1	A reviser's bill to be entitled
2	An act relating to the Florida Statutes; repealing ss.
3	29.0086, 29.014, 120.551, 215.18(2), 216.181(17),
4	218.503(6), 253.034(6)(f)2., 287.057(14)(b) and (25),
5	339.135(8), 375.041(6), 394.76(3)(b)2., 402.305(2)(g),
6	420.0005(2), 420.36(4)(d), 497.161(1)(g), 499.0051(2)(a),
7	499.0121(6)(d) and (e), and 1004.065, F.S., all of which
8	provisions have become inoperative by noncurrent repeal or
9	expiration and, pursuant to s. 11.242(5)(b) and (i), may
10	be omitted from the 2007 Florida Statutes only through a
11	reviser's bill duly enacted by the Legislature; amending
12	s. 29.008, F.S., to conform to the repeal of s. 29.0086,
13	F.S.; and amending ss. 499.003, 499.005, 499.012,
14	499.0121, 499.01211, 499.0122, 499.014, and 499.051, F.S.,
15	to conform to the repeal of s. 499.0121(6)(d) and (e),
16	F.S.; providing an effective date.
17	
18	Be It Enacted by the Legislature of the State of Florida:
19	
20	Section 1. Section 29.0086, Florida Statutes, is repealed.
21	
22	Reviser's noteThe cited section, which relates to
23	the Article V Technology Board, was repealed pursuant
24	to its own terms, effective July 1, 2006.
25	
26	Section 2. Section 29.014, Florida Statutes, is repealed.
27	
28	Reviser's noteThe cited section, which relates to
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	v

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29	the Article V Indigent Services Advisory Board was
30	repealed by s. 70, ch. 2005-236, Laws of Florida,
31	effective July 1, 2006. Since the section was not
32	repealed by a "current session" of the Legislature, it
33	may be omitted from the 2007 Florida Statutes only
34	through a reviser's bill duly enacted by the
35	Legislature. See s. 11.242(5)(b) and (i).
36	
37	Section 3. Section 120.551, Florida Statutes, is repealed.
38	
39	Reviser's noteThe cited section, which relates to
40	Internet publication of agency notices in the Florida
41	Administrative Weekly, was repealed pursuant to its
42	own terms, effective July 1, 2006.
43	
44	Section 4. Subsection (2) of section 215.18, Florida
45	Statutes, is repealed.
46	
47	Reviser's noteThe cited subsection, which relates
48	to extension of a repayment period, for the 2005-2006
49	fiscal year only, for certain funds to meet
50	deficiencies resulting from 2004 hurricanes, expired
51	pursuant to its own terms, effective July 1, 2006.
52	
53	Section 5. Subsection (17) of section 216.181, Florida
54	Statutes, is repealed.
55	
56	Reviser's noteThe cited subsection, which relates
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57 to amendments to approved operating budgets 58 authorizing the expenditure of moneys from the Working Capital Fund as specifically authorized in the General 59 60 Appropriations Act, expired pursuant to its own terms, effective July 1, 2006. 61 62 Subsection (6) of section 218.503, Florida Section 6. 63 64 Statutes, is repealed. 65 Reviser's note. -- The cited subsection, which relates 66 67 to a discretionary per-vehicle surcharge by a governing authority of a municipality with a resident 68 69 population of 300,000 or more on or after April 1, 70 1999, which has been declared in a state of financial emergency pursuant to s. 218.503, expired pursuant to 71 its own terms, effective June 30, 2006. 72 73 74 Section 7. Subparagraph 2. of paragraph (f) of subsection 75 (6) of section 253.034, Florida Statutes, is repealed. 76 77 Reviser's note. -- The cited subparagraph, which relates to a requirement that certain surplus state lands that 78 79 were acquired from a municipality for no consideration 80 prior to 1958 must be first offered for reconveyance to the municipality at no cost, expired pursuant to 81 its own terms, effective July 1, 2006. 82 83 84 Section 8. Paragraph (b) of subsection (14) and subsection Page 3 of 27

