

LEGISLATIVE ACTION

Senate		House
Comm: RCS		
03/14/2011		
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The Committee on Health Regulation (Fasano) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Subsections (4) and (7) of section 400.9905, Florida Statutes, are amended to read:

400.9905 Definitions.-

8 (4) "Clinic" means an entity at which health care services 9 are provided to individuals and which tenders charges for 10 reimbursement <u>or payment</u> for such services, including a mobile 11 clinic and a portable equipment provider. For purposes of this 12 part, the term does not include and the licensure requirements



13 of this part do not apply to:

(a) Entities licensed or registered by the state under 14 chapter 395; or entities licensed or registered by the state and 15 providing only health care services within the scope of services 16 17 authorized under their respective licenses granted under ss. 383.30-383.335, chapter 390, chapter 394, chapter 397, this 18 chapter except part X, chapter 429, chapter 463, chapter 465, 19 chapter 466, chapter 478, part I of chapter 483, chapter 484, or 20 21 chapter 651; end-stage renal disease providers authorized under 22 42 C.F.R. part 405, subpart U; or providers certified under 42 23 C.F.R. part 485, subpart B or subpart H; or any entity that 24 provides neonatal or pediatric hospital-based health care 25 services or other health care services by licensed practitioners 26 solely within a hospital licensed under chapter 395.

(b) Entities that own, directly or indirectly, entities 27 licensed or registered by the state pursuant to chapter 395; or 28 29 entities that own, directly or indirectly, entities licensed or registered by the state and providing only health care services 30 31 within the scope of services authorized pursuant to their 32 respective licenses granted under ss. 383.30-383.335, chapter 33 390, chapter 394, chapter 397, this chapter except part X, 34 chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, part I of chapter 483, chapter 484, chapter 651; end-stage renal 35 36 disease providers authorized under 42 C.F.R. part 405, subpart 37 U; or providers certified under 42 C.F.R. part 485, subpart B or 38 subpart H; or any entity that provides neonatal or pediatric 39 hospital-based health care services by licensed practitioners 40 solely within a hospital licensed under chapter 395.

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(c) Entities that are owned, directly or indirectly, by an



42 entity licensed or registered by the state pursuant to chapter 395; or entities that are owned, directly or indirectly, by an 43 44 entity licensed or registered by the state and providing only health care services within the scope of services authorized 45 46 pursuant to their respective licenses granted under ss. 383.30-47 383.335, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 48 466, chapter 478, part I of chapter 483, chapter 484, or chapter 49 50 651; end-stage renal disease providers authorized under 42 51 C.F.R. part 405, subpart U; or providers certified under 42 52 C.F.R. part 485, subpart B or subpart H; or any entity that 53 provides neonatal or pediatric hospital-based health care 54 services by licensed practitioners solely within a hospital 55 under chapter 395.

(d) Entities that are under common ownership, directly or 56 57 indirectly, with an entity licensed or registered by the state 58 pursuant to chapter 395; or entities that are under common 59 ownership, directly or indirectly, with an entity licensed or 60 registered by the state and providing only health care services 61 within the scope of services authorized pursuant to their 62 respective licenses granted under ss. 383.30-383.335, chapter 63 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, 64 65 part I of chapter 483, chapter 484, or chapter 651; end-stage 66 renal disease providers authorized under 42 C.F.R. part 405, subpart U; or providers certified under 42 C.F.R. part 485, 67 68 subpart B or subpart H; or any entity that provides neonatal or pediatric hospital-based health care services by licensed 69 70 practitioners solely within a hospital licensed under chapter



71 395.

(e) An entity that is exempt from federal taxation under 26 72 U.S.C. s. 501(c)(3) or (4), an employee stock ownership plan 73 74 under 26 U.S.C. s. 409 that has a board of trustees not less than two-thirds of which are Florida-licensed health care 75 76 practitioners and provides only physical therapy services under 77 physician orders, any community college or university clinic, 78 and any entity owned or operated by the federal or state 79 government, including agencies, subdivisions, or municipalities 80 thereof.

