

CHAMBER ACTION

1 The Committee on Health Care recommends the following:

2
3 **Committee Substitute**

4 Remove the entire bill and insert:

5 A bill to be entitled

6 An act relating to pharmacy; amending s. 465.003, F.S.;
7 defining the term "Internet pharmacy"; amending s.
8 465.0156, F.S.; exempting Internet pharmacies from
9 registration requirements applicable to nonresident
10 pharmacies; requiring a registered nonresident pharmacy
11 and the pharmacist designated by that pharmacy to serve as
12 the prescription department manager or the equivalent to
13 be licensed in the state of location to dispense medicinal
14 drugs into this state; amending s. 465.016, F.S.;
15 providing for disciplinary action for dispensing a
16 medicinal drug when the pharmacist knows or has reason to
17 believe a prescription is not based on a valid
18 practitioner-patient relationship; creating s. 465.0161,
19 F.S.; prohibiting the distribution of medicinal drugs by
20 an Internet pharmacy without a permit; providing
21 penalties; amending s. 465.0196, F.S., relating to special
22 pharmacy permits, to conform; creating s. 465.0197, F.S.;
23 requiring Internet pharmacies to be permitted and

24 providing requirements therefor; requiring the Internet
 25 pharmacy and the pharmacist designated by that pharmacy to
 26 serve as the prescription department manager or its
 27 equivalent to be licensed in the state of location to
 28 dispense medicinal drugs into this state; amending s.
 29 465.023, F.S.; providing an additional ground for which
 30 the Department of Health or the Board of Pharmacy may take
 31 action against a permitted pharmacy; amending s. 465.0255,
 32 F.S.; revising requirements for certain pharmacists and
 33 practitioners to deliver specified disclosures to
 34 purchasers when dispensing a medicinal drug; amending s.
 35 465.026, F.S.; creating an exception to the requirements
 36 for filling or refilling a transferred prescription for a
 37 medicinal drug listed in Schedule II under ch. 893, F.S.;
 38 amending s. 499.0121, F.S.; providing recordkeeping
 39 requirements relating to the storage and handling of
 40 prescription drugs which affiliated groups must fulfill;
 41 providing for future repeal; amending s. 895.02, F.S.;
 42 including violation of s. 465.0161, F.S., in the
 43 definition of the term "racketeering activity" for
 44 prosecution under ch. 895, F.S.; providing an
 45 appropriation and authorizing positions; providing an
 46 effective date.

47
 48 Be It Enacted by the Legislature of the State of Florida:

49
 50 Section 1. Paragraph (a) of subsection (11) of section
 51 465.003, Florida Statutes, is amended to read:

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

HB 141

2004
CS

52 465.003 Definitions.--As used in this chapter, the term:

53 (11)(a) "Pharmacy" includes a community pharmacy, an
54 institutional pharmacy, a nuclear pharmacy, ~~and~~ a special
55 pharmacy, and an Internet pharmacy.

56 1. The term "community pharmacy" includes every location
57 where medicinal drugs are compounded, dispensed, stored, or sold
58 or where prescriptions are filled or dispensed on an outpatient
59 basis.

60 2. The term "institutional pharmacy" includes every
61 location in a hospital, clinic, nursing home, dispensary,
62 sanitarium, extended care facility, or other facility,
63 hereinafter referred to as "health care institutions," where
64 medicinal drugs are compounded, dispensed, stored, or sold.

65 3. The term "nuclear pharmacy" includes every location
66 where radioactive drugs and chemicals within the classification
67 of medicinal drugs are compounded, dispensed, stored, or sold.
68 The term "nuclear pharmacy" does not include hospitals licensed
69 under chapter 395 or the nuclear medicine facilities of such
70 hospitals.

71 4. The term "special pharmacy" includes every location
72 where medicinal drugs are compounded, dispensed, stored, or sold
73 if such locations are not otherwise defined in this subsection.

