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2 An act relating to the distribution 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; amending s.
8 499.005, F.S.; prohibiting the purchase or sale
9 of prescription drugs in wholesale distribution
10 in exchange for currency; clarifying provisions
11 prohibiting the transfer of legend drugs from
12 or to any person not authorized to possess such
13 drugs; prohibiting additional acts concerning
14 the distribution of prescription drugs;
15 creating s. 499.0051, F.S.; providing that
16 failure to maintain or deliver pedigree papers,
17 failure to authenticate pedigree papers,
18 forgery of pedigree papers, purchase of legend
19 drugs from an unlicensed person, sale of legend
20 drugs to an unlicensed person, possession or
21 sale of contraband legend drugs and possession
22 with intent to sell or deliver contraband
23 legend drugs, and forgery of prescription
24 labels or legend drug labels are felony
25 offenses; providing penalties; creating s.
26 499.0052, F.S.; providing that trafficking in
27 contraband legend drugs is a felony offense;
28 providing penalties; providing enhanced
29 penalties if the defendant is a corporation or
30 not a natural person; creating s. 499.0053,
31 F.S.; providing that the sale or purchase of a

1 contraband legend drug resulting in great
2 bodily harm is a first-degree felony; creating
3 s. 499.0054, F.S.; providing that the sale or
4 purchase of a contraband legend drug resulting
5 in death is a first-degree felony; amending s.
6 499.006, F.S.; providing that a legend drug
7 that is unaccompanied by a proper pedigree
8 paper or that has been in the possession of an
9 unauthorized person is an adulterated drug;
10 amending s. 499.007, F.S.; revising labeling
11 requirements to conform to federal law;
12 amending s. 499.01, F.S.; requiring that
13 prescription drug repackagers, nonresident
14 prescription drug manufacturers, and freight
15 forwarders obtain a permit from the Department
16 of Health in order to do business; prohibiting
17 a county or municipality from issuing an
18 occupational license prior to an establishment
19 obtaining a permit required under ch. 499,
20 F.S., under specified circumstances; providing
21 for early expiration of certain permits;
22 amending s. 499.012, F.S.; excluding the
23 transfer of prescription drugs within a
24 hospital from the definition of wholesale
25 distribution; providing bond requirements for
26 prescription drug wholesalers; deleting
27 provisions authorizing the department to grant
28 out-of-state wholesalers reciprocity; requiring
29 freight forwarders and nonresident prescription
30 drug manufacturers to obtain a permit;
31 providing requirements for permit applications;

1 providing definitions; providing requirements
2 for the permitting of prescription drug
3 wholesalers and out-of-state prescription drug
4 wholesalers; providing criteria for permit
5 denials; requiring prescription drug
6 wholesalers to designate a representative;
7 providing criteria for designation as a
8 representative; correcting a cross-reference;
9 amending s. 499.0121, F.S.; requiring record
10 review; requiring pedigree papers for the
11 transfer and sale of legend drugs; providing
12 exemptions; providing documentation
13 requirements for the shipment of prescription
14 drugs; providing requirements for wholesale
15 drug distributors with respect to the exercise
16 of due diligence; providing rulemaking
17 authority; creating s. 499.01211, F.S.;
18 creating the Drug Wholesaler Advisory Council
19 within the Department of Health; providing for
20 membership of the council and terms of office;
21 requiring the council to review rules and make
22 recommendations to the secretary of the
23 department; amending s. 499.013, F.S.;
24 providing requirements for repackagers of
25 drugs, devices, and cosmetics; requiring that a
26 repackager obtain a permit from the department;
27 providing labeling requirements; amending s.
28 499.014, F.S.; specifying that certain
29 restricted distributors are exempt from the
30 requirements concerning pedigree papers;
31 amending s. 499.041, F.S.; revising the

1 schedule of fees for permits; amending s.
2 499.051, F.S.; correcting a cross-reference;
3 revising the authority of the Department of
4 Health to inspect pharmacies and pharmacy
5 wholesalers; authorizing the department and the
6 Department of Law Enforcement to inspect
7 certain financial documents and records;
8 amending s. 499.055, F.S.; requiring the
9 Department of Health to establish a website
10 listing all permitholders and pending
11 enforcement actions; creating s. 499.065, F.S.;
12 authorizing the department to enter and inspect
13 all permitted facilities at any reasonable
14 time; authorizing the department to seize and
15 destroy prescription drugs representing a
16 threat to public health; authorizing the
17 department to close facilities that represent
18 an imminent danger to public health; amending
19 s. 499.066, F.S.; providing for administrative
20 actions by the department; creating s.
21 499.0661, F.S.; providing for the department to
22 issue cease and desist orders; providing for
23 the department to order the removal of certain
24 persons from involvement with certain drug
25 wholesalers; providing penalties; amending s.
26 499.067, F.S.; specifying additional grounds
27 for denial of a permit or certification;
28 amending s. 499.069, F.S.; revising certain
29 penalty provisions; creating s. 499.0691, F.S.;
30 providing criminal penalties for violations
31 related to drugs or false advertisement;

1 amending s. 921.0022, F.S., relating to the
2 offense severity ranking chart of the Criminal
3 Punishment Code; conforming provisions to
4 changes made by the act; amending s. 895.02,
5 F.S.; including certain violations of part I of
6 ch. 499, F.S., within the definition of
7 racketeering activity; amending ss. 16.56 and
8 905.34, F.S.; authorizing criminal violations
9 of part I of ch. 499, F.S., to be prosecuted by
10 the Office of Statewide Prosecution and heard
11 by the Statewide Grand Jury; providing for
12 severability; providing an effective date.

13

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

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

18

19 Section 2. Legislative findings and intent.--Based on
20 the report of the Seventeenth Statewide Grand Jury in its
21 First Interim Report the Legislature finds that prescription
22 drugs brought into the state by wholesalers are being
23 relabeled and falsely represented as being of a higher dosage
24 by other wholesalers in order to charge higher prices for
25 those drugs and that counterfeit substances labeled as genuine
26 pharmaceuticals are being distributed, thereby causing an
27 extreme danger that persons eventually receiving the drugs by
28 prescription are receiving ineffective drugs in nontherapeutic
29 doses, or even receiving dangerous or unwholesome substances,
30 with the result that the health and well-being of the public
31 is at risk. The Statewide Grand Jury also found that the lack
of an effective pedigree paper requirement has resulted in the

1 inability of prescription drug users to have confidence in the
2 purity and efficacy of the drugs they use. The Statewide Grand
3 Jury further noted that present laws do not allow effective
4 criminal prosecution of persons involved in such false
5 representations. It is the intent of the Legislature that the
6 statutory changes and recommendations outlined in the
7 Statewide Grand Jury's report be implemented as provided by
8 this act.

9 Section 3. Section 499.003, Florida Statutes, is
10 amended to read:

11 499.003 Definitions of terms used in ss.

12 499.001-499.081.--As used in ss. 499.001-499.081, the term:

13 (1) "Advertisement" means any representation
14 disseminated in any manner or by any means, other than by
15 labeling, for the purpose of inducing, or which is likely to
16 induce, directly or indirectly, the purchase of drugs,
17 devices, or cosmetics.

18 (2) "Affiliated party" means:

19 (a) A director, officer, trustee, partner, or
20 committee member of a permittee or applicant or a subsidiary
21 or service corporation of the permittee or applicant;

22 (b) A person who, directly or indirectly, manages,
23 controls, or oversees the operation of a permittee or
24 applicant, regardless of whether such person is a partner,
25 shareholder, manager, member, officer, director, independent
26 contractor, or employee of the permittee or applicant;

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

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

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

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

8 ~~(5)(2)~~ "Certificate of free sale" means a document
9 prepared by the department which certifies a drug, device, or
10 cosmetic, that is registered with the department, as one that
11 can be legally sold in the state.

12 ~~(6)(3)~~ "Closed pharmacy" means a pharmacy that is
13 licensed under chapter 465 and purchases prescription drugs
14 for use by a limited patient population and not for wholesale
15 distribution or sale to the public. The term does not include
16 retail pharmacies.

17 ~~(7)(4)~~ "Color" includes black, white, and intermediate
18 grays.

19 ~~(8)(5)~~ "Color additive" means a material that:

20 (a) Is a dye pigment, or other substance, made by a
21 process of synthesis or similar artifice, or extracted,
22 isolated, or otherwise derived, with or without intermediate
23 or final change of identity from a vegetable, animal, mineral,
24 or other source; or

25 (b) When added or applied to a drug or cosmetic or to
26 the human body, or any part thereof, is capable alone, or
27 through reaction with other substances, of imparting color
28 thereto;

29
30 except that the term does not include any material which has
31 been or hereafter is exempt under the federal act.

1 ~~(9)(6)~~ "Compressed medical gas" means any liquefied or
2 vaporized gas that is a prescription drug, whether it is alone
3 or in combination with other gases.

4 (10) "Contraband legend drug" means any adulterated
5 drug, as defined in s. 499.006, any counterfeit drug, as
6 defined in this section, and also means any legend drug for
7 which a pedigree paper does not exist, or for which the
8 pedigree paper in existence has been forged, counterfeited,
9 falsely created, or contains any altered, false, or
10 misrepresented matter.

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

12 (a) Intended to be rubbed, poured, sprinkled, or
13 sprayed on; introduced into; or otherwise applied to the human
14 body or any part thereof for cleansing, beautifying, promoting
15 attractiveness, or altering the appearance; or

16 (b) Intended for use as a component of any such
17 article;

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19 except that the term does not include soap.

20 ~~(12)(8)~~ "Counterfeit drug, counterfeit device, or
21 counterfeit cosmetic" means a drug, device, or cosmetic which,
22 or the container, seal, or labeling of which, without
23 authorization, bears the trademark, trade name, or other
24 identifying mark, imprint, or device, or any likeness thereof,
25 of a drug, device, or cosmetic manufacturer, processor,
26 packer, or distributor other than the person that in fact
27 manufactured, processed, packed, or distributed that drug,
28 device, or cosmetic and which thereby falsely purports or is
29 represented to be the product of, or to have been packed or
30 distributed by, that other drug, device, or cosmetic
31 manufacturer, processor, packer, or distributor.

1 ~~(13)(9)~~ "Department" means the Department of Health.

2 ~~(14)(10)~~ "Device" means any instrument, apparatus,
3 implement, machine, contrivance, implant, in vitro reagent, or
4 other similar or related article, including its components,
5 parts, or accessories, which is:

6 (a) Recognized in the current edition of the United
7 States Pharmacopoeia and National Formulary, or any supplement
8 thereof,

9 (b) Intended for use in the diagnosis, cure,
10 mitigation, treatment, therapy, or prevention of disease in
11 humans or other animals, or

12 (c) Intended to affect the structure or any function
13 of the body of humans or other animals,

14

15 and which does not achieve any of its principal intended
16 purposes through chemical action within or on the body of
17 humans or other animals and which is not dependent upon being
18 metabolized for the achievement of any of its principal
19 intended purposes.

20 ~~(15)(11)~~ "Distribute or distribution" means to sell;
21 offer to sell; give away; transfer, whether by passage of
22 title, physical movement, or both; deliver; or offer to
23 deliver. The term does not mean to administer or dispense.

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

27 ~~(17)(12)~~ "Drug" means an article that is:

28 (a) Recognized in the current edition of the United
29 States Pharmacopoeia and National Formulary, official
30 Homeopathic Pharmacopoeia of the United States, or any
31 supplement to any of those publications;

1 (b) Intended for use in the diagnosis, cure,
2 mitigation, treatment, therapy, or prevention of disease in
3 humans or other animals;

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

6 (d) Intended for use as a component of any article
7 specified in paragraph (a), paragraph (b), or paragraph (c),
8 but does not include devices or their components, parts, or
9 accessories.

10 (18)~~(13)~~ "Establishment" means a place of business at
11 one general physical location.

12 (19)~~(14)~~ "Federal act" means the Federal Food, Drug,
13 and Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et
14 seq.

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

18 (21)~~(15)~~ "Health care entity" means a closed pharmacy
19 or any person, organization, or business entity that provides
20 diagnostic, medical, surgical, or dental treatment or care, or
21 chronic or rehabilitative care, but does not include any
22 wholesale distributor or retail pharmacy licensed under state
23 law to deal in prescription drugs.

24 (22)~~(16)~~ "Immediate container" does not include
25 package liners.

26 (23)~~(17)~~ "Label" means a display of written, printed,
27 or graphic matter upon the immediate container of any drug,
28 device, or cosmetic. A requirement made by or under authority
29 of ss. 499.001-499.081 or rules adopted under those sections
30 that any word, statement, or other information appear on the
31 label is not complied with unless such word, statement, or

1 other information also appears on the outside container or
2 wrapper, if any, of the retail package of such drug, device,
3 or cosmetic or is easily legible through the outside container
4 or wrapper.

5 (24)~~(18)~~ "Labeling" means all labels and other
6 written, printed, or graphic matters:

7 (a) Upon a drug, device, or cosmetic, or any of its
8 containers or wrappers; or

9 (b) Accompanying or related to such drug, device, or
10 cosmetic.

11 (25)~~(19)~~ "Legend drug," "prescription drug," or
12 "medicinal drug" means any drug, including, but not limited
13 to, finished dosage forms, or active ingredients subject to,
14 defined by, or described by s. 503(b) of the Federal Food,
15 Drug, and Cosmetic Act or s. 465.003(8), s. 499.007(12), or s.
16 499.0122(1)(b) or (c).

17 (26) "Legend drug label" means any display of written,
18 printed, or graphic matter upon the immediate container of any
19 legend drug prior to its dispensing to an individual patient
20 pursuant to a prescription of a practitioner authorized by law
21 to prescribe.

22 (27)~~(20)~~ "Manufacture" means the preparation,
23 deriving, compounding, propagation, processing, producing, or
24 fabrication of any drug, device, or cosmetic. ~~The term~~
25 ~~includes repackaging or otherwise changing the container,~~
26 ~~wrapper, or labeling to further the distribution of the drug,~~
27 ~~device, or cosmetic.~~

28 (28)~~(21)~~ "Manufacturer" means a person who prepares,
29 derives, manufactures, or produces a drug, device, or
30 cosmetic. The term excludes pharmacies that are operating in
31

1 compliance with pharmacy practice standards as defined in
2 chapter 465 and rules adopted under that chapter.

3 ~~(29)(22)~~ "New drug" means:

4 (a) Any drug the composition of which is such that the
5 drug is not generally recognized, among experts qualified by
6 scientific training and experience to evaluate the safety and
7 effectiveness of drugs, as safe and effective for use under
8 the conditions prescribed, recommended, or suggested in the
9 labeling of that drug; or

10 (b) Any drug the composition of which is such that the
11 drug, as a result of investigations to determine its safety
12 and effectiveness for use under certain conditions, has been
13 recognized for use under such conditions, but which drug has
14 not, other than in those investigations, been used to a
15 material extent or for a material time under such conditions.

16 ~~(30)(23)~~ "Official compendium" means the current
17 edition of the official United States Pharmacopoeia and
18 National Formulary, or any supplement thereto.

19 (31) "Pedigree paper" means:

20 (a) A document required pursuant to s. 499.0121(6)(d)
21 or (e); or

22 (b) Effective July 1, 2006, a document in a form
23 approved by the Department of Health and containing
24 information that records each distribution of any given legend
25 drug, from sale by a pharmaceutical manufacturer, through
26 acquisition and sale by any wholesaler or repackager, until
27 final sale to a pharmacy or other person administering or
28 dispensing the drug. The information required to be included
29 on a legend drug's pedigree paper must at least detail the
30 amount of the legend drug, its dosage form and strength, its
31 lot numbers, the name and address of each owner of the legend

1 drug and his or her signature, its shipping information,
2 including the name and address of each person certifying
3 delivery or receipt of the legend drug, and a certification
4 that the recipient has authenticated the pedigree papers. It
5 must also include the name, address, telephone number and, if
6 available, e-mail contact information of each wholesaler
7 involved in the chain of the legend drug's custody. The
8 department shall adopt rules and a form relating to the
9 requirements of this paragraph no later than 90 days after the
10 effective date of this act.

11 (32)(24) "Person" means any individual, child, joint
12 venture, syndicate, fiduciary, partnership, corporation,
13 division of a corporation, firm, trust, business trust,
14 company, estate, public or private institution, association,
15 organization, group, city, county, city and county, political
16 subdivision of this state, other governmental agency within
17 this state, and any representative, agent, or agency of any of
18 the foregoing, or any other group or combination of the
19 foregoing.

20 (33)(25) "Prepackaged drug product" means a drug that
21 originally was in finished packaged form sealed by a
22 manufacturer and that is placed in a properly labeled
23 container by a pharmacy or practitioner authorized to dispense
24 pursuant to chapter 465 for the purpose of dispensing in the
25 establishment in which the prepackaging occurred.

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

30 (35)(26) "Prescription medical oxygen" means oxygen
31 USP which is a drug that can only be sold on the order or

1 prescription of a practitioner authorized by law to prescribe.
2 The label of prescription medical oxygen must comply with
3 current labeling requirements for oxygen under the Federal
4 Food, Drug, and Cosmetic Act.

5 (36)~~(27)~~ "Proprietary drug," or "OTC drug," means a
6 patent or over-the-counter drug in its unbroken, original
7 package, which drug is sold to the public by, or under the
8 authority of, the manufacturer or primary distributor thereof,
9 is not misbranded under the provisions of ss. 499.001-499.081,
10 and can be purchased without a prescription.

11 (37) "Repackage" includes repackaging or otherwise
12 changing the container, wrapper, or labeling to further the
13 distribution of the drug, device, or cosmetic.

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

18 (39)~~(28)~~ "Veterinary prescription drug" means a legend
19 drug intended solely for veterinary use. The label of the
20 drug must bear the statement, "Caution: Federal law restricts
21 this drug to sale by or on the order of a licensed
22 veterinarian."

23 Section 4. Section 499.005, Florida Statutes, is
24 amended to read:

25 499.005 Prohibited acts.--It is unlawful for a person
26 to perform or cause the performance of any of the following
27 acts in this state:

28 (1) The manufacture, repackaging, sale, delivery, or
29 holding or offering for sale of any drug, device, or cosmetic
30 that is adulterated or misbranded or has otherwise been
31 rendered unfit for human or animal use.

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

3 (3) The receipt of any drug, device, or cosmetic that
4 is adulterated or misbranded, and the delivery or proffered
5 delivery of such drug, device, or cosmetic, for pay or
6 otherwise.

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

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

12 (6) The refusal or constructive refusal:

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

16 (b) To allow inspection of any record of that
17 establishment;

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

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

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

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1 (8) Committing any act that causes a drug, device, or
2 cosmetic to be a counterfeit drug, device, or cosmetic; or
3 selling, dispensing, or holding for sale a counterfeit drug,
4 device, or cosmetic.

5 (9) The alteration, mutilation, destruction,
6 obliteration, or removal of the whole or any part of the
7 labeling of a drug, device, or cosmetic, or the doing of any
8 other act with respect to a drug, device, or cosmetic, if the
9 act is done while the drug, device, or cosmetic is held for
10 sale and the act results in the drug, device, or cosmetic
11 being misbranded.

