			device offense.
16	790.166(2)	1st,PBL	Possessing, selling, using, or
17			attempting to use a weapon of
18			mass destruction.
19	794.011(2)	1st	Attempted sexual battery; victim
20			less than 12 years of age.
21	794.011(2)	Life	Sexual battery; offender younger
22			than 18 years and commits sexual
23			battery on a person less than 12
24			years.
25	794.011(4)	1st	Sexual battery; victim 12 years
26			or older, certain circumstances.
27	794.011(8)(b)	1st	Sexual battery; engage in sexual
28			conduct with minor 12 to 18 years
29			by person in familial or
30			custodial authority.
31			

1	800.04(5)(b)	1st	Lewd or lascivious molestation;
2			victim less than 12 years;
3			offender 18 years or older.
4	812.13(2)(a)	1st,PBL	Robbery with firearm or other
5			deadly weapon.
6	812.133(2)(a)	1st,PBL	Carjacking; firearm or other
7			deadly weapon.
8	827.03(2)	1st	Aggravated child abuse.
9	847.0145(1)	1st	Selling, or otherwise
10			transferring custody or control,
11			of a minor.
12	847.0145(2)	1st	Purchasing, or otherwise
13			obtaining custody or control, of
14			a minor.
15	859.01	1st	Poisoning or introducing
16			bacteria, radioactive materials,
17			viruses, or chemical compounds
18			into food, drink, medicine, or
19			water with intent to kill or
20			injure another person.
21	893.135	1st	Attempted capital trafficking
22			offense.
23	893.135(1)(a)3.	1st	Trafficking in cannabis, more
24			than 10,000 lbs.
25	893.135		
26	(1)(b)1.c.	1st	Trafficking in cocaine, more than
27			400 grams, less than 150
28			kilograms.
29			
30			
31			

1	893.135		
2	(1)(c)1.c.	1st	Trafficking in illegal drugs,
3			more than 28 grams, less than 30
4			kilograms.
5	893.135		
6	(1)(d)1.c.	1st	Trafficking in phencyclidine,
7			more than 400 grams.
8	893.135		
9	(1)(e)1.c.	1st	Trafficking in methaqualone, more
10			than 25 kilograms.
11	893.135		
12	(1)(f)1.c.	1st	Trafficking in amphetamine, more
13			than 200 grams.
14	893.135		
15	(1)(h)1.c.	1st	Trafficking in
16			gamma-hydroxybutyric acid (GHB),
17			10 kilograms or more.
18	893.135		
19	(1)(j)1.c.	1st	Trafficking in 1,4-Butanediol, 10
20			kilograms or more.
21	893.135		
22	(1)(k)2.c.	1st	Trafficking in Phenethylamines,
23			400 grams or more.
24	896.101(5)(c)	1st	Money laundering, financial
25			instruments totaling or exceeding
26			\$100,000.
27	896.104(4)(a)3.	1st	Structuring transactions to evade
28			reporting or registration
29			requirements, financial
30			transactions totaling or
31			exceeding \$100,000.

1 (j) LEVEL 10
2 499.0054 1st Sale or purchase of contraband
3 legend drugs resulting in death.
4 782.04(2) 1st,PBL Unlawful killing of human; act is
5 homicide, unpremeditated.
6 787.01(1)(a)3. 1st,PBL Kidnapping; inflict bodily harm
7 upon or terrorize victim.
8 787.01(3)(a) Life Kidnapping; child under age 13,
9 perpetrator also commits
10 aggravated child abuse, sexual
11 battery, or lewd or lascivious
12 battery, molestation, conduct, or
13 exhibition.
14 782.07(3) 1st Aggravated manslaughter of a
15 child.
16 794.011(3) Life Sexual battery; victim 12 years
17 or older, offender uses or
18 threatens to use deadly weapon or
19 physical force to cause serious
20 injury.
21 876.32 1st Treason against the state.
22 Section 28. Paragraph (a) of subsection (1) of section
23 16.56, Florida Statutes, is amended to read:
24 16.56 Office of Statewide Prosecution.--
25 (1) There is created in the Department of Legal
26 Affairs an Office of Statewide Prosecution. The office shall
27 be a separate "budget entity" as that term is defined in
28 chapter 216. The office may:
29 (a) Investigate and prosecute the offenses of:
30
31