74 5. The term "Internet pharmacy" includes locations not
75 otherwise licensed or issued a permit under this chapter, within
76 or outside this state, which use the Internet to communicate
77 with or obtain information from consumers in this state and use
78 such communication or information to fill or refill
79 prescriptions or to dispense, distribute, or otherwise engage in

HB 141

2004
CS

80 the practice of pharmacy in this state. Any act described in
 81 this subparagraph constitutes the practice of the profession of
 82 pharmacy as defined in subsection (13).

83 Section 2. Subsections (7) and (8) are added to section
 84 465.0156, Florida Statutes, to read:

85 465.0156 Registration of nonresident pharmacies.--

86 (7) This section does not apply to Internet pharmacies
 87 required to be permitted under s. 465.0197.

88 (8) Notwithstanding s. 465.003(10), for purposes of this
 89 section, the registered pharmacy and the pharmacist designated
 90 by the registered pharmacy as the prescription department
 91 manager or the equivalent must be licensed in the state of
 92 location in order to dispense medicinal drugs into this state.

93 Section 3. Paragraph (s) is added to subsection (1) of
 94 section 465.016, Florida Statutes, to read:

95 465.016 Disciplinary actions.--

96 (1) The following acts constitute grounds for denial of a
 97 license or disciplinary action, as specified in s. 456.072(2):

98 (s) Dispensing any medicinal drug based upon a
 99 communication that purports to be a prescription as defined in
 100 s. 465.003(14) or s. 893.02(20) when the pharmacist knows or has
 101 reason to believe that the purported prescription is not based
 102 upon a valid practitioner-patient relationship.

103 Section 4. Section 465.0161, Florida Statutes, is created
 104 to read:

105 465.0161 Distribution of medicinal drugs without a
 106 permit.--An Internet pharmacy that distributes a medicinal drug
 107 to any person in this state without being permitted as a

HB 141

2004
CS

108 | pharmacy under this chapter commits a felony of the second
 109 | degree, punishable as provided in s. 775.082, s. 775.083, or s.
 110 | 775.084.

111 | Section 5. Section 465.0196, Florida Statutes, is amended
 112 | to read:

113 | 465.0196 Special pharmacy permits.--Any person desiring a
 114 | permit to operate a special pharmacy ~~which does not fall within~~
 115 | ~~the definitions set forth in s. 465.003(11)(a)1., 2., and 3.~~
 116 | shall apply to the department for a special pharmacy permit. If
 117 | the board certifies that the application complies with the
 118 | applicable laws and rules of the board governing the practice of
 119 | the profession of pharmacy, the department shall issue the
 120 | permit. No permit shall be issued unless a licensed pharmacist
 121 | is designated to undertake the professional supervision of the
 122 | compounding and dispensing of all drugs dispensed by the
 123 | pharmacy. The licensed pharmacist shall be responsible for
 124 | maintaining all drug records and for providing for the security
 125 | of the area in the facility in which the compounding, storing,
 126 | and dispensing of medicinal drugs occurs. The permittee shall
 127 | notify the department within 10 days of any change of the
 128 | licensed pharmacist responsible for such duties. Every permittee
 129 | that employs or otherwise utilizes pharmacy technicians shall
 130 | have a written policy and procedures manual specifying those
 131 | duties, tasks, and functions which a pharmacy technician is
 132 | allowed to perform.

133 | Section 6. Section 465.0197, Florida Statutes, is created
 134 | to read:

135 | 465.0197 Internet pharmacy permits.--

136 (1) Any person desiring a permit to operate an Internet
 137 pharmacy shall apply to the department for an Internet pharmacy
 138 permit. If the board certifies that the application complies
 139 with the applicable laws and rules of the board governing the
 140 practice of the profession of pharmacy, the department shall
 141 issue the permit. No permit shall be issued unless a licensed
 142 pharmacist is designated as the prescription department manager
 143 for dispensing medicinal drugs to persons in this state. The
 144 licensed pharmacist shall be responsible for maintaining all
 145 drug records and for providing for the security of the area in
 146 the facility in which the compounding, storing, and dispensing
 147 of medicinal drugs to persons in this state occurs. The
 148 permittee shall notify the department within 30 days of any
 149 change of the licensed pharmacist responsible for such duties.
 150 Every permittee that employs or otherwise utilizes pharmacy
 151 technicians shall have a written policy and procedures manual
 152 specifying those duties, tasks, and functions which a pharmacy
 153 technician is allowed to perform.