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

17 (11) The use, on the labeling of any drug or in any
18 advertisement relating to such drug, of any representation or
19 suggestion that an application of the drug is effective when
20 it is not or that the drug complies with ss. 499.001-499.081
21 when it does not.

22 (12) The possession of any drug in violation of ss.
23 499.001-499.081.

24 (13) The sale, delivery, holding, or offering for sale
25 of any self-testing kits designed to tell persons their status
26 concerning human immunodeficiency virus or acquired immune
27 deficiency syndrome or related disorders or conditions. This
28 prohibition shall not apply to home access HIV test kits
29 approved for distribution and sale by the United States Food
30 and Drug Administration.

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

4 (15) The sale or transfer of a legend drug to a person
5 that is not authorized under the law of the jurisdiction in
6 which the person receives the drug to purchase or possess
7 legend drugs from the person selling or transferring the
8 legend drug.

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

12 (17) The sale, purchase, or trade, or the offer to
13 sell, purchase, or trade, a drug sample as defined in s.
14 499.028; the distribution of a drug sample in violation of s.
15 499.028; or the failure to otherwise comply with s. 499.028.

16 (18) Failure to maintain records as required by ss.
17 499.001-499.081 and rules adopted under those sections.

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

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

24 (21) The wholesale distribution of any prescription
25 drug that was:

26 (a) Purchased by a public or private hospital or other
27 health care entity; or

28 (b) Donated or supplied at a reduced price to a
29 charitable organization.

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

4 (23) Obtaining or attempting to obtain a prescription
5 drug or device by fraud, deceit, misrepresentation or
6 subterfuge, or engaging in misrepresentation or fraud in the
7 distribution of a drug or device.

8 (24) The distribution of a legend device to the
9 patient or ultimate consumer without a prescription or order
10 from a practitioner licensed by law to use or prescribe the
11 device.

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

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

17 (27) Distributing a prescription drug that was
18 previously dispensed by a licensed pharmacy, unless such
19 distribution was authorized in chapter 465 or the rules
20 adopted under chapter 465.

21 (28) Failure to obtain or pass on a pedigree paper.

22 (29) The receipt of a prescription drug pursuant to a
23 wholesale distribution without first receiving a pedigree
24 paper that was attested to as accurate and complete by the
25 wholesale distributor.

26 Section 5. Section 499.0051, Florida Statutes, is
27 created to read:

28 499.0051 Criminal acts involving contraband or
29 adulterated drugs.--

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

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1 (a) A person, other than a manufacturer, engaged in
2 the wholesale distribution of legend drugs who fails to
3 deliver to another person complete and accurate pedigree
4 papers concerning a legend drug or contraband legend drug
5 prior to transferring the legend drug or contraband legend
6 drug to another person commits a felony of the third degree,
7 punishable as provided in s. 775.082, s. 775.083, or s.
8 775.084.

9 (b) A person engaged in the wholesale distribution of
10 legend drugs who fails to acquire complete and accurate
11 pedigree papers concerning a legend drug or contraband legend
12 drug prior to obtaining the legend drug or contraband legend
13 drug from another person commits a felony of the third degree,
14 punishable as provided in s. 775.082, s. 775.083, or s.
15 775.084.

16 (c) Any person who knowingly destroys, alters,
17 conceals, or fails to maintain complete and accurate pedigree
18 papers concerning any legend drug or contraband legend drug in
19 his or her possession commits a felony of the third degree,
20 punishable as provided in s. 775.082, s. 775.083, or s.
21 775.084.

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

23 (a)1. A person engaged in the wholesale distribution
24 of legend drugs who is in possession of documents required
25 under s. 499.0121(6)(e) and who fails to authenticate the
26 matters contained in the documents and who nevertheless
27 attempts to further distribute legend drugs or contraband
28 legend drugs commits a felony of the third degree, punishable
29 as provided in s. 775.082, s. 775.083, or s. 775.084.

30 2. A person in possession of documents required under
31 s. 499.0121(6)(e) who falsely swears or certifies that he or

1 she has authenticated the matters contained in the documents
2 commits a felony of the third degree, punishable as provided
3 in s. 775.082, s. 775.083, or s. 775.084.

4 3. This paragraph expires July 1, 2006.

5 (b) Effective July 1, 2006:

6 1. A person engaged in the wholesale distribution of
7 legend drugs who is in possession of pedigree papers
8 concerning legend drugs or contraband legend drugs and who
9 fails to authenticate the matters contained in the pedigree
10 papers and who nevertheless attempts to further distribute
11 legend drugs or contraband legend drug commits a felony of the
12 third degree, punishable as provided in s. 775.082, s.
13 775.083, or s. 775.084.

14 2. A person in possession of pedigree papers
15 concerning legend drugs or contraband legend drugs who falsely
16 swears or certifies that he or she has authenticated the
17 matters contained in the pedigree papers commits a felony of
18 the third degree, punishable as provided in s. 775.082, s.
19 775.083, or s. 775.084.

20 (3) FORGERY OF PEDIGREE PAPERS.--A person who
21 knowingly forges, counterfeits, or falsely creates any
22 pedigree paper; who falsely represents any factual matter
23 contained on any pedigree paper; or who knowingly omits to
24 record material information required to be recorded in a
25 pedigree paper, commits a felony of the second degree,
26 punishable as provided in s. 775.082, s. 775.083, or s.
27 775.084.

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

1 distribution transaction commits a felony of the second
2 degree, punishable as provided in s. 775.082, s. 775.083, or
3 s. 775.084.

4 (5) SALE OR TRANSFER OF LEGEND DRUG TO UNAUTHORIZED
5 PERSON.--A person who knowingly sells or transfers to a person
6 not authorized to purchase or possess legend drugs, under the
7 law of the jurisdiction in which the person receives the drug,
8 a legend drug in a wholesale distribution transaction commits
9 a felony of the second degree, punishable as provided in s.
10 775.082, s. 775.083, or s. 775.084.

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

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

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

28 499.0052 Trafficking in contraband legend drugs.--A
29 person who knowingly sells, purchases, manufactures, delivers,
30 or brings into this state, or who is knowingly in actual or
31 constructive possession of any amount of contraband legend

1 drugs valued at \$25,000 or more commits a felony of the first
2 degree, punishable as provided in s. 775.082, s. 775.083, or
3 s. 775.084. Upon conviction, each defendant shall be ordered
4 to pay a mandatory fine according to the following schedule:

5 (1) If the value of contraband legend drugs involved
6 is \$25,000 or more, but less than \$100,000, the defendant
7 shall pay a mandatory fine of \$25,000. If the defendant is a
8 corporation or other person that is not a natural person, it
9 shall pay a mandatory fine of \$75,000.

10 (2) If the value of contraband legend drugs involved
11 is \$100,000 or more, but less than \$250,000, the defendant
12 shall pay a mandatory fine of \$100,000. If the defendant is a
13 corporation or other person that is not a natural person, it
14 shall pay a mandatory fine of \$300,000.

15 (3) If the value of contraband legend drugs involved
16 is \$250,000 or more, the defendant shall pay a mandatory fine
17 of \$200,000. If the defendant is a corporation or other person
18 that is not a natural person, it shall pay a mandatory fine of
19 \$600,000.

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

31

1 Section 7. Section 499.0053, Florida Statutes, is
2 created, to read:

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

11 Section 8. Section 499.0054, Florida Statutes, is
12 created to read:

13 499.0054 Sale or purchase of contraband legend drugs
14 resulting in death.--A person who knowingly manufactures,
15 sells, purchases, delivers, or brings into this state, or who
16 is knowingly in actual or constructive possession of any
17 amount of contraband legend drugs, and whose acts in violation
18 of this section result in the death of a person, commits a
19 felony of the first degree, punishable by a term of years not
20 exceeding life, as provided in s. 775.082, s. 775.083, or s.
21 775.084.

22 Section 9. Section 499.006, Florida Statutes, is
23 amended to read:

24 499.006 Adulterated drug or device.--A drug or device
25 is adulterated:

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

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

31

1 (3) If it is a drug and the methods used in, or the
2 facilities or controls used for, its manufacture, processing,
3 packing, or holding do not conform to, or are not operated or
4 administered in conformity with, current good manufacturing
5 practices to assure that the drug meets the requirements of
6 ss. 499.001-499.081 and that the drug has the identity and
7 strength, and meets the standard of quality and purity, which
8 it purports or is represented to possess;

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

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

18 (6) If it purports to be, or is represented as, a drug
19 the name of which is recognized in the official compendium,
20 and its strength differs from, or its quality or purity falls
21 below, the standard set forth in such compendium. The
22 determination as to strength, quality, or purity must be made
23 in accordance with the tests or methods of assay set forth in
24 such compendium, or, when such tests or methods of assay are
25 absent or inadequate, in accordance with those tests or
26 methods of assay prescribed under authority of the federal
27 act. A drug defined in the official compendium is not
28 adulterated under this subsection merely because it differs
29 from the standard of strength, quality, or purity set forth
30 for that drug in such compendium if its difference in
31

1 strength, quality, or purity from such standard is plainly
2 stated on its label;

3 (7) If it is not subject to subsection (6) and its
4 strength differs from, or its purity or quality falls below
5 the standard of, that which it purports or is represented to
6 possess; ~~or~~

7 (8) If it is a drug:

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

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

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

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

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

22 499.007 Misbranded drug or device.--A drug or device
23 is misbranded:

24 (2) Unless, if in package form, it bears a label
25 containing:

26 (a) The name and place of business of the
27 manufacturer, repackager, or distributor; ~~in addition, for a~~
28 ~~medicinal drug, as defined in s. 499.003, the label must~~
29 ~~contain the name and place of business of the manufacturer of~~
30 the finished dosage form of the drug. For the purpose of this
31 paragraph, the finished dosage form of a medicinal drug is

1 that form of the drug which is, or is intended to be,
2 dispensed or administered to the patient and requires no
3 further manufacturing or processing other than packaging,
4 reconstitution, and labeling; and

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

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

12 499.01 Permits; applications; renewal; general
13 requirements.--

14 (1) Any person that is required under ss.
15 499.001-499.081 to have a permit must apply to the department
16 on forms furnished by the department.

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

25 (b) An establishment that is a place of residence may
26 not receive a permit and may not operate under ss.
27 499.001-499.081.

28 (c) A person that applies for or renews a permit to
29 manufacture or distribute legend drugs may not use a name
30 identical to the name used by any other establishment or
31 licensed person authorized to purchase prescription drugs in

1 this state, except that a restricted drug distributor permit
2 issued to a health care entity will be issued in the name in
3 which the institutional pharmacy permit is issued and a retail
4 pharmacy drug wholesaler will be issued a permit in the name
5 of its retail pharmacy permit.

6 (d) A permit is required for each establishment that
7 operates as a:

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

21 (e) A permit for a prescription drug manufacturer,
22 prescription drug wholesaler, or retail pharmacy wholesaler
23 may not be issued to the address of a health care entity or to
24 a pharmacy licensed under chapter 465, except as provided in
25 this paragraph. The department may issue a prescription drug
26 manufacturer permit to an applicant at the same address as a
27 licensed nuclear pharmacy, which is a health care entity, for
28 the purpose of manufacturing prescription drugs used in
29 positron emission tomography or other radiopharmaceuticals, as
30 listed in a rule adopted by the department pursuant to this
31 paragraph. The purpose of this exemption is to assure

1 availability of state-of-the-art pharmaceuticals that would
2 pose a significant danger to the public health if manufactured
3 at a separate establishment address from the nuclear pharmacy
4 from which the prescription drugs are dispensed. The
5 department may also issue a retail pharmacy wholesaler permit
6 to the address of a community pharmacy licensed under chapter
7 465 which does not meet the definition of a closed pharmacy in
8 s. 499.003.

9 (f) A county or municipality may not issue an
10 occupational license for any licensing period beginning on or
11 after October 1, 2003, for any establishment that requires a
12 permit pursuant to ss. 499.001-499.081, unless the
13 establishment exhibits a current permit issued by the
14 department for the establishment. Upon presentation of the
15 requisite permit issued by the department, an occupational
16 license may be issued by the municipality or county in which
17 application is made. The department shall furnish to local
18 agencies responsible for issuing occupational licenses a
19 current list of all establishments licensed pursuant to ss.
20 499.001-499.081.

21 (g)(f) Notwithstanding subsection (4), a permitted
22 person in good standing may change the type of permit issued
23 to that person by completing a new application for the
24 requested permit, paying the amount of the difference in the
25 permit fees if the fee for the new permit is more than the fee
26 for the original permit, and meeting the applicable permitting
27 conditions for the new permit type. The new permit expires on
28 the expiration date of the original permit being changed;
29 however, a new permit for a prescription drug wholesaler and
30 an out-of-state prescription drug wholesaler shall expire on
31 the expiration date of the original permit or 1 year after the

1 date of issuance of the new permit, whichever is earlier. A
2 refund may not be issued if the ~~biennial~~ fee for the new
3 permit is less than the fee that was paid original permit ~~for~~
4 ~~which a fee was paid.~~

5 (3) The department shall adopt rules for the biennial
6 renewal of permits.

7 (a) The department shall renew a permit upon receipt
8 of the renewal application and renewal fee if the applicant
9 meets the requirements established under ss. 499.001-499.081
10 and the rules adopted under those sections.

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

1 date stated on the permit. A permittee that submits a renewal
2 application for a permit with a stated expiration date between
3 July 1, 2004, and December 31, 2004, shall receive a credit of
4 one-fourth of the permit fee paid when the application for the
5 expiring permit was submitted. A permittee whose permit
6 expiration date was accelerated in this paragraph may request
7 a pro rata refund equivalent to the credit available for
8 submission of a renewal application if the permittee does not
9 submit a renewal application.A permit issued under ss.
10 499.001-499.081 ~~may~~ must be renewed by making application for
11 renewal on forms furnished by the department and paying the
12 appropriate fees. If a renewal application and fee are ~~not~~
13 submitted and postmarked after ~~by~~ the expiration date of the
14 permit, the permit may be renewed ~~reinstated~~ only upon payment
15 of a late renewal delinquent fee of \$100, plus the required
16 renewal fee, not later than ~~within~~ 60 days after the
17 expiration date.

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

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

1 499.01 Permits; applications; renewal; general
2 requirements.--
3 (1) Prior to operating, a permit is required for each
4 person and establishment that intends to operate as:
5 (a) A prescription drug manufacturer;
6 (b) A prescription drug repackager;
7 (c) An over-the-counter drug manufacturer;
8 (d) A compressed medical gas manufacturer;
9 (e) A device manufacturer;
10 (f) A cosmetic manufacturer;
11 (g) A prescription drug wholesaler;
12 (h) A compressed medical gas wholesaler;
13 (i) An out-of-state prescription drug wholesaler;
14 (j) A nonresident prescription drug manufacturer;
15 (k) A freight forwarder;
16 (l) A retail pharmacy drug wholesaler;
17 (m) A veterinary legend drug retail establishment;
18 (n) A medical oxygen retail establishment;
19 (o) A complimentary drug distributor; or
20 (p) A restricted prescription drug distributor.
21 ~~(1) Any person that is required under ss.~~
22 ~~499.001-499.081 to have a permit must apply to the department~~
23 ~~on forms furnished by the department.~~
24 (2)(a) A permit issued pursuant to ss. 499.001-499.081
25 may be issued only to a natural person who is at least 18
26 years of age or to an applicant that is not a natural person
27 if each person who, directly or indirectly, manages, controls,
28 or oversees the operation of that applicant is at least 18
29 years of age.
30
31

1 (b) An establishment that is a place of residence may
2 not receive a permit and may not operate under ss.
3 499.001-499.081.

4 (c) A person that applies for or renews a permit to
5 manufacture or distribute legend drugs may not use a name
6 identical to the name used by any other establishment or
7 licensed person authorized to purchase prescription drugs in
8 this state, except that a restricted drug distributor permit
9 issued to a health care entity will be issued in the name in
10 which the institutional pharmacy permit is issued and a retail
11 pharmacy drug wholesaler will be issued a permit in the name
12 of its retail pharmacy permit.

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

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

28 (d)(e) A permit for a prescription drug manufacturer,
29 prescription drug repackager, prescription drug wholesaler, or
30 retail pharmacy wholesaler may not be issued to the address of
31 a health care entity or to a pharmacy licensed under chapter

1 465, except as provided in this paragraph. The department may
2 issue a prescription drug manufacturer permit to an applicant
3 at the same address as a licensed nuclear pharmacy, which is a
4 health care entity, for the purpose of manufacturing
5 prescription drugs used in positron emission tomography or
6 other radiopharmaceuticals, as listed in a rule adopted by the
7 department pursuant to this paragraph. The purpose of this
8 exemption is to assure availability of state-of-the-art
9 pharmaceuticals that would pose a significant danger to the
10 public health if manufactured at a separate establishment
11 address from the nuclear pharmacy from which the prescription
12 drugs are dispensed. The department may also issue a retail
13 pharmacy wholesaler permit to the address of a community
14 pharmacy licensed under chapter 465 which does not meet the
15 definition of a closed pharmacy in s. 499.003.

16 (e)~~(f)~~ A county or municipality may not issue an
17 occupational license for any licensing period beginning on or
18 after October 1, 2003, for any establishment that requires a
19 permit pursuant to ss. 499.001-499.081, unless the
20 establishment exhibits a current permit issued by the
21 department for the establishment. Upon presentation of the
22 requisite permit issued by the department, an occupational
23 license may be issued by the municipality or county in which
24 application is made. The department shall furnish to local
25 agencies responsible for issuing occupational licenses a
26 current list of all establishments licensed pursuant to ss.
27 499.001-499.081.

28 (3)~~(g)~~ Notwithstanding subsection (7)~~(4)~~, a permitted
29 person in good standing may change the type of permit issued
30 to that person by completing a new application for the
31 requested permit, paying the amount of the difference in the

1 permit fees if the fee for the new permit is more than the fee
2 for the original permit, and meeting the applicable permitting
3 conditions for the new permit type. The new permit expires on
4 the expiration date of the original permit being changed;
5 however, a new permit for a prescription drug wholesaler, an
6 out-of-state prescription drug wholesaler, or a retail
7 pharmacy drug wholesaler shall expire on the expiration date
8 of the original permit or 1 year after the date of issuance of
9 the new permit, whichever is earlier. A refund may not be
10 issued if the fee for the new permit is less than the fee that
11 was paid original permit.

12 (4)(2) A written application for a permit or to renew
13 a permit must be filed with the department on forms furnished
14 by the department.The department shall establish, by rule,
15 the form and content of the application to obtain or renew a
16 permit. The applicant must submit to the department with the
17 application a statement that swears or affirms that the
18 information is true and correct.