1 1. Bribery, burglary, criminal usury, extortion,
2 gambling, kidnapping, larceny, murder, prostitution, perjury,
3 robbery, carjacking, and home-invasion robbery;
4 2. Any crime involving narcotic or other dangerous
5 drugs;
6 3. Any violation of the provisions of the Florida RICO
7 (Racketeer Influenced and Corrupt Organization) Act, including
8 any offense listed in the definition of racketeering activity
9 in s. 895.02(1)(a), providing such listed offense is
10 investigated in connection with a violation of s. 895.03 and
11 is charged in a separate count of an information or indictment
12 containing a count charging a violation of s. 895.03, the
13 prosecution of which listed offense may continue independently
14 if the prosecution of the violation of s. 895.03 is terminated
15 for any reason;
16 4. Any violation of the provisions of the Florida
17 Anti-Fencing Act;
18 5. Any violation of the provisions of the Florida
19 Antitrust Act of 1980, as amended;
20 6. Any crime involving, or resulting in, fraud or
21 deceit upon any person;
22 7. Any violation of s. 847.0135, relating to computer
23 pornography and child exploitation prevention, or any offense
24 related to a violation of s. 847.0135; ~~or~~
25 8. Any violation of the provisions of chapter 815; or
26 9. Any criminal violation of part I of chapter 499.
27
28 or any attempt, solicitation, or conspiracy to commit any of
29 the crimes specifically enumerated above. The office shall
30 have such power only when any such offense is occurring, or
31 has occurred, in two or more judicial circuits as part of a

1 related transaction, or when any such offense is connected
2 with an organized criminal conspiracy affecting two or more
3 judicial circuits.

4 Section 29. Paragraph (a) of subsection (1) of section
5 895.02, Florida Statutes, is amended to read:

6 895.02 Definitions.--As used in ss. 895.01-895.08, the
7 term:

8 (1) "Racketeering activity" means to commit, to
9 attempt to commit, to conspire to commit, or to solicit,
10 coerce, or intimidate another person to commit:

11 (a) Any crime which is chargeable by indictment or
12 information under the following provisions of the Florida
13 Statutes:

14 1. Section 210.18, relating to evasion of payment of
15 cigarette taxes.

16 2. Section 403.727(3)(b), relating to environmental
17 control.

18 3. Section 414.39, relating to public assistance
19 fraud.

20 4. Section 409.920, relating to Medicaid provider
21 fraud.

22 5. Section 440.105 or s. 440.106, relating to workers'
23 compensation.

24 6. Sections 499.0051, 499.0052, 499.0053, 499.0054,
25 and 499.0691, relating to crimes involving contraband and
26 adulterated drugs.

27 7.6. Part IV of chapter 501, relating to
28 telemarketing.

29 8.7. Chapter 517, relating to sale of securities and
30 investor protection.

31

1 ~~9.8.~~ Section 550.235, s. 550.3551, or s. 550.3605,
2 relating to dogracing and horseracing.
3 ~~10.9.~~ Chapter 550, relating to jai alai frontons.
4 ~~11.10.~~ Chapter 552, relating to the manufacture,
5 distribution, and use of explosives.
6 ~~12.11.~~ Chapter 560, relating to money transmitters, if
7 the violation is punishable as a felony.
8 ~~13.12.~~ Chapter 562, relating to beverage law
9 enforcement.
10 ~~14.13.~~ Section 624.401, relating to transacting
11 insurance without a certificate of authority, s.
12 624.437(4)(c)1., relating to operating an unauthorized
13 multiple-employer welfare arrangement, or s. 626.902(1)(b),
14 relating to representing or aiding an unauthorized insurer.
15 ~~15.14.~~ Section 655.50, relating to reports of currency
16 transactions, when such violation is punishable as a felony.
17 ~~16.15.~~ Chapter 687, relating to interest and usurious
18 practices.
19 ~~17.16.~~ Section 721.08, s. 721.09, or s. 721.13,
20 relating to real estate timeshare plans.
21 ~~18.17.~~ Chapter 782, relating to homicide.
22 ~~19.18.~~ Chapter 784, relating to assault and battery.
23 ~~20.19.~~ Chapter 787, relating to kidnapping.
24 ~~21.20.~~ Chapter 790, relating to weapons and firearms.
25 ~~22.21.~~ Section 796.03, s. 796.04, s. 796.05, or s.
26 796.07, relating to prostitution.
27 ~~23.22.~~ Chapter 806, relating to arson.
28 ~~24.23.~~ Section 810.02(2)(c), relating to specified
29 burglary of a dwelling or structure.
30 ~~25.24.~~ Chapter 812, relating to theft, robbery, and
31 related crimes.