154 (2) An Internet pharmacy must obtain a permit under this
 155 section to sell medicinal drugs to persons in this state.

156 (3) An Internet pharmacy shall provide pharmacy services
 157 at a high level of protection and competence and shall disclose
 158 to the board the following specific information:

159 (a) That it maintains at all times a valid, unexpired
 160 license, permit, or registration to operate the pharmacy in
 161 compliance with the laws of the state in which the dispensing
 162 facility is located and from which the medicinal drugs shall be
 163 dispensed.

HB 141

2004
CS

164 (b) The location, names, and titles of all principal
165 corporate officers and the pharmacist who serves as the
166 prescription department manager for dispensing medicinal drugs
167 to persons in this state. This disclosure shall be made within
168 30 days after any change of location, principal corporate
169 officer, or pharmacist serving as the prescription department
170 manager for dispensing medicinal drugs to persons in this state.

171 (c) That it complies with all lawful directions and
172 requests for information from the regulatory or licensing agency
173 of all states in which it is licensed as well as with all
174 requests for information made by the board pursuant to this
175 section. It shall respond directly to all communications from
176 the board concerning emergency circumstances arising from errors
177 in the dispensing of medicinal drugs to persons in this state.

178 (d) That it maintains its records of medicinal drugs
179 dispensed to patients in this state so that the records are
180 readily retrievable from the other business records of the
181 pharmacy and from the records of other medicinal drugs
182 dispensed.

183 (e) That during its regular hours of operation but not
184 less than 6 days per week, for a minimum of 40 hours per week, a
185 toll-free telephone service shall be provided to facilitate
186 communication between patients in this state and a pharmacist at
187 the pharmacy who has access to the patient's records. This toll-
188 free number must be disclosed on the label affixed to each
189 container of dispensed medicinal drugs.

190 (4) Notwithstanding s. 465.003(10), for purposes of this
191 section, the Internet pharmacy and the pharmacist designated by

HB 141

2004
CS

192 the Internet pharmacy as the prescription department manager or
 193 the equivalent must be licensed in the state of location in
 194 order to dispense medicinal drugs into this state.

195 Section 7. Subsection (1) of section 465.023, Florida
 196 Statutes, is amended to read:

197 465.023 Pharmacy permittee; disciplinary action.--

198 (1) The department or the board may revoke or suspend the
 199 permit of any pharmacy permittee, and may fine, place on
 200 probation, or otherwise discipline any pharmacy permittee who
 201 has:

202 (a) Obtained a permit by misrepresentation or fraud or
 203 through an error of the department or the board;

204 (b) Attempted to procure, or has procured, a permit for
 205 any other person by making, or causing to be made, any false
 206 representation;

207 (c) Violated any of the requirements of this chapter or
 208 any of the rules of the Board of Pharmacy; of chapter 499, known
 209 as the "Florida Drug and Cosmetic Act"; of 21 U.S.C. ss. 301-
 210 392, known as the "Federal Food, Drug, and Cosmetic Act"; of 21
 211 U.S.C. ss. 821 et seq., known as the Comprehensive Drug Abuse
 212 Prevention and Control Act; or of chapter 893; ~~or~~

213 (d) Been convicted or found guilty, regardless of
 214 adjudication, of a felony or any other crime involving moral
 215 turpitude in any of the courts of this state, of any other
 216 state, or of the United States; or

217 (e) Dispensed any medicinal drug based upon a
 218 communication that purports to be a prescription as defined in
 219 s. 465.003(14) or s. 893.02(20) when the pharmacist knows or has

HB 141

2004
CS

220 reason to believe that the purported prescription is not based
 221 upon a valid practitioner-patient relationship that includes a
 222 documented patient evaluation, including history and a physical
 223 examination adequate to establish the diagnosis for which any
 224 drug is prescribed and any other requirement established by
 225 board rule under chapter 458, chapter 459, chapter 461, chapter
 226 463, chapter 464, or chapter 466.

