```
A reviser's bill to be entitled
An act relating to the Florida Statutes; repealing ss.
29.0086, 29.014, 120.551, 215.18(2), 216.181(17),
218.503(6), 253.034(6)(f)2., 287.057(14)(b) and (25),
339.135(8), 375.041(6), 394.76(3)(b)2., 402.305(2)(q),
420.0005(2), 420.36(4)(d), 497.161(1)(g), 499.0051(2)(a),
499.0121(6)(d) and (e), and 1004.065, F.S., all of which
provisions have become inoperative by noncurrent repeal or
expiration and, pursuant to s. 11.242(5)(b) and (i), may
be omitted from the 2007 Florida Statutes only through a
reviser's bill duly enacted by the Legislature; amending
s. 29.008, F.S., to conform to the repeal of s. 29.0086,
F.S.; and amending ss. 499.003, 499.005, 499.012,
499.0121, 499.01211, 499.0122, 499.014, and 499.051, F.S.,
to conform to the repeal of s. 499.0121(6)(d) and (e),
F.S.
```

1718

1 2

3

4 5

6 7

8 9

10

11

12

13

14

15

16

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

19 20

Section 1. Section 29.0086, Florida Statutes, is repealed.

2122

23

Reviser's note.--The cited section, which relates to the Article V Technology Board, was repealed pursuant to its own terms, effective July 1, 2006.

242526

Section 2. Section 29.014, Florida Statutes, is repealed.

27

Reviser's note.--The cited section, which relates to the Article V Indigent Services Advisory Board was

28 29

Page 1 of 26

PCB RCC 07-02

repealed by s. 70, ch. 2005-236, Laws of Florida, effective July 1, 2006. Since the section was not repealed by a "current session" of the Legislature, it may be omitted from the 2007 Florida Statutes only through a reviser's bill duly enacted by the Legislature. See s. 11.242(5)(b) and (i).

Section 3. Section 120.551, Florida Statutes, is repealed.

Reviser's note.--The cited section, which relates to Internet publication of agency notices in the Florida Administrative Weekly, was repealed pursuant to its own terms, effective July 1, 2006.

Section 4. Subsection (2) of section 215.18, Florida Statutes, is repealed.

Reviser's note.--The cited subsection, which relates to extension of a repayment period, for the 2005-2006 fiscal year only, for certain funds to meet deficiencies resulting from 2004 hurricanes, expired pursuant to its own terms, effective July 1, 2006.

Section 5. Subsection (17) of section 216.181, Florida Statutes, is repealed.

Reviser's note.--The cited subsection, which relates to amendments to approved operating budgets authorizing the expenditure of moneys from the Working Capital Fund

Page 2 of 26

PCB RCC 07-02

as specifically authorized in the General Appropriations Act, expired pursuant to its own terms, effective July 1, 2006.

Section 6. Subsection (6) of section 218.503, Florida Statutes, is repealed.

Reviser's note.--The cited subsection, which relates to a discretionary per-vehicle surcharge by a governing authority of a municipality with a resident population of 300,000 or more on or after April 1, 1999, which has been declared in a state of financial emergency pursuant to s. 218.503, expired pursuant to its own terms, effective June 30, 2006.

Section 7. Subparagraph 2. of paragraph (f) of subsection (6) of section 253.034, Florida Statutes, is repealed.

Reviser's note.--The cited subparagraph, which relates to a requirement that certain surplus state lands that were acquired from a municipality for no consideration prior to 1958 must be first offered for reconveyance to the municipality at no cost, expired pursuant to its own terms, effective July 1, 2006.

Section 8. Paragraph (b) of subsection (14) and subsection (25) of section 287.057, Florida Statutes, are repealed.

Reviser's note. -- Paragraph (14)(b), which authorizes

Page 3 of 26

PCB RCC 07-02

the Department of Children and Family Services to enter into certain agreements with a private provider to finance, design, and construct a forensic treatment facility, expired pursuant to its own terms, effective July 1, 2006. Subsection (25), which authorizes the Department of Management Services to issue an invitation to negotiate to contract for specified additional beds for certain correctional facilities, for the 2005-2006 fiscal year only, expired pursuant to its own terms, effective July 1, 2006.

Section 9. Subsection (8) of section 339.135, Florida Statutes, is repealed.

Reviser's note.--The cited subsection, which relates to certain increased appropriations for projects funded within the Department of Transportation, expired pursuant to its own terms, effective July 1, 2006.

