

By Senator King

rb07sa-07

1 A reviser's bill to be entitled
2 An act relating to the Florida Statutes;
3 repealing ss. 29.0086, 29.014, 120.551,
4 215.18(2), 216.181(17), 218.503(6),
5 253.034(6)(f)2., 287.057(14)(b) and (25),
6 339.135(8), 375.041(6), 394.76(3)(b)2.,
7 402.305(2)(g), 420.0005(2), 420.36(4)(d),
8 497.161(1)(g), 499.0051(2)(a), 499.0121(6)(d)
9 and (e), and 1004.065, F.S., all of which
10 provisions have become inoperative by
11 noncurrent repeal or expiration and, pursuant
12 to s. 11.242(5)(b) and (i), may be omitted from
13 the 2007 Florida Statutes only through a
14 reviser's bill duly enacted by the Legislature;
15 amending s. 29.008, F.S., to conform to the
16 repeal of s. 29.0086, F.S.; and amending ss.
17 499.003, 499.005, 499.012, 499.0121, 499.01211,
18 499.0122, 499.014, and 499.051, F.S., to
19 conform to the repeal of s. 499.0121(6)(d) and
20 (e), F.S.

21
22 Be It Enacted by the Legislature of the State of Florida:
23

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25 repealed.

26
27 Reviser's note.--The cited section, which
28 relates to the Article V Technology Board, was
29 repealed pursuant to its own terms, effective
30 July 1, 2006.
31

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2 repealed.

3
4 Reviser's note.--The cited section, which
5 relates to the Article V Indigent Services
6 Advisory Board was repealed by s. 70, ch.
7 2005-236, Laws of Florida, effective July 1,
8 2006. Since the section was not repealed by a
9 "current session" of the Legislature, it may be
10 omitted from the 2007 Florida Statutes only
11 through a reviser's bill duly enacted by the
12 Legislature. See s. 11.242(5)(b) and (i).

13
14 Section 3. Section 120.551, Florida Statutes, is
15 repealed.

16
17 Reviser's note.--The cited section, which
18 relates to Internet publication of agency
19 notices in the Florida Administrative Weekly,
20 was repealed pursuant to its own terms,
21 effective July 1, 2006.

22
23 Section 4. Subsection (2) of section 215.18, Florida
24 Statutes, is repealed.

25
26 Reviser's note.--The cited subsection, which
27 relates to extension of a repayment period, for
28 the 2005-2006 fiscal year only, for certain
29 funds to meet deficiencies resulting from 2004
30 hurricanes, expired pursuant to its own terms,
31 effective July 1, 2006.

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2 Statutes, is repealed.

3

4 Reviser's note.--The cited subsection, which
5 relates to amendments to approved operating
6 budgets authorizing the expenditure of moneys
7 from the Working Capital Fund as specifically
8 authorized in the General Appropriations Act,
9 expired pursuant to its own terms, effective
10 July 1, 2006.

11

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

14

15 Reviser's note.--The cited subsection, which
16 relates to a discretionary per-vehicle
17 surcharge by a governing authority of a
18 municipality with a resident population of
19 300,000 or more on or after April 1, 1999,
20 which has been declared in a state of financial
21 emergency pursuant to s. 218.503, expired
22 pursuant to its own terms, effective June 30,
23 2006.

24

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

28

29 Reviser's note.--The cited subparagraph, which
30 relates to a requirement that certain surplus
31 state lands that were acquired from a

1 municipality for no consideration prior to 1958
2 must be first offered for reconveyance to the
3 municipality at no cost, expired pursuant to
4 its own terms, effective July 1, 2006.

5
6 Section 8. Paragraph (b) of subsection (14) and
7 subsection (25) of section 287.057, Florida Statutes, are
8 repealed.

9
10 Reviser's note.--Paragraph (14)(b), which
11 authorizes the Department of Children and
12 Family Services to enter into certain
13 agreements with a private provider to finance,
14 design, and construct a forensic treatment
15 facility, expired pursuant to its own terms,
16 effective July 1, 2006. Subsection (25), which
17 authorizes the Department of Management
18 Services to issue an invitation to negotiate to
19 contract for specified additional beds for
20 certain correctional facilities, for the
21 2005-2006 fiscal year only, expired pursuant to
22 its own terms, effective July 1, 2006.

23
24 Section 9. Subsection (8) of section 339.135, Florida
25 Statutes, is repealed.