227 Section 8. Section 465.0255, Florida Statutes, is amended
 228 to read:

229 465.0255 Expiration date of medicinal drugs; display;
 230 related use and storage instructions.--

231 (1) The manufacturer, repackager, or other distributor of
 232 any medicinal drug shall display the expiration date of each
 233 drug in a readable fashion on the container and on its
 234 packaging. The term "readable" means conspicuous and bold.

235 (2) Each pharmacist for a community pharmacy dispensing
 236 medicinal drugs and each practitioner dispensing medicinal drugs
 237 on an outpatient basis shall display on the outside of the
 238 container of each medicinal drug dispensed, or in other written
 239 form delivered to the purchaser:7

240 (a) The expiration date when provided by the manufacturer,
 241 repackager, or other distributor of the drug; ~~or~~ and

242 (b) An earlier beyond-use date for expiration, which may
 243 be up to 1 year after the date of dispensing.

244
 245 The dispensing pharmacist or practitioner must provide
 246 information concerning the expiration date to the purchaser upon

HB 141

2004
CS

247 | request and must provide appropriate instructions regarding the
 248 | proper use and storage of the drug.

249 | (3) ~~Nothing in~~ This section does not ~~shall~~ impose
 250 | liability on the dispensing pharmacist or practitioner for
 251 | damages related to, or caused by, a medicinal drug that loses
 252 | its effectiveness prior to the expiration date displayed by the
 253 | dispensing pharmacist or practitioner.

254 | (4)~~(3)~~ The provisions of this section are intended to
 255 | notify the patient receiving a medicinal drug of the information
 256 | required by this section, and the dispensing pharmacist or
 257 | practitioner shall not be liable for the patient's failure to
 258 | heed such notice or to follow the instructions for storage.

259 | Section 9. Subsection (7) is added to section 465.026,
 260 | Florida Statutes, to read:

261 | 465.026 Filling of certain prescriptions.--Nothing
 262 | contained in this chapter shall be construed to prohibit a
 263 | pharmacist licensed in this state from filling or refilling a
 264 | valid prescription which is on file in a pharmacy located in
 265 | this state or in another state and has been transferred from one
 266 | pharmacy to another by any means, including any electronic
 267 | means, under the following conditions:

268 | (7) A community pharmacy licensed under this chapter which
 269 | only receives and transfers prescriptions for dispensing by
 270 | another pharmacy may transfer a prescription for a medicinal
 271 | drug listed in Schedule II under chapter 893. The pharmacy
 272 | receiving the prescription may ship, mail, or deliver into this
 273 | state, in any manner, the dispensed Schedule II medicinal drug
 274 | under the following conditions:

HB 141

2004
CS

275 (a) The pharmacy receiving and dispensing the transferred
 276 prescription maintains at all times a valid, unexpired license,
 277 permit, or registration to operate the pharmacy in compliance
 278 with the laws of the state in which the pharmacy is located and
 279 from which the medicinal drugs are dispensed.

280 (b) The community pharmacy and the receiving pharmacy are
 281 owned and operated by the same person and share a centralized
 282 database.

283 (c) The community pharmacy assures its compliance with
 284 federal laws and subsections (1)-(5).

285 Section 10. Paragraph (h) is added to subsection (6) of
 286 section 499.0121, Florida Statutes, to read:

287 499.0121 Storage and handling of prescription drugs;
 288 recordkeeping.--The department shall adopt rules to implement
 289 this section as necessary to protect the public health, safety,
 290 and welfare. Such rules shall include, but not be limited to,
 291 requirements for the storage and handling of prescription drugs
 292 and for the establishment and maintenance of prescription drug
 293 distribution records.