Section 10. Subsection (6) of section 375.041, Florida Statutes, is repealed.

Reviser's note.--The cited subsection, which authorizes appropriations of funds allocated to the Land Acquisition Trust Fund for water quality issues in the General Appropriations Act for the 2005-2006 fiscal year only, expired pursuant to its own terms, effective July 1, 2006.

Page 4 of 26

PCB RCC 07-02

Section 11. Subparagraph 2. of paragraph (b) of subsection (3) of section 394.76, Florida Statutes, is repealed.

Reviser's note.--The cited subparagraph, which requires a 75-to-25 state-to-local ratio for specified

contracted community alcohol and mental health services and programs for the 2005-2006 fiscal year only,

expired pursuant to its own terms, effective July 1,

2006.

126127

122123

124

125

Section 12. Paragraph (g) of subsection (2) of section 402.305, Florida Statutes, is repealed.

128129

130

131

132133

Reviser's note.--The cited paragraph, which requires the Department of Children and Family Services to provide at least one Child Care Competency Exam in Spanish during the 2005-2006 fiscal year, expired pursuant to its own terms, effective July 1, 2006.

134135

136

137

Section 13. Subsection (2) of section 420.0005, Florida Statutes, is repealed.

138139

140

141

142143

Reviser's note.--The cited subsection, which permits, for the 2005-2006 fiscal year only, any unappropriated balance in the State Housing Trust Fund in the Department of Community Affairs to be transferred by the General Appropriations Act to the Emergency Management Preparedness and Assistance Trust Fund, expired pursuant to its own terms, effective July 1,

144

Page 5 of 26

PCB RCC 07-02

PCB RCC 07-02 **ORIGINAL** 2006. 146 147 Section 14. Paragraph (d) of subsection (4) of section 148 420.36, Florida Statutes, is repealed. 149 150 Reviser's note. -- The cited paragraph, which authorizes 151 152 transfer, by the General Appropriations Act and for the 153 2005-2006 fiscal year only, of any unappropriated balance in the Energy Consumption Trust Fund to the 154 155 Emergency Management Preparedness and Assistance Trust 156 Fund, expired pursuant to its own terms, effective July 1, 2006. 157 158 159 Section 15. Paragraph (g) of subsection (1) of section 160 497.161, Florida Statutes, is repealed. 161 162 Reviser's note. -- The cited paragraph, which provides 163 for extraordinary rulemaking authority relating to the merging of chapters 470 and 497, specifies that the 164 165 rulemaking authority and rules adopted under that authority expired July 1, 2006. 166 167 168 Section 16. Paragraph (a) of subsection (2) of section 499.0051, Florida Statutes, is repealed. 169 170 Reviser's note. -- The cited paragraph, which relates to 171 failure to authenticate pedigree papers relating to 172

Page 6 of 26

similar provisions in paragraph (2)(b) effective July

legend drug distribution and which is replaced by

PCB RCC 07-02

173174

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

1, 2006, expired pursuant to its own terms, effective July 1, 2006.

176177

178

179

180

187

188

189 190

191

192

193194

195

196

197

198

199200

201

202203

distribution records.

175

Section 17. Paragraphs (d) and (e) of subsection (6) of section 499.0121, Florida Statutes, are repealed, and paragraphs (f), (g), and (h) of that subsection are amended to read:

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

- (6) RECORDKEEPING.--The department shall adopt rules that require keeping such records of prescription drugs as are
- necessary for the protection of the public health.
- $\underline{(d)}$ (f)1. Effective July 1, 2006, each person who is engaged in the wholesale distribution of a prescription drug and who is not the manufacturer of that drug must, before each wholesale distribution of such drug, provide to the person who receives the drug a pedigree paper as defined in s. 499.003(31).
 - 2. A repackager must comply with this paragraph.
- 3. The pedigree paper requirements in this paragraph do not apply to compressed medical gases or veterinary legend drugs.
- 4. Each wholesale distributor of prescription drugs must maintain separate and distinct from other required records all statements that are required under subparagraph 1.
- 5. In order to verify compliance with subparagraph (d)1., each manufacturer of a prescription drug sold in this state must

Page 7 of 26

make available upon request distribution documentation related to its sales of prescription drugs, regardless of whether the prescription drug was sold directly by the manufacturer to a person in Florida.