(f) A sole proprietorship, group practice, partnership, or corporation that provides health care services by physicians covered by s. 627.419, that is directly supervised by one or more of such physicians, and that is wholly owned by one or more of those physicians or by a physician and the spouse, parent, child, or sibling of that physician.

87 (g) A sole proprietorship, group practice, partnership, or corporation that provides health care services by licensed 88 89 health care practitioners under chapter 457, chapter 458, 90 chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, 91 chapter 466, chapter 467, chapter 480, chapter 484, chapter 486, 92 chapter 490, chapter 491, or part I, part III, part X, part 93 XIII, or part XIV of chapter 468, or s. 464.012, which are 94 wholly owned by one or more licensed health care practitioners, 95 or the licensed health care practitioners set forth in this 96 paragraph and the spouse, parent, child, or sibling of a 97 licensed health care practitioner, so long as one of the owners who is a licensed health care practitioner is supervising the 98 99 business activities and is legally responsible for the entity's

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100 compliance with all federal and state laws. However, a health 101 care practitioner may not supervise services beyond the scope of 102 the practitioner's license, except that, for the purposes of 103 this part, a clinic owned by a licensee in s. 456.053(3)(b) that 104 provides only services authorized pursuant to s. 456.053(3)(b) 105 may be supervised by a licensee specified in s. 456.053(3)(b).

(h) Clinical facilities affiliated with an accredited
medical school at which training is provided for medical
students, residents, or fellows.

(i) Entities that provide only oncology or radiation therapy services by physicians licensed under chapter 458 or chapter 459 or entities that provide oncology or radiation therapy services by physicians licensed under chapter 458 or chapter 459 which are owned by a corporation whose shares are publicly traded on a recognized stock exchange.

(j) Clinical facilities affiliated with a college of chiropractic accredited by the Council on Chiropractic Education at which training is provided for chiropractic students.

(k) Entities that provide licensed practitioners to staff emergency departments or to deliver anesthesia services in facilities licensed under chapter 395 and that derive at least 90 percent of their gross annual revenues from the provision of such services. Entities claiming an exemption from licensure under this paragraph must provide documentation demonstrating compliance.

(1) Orthotic or prosthetic clinical facilities that are a publicly traded corporation or that are wholly owned, directly or indirectly, by a publicly traded corporation. As used in this paragraph, a publicly traded corporation is a corporation that



129 issues securities traded on an exchange registered with the 130 United States Securities and Exchange Commission as a national 131 securities exchange.

(7) "Portable equipment provider" means an entity that contracts with or employs persons to provide portable equipment to multiple locations performing treatment or diagnostic testing of individuals, that bills third-party payors for those services, and that otherwise meets the definition of a clinic in subsection (4).

Section 2. Subsection (7) of section 456.013, Florida Statutes, is amended to read:

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456.013 Department; general licensing provisions.-

141 (7) (a) The boards, or the department when there is no 142 board, shall require the completion of a 2-hour course relating to prevention of medical errors as part of the licensure and 143 144 renewal process. The 2-hour course counts shall count towards the total number of continuing education hours required for the 145 146 profession. The board or department shall approve the course 147 shall be approved by the board or department, as appropriate, 148 which must and shall include a study of root-cause analysis, 149 error reduction and prevention, and patient safety. In addition, 150 the course approved by the Board of Medicine and the Board of 151 Osteopathic Medicine must shall include information relating to 152 the five most misdiagnosed conditions during the previous 153 biennium, as determined by the board. If the course is being 154 offered by a facility licensed under pursuant to chapter 395 for 155 its employees, the board may approve up to 1 hour of the 2-hour course to be specifically related to error reduction and 156 157 prevention methods used in that facility.