26
27 Reviser's note.--The cited subsection, which
28 relates to certain increased appropriations for
29 projects funded within the Department of
30 Transportation, expired pursuant to its own
31 terms, effective July 1, 2006.

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

3
4 Reviser's note.--The cited subsection, which
5 authorizes appropriations of funds allocated to
6 the Land Acquisition Trust Fund for water
7 quality issues in the General Appropriations
8 Act for the 2005-2006 fiscal year only, expired
9 pursuant to its own terms, effective July 1,
10 2006.

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

15
16 Reviser's note.--The cited subparagraph, which
17 requires a 75-to-25 state-to-local ratio for
18 specified contracted community alcohol and
19 mental health services and programs for the
20 2005-2006 fiscal year only, expired pursuant to
21 its own terms, effective July 1, 2006.

22
23 Section 12. Paragraph (g) of subsection (2) of section
24 402.305, Florida Statutes, is repealed.

25
26 Reviser's note.--The cited paragraph, which
27 requires the Department of Children and Family
28 Services to provide at least one Child Care
29 Competency Exam in Spanish during the 2005-2006
30 fiscal year, expired pursuant to its own terms,
31 effective July 1, 2006.

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

3
4 Reviser's note.--The cited subsection, which
5 permits, for the 2005-2006 fiscal year only,
6 any unappropriated balance in the State Housing
7 Trust Fund in the Department of Community
8 Affairs to be transferred by the General
9 Appropriations Act to the Emergency Management
10 Preparedness and Assistance Trust Fund, expired
11 pursuant to its own terms, effective July 1,
12 2006.

13
14 Section 14. Paragraph (d) of subsection (4) of section
15 420.36, Florida Statutes, is repealed.

16
17 Reviser's note.--The cited paragraph, which
18 authorizes transfer, by the General
19 Appropriations Act and for the 2005-2006 fiscal
20 year only, of any unappropriated balance in the
21 Energy Consumption Trust Fund to the Emergency
22 Management Preparedness and Assistance Trust
23 Fund, expired pursuant to its own terms,
24 effective July 1, 2006.

25
26 Section 15. Paragraph (g) of subsection (1) of section
27 497.161, Florida Statutes, is repealed.

28
29 Reviser's note.--The cited paragraph, which
30 provides for extraordinary rulemaking authority
31 relating to the merging of chapters 470 and

1 497, specifies that the rulemaking authority
2 and rules adopted under that authority expired
3 July 1, 2006.
4

5 Section 16. Paragraph (a) of subsection (2) of section
6 499.0051, Florida Statutes, is repealed.
7

8 Reviser's note.--The cited paragraph, which
9 relates to failure to authenticate pedigree
10 papers relating to legend drug distribution and
11 which is replaced by similar provisions in
12 paragraph (2)(b) effective July 1, 2006,
13 expired pursuant to its own terms, effective
14 July 1, 2006.
15

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

20 499.0121 Storage and handling of prescription drugs;
21 recordkeeping.--The department shall adopt rules to implement
22 this section as necessary to protect the public health,
23 safety, and welfare. Such rules shall include, but not be
24 limited to, requirements for the storage and handling of
25 prescription drugs and for the establishment and maintenance
26 of prescription drug distribution records.

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

30 (d)~~(f)~~1. Effective July 1, 2006, each person who is
31 engaged in the wholesale distribution of a prescription drug

1 and who is not the manufacturer of that drug must, before each
2 wholesale distribution of such drug, provide to the person who
3 receives the drug a pedigree paper as defined in s.
4 499.003(31).

5 2. A repackager must comply with this paragraph.

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

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

12 ~~5. In order to verify compliance with subparagraph~~
13 ~~(d)1., each manufacturer of a prescription drug sold in this~~
14 ~~state must make available upon request distribution~~
15 ~~documentation related to its sales of prescription drugs,~~
16 ~~regardless of whether the prescription drug was sold directly~~
17 ~~by the manufacturer to a person in Florida.~~

18 ~~5.6.~~ Subparagraph 1. is satisfied when a wholesale
19 distributor takes title to, but not possession of, a
20 prescription drug and the prescription drug's manufacturer
21 ships the prescription drug directly to a person authorized by
22 law to purchase prescription drugs for the purpose of
23 administering or dispensing the drug, as defined in s.
24 465.003, or a member of an affiliated group, as described in
25 paragraph (f) ~~(h)~~, with the exception of a repackager.