19 (5)(a) Except for a permit for a prescription drug
20 wholesaler or an out-of-state prescription drug wholesaler, an
21 application for a permit must include information that an
22 applicant must provide includes, but need not be limited to:

- 23 1. The name, full business address, and telephone
24 number of the applicant;
- 25 2. All trade or business names used by the applicant;
- 26 3. The address, telephone numbers, and the names of
27 contact persons for each facility used by the applicant for
28 the storage, handling, and distribution of prescription drugs;
- 29 4. The type of ownership or operation, such as a
30 partnership, corporation, or sole proprietorship; and

31

- 1 5. The names of the owner and the operator of the
2 establishment, including:
- 3 a. If an individual, the name of the individual;
4 b. If a partnership, the name of each partner and the
5 name of the partnership;
6 c. If a corporation, the name and title of each
7 corporate officer and director, the corporate names, and the
8 name of the state of incorporation;
9 d. If a sole proprietorship, the full name of the sole
10 proprietor and the name of the business entity; ~~and~~
11 e. If a limited liability company, the name of each
12 member, the name of each manager, the name of the limited
13 liability company, and the name of the state in which the
14 limited liability company was organized; and
15 ~~f.e.~~ Any other relevant information that the
16 department requires.
- 17 (b) Upon approval of the application by the department
18 and payment of the required fee, the department shall issue a
19 permit to the applicant, if the applicant meets the
20 requirements of ss. 499.001-499.081 and rules adopted under
21 those sections.
- 22 (c) Any change in information required under paragraph
23 (a) must be submitted to the department before the change
24 occurs.
- 25 (d) The department shall consider, at a minimum, the
26 following factors in reviewing the qualifications of persons
27 to be permitted under ss. 499.001-499.081:
- 28 1. The applicant's having been found guilty,
29 regardless of adjudication, in a court of this state or other
30 jurisdiction, of a violation of a law that directly relates to
31 a drug, device, or cosmetic. A plea of nolo contendere

1 constitutes a finding of guilt for purposes of this
2 subparagraph.

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

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

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

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

13 6. Suspension or revocation by a federal, state, or
14 local government of any permit currently or previously held by
15 the applicant for the manufacture or distribution of any
16 drugs, devices, or cosmetics;

17 7. Compliance with permitting requirements under any
18 previously granted permits;

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

23 9. Any other factors or qualifications the department
24 considers relevant to and consistent with the public health
25 and safety.

26 (6) Except for permits for prescription drug
27 wholesalers or out-of-state prescription drug wholesalers:

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

30 (b)~~(a)~~ The department shall renew a permit upon
31 receipt of the renewal application and renewal fee if the

1 applicant meets the requirements established under ss.
2 499.001-499.081 and the rules adopted under those sections.
3 (c)~~(b)~~ A permit, unless sooner suspended or revoked,
4 automatically expires 2 years after the last day of the
5 anniversary month in which the permit was originally issued+
6 ~~except that a prescription drug wholesaler permit and an~~
7 ~~out-of-state prescription drug wholesaler permit, issued from~~
8 ~~July 1, 2003, through December 31, 2003, shall expire 1 year~~
9 ~~after the last day of the anniversary month in which the~~
10 ~~permit was issued. Any valid prescription drug wholesaler or~~
11 ~~out-of-state prescription drug wholesaler permit issued by the~~
12 ~~department on or before June 30, 2003, with an expiration date~~
13 ~~between January 1, 2005, and June 30, 2005, shall~~
14 ~~automatically expire 1 year prior to the expiration date~~
15 ~~stated on the permit. A permittee that submits a renewal~~
16 ~~application for a permit with a stated expiration date between~~
17 ~~January 1, 2005, and June 30, 2005, shall receive a credit of~~
18 ~~one-half of the permit fee paid when the application for the~~
19 ~~expiring permit was submitted. Any valid prescription drug~~
20 ~~wholesaler or out-of-state prescription drug wholesaler permit~~
21 ~~issued by the department on or before June 30, 2003, with an~~
22 ~~expiration date between July 1, 2004, and December 31, 2004,~~
23 ~~shall automatically expire 6 months prior to the expiration~~
24 ~~date stated on the permit. A permittee that submits a renewal~~
25 ~~application for a permit with a stated expiration date between~~
26 ~~July 1, 2004, and December 31, 2004, shall receive a credit of~~
27 ~~one-fourth of the permit fee paid when the application for the~~
28 ~~expiring permit was submitted. A permittee whose permit~~
29 ~~expiration date was accelerated in this paragraph may request~~
30 ~~a pro rata refund equivalent to the credit available for~~
31 ~~submission of a renewal application if the permittee does not~~

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

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

18 (7)~~(4)~~ A permit issued by the department is
19 nontransferable. Each permit is valid only for the person or
20 governmental unit to which it is issued and is not subject to
21 sale, assignment, or other transfer, voluntarily or
22 involuntarily; nor is a permit valid for any establishment
23 other than the establishment for which it was originally
24 issued.

25 (a) A person permitted under ss. 499.001-499.081 must
26 notify the department before making a change of address. The
27 department shall set a change of location fee not to exceed
28 \$100.

29 (b)1. An application for a new permit is required when
30 a majority of the ownership or controlling interest of a
31 permitted establishment is transferred or assigned or when a

1 lessee agrees to undertake or provide services to the extent
2 that legal liability for operation of the establishment will
3 rest with the lessee. The application for the new permit must
4 be made before the date of the sale, transfer, assignment, or
5 lease.

6 2. A permittee that is authorized to distribute legend
7 drugs may transfer such drugs to the new owner or lessee under
8 subparagraph 1. only after the new owner or lessee has been
9 approved for a permit to distribute legend drugs.

10 ~~(c) The department shall deny, suspend, or revoke the~~
11 ~~permit of any person or establishment if the assignment, sale,~~
12 ~~transfer, or lease of an establishment permitted under ss.~~
13 ~~499.001-499.081 will avoid an administrative penalty, civil~~
14 ~~action, or criminal prosecution.~~

15 (c)(d) If an establishment permitted under ss.
16 499.001-499.081 closes, the owner must notify the department
17 in writing before the effective date of closure and must:

- 18 1. Return the permit to the department;
- 19 2. If the permittee is authorized to distribute legend
20 drugs, indicate the disposition of such drugs, including the
21 name, address, and inventory, and provide the name and address
22 of a person to contact regarding access to records that are
23 required to be maintained under ss. 499.001-499.081. Transfer
24 of ownership of legend drugs may be made only to persons
25 authorized to possess legend drugs under ss. 499.001-499.081.

26
27 The department may revoke the permit of any person that fails
28 to comply with the requirements of this subsection.

29 (8)(5) A permit must be posted in a conspicuous place
30 on the licensed premise.

31

1 Section 13. Section 499.012, Florida Statutes, is
2 amended to read:

3 499.012 Wholesale distribution; definitions; permits;
4 applications; general requirements.--

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

6 (a) "Wholesale distribution" means distribution of
7 prescription drugs to persons other than a consumer or
8 patient, but does not include:

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

12 a. The purchase or other acquisition by a hospital or
13 other health care entity that is a member of a group
14 purchasing organization of a prescription drug for its own use
15 from the group purchasing organization or from other hospitals
16 or health care entities that are members of that organization.

17 b. The sale, purchase, or trade of a prescription drug
18 or an offer to sell, purchase, or trade a prescription drug by
19 a charitable organization described in s. 501(c)(3) of the
20 Internal Revenue Code of 1986, as amended and revised, to a
21 nonprofit affiliate of the organization to the extent
22 otherwise permitted by law.

23 c. The sale, purchase, or trade of a prescription drug
24 or an offer to sell, purchase, or trade a prescription drug
25 among hospitals or other health care entities that are under
26 common control. For purposes of this section, "common control"
27 means the power to direct or cause the direction of the
28 management and policies of a person or an organization,
29 whether by ownership of stock, by voting rights, by contract,
30 or otherwise.

31

1 d. The sale, purchase, trade, or other transfer of a
2 prescription drug from or for any federal, state, or local
3 government agency or any entity eligible to purchase
4 prescription drugs at public health services prices pursuant
5 to Pub. L. No. 102-585, s. 602 to a contract provider or its
6 subcontractor for eligible patients of the agency or entity
7 under the following conditions:

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

12 (II) The contract provider or subcontractor must be
13 authorized by law to administer or dispense prescription
14 drugs.

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

17 (IV) A contract provider or subcontractor must
18 maintain separate and apart from other prescription drug
19 inventory any prescription drugs of the agency or entity in
20 its possession.

21 (V) The contract provider and subcontractor must
22 maintain and produce immediately for inspection all records of
23 movement or transfer of all the prescription drugs belonging
24 to the agency or entity, including, but not limited to, the
25 records of receipt and disposition of prescription drugs. Each
26 contractor and subcontractor dispensing or administering these
27 drugs must maintain and produce records documenting the
28 dispensing or administration. Records that are required to be
29 maintained include, but are not limited to, a perpetual
30 inventory itemizing drugs received and drugs dispensed by
31

1 prescription number or administered by patient identifier,
2 which must be submitted to the agency or entity quarterly.

3 (VI) The contract provider or subcontractor may
4 administer or dispense the prescription drugs only to the
5 eligible patients of the agency or entity or must return the
6 prescription drugs for or to the agency or entity. The
7 contract provider or subcontractor must require proof from
8 each person seeking to fill a prescription or obtain treatment
9 that the person is an eligible patient of the agency or entity
10 and must, at a minimum, maintain a copy of this proof as part
11 of the records of the contractor or subcontractor required
12 under sub-sub-subparagraph (V).

13 (VII) In addition to the departmental inspection
14 authority set forth in s. 499.051, the establishment of the
15 contract provider and subcontractor and all records pertaining
16 to prescription drugs subject to this sub-subparagraph shall
17 be subject to inspection by the agency or entity. All records
18 relating to prescription drugs of a manufacturer under this
19 sub-subparagraph shall be subject to audit by the manufacturer
20 of those drugs, without identifying individual patient
21 information.

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

25 a. The sale, purchase, or trade of a prescription drug
26 among federal, state, or local government health care entities
27 that are under common control and are authorized to purchase
28 such prescription drug.

29 b. The sale, purchase, or trade of a prescription drug
30 or an offer to sell, purchase, or trade a prescription drug
31 for emergency medical reasons. For purposes of this

1 sub-subparagraph, the term "emergency medical reasons"
2 includes transfers of prescription drugs by a retail pharmacy
3 to another retail pharmacy to alleviate a temporary shortage.

4 c. The transfer of a prescription drug acquired by a
5 medical director on behalf of a licensed emergency medical
6 services provider to that emergency medical services provider
7 and its transport vehicles for use in accordance with the
8 provider's license under chapter 401.

9 d. The revocation of a sale or the return of a
10 prescription drug to the person's prescription drug wholesale
11 supplier.

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

17 f. The transfer of a prescription drug by a person
18 authorized to purchase or receive prescription drugs to a
19 person licensed or permitted to handle reverse distributions
20 or destruction under the laws of the jurisdiction in which the
21 person handling the reverse distribution or destruction
22 receives the drug.

23 g. The transfer of a prescription drug by a hospital
24 or other health care entity to a person licensed under this
25 chapter to repackage prescription drugs for the purpose of
26 repackaging the prescription drug for use by that hospital, or
27 other health care entity and other health care entities that
28 are under common control, if ownership of the prescription
29 drugs remains with the hospital or other health care entity at
30 all times. In addition to the recordkeeping requirements of s.
31 499.0121(6), the hospital or health care entity that transfers

1 prescription drugs pursuant to this sub-subparagraph must
2 reconcile all drugs transferred and returned and resolve any
3 discrepancies in a timely manner.

4 3. The distribution of prescription drug samples by
5 manufacturers' representatives or distributors'
6 representatives conducted in accordance with s. 499.028.

7 4. The sale, purchase, or trade of blood and blood
8 components intended for transfusion. As used in this
9 subparagraph, the term "blood" means whole blood collected
10 from a single donor and processed either for transfusion or
11 further manufacturing, and the term "blood components" means
12 that part of the blood separated by physical or mechanical
13 means.

14 5. The lawful dispensing of a prescription drug in
15 accordance with chapter 465.

16 (b) "Wholesale distributor" means any person engaged
17 in wholesale distribution of prescription drugs in or into
18 this state, including, but not limited to, manufacturers;
19 repackagers ~~repackers~~; own-label distributors; jobbers;
20 private-label distributors; brokers; warehouses, including
21 manufacturers' and distributors' warehouses, chain drug
22 warehouses, and wholesale drug warehouses; independent
23 wholesale drug traders; exporters; retail pharmacies; and the
24 agents thereof that conduct wholesale distributions.

25 (c) "Retail pharmacy" means a community pharmacy
26 licensed under chapter 465 that purchases prescription drugs
27 at fair market prices and provides prescription services to
28 the public.

29 (d) "Primary wholesaler" means any wholesale
30 distributor that:

31

1 1. Purchased 90 percent or more of the total dollar
2 volume of its purchases of prescription drugs directly from
3 manufacturers in the previous year; and

4 2.a. Directly purchased prescription drugs from not
5 fewer than 50 different prescription drug manufacturers in the
6 previous year; or

7 b. Has, or the affiliated group, as defined in s. 1504
8 of the Internal Revenue Code, of which the wholesale
9 distributor is a member has, not fewer than 250 employees.

10 (e) "Directly from a manufacturer" means:

11 1. Purchases made by the wholesale distributor
12 directly from the manufacturer of prescription drugs; and

13 2. Transfers from a member of an affiliated group, as
14 defined in s. 1504 of the Internal Revenue Code, of which the
15 wholesale distributor is a member, if:

16 a. The affiliated group purchases 90 percent or more
17 of the total dollar volume of its purchases of prescription
18 drugs from the manufacturer in the previous year; and

19 b. The wholesale distributor discloses to the
20 department the names of all members of the affiliated group of
21 which the wholesale distributor is a member and the affiliated
22 group agrees in writing to provide records on prescription
23 drug purchases by the members of the affiliated group not
24 later than 48 hours after the department requests access to
25 such records, regardless of the location where the records are
26 stored.

27 (f) "Secondary wholesaler" means a wholesale
28 distributor that is not a primary wholesaler.

29 (2) The following types of wholesaler permits are
30 established:

31

1 (a) A prescription drug wholesaler's permit. A
2 prescription drug wholesaler is a wholesale distributor that
3 may engage in the wholesale distribution of prescription
4 drugs. A prescription drug wholesaler that applies to the
5 department for a new permit or the renewal of a permit after
6 July 1, 2003 ~~January 1, 1993~~, must submit a bond of \$100,000,
7 or other equivalent means of security acceptable to the
8 department, such as an irrevocable letter of credit or a
9 deposit in a trust account or financial institution~~\$200~~,
10 payable to the Florida Drug, Device, and Cosmetic Trust Fund.
11 The purpose of the bond is to secure payment of any
12 administrative penalties imposed by the department and any
13 fees and costs incurred by the department regarding that
14 permit which are authorized under state law and which the
15 permittee fails to pay 30 days after the fine or costs become
16 final. The department may make a claim against such bond or
17 security until 1 year after the permittee's license ceases to
18 be valid or until 60 days after any administrative or legal
19 proceeding authorized in ss. 499.001-499.081 which involves
20 the permittee is concluded, including any appeal, whichever
21 occurs later.~~This bond will be refunded to the permittee when~~
22 ~~the permit is returned to the department and the permittee~~
23 ~~ceases to function as a business. A permittee that fails to~~
24 ~~notify the department before changing the address of the~~
25 ~~business, fails to notify the department before closing the~~
26 ~~business, or fails to notify the department before a change of~~
27 ~~ownership forfeits its bond.~~The department may adopt rules
28 for issuing a prescription drug wholesaler-broker permit to a
29 person who engages in the wholesale distribution of
30 prescription drugs and does not take physical possession of
31 any prescription drugs.

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

15 (c) An out-of-state prescription drug wholesaler's
16 permit. An out-of-state prescription drug wholesaler is a
17 wholesale distributor located outside this state which engages
18 in the wholesale distribution of prescription drugs into this
19 state and which must be permitted by the department and comply
20 with all the provisions required of a wholesale distributor
21 under ss. 499.001-499.081. An out-of-state prescription drug
22 wholesaler that applies to the department for a new permit or
23 the renewal of a permit after July 1, 2003, must submit a bond
24 of \$100,000, or other equivalent means of security acceptable
25 to the department, such as an irrevocable letter of credit or
26 a deposit in a trust account or financial institution, payable
27 to the Florida Drug, Device, and Cosmetic Trust Fund. The
28 purpose of the bond is to secure payment of any administrative
29 penalties imposed by the department and any fees and costs
30 incurred by the department regarding that permit which are
31 authorized under state law and which the permittee fails to

1 pay 30 days after the fine or costs become final. The
2 department may make a claim against such bond or security
3 until 1 year after the permittee's license ceases to be valid
4 or until 60 days after any administrative or legal proceeding
5 authorized in ss. 499.001-499.081 which involves the permittee
6 is concluded, including any appeal, whichever occurs later.

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

11 2. An out-of-state prescription drug wholesaler's
12 permit is not required for an intracompany sale or transfer of
13 a prescription drug from an out-of-state establishment that is
14 duly licensed as a prescription drug wholesaler, in its state
15 of residence, to a licensed prescription drug wholesaler in
16 this state, if both wholesalers conduct wholesale
17 distributions of prescription drugs under the same business
18 name are under common control. The recordkeeping requirements
19 of s. 499.0121(6) must be followed for this transaction.

20 ~~3. The department may adopt rules that allow~~
21 ~~out-of-state drug wholesalers to obtain a drug wholesale~~
22 ~~permit on the basis of reciprocity to the extent that an~~
23 ~~out-of-state drug wholesaler:~~

24 a. ~~Possesses a valid permit granted by another state~~
25 ~~that has requirements comparable to those that a drug~~
26 ~~wholesaler in this state must meet as prerequisites to~~
27 ~~obtaining a permit under the laws of this state.~~

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

31

1 (d) A retail pharmacy wholesaler's permit. A retail
2 pharmacy wholesaler is a retail pharmacy engaged in wholesale
3 distribution of prescription drugs within this state under the
4 following conditions:

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

8 2. The wholesale distribution activity does not exceed
9 30 percent of the total annual purchases of prescription
10 drugs. If the wholesale distribution activity exceeds the
11 30-percent maximum, the pharmacy must obtain a prescription
12 drug wholesaler's permit.

13 3. The transfer of prescription drugs that appear in
14 any schedule contained in chapter 893 is subject to chapter
15 893 and the federal Comprehensive Drug Abuse Prevention and
16 Control Act of 1970.

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

22 5. All records of sales of prescription drugs subject
23 to this section must be maintained separate and distinct from
24 other records and comply with the recordkeeping requirements
25 of ss. 499.001-499.081.

26 (3) A person that engages in wholesale distribution of
27 prescription drugs in this state must have a wholesale
28 distributor's permit issued by the department, except as noted
29 in this section. Each establishment must be separately
30 permitted except as noted in this subsection.

31

1 (a) A separate establishment permit is not required
2 when a permitted prescription drug wholesaler consigns a
3 prescription drug to a pharmacy that is permitted under
4 chapter 465 and located in this state, provided that:

5 1. The consignor wholesaler notifies the department in
6 writing of the contract to consign prescription drugs to a
7 pharmacy along with the identity and location of each
8 consignee pharmacy;

9 2. The pharmacy maintains its permit under chapter
10 465;

11 3. The consignor wholesaler, which has no legal
12 authority to dispense prescription drugs, complies with all
13 wholesale distribution requirements of s. 499.0121 with
14 respect to the consigned drugs and maintains records
15 documenting the transfer of title or other completion of the
16 wholesale distribution of the consigned prescription drugs;

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

19 5. Open packages containing prescription drugs within
20 a pharmacy are the responsibility of the pharmacy, regardless
21 of how the drugs are titled; and

22 6. The pharmacy dispenses the consigned prescription
23 drug in accordance with the limitations of its permit under
24 chapter 465 or returns the consigned prescription drug to the
25 consignor wholesaler. In addition, a person who holds title to
26 prescription drugs may transfer the drugs to a person
27 permitted or licensed to handle the reverse distribution or
28 destruction of drugs. Any other distribution by and means of
29 the consigned prescription drug by any person, not limited to
30 the consignor wholesaler or consignee pharmacy, to any other
31 person is prohibited.

