

ENROLLED
 HB 7005, Engrossed 1

2007 Legislature

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 Section 29.0086, Florida Statutes, is repealed.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 note.--The 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 23 the Article V Technology Board, was repealed pursuant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 Section 29.014, Florida Statutes, is repealed.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 note.--The cited section, which relates to

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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30 | repealed by s. 70, ch. 2005-236, Laws of Florida,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32 | repealed by a "current session" of the Legislature, it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 Section 120.551, Florida Statutes, is repealed.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 note.--The 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41 | Administrative Weekly, was repealed pursuant to its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45 | Statutes, is repealed.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 note.--The 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 note.--The cited subsection, which relates

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57 | to amendments to approved operating budgets
58 | authorizing the expenditure of moneys from the Working
59 | Capital Fund as specifically authorized in the General
60 | Appropriations Act, expired pursuant to its own terms,
61 | effective July 1, 2006.

62 |
63 | Section 6. Subsection (6) of section 218.503, Florida
64 | Statutes, is repealed.

65 |
66 | Reviser's note.--The cited subsection, which relates
67 | to a discretionary per-vehicle surcharge by a
68 | governing authority of a municipality with a resident
69 | population of 300,000 or more on or after April 1,
70 | 1999, which has been declared in a state of financial
71 | emergency pursuant to s. 218.503, expired pursuant to
72 | its own terms, effective June 30, 2006.

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
78 | to a requirement that certain surplus state lands that
79 | were acquired from a municipality for no consideration
80 | prior to 1958 must be first offered for reconveyance
81 | to the municipality at no cost, expired pursuant to
82 | its own terms, effective July 1, 2006.

83 |
84 | Section 8. Paragraph (b) of subsection (14) and subsection

85 (25) of section 287.057, Florida Statutes, are repealed.

86
 87 Reviser's note.--Paragraph (14)(b), which authorizes
 88 the Department of Children and Family Services to
 89 enter into certain agreements with a private provider
 90 to finance, design, and construct a forensic treatment
 91 facility, expired pursuant to its own terms, effective
 92 July 1, 2006. Subsection (25), which authorizes the
 93 Department of Management Services to issue an
 94 invitation to negotiate to contract for specified
 95 additional beds for certain correctional facilities,
 96 for the 2005-2006 fiscal year only, expired pursuant
 97 to its own terms, effective July 1, 2006.

98
 99 Section 9. Subsection (8) of section 339.135, Florida
 100 Statutes, is repealed.

101
 102 Reviser's note.--The cited subsection, which relates
 103 to certain increased appropriations for projects
 104 funded within the Department of Transportation,
 105 expired pursuant to its own terms, effective July 1,
 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 note.--The 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 note.--The 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 note.--The 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
 143 Department of Community Affairs to be transferred by
 144 the General Appropriations Act to the Emergency
 145 Management Preparedness and Assistance Trust Fund,
 146 expired pursuant to its own terms, effective July 1,
 147 2006.

148
 149 Section 14. Paragraph (d) of subsection (4) of section
 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
 154 the 2005-2006 fiscal year only, of any unappropriated
 155 balance in the Energy Consumption Trust Fund to the
 156 Emergency Management Preparedness and Assistance Trust
 157 Fund, expired pursuant to its own terms, effective
 158 July 1, 2006.

159
 160 Section 15. Paragraph (g) of subsection (1) of section
 161 497.161, Florida Statutes, is repealed.

162
 163 Reviser's note.--The cited paragraph, which provides
 164 for extraordinary rulemaking authority relating to the
 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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169 Section 16. Paragraph (a) of subsection (2) of section
 170 499.0051, Florida Statutes, is repealed.

171
 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
 177 July 1, 2006.

178
 179 Section 17. Paragraphs (d) and (e) of subsection (6) of
 180 section 499.0121, Florida Statutes, are repealed, and paragraphs
 181 (f), (g), and (h) of that subsection are amended to read:

182 499.0121 Storage and handling of prescription drugs;
 183 recordkeeping.--The department shall adopt rules to implement
 184 this section as necessary to protect the public health, safety,
 185 and welfare. Such rules shall include, but not be limited to,
 186 requirements for the storage and handling of prescription drugs
 187 and for the establishment and maintenance of prescription drug
 188 distribution records.