26 a. The wholesale distributor must deliver to the
27 recipient of the prescription drug, within 14 days after the
28 shipment notification from the manufacturer, an invoice and
29 the following sworn statement: "This wholesale distributor
30 purchased the specific unit of the prescription drug listed on
31 the invoice directly from the manufacturer, and the specific

1 unit of prescription drug was shipped by the manufacturer
2 directly to a person authorized by law to administer or
3 dispense the legend drug, as defined in s. 465.003, Florida
4 Statutes, or a member of an affiliated group, as described in
5 s. 499.0121(6)(f) ~~499.0121(6)(h)~~, Florida Statutes, with the
6 exception of a repackager." The invoice must contain a unique
7 cross-reference to the shipping document sent by the
8 manufacturer to the recipient of the prescription drug.

9 b. The manufacturer of the prescription drug shipped
10 directly to the recipient under this section must provide and
11 the recipient of the prescription drug must acquire, within 14
12 days after receipt of the prescription drug, a shipping
13 document from the manufacturer that contains, at a minimum:

14 (I) The name and address of the manufacturer,
15 including the point of origin of the shipment, and the names
16 and addresses of the wholesaler and the purchaser.

17 (II) The name of the prescription drug as it appears
18 on the label.

19 (III) The quantity, dosage form, and strength of the
20 prescription drug.

21 (IV) The date of the shipment from the manufacturer.

22 c. The wholesale distributor must also maintain and
23 make available to the department, upon request, the lot number
24 of such drug if not contained in the shipping document
25 acquired by the recipient.

26 ~~6.7.~~ Failure of the manufacturer to provide, the
27 recipient to acquire, or the wholesale distributor to deliver,
28 the documentation required under subparagraph ~~5.6.~~ shall
29 constitute failure to acquire or deliver a pedigree paper
30 under s. 499.0051. Forgery by the manufacturer, the recipient,
31 or the wholesale distributor of the documentation required to

1 be acquired or delivered under subparagraph ~~5.6~~ shall
2 constitute forgery of a pedigree paper under s. 499.0051.

3 ~~7.8~~ The department may, by rule, specify alternatives
4 to compliance with subparagraph 1. for a prescription drug in
5 the inventory of a permitted prescription drug wholesaler as
6 of June 30, 2006, and the return of a prescription drug
7 purchased prior to July 1, 2006. The department may specify
8 time limits for such alternatives.

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

20 ~~(f)(h)~~1. This paragraph applies only to an affiliated
21 group, as defined by s. 1504 of the Internal Revenue Code of
22 1986, as amended, which is composed of chain drug entities,
23 including at least 50 retail pharmacies, warehouses, or
24 repackagers, which are members of the same affiliated group,
25 if the affiliated group:

26 a. Discloses to the department the names of all its
27 members; and

28 b. Agrees in writing to provide records on
29 prescription drug purchases by members of the affiliated group
30 not later than 48 hours after the department requests such
31

1 records, regardless of the location where the records are
2 stored.

3 2. Each warehouse within the affiliated group must
4 comply with all applicable federal and state drug wholesale
5 permit requirements and must purchase, receive, hold, and
6 distribute prescription drugs only to a retail pharmacy or
7 warehouse within the affiliated group. Such a warehouse is
8 exempt from providing a pedigree paper in accordance with
9 paragraph (d) ~~paragraphs (d), (e), and (f)~~ to its affiliated
10 group member warehouse or retail pharmacy, provided that:

11 a. Any affiliated group member that purchases or
12 receives a prescription drug from outside the affiliated group
13 must receive a pedigree paper if the prescription drug is
14 distributed in or into this state and a pedigree paper is
15 required under this section and must authenticate the
16 documentation as required in subsection (4), regardless of
17 whether the affiliated group member is directly subject to
18 regulation under this chapter; and

19 b. The affiliated group makes available to the
20 department on request all records related to the purchase or
21 acquisition of prescription drugs by members of the affiliated
22 group, regardless of the location where the records are
23 stored, if the prescription drugs were distributed in or into
24 this state.