1 ~~26.25.~~ Chapter 815, relating to computer-related
2 crimes.
3 ~~27.26.~~ Chapter 817, relating to fraudulent practices,
4 false pretenses, fraud generally, and credit card crimes.
5 ~~28.27.~~ Chapter 825, relating to abuse, neglect, or
6 exploitation of an elderly person or disabled adult.
7 ~~29.28.~~ Section 827.071, relating to commercial sexual
8 exploitation of children.
9 ~~30.29.~~ Chapter 831, relating to forgery and
10 counterfeiting.
11 ~~31.30.~~ Chapter 832, relating to issuance of worthless
12 checks and drafts.
13 ~~32.31.~~ Section 836.05, relating to extortion.
14 ~~33.32.~~ Chapter 837, relating to perjury.
15 ~~34.33.~~ Chapter 838, relating to bribery and misuse of
16 public office.
17 ~~35.34.~~ Chapter 843, relating to obstruction of
18 justice.
19 ~~36.35.~~ Section 847.011, s. 847.012, s. 847.013, s.
20 847.06, or s. 847.07, relating to obscene literature and
21 profanity.
22 ~~37.36.~~ Section 849.09, s. 849.14, s. 849.15, s.
23 849.23, or s. 849.25, relating to gambling.
24 ~~38.37.~~ Chapter 874, relating to criminal street gangs.
25 ~~39.38.~~ Chapter 893, relating to drug abuse prevention
26 and control.
27 ~~40.39.~~ Chapter 896, relating to offenses related to
28 financial transactions.
29 ~~41.40.~~ Sections 914.22 and 914.23, relating to
30 tampering with a witness, victim, or informant, and
31 retaliation against a witness, victim, or informant.

1 42.41. Sections 918.12 and 918.13, relating to
2 tampering with jurors and evidence.

3 Section 30. Section 905.34, Florida Statutes, is
4 amended to read:

5 905.34 Powers and duties; law applicable.--The
6 jurisdiction of a statewide grand jury impaneled under this
7 chapter shall extend throughout the state. The subject matter
8 jurisdiction of the statewide grand jury shall be limited to
9 the offenses of:

10 (1) Bribery, burglary, carjacking, home-invasion
11 robbery, criminal usury, extortion, gambling, kidnapping,
12 larceny, murder, prostitution, perjury, and robbery;

13 (2) Crimes involving narcotic or other dangerous
14 drugs;

15 (3) Any violation of the provisions of the Florida
16 RICO (Racketeer Influenced and Corrupt Organization) Act,
17 including any offense listed in the definition of racketeering
18 activity in s. 895.02(1)(a), providing such listed offense is
19 investigated in connection with a violation of s. 895.03 and
20 is charged in a separate count of an information or indictment
21 containing a count charging a violation of s. 895.03, the
22 prosecution of which listed offense may continue independently
23 if the prosecution of the violation of s. 895.03 is terminated
24 for any reason;

25 (4) Any violation of the provisions of the Florida
26 Anti-Fencing Act;

27 (5) Any violation of the provisions of the Florida
28 Antitrust Act of 1980, as amended;

29 (6) Any violation of the provisions of chapter 815;

30 (7) Any crime involving, or resulting in, fraud or
31 deceit upon any person;

1 (8) Any violation of s. 847.0135, s. 847.0137, or s.
2 847.0138 relating to computer pornography and child
3 exploitation prevention, or any offense related to a violation
4 of s. 847.0135, s. 847.0137, or s. 847.0138; or

5 (9) Any criminal violation of part I of chapter 499.

6
7 or any attempt, solicitation, or conspiracy to commit any
8 violation of the crimes specifically enumerated above, when
9 any such offense is occurring, or has occurred, in two or more
10 judicial circuits as part of a related transaction or when any
11 such offense is connected with an organized criminal
12 conspiracy affecting two or more judicial circuits. The
13 statewide grand jury may return indictments and presentments
14 irrespective of the county or judicial circuit where the
15 offense is committed or triable. If an indictment is
16 returned, it shall be certified and transferred for trial to
17 the county where the offense was committed. The powers and
18 duties of, and law applicable to, county grand juries shall
19 apply to a statewide grand jury except when such powers,
20 duties, and law are inconsistent with the provisions of ss.
21 905.31-905.40.

22 Section 31. If any provision of this act or its
23 application to any person or circumstance is held invalid, the
24 invalidity does not affect other provisions or applications of
25 the act which can be given effect without the invalid
26 provision or application, and to this end the provisions of
27 this act are severable.

28 Section 32. Except as otherwise expressly provided in
29 this act, this act shall take effect July 1, 2003.

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SENATE SUMMARY

Creates the Prescription Drug Protection Act. Provides requirements for the regulation of prescription drug wholesalers, repackagers, and manufacturers by the Department of Health. Provides certain felony penalties for violations involving the failure to maintain, deliver, or authenticate pedigree papers; purchasing or selling unlicensed drugs; the possession or selling of contraband legend drugs; and the forging of certain labels. Requires that drug repackagers, nonresident manufacturers, and freight forwarders obtain a permit from the Department of Health. Provides bond requirements for drug wholesalers. Authorizes the department to conduct inspections and close facilities that present a danger to public health. Includes certain violations of pt. I of ch. 499, F.S., within the definition of racketeering activities and authorizes prosecution by the Office of Statewide Prosecution. (See bill for details.)