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85 (25) of section 287.057, Florida Statutes, are repealed. 86 Reviser's note.--Paragraph (14)(b), which authorizes 87 the Department of Children and Family Services to 88 enter into certain agreements with a private provider 89 90 to finance, design, and construct a forensic treatment facility, expired pursuant to its own terms, effective 91 92 July 1, 2006. Subsection (25), which authorizes the Department of Management Services to issue an 93 invitation to negotiate to contract for specified 94 95 additional beds for certain correctional facilities, for the 2005-2006 fiscal year only, expired pursuant 96 97 to its own terms, effective July 1, 2006. 98 Subsection (8) of section 339.135, Florida 99 Section 9. Statutes, is repealed. 100 101 102 Reviser's note. -- The cited subsection, which relates 103 to certain increased appropriations for projects 104 funded within the Department of Transportation, expired pursuant to its own terms, effective July 1, 105 106 2006. 107 108 Section 10. Subsection (6) of section 375.041, Florida 109 Statutes, is repealed. 110 111 Reviser's note.--The cited subsection, which 112 authorizes appropriations of funds allocated to the

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113	Land Acquisition Trust Fund for water quality issues
114	in the General Appropriations Act for the 2005-2006
115	fiscal year only, expired pursuant to its own terms,
116	effective July 1, 2006.
117	
118	Section 11. Subparagraph 2. of paragraph (b) of subsection
119	(3) of section 394.76, Florida Statutes, is repealed.
120	
121	Reviser's noteThe cited subparagraph, which
122	requires a 75-to-25 state-to-local ratio for specified
123	contracted community alcohol and mental health
124	services and programs for the 2005-2006 fiscal year
125	only, expired pursuant to its own terms, effective
126	July 1, 2006.
127	
128	Section 12. Paragraph (g) of subsection (2) of section
129	402.305, Florida Statutes, is repealed.
130	
131	Reviser's noteThe cited paragraph, which requires
132	the Department of Children and Family Services to
133	provide at least one Child Care Competency Exam in
134	Spanish during the 2005-2006 fiscal year, expired
135	pursuant to its own terms, effective July 1, 2006.
136	
137	Section 13. Subsection (2) of section 420.0005, Florida
138	Statutes, is repealed.
139	
140	Reviser's noteThe cited subsection, which permits,
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141 for the 2005-2006 fiscal year only, any unappropriated 142 balance in the State Housing Trust Fund in the Department of Community Affairs to be transferred by 143 the General Appropriations Act to the Emergency 144 Management Preparedness and Assistance Trust Fund, 145 expired pursuant to its own terms, effective July 1, 146 147 2006. 148 Section 14. Paragraph (d) of subsection (4) of section 149 150 420.36, Florida Statutes, is repealed. 151 152 Reviser's note.--The cited paragraph, which authorizes 153 transfer, by the General Appropriations Act and for the 2005-2006 fiscal year only, of any unappropriated 154 balance in the Energy Consumption Trust Fund to the 155 156 Emergency Management Preparedness and Assistance Trust Fund, expired pursuant to its own terms, effective 157 158 July 1, 2006. 159 160 Section 15. Paragraph (g) of subsection (1) of section 161 497.161, Florida Statutes, is repealed. 162 Reviser's note. -- The cited paragraph, which provides 163 for extraordinary rulemaking authority relating to the 164 165 merging of chapters 470 and 497, specifies that the 166 rulemaking authority and rules adopted under that 167 authority expired July 1, 2006. 168

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169Section 16. Paragraph (a) of subsection (2) of section170499.0051, Florida Statutes, is repealed.

172 Reviser's note.--The cited paragraph, which relates to 173 failure to authenticate pedigree papers relating to 174 legend drug distribution and which is replaced by 175 similar provisions in paragraph (2)(b) effective July 176 1, 2006, expired pursuant to its own terms, effective July 1, 2006.

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 distribution records.

(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.

(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).

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2. A repackager must comply with this paragraph.

198 3. The pedigree paper requirements in this paragraph do
199 not apply to compressed medical gases or veterinary legend
200 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.

204 5. In order to verify compliance with subparagraph (d)1., 205 each manufacturer of a prescription drug sold in this state must 206 make available upon request distribution documentation related 207 to its sales of prescription drugs, regardless of whether the 208 prescription drug was sold directly by the manufacturer to a 209 person in Florida.