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158	(b) As a condition of initial licensure and at each
159	subsequent license renewal, the boards, or the department if
160	there is no board, shall allow each practitioner licensed under
161	chapter 458, chapter 459, chapter 461, chapter 465, or chapter
162	466 whose lawful scope of practice authorizes the practitioner
163	to prescribe, administer, or dispense controlled substances to
164	complete a 1-hour continuing education course relating to the
165	prescription drug monitoring program. The course must include,
166	but need not be limited to:
167	1. The purpose of the prescription drug monitoring program.
168	2. The practitioners' capabilities for improving the
169	standard of care for patients by using the prescription drug
170	monitoring program.
171	3. How the prescription drug monitoring program can help
172	practitioners detect doctor shopping.
173	4. The involvement of law enforcement personnel, the
174	Attorney General's Medicaid Fraud Unit, and medical regulatory
175	investigators with the prescription drug monitoring program.
176	5. The procedures for registering for access to the
177	prescription drug monitoring program.
178	
179	The course hours may be included in the total number of hours of
180	continuing education required by the profession and must be
181	approved by the board or by the department if there is no board.
182	The boards, or the department if there is no board, shall
183	approve the course offered through a facility licensed under
184	chapter 395 for its employees if the course is at least 3 hours
185	and covers the education requirements.
186	(c) The course requirements in paragraph (b) apply to each

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187	licensee renewing his or her license on or after July 1, 2012,
188	and to each applicant approved for licensure on or after January
189	<u>1, 2013.</u>
190	(d) By October 1, 2011, the boards, or the department if
191	there is no board, shall adopt rules as necessary to administer
192	this subsection.
193	Section 3. Section 458.305, Florida Statutes, is amended to
194	read:
195	458.305 DefinitionsAs used in this chapter:
196	(1) "Board" means the Board of Medicine.
197	(2) "Department" means the Department of Health.
198	(3) "Dispensing physician" means a physician who is
199	registered as a dispensing practitioner under s. 465.0276.
200	(4) (3) "Practice of medicine" means the diagnosis,
201	treatment, operation, or prescription for any human disease,
202	pain, injury, deformity, or other physical or mental condition.
203	(5)(4) "Physician" means a person who is licensed to
204	practice medicine in this state.
205	Section 4. Advertising of controlled substances by a
206	dispensing physician
207	(1)(a) Only a dispensing physician licensed under chapter
208	458 or chapter 459, Florida Statutes, may use the title
209	"dispensing physician" or "dispenser" or otherwise lead the
210	public to believe that he or she is engaged in the dispensing of
211	controlled substances.
212	(b) A person, other than an owner of a:
213	1. Pain-management clinic registered under chapter 458 or
214	chapter 459, Florida Statutes; or
215	2. Health clinic licensed under chapter 400, Florida
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216 Statutes, 217 218 may not display any sign or take any other action that would 219 lead the public to believe that such person is engaged in the 220 business of dispensing a controlled substance. Any advertisement 221 that states "dispensing onsite" or "onsite pharmacy" violates 222 this paragraph. This paragraph does not preclude a person who is 223 not licensed as a medical practitioner from owning a pain-224 management clinic. 225 (c) A person, firm, or corporation, unless licensed under 226 chapter 465, Florida Statutes, may not use in a trade name, 227 sign, letter, or advertisement any term, including "drug," "pharmacy," "onsite pharmacy," "dispensing," "dispensing 228 onsite," "prescription drugs," "Rx," or "apothecary," which 229 230 implies that the person, firm, or corporation is licensed or 231 registered to dispense prescription drugs in this state. 232 (2) A person who violates paragraph (1)(a) or paragraph 233 (1) (b) commits a misdemeanor of the first degree, punishable as 234 provided in s. 775.082 or s. 775.083, Florida Statutes. A person 235 who violates paragraph (1)(c) commits a felony of the third 236 degree, punishable as provided in s. 775.082, s. 775.083, or s. 237 775.084, Florida Statutes. In any warrant, information, or 238 indictment, it is not necessary to negate any exceptions, and 239 the burden of any exception is upon the defendant. 240 Section 5. Paragraph (a) of subsection (1) of section 241 458.3191, Florida Statutes, is amended to read: 242 458.3191 Physician survey.-(1) Each person who applies for licensure renewal as a 243 244 physician under this chapter or chapter 459 must, in conjunction