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

192 (d)~~(f)~~1. Effective July 1, 2006, each person who is
 193 engaged in the wholesale distribution of a prescription drug and
 194 who is not the manufacturer of that drug must, before each
 195 wholesale distribution of such drug, provide to the person who
 196 receives the drug a pedigree paper as defined in s. 499.003(31).

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197 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.

201 4. Each wholesale distributor of prescription drugs must
 202 maintain separate and distinct from other required records all
 203 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
 212 prescription drug and the prescription drug's manufacturer ships
 213 the prescription drug directly to a person authorized by law to
 214 purchase prescription drugs for the purpose of administering or
 215 dispensing the drug, as defined in s. 465.003, or a member of an
 216 affiliated group, as described in paragraph (f)~~(h)~~, with the
 217 exception of a repackager.

218 a. The wholesale distributor must deliver to the recipient
 219 of the prescription drug, within 14 days after the shipment
 220 notification from the manufacturer, an invoice and the following
 221 sworn statement: "This wholesale distributor purchased the
 222 specific unit of the prescription drug listed on the invoice
 223 directly from the manufacturer, and the specific unit of
 224 prescription drug was shipped by the manufacturer directly to a

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225 person authorized by law to administer or dispense the legend
 226 drug, as defined in s. 465.003, Florida Statutes, or a member of
 227 an affiliated group, as described in s. 499.0121(6)(f)
 228 ~~499.0121(6)(h)~~, Florida Statutes, with the exception of a
 229 repackager." The invoice must contain a unique cross-reference
 230 to the shipping document sent by the manufacturer to the
 231 recipient of the prescription drug.

232 b. The manufacturer of the prescription drug shipped
 233 directly to the recipient under this section must provide and
 234 the recipient of the prescription drug must acquire, within 14
 235 days after receipt of the prescription drug, a shipping document
 236 from the manufacturer that contains, at a minimum:

237 (I) The name and address of the manufacturer, including
 238 the point of origin of the shipment, and the names and addresses
 239 of the wholesaler and the purchaser.

240 (II) The name of the prescription drug as it appears on
 241 the label.

242 (III) The quantity, dosage form, and strength of the
 243 prescription drug.

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

245 c. The wholesale distributor must also maintain and make
 246 available to the department, upon request, the lot number of
 247 such drug if not contained in the shipping document acquired by
 248 the recipient.

249 ~~6.7-~~ Failure of the manufacturer to provide, the recipient
 250 to acquire, or the wholesale distributor to deliver, the
 251 documentation required under subparagraph ~~5.6-~~ shall constitute
 252 failure to acquire or deliver a pedigree paper under s.

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253 499.0051. Forgery by the manufacturer, the recipient, or the
 254 wholesale distributor of the documentation required to be
 255 acquired or delivered under subparagraph 5.6 shall constitute
 256 forgery of a pedigree paper under s. 499.0051.

257 7.8 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
 264 manufacturer, shall annually provide the department with a
 265 written list of all wholesale distributors and manufacturers
 266 from whom the wholesale distributor purchases prescription
 267 drugs. A wholesale distributor, except a manufacturer, shall
 268 notify the department not later than 10 days after any change to
 269 either list. Such portions of the information required pursuant
 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 (f)~~(h)~~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:

279 a. Discloses to the department the names of all its
 280 members; and

281 b. Agrees in writing to provide records on prescription
 282 drug purchases by members of the affiliated group not later than
 283 48 hours after the department requests such records, regardless
 284 of the location where the records are stored.

285 2. Each warehouse within the affiliated group must comply
 286 with all applicable federal and state drug wholesale permit
 287 requirements and must purchase, receive, hold, and distribute
 288 prescription drugs only to a retail pharmacy or warehouse within
 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
 292 retail pharmacy, provided that:

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

300 b. The affiliated group makes available to the department
 301 on request all records related to the purchase or acquisition of
 302 prescription drugs by members of the affiliated group,
 303 regardless of the location where the records are stored, if the
 304 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

309 member:

310 a. The repackager must:

311 (I) In lieu of the written statement required by paragraph

312 ~~(d), paragraph (e), or paragraph (f)~~, for all repackaged

313 prescription drugs distributed in or into this state, state in

314 writing under oath with each distribution of a repackaged

315 prescription drug to an affiliated group member warehouse or

316 repackager: "All repackaged prescription drugs are purchased by

317 the affiliated group directly from the manufacturer or from a

318 prescription drug wholesaler that purchased the prescription

319 drugs directly from the manufacturer.";

320 (II) Purchase all prescription drugs it repackages:

321 (A) Directly from the manufacturer; or

322 (B) From a prescription drug wholesaler that purchased the

323 prescription drugs directly from the manufacturer; and

324 (III) Maintain records in accordance with this section to

325 document that it purchased the prescription drugs directly from

326 the manufacturer or that its prescription drug wholesale

327 supplier purchased the prescription drugs directly from the

328 manufacturer.