- 5.6. Subparagraph 1. is satisfied when a wholesale distributor takes title to, but not possession of, a prescription drug and the prescription drug's manufacturer ships the prescription drug directly to a person authorized by law to purchase prescription drugs for the purpose of administering or dispensing the drug, as defined in s. 465.003, or a member of an affiliated group, as described in paragraph (f)(h), with the exception of a repackager.
- a. The wholesale distributor must deliver to the recipient of the prescription drug, within 14 days after the shipment notification from the manufacturer, an invoice and the following sworn statement: "This wholesale distributor purchased the specific unit of the prescription drug listed on the invoice directly from the manufacturer, and the specific unit of prescription drug was shipped by the manufacturer directly to a person authorized by law to administer or dispense the legend drug, as defined in s. 465.003, Florida Statutes, or a member of an affiliated group, as described in s. 499.0121(6)(f) 499.0121(6)(h), Florida Statutes, with the exception of a repackager." The invoice must contain a unique cross-reference to the shipping document sent by the manufacturer to the recipient of the prescription drug.
- b. The manufacturer of the prescription drug shipped directly to the recipient under this section must provide and the recipient of the prescription drug must acquire, within 14 days

Page 8 of 26

after receipt of the prescription drug, a shipping document from the manufacturer that contains, at a minimum:

- (I) The name and address of the manufacturer, including the point of origin of the shipment, and the names and addresses of the wholesaler and the purchaser.
- (II) The name of the prescription drug as it appears on the label.
- (III) The quantity, dosage form, and strength of the prescription drug.
 - (IV) The date of the shipment from the manufacturer.
- c. The wholesale distributor must also maintain and make available to the department, upon request, the lot number of such drug if not contained in the shipping document acquired by the recipient.
- 6.7. Failure of the manufacturer to provide, the recipient to acquire, or the wholesale distributor to deliver, the documentation required under subparagraph 5.6. shall constitute failure to acquire or deliver a pedigree paper under s. 499.0051. Forgery by the manufacturer, the recipient, or the wholesale distributor of the documentation required to be acquired or delivered under subparagraph 5.6. shall constitute forgery of a pedigree paper under s. 499.0051.
- 7.8. The department may, by rule, specify alternatives to compliance with subparagraph 1. for a prescription drug in the inventory of a permitted prescription drug wholesaler as of June 30, 2006, and the return of a prescription drug purchased prior to July 1, 2006. The department may specify time limits for such alternatives.
 - (e) (g) Each wholesale distributor, except for a

Page 9 of 26

manufacturer, shall annually provide the department with a written list of all wholesale distributors and manufacturers from whom the wholesale distributor purchases prescription drugs. A wholesale distributor, except a manufacturer, shall notify the department not later than 10 days after any change to either list. Such portions of the information required pursuant to this paragraph which are a trade secret, as defined in s. 812.081, shall be maintained by the department as trade secret information is required to be maintained under s. 499.051.

- (f)(h)1. This paragraph applies only to an affiliated group, as defined by s. 1504 of the Internal Revenue Code of 1986, as amended, which is composed of chain drug entities, including at least 50 retail pharmacies, warehouses, or repackagers, which are members of the same affiliated group, if the affiliated group:
- a. Discloses to the department the names of all its members; and
- b. Agrees in writing to provide records on prescription drug purchases by members of the affiliated group not later than 48 hours after the department requests such records, regardless of the location where the records are stored.
- 2. Each warehouse within the affiliated group must comply with all applicable federal and state drug wholesale permit requirements and must purchase, receive, hold, and distribute prescription drugs only to a retail pharmacy or warehouse within the affiliated group. Such a warehouse is exempt from providing a pedigree paper in accordance with <u>paragraph (d)</u> paragraphs (d), (e), and (f) to its affiliated group member warehouse or retail pharmacy, provided that:

- a. Any affiliated group member that purchases or receives a prescription drug from outside the affiliated group must receive a pedigree paper if the prescription drug is distributed in or into this state and a pedigree paper is required under this section and must authenticate the documentation as required in subsection (4), regardless of whether the affiliated group member is directly subject to regulation under this chapter; and
- b. The affiliated group makes available to the department on request all records related to the purchase or acquisition of prescription drugs by members of the affiliated group, regardless of the location where the records are stored, if the prescription drugs were distributed in or into this state.
- 3. If a repackager repackages prescription drugs solely for distribution to its affiliated group members for the exclusive distribution to and among retail pharmacies that are members of the affiliated group to which the repackager is a member:
 - a. The repackager must:
- (I) In lieu of the written statement required by paragraph (d), paragraph (e), or paragraph (f), for all repackaged prescription drugs distributed in or into this state, state in writing under oath with each distribution of a repackaged prescription drug to an affiliated group member warehouse or repackager: "All repackaged prescription drugs are purchased by the affiliated group directly from the manufacturer or from a prescription drug wholesaler that purchased the prescription drugs directly from the manufacturer.";
 - (II) Purchase all prescription drugs it repackages:
 - (A) Directly from the manufacturer; or
 - (B) From a prescription drug wholesaler that purchased the

prescription drugs directly from the manufacturer; and

(III) Maintain records in accordance with this section to
document that it purchased the prescription drugs directly from
the manufacturer or that its prescription drug wholesale supplier
purchased the prescription drugs directly from the manufacturer.

b. All members of the affiliated group must provide to agents of the department on request records of purchases by all members of the affiliated group of prescription drugs that have been repackaged, regardless of the location where the records are stored or where the repackager is located.

Reviser's note.--Paragraphs (6)(d) and (e), which relate to certain recordkeeping requirements for persons engaged in the manufacture or wholesale distribution of a prescription drug and placement of prescription drugs on a list of specified drugs, expired pursuant to their own terms, effective July 1, 2006. Paragraphs (6)(f), (g), and (h) are redesignated and amended to conform to the expiration of paragraphs (d) and (e).

Section 18. Section 1004.065, Florida Statutes, is repealed.

Reviser's note.--The cited section, which relates to a limitation on university and direct-support organization financings, expired pursuant to its own terms, effective July 1, 2006.

Page 12 of 26

PCB RCC 07-02

Section 19. Paragraph (f) of subsection (1) of section 29.008, Florida Statutes, is amended to read:

- 29.008 County funding of court-related functions .--
- (1) Counties are required by s. 14, Art. V of the State Constitution to fund the cost of communications services, existing radio systems, existing multiagency criminal justice information systems, and the cost of construction or lease, maintenance, utilities, and security of facilities for the circuit and county courts, public defenders' offices, state attorneys' offices, guardian ad litem offices, and the offices of the clerks of the circuit and county courts performing court-related functions. For purposes of this section, the term "circuit and county courts" shall include the offices and staffing of the guardian ad litem programs. The county designated under s. 35.05(1) as the headquarters for each appellate district shall fund these costs for the appellate division of the public defender's office in that county. For purposes of implementing these requirements, the term:
- (f) "Communications services" are defined as any reasonable and necessary transmission, emission, and reception of signs, signals, writings, images, and sounds of intelligence of any nature by wire, radio, optical, audio equipment, or other electromagnetic systems and includes all facilities and equipment owned, leased, or used by judges, clerks, public defenders, state attorneys, and all staff of the state courts system, state attorneys' offices, public defenders' offices, and clerks of the circuit and county courts performing court-related functions. Such system or services shall include, but not be limited to:
 - 1. Telephone system infrastructure, including computer

Page 13 of 26

lines, telephone switching equipment, and maintenance, and facsimile equipment, wireless communications, cellular telephones, pagers, and video teleconferencing equipment and line charges. Each county shall continue to provide access to a local carrier for local and long distance service and shall pay toll charges for local and long distance service.

All computer networks, systems and equipment, including computer hardware and software, modems, printers, wiring, network connections, maintenance, support staff or services including any county-funded support staff located in the offices of the circuit court, county courts, state attorneys, and public defenders, training, supplies, and line charges necessary for an integrated computer system to support the operations and management of the state courts system, the offices of the public defenders, the offices of the state attorneys, and the offices of the clerks of the circuit and county courts and the capability to connect those entities and reporting data to the state as required for the transmission of revenue, performance accountability, case management, data collection, budgeting, and auditing purposes. The integrated computer system shall be operational by July 1, 2006, and, at a minimum, permit the exchange of financial, performance accountability, case management, case disposition, and other data across multiple state and county information systems involving multiple users at both the state level and within each judicial circuit and be able to electronically exchange judicial case background data, sentencing scoresheets, and video evidence information stored in integrated case management systems over secure networks. Once the integrated system becomes operational, counties may reject requests to

378

379380

381

382383

384 385

386

387

388

389

390 391

392

393

394

395

396397

398

399400

401

402403

404

405

purchase communication services included in this subparagraph not in compliance with standards, protocols, or processes adopted by the board established pursuant to s. 29.0086.