210 5.6. Subparagraph 1. is satisfied when a wholesale 211 distributor takes title to, but not possession of, a prescription drug and the prescription drug's manufacturer ships 212 the prescription drug directly to a person authorized by law to 213 214 purchase prescription drugs for the purpose of administering or dispensing the drug, as defined in s. 465.003, or a member of an 215 216 affiliated group, as described in paragraph (f) (h), with the 217 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

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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. <u>499.0121(6)(f)</u> <u>499.0121(6)(h)</u>, 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 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 onthe label.

(III) The quantity, dosage form, and strength of theprescription drug.

244

(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.

<u>6.7.</u> Failure of the manufacturer to provide, the recipient
 to acquire, or the wholesale distributor to deliver, the
 documentation required under subparagraph <u>5.6.</u> shall constitute
 failure to acquire or deliver a pedigree paper under s.

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499.0051. Forgery by the manufacturer, the recipient, or the wholesale distributor of the documentation required to be acquired or delivered under subparagraph <u>5.6</u>. shall constitute forgery of a pedigree paper under s. 499.0051.

257 <u>7.8.</u> The department may, by rule, specify alternatives to 258 compliance with subparagraph 1. for a prescription drug in the 259 inventory of a permitted prescription drug wholesaler as of June 260 30, 2006, and the return of a prescription drug purchased prior 261 to July 1, 2006. The department may specify time limits for such 262 alternatives.

263 (e) (g) Each wholesale distributor, except for a manufacturer, shall annually provide the department with a 264 265 written list of all wholesale distributors and manufacturers from whom the wholesale distributor purchases prescription 266 drugs. A wholesale distributor, except a manufacturer, shall 267 notify the department not later than 10 days after any change to 268 either list. Such portions of the information required pursuant 269 270 to this paragraph which are a trade secret, as defined in s. 271 812.081, shall be maintained by the department as trade secret 272 information is required to be maintained under s. 499.051.

273 <u>(f)(h)</u>1. This paragraph applies only to an affiliated 274 group, as defined by s. 1504 of the Internal Revenue Code of 275 1986, as amended, which is composed of chain drug entities, 276 including at least 50 retail pharmacies, warehouses, or 277 repackagers, which are members of the same affiliated group, if 278 the affiliated group:

a. Discloses to the department the names of all itsmembers; and

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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.

Each warehouse within the affiliated group must comply 285 2. with all applicable federal and state drug wholesale permit 286 287 requirements and must purchase, receive, hold, and distribute prescription drugs only to a retail pharmacy or warehouse within 288 289 the affiliated group. Such a warehouse is exempt from providing 290 a pedigree paper in accordance with paragraph (d) paragraphs 291 (d), (e), and (f) to its affiliated group member warehouse or retail pharmacy, provided that: 292

293 a. Any affiliated group member that purchases or receives 294 a prescription drug from outside the affiliated group must 295 receive a pedigree paper if the prescription drug is distributed 296 in or into this state and a pedigree paper is required under 297 this section and must authenticate the documentation as required 298 in subsection (4), regardless of whether the affiliated group 299 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.

305 3. If a repackager repackages prescription drugs solely 306 for distribution to its affiliated group members for the 307 exclusive distribution to and among retail pharmacies that are 308 members of the affiliated group to which the repackager is a

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309 member:

310

a. The repackager must:

(I) In lieu of the written statement required by paragraph 311 (d), paragraph (e), or paragraph (f), for all repackaged 312 prescription drugs distributed in or into this state, state in 313 writing under oath with each distribution of a repackaged 314 prescription drug to an affiliated group member warehouse or 315 316 repackager: "All repackaged prescription drugs are purchased by 317 the affiliated group directly from the manufacturer or from a prescription drug wholesaler that purchased the prescription 318 drugs directly from the manufacturer."; 319

320

(II) Purchase all prescription drugs it repackages:

321

(A) Directly from the manufacturer; or

(B) From a prescription drug wholesaler that purchased theprescription 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.