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

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

21 (4) Personnel employed in wholesale distribution must
22 have appropriate education and experience to enable them to
23 perform their duties in compliance with state permitting
24 requirements.

25 (5) The department may adopt rules governing the
26 recordkeeping, storage, and handling with respect to each of
27 the distributions of prescription drugs specified in
28 subparagraphs (1)(a)1.-4.

29 Section 14. Effective January 1, 2004, section
30 499.012, Florida Statutes, as amended by this act, is amended
31 to read:

1 499.012 Wholesale distribution; definitions; permits;
2 applications; general requirements.--

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

4 (a) "Wholesale distribution" means distribution of
5 prescription drugs to persons other than a consumer or
6 patient, but does not include:

7 1. 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 s. 499.014:

10 a. The purchase or other acquisition by a hospital or
11 other health care entity that is a member of a group
12 purchasing organization of a prescription drug for its own use
13 from the group purchasing organization or from other hospitals
14 or health care entities that are members of that organization.

15 b. The sale, purchase, or trade of a prescription drug
16 or an offer to sell, purchase, or trade a prescription drug by
17 a charitable organization described in s. 501(c)(3) of the
18 Internal Revenue Code of 1986, as amended and revised, to a
19 nonprofit affiliate of the organization to the extent
20 otherwise permitted by law.

21 c. The sale, purchase, or trade of a prescription drug
22 or an offer to sell, purchase, or trade a prescription drug
23 among hospitals or other health care entities that are under
24 common control. For purposes of this section, "common control"
25 means the power to direct or cause the direction of the
26 management and policies of a person or an organization,
27 whether by ownership of stock, by voting rights, by contract,
28 or otherwise.

29 d. The sale, purchase, trade, or other transfer of a
30 prescription drug from or for any federal, state, or local
31 government agency or any entity eligible to purchase

1 prescription drugs at public health services prices pursuant
2 to Pub. L. No. 102-585, s. 602 to a contract provider or its
3 subcontractor for eligible patients of the agency or entity
4 under the following conditions:

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

9 (II) The contract provider or subcontractor must be
10 authorized by law to administer or dispense prescription
11 drugs.

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

14 (IV) A contract provider or subcontractor must
15 maintain separate and apart from other prescription drug
16 inventory any prescription drugs of the agency or entity in
17 its possession.

18 (V) The contract provider and subcontractor must
19 maintain and produce immediately for inspection all records of
20 movement or transfer of all the prescription drugs belonging
21 to the agency or entity, including, but not limited to, the
22 records of receipt and disposition of prescription drugs. Each
23 contractor and subcontractor dispensing or administering these
24 drugs must maintain and produce records documenting the
25 dispensing or administration. Records that are required to be
26 maintained include, but are not limited to, a perpetual
27 inventory itemizing drugs received and drugs dispensed by
28 prescription number or administered by patient identifier,
29 which must be submitted to the agency or entity quarterly.

30 (VI) The contract provider or subcontractor may
31 administer or dispense the prescription drugs only to the

1 eligible patients of the agency or entity or must return the
2 prescription drugs for or to the agency or entity. The
3 contract provider or subcontractor must require proof from
4 each person seeking to fill a prescription or obtain treatment
5 that the person is an eligible patient of the agency or entity
6 and must, at a minimum, maintain a copy of this proof as part
7 of the records of the contractor or subcontractor required
8 under sub-sub-subparagraph (V).

9 (VII) In addition to the departmental inspection
10 authority set forth in s. 499.051, the establishment of the
11 contract provider and subcontractor and all records pertaining
12 to prescription drugs subject to this sub-subparagraph shall
13 be subject to inspection by the agency or entity. All records
14 relating to prescription drugs of a manufacturer under this
15 sub-subparagraph shall be subject to audit by the manufacturer
16 of those drugs, without identifying individual patient
17 information.

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

21 a. The sale, purchase, or trade of a prescription drug
22 among federal, state, or local government health care entities
23 that are under common control and are authorized to purchase
24 such prescription drug.

25 b. The sale, purchase, or trade of a prescription drug
26 or an offer to sell, purchase, or trade a prescription drug
27 for emergency medical reasons. For purposes of this
28 sub-subparagraph, the term "emergency medical reasons"
29 includes transfers of prescription drugs by a retail pharmacy
30 to another retail pharmacy to alleviate a temporary shortage.

31

1 c. The transfer of a prescription drug acquired by a
2 medical director on behalf of a licensed emergency medical
3 services provider to that emergency medical services provider
4 and its transport vehicles for use in accordance with the
5 provider's license under chapter 401.

6 d. The revocation of a sale or the return of a
7 prescription drug to the person's prescription drug wholesale
8 supplier.

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

14 f. The transfer of a prescription drug by a person
15 authorized to purchase or receive prescription drugs to a
16 person licensed or permitted to handle reverse distributions
17 or destruction under the laws of the jurisdiction in which the
18 person handling the reverse distribution or destruction
19 receives the drug.

20 g. The transfer of a prescription drug by a hospital
21 or other health care entity to a person licensed under this
22 chapter to repackage prescription drugs for the purpose of
23 repackaging the prescription drug for use by that hospital, or
24 other health care entity and other health care entities that
25 are under common control, if ownership of the prescription
26 drugs remains with the hospital or other health care entity at
27 all times. In addition to the recordkeeping requirements of
28 s. 499.0121(6)~~s. 499.0121(7)~~, the hospital or health care
29 entity that transfers prescription drugs pursuant to this
30 sub-subparagraph must reconcile all drugs transferred and
31 returned and resolve any discrepancies in a timely manner.

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

4 4. The sale, purchase, or trade of blood and blood
5 components intended for transfusion. As used in this
6 subparagraph, the term "blood" means whole blood collected
7 from a single donor and processed either for transfusion or
8 further manufacturing, and the term "blood components" means
9 that part of the blood separated by physical or mechanical
10 means.

11 5. The lawful dispensing of a prescription drug in
12 accordance with chapter 465.

13 (b) "Wholesale distributor" means any person engaged
14 in wholesale distribution of prescription drugs in or into
15 this state, including, but not limited to, manufacturers;
16 repackagers; own-label distributors; jobbers; private-label
17 distributors; brokers; warehouses, including manufacturers'
18 and distributors' warehouses, chain drug warehouses, and
19 wholesale drug warehouses; independent wholesale drug traders;
20 exporters; retail pharmacies; and the agents thereof that
21 conduct wholesale distributions.

22 (c) "Retail pharmacy" means a community pharmacy
23 licensed under chapter 465 that purchases prescription drugs
24 at fair market prices and provides prescription services to
25 the public.

26 (d) "Primary wholesaler" means any wholesale
27 distributor that:

28 1. Purchased 90 percent or more of the total dollar
29 volume of its purchases of prescription drugs directly from
30 manufacturers in the previous year; and
31

1 2.a. Directly purchased prescription drugs from not
2 fewer than 50 different prescription drug manufacturers in the
3 previous year; or

4 b. Has, or the affiliated group, as defined in s. 1504
5 of the Internal Revenue Code, of which the wholesale
6 distributor is a member has, not fewer than 250 employees.

7 (e) "Directly from a manufacturer" means:

8 1. Purchases made by the wholesale distributor
9 directly from the manufacturer of prescription drugs; and

10 2. Transfers from a member of an affiliated group, as
11 defined in s. 1504 of the Internal Revenue Code, of which the
12 wholesale distributor is a member, if:

13 a. The affiliated group purchases 90 percent or more
14 of the total dollar volume of its purchases of prescription
15 drugs from the manufacturer in the previous year; and

16 b. The wholesale distributor discloses to the
17 department the names of all members of the affiliated group of
18 which the wholesale distributor is a member and the affiliated
19 group agrees in writing to provide records on prescription
20 drug purchases by the members of the affiliated group not
21 later than 48 hours after the department requests access to
22 such records, regardless of the location where the records are
23 stored.

24 (f) "Secondary wholesaler" means a wholesale
25 distributor that is not a primary wholesaler.

26 (2) The following types of wholesaler permits are
27 established:

28 (a) A prescription drug wholesaler's permit. A
29 prescription drug wholesaler is a wholesale distributor that
30 may engage in the wholesale distribution of prescription
31 drugs. A prescription drug wholesaler that applies to the

1 department for a new permit or the renewal of a permit ~~after~~
2 ~~July 1, 2003~~, must submit a bond of \$100,000, or other
3 equivalent means of security acceptable to the department,
4 such as an irrevocable letter of credit or a deposit in a
5 trust account or financial institution, payable to the Florida
6 Drug, Device, and Cosmetic Trust Fund. The purpose of the bond
7 is to secure payment of any administrative penalties imposed
8 by the department and any fees and costs incurred by the
9 department regarding that permit which are authorized under
10 state law and which the permittee fails to pay 30 days after
11 the fine or costs become final. The department may make a
12 claim against such bond or security until 1 year after the
13 permittee's license ceases to be valid or until 60 days after
14 any administrative or legal proceeding authorized in ss.
15 499.001-499.081 which involves the permittee is concluded,
16 including any appeal, whichever occurs later. The department
17 may adopt rules for issuing a prescription drug
18 wholesaler-broker permit to a person who engages in the
19 wholesale distribution of prescription drugs and does not take
20 physical possession of any prescription drugs.

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

1 prescription medical oxygen, those rules may not be
2 inconsistent with rules and regulations of federal agencies
3 unless the Legislature specifically directs otherwise.

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

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

31

1 2. An out-of-state prescription drug wholesaler's
2 permit is not required for an intracompany sale or transfer of
3 a prescription drug from an out-of-state establishment that is
4 duly licensed as a prescription drug wholesaler, in its state
5 of residence, to a licensed prescription drug wholesaler in
6 this state, if both wholesalers conduct wholesale
7 distributions of prescription drugs under the same business
8 name. The recordkeeping requirements of s. 499.0121(6) must be
9 followed for this transaction.

10 (d) A retail pharmacy wholesaler's permit. A retail
11 pharmacy wholesaler is a retail pharmacy engaged in wholesale
12 distribution of prescription drugs within this state under the
13 following conditions:

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

17 2. The wholesale distribution activity does not exceed
18 30 percent of the total annual purchases of prescription
19 drugs. If the wholesale distribution activity exceeds the
20 30-percent maximum, the pharmacy must obtain a prescription
21 drug wholesaler's permit.

22 3. The transfer of prescription drugs that appear in
23 any schedule contained in chapter 893 is subject to chapter
24 893 and the federal Comprehensive Drug Abuse Prevention and
25 Control Act of 1970.

26 4. The transfer is between a retail pharmacy and
27 another retail pharmacy, or a Modified Class II institutional
28 pharmacy, or a health care practitioner licensed in this state
29 and authorized by law to dispense or prescribe prescription
30 drugs.

31

1 5. All records of sales of prescription drugs subject
2 to this section must be maintained separate and distinct from
3 other records and comply with the recordkeeping requirements
4 of ss. 499.001-499.081.

5 (e) A nonresident prescription drug manufacturer
6 permit is required for any person that is a manufacturer of
7 prescription drugs, or the distribution point for a
8 manufacturer of prescription drugs, and located outside of
9 this state, or that is an an entity to whom an approved new
10 drug application has been issued by the United States Food and
11 Drug Administration, or the contracted manufacturer of the
12 approved new drug application holder, and located outside the
13 United States, which engages in the wholesale distribution in
14 this state of the prescription drugs it manufactures or is
15 responsible for manufacturing. Each such manufacturer or
16 entity must be permitted by the department and comply with all
17 the provisions required of a wholesale distributor under ss.
18 499.001-499.081, except s. 499.0121(6)(d), (e), or (f).

19 1. A person that distributes prescription drugs that
20 it did not manufacture must also obtain an out-of-state
21 prescription drug wholesaler permit pursuant this section to
22 engage in the wholesale distribution of the prescription drugs
23 manufactured by another person and comply with the
24 requirements of an out-of-state prescription drug wholesaler.

25 2. Any such person must comply with the licensing or
26 permitting requirements of the jurisdiction in which the
27 establishment is located and the federal act, and any product
28 wholesaled into this state must comply with ss.
29 499.001-499.081. If a person intends to import prescription
30 drugs from a foreign country into this state, the nonresident
31 prescription drug manufacturer must provide to the department

1 a list identifying each prescription drug it intends to import
2 and document approval by the United States Food and Drug
3 Administration for such importation.

4 (f) A freight forwarder permit is required for any
5 person that engages in the distribution of a legend drug as a
6 freight forwarder unless the person is a common carrier. The
7 storage, handling, and recordkeeping of such distributions
8 must comply with the requirements for wholesale distributors
9 under s. 499.0121, except those set forth in s.

10 499.0121(6)(d), (e), or (f). A freight forwarder must provide
11 the source of the legend drugs with a validated airway bill,
12 bill of lading, or other appropriate documentation to evidence
13 the exportation of the product.

14 (3) An application for a permit or to renew a permit
15 for a prescription drug wholesaler or an out-of-state
16 prescription drug wholesaler submitted to the department must
17 include:

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

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

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

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

26 (e) The names of the owner and the operator of the
27 establishment, including:

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

29 2. If a partnership, the name of each partner and the
30 name of the partnership.

31 3. If a corporation:

- 1 a. The name, address, and title of each corporate
2 officer and director.
- 3 b. The name and address of the corporation, resident
4 agent of the corporation, the resident agent's address, and
5 the corporation's state of incorporation.
- 6 c. The name and address of each shareholder of the
7 corporation that owns 5 percent or more of the outstanding
8 stock of the corporation.
- 9 4. If a sole proprietorship, the full name of the sole
10 proprietor and the name of the business entity.
- 11 5. If a limited liability company:
- 12 a. The name and address of each member.
- 13 b. The name and address of each manager.
- 14 c. The name and address of the limited liability
15 company, the resident agent of the limited liability company,
16 and the name of the state in which the limited liability
17 company was organized.
- 18 (f) If applicable, the name and address of each member
19 of the affiliated group of which the applicant is a member.
- 20 (g)1. For an application for a new permit, the
21 estimated annual dollar volume of prescription drug sales of
22 the applicant, the estimated annual percentage of the
23 applicant's total company sales that are prescription drugs,
24 the applicant's estimated annual total dollar volume of
25 purchases of prescription drugs, and the applicant's estimated
26 annual total dollar volume of prescription drug purchases
27 directly from manufacturers.
- 28 2. For an application to renew a permit, the total
29 dollar volume of prescription drug sales in the previous year,
30 the total dollar volume of prescription drug sales made in the
31 previous 6 months, the percentage of total company sales that

1 were prescription drugs in the previous year, the total dollar
2 volume of purchases of prescription drugs in the previous
3 year, and the total dollar volume of prescription drug
4 purchases directly from manufacturers in the previous year.

5
6 Such portions of the information required pursuant to this
7 paragraph which are a trade secret, as defined in s. 812.081,
8 shall be maintained by the department as trade secret
9 information is required to be maintained under s. 499.051.

10 (h) The tax year of the applicant.

11 (i) A copy of the deed for the property on which
12 applicant's establishment is located, if the establishment is
13 owned by the applicant, or a copy of the applicant's lease for
14 the property on which applicant's establishment is located
15 that has an original term of not less than 1 calendar year, if
16 the establishment is not owned by the applicant.

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

20 (k) The name of the manager of the establishment that
21 is applying for the permit or to renew the permit, the next
22 four highest ranking employees responsible for prescription
23 drug wholesale operations for the establishment, and the name
24 of all affiliated parties for the establishment, together with
25 the personal information statement and fingerprints required
26 pursuant to subsection (4) for each of such persons.

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

31

1 (m) For an applicant that is a secondary wholesaler,
2 each of the following:

3 1. A personal background information statement
4 containing the background information and fingerprints
5 required pursuant to subsection (4) for each person named in
6 the applicant's response to paragraphs (k) and (l) and for
7 each affiliated party of the applicant.

8 2. If any of the five largest shareholders of the
9 corporation seeking the permit is a corporation, the name,
10 address, and title of each corporate officer and director of
11 each such corporation; the name and address of such
12 corporation; the name of such corporation's resident agent,
13 such corporation's resident agent's address, and such
14 corporation's state of its incorporation; and the name and
15 address of each shareholder of such corporation that owns 5
16 percent or more of the stock of such corporation.

17 3. The name and address of all financial institutions
18 in which the applicant has an account which is used to pay for
19 the operation of the establishment or to pay for drugs
20 purchased for the establishment, together with the names of
21 all persons that are authorized signatories on such accounts.
22 The portions of the information required pursuant to this
23 subparagraph which are a trade secret, as defined in s.
24 812.081, shall be maintained by the department as trade secret
25 information is required to be maintained under s. 499.051.

26 4. The sources of all funds and the amounts of such
27 funds used to purchase or finance purchases of prescription
28 drugs or to finance the premises on which the establishment is
29 to be located.

30
31

1 5. If any of the funds identified in subparagraph 4.
2 were borrowed, copies of all promissory notes or loans used to
3 obtain such funds.

4 (n) Any other relevant information that the department
5 requires, including, but not limited to, any information
6 related to whether the applicant satisfies the definition of a
7 primary wholesaler or a secondary wholesaler.

8 (4)(a) Each person required by subsection (3) to
9 provide a personal information statement and fingerprints
10 shall provide the following information to the department on
11 forms prescribed by the department:

12 1. The person's places of residence for the past 7
13 years.

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

15 3. The person's occupations, positions of employment,
16 and offices held during the past 7 years.

17 4. The principal business and address of any business,
18 corporation, or other organization in which each such office
19 of the person was held or in which each such occupation or
20 position of employment was carried on.

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

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

31

1 7. A description of any involvement by the person with
2 any business, including any investments, other than the
3 ownership of stock in a publicly traded company or mutual
4 fund, during the past 7 years, which manufactured,
5 administered, prescribed, distributed, or stored
6 pharmaceutical products and any lawsuits in which such
7 businesses were named as a party.

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

19 9. A photograph of the person taken in the previous 30
20 days.

21 10. A set of fingerprints for the person on a form and
22 under procedures specified by the department, together with
23 payment of an amount equal to the costs incurred by the
24 department for the criminal record check of the person.

25 11. The name, address, occupation, and date and place
26 of birth for each member of the person's immediate family who
27 is 18 years of age or older. As used in this subparagraph, the
28 term "member of the person's immediate family" includes the
29 person's spouse, children, parents, siblings, the spouses of
30 the person's children, and the spouses of the person's
31 siblings.

1 12. Any other relevant information that the department
2 requires.

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

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

27 (5) The department may deny an application for a
28 permit or refuse to renew a permit for a prescription drug
29 wholesaler or an out-of-state prescription drug wholesaler if:

30 (a) The applicant has not met the requirements for the
31 permit.