329 b. All members of the affiliated group must provide to

330 agents of the department on request records of purchases by all

331 members of the affiliated group of prescription drugs that have

332 been repackaged, regardless of the location where the records

333 are stored or where the repackager is located.

334

335 Reviser's note.--Paragraphs (6)(d) and (e), which

336 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
339 prescription drugs on a list of specified drugs,
340 expired pursuant to their own terms, effective July 1,
341 2006. Paragraphs (6)(f), (g), and (h) are redesignated
342 and amended to conform to the expiration of paragraphs
343 (d) and (e).

344

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

347

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

352

353 Section 19. Paragraph (f) of subsection (1) of section
354 29.008, Florida Statutes, is amended to read:

355 29.008 County funding of court-related functions.--

356 (1) Counties are required by s. 14, Art. V of the State
357 Constitution to fund the cost of communications services,
358 existing radio systems, existing multiagency criminal justice
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, guardian 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
376 equipment owned, leased, or used by judges, clerks, public
377 defenders, state attorneys, and all staff of the state courts
378 system, state attorneys' offices, public defenders' offices, and
379 clerks of the circuit and county courts performing court-related
380 functions. Such system or services shall include, but not be
381 limited to:

382 1. Telephone system infrastructure, including computer
383 lines, telephone switching equipment, and maintenance, and
384 facsimile equipment, wireless communications, cellular
385 telephones, pagers, and video teleconferencing equipment and
386 line charges. Each county shall continue to provide access to a
387 local carrier for local and long distance service and shall pay
388 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
395 integrated computer system to support the operations and
396 management of the state courts system, the offices of the public
397 defenders, the offices of the state attorneys, and the offices
398 of the clerks of the circuit and county courts and the
399 capability to connect those entities and reporting data to the
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
405 management, case disposition, and other data across multiple
406 state and county information systems involving multiple users at
407 both the state level and within each judicial circuit and be
408 able to electronically exchange judicial case background data,
409 sentencing scoresheets, and video evidence information stored in
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
413 subparagraph not in compliance with standards, protocols, or
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.

428

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

432

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

435 499.003 Definitions of terms used in ss. 499.001-
 436 499.081.--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
 441 form approved by the Department of Health and containing
 442 information that records each distribution of any given legend
 443 drug, from sale by a pharmaceutical manufacturer, through
 444 acquisition and sale by any wholesaler or repackager, until
 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
 448 ~~subparagraph~~ must at least detail the amount of the legend drug;

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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
451 | signature; its shipping information, including the name and
452 | address of each person certifying delivery or receipt of the
453 | legend drug; an invoice number, a shipping document number, or
454 | another number uniquely identifying the transaction; and a
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,
460 | address, telephone number and, if available, e-mail contact
461 | information of each wholesaler involved in the chain of the
462 | legend drug's custody; or

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

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477 ~~499.0121(6)(h)1.~~

478 1.a. The information required to be included pursuant to
 479 this paragraph ~~subparagraph~~ must include:

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

483 b.(II) 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 c.(III) The name of the prescription drug as it appears on
 487 the label.

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

490 2.b. 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.

496

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

499

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.~~

515
 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
 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 are
 527 established:

528 (e) Nonresident prescription drug manufacturer permit.--A
 529 nonresident prescription drug manufacturer permit is required
 530 for any person that is a manufacturer of prescription drugs, or
 531 the distribution point for a manufacturer of prescription drugs,
 532 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
 535 | manufacturer of the approved new drug application holder, and
 536 | located outside the United States, which engages in the
 537 | wholesale distribution in this state of the prescription drugs
 538 | it manufactures or is responsible for manufacturing. Each such
 539 | manufacturer or entity must be permitted by the department and
 540 | comply with all the provisions required of a wholesale
 541 | distributor under ss. 499.001-499.081, except s. 499.0121(6)(d)~~7~~
 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.

549 | 2. Any such person must comply with the licensing or
 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.