- Courier messenger and subpoena services.
- 4. Auxiliary aids and services for qualified individuals with a disability which are necessary to ensure access to the courts. Such auxiliary aids and services include, but are not limited to, sign language interpretation services required under the federal Americans with Disabilities Act other than services required to satisfy due-process requirements and identified as a state funding responsibility pursuant to ss. 29.004, 29.005, 29.006, and 29.007, real-time transcription services for individuals who are hearing impaired, and assistive listening devices and the equipment necessary to implement such accommodations.

Reviser's note.--Amended to delete language relating to compliance with standards, protocols, or processes adopted by the Article V Technology Board. Section 29.0086, which created the board, expired July 1, 2006; that expiration is confirmed by this act.

Section 20. Subsection (31) of section 499.003, Florida Statutes, is amended to read:

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

(31) "Pedigree paper" means:

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

Page 15 of 26

PCB RCC 07-02

(a) (b) 1. Effective July 1, 2006, a document or electronic form approved by the Department of Health and containing information that records each distribution of any given legend drug, from sale by a pharmaceutical manufacturer, through acquisition and sale by any wholesaler or repackager, until final sale to a pharmacy or other person administering or dispensing the drug. The information required to be included on the form approved by the department pursuant to this paragraph subparagraph must at least detail the amount of the legend drug; its dosage form and strength; its lot numbers; the name and address of each owner of the legend drug and his or her signature; its shipping information, including the name and address of each person certifying delivery or receipt of the legend drug; an invoice number, a shipping document number, or another number uniquely identifying the transaction; and a certification that the recipient wholesaler has authenticated the pedigree papers. If the manufacturer or repackager has uniquely serialized the individual legend drug unit, that identifier must also be included on the form approved pursuant to this paragraph subparagraph. It must also include the name, address, telephone number and, if available, e-mail contact information of each wholesaler involved in the chain of the legend drug's custody; or

(b) 2. A statement, under oath, in written or electronic form, confirming that a wholesale distributor purchases and receives the specific unit of the prescription drug directly from the manufacturer of the prescription drug and distributes the prescription drug directly, or through an intracompany transfer, to a chain pharmacy warehouse or a person authorized by law to purchase prescription drugs for the purpose of administering or

Page 16 of 26

PCB RCC 07-02

436

437

438

439 440

441

442443

444

445446

447

448449

450

451

452

453

454

455

456457

458

459

460

461

462

463464

dispensing the drug, as defined in s. 465.003. For purposes of this <u>subsection</u> paragraph, the term "chain pharmacy warehouse" means a wholesale distributor permitted pursuant to s. 499.01 that maintains a physical location for prescription drugs that functions solely as a central warehouse to perform intracompany transfers of such drugs to a member of its affiliated group as described in s. 499.0121(6)(f)1. 499.0121(6)(h)1.

- <u>1.a.</u> The information required to be included pursuant to this paragraph subparagraph must include:
- $\underline{a.(I)}$ The following statement: "This wholesale distributor purchased the specific unit of the prescription drug directly from the manufacturer."
- $\underline{\text{b.}(II)}$ The manufacturer's national drug code identifier and the name and address of the wholesaler and the purchaser of the prescription drug.
- $\underline{\text{c.}(\text{III})}$ The name of the prescription drug as it appears on the label.
- $\underline{\text{d.}}(\text{IV})$ The quantity, dosage form, and strength of the prescription drug.
- 2.b. The wholesale distributor must also maintain and make available to the department, upon request, the point of origin of the prescription drugs, including intracompany transfers; the date of the shipment from the manufacturer to the wholesale distributor; the lot numbers of such drugs; and the invoice numbers from the manufacturer.

The department may adopt rules and forms relating to the requirements of this subsection.

PCB RCC 07-02

Page 17 of 26

Reviser's note.--Amended to conform to the expiration of s. 499.0121(6)(d) and (e) by their own terms, effective July 1, 2006; those expirations are confirmed by this act.