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

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

7 (d) The applicant is so lacking in experience in
8 managing a wholesale distributor as to jeopardize the
9 reasonable promise of successful operation of the wholesale
10 distributor.

11 (e) The applicant is lacking in experience in the
12 distribution of prescription drugs.

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

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

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

26 (i) The applicant or any affiliated party has been
27 charged with a felony in a state or federal court and the
28 disposition of that charge is pending during the application
29 review or renewal review period.

30 (j) The applicant has furnished false or fraudulent
31 information or material in any application made in this state

1 or any other state in connection with obtaining a permit or
2 license to manufacture or distribute drugs, devices, or
3 cosmetics.

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

9 (l) The applicant does not possess the financial or
10 physical resources to operate in compliance with the permit
11 being sought, this chapter, and the rules adopted under this
12 chapter.

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

19 (n) The applicant or any affiliated party receives,
20 directly or indirectly, financial support and assistance from
21 a person who has been found guilty of any violation of ss.
22 499.001-499.081 or chapter 465, chapter 501, or chapter 893,
23 any rules adopted under any of those sections or chapters, any
24 federal or state drug law, or any felony where the underlying
25 facts related to drugs, regardless of whether the person has
26 been pardoned, had her or his civil rights restored, or had
27 adjudication withheld, other than through the ownership of
28 stock in a publicly traded company or a mutual fund.

29 (o) The applicant for renewal of a permit under
30 paragraph (2)(a) or paragraph (2)(c) has not actively engaged
31 in the wholesale distribution of prescription drugs, as

1 demonstrated by the regular and systematic distribution of
2 prescription drugs throughout the year as evidenced by not
3 fewer than 12 wholesale distributions in the previous year and
4 not fewer than three wholesale distributions in the previous 6
5 months.

6 (p) Information obtained in response to paragraph
7 (2)(a) or paragraph (2)(c) demonstrates it would not be in the
8 best interest of the public health, safety, and welfare to
9 issue a permit.

10 (q) The applicant does not possess the financial
11 standing and business experience for the successful operation
12 of the applicant.

13 (r) The applicant or any affiliated party has failed
14 to comply with the requirements for manufacturing or
15 distributing prescription drugs under ss. 499.001-499.081,
16 similar federal laws, similar laws in other states, or the
17 rules adopted under such laws.

18 (6) Upon approval of the application by the department
19 and payment of the required fee, the department shall issue or
20 renew a prescription drug wholesaler or an out-of-state
21 prescription drug wholesaler permit to the applicant.

22 (7) For permits for prescription drug wholesalers or
23 out-of-state prescription drug wholesalers:

24 (a) The department shall adopt rules for the annual
25 renewal of permits. At least 90 days before the expiration of
26 a permit, the department shall forward a permit renewal
27 notification and renewal application to the prescription drug
28 wholesaler or out-of-state prescription drug wholesaler at the
29 mailing address of the permitted establishment on file with
30 the department. The permit renewal notification must state
31 conspicuously the date on which the permit for the

1 establishment will expire and that the establishment may not
2 operate unless the permit for the establishment is renewed
3 timely.

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

17 (c) Failure to renew a permit in accordance with this
18 section precludes any future renewal of that permit. If a
19 permit issued pursuant to this section has expired and cannot
20 be renewed, before an establishment may engage in activities
21 that require a permit under ss. 499.001-499.081, the
22 establishment must submit an application for a new permit; pay
23 the applicable application fee, initial permit fee, and all
24 applicable penalties; and be issued a new permit by the
25 department.

26 (8)(3) A person that engages in wholesale distribution
27 of prescription drugs in this state must have a wholesale
28 distributor's permit issued by the department, except as noted
29 in this section. Each establishment must be separately
30 permitted except as noted in this subsection.

31

1 (a) A separate establishment permit is not required
2 when a permitted prescription drug wholesaler consigns a
3 prescription drug to a pharmacy that is permitted under
4 chapter 465 and located in this state, provided that:

5 1. The consignor wholesaler notifies the department in
6 writing of the contract to consign prescription drugs to a
7 pharmacy along with the identity and location of each
8 consignee pharmacy;

9 2. The pharmacy maintains its permit under chapter
10 465;

11 3. The consignor wholesaler, which has no legal
12 authority to dispense prescription drugs, complies with all
13 wholesale distribution requirements of s. 499.0121 with
14 respect to the consigned drugs and maintains records
15 documenting the transfer of title or other completion of the
16 wholesale distribution of the consigned prescription drugs;

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

19 5. Open packages containing prescription drugs within
20 a pharmacy are the responsibility of the pharmacy, regardless
21 of how the drugs are titled; and

22 6. The pharmacy dispenses the consigned prescription
23 drug in accordance with the limitations of its permit under
24 chapter 465 or returns the consigned prescription drug to the
25 consignor wholesaler. In addition, a person who holds title to
26 prescription drugs may transfer the drugs to a person
27 permitted or licensed to handle the reverse distribution or
28 destruction of drugs. Any other distribution by and means of
29 the consigned prescription drug by any person, not limited to
30 the consignor wholesaler or consignee pharmacy, to any other
31 person is prohibited.

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

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

21 ~~(9)(4)~~ Personnel employed in wholesale distribution
22 must have appropriate education and experience to enable them
23 to perform their duties in compliance with state permitting
24 requirements.

25 (10) The name of a permittee or establishment on a
26 prescription drug wholesaler permit or an out-of-state
27 prescription drug wholesaler permit may not include any
28 indicia of attainment of any educational degree, any indicia
29 that the permittee or establishment possesses a professional
30 license, or any name or abbreviation that the department
31 determines is likely to cause confusion or mistake or that the

1 department determines is deceptive, including that of any
2 other entity authorized to purchase prescription drugs.

3 (11)(a) Each establishment that is issued an initial
4 or renewal permit as a prescription drug wholesaler or an
5 out-of-state prescription drug wholesaler must designate in
6 writing to the department at least one natural person to serve
7 as the designated representative of the wholesaler. Such
8 person must have an active certification as a designated
9 representative from the department.

10 (b) To be certified as a designated representative, a
11 natural person must:

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

14 2. Be at least 18 years of age;

15 3. Have not less than 2 years of verifiable full-time
16 work experience in a pharmacy licensed in this state or
17 another state, where the person's responsibilities included,
18 but were not limited to, recordkeeping for prescription drugs,
19 or have not less than 2 years of verifiable full-time
20 managerial experience with a prescription drug wholesaler
21 licensed in this state or in another state;

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

25 499.001-499.081 and the rules adopted by the department
26 governing the wholesale distribution of prescription drugs.

27 This requirement shall be effective 1 year after the results
28 of the initial examination are mailed to the persons that took
29 the examination. The department shall offer such examinations
30 at least four times each calendar year; and

31

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

3 (c) The department may deny an application for
4 certification as a designated representative or may suspend or
5 revoke a certification of a designated representative pursuant
6 to s. 499.067.

7 (d) A designated representative:

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

10 2. Must be employed full time in a managerial position
11 by the wholesale distributor.

12 3. Must be physically present at the establishment
13 during normal business hours, except for time periods when
14 absent due to illness, family illness or death, scheduled
15 vacation, or other authorized absence.

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

18 (e) A wholesale distributor must notify the department
19 when a designated representative leaves the employ of the
20 wholesale distributor. Such notice must be provided to the
21 department within 10 business days after the last day of
22 designated representative's employment with the wholesale
23 distributor.

24 (f) A wholesale distributor may not operate under a
25 prescription drug wholesaler permit or an out-of-state
26 prescription drug wholesaler permit for more than 10 business
27 days after the designated representative leaves the employ of
28 the wholesale distributor, unless the wholesale distributor
29 employs another designated representative and notifies the
30 department within 10 business days of the identity of the new
31 designated representative.

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

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

8 499.0121 Storage and handling of prescription drugs;
9 recordkeeping.--The department shall adopt rules to implement
10 this section as necessary to protect the public health,
11 safety, and welfare. Such rules shall include, but not be
12 limited to, requirements for the storage and handling of
13 prescription drugs and for the establishment and maintenance
14 of prescription drug distribution records.

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

16 (a) Upon receipt, each outside shipping container must
17 be visually examined for identity and to prevent the
18 acceptance of contaminated prescription drugs that are
19 otherwise unfit for distribution. This examination must be
20 adequate to reveal container damage that would suggest
21 possible contamination or other damage to the contents.

22 (b) Each outgoing shipment must be carefully inspected
23 for identity of the prescription drug products and to ensure
24 that there is no delivery of prescription drugs that have
25 expired or been damaged in storage or held under improper
26 conditions.

27 (c) The recordkeeping requirements in subsection (6)
28 must be followed for all incoming and outgoing prescription
29 drugs.

30 (d) Upon receipt, a wholesaler must review records
31 required under this section for the acquisition of

1 prescription drugs for accuracy and completeness, considering
2 the total facts and circumstances surrounding the transactions
3 and the wholesale distributors involved. This includes
4 authenticating each transaction listed on a pedigree paper, as
5 defined in s. 499.001(31).

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

9 (a) Wholesale drug distributors must establish and
10 maintain inventories and records of all transactions regarding
11 the receipt and distribution or other disposition of
12 prescription drugs. These records must provide a complete
13 audit trail from receipt to sale or other disposition, be
14 readily retrievable for inspection, and include, at a minimum,
15 the following information:

16 1. The source of the drugs, including the name and
17 principal address of the seller or transferor, and the address
18 of the location from which the drugs were shipped;

19 2. The name, principal address, and state license
20 permit or registration number of the person authorized to
21 purchase prescription drugs;

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

24 4. The dates of receipt and distribution or other
25 disposition of the drugs; ~~and~~

26 5. Any financial documentation supporting the
27 transaction.

28 (b) Inventories and records must be made available for
29 inspection and photocopying by authorized federal, state, or
30 local officials for a period of 2 years following disposition

31

1 of the drugs or 3 years after the creation of the records,
2 whichever period is longer.

3 (c) Records described in this section that are kept at
4 the inspection site or that can be immediately retrieved by
5 computer or other electronic means must be readily available
6 for authorized inspection during the retention period.
7 Records that are kept at a central location outside of this
8 state and that are not electronically retrievable must be made
9 available for inspection within 2 working days after a request
10 by an authorized official of a federal, state, or local law
11 enforcement agency. Records that are maintained at a central
12 location within this state must be maintained at an
13 establishment that is permitted pursuant to ss.
14 499.001-499.081 and must be readily available.

15 (d)1. Each person who is engaged in the wholesale
16 distribution of a prescription drug, and who is not an
17 authorized distributor of record for the drug manufacturer's
18 products of such drug, must provide to each wholesale
19 distributor of such drug, before the sale is made to such
20 wholesale distributor, a written statement under oath
21 identifying each previous sale of the drug back to the last
22 authorized distributor of record, the lot number of the drug,
23 and the sales invoice number of the invoice evidencing the
24 sale of the drug. The written statement ~~identifying all sales~~
25 ~~of such drug~~ must accompany the drug ~~for each subsequent~~
26 ~~wholesale distribution of the drug to the next~~ a wholesale
27 distributor. The department shall adopt rules relating to the
28 requirements of this written statement. This paragraph does
29 not apply to a manufacturer unless the manufacturer is
30 performing the manufacturing operation of repackaging
31 prescription drugs.

1 2. Each wholesale distributor of prescription drugs
2 must maintain separate and distinct from other required
3 records all statements that are required under subparagraph 1.
4 and paragraph (e).

5 3. Each manufacturer of a prescription drug sold in
6 this state must maintain at its corporate offices a current
7 list of authorized distributors and must make such list
8 available to the department upon request.

9 4. Each manufacturer shall file a written list of all
10 of the manufacturer's authorized distributors of record with
11 the department. A manufacturer shall notify the department not
12 later than 10 days after any change to the list. The
13 department shall publish a list of all authorized distributors
14 of record on its website.

15 5. For the purposes of this subsection, the term
16 "authorized distributors of record" means a wholesale
17 distributor ~~those distributors~~ with whom a manufacturer has
18 established an ongoing relationship to distribute the
19 manufacturer's products. Effective March 1, 2004, an ongoing
20 relationship is deemed to exist when a wholesale distributor,
21 including any affiliated group, as defined in s. 1504 of the
22 Internal Revenue Code, of which the wholesale distributor is a
23 member:

24 a. Is listed on the manufacturer's current list of
25 authorized distributors of record.

26 b. Annually purchases not less than 90 percent of all
27 of its purchases of a manufacturer's prescription drug
28 products, based on dollar volume, directly from that
29 manufacturer and has total annual prescription drug sales of
30 \$100 million or more.

31

1 c. Has reported to the department pursuant to s.
2 499.012(2)(g)2. that the wholesale distributor has total
3 annual prescription drug sales of \$100 million or more, and
4 has a verifiable account number issued by the manufacturer
5 authorizing the wholesale distributor to purchase the
6 manufacturer's drug products directly from that manufacturer
7 and that wholesale distributor makes not fewer than 12
8 purchases of that manufacturer's drug products directly from
9 the manufacturer using said verifiable account number in 12
10 months. The provisions of this sub-subparagraph apply with
11 respect to a manufacturer that fails to file a copy of the
12 manufacturer's list of authorized distributors of record with
13 the department by July 1, 2003; that files a list of
14 authorized distributors of record which contains fewer than
15 ten wholesale distributors permitted in this state, excluding
16 the wholesale distributors described in sub-subparagraph b.;
17 or that, as a result of changes to the list of authorized
18 distributors of record filed with the department, has fewer
19 than ten wholesale distributors permitted in this state as
20 authorized distributors of record, excluding the wholesale
21 distributors described in sub-subparagraph b.

22
23 A wholesale distributor that satisfies the requirements of
24 sub-subparagraph b. or sub-subparagraph c. shall submit to the
25 department documentation substantiating its qualification
26 pursuant to sub-subparagraph b. or sub-subparagraph c. The
27 department shall add those wholesale distributors that the
28 department has determined have met the requirements of
29 sub-subparagraph b. or sub-subparagraph c. to the list of
30 authorized distributors of record on the department's website.

31 6. This paragraph expires July 1, 2006.

1 (e)1. Notwithstanding paragraph (d), each person who
2 is engaged in the wholesale distribution of a specified drug
3 must provide to each wholesale distributor of such specified
4 drug:

5 a. Upon any sale, a written statement that:

6 (I) If the establishment is not a member of an
7 affiliated group: "This establishment purchased the specific
8 unit of the specified drug directly from the manufacturer"; or

9 (II) If the establishment is a member of an affiliated
10 group: "This establishment or a member of my affiliated group
11 purchased the specific unit of the specified drug directly
12 from the manufacturer"; or

13 b. Before the wholesale distribution, a written
14 statement, under oath, that identifies each previous sale of
15 the specific unit of the specified drug back to the
16 manufacturer of the specified drug, the lot number of the
17 specific unit of the specified prescription drug, and the
18 sales invoice number of the invoice evidencing each previous
19 sale of the specific unit of the specified drug. The written
20 statement identifying all sales of such specific unit of the
21 specified drug must accompany the specific unit of the
22 specified drug for each subsequent wholesale distribution of
23 the specific unit of the specified drug to a wholesale
24 distributor.

25
26 The department shall adopt rules to administer the
27 requirements of these written statements.

28 2. As used in this paragraph, the term "specified
29 drug" means a specific prescription drug on the list of drugs
30 adopted by the department by rule.

31

1 3.a. A drug may be placed on the list of specified
2 drugs if the department has seized or issued a stop sale
3 notice on the prescription drug because of the adulteration,
4 counterfeiting, or diversion of the prescription drug from the
5 legal channels of distribution for prescription drugs, or the
6 United States Food and Drug Administration, a manufacturer, a
7 wholesale distributor, a law enforcement agency, or a
8 government agency responsible for regulating the sale or
9 distribution of prescription drugs in another state has
10 notified the department in writing or through a website
11 operated by one of said entities that the prescription drug
12 has been adulterated, counterfeit or diverted from the legal
13 channels of distribution for prescription drugs; and the
14 prescription drug satisfies one of the following criteria:
15 (I) The prescription drug is included among the top
16 150 prescription drugs for which the state has incurred the
17 highest amount of Medicaid claims in the most recently ended
18 state fiscal year;
19 (II) The prescription drug is available for normal
20 prescription use in dosages or strengths that have a wholesale
21 cost \$200 or more;
22 (III) The prescription drug is used extensively for
23 patients with human immunodeficiency virus, acquired immune
24 deficiency syndrome, cancer, or other serious, life
25 threatening conditions, where drug nonresponsiveness would not
26 be considered to be medically unusual;
27 (IV) The prescription drug is an injectable drug;
28 (V) The prescription drug is subject to a special,
29 limited distribution process and is not generally sold to
30 wholesale distributors by the manufacturer of the prescription
31 drug;

1 (VI) The department has found not less than five
2 instances where statements required pursuant to paragraph (d)
3 for the prescription drug were not passed on other than
4 because of unintentional oversight, or have been passed on by
5 or to a wholesale distributor and such statements were
6 fraudulent; or

7 (VII) A shipment of a prescription drug has been
8 reported to a law enforcement agency as having been stolen or
9 as missing.

10 b. A prescription drug may be placed on the list of
11 specified drugs if the prescription drug satisfies any three
12 of the seven criteria set forth in sub-sub-subparagraphs
13 (I)-(VII). However, a prescription drug may not be included on
14 the list of specified drugs if the prescription drug is
15 unlikely to be counterfeited or diverted from the legal
16 channels of distribution for prescription drugs.

17 c. Before the department begins the rulemaking process
18 to place a drug on the list of specified drugs, except when
19 the department files a rule under the procedure specified in
20 s. 499.0121(6)(e)3.e., the Drug Wholesaler Advisory Council
21 created in s. 499.01211 shall consider whether a prescription
22 drug should be included on or added to the list of specified
23 drugs using the criteria enumerated in sub-subparagraph 3.a.
24 or sub-subparagraph 3.b. and provide a written recommendation
25 adopted by majority vote to the secretary of the department
26 concerning each such drug. This paragraph does not apply to
27 any list of prescription drugs on which the department has
28 begun rulemaking prior to this paragraph becoming law.

29 d. When a prescription drug is added to the list of
30 specified drugs, the requirements of this paragraph shall be
31 effective as to the prescription drug beginning 60 days after

1 the effective date of the rule adding the prescription drug to
2 the list, except when the department files a rule under the
3 procedure specified in s. 499.0121(6)(e)3.e.

4 e.(I) Notwithstanding chapter 120, if the Attorney
5 General or Statewide Prosecutor certifies to the secretary of
6 the department that a prescription drug should be added to the
7 list of specified drugs by emergency rule, the department may
8 proceed to add such drug to the list of specified drugs and
9 the emergency rule shall be effective for a period of one year
10 from the date on which the emergency rule is filed, if the
11 department begins the rulemaking process to adopt a permanent
12 rule to place the drug on the list of specified drugs not
13 later than 90 days after the date on which the emergency rule
14 was filed. An emergency rule adding a drug to the list of
15 specified drugs may not be renewed.