559 | (f) Freight forwarder permit.--A freight forwarder permit
 560 | is 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
 563 | distributions must comply with the requirements for wholesale
 564 | distributors under s. 499.0121, except those set forth in s.
 565 | 499.0121(6) (d), ~~(e)~~, ~~or (f)~~. A freight forwarder must provide
 566 | the source of the legend drugs with a validated airway bill,
 567 | bill of lading, or other appropriate documentation to evidence
 568 | the exportation of the product.

569 | (g) A veterinary prescription drug wholesaler permit.--A
 570 | veterinary prescription drug wholesaler permit is required for
 571 | any person that engages in the distribution of veterinary
 572 | prescription drugs in or into this state. A veterinary
 573 | prescription drug wholesaler that also distributes prescription
 574 | drugs subject to, defined by, or described by s. 503(b) of the
 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
 579 | veterinary prescription drug wholesaler permit. A veterinary
 580 | prescription drug wholesaler must comply with the requirements
 581 | for wholesale distributors under s. 499.0121, except those set
 582 | forth in s. 499.0121(6) (d), ~~(e)~~, ~~or (f)~~.

583 | (h) Limited prescription drug veterinary wholesaler
 584 | permit.--Unless engaging in the activities of and permitted as a
 585 | prescription drug manufacturer, nonresident prescription drug
 586 | manufacturer, prescription drug wholesaler, or out-of-state
 587 | prescription drug wholesaler, a limited prescription drug
 588 | 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.

615 4. A limited prescription drug veterinary wholesaler that
616 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
 619 letter of credit or a deposit in a trust account or financial
 620 institution, payable to the Florida Drug, Device, and Cosmetic
 621 Trust Fund. The purpose of the bond is to secure payment of any
 622 administrative penalties imposed by the department and any fees
 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
 628 days after any administrative or legal proceeding authorized in
 629 ss. 499.001-499.081 which involves the permittee is concluded,
 630 including any appeal, whichever occurs later.

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

635 6. A limited prescription drug veterinary wholesaler must
 636 comply with the requirements for wholesale distributors under s.
 637 499.0121, except that a limited prescription drug veterinary
 638 wholesaler is not required to provide a pedigree paper as
 639 required by s. 499.0121(6)(d) ~~499.0121(6)(f)~~ upon the wholesale
 640 distribution of a prescription drug to a veterinarian.

641 7. A limited prescription drug veterinary wholesaler may
 642 not return to inventory for subsequent wholesale distribution
 643 any prescription drug subject to, defined by, or described by s.
 644 503(b) of the Federal Food, Drug, and Cosmetic Act which has

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645 | been returned by a veterinarian.

646 | 8. An out-of-state prescription drug wholesaler's permit
 647 | or a limited prescription drug veterinary wholesaler permit is
 648 | not required for an intracompany sale or transfer of a
 649 | prescription drug from an out-of-state establishment that is
 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.

657 |
 658 | Reviser's note.--Amended to conform to the expiration
 659 | of s. 499.0121(6) (d) and (e) by their own terms,
 660 | effective July 1, 2006; those expirations are
 661 | confirmed by this act.

662 |
 663 | Section 23. Subsection (3) of section 499.01211, Florida
 664 | 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
 672 | recommendations to the department to improve the protection of

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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.

679
 680 Reviser's note.--Amended to conform to the expiration
 681 of s. 499.0121(6) (e) by its own terms, effective July
 682 1, 2006; that expiration is confirmed by this act.

683
 684 Section 24. Paragraph (c) of subsection (2) of section
 685 499.0122, Florida Statutes, is amended to read:

686 499.0122 Medical oxygen and veterinary legend drug retail
 687 establishments; definitions, permits, general requirements.--

688 (2)

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

692
 693 Reviser's note.--Amended to conform to the expiration
 694 of s. 499.0121(6) (d) by its own terms, effective July
 695 1, 2006; that expiration is confirmed by this act.

696
 697 Section 25. Subsection (3) of section 499.014, Florida
 698 Statutes, is amended to read:

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

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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 note.--Amended 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.

711
 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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729 subsection. In addition, this subsection is not intended to
730 prevent compliance with the provisions of s. 499.0121(6)(d),
731 ~~(e), or (f)~~, and the pedigree papers required in that subsection
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,
736 effective July 1, 2006; those expirations are
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
741 which enacted.