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

297 (h)1. This paragraph applies only to an affiliated group,
 298 as defined in s. 1504 of the Internal Revenue Code of 1986, as
 299 amended, which is composed of chain drug entities, including at
 300 least 50 retail pharmacies, warehouses, or repackagers, which
 301 are members of the same affiliated group if:

302 a. The group discloses to the department the names of all
 303 the members of the affiliated group; and

304 b. The affiliated group agrees in writing to provide
 305 records on prescription drug purchases by the members of the
 306 affiliated group not later than 48 hours after the department
 307 requests access to such records, regardless of the location of
 308 where the records are stored.

309 2. Each warehouse within the affiliated group must comply
 310 with all applicable federal and state drug wholesale permit
 311 requirements and must purchase, receive, hold, and distribute
 312 prescription drugs only to a retail pharmacy or warehouse within
 313 the affiliated group. Such a warehouse is exempt from providing
 314 a pedigree paper in accordance with paragraph (d) or paragraph
 315 (e) to its affiliated group member warehouse, provided that:

316 a. Any affiliated group member that purchases or receives
 317 a prescription drug from outside the affiliated group must
 318 receive a pedigree paper if the prescription drug is distributed
 319 in or into this state and a pedigree paper is required under
 320 this section and must authenticate the documentation as required
 321 in subsection (4), regardless of whether the affiliated group
 322 member is directly subject to regulation under this chapter; and

323 b. The affiliated group makes available to the department
 324 on request all records related to the purchase or acquisition of
 325 prescription drugs by members of the affiliated group,
 326 regardless of the location where the records are stored, if the
 327 prescription drugs were distributed in or into this state.

328 3. If a repackager repackages prescription drugs solely
 329 for distribution to its affiliated group members for the

330 exclusive distribution to and among retail pharmacies that are
 331 members of the affiliated group to which the repackager is a
 332 member:

333 a. The repackager must:

334 (I) In lieu of the written statement required by paragraph
 335 (d) or paragraph (e), for all repackaged prescription drugs
 336 distributed in or into this state, state in writing under oath
 337 with each distribution of a repackaged prescription drug to an
 338 affiliated group member warehouse or repackager: "All repackaged
 339 prescription drugs are purchased by the affiliated group
 340 directly from the manufacturer or from a prescription drug
 341 wholesaler that purchased the prescription drugs directly from
 342 the manufacturer.";

343 (II) Purchase all prescription drugs it repackages:

344 (A) Directly from the manufacturer; or

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

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

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

357 4. This paragraph expires July 1, 2006.

HB 141

2004
CS

358 Section 11. Paragraph (a) of subsection (1) of section
359 895.02, Florida Statutes, is amended to read:

360 895.02 Definitions.--As used in ss. 895.01-895.08, the
361 term:

362 (1) "Racketeering activity" means to commit, to attempt to
363 commit, to conspire to commit, or to solicit, coerce, or
364 intimidate another person to commit:

365 (a) Any crime which is chargeable by indictment or
366 information under the following provisions of the Florida
367 Statutes:

368 1. Section 210.18, relating to evasion of payment of
369 cigarette taxes.

370 2. Section 403.727(3)(b), relating to environmental
371 control.

372 ~~3.4.~~ Section 409.920, relating to Medicaid provider fraud.

373 ~~4.3.~~ Section 414.39, relating to public assistance fraud.

374 5. Section 440.105 or s. 440.106, relating to workers'
375 compensation.

376 6. Section 465.0161, relating to distribution of medicinal
377 drugs without a permit as an Internet pharmacy.

378 ~~7.6.~~ Sections 499.0051, 499.0052, 499.0053, 499.0054, and
379 499.0691, relating to crimes involving contraband and
380 adulterated drugs.

381 ~~8.7.~~ Part IV of chapter 501, relating to telemarketing.

382 ~~9.8.~~ Chapter 517, relating to sale of securities and
383 investor protection.

384 ~~10.9.~~ Section 550.235, s. 550.3551, or s. 550.3605,
385 relating to dogracing and horseracing.