16 (II) A prescription drug may be placed on the list of
17 specified drugs through the procedure provided in
18 sub-subparagraph (e)3.e. when:

19 (A) The prescription drug satisfies any two of the
20 criteria specified in sub-subparagraph (e)3.a. or
21 sub-subparagraph (e)3.b.; or

22 (B) The prescription drug satisfies any one of the
23 criteria specified in sub-subparagraph (e)3.a. or
24 sub-subparagraph (e)3.b. if the prescription drug has not yet
25 become available for wholesale distribution or has been
26 available for wholesale distribution for not more than 60
27 days.

28 (III) Notwithstanding chapter 120, any emergency rule
29 that places a prescription drug on the list of specified drugs
30 may be challenged as being an invalid exercise of the
31 delegated legislative authority only if the department lacks

1 any substantial competent evidence that the prescription drug
2 satisfied the criteria required pursuant to
3 sub-sub-subparagraph (I) or sub-sub-subparagraph (II). Not
4 later than seven days after any request by any person, the
5 department shall provide such person with the substantial
6 competent evidence that justifies the department's adoption of
7 an emergency rule placing a prescription drug on the list of
8 specified drugs.

9 (IV) The department shall notify all prescription drug
10 wholesalers and out-of-state-prescription drug wholesalers by
11 electronic means, facsimile, or United States mail and on the
12 bureau's website when any emergency rule is adopted which
13 places a prescription drug on the list of specified drugs. Not
14 later than seven days after the department adopts an emergency
15 rule placing a prescription drug on the list of specified
16 drugs, wholesalers shall provide the department with the lot
17 numbers and quantities of such prescription drug which the
18 wholesaler owns or has in transit on the date that the
19 department adopted the emergency rule placing the prescription
20 drug on the list of specified drugs.

21 (V) The requirements of subparagraph (e)1. do not
22 apply to those lot numbers and quantities of a prescription
23 drug which are included on a report filed pursuant to
24 sub-sub-subparagraph (e)3.e.(IV), and paragraph (6)(d) shall
25 apply to those lot numbers and quantities of the prescription
26 drug. In addition to the requirements of paragraph (6)(d), any
27 wholesale distributor selling a prescription drug included on
28 a report filed pursuant to sub-sub-subparagraph (e)3.e.(IV)
29 shall provide any wholesaler purchasing the prescription drugs
30 with a statement under oath that the prescription drugs are
31 among those included on a report filed pursuant to

1 sub-sub-subparagraph (e)3.e.(IV) and with a copy of the report
2 filed by the wholesale distributor with the department for
3 those prescription drugs.

4 f. Not less than annually, the council and department
5 shall evaluate whether each prescription drug included on the
6 list of specified drugs should remain on the list. In
7 determining whether a prescription drug should remain on the
8 list of specified drugs, the council and department must
9 consider:

10 (I) The availability of generic forms of the drug.

11 (II) Changes in the price of the drug since the
12 prescription drug was placed on the list.

13 (III) The current status of the drug that caused the
14 department to place the prescription drug on the list of
15 specified drugs.

16
17 The council shall provide a written recommendation adopted by
18 majority vote to the secretary of the department concerning
19 each drug that the council recommends be removed from the list
20 of specified drugs.

21 4. This paragraph does not apply to a manufacturer;
22 however, a repackager must comply with this paragraph.

23 5. This paragraph expires July 1, 2006.

24 (f)1. Effective July 1, 2006, each person who is
25 engaged in the wholesale distribution of a prescription drug
26 and who is not the manufacturer of that drug must, before each
27 wholesale distribution of such drug, provide to the person who
28 receives the drug a pedigree paper as defined in s.

29 499.003(31).

30 2. A repackager must comply with this paragraph.

31

1 3. The pedigree paper requirements in this paragraph
2 do not apply to compressed medical gases or veterinary legend
3 drugs.

4 4. Each wholesale distributor of prescription drugs
5 must maintain separate and distinct from other required
6 records all statements that are required under subparagraph 1.

7 5. In order to verify compliance with paragraph (d)1.,
8 each manufacturer of a prescription drug sold in this state
9 must make available upon request distribution documentation
10 related to its sales of prescription drugs, regardless of
11 whether the prescription drug was sold directly by the
12 manufacturer to a person in Florida.

13 (g) Each wholesale distributor, except for a
14 manufacturer, shall annually provide the department with a
15 written list of all wholesale distributors and manufacturers
16 from whom the wholesale distributor purchases prescription
17 drugs. A wholesale distributor, except a manufacturer, shall
18 notify the department not later than 10 days after any change
19 to either list. Such portions of the information required
20 pursuant to this paragraph which are a trade secret, as
21 defined in s. 812.081, shall be maintained by the department
22 as trade secret information is required to be maintained under
23 s. 499.051.

24 (7) WRITTEN POLICIES AND PROCEDURES.--Wholesale drug
25 distributors must establish, maintain, and adhere to written
26 policies and procedures, which must be followed for the
27 receipt, security, storage, inventory, and distribution of
28 prescription drugs, including policies and procedures for
29 identifying, recording, and reporting losses or thefts, and
30 for correcting all errors and inaccuracies in inventories.

31

1 Wholesale drug distributors must include in their written
2 policies and procedures:

3 (a) A procedure whereby the oldest approved stock of a
4 prescription drug product is distributed first. The procedure
5 may permit deviation from this requirement, if the deviation
6 is temporary and appropriate.

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

10 1. Any action initiated at the request of the Food and
11 Drug Administration or any other federal, state, or local law
12 enforcement or other government agency, including the
13 department.

14 2. Any voluntary action by the manufacturer or
15 repackager to remove defective or potentially defective drugs
16 from the market; or

17 3. Any action undertaken to promote public health and
18 safety by replacing existing merchandise with an improved
19 product or new package design.

20 (c) A procedure to ensure that wholesale drug
21 distributors prepare for, protect against, and handle any
22 crisis that affects security or operation of any facility if a
23 strike, fire, flood, or other natural disaster, or a local,
24 state, or national emergency, occurs.

25 (d) A procedure to ensure that any outdated
26 prescription drugs are segregated from other drugs and either
27 returned to the manufacturer or repackager or destroyed. This
28 procedure must provide for written documentation of the
29 disposition of outdated prescription drugs. This documentation
30 must be maintained for 2 years after disposition of the
31 outdated drugs.

1 (8) RESPONSIBLE PERSONS.--Wholesale drug distributors
2 must establish and maintain lists of officers, directors,
3 managers, designated representatives, and other persons in
4 charge of wholesale drug distribution, storage, and handling,
5 including a description of their duties and a summary of their
6 qualifications.

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

27 Section 16. Effective January 1, 2004, subsection (12)
28 is added to section 499.0121, Florida Statutes, to read:

29 499.0121 Storage and handling of prescription drugs;
30 recordkeeping.--The department shall adopt rules to implement
31 this section as necessary to protect the public health,

1 safety, and welfare. Such rules shall include, but not be
2 limited to, requirements for the storage and handling of
3 prescription drugs and for the establishment and maintenance
4 of prescription drug distribution records.

5 (12) DUE DILIGENCE OF SUPPLIERS.--Prior to purchasing
6 any prescription drugs from another wholesale drug
7 distributor, a wholesale drug distributor must:

8 (a) Enter an agreement with the selling wholesale drug
9 distributor by which the selling wholesale drug distributor
10 will indemnify the purchasing wholesale drug distributor for
11 any loss caused to the purchasing wholesale drug distributor
12 related to the purchase of drugs from the selling wholesale
13 drug distributor which are determined to be counterfeit or to
14 have been distributed in violation of any federal or state law
15 governing the distribution of drugs.

16 (b) Determine that the selling wholesale drug
17 distributor has insurance coverage of not less than the
18 greater of 1 percent of the amount of total dollar volume of
19 the prescription drug sales reported to the department
20 pursuant to s. 499.012(3)(g) or \$500,000; however the coverage
21 need not exceed \$2 million.

22 (c) Obtain information from the selling wholesale drug
23 distributor, including the length of time the selling
24 wholesale drug distributor has been licensed in this state, a
25 copy of the selling wholesale drug distributor's licenses or
26 permits, and background information concerning the ownership
27 of the selling wholesale drug distributor, including the
28 experience of the wholesale distributor in the wholesale
29 distribution of prescription drugs.

30 (d) Verify that the selling wholesale drug
31 distributor's Florida permit is valid.

1 (e) Inspect the selling wholesale drug distributor's
2 licensed establishment to document that it has a policies and
3 procedures manual relating to the distribution of drugs, the
4 appropriate temperature controlled environment for drugs
5 requiring temperature control, an alarm system, appropriate
6 access restrictions, and procedures to ensure that records
7 related to the wholesale distribution of prescription drugs
8 are maintained as required by law:

9 1. Before purchasing any drug from the wholesale drug
10 distributor, and at least once each subsequent year; or

11 2. Before purchasing any drug from the wholesale drug
12 distributor, and each subsequent year obtain a complete copy
13 of the most recent inspection report for the establishment
14 which was prepared by the department or the regulatory
15 authority responsible for wholesale drug distributors in the
16 state in which the establishment is located.

17 Section 17. Section 499.01211, Florida Statutes, is
18 created to read:

19 499.01211 Drug Wholesaler Advisory Council.--

20 (1) There is created the Drug Wholesaler Advisory
21 Council within the department. The council shall meet at least
22 once each calendar quarter. Staff for the council shall be
23 provided by the department. The council shall consist of 11
24 members who shall serve without compensation. The council
25 shall elect a chairperson and a vice chairperson annually.

26 (2) The secretary of the department, or his or her
27 designee, and the Secretary of Health Care Administration, or
28 her or his designee, shall be members of the council. The
29 Secretary of Health shall appoint nine additional members to
30 the council who shall be appointed to a term of 4 years each,
31 as follows:

1 (a) Three different persons each of whom is employed
2 by a different prescription drug wholesaler licensed under
3 this chapter which operates nationally and is a primary
4 wholesaler, as defined in s. 499.012 (1)(d).

5 (b) One person employed by a prescription drug
6 wholesaler licensed under this chapter which is a secondary
7 wholesaler, as defined in s. 499.012(1)(f).

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

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

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

14 (f) One person who is an employee of a hospital
15 licensed pursuant to chapter 395 and is a pharmacist licensed
16 pursuant to chapter 465.

17 (g) One person who is an employee of a pharmaceutical
18 manufacturer.

19 (3) The council shall review ss. 499.001-499.081 and
20 the rules adopted to administer ss. 499.001-499.081 annually,
21 provide input to the department regarding all proposed rules
22 to administer ss. 499.001-499.081, make written recommendation
23 to the secretary of the department regarding the listing of
24 all specified drugs pursuant to s. 499.0121(6)(e), make
25 recommendations to the department to improve the protection of
26 the prescription drugs and public health, make recommendations
27 to improve coordination with other states' regulatory agencies
28 and the federal government concerning the wholesale
29 distribution of drugs, and make recommendations to minimize
30 the impact of regulation of the wholesale distribution
31 industry while ensuring protection of the public health.

1 Section 18. Effective January 1, 2004, section
2 499.013, Florida Statutes, is amended to read:

3 499.013 Manufacturers and repackagers of drugs,
4 devices, and cosmetics; definitions, permits, and general
5 requirements.--

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

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

16 (a) A prescription drug manufacturer's permit is
17 required for any person that manufactures a prescription drug
18 in this state. A prescription drug repackager's permit is
19 required for any person that repackages a prescription drug in
20 this state.

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

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

31

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

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

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

10 3. An over-the-counter drug manufacturer permittee
11 must comply with all appropriate state and federal good
12 manufacturing practices.

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

17 1. A compressed medical gas manufacturer permittee may
18 not manufacture or possess any prescription drug other than
19 compressed medical gases.

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

25 3. A compressed medical gas manufacturer permittee
26 must comply with all appropriate state and federal good
27 manufacturing practices.

28 (d) A device manufacturer's permit is required for any
29 person that engages in the manufacture, repackaging, or
30 assembly of medical devices for human use in this state,
31 except that a permit is not required if the person is engaged

1 only in manufacturing, repackaging, or assembling a medical
2 device pursuant to a practitioner's order for a specific
3 patient.

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

7 2. The department shall adopt rules related to
8 storage, handling, and recordkeeping requirements for
9 manufacturers of medical devices for human use.

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

16 (3) The department may adopt such rules as are
17 necessary for the protection of the public health, safety, and
18 welfare regarding good manufacturing practices that
19 manufacturers and repackers must follow to ensure the safety
20 of the products.

21 (4) Each manufacturer or repackager of medical
22 devices, over-the-counter drugs, or cosmetics must maintain
23 records that include the name and principal address of the
24 seller or transferor of the product, the address of the
25 location from which the product was shipped, the date of the
26 transaction, the name and quantity of the product involved,
27 and the name and principal address of the person who purchased
28 the product.

29 Section 19. Subsection (3) of section 499.014, Florida
30 Statutes, is amended to read:

31

1 499.014 Distribution of legend drugs by hospitals,
2 health care entities, charitable organizations, and return or
3 destruction companies; permits, general requirements.--

4 (3) Storage, ~~and~~ handling, and recordkeeping of these
5 distributions must comply with the requirements for wholesale
6 distributors under s. 499.0121, except those set forth in s.
7 499.0121(6)(d), (e), or (f).

8 Section 20. Section 499.041, Florida Statutes, is
9 amended to read:

10 499.041 Schedule of fees for drug, device, and
11 cosmetic applications and permits, product registrations, and
12 free-sale certificates.--

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

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

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

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

24 (d) The fee for an over-the-counter drug
25 manufacturer's permit may not be less than \$300 or more than
26 \$400 annually.

27 (e) The fee for a compressed medical gas
28 manufacturer's permit may not be less than \$400 or more than
29 \$500 annually.

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

1 ~~(g)(f)~~ A manufacturer may not be required to pay more
2 than one fee per establishment to obtain an additional
3 manufacturing permit, but each manufacturer must pay the
4 highest fee applicable to his or her operation in each
5 establishment.

6 (2) The department shall assess an applicant that is
7 required to have a wholesaling permit an annual fee within the
8 ranges established in this section for the specific type of
9 wholesaling.

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

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

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

18 (d) The fee for a nonresident prescription drug
19 manufacturer's permit may not be less than \$300 or more than
20 \$500 annually.

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

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

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

29 (a) The fee for a veterinary legend drug retail
30 establishment permit may not be less than \$200 or more than
31 \$300 annually.~~†~~

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

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

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

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

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

22 (8) The department shall assess an out-of-state
23 prescription drug wholesaler applicant or permittee an on-site
24 inspection fee of not less than \$1,000 or more than \$3,000
25 annually, to be based on the actual cost of the inspection if
26 an on-site inspection is performed by agents of the
27 department.

28 (9) The department shall assess each person applying
29 for certification as a designated representative a fee of
30 \$150, plus the cost of processing the criminal history record
31 check.

1 ~~(10)(8)~~ The department shall assess other fees as
2 provided in ss. 499.001-499.081.

3 Section 21. Subsection (2) and present subsection (5)
4 of section 499.051, Florida Statutes, are amended, present
5 subsections (4) and (5) of that section are redesignated as
6 subsections (6) and (7), respectively, and new subsections (4)
7 and (5) are added to that section, to read:

8 499.051 Inspections and investigations.--

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

23 (4) Any application for a permit made pursuant to ss.
24 499.01 and 499.012 and rules adopted under those sections
25 constitutes permission for agents of the Department of Health
26 and the Department of Law Enforcement, after presenting proper
27 identification, to inspect, review, and copy any financial
28 document or record related to the manufacture, repackaging, or
29 distribution of a drug as is necessary to verify compliance
30 with ss. 499.001-499.081 and the rules adopted by the
31 department to administer those sections, in order to discover,

1 investigate, and determine the existence of compliance, or to
2 elicit, receive, respond to, and resolve complaints and
3 violations.

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

8 ~~(7)(5)~~ The complaint and all information obtained
9 pursuant to the investigation by the department are
10 confidential and exempt from the provisions of s. 119.07(1)
11 and s. 24(a), Art. I of the State Constitution until the
12 investigation and the enforcement action are completed.
13 However, trade secret information contained therein as defined
14 by s. 812.081(1)(c) shall remain confidential and exempt from
15 the provisions of s. 119.07(1) and s. 24(a), Art. I of the
16 State Constitution, as long as the information is retained by
17 the department. This subsection does not prohibit the
18 department from using such information for regulatory or
19 enforcement proceedings under this chapter or from providing
20 such information to any law enforcement agency or any other
21 regulatory agency. However, the receiving agency shall keep
22 such records confidential and exempt as provided in this
23 subsection. In addition, this subsection is not intended to
24 prevent compliance with the provisions of s. 499.0121(6)(d),
25 (e), or (f), and the pedigree papers required in that
26 subsection shall not be deemed a trade secret.

27 Section 22. Subsection (4) is added to section
28 499.055, Florida Statutes, to read:

29 499.055 Reports and dissemination of information by
30 department.--

31

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

3 (a) A list of the prescription drug wholesalers,
4 out-of-state prescription drug wholesalers, and retail
5 pharmacy drug wholesalers against whom the department has
6 initiated enforcement action pursuant to ss. 499.001-499.081
7 to suspend or revoke a permit, seek an injunction, or
8 otherwise file an administrative complaint and the permit
9 number of each such wholesaler.

10 (b) A list of the prescription drug wholesalers,
11 out-of-state prescription drug wholesalers, and retail
12 pharmacy drug wholesalers to which the department has issued a
13 permit, including the date on which each permit will expire.

14 (c) A list of the prescription drug wholesalers,
15 out-of-state prescription drug wholesalers, and retail
16 pharmacy drug wholesalers' permits that have been returned to
17 the department, were suspended, were revoked, have expired, or
18 were not renewed in the previous year.

19 Section 23. Section 499.065, Florida Statutes, is
20 created to read:

21 499.065 Imminent danger.--

22 (1) Notwithstanding s. 499.051, the department shall
23 inspect each prescription drug wholesale establishment,
24 prescription drug repackager establishment, and retail
25 pharmacy drug wholesaler establishment that is required to be
26 permitted under this chapter as often as necessary to ensure
27 compliance with applicable laws and rules. The department
28 shall have the right of entry and access to these facilities
29 at any reasonable time.

30 (2) To protect the public from prescription drugs that
31 are adulterated or otherwise unfit for human consumption, the

1 department may examine, sample, seize, and stop the sale or
2 use of prescription drugs to determine the condition of those
3 drugs. The department may immediately seize and remove any
4 prescription drugs if the Secretary of Health or his or her
5 designee determines that such prescription drugs represent a
6 threat to the public health. The owner of any property seized
7 under this section may, within 10 days after the seizure,
8 apply to a court of competent jurisdiction for whatever relief
9 is appropriate. At any time after 10 days, the department may
10 destroy the drugs as contraband.

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

22
23 For purposes of this section, a refusal to allow entry to the
24 department for inspection at reasonable times, or a failure or
25 refusal to provide the department with required documentation
26 for purposes of inspection, constitutes an imminent danger to
27 the public health.