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245	with the renewal of such license under procedures adopted by the
246	Department of Health and in addition to any other information
247	that may be required from the applicant, furnish the following
248	to the Department of Health in a physician survey:
249	(a) Licensee information, including, but not limited to:
250	1. Frequency and geographic location of practice within the
251	state.
252	2. Practice setting.
253	3. Percentage of time spent in direct patient care.
254	4. Anticipated change to license or practice status.
255	5. Areas of specialty or certification.
256	6. Whether the department has ever approved or denied the
257	physician's registration for access to a patient's information
258	in the prescription drug monitoring program's database.
259	7. Whether the physician uses the prescription drug
260	monitoring program with patients in his or her medical practice.
261	Section 6. Subsection (3) is added to section 458.3192,
262	Florida Statutes, to read:
263	458.3192 Analysis of survey results; report
264	(3) By November 1 each year, the Department of Health shall
265	provide nonidentifying information to the prescription drug
266	monitoring program's Implementation and Oversight Task Force
267	regarding the number of physicians who are registered with the
268	prescription drug monitoring program and who also use the
269	database from the prescription drug monitoring program for their
270	patients in their medical practice.
271	Section 7. Paragraphs (a) of subsection (1), and paragraphs
272	(a) and (c) of subsection (2) of section 458.3265, Florida
273	Statutes, are amended, and paragraphs (f) and (g) are added to

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274	subsection (5) of that section, to read:
275	458.3265 Pain-management clinics
276	(1) REGISTRATION
277	(a) All privately owned pain-management clinics,
278	facilities, or offices, hereinafter referred to as "clinics,"
279	which advertise in any medium for any type of pain-management
280	services, or employ a physician who is primarily engaged in the
281	treatment of pain by prescribing or dispensing controlled
282	substance medications, must register with the department unless:
283	1. That clinic is licensed as a facility pursuant to
284	chapter 395;
285	2. The majority of the physicians who provide services in
286	the clinic primarily provide surgical services;
287	3. The clinic is owned by a publicly held corporation whose
288	shares are traded on a national exchange or on the over-the-
289	counter market and whose total assets at the end of the
290	corporation's most recent fiscal quarter exceeded \$50 million;
291	4. The clinic is affiliated with an accredited medical
292	school at which training is provided for medical students,
293	residents, or fellows;
294	5. The clinic does not prescribe or dispense controlled
295	substances for the treatment of pain; or
296	6. The clinic is owned by a corporate entity exempt from
297	federal taxation under 26 U.S.C. s. 501(c)(3) <u>; or</u> -
298	7. The majority of the physicians who provide services in
299	the clinic are physicians who specialize in interventional pain
300	management in accordance with the American Society of
301	Interventional Pain Physicians.
302	(2) PHYSICIAN RESPONSIBILITIES.—These responsibilities



303 apply to any physician who provides professional services in a 304 pain-management clinic that is required to be registered in 305 subsection (1).

306 (a) A physician may not practice medicine in a pain 307 management clinic, as described in subsection (4), if:

308 1. the pain-management clinic is not registered with the 309 department as required by this section.; or

310 2. Effective July 1, 2012, the physician has not successfully completed a pain-medicine fellowship that is accredited by the Accreditation Council for Graduate Medical Education or a pain-medicine residency that is accredited by the Accreditation Council for Graduate Medical Education or, prior to July 1, 2012, does not comply with rules adopted by the board.

Any physician who qualifies to practice medicine in a painmanagement clinic pursuant to rules adopted by the Board of Medicine as of July 1, 2012, may continue to practice medicine in a pain-management clinic as long as the physician continues to meet the qualifications set forth in the board rules. A physician who violates this paragraph is subject to disciplinary action by his or her appropriate medical regulatory board.

(c) A physician must perform a physical examination of a patient on the same day that he or she dispenses or prescribes a controlled substance to a patient at a pain-management clinic. If the physician prescribes or dispenses more than a 72-hour dose of controlled substances for the treatment of chronic nonmalignant pain, the physician must document in the patient's record the reason <u>such dosage is within the standard of care.</u>