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Reviser's note.--Paragraphs (6)(d) and (e), which relate to certain recordkeeping requirements for

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337 persons engaged in the manufacture or wholesale 338 distribution of a prescription drug and placement of prescription drugs on a list of specified drugs, 339 expired pursuant to their own terms, effective July 1, 340 2006. Paragraphs (6)(f), (g), and (h) are redesignated 341 and amended to conform to the expiration of paragraphs 342 (d) and (e). 343 344 345 Section 18. Section 1004.065, Florida Statutes, is 346 repealed. 347 Reviser's note. -- The cited section, which relates to a 348 limitation on university and direct-support 349 organization financings, expired pursuant to its own 350 terms, effective July 1, 2006. 351 352 Section 19. Paragraph (f) of subsection (1) of section 353 354 29.008, Florida Statutes, is amended to read: 29.008 County funding of court-related functions .--355 356 (1)Counties are required by s. 14, Art. V of the State 357 Constitution to fund the cost of communications services, existing radio systems, existing multiagency criminal justice 358 359 information systems, and the cost of construction or lease, 360 maintenance, utilities, and security of facilities for the 361 circuit and county courts, public defenders' offices, state 362 attorneys' offices, quardian ad litem offices, and the offices 363 of the clerks of the circuit and county courts performing court-364 related functions. For purposes of this section, the term

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365 "circuit and county courts" shall include the offices and 366 staffing of the guardian ad litem programs. The county 367 designated under s. 35.05(1) as the headquarters for each 368 appellate district shall fund these costs for the appellate 369 division of the public defender's office in that county. For 370 purposes of implementing these requirements, the term:

371 (f) "Communications services" are defined as any 372 reasonable and necessary transmission, emission, and reception 373 of signs, signals, writings, images, and sounds of intelligence 374 of any nature by wire, radio, optical, audio equipment, or other 375 electromagnetic systems and includes all facilities and equipment owned, leased, or used by judges, clerks, public 376 377 defenders, state attorneys, and all staff of the state courts system, state attorneys' offices, public defenders' offices, and 378 379 clerks of the circuit and county courts performing court-related 380 functions. Such system or services shall include, but not be limited to: 381

1. Telephone system infrastructure, including computer 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.

389 2. All computer networks, systems and equipment, including 390 computer hardware and software, modems, printers, wiring, 391 network connections, maintenance, support staff or services 392 including any county-funded support staff located in the offices

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393 of the circuit court, county courts, state attorneys, and public 394 defenders, training, supplies, and line charges necessary for an integrated computer system to support the operations and 395 management of the state courts system, the offices of the public 396 397 defenders, the offices of the state attorneys, and the offices of the clerks of the circuit and county courts and the 398 capability to connect those entities and reporting data to the 399 400 state as required for the transmission of revenue, performance 401 accountability, case management, data collection, budgeting, and 402 auditing purposes. The integrated computer system shall be 403 operational by July 1, 2006, and, at a minimum, permit the 404 exchange of financial, performance accountability, case management, case disposition, and other data across multiple 405 406 state and county information systems involving multiple users at 407 both the state level and within each judicial circuit and be able to electronically exchange judicial case background data, 408 sentencing scoresheets, and video evidence information stored in 409 410 integrated case management systems over secure networks. Once 411 the integrated system becomes operational, counties may reject 412 requests to purchase communication services included in this subparagraph not in compliance with standards, protocols, or 413 414 processes adopted by the board established pursuant to former s. 415 29.0086.

416

3. Courier messenger and subpoena services.

417 4. Auxiliary aids and services for qualified individuals 418 with a disability which are necessary to ensure access to the 419 courts. Such auxiliary aids and services include, but are not 420 limited to, sign language interpretation services required under

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421 the federal Americans with Disabilities Act other than services 422 required to satisfy due-process requirements and identified as a 423 state funding responsibility pursuant to ss. 29.004, 29.005, 424 29.006, and 29.007, real-time transcription services for 425 individuals who are hearing impaired, and assistive listening 426 devices and the equipment necessary to implement such 427 accommodations.