28 Section 24. Subsection (1) of section 499.066, Florida
29 Statutes, is amended, and subsection (7) is added to that
30 section, to read:

31

1 499.066 Penalties; remedies.--In addition to other
2 penalties and other enforcement provisions:

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

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

19 Section 25. Section 499.0661, Florida Statutes, is
20 created to read:

21 499.0661 Cease and desist orders; removal of certain
22 persons.--

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

26 (2) CEASE AND DESIST ORDERS.--

27 (a) In addition to any authority otherwise provided in
28 this chapter, the department may issue and serve a complaint
29 stating charges upon any permittee or upon any affiliated
30 party, whenever the department has reasonable cause to believe
31

1 that the person or individual named therein is engaging in or
2 has engaged in conduct that is:

3 1. An act that demonstrates a lack of fitness or
4 trustworthiness to engage in the business authorized under the
5 permit issued pursuant to ss. 499.001-499.081, is hazardous to
6 the public health, or constitutes business operations that are
7 a detriment to the public health;

8 2. A violation of any provision of ss.
9 499.001-499.081;

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

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

12 5. A breach of any written agreement with the
13 department.

14 (b) The complaint must contain a statement of facts
15 and notice of opportunity for a hearing pursuant to ss.
16 120.569 and 120.57.

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

25 (d) A contested or default cease and desist order is
26 effective when reduced to writing and served upon the
27 permittee or affiliated party named therein. An uncontested
28 cease and desist order is effective as agreed.

29 (e) Whenever the department finds that conduct
30 described in paragraph (a) is likely to cause an immediate
31 threat to the public health, it may issue an emergency cease

1 and desist order requiring the permittee or any affiliated
2 party to immediately cease and desist from engaging in the
3 conduct complained of and to take corrective and remedial
4 action. The emergency order is effective immediately upon
5 service of a copy of the order upon the permittee or
6 affiliated party named therein and remains effective for 90
7 days. If the department begins nonemergency cease and desist
8 proceedings under this subsection, the emergency order remains
9 effective until the conclusion of the proceedings under ss.
10 120.569 and 120.57.

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

12 (a) The department may issue and serve a complaint
13 stating charges upon any affiliated party and upon the
14 permittee involved whenever the department has reason to
15 believe that an affiliated party is engaging in or has engaged
16 in conduct that constitutes:

17 1. An act that demonstrates a lack of fitness or
18 trustworthiness to engage in the business authorized under the
19 permit issued pursuant to ss. 499.001-499.081, is hazardous to
20 the public health, or constitutes business operations that are
21 a detriment to the public health;

22 2. A willful violation of ss. 499.001-499.081;
23 however, if the violation constitutes a misdemeanor, a
24 complaint may not be served as provided in this section until
25 the affiliated party is notified in writing of the matter of
26 the violation and has been afforded a reasonable period of
27 time, as set forth in the notice, to correct the violation and
28 has failed to do so;

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

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

1 5. A willful violation of any order of the department;
2 or

3 6. A material misrepresentation of fact, made
4 knowingly and willfully or made with reckless disregard for
5 the truth of the matter.

6 (b) The complaint must contain a statement of facts
7 and notice of opportunity for a hearing pursuant to ss.
8 120.569 and 120.57.

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

16 (d) A contested or default order of removal,
17 restriction, or prohibition is effective when reduced to
18 writing and served on the permittee and the affiliated party.
19 An uncontested order of removal, restriction, or prohibition
20 is effective as agreed.

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

26 2. Whenever any affiliated party is charged with a
27 felony in a state or federal court or with the equivalent of a
28 felony in the courts of any foreign country with which the
29 United States maintains diplomatic relations, and the charge
30 alleges violation of any law involving prescription drugs,
31 pharmaceuticals, fraud, theft, or moral turpitude, the

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

25 (f) Any affiliated party removed pursuant to this
26 section is not eligible for reemployment by the permittee or
27 to be an affiliated party of any permittee except upon the
28 written consent of the department. Any affiliated party who is
29 removed, restricted, or prohibited from participating in the
30 affairs of a permittee pursuant to this section may petition
31

1 the department for modification or termination of the removal,
2 restriction, or prohibition.

3 Section 26. Effective January 1, 2004, subsection (1)
4 of section 499.067, Florida Statutes, is amended, and
5 subsections (6) and (7) are added to that section, to read:

6 499.067 Denial, suspension, or revocation of permit,
7 certification, or registration.--

8 (1)(a) The department may deny, suspend, or revoke a
9 permit if it finds that there has been a substantial failure
10 to comply with ss. 499.001-499.081 or chapter 465, chapter
11 501, or chapter 893, the rules adopted under any of those
12 sections or chapters, any final order of the department, or
13 applicable federal laws or regulations or other state laws or
14 rules governing drugs, devices, or cosmetics.

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

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

22 2. The applicant has not met the requirements for the
23 permit or certification.

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

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

30
31

1 5. The applicant, permittee, or person certified under
2 s. 499.012(11) has committed any violation of ss.
3 499.005-499.0054.

4 (6) The department shall deny, suspend, or revoke the
5 permit of any person or establishment if the assignment, sale,
6 transfer, or lease of an establishment permitted under ss.
7 499.001-499.081 will avoid an administrative penalty, civil
8 action, or criminal prosecution.

9 (7) Notwithstanding s. 120.60(5), if a permittee fails
10 to comply with s. 499.01(7), the department may revoke the
11 permit of the permittee and shall provide notice of the
12 intended agency action by posting a notice at the department's
13 headquarters and by mailing a copy of the notice of intended
14 agency action by certified mail to the most recent mailing
15 address on record with the department and, if the permittee is
16 not a natural person, to the permittee's registered agent on
17 file with the Department of State.

18 Section 27. Section 499.069, Florida Statutes, is
19 amended to read:

20 499.069 Criminal punishment for violations of s.
21 499.005 related to devices and cosmetics; dissemination of
22 false advertisement.--

23 (1) Any person who violates any of the provisions of
24 s. 499.005 with respect to a device or cosmetic commits is
25 guilty of a misdemeanor of the second degree, punishable as
26 provided in s. 775.082 or s. 775.083; but, if the violation is
27 committed after a conviction of such person under this section
28 has become final, such person is guilty of a misdemeanor of
29 the first degree, punishable as provided in s. 775.082 or s.
30 775.083 or as otherwise provided in ss. 499.001-499.081,
31 except that any person who violates subsection (8), or

1 subsection (10), ~~subsection (14), subsection (15), or~~
2 ~~subsection (17)~~ of s. 499.005 with respect to a device or
3 cosmetic commits is guilty of a felony of the third degree,
4 punishable as provided in s. 775.082, s. 775.083, or s.
5 775.084, or as otherwise provided in ss. 499.001-499.081.

6 ~~(2) A person is not subject to the penalties of~~
7 ~~subsection (1) for having violated any of the provisions of s.~~
8 ~~499.005 if he or she establishes a guaranty or undertaking,~~
9 ~~which guaranty or undertaking is signed by and contains the~~
10 ~~name and address of the person residing in the state, or the~~
11 ~~manufacturer, from whom he or she received the article in good~~
12 ~~faith, to the effect that such article is not adulterated or~~
13 ~~misbranded within the meaning of ss. 499.001-499.081, citing~~
14 ~~such sections.~~

15 ~~(2)(3)~~ A publisher, radio broadcast licensee, or
16 agency or medium for the dissemination of an advertisement,
17 except the manufacturer, wholesaler, or seller of the article
18 to which a false advertisement relates, is not liable under
19 this section by reason of the dissemination by him or her of
20 such false advertisement, unless he or she has refused, on the
21 request of the department, to furnish to the department the
22 name and post office address of the manufacturer, wholesaler,
23 seller, or advertising agency that asked him or her to
24 disseminate such advertisement.

25 Section 28. Section 499.0691, Florida Statutes, is
26 created to read:

27 499.0691 Criminal punishment for violations related to
28 drugs; dissemination of false advertisement.--

29 (1) Any person who violates any of the following
30 provisions commits a misdemeanor of the second degree,
31 punishable as provided in s. 775.082 or s. 775.083; but, if

1 the violation is committed after a conviction of such person
2 under this section has become final, such person commits a
3 misdemeanor of the first degree, punishable as provided in s.
4 775.082 or s. 775.083, or as otherwise provided in ss.
5 499.001-499.081:

6 (a) The manufacture, repackaging, sale, delivery, or
7 holding or offering for sale of any drug that is adulterated
8 or misbranded or has otherwise been rendered unfit for human
9 or animal use.

10 (b) The adulteration or misbranding of any drug
11 intended for further distribution.

12 (c) The receipt of any drug that is adulterated or
13 misbranded, and the delivery or proffered delivery of such
14 drug, for pay or otherwise.

15 (d) The dissemination of any false or misleading
16 advertisement of a drug.

17 (e) The use, on the labeling of any drug or in any
18 advertisement relating to such drug, of any representation or
19 suggestion that an application of the drug is effective when
20 it is not or that the drug complies with ss. 499.001-499.081
21 when it does not.

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

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

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

31

1 (i) The possession of any drug in violation of ss.
2 499.001-499.081, except if the violation relates to a
3 deficiency in pedigree papers.

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

8 (a) The refusal or constructive refusal to allow:

9 1. The department to enter or inspect an establishment
10 in which drugs are manufactured, processed, repackaged, sold,
11 brokered, or held;

12 2. Inspection of any record of that establishment;

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

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

16 (b) The sale, purchase, or trade, or the offer to
17 sell, purchase, or trade, a drug sample as defined in s.
18 499.028; the distribution of a drug sample in violation of s.
19 499.028; or the failure to otherwise comply with s. 499.028.

20 (c) Providing the department with false or fraudulent
21 records, or making false or fraudulent statements, regarding
22 any matter within the provisions of this chapter related to a
23 drug.

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

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

30 (f) The wholesale distribution of any prescription
31 drug that was:

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

3 2. Donated or supplied at a reduced price to a
4 charitable organization.

5 (g) The failure to obtain a permit as a prescription
6 drug wholesaler when a permit is required by ss.
7 499.001-499.081 for that activity.

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

10 (i) The purchase or sale of prescription drugs for
11 wholesale distribution in exchange for currency, as defined in
12 s. 560.103(6).

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

17 (a) Knowingly manufacturing, repackaging, selling,
18 delivering, or holding or offering for sale any drug that is
19 adulterated or misbranded or has otherwise been rendered unfit
20 for human or animal use.

21 (b) Knowingly adulterating a drug that is intended for
22 further distribution.

23 (c) Knowingly receiving a drug that is adulterated and
24 delivering or proffering delivery of such drug for pay or
25 otherwise.

26 (d) Committing any act that causes a drug to be a
27 counterfeit drug, or selling, dispensing, or knowingly holding
28 for sale a counterfeit drug.

29 (e) Forging, counterfeiting, simulating, or falsely
30 representing any drug, or, without the authority of the
31 manufacturer, using any mark, stamp, tag, label, or other

1 identification device authorized or required by rules adopted
2 under ss. 499.001-499.081.

3 (f) Knowingly obtaining or attempting to obtain a
4 prescription drug for wholesale distribution by fraud, deceit,
5 misrepresentation, or subterfuge, or engaging in
6 misrepresentation or fraud in the distribution of a drug.

7 (g) Removing a pharmacy's dispensing label from a
8 dispensed prescription drug with the intent to further
9 distribute the prescription drug.

10 (h) Knowingly distributing a prescription drug that
11 was previously dispensed by a licensed pharmacy, unless such
12 distribution was authorized in chapter 465 or the rules
13 adopted under chapter 465.

14 (4) A publisher, radio broadcast licensee, or agency
15 or medium for the dissemination of an advertisement, except
16 the manufacturer, repackager, wholesaler, or seller of the
17 article to which a false advertisement relates, is not liable
18 under this section by reason of the dissemination by him or
19 her of such false advertisement, unless he or she has refused,
20 on the request of the department, to furnish to the department
21 the name and post office address of the manufacturer,
22 repackager, wholesaler, seller, or advertising agency that
23 asked him or her to disseminate such advertisement.

24 Section 29. Paragraphs (d), (f), (h), (i), and (j) of
25 subsection (3) of section 921.0022, Florida Statutes, are
26 amended to read:

27 921.0022 Criminal Punishment Code; offense severity
28 ranking chart.--

29 (3) OFFENSE SEVERITY RANKING CHART
30
31

1	Florida	Felony	
2	Statute	Degree	Description
3			
4			
5			(d) LEVEL 4
6	316.1935(3)	2nd	Driving at high speed or with
7			wanton disregard for safety while
8			fleeing or attempting to elude
9			law enforcement officer who is in
10			a marked patrol vehicle with
11			siren and lights activated.
12	<u>499.0051(1)</u>	<u>3rd</u>	<u>Failure to maintain or deliver</u>
13			<u>pedigree papers.</u>
14	<u>499.0051(2)</u>	<u>3rd</u>	<u>Failure to authenticate pedigree</u>
15			<u>papers.</u>
16	<u>499.0051(6)</u>	<u>2nd</u>	<u>Sale or delivery, or possession</u>
17			<u>with intent to sell, contraband</u>
18			<u>legend drugs.</u>
19	784.07(2)(b)	3rd	Battery of law enforcement
20			officer, firefighter, intake
21			officer, etc.
22	784.074(1)(c)	3rd	Battery of sexually violent
23			predators facility staff.
24	784.075	3rd	Battery on detention or
25			commitment facility staff.
26	784.078	3rd	Battery of facility employee by
27			throwing, tossing, or expelling
28			certain fluids or materials.
29	784.08(2)(c)	3rd	Battery on a person 65 years of
30			age or older.
31			

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1	784.081(3)	3rd	Battery on specified official or
2			employee.
3	784.082(3)	3rd	Battery by detained person on
4			visitor or other detainee.
5	784.083(3)	3rd	Battery on code inspector.
6	784.085	3rd	Battery of child by throwing,
7			tossing, projecting, or expelling
8			certain fluids or materials.
9	787.03(1)	3rd	Interference with custody;
10			wrongly takes child from
11			appointed guardian.
12	787.04(2)	3rd	Take, entice, or remove child
13			beyond state limits with criminal
14			intent pending custody
15			proceedings.
16	787.04(3)	3rd	Carrying child beyond state lines
17			with criminal intent to avoid
18			producing child at custody
19			hearing or delivering to
20			designated person.
21	790.115(1)	3rd	Exhibiting firearm or weapon
22			within 1,000 feet of a school.
23	790.115(2)(b)	3rd	Possessing electric weapon or
24			device, destructive device, or
25			other weapon on school property.
26	790.115(2)(c)	3rd	Possessing firearm on school
27			property.
28	800.04(7)(d)	3rd	Lewd or lascivious exhibition;
29			offender less than 18 years.
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31			

ENROLLED

2003 Legislature

CS for CS for SB 2312, 1st Engrossed

1	810.02(4)(a)	3rd	Burglary, or attempted burglary,
2			of an unoccupied structure;
3			unarmed; no assault or battery.
4	810.02(4)(b)	3rd	Burglary, or attempted burglary,
5			of an unoccupied conveyance;
6			unarmed; no assault or battery.
7	810.06	3rd	Burglary; possession of tools.
8	810.08(2)(c)	3rd	Trespass on property, armed with
9			firearm or dangerous weapon.
10	812.014(2)(c)3.	3rd	Grand theft, 3rd degree \$10,000
11			or more but less than \$20,000.
12	812.014		
13	(2)(c)4.-10.	3rd	Grand theft, 3rd degree, a will,
14			firearm, motor vehicle,
15			livestock, etc.
16	812.0195(2)	3rd	Dealing in stolen property by use
17			of the Internet; property stolen
18			\$300 or more.
19	817.563(1)	3rd	Sell or deliver substance other
20			than controlled substance agreed
21			upon, excluding s. 893.03(5)
22			drugs.
23	817.568(2)(a)	3rd	Fraudulent use of personal
24			identification information.
25	817.625(2)(a)	3rd	Fraudulent use of scanning device
26			or reencoder.
27	828.125(1)	2nd	Kill, maim, or cause great bodily
28			harm or permanent breeding
29			disability to any registered
30			horse or cattle.
31	837.02(1)	3rd	Perjury in official proceedings.

ENROLLED

2003 Legislature

CS for CS for SB 2312, 1st Engrossed

1	837.021(1)	3rd	Make contradictory statements in
2			official proceedings.
3	839.13(2)(a)	3rd	Falsifying records of an
4			individual in the care and
5			custody of a state agency.
6	839.13(2)(c)	3rd	Falsifying records of the
7			Department of Children and Family
8			Services.
9	843.021	3rd	Possession of a concealed
10			handcuff key by a person in
11			custody.
12	843.025	3rd	Deprive law enforcement,
13			correctional, or correctional
14			probation officer of means of
15			protection or communication.
16	843.15(1)(a)	3rd	Failure to appear while on bail
17			for felony (bond estreature or
18			bond jumping).
19	874.05(1)	3rd	Encouraging or recruiting another
20			to join a criminal street gang.
21	893.13(2)(a)1.	2nd	Purchase of cocaine (or other s.
22			893.03(1)(a), (b), or (d),
23			(2)(a), (2)(b), or (2)(c)4.
24			drugs).
25	914.14(2)	3rd	Witnesses accepting bribes.
26	914.22(1)	3rd	Force, threaten, etc., witness,
27			victim, or informant.
28	914.23(2)	3rd	Retaliation against a witness,
29			victim, or informant, no bodily
30			injury.
31	918.12	3rd	Tampering with jurors.