Section 21. Subsection (29) of section 499.005, Florida Statutes, is amended to read:

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

(29) The receipt of a prescription drug pursuant to a wholesale distribution without either first receiving a pedigree paper that was attested to as accurate and complete by the wholesale distributor or complying with the provisions of s. $499.0121(6)(d)6. \frac{499.0121(6)(f)6}{}$

Reviser's note.--Amended to conform to the expiration of s. 499.0121(6)(d) and (e) by their own terms, effective July 1, 2006; those expirations are confirmed by this act.

- Section 22. Paragraphs (e), (f), (g), and (h) of subsection (2) of section 499.012, Florida Statutes, are amended to read:
- 499.012 Wholesale distribution; definitions; permits; applications; general requirements.--
- (2) The following types of wholesaler permits are established:
- (e) Nonresident prescription drug manufacturer permit.--A nonresident prescription drug manufacturer permit is required for

Page 18 of 26

PCB RCC 07-02

any person that is a manufacturer of prescription drugs, or the distribution point for a manufacturer of prescription drugs, and located outside of this state, or that is an entity to whom an approved new drug application has been issued by the United States Food and Drug Administration, or the contracted manufacturer of the approved new drug application holder, and located outside the United States, which engages in the wholesale distribution in this state of the prescription drugs it manufactures or is responsible for manufacturing. Each such manufacturer or entity must be permitted by the department and comply with all the provisions required of a wholesale distributor under ss. 499.001-499.081, except s. 499.0121(6)(d) $_{7}$ (e), or (f).

- 1. A person that distributes prescription drugs that it did not manufacture must also obtain an out-of-state prescription drug wholesaler permit pursuant to this section to engage in the wholesale distribution of the prescription drugs manufactured by another person and comply with the requirements of an out-of-state prescription drug wholesaler.
- 2. Any such person must comply with the licensing or permitting requirements of the jurisdiction in which the establishment is located and the federal act, and any product wholesaled into this state must comply with ss. 499.001-499.081. If a person intends to import prescription drugs from a foreign country into this state, the nonresident prescription drug manufacturer must provide to the department a list identifying each prescription drug it intends to import and document approval by the United States Food and Drug Administration for such importation.

- (f) Freight forwarder permit.--A freight forwarder permit is required for any person that engages in the distribution of a legend drug as a freight forwarder unless the person is a common carrier. The storage, handling, and recordkeeping of such distributions must comply with the requirements for wholesale distributors under s. 499.0121, except those set forth in s. 499.0121(6)(d), (e), or (f). A freight forwarder must provide the source of the legend drugs with a validated airway bill, bill of lading, or other appropriate documentation to evidence the exportation of the product.
- veterinary prescription drug wholesaler permit.--A veterinary prescription drug wholesaler permit is required for any person that engages in the distribution of veterinary prescription drugs in or into this state. A veterinary prescription drug wholesaler that also distributes prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which it did not manufacture must obtain a permit as a prescription drug wholesaler, an out-of-state prescription drug wholesaler, or a limited prescription drug veterinary wholesaler in lieu of the veterinary prescription drug wholesaler permit. A veterinary prescription drug wholesaler must comply with the requirements for wholesale distributors under s. 499.0121, except those set forth in s. 499.0121(6)(d)₇ (e), or (f).
- (h) Limited prescription drug veterinary wholesaler permit.--Unless engaging in the activities of and permitted as a prescription drug manufacturer, nonresident prescription drug manufacturer, prescription drug wholesaler, or out-of-state prescription drug wholesaler, a limited prescription drug

Page 20 of 26

PCB RCC 07-02

veterinary wholesaler permit is required for any person that engages in the distribution in or into this state of veterinary prescription drugs and prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act under the following conditions:

- 1. The person is engaged in the business of wholesaling prescription and veterinary legend drugs to persons:
- a. Licensed as veterinarians practicing on a full-time basis;
- b. Regularly and lawfully engaged in instruction in veterinary medicine;
- c. Regularly and lawfully engaged in law enforcement activities;
 - d. For use in research not involving clinical use; or
- e. For use in chemical analysis or physical testing or for purposes of instruction in law enforcement activities, research, or testing.
- 2. No more than 30 percent of total annual prescription drug sales may be prescription drugs approved for human use which are subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act.
- 3. The person is not permitted, licensed, or otherwise authorized in any state to wholesale prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act to any person who is authorized to sell, distribute, purchase, trade, or use these drugs on or for humans.
- 4. A limited prescription drug veterinary wholesaler that applies to the department for a new permit or the renewal of a permit must submit a bond of \$20,000, or other equivalent means