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

432

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433 Section 20. Subsection (31) of section 499.003, Florida434 Statutes, is amended to read:

435 499.003 Definitions of terms used in ss. 499.001436 499.081.--As used in ss. 499.001-499.081, the term:

437

(31) "Pedigree paper" means:

438 (a) A document required pursuant to s. 499.0121(6)(d) or 439 (e); or

440 (a) (b) 1. Effective July 1, 2006, a document or electronic form approved by the Department of Health and containing 441 information that records each distribution of any given legend 442 drug, from sale by a pharmaceutical manufacturer, through 443 acquisition and sale by any wholesaler or repackager, until 444 445 final sale to a pharmacy or other person administering or 446 dispensing the drug. The information required to be included on 447 the form approved by the department pursuant to this paragraph subparagraph must at least detail the amount of the legend drug; 448

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449 its dosage form and strength; its lot numbers; the name and 450 address of each owner of the legend drug and his or her signature; its shipping information, including the name and 451 address of each person certifying delivery or receipt of the 452 legend drug; an invoice number, a shipping document number, or 453 another number uniquely identifying the transaction; and a 454 455 certification that the recipient wholesaler has authenticated 456 the pedigree papers. If the manufacturer or repackager has 457 uniquely serialized the individual legend drug unit, that 458 identifier must also be included on the form approved pursuant 459 to this paragraph subparagraph. It must also include the name, address, telephone number and, if available, e-mail contact 460 information of each wholesaler involved in the chain of the 461 462 legend drug's custody; or

(b)2. A statement, under oath, in written or electronic 463 464 form, confirming that a wholesale distributor purchases and receives the specific unit of the prescription drug directly 465 466 from the manufacturer of the prescription drug and distributes the prescription drug directly, or through an intracompany 467 468 transfer, to a chain pharmacy warehouse or a person authorized 469 by law to purchase prescription drugs for the purpose of 470 administering or dispensing the drug, as defined in s. 465.003. For purposes of this subsection paragraph, the term "chain 471 pharmacy warehouse" means a wholesale distributor permitted 472 pursuant to s. 499.01 that maintains a physical location for 473 474 prescription drugs that functions solely as a central warehouse 475 to perform intracompany transfers of such drugs to a member of its affiliated group as described in s. 499.0121(6)(f)1. 476

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477 499.0121(6)(h)1.

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478 <u>1.a.</u> The information required to be included pursuant to 479 this paragraph subparagraph must include:

480 <u>a.(I)</u> The following statement: "This wholesale distributor
 481 purchased the specific unit of the prescription drug directly
 482 from the manufacturer."

483 <u>b.(II)</u> The manufacturer's national drug code identifier 484 and the name and address of the wholesaler and the purchaser of 485 the prescription drug.

486 $\underline{c.(III)}$ The name of the prescription drug as it appears on 487 the label.

488 $\underline{d.}$ (IV) The quantity, dosage form, and strength of the 489 prescription drug.

490 <u>2.b.</u> The wholesale distributor must also maintain and make 491 available to the department, upon request, the point of origin 492 of the prescription drugs, including intracompany transfers; the 493 date of the shipment from the manufacturer to the wholesale 494 distributor; the lot numbers of such drugs; and the invoice 495 numbers from the manufacturer.

497 The department may adopt rules and forms relating to the498 requirements of this subsection.

500 Reviser's note.--Amended to conform to the expiration 501 of s. 499.0121(6)(d) and (e) by their own terms, 502 effective July 1, 2006; those expirations are 503 confirmed by this act.

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505 Section 21. Subsection (29) of section 499.005, Florida 506 Statutes, is amended to read:

507 499.005 Prohibited acts.--It is unlawful for a person to 508 perform or cause the performance of any of the following acts in 509 this state:

510 (29) The receipt of a prescription drug pursuant to a 511 wholesale distribution without either first receiving a pedigree 512 paper that was attested to as accurate and complete by the 513 wholesale distributor or complying with the provisions of s. 514 499.0121(6)(d)5. 499.0121(6)(f)6.

516 Reviser's note.--Amended to conform to the expiration 517 of s. 499.0121(6)(d) and (e) by their own terms, 518 effective July 1, 2006; those expirations are 519 confirmed by this act.

520

515

521 Section 22. Paragraphs (e), (f), (g), and (h) of 522 subsection (2) of section 499.012, Florida Statutes, are amended 523 to read:

524 499.012 Wholesale distribution; definitions; permits; 525 applications; general requirements.--

526 (2) The following types of wholesaler permits are527 established:

(e) Nonresident prescription drug manufacturer permit.--A
nonresident prescription drug manufacturer permit is required
for 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

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533 an approved new drug application has been issued by the United 534 States Food and Drug Administration, or the contracted manufacturer of the approved new drug application holder, and 535 located outside the United States, which engages in the 536 wholesale distribution in this state of the prescription drugs 537 538 it manufactures or is responsible for manufacturing. Each such manufacturer or entity must be permitted by the department and 539 540 comply with all the provisions required of a wholesale 541 distributor under ss. 499.001-499.081, except s. 499.0121(6)(d), 542 (e), or (f).