ENROLLED

2003 Legislature

CS for CS for SB 2312, 1st Engrossed

1	934.215	3rd	Use of two-way communications
2			device to facilitate commission
3			of a crime.
4			(f) LEVEL 6
5	316.027(1)(b)	2nd	Accident involving death, failure
6			to stop; leaving scene.
7	316.193(2)(b)	3rd	Felony DUI, 4th or subsequent
8			conviction.
9	<u>499.0051(3)</u>	<u>2nd</u>	<u>Forgery of pedigree papers.</u>
10	<u>499.0051(4)</u>	<u>2nd</u>	<u>Purchase or receipt of legend</u>
11			<u>drug from unauthorized person.</u>
12	<u>499.0051(5)</u>	<u>2nd</u>	<u>Sale of legend drug to</u>
13			<u>unauthorized person.</u>
14	775.0875(1)	3rd	Taking firearm from law
15			enforcement officer.
16	775.21(10)	3rd	Sexual predators; failure to
17			register; failure to renew
18			driver's license or
19			identification card.
20	784.021(1)(a)	3rd	Aggravated assault; deadly weapon
21			without intent to kill.
22	784.021(1)(b)	3rd	Aggravated assault; intent to
23			commit felony.
24	784.041	3rd	Felony battery.
25	784.048(3)	3rd	Aggravated stalking; credible
26			threat.
27	784.048(5)	3rd	Aggravated stalking of person
28			under 16.
29	784.07(2)(c)	2nd	Aggravated assault on law
30			enforcement officer.
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ENROLLED

2003 Legislature

CS for CS for SB 2312, 1st Engrossed

1	784.074(1)(b)	2nd	Aggravated assault on sexually
2			violent predators facility staff.
3	784.08(2)(b)	2nd	Aggravated assault on a person 65
4			years of age or older.
5	784.081(2)	2nd	Aggravated assault on specified
6			official or employee.
7	784.082(2)	2nd	Aggravated assault by detained
8			person on visitor or other
9			detainee.
10	784.083(2)	2nd	Aggravated assault on code
11			inspector.
12	787.02(2)	3rd	False imprisonment; restraining
13			with purpose other than those in
14			s. 787.01.
15	790.115(2)(d)	2nd	Discharging firearm or weapon on
16			school property.
17	790.161(2)	2nd	Make, possess, or throw
18			destructive device with intent to
19			do bodily harm or damage
20			property.
21	790.164(1)	2nd	False report of deadly explosive,
22			weapon of mass destruction, or
23			act of arson or violence to state
24			property.
25	790.19	2nd	Shooting or throwing deadly
26			missiles into dwellings, vessels,
27			or vehicles.
28	794.011(8)(a)	3rd	Solicitation of minor to
29			participate in sexual activity by
30			custodial adult.
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ENROLLED

2003 Legislature

CS for CS for SB 2312, 1st Engrossed

1	794.05(1)	2nd	Unlawful sexual activity with
2			specified minor.
3	800.04(5)(d)	3rd	Lewd or lascivious molestation;
4			victim 12 years of age or older
5			but less than 16 years; offender
6			less than 18 years.
7	800.04(6)(b)	2nd	Lewd or lascivious conduct;
8			offender 18 years of age or
9			older.
10	806.031(2)	2nd	Arson resulting in great bodily
11			harm to firefighter or any other
12			person.
13	810.02(3)(c)	2nd	Burglary of occupied structure;
14			unarmed; no assault or battery.
15	812.014(2)(b)1.	2nd	Property stolen \$20,000 or more,
16			but less than \$100,000, grand
17			theft in 2nd degree.
18	812.014(2)(b)2.	2nd	Property stolen; cargo valued at
19			less than \$50,000, grand theft in
20			2nd degree.
21	812.015(9)	2nd	Retail theft; property stolen
22			\$300 or more; second or
23			subsequent conviction.
24	812.13(2)(c)	2nd	Robbery, no firearm or other
25			weapon (strong-arm robbery).
26	817.034(4)(a)1.	1st	Communications fraud, value
27			greater than \$50,000.
28	817.4821(5)	2nd	Possess cloning paraphernalia
29			with intent to create cloned
30			cellular telephones.
31			

ENROLLED

2003 Legislature

CS for CS for SB 2312, 1st Engrossed

1	825.102(1)	3rd	Abuse of an elderly person or
2			disabled adult.
3	825.102(3)(c)	3rd	Neglect of an elderly person or
4			disabled adult.
5	825.1025(3)	3rd	Lewd or lascivious molestation of
6			an elderly person or disabled
7			adult.
8	825.103(2)(c)	3rd	Exploiting an elderly person or
9			disabled adult and property is
10			valued at less than \$20,000.
11	827.03(1)	3rd	Abuse of a child.
12	827.03(3)(c)	3rd	Neglect of a child.
13	827.071(2)&(3)	2nd	Use or induce a child in a sexual
14			performance, or promote or direct
15			such performance.
16	836.05	2nd	Threats; extortion.
17	836.10	2nd	Written threats to kill or do
18			bodily injury.
19	843.12	3rd	Aids or assists person to escape.
20	847.0135(3)	3rd	Solicitation of a child, via a
21			computer service, to commit an
22			unlawful sex act.
23	914.23	2nd	Retaliation against a witness,
24			victim, or informant, with bodily
25			injury.
26	943.0435(9)	3rd	Sex offenders; failure to comply
27			with reporting requirements.
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ENROLLED

2003 Legislature

CS for CS for SB 2312, 1st Engrossed

1	944.35(3)(a)2.	3rd	Committing malicious battery upon
2			or inflicting cruel or inhuman
3			treatment on an inmate or
4			offender on community
5			supervision, resulting in great
6			bodily harm.
7	944.40	2nd	Escapes.
8	944.46	3rd	Harboring, concealing, aiding
9			escaped prisoners.
10	944.47(1)(a)5.	2nd	Introduction of contraband
11			(firearm, weapon, or explosive)
12			into correctional facility.
13	951.22(1)	3rd	Intoxicating drug, firearm, or
14			weapon introduced into county
15			facility.
16			(h) LEVEL 8
17	316.193		
18	(3)(c)3.a.	2nd	DUI manslaughter.
19	327.35(3)(c)3.	2nd	Vessel BUI manslaughter.
20	<u>499.0051(7)</u>	<u>1st</u>	<u>Forgery of prescription or legend</u>
21			<u>drug labels.</u>
22	<u>499.0052</u>	<u>1st</u>	<u>Trafficking in contraband legend</u>
23			<u>drugs.</u>
24	560.123(8)(b)2.	2nd	Failure to report currency or
25			payment instruments totaling or
26			exceeding \$20,000, but less than
27			\$100,000 by money transmitter.
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ENROLLED

2003 Legislature

CS for CS for SB 2312, 1st Engrossed

1	560.125(5)(b)	2nd	Money transmitter business by
2			unauthorized person, currency or
3			payment instruments totaling or
4			exceeding \$20,000, but less than
5			\$100,000.
6	655.50(10)(b)2.	2nd	Failure to report financial
7			transactions totaling or
8			exceeding \$20,000, but less than
9			\$100,000 by financial
10			institutions.
11	777.03(2)(a)	1st	Accessory after the fact, capital
12			felony.
13	782.04(4)	2nd	Killing of human without design
14			when engaged in act or attempt of
15			any felony other than arson,
16			sexual battery, robbery,
17			burglary, kidnapping, aircraft
18			piracy, or unlawfully discharging
19			bomb.
20	782.051(2)	1st	Attempted felony murder while
21			perpetrating or attempting to
22			perpetrate a felony not
23			enumerated in s. 782.04(3).
24	782.071(1)(b)	1st	Committing vehicular homicide and
25			failing to render aid or give
26			information.
27	782.072(2)	1st	Committing vessel homicide and
28			failing to render aid or give
29			information.
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ENROLLED

2003 Legislature

CS for CS for SB 2312, 1st Engrossed

1	790.161(3)	1st	Discharging a destructive device
2			which results in bodily harm or
3			property damage.
4	794.011(5)	2nd	Sexual battery, victim 12 years
5			or over, offender does not use
6			physical force likely to cause
7			serious injury.
8	800.04(4)	2nd	Lewd or lascivious battery.
9	806.01(1)	1st	Maliciously damage dwelling or
10			structure by fire or explosive,
11			believing person in structure.
12	810.02(2)(a)	1st,PBL	Burglary with assault or battery.
13	810.02(2)(b)	1st,PBL	Burglary; armed with explosives
14			or dangerous weapon.
15	810.02(2)(c)	1st	Burglary of a dwelling or
16			structure causing structural
17			damage or \$1,000 or more property
18			damage.
19	812.13(2)(b)	1st	Robbery with a weapon.
20	812.135(2)	1st	Home-invasion robbery.
21	825.102(2)	2nd	Aggravated abuse of an elderly
22			person or disabled adult.
23	825.1025(2)	2nd	Lewd or lascivious battery upon
24			an elderly person or disabled
25			adult.
26	825.103(2)(a)	1st	Exploiting an elderly person or
27			disabled adult and property is
28			valued at \$100,000 or more.
29	837.02(2)	2nd	Perjury in official proceedings
30			relating to prosecution of a
31			capital felony.

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

2003 Legislature

CS for CS for SB 2312, 1st Engrossed

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

2003 Legislature

CS for CS for SB 2312, 1st Engrossed

1	895.03(1)	1st	Use or invest proceeds derived
2			from pattern of racketeering
3			activity.
4	895.03(2)	1st	Acquire or maintain through
5			racketeering activity any
6			interest in or control of any
7			enterprise or real property.
8	895.03(3)	1st	Conduct or participate in any
9			enterprise through pattern of
10			racketeering activity.
11	896.101(5)(b)	2nd	Money laundering, financial
12			transactions totaling or
13			exceeding \$20,000, but less than
14			\$100,000.
15	896.104(4)(a)2.	2nd	Structuring transactions to evade
16			reporting or registration
17			requirements, financial
18			transactions totaling or
19			exceeding \$20,000 but less than
20			\$100,000.
21			(i) LEVEL 9
22	316.193		
23	(3)(c)3.b.	1st	DUI manslaughter; failing to
24			render aid or give information.
25	327.35(3)(c)3.b.	1st	BUI manslaughter; failing to
26			render aid or give information.
27	<u>499.0053</u>	<u>1st</u>	<u>Sale or purchase of contraband</u>
28			<u>legend drugs resulting in great</u>
29			<u>bodily harm.</u>
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ENROLLED

2003 Legislature

CS for CS for SB 2312, 1st Engrossed

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

1	787.01(1)(a)4.	1st,PBL	Kidnapping with intent to
2			interfere with performance of any
3			governmental or political
4			function.
5	787.02(3)(a)	1st	False imprisonment; child under
6			age 13; perpetrator also commits
7			aggravated child abuse, sexual
8			battery, or lewd or lascivious
9			battery, molestation, conduct, or
10			exhibition.
11	790.161	1st	Attempted capital destructive
12			device offense.
13	790.166(2)	1st,PBL	Possessing, selling, using, or
14			attempting to use a weapon of
15			mass destruction.
16	794.011(2)	1st	Attempted sexual battery; victim
17			less than 12 years of age.
18	794.011(2)	Life	Sexual battery; offender younger
19			than 18 years and commits sexual
20			battery on a person less than 12
21			years.
22	794.011(4)	1st	Sexual battery; victim 12 years
23			or older, certain circumstances.
24	794.011(8)(b)	1st	Sexual battery; engage in sexual
25			conduct with minor 12 to 18 years
26			by person in familial or
27			custodial authority.
28	800.04(5)(b)	1st	Lewd or lascivious molestation;
29			victim less than 12 years;
30			offender 18 years or older.
31			

ENROLLED

2003 Legislature

CS for CS for SB 2312, 1st Engrossed

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

2003 Legislature

CS for CS for SB 2312, 1st Engrossed

1	893.135		
2	(1)(d)1.c.	1st	Trafficking in phencyclidine,
3			more than 400 grams.
4	893.135		
5	(1)(e)1.c.	1st	Trafficking in methaqualone, more
6			than 25 kilograms.
7	893.135		
8	(1)(f)1.c.	1st	Trafficking in amphetamine, more
9			than 200 grams.
10	893.135		
11	(1)(h)1.c.	1st	Trafficking in
12			gamma-hydroxybutyric acid (GHB),
13			10 kilograms or more.
14	893.135		
15	(1)(j)1.c.	1st	Trafficking in 1,4-Butanediol, 10
16			kilograms or more.
17	893.135		
18	(1)(k)2.c.	1st	Trafficking in Phenethylamines,
19			400 grams or more.
20	896.101(5)(c)	1st	Money laundering, financial
21			instruments totaling or exceeding
22			\$100,000.
23	896.104(4)(a)3.	1st	Structuring transactions to evade
24			reporting or registration
25			requirements, financial
26			transactions totaling or
27			exceeding \$100,000.
28			(j) LEVEL 10
29	<u>499.0054</u>	<u>1st</u>	<u>Sale or purchase of contraband</u>
30			<u>legend drugs resulting in death.</u>
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ENROLLED

2003 Legislature

CS for CS for SB 2312, 1st Engrossed

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

1 3. Any violation of the provisions of the Florida RICO
2 (Racketeer Influenced and Corrupt Organization) Act, including
3 any offense listed in the definition of racketeering activity
4 in s. 895.02(1)(a), providing such listed offense is
5 investigated in connection with a violation of s. 895.03 and
6 is charged in a separate count of an information or indictment
7 containing a count charging a violation of s. 895.03, the
8 prosecution of which listed offense may continue independently
9 if the prosecution of the violation of s. 895.03 is terminated
10 for any reason;

11 4. Any violation of the provisions of the Florida
12 Anti-Fencing Act;

13 5. Any violation of the provisions of the Florida
14 Antitrust Act of 1980, as amended;

15 6. Any crime involving, or resulting in, fraud or
16 deceit upon any person;

17 7. Any violation of s. 847.0135, relating to computer
18 pornography and child exploitation prevention, or any offense
19 related to a violation of s. 847.0135; ~~or~~

20 8. Any violation of the provisions of chapter 815; or

21 9. Any criminal violation of part I of chapter 499.

22

23 or any attempt, solicitation, or conspiracy to commit any of
24 the crimes specifically enumerated above. The office shall
25 have such power only when any such offense is occurring, or
26 has occurred, in two or more judicial circuits as part of a
27 related transaction, or when any such offense is connected
28 with an organized criminal conspiracy affecting two or more
29 judicial circuits.

30 Section 31. Paragraph (a) of subsection (1) of section
31 895.02, Florida Statutes, is amended to read:

1 895.02 Definitions.--As used in ss. 895.01-895.08, the
2 term:

3 (1) "Racketeering activity" means to commit, to
4 attempt to commit, to conspire to commit, or to solicit,
5 coerce, or intimidate another person to commit:

6 (a) Any crime which is chargeable by indictment or
7 information under the following provisions of the Florida
8 Statutes:

9 1. Section 210.18, relating to evasion of payment of
10 cigarette taxes.

11 2. Section 403.727(3)(b), relating to environmental
12 control.

13 3. Section 414.39, relating to public assistance
14 fraud.

15 4. Section 409.920, relating to Medicaid provider
16 fraud.

17 5. Section 440.105 or s. 440.106, relating to workers'
18 compensation.

19 6. Sections 499.0051, 499.0052, 499.0053, 499.0054,
20 and 499.0691, relating to crimes involving contraband and
21 adulterated drugs.

22 ~~7.6.~~ Part IV of chapter 501, relating to
23 telemarketing.

24 ~~8.7.~~ Chapter 517, relating to sale of securities and
25 investor protection.

26 ~~9.8.~~ Section 550.235, s. 550.3551, or s. 550.3605,
27 relating to dogracing and horseracing.

28 ~~10.9.~~ Chapter 550, relating to jai alai frontons.

29 ~~11.10.~~ Chapter 552, relating to the manufacture,
30 distribution, and use of explosives.

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1 ~~12.11.~~ Chapter 560, relating to money transmitters, if
2 the violation is punishable as a felony.

3 ~~13.12.~~ Chapter 562, relating to beverage law
4 enforcement.

5 ~~14.13.~~ Section 624.401, relating to transacting
6 insurance without a certificate of authority, s.
7 624.437(4)(c)1., relating to operating an unauthorized
8 multiple-employer welfare arrangement, or s. 626.902(1)(b),
9 relating to representing or aiding an unauthorized insurer.

10 ~~15.14.~~ Section 655.50, relating to reports of currency
11 transactions, when such violation is punishable as a felony.

12 ~~16.15.~~ Chapter 687, relating to interest and usurious
13 practices.

14 ~~17.16.~~ Section 721.08, s. 721.09, or s. 721.13,
15 relating to real estate timeshare plans.

16 ~~18.17.~~ Chapter 782, relating to homicide.

17 ~~19.18.~~ Chapter 784, relating to assault and battery.

18 ~~20.19.~~ Chapter 787, relating to kidnapping.

19 ~~21.20.~~ Chapter 790, relating to weapons and firearms.

20 ~~22.21.~~ Section 796.03, s. 796.04, s. 796.05, or s.
21 796.07, relating to prostitution.

22 ~~23.22.~~ Chapter 806, relating to arson.

23 ~~24.23.~~ Section 810.02(2)(c), relating to specified
24 burglary of a dwelling or structure.

25 ~~25.24.~~ Chapter 812, relating to theft, robbery, and
26 related crimes.

27 ~~26.25.~~ Chapter 815, relating to computer-related
28 crimes.

29 ~~27.26.~~ Chapter 817, relating to fraudulent practices,
30 false pretenses, fraud generally, and credit card crimes.

31

1 ~~28.27.~~ Chapter 825, relating to abuse, neglect, or
2 exploitation of an elderly person or disabled adult.
3 ~~29.28.~~ Section 827.071, relating to commercial sexual
4 exploitation of children.
5 ~~30.29.~~ Chapter 831, relating to forgery and
6 counterfeiting.
7 ~~31.30.~~ Chapter 832, relating to issuance of worthless
8 checks and drafts.
9 ~~32.31.~~ Section 836.05, relating to extortion.
10 ~~33.32.~~ Chapter 837, relating to perjury.
11 ~~34.33.~~ Chapter 838, relating to bribery and misuse of
12 public office.
13 ~~35.34.~~ Chapter 843, relating to obstruction of
14 justice.
15 ~~36.35.~~ Section 847.011, s. 847.012, s. 847.013, s.
16 847.06, or s. 847.07, relating to obscene literature and
17 profanity.
18 ~~37.36.~~ Section 849.09, s. 849.14, s. 849.15, s.
19 849.23, or s. 849.25, relating to gambling.
20 ~~38.37.~~ Chapter 874, relating to criminal street gangs.
21 ~~39.38.~~ Chapter 893, relating to drug abuse prevention
22 and control.
23 ~~40.39.~~ Chapter 896, relating to offenses related to
24 financial transactions.
25 ~~41.40.~~ Sections 914.22 and 914.23, relating to
26 tampering with a witness, victim, or informant, and
27 retaliation against a witness, victim, or informant.
28 ~~42.41.~~ Sections 918.12 and 918.13, relating to
29 tampering with jurors and evidence.
30 Section 32. Section 905.34, Florida Statutes, is
31 amended to read:

1 905.34 Powers and duties; law applicable.--The
2 jurisdiction of a statewide grand jury impaneled under this
3 chapter shall extend throughout the state. The subject matter
4 jurisdiction of the statewide grand jury shall be limited to
5 the offenses of:

6 (1) Bribery, burglary, carjacking, home-invasion
7 robbery, criminal usury, extortion, gambling, kidnapping,
8 larceny, murder, prostitution, perjury, and robbery;

9 (2) Crimes involving narcotic or other dangerous
10 drugs;

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

21 (4) Any violation of the provisions of the Florida
22 Anti-Fencing Act;

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

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

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

28 (8) Any violation of s. 847.0135, s. 847.0137, or s.
29 847.0138 relating to computer pornography and child
30 exploitation prevention, or any offense related to a violation
31 of s. 847.0135, s. 847.0137, or s. 847.0138; or

1 (9) Any criminal violation of part I of chapter 499.
2
3 or any attempt, solicitation, or conspiracy to commit any
4 violation of the crimes specifically enumerated above, when
5 any such offense is occurring, or has occurred, in two or more
6 judicial circuits as part of a related transaction or when any
7 such offense is connected with an organized criminal
8 conspiracy affecting two or more judicial circuits. The
9 statewide grand jury may return indictments and presentments
10 irrespective of the county or judicial circuit where the
11 offense is committed or triable. If an indictment is
12 returned, it shall be certified and transferred for trial to
13 the county where the offense was committed. The powers and
14 duties of, and law applicable to, county grand juries shall
15 apply to a statewide grand jury except when such powers,
16 duties, and law are inconsistent with the provisions of ss.
17 905.31-905.40.

18 Section 33. If any provision of this act or its
19 application to any person or circumstance is held invalid, the
20 invalidity does not affect other provisions or applications of
21 the act which can be given effect without the invalid
22 provision or application, and to this end the provisions of
23 this act are severable.

24 Section 34. Except as otherwise expressly provided in
25 this act, this act shall take effect July 1, 2003.
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