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332 For the purpose of this paragraph, the standard of care is set forth in rule 64B8-9.013(3), Florida Administrative Code for 333 334 prescribing or dispensing that quantity. 335 (5) PENALTIES; ENFORCEMENT.-336 (f) A licensee or other person who serves as the designated 337 physician of a pain-management clinic as defined in this section 338 or s. 459.0137 and registers a pain-management clinic through 339 misrepresentation or fraud or procures or attempts to procure 340 the registration of a pain-management clinic for any other person by making or causing to be made any false or fraudulent 341 342 representation commits a felony of the third degree, punishable 343 as provided in s. 775.082, s. 775.083, or s. 775.084. 344 (q) Any person who registers a pain-management clinic 345 through misrepresentation or fraud or who procures or attempts 346 to procure the registration of a pain-management clinic for any 347 other person by making or causing to be made any false or 348 fraudulent representation, commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. 349 350 Section 8. Paragraphs (f) and (g) are added to subsection 351 (1), paragraphs (g) and (h) are added to subsection (2), and 352 subsection (3) is added to section 458.327, Florida Statutes, to 353 read: 354 458.327 Penalty for violations.-355 (1) Each of the following acts constitutes a felony of the 356 third degree, punishable as provided in s. 775.082, s. 775.083, 357 or s. 775.084: 358 (f) Failing to perform a physical examination of a patient 359 by a physician or a licensed designee acting under the 360 physician's supervision on the same day that the treating

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361physician dispenses or prescribes a controlled substance to the362patient at a pain-management clinic occurring three or more363times within a 6-month period, or failing to perform a physical364examination on three or more different patients on the same day365that the treating physician dispenses or prescribes a controlled366substance to each patient at a pain-management clinic within a3676-month period.368(g) Prescribing or dispensing in excess of a 72-hour dose369of controlled substances for the treatment of chronic370nommalignant pain of a patient occurring three or more times371within a 6-month period without documenting in the patient's372record the reason that such dosage is within the standard of373care. For the purpose of this paragraph, the standard of care is374set forth in rule 6488-9.013(3), Florida Administrative Code.375(2) Each of the following acts constitutes a misdemeanor of376the first degree, punishable as provided in s. 775.082 or s.377775.083:378(g) Failing to perform a physical examination of a patient379on the same day that the treating physician dispenses or389perform a physical examination on two different patients on the381same day that the treating physician dispenses or prescribes a372controlled substance to each patient at a pain-management clinic374same day that the treating physician dispenses or prescribes a375(h) Prescribing or dispensing in	1	
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383 <u>same day that the treating physician dispenses or prescribes a</u> 384 <u>controlled substance to each patient at a pain-management clinic</u> 385 <u>within a 6-month period.</u> 386 <u>(h) Prescribing or dispensing in excess of a 72-hour dose</u> 387 <u>of controlled substances for the treatment of chronic</u> 388 <u>nonmalignant pain of a patient occurring two times within a 6-</u>	381	management clinic two times in a 6-month period, or failing to
384 <u>controlled substance to each patient at a pain-management clinic</u> 385 <u>within a 6-month period.</u> 386 <u>(h) Prescribing or dispensing in excess of a 72-hour dose</u> 387 <u>of controlled substances for the treatment of chronic</u> 388 <u>nonmalignant pain of a patient occurring two times within a 6-</u>	382	perform a physical examination on two different patients on the
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	387	of controlled substances for the treatment of chronic
389 month period without documenting in the patient's record the	388	nonmalignant pain of a patient occurring two times within a 6-
	389	month period without documenting in the patient's record the

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390	reason that such dosage is within the standard of care. For the
391	purpose of this paragraph, the standard of care is set forth in
392	rule 64B8-9.013(3), Florida Administrative Code.
393	(3) Each of the following acts constitutes a misdemeanor of
394	the second degree, punishable as provided in s. 775.082 or s.
395	<u>775.083:</u>
396	(a) A first offense of failing to perform a physical
397	examination of a patient on the same day that the treating
398	physician dispenses or prescribes a controlled substance to the
399	patient at a pain-management clinic.
400	(b) A first offense of failing to document in a patient's
401	record the reason that such dosage is within the standard of
402	care for prescribing or dispensing in excess of a 72-hour dose
403	of controlled substances for the treatment of chronic
404	nonmalignant pain.
405	Section 9. Subsection (11) is added to section 458.331,
406	Florida Statutes, to read:
407	458.331 Grounds for disciplinary action; action by the
408	board and department
409	(11) Notwithstanding subsection (2), upon finding that a
410	physician has prescribed or dispensed, or caused to be
411	prescribed or dispensed, a controlled substance in a pain-
412	management clinic in a manner that violates the standard of
413	practice as set forth in chapter 458 or rules adopted pursuant
414	to chapter 458, the board shall, at a minimum, suspend the
415	physician's license for at least 6 months and impose a fine of
416	at least \$10,000 per count. Repeated violations shall result in
417	increased penalties.
418	Section 10. Present subsections (3), (4), and (5) of