Page 21 of 26

PCB RCC 07-02

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

- 5. A limited prescription drug veterinary wholesaler must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident.
- 6. A limited prescription drug veterinary wholesaler must comply with the requirements for wholesale distributors under s. 499.0121, except that a limited prescription drug veterinary wholesaler is not required to provide a pedigree paper as required by s. $\underline{499.0121(6)(d)}$ $\underline{499.0121(6)(f)}$ upon the wholesale distribution of a prescription drug to a veterinarian.
- 7. A limited prescription drug veterinary wholesaler may not return to inventory for subsequent wholesale distribution any prescription drug subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which has been returned by a veterinarian.
 - 8. An out-of-state prescription drug wholesaler's permit or

a limited prescription drug veterinary wholesaler permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed to engage in the wholesale distribution of prescription drugs in its state of residence to a licensed limited prescription drug veterinary wholesaler in this state if both wholesalers conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of s. 499.0121(6) must be followed for this transaction.

Reviser's note.--Amended to conform to the expiration of s. 499.0121(6)(d) and (e) by their own terms, effective July 1, 2006; those expirations are confirmed by this act.

Section 23. Subsection (3) of section 499.01211, Florida Statutes, is amended to read:

499.01211 Drug Wholesaler Advisory Council.--

(3) The council shall review ss. 499.001-499.081 and the rules adopted to administer ss. 499.001-499.081 annually, provide input to the department regarding all proposed rules to administer ss. 499.001-499.081, make written recommendation to the secretary of the department regarding the listing of all specified drugs pursuant to s. 499.0121(6)(e), make recommendations to the department to improve the protection of the prescription drugs and public health, make recommendations to improve coordination with other states' regulatory agencies and the federal government concerning the wholesale distribution of drugs, and make recommendations to minimize the impact of

Page 23 of 26

PCB RCC 07-02

regulation of the wholesale distribution industry while ensuring protection of the public health.

Reviser's note.--Amended to conform to the expiration of s. 499.0121(6)(e) by its own terms, effective July 1, 2006; that expiration is confirmed by this act.

Section 24. Paragraph (c) of subsection (2) of section 499.0122, Florida Statutes, is amended to read:

499.0122 Medical oxygen and veterinary legend drug retail establishments; definitions, permits, general requirements.--

(2)

(c) A retail establishment must comply with all of the wholesale distribution requirements of s. 499.0121 except those set forth in s. 499.0121(6)(d).

Reviser's note.--Amended to conform to the expiration of s. 499.0121(6)(d) by its own terms, effective July 1, 2006; that expiration is confirmed by this act.

Section 25. Subsection (3) of section 499.014, Florida Statutes, is amended to read:

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

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

Page 24 of 26

PCB RCC 07-02

697

698699

700 701 Reviser's note.--Amended to conform to the expiration of s. 499.0121(6)(d) and (e) by their own terms, effective July 1, 2006; those expirations are confirmed by this act.

702703

704

705

706

707

708

709

710

711

712

713

714

715

716

717

718

719

720

721722

Section 26. Subsection (7) of section 499.051, Florida Statutes, is amended to read:

499.051 Inspections and investigations.--

The complaint and all information obtained pursuant to the investigation by the department are confidential and exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I of the State Constitution until the investigation and the enforcement action are completed. However, trade secret information contained therein as defined by s. 812.081(1)(c) shall remain confidential and exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I of the State Constitution, as long as the information is retained by the department. This subsection does not prohibit the department from using such information for regulatory or enforcement proceedings under this chapter or from providing such information to any law enforcement agency or any other regulatory However, the receiving agency shall keep such records agency. confidential and exempt as provided in this subsection. addition, this subsection is not intended to prevent compliance with the provisions of s. 499.0121(6)(d), $\frac{(e)}{}$, or $\frac{(f)}{}$, and the pedigree papers required in that subsection shall not be deemed a trade secret.

724725

723

Reviser's note.--Amended to conform to the expiration

Page 25 of 26

PCB RCC 07-02

of s. 499.0121(6)(d) and (e) by their own terms, effective July 1, 2006; those expirations are confirmed by this act.

729 730

731

732

726

727

728

Section 27. This act shall take effect on the 60th day after adjournment sine die of the session of the Legislature in which enacted.

Page 26 of 26