HB 141

2004
CS

- 386 | ~~11.10.~~ Chapter 550, relating to jai alai frontons.
- 387 | ~~12.11.~~ Chapter 552, relating to the manufacture,
- 388 | distribution, and use of explosives.
- 389 | ~~13.12.~~ Chapter 560, relating to money transmitters, if the
- 390 | violation is punishable as a felony.
- 391 | ~~14.13.~~ Chapter 562, relating to beverage law enforcement.
- 392 | ~~15.14.~~ Section 624.401, relating to transacting insurance
- 393 | without a certificate of authority, s. 624.437(4)(c)1., relating
- 394 | to operating an unauthorized multiple-employer welfare
- 395 | arrangement, or s. 626.902(1)(b), relating to representing or
- 396 | aiding an unauthorized insurer.
- 397 | ~~16.15.~~ Section 655.50, relating to reports of currency
- 398 | transactions, when such violation is punishable as a felony.
- 399 | ~~17.16.~~ Chapter 687, relating to interest and usurious
- 400 | practices.
- 401 | ~~18.17.~~ Section 721.08, s. 721.09, or s. 721.13, relating
- 402 | to real estate timeshare plans.
- 403 | ~~19.18.~~ Chapter 782, relating to homicide.
- 404 | ~~20.19.~~ Chapter 784, relating to assault and battery.
- 405 | ~~21.20.~~ Chapter 787, relating to kidnapping.
- 406 | ~~22.21.~~ Chapter 790, relating to weapons and firearms.
- 407 | ~~23.22.~~ Section 796.03, s. 796.04, s. 796.05, or s. 796.07,
- 408 | relating to prostitution.
- 409 | ~~24.23.~~ Chapter 806, relating to arson.
- 410 | ~~25.24.~~ Section 810.02(2)(c), relating to specified
- 411 | burglary of a dwelling or structure.
- 412 | ~~26.25.~~ Chapter 812, relating to theft, robbery, and
- 413 | related crimes.

HB 141

2004
CS

414 ~~27.26.~~ Chapter 815, relating to computer-related crimes.

415 ~~28.27.~~ Chapter 817, relating to fraudulent practices,
416 false pretenses, fraud generally, and credit card crimes.

417 ~~29.28.~~ Chapter 825, relating to abuse, neglect, or
418 exploitation of an elderly person or disabled adult.

419 ~~30.29.~~ Section 827.071, relating to commercial sexual
420 exploitation of children.

421 ~~31.30.~~ Chapter 831, relating to forgery and
422 counterfeiting.

423 ~~32.31.~~ Chapter 832, relating to issuance of worthless
424 checks and drafts.

425 ~~33.32.~~ Section 836.05, relating to extortion.

426 ~~34.33.~~ Chapter 837, relating to perjury.

427 ~~35.34.~~ Chapter 838, relating to bribery and misuse of
428 public office.

429 ~~36.35.~~ Chapter 843, relating to obstruction of justice.

430 ~~37.36.~~ Section 847.011, s. 847.012, s. 847.013, s. 847.06,
431 or s. 847.07, relating to obscene literature and profanity.

432 ~~38.37.~~ Section 849.09, s. 849.14, s. 849.15, s. 849.23, or
433 s. 849.25, relating to gambling.

434 ~~39.38.~~ Chapter 874, relating to criminal street gangs.

435 ~~40.39.~~ Chapter 893, relating to drug abuse prevention and
436 control.

437 ~~41.40.~~ Chapter 896, relating to offenses related to
438 financial transactions.

439 ~~42.41.~~ Sections 914.22 and 914.23, relating to tampering
440 with a witness, victim, or informant, and retaliation against a
441 witness, victim, or informant.

HB 141

2004
CS

442 ~~43.42.~~ Sections 918.12 and 918.13, relating to tampering
443 with jurors and evidence.

444 Section 12. The sum of \$590,051 is appropriated from the
445 Medical Quality Assurance Trust Fund to the Department of
446 Health, and nine full-time equivalent positions are authorized,
447 for the 2004-2005 fiscal year for the purpose of implementing
448 this act.

449 Section 13. This act shall take effect July 1, 2004.