25 3. If a repackager repackages prescription drugs
26 solely for distribution to its affiliated group members for
27 the exclusive distribution to and among retail pharmacies that
28 are members of the affiliated group to which the repackager is
29 a member:

30 a. The repackager must:
31

1 (I) In lieu of the written statement required by
2 paragraph (d), ~~paragraph (e), or paragraph (f)~~, for all
3 repackaged prescription drugs distributed in or into this
4 state, state in writing under oath with each distribution of a
5 repackaged prescription drug to an affiliated group member
6 warehouse or repackager: "All repackaged prescription drugs
7 are purchased by the affiliated group directly from the
8 manufacturer or from a prescription drug wholesaler that
9 purchased the prescription drugs directly from the
10 manufacturer.";

11 (II) Purchase all prescription drugs it repackages:

12 (A) Directly from the manufacturer; or

13 (B) From a prescription drug wholesaler that purchased
14 the prescription drugs directly from the manufacturer; and

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

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

25
26 Reviser's note.--Paragraphs (6)(d) and (e),
27 which relate to certain recordkeeping
28 requirements for persons engaged in the
29 manufacture or wholesale distribution of a
30 prescription drug and placement of prescription
31 drugs on a list of specified drugs, expired

1 pursuant to their own terms, effective July 1,
2 2006. Paragraphs (6)(f), (g), and (h) are
3 redesignated and amended to conform to the
4 expiration of paragraphs (d) and (e).

5
6 Section 18. Section 1004.065, Florida Statutes, is
7 repealed.

8
9 Reviser's note.--The cited section, which
10 relates to a limitation on university and
11 direct-support organization financings, expired
12 pursuant to its own terms, effective July 1,
13 2006.

14
15 Section 19. Paragraph (f) of subsection (1) of section
16 29.008, Florida Statutes, is amended to read:

17 29.008 County funding of court-related functions.--

18 (1) Counties are required by s. 14, Art. V of the
19 State Constitution to fund the cost of communications
20 services, existing radio systems, existing multiagency
21 criminal justice information systems, and the cost of
22 construction or lease, maintenance, utilities, and security of
23 facilities for the circuit and county courts, public
24 defenders' offices, state attorneys' offices, guardian ad
25 litem offices, and the offices of the clerks of the circuit
26 and county courts performing court-related functions. For
27 purposes of this section, the term "circuit and county courts"
28 shall include the offices and staffing of the guardian ad
29 litem programs. The county designated under s. 35.05(1) as the
30 headquarters for each appellate district shall fund these
31 costs for the appellate division of the public defender's

1 office in that county. For purposes of implementing these
2 requirements, the term:

3 (f) "Communications services" are defined as any
4 reasonable and necessary transmission, emission, and reception
5 of signs, signals, writings, images, and sounds of
6 intelligence of any nature by wire, radio, optical, audio
7 equipment, or other electromagnetic systems and includes all
8 facilities and equipment owned, leased, or used by judges,
9 clerks, public defenders, state attorneys, and all staff of
10 the state courts system, state attorneys' offices, public
11 defenders' offices, and clerks of the circuit and county
12 courts performing court-related functions. Such system or
13 services shall include, but not be limited to:

14 1. Telephone system infrastructure, including computer
15 lines, telephone switching equipment, and maintenance, and
16 facsimile equipment, wireless communications, cellular
17 telephones, pagers, and video teleconferencing equipment and
18 line charges. Each county shall continue to provide access to
19 a local carrier for local and long distance service and shall
20 pay toll charges for local and long distance service.

21 2. All computer networks, systems and equipment,
22 including computer hardware and software, modems, printers,
23 wiring, network connections, maintenance, support staff or
24 services including any county-funded support staff located in
25 the offices of the circuit court, county courts, state
26 attorneys, and public defenders, training, supplies, and line
27 charges necessary for an integrated computer system to support
28 the operations and management of the state courts system, the
29 offices of the public defenders, the offices of the state
30 attorneys, and the offices of the clerks of the circuit and
31 county courts and the capability to connect those entities and

1 reporting data to the state as required for the transmission
2 of revenue, performance accountability, case management, data
3 collection, budgeting, and auditing purposes. The integrated
4 computer system shall be operational by July 1, 2006, and, at
5 a minimum, permit the exchange of financial, performance
6 accountability, case management, case disposition, and other
7 data across multiple state and county information systems
8 involving multiple users at both the state level and within
9 each judicial circuit and be able to electronically exchange
10 judicial case background data, sentencing scoresheets, and
11 video evidence information stored in integrated case
12 management systems over secure networks. Once the integrated
13 system becomes operational, counties may reject requests to
14 purchase communication services included in this subparagraph
15 not in compliance with standards, protocols, or processes
16 adopted by the board established pursuant to former s.
17 29.0086.