543 1. A person that distributes prescription drugs that it 544 did not manufacture must also obtain an out-of-state 545 prescription drug wholesaler permit pursuant to this section to 546 engage in the wholesale distribution of the prescription drugs 547 manufactured by another person and comply with the requirements 548 of an out-of-state prescription drug wholesaler.

Any such person must comply with the licensing or 549 2. 550 permitting requirements of the jurisdiction in which the 551 establishment is located and the federal act, and any product 552 wholesaled into this state must comply with ss. 499.001-499.081. 553 If a person intends to import prescription drugs from a foreign 554 country into this state, the nonresident prescription drug 555 manufacturer must provide to the department a list identifying 556 each prescription drug it intends to import and document 557 approval by the United States Food and Drug Administration for 558 such importation.

(f) Freight forwarder permit.--A freight forwarder permitis required for any person that engages in the distribution of a

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561 legend drug as a freight forwarder unless the person is a common 562 carrier. The storage, handling, and recordkeeping of such distributions must comply with the requirements for wholesale 563 distributors under s. 499.0121, except those set forth in s. 564 499.0121(6)(d), (e), or (f). A freight forwarder must provide 565 the source of the legend drugs with a validated airway bill, 566 567 bill of lading, or other appropriate documentation to evidence 568 the exportation of the product.

569 A veterinary prescription drug wholesaler permit. -- A (q) 570 veterinary prescription drug wholesaler permit is required for 571 any person that engages in the distribution of veterinary prescription drugs in or into this state. A veterinary 572 prescription drug wholesaler that also distributes prescription 573 drugs subject to, defined by, or described by s. 503(b) of the 574 575 Federal Food, Drug, and Cosmetic Act which it did not 576 manufacture must obtain a permit as a prescription drug 577 wholesaler, an out-of-state prescription drug wholesaler, or a 578 limited prescription drug veterinary wholesaler in lieu of the veterinary prescription drug wholesaler permit. A veterinary 579 580 prescription drug wholesaler must comply with the requirements for wholesale distributors under s. 499.0121, except those set 581 forth in s. 499.0121(6)(d), (e), or (f). 582

(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
veterinary wholesaler permit is required for any person that

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589	engages in the distribution in or into this state of veterinary
590	prescription drugs and prescription drugs subject to, defined
591	by, or described by s. 503(b) of the Federal Food, Drug, and
592	Cosmetic Act under the following conditions:
593	1. The person is engaged in the business of wholesaling
594	prescription and veterinary legend drugs to persons:
595	a. Licensed as veterinarians practicing on a full-time
596	basis;
597	b. Regularly and lawfully engaged in instruction in
598	veterinary medicine;
599	c. Regularly and lawfully engaged in law enforcement
600	activities;
601	d. For use in research not involving clinical use; or
602	e. For use in chemical analysis or physical testing or for
603	purposes of instruction in law enforcement activities, research,
604	or testing.
605	2. No more than 30 percent of total annual prescription
606	drug sales may be prescription drugs approved for human use
607	which are subject to, defined by, or described by s. 503(b) of
608	the Federal Food, Drug, and Cosmetic Act.
609	3. The person is not permitted, licensed, or otherwise
610	authorized in any state to wholesale prescription drugs subject
611	to, defined by, or described by s. 503(b) of the Federal Food,
612	Drug, and Cosmetic Act to any person who is authorized to sell,
613	distribute, purchase, trade, or use these drugs on or for
614	humans.

A limited prescription drug veterinary wholesaler that 4. applies to the department for a new permit or the renewal of a

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617 permit must submit a bond of \$20,000, or other equivalent means 618 of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial 619 institution, payable to the Florida Drug, Device, and Cosmetic 620 Trust Fund. The purpose of the bond is to secure payment of any 621 administrative penalties imposed by the department and any fees 622 623 and costs incurred by the department regarding that permit which 624 are authorized under state law and which the permittee fails to 625 pay 30 days after the fine or costs become final. The department 626 may make a claim against such bond or security until 1 year 627 after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in 628 ss. 499.001-499.081 which involves the permittee is concluded, 629 including any appeal, whichever occurs later. 630

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. <u>499.0121(6)(d)</u> <u>499.0121(6)(f)</u> 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

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645 been returned by a veterinarian.

646 An out-of-state prescription drug wholesaler's permit 8. or a limited prescription drug veterinary wholesaler permit is 647 not required for an intracompany sale or transfer of a 648 prescription drug from an out-of-state establishment that is 649 650 duly licensed to engage in the wholesale distribution of 651 prescription drugs in its state of residence to a licensed 652 limited prescription drug veterinary wholesaler in this state if 653 both wholesalers conduct wholesale distributions of prescription 654 drugs under the same business name. The recordkeeping 655 requirements of s. 499.0121(6) must be followed for this 656 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.

663 Section 23. Subsection (3) of section 499.01211, Florida664 Statutes, is amended to read:

665 499.01211 Drug Wholesaler Advisory Council.--666 (3) The council shall review ss. 499.001-499.081 and the 667 rules adopted to administer ss. 499.001-499.081 annually, 668 provide input to the department regarding all proposed rules to 669 administer ss. 499.001-499.081, make written recommendation to 670 the secretary of the department regarding the listing of all 671 specified drugs pursuant to s. 499.0121(6)(e), make recommendations to the department to improve the protection of 672

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673 the prescription drugs and public health, make recommendations 674 to improve coordination with other states' regulatory agencies 675 and the federal government concerning the wholesale distribution 676 of drugs, and make recommendations to minimize the impact of 677 regulation of the wholesale distribution industry while ensuring 678 protection of the public health.

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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.

684 Section 24. Paragraph (c) of subsection (2) of section685 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.

697 Section 25. Subsection (3) of section 499.014, Florida698 Statutes, is amended to read:

699 499.014 Distribution of legend drugs by hospitals, health700 care entities, charitable organizations, and return or

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FLORIDA HOUSE OF REPRESENTATIVE	F	L	0	R		D	А		Н	0	U	S	Е	0	F	R	Е	Р	R	Е	S	Е	Ν	Т	Α	Т		V	Е	S
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701	destruction companies; permits, general requirements
702	(3) Storage, handling, and recordkeeping of these
703	distributions must comply with the requirements for wholesale
704	distributors under s. 499.0121, except those set forth in s.
705	499.0121(6)(d) , (e), or (f) .
706	
707	Reviser's noteAmended to conform to the expiration
708	of s. 499.0121(6)(d) and (e) by their own terms,
709	effective July 1, 2006; those expirations are
710	confirmed by this act.
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712	Section 26. Subsection (7) of section 499.051, Florida
713	Statutes, is amended to read:
714	499.051 Inspections and investigations
715	(7) The complaint and all information obtained pursuant to
716	the investigation by the department are confidential and exempt
717	from the provisions of s. 119.07(1) and s. 24(a), Art. I of the
718	State Constitution until the investigation and the enforcement
719	action are completed. However, trade secret information
720	contained therein as defined by s. 812.081(1)(c) shall remain
721	confidential and exempt from the provisions of s. 119.07(1) and
722	s. 24(a), Art. I of the State Constitution, as long as the
723	information is retained by the department. This subsection does
724	not prohibit the department from using such information for
725	regulatory or enforcement proceedings under this chapter or from
726	providing such information to any law enforcement agency or any
727	other regulatory agency. However, the receiving agency shall
728	keep such records confidential and exempt as provided in this

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2007 HB 7005, Engrossed 1 729 subsection. In addition, this subsection is not intended to 730 prevent compliance with the provisions of s. 499.0121(6)(d), (e), or (f), and the pedigree papers required in that subsection 731 732 shall not be deemed a trade secret. 733 734 Reviser's note.--Amended to conform to the expiration 735 of s. 499.0121(6)(d) and (e) by their own terms, effective July 1, 2006; those expirations are 736 737 confirmed by this act. 738 739 Section 27. This act shall take effect on the 60th day 740 after adjournment sine die of the session of the Legislature in which enacted. 741