18 3. Courier messenger and subpoena services.

19 4. Auxiliary aids and services for qualified
20 individuals with a disability which are necessary to ensure
21 access to the courts. Such auxiliary aids and services
22 include, but are not limited to, sign language interpretation
23 services required under the federal Americans with
24 Disabilities Act other than services required to satisfy
25 due-process requirements and identified as a state funding
26 responsibility pursuant to ss. 29.004, 29.005, 29.006, and
27 29.007, real-time transcription services for individuals who
28 are hearing impaired, and assistive listening devices and the
29 equipment necessary to implement such accommodations.

30
31

1 Reviser's note.--Amended to conform to the
2 expiration of s. 29.0086, effective July 1,
3 2006; that expiration is confirmed by this act.
4

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

7 499.003 Definitions of terms used in ss.
8 499.001-499.081.--As used in ss. 499.001-499.081, the term:

9 (31) "Pedigree paper" means:

10 ~~(a) A document required pursuant to s. 499.0121(6)(d)~~
11 ~~or (c); or~~

12 (a)(b)1. Effective July 1, 2006, a document or
13 electronic form approved by the Department of Health and
14 containing information that records each distribution of any
15 given legend drug, from sale by a pharmaceutical manufacturer,
16 through acquisition and sale by any wholesaler or repackager,
17 until final sale to a pharmacy or other person administering
18 or dispensing the drug. The information required to be
19 included on the form approved by the department pursuant to
20 this paragraph ~~subparagraph~~ must at least detail the amount of
21 the legend drug; its dosage form and strength; its lot
22 numbers; the name and address of each owner of the legend drug
23 and his or her signature; its shipping information, including
24 the name and address of each person certifying delivery or
25 receipt of the legend drug; an invoice number, a shipping
26 document number, or another number uniquely identifying the
27 transaction; and a certification that the recipient wholesaler
28 has authenticated the pedigree papers. If the manufacturer or
29 repackager has uniquely serialized the individual legend drug
30 unit, that identifier must also be included on the form
31 approved pursuant to this paragraph ~~subparagraph~~. It must also

1 include the name, address, telephone number and, if available,
2 e-mail contact information of each wholesaler involved in the
3 chain of the legend drug's custody; or

4 ~~(b)2-~~ A statement, under oath, in written or
5 electronic form, confirming that a wholesale distributor
6 purchases and receives the specific unit of the prescription
7 drug directly from the manufacturer of the prescription drug
8 and distributes the prescription drug directly, or through an
9 intracompany transfer, to a chain pharmacy warehouse or a
10 person authorized by law to purchase prescription drugs for
11 the purpose of administering or dispensing the drug, as
12 defined in s. 465.003. For purposes of this subsection
13 ~~paragraph~~, the term "chain pharmacy warehouse" means a
14 wholesale distributor permitted pursuant to s. 499.01 that
15 maintains a physical location for prescription drugs that
16 functions solely as a central warehouse to perform
17 intracompany transfers of such drugs to a member of its
18 affiliated group as described in s. 499.0121(6)(f)1.
19 ~~499.0121(6)(h)1.~~

20 1.a- The information required to be included pursuant
21 to this paragraph ~~subparagraph~~ must include:

22 a.(I) The following statement: "This wholesale
23 distributor purchased the specific unit of the prescription
24 drug directly from the manufacturer."

25 b.(II) The manufacturer's national drug code
26 identifier and the name and address of the wholesaler and the
27 purchaser of the prescription drug.

28 c.(III) The name of the prescription drug as it
29 appears on the label.

30 d.(IV) The quantity, dosage form, and strength of the
31 prescription drug.

1 ~~2.b.~~ The wholesale distributor must also maintain and
2 make available to the department, upon request, the point of
3 origin of the prescription drugs, including intracompany
4 transfers; the date of the shipment from the manufacturer to
5 the wholesale distributor; the lot numbers of such drugs; and
6 the invoice numbers from the manufacturer.

7
8 The department may adopt rules and forms relating to the
9 requirements of this subsection.

10
11 Reviser's note.--Amended to conform to the
12 expiration of s. 499.0121(6)(d) and (e) by
13 their own terms, effective July 1, 2006; those
14 expirations are confirmed by this act.

15
16 Section 21. Subsection (29) of section 499.005,
17 Florida Statutes, is amended to read:

18 499.005 Prohibited acts.--It is unlawful for a person
19 to perform or cause the performance of any of the following
20 acts in this state:

21 (29) The receipt of a prescription drug pursuant to a
22 wholesale distribution without either first receiving a
23 pedigree paper that was attested to as accurate and complete
24 by the wholesale distributor or complying with the provisions
25 of s. 499.0121(6)(d)5. ~~499.0121(6)(f)6.~~

26
27 Reviser's note.--Amended to conform to the
28 expiration of s. 499.0121(6)(d) and (e) by
29 their own terms, effective July 1, 2006; those
30 expirations are confirmed by this act.

1 Section 22. Paragraphs (e), (f), (g), and (h) of
2 subsection (2) of section 499.012, Florida Statutes, are
3 amended to read:

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

6 (2) The following types of wholesaler permits are
7 established:

8 (e) Nonresident prescription drug manufacturer
9 permit.--A nonresident prescription drug manufacturer permit
10 is required for any person that is a manufacturer of
11 prescription drugs, or the distribution point for a
12 manufacturer of prescription drugs, and located outside of
13 this state, or that is an entity to whom an approved new drug
14 application has been issued by the United States Food and Drug
15 Administration, or the contracted manufacturer of the approved
16 new drug application holder, and located outside the United
17 States, which engages in the wholesale distribution in this
18 state of the prescription drugs it manufactures or is
19 responsible for manufacturing. Each such manufacturer or
20 entity must be permitted by the department and comply with all
21 the provisions required of a wholesale distributor under ss.
22 499.001-499.081, except s. 499.0121(6)(d), ~~(e), or (f)~~.

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

29 2. Any such person must comply with the licensing or
30 permitting requirements of the jurisdiction in which the
31 establishment is located and the federal act, and any product

1 wholesaled into this state must comply with ss.
2 499.001-499.081. If a person intends to import prescription
3 drugs from a foreign country into this state, the nonresident
4 prescription drug manufacturer must provide to the department
5 a list identifying each prescription drug it intends to import
6 and document approval by the United States Food and Drug
7 Administration for such importation.

8 (f) Freight forwarder permit.--A freight forwarder
9 permit is required for any person that engages in the
10 distribution of a legend drug as a freight forwarder unless
11 the person is a common carrier. The storage, handling, and
12 recordkeeping of such distributions must comply with the
13 requirements for wholesale distributors under s. 499.0121,
14 except those set forth in s. 499.0121(6)(d), ~~(e), or (f)~~. A
15 freight forwarder must provide the source of the legend drugs
16 with a validated airway bill, bill of lading, or other
17 appropriate documentation to evidence the exportation of the
18 product.

19 (g) A veterinary prescription drug wholesaler
20 permit.--A veterinary prescription drug wholesaler permit is
21 required for any person that engages in the distribution of
22 veterinary prescription drugs in or into this state. A
23 veterinary prescription drug wholesaler that also distributes
24 prescription drugs subject to, defined by, or described by s.
25 503(b) of the Federal Food, Drug, and Cosmetic Act which it
26 did not manufacture must obtain a permit as a prescription
27 drug wholesaler, an out-of-state prescription drug wholesaler,
28 or a limited prescription drug veterinary wholesaler in lieu
29 of the veterinary prescription drug wholesaler permit. A
30 veterinary prescription drug wholesaler must comply with the
31

1 requirements for wholesale distributors under s. 499.0121,
2 except those set forth in s. 499.0121(6)(d), ~~(e), or (f)~~.

3 (h) Limited prescription drug veterinary wholesaler
4 permit.--Unless engaging in the activities of and permitted as
5 a prescription drug manufacturer, nonresident prescription
6 drug manufacturer, prescription drug wholesaler, or
7 out-of-state prescription drug wholesaler, a limited
8 prescription drug veterinary wholesaler permit is required for
9 any person that engages in the distribution in or into this
10 state of veterinary prescription drugs and prescription drugs
11 subject to, defined by, or described by s. 503(b) of the
12 Federal Food, Drug, and Cosmetic Act under the following
13 conditions:

14 1. The person is engaged in the business of
15 wholesaling prescription and veterinary legend drugs to
16 persons:

17 a. Licensed as veterinarians practicing on a full-time
18 basis;

19 b. Regularly and lawfully engaged in instruction in
20 veterinary medicine;

21 c. Regularly and lawfully engaged in law enforcement
22 activities;

23 d. For use in research not involving clinical use; or

24 e. For use in chemical analysis or physical testing or
25 for purposes of instruction in law enforcement activities,
26 research, or testing.

27 2. No more than 30 percent of total annual
28 prescription drug sales may be prescription drugs approved for
29 human use which are subject to, defined by, or described by s.
30 503(b) of the Federal Food, Drug, and Cosmetic Act.

31

1 3. The person is not permitted, licensed, or otherwise
2 authorized in any state to wholesale prescription drugs
3 subject to, defined by, or described by s. 503(b) of the
4 Federal Food, Drug, and Cosmetic Act to any person who is
5 authorized to sell, distribute, purchase, trade, or use these
6 drugs on or for humans.

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

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

28 6. A limited prescription drug veterinary wholesaler
29 must comply with the requirements for wholesale distributors
30 under s. 499.0121, except that a limited prescription drug
31 veterinary wholesaler is not required to provide a pedigree

1 | paper as required by s. 499.0121(6)(d) ~~499.0121(6)(f)~~ upon the
2 | wholesale distribution of a prescription drug to a
3 | veterinarian.

4 | 7. A limited prescription drug veterinary wholesaler
5 | may not return to inventory for subsequent wholesale
6 | distribution any prescription drug subject to, defined by, or
7 | described by s. 503(b) of the Federal Food, Drug, and Cosmetic
8 | Act which has been returned by a veterinarian.

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

20 |
21 | Reviser's note.--Amended to conform to the
22 | expiration of s. 499.0121(6)(d) and (e) by
23 | their own terms, effective July 1, 2006; those
24 | expirations are confirmed by this act.

25 |
26 | Section 23. Subsection (3) of section 499.01211,
27 | Florida Statutes, is amended to read:

28 | 499.01211 Drug Wholesaler Advisory Council.--

29 | (3) The council shall review ss. 499.001-499.081 and
30 | the rules adopted to administer ss. 499.001-499.081 annually,
31 | provide input to the department regarding all proposed rules

1 to administer ss. 499.001-499.081, ~~make written recommendation~~
2 ~~to the secretary of the department regarding the listing of~~
3 ~~all specified drugs pursuant to s. 499.0121(6)(e)~~, make
4 recommendations to the department to improve the protection of
5 the prescription drugs and public health, make recommendations
6 to improve coordination with other states' regulatory agencies
7 and the federal government concerning the wholesale
8 distribution of drugs, and make recommendations to minimize
9 the impact of regulation of the wholesale distribution
10 industry while ensuring protection of the public health.

11

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

16

17 Section 24. Paragraph (c) of subsection (2) of section
18 499.0122, Florida Statutes, is amended to read:

19 499.0122 Medical oxygen and veterinary legend drug
20 retail establishments; definitions, permits, general
21 requirements.--

22 (2)

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

26

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

31

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

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

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

10
11 Reviser's note.--Amended to conform to the
12 expiration of s. 499.0121(6)(d) and (e) by
13 their own terms, effective July 1, 2006; those
14 expirations are confirmed by this act.

15
16 Section 26. Subsection (7) of section 499.051, Florida
17 Statutes, is amended to read:

18 499.051 Inspections and investigations.--

19 (7) The complaint and all information obtained
20 pursuant to the investigation by the department are
21 confidential and exempt from the provisions of s. 119.07(1)
22 and s. 24(a), Art. I of the State Constitution until the
23 investigation and the enforcement action are completed.
24 However, trade secret information contained therein as defined
25 by s. 812.081(1)(c) shall remain confidential and exempt from
26 the provisions of s. 119.07(1) and s. 24(a), Art. I of the
27 State Constitution, as long as the information is retained by
28 the department. This subsection does not prohibit the
29 department from using such information for regulatory or
30 enforcement proceedings under this chapter or from providing
31 such information to any law enforcement agency or any other

1 regulatory agency. However, the receiving agency shall keep
2 such records confidential and exempt as provided in this
3 subsection. In addition, this subsection is not intended to
4 prevent compliance with the provisions of s. 499.0121(6)(d),
5 ~~(e), or (f),~~ and the pedigree papers required in that
6 subsection shall not be deemed a trade secret.

7
8 Reviser's note.--Amended to conform to the
9 expiration of s. 499.0121(6)(d) and (e) by
10 their own terms, effective July 1, 2006; those
11 expirations are confirmed by this act.

12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31