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419	section 459.003, Florida Statutes, are redesignated as
420	subsections (4), (5), and (6), respectively, and a new
421	subsection (3) is added to that section, to read:
422	459.003 DefinitionsAs used in this chapter:
423	(3) "Dispensing physician" means an osteopathic physician
424	who is registered as a dispensing practitioner under s.
425	465.0276.
426	Section 11. Paragraphs (f) and (g) are added to subsection
427	(1), paragraphs (e) and (f) are added to subsection (2), and
428	paragraphs (d) and (e) are added to subsection (3) of section
429	459.013, Florida Statutes, to read:
430	459.013 Penalty for violations
431	(1) Each of the following acts constitutes a felony of the
432	third degree, punishable as provided in s. 775.082, s. 775.083,
433	or s. 775.084:
434	(f) Failing to perform a physical examination of a patient
435	on the same day that the osteopathic physician dispenses or
436	prescribes a controlled substance to the patient at a pain-
437	management clinic occurring three or more times within a 6-month
438	period, or failing to perform a physical examination on three or
439	more different patients on the same day that the osteopathic
440	physician dispenses or prescribes a controlled substance to each
441	patient at a pain-management clinic within a 6-month period.
442	(g) Prescribing or dispensing in excess of a 72-hour dose
443	of controlled substances for the treatment of chronic
444	nonmalignant pain of a patient occurring three or more times
445	within a 6-month period without documenting in the patient's
446	record the reason that such dosage is within the standard of
447	care. For the purpose of this paragraph, the standard of care is

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448 set forth in rule 64B8-9.013(3), Florida Administrative Code. 449 (2) Each of the following acts constitutes a misdemeanor of 450 the first degree, punishable as provided in s. 775.082 or s. 451 775.083: 452 (e) Failing to perform a physical examination of a patient 453 on the same day that the osteopathic physician dispenses or 454 prescribes a controlled substance to the patient at a pain-455 management clinic occurring two times within a 6-month period, 456 or failing to perform a physical examination on two different 457 patients on the same day that the osteopathic physician 458 dispenses or prescribes a controlled substance to each patient 459 at a pain-management clinic within a 6-month period. 460 (f) Prescribing or dispensing in excess of a 72-hour dose 461 of controlled substances for the treatment of chronic 462 nonmalignant pain of a patient occurring two times within a 6-463 month period without documenting in the patient's record the 464 reason that such dosage is within the standard of care. For the 465 purpose of this paragraph, the standard of care is set forth in 466 rule 64B8-9.013(3), Florida Administrative Code. 467 (3) Each of the following constitutes a misdemeanor of the 468 second degree, punishable as provided in s. 775.082 or s. 469 775.083: 470 (d) A first offense of failing to perform a physical examination of a patient on the same day that the osteopathic 471 472 physician dispenses or prescribes a controlled substance to the 473 patient at a pain-management clinic. 474 (e) A first offense of failing to document in a patient's 475 record the reason that such dosage is within the standard of care for prescribing or dispensing in excess of a 72-hour dose 476

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477 of controlled substances for the treatment of chronic 478 nonmalignant pain. For the purpose of this paragraph, the 479 standard of care is set forth in rule 64B8-9.013(3), Florida 480 Administrative Code. 481 Section 12. Paragraph (c) of subsection (2) of section 482 459.0137, Florida Statutes, is amended, and a new paragraphs (f) 483 and (q) are added to subsection (5) of that section, to read: 484 459.0137 Pain-management clinics.-485 (2) PHYSICIAN RESPONSIBILITIES. - These responsibilities 486 apply to any osteopathic physician who provides professional 487 services in a pain-management clinic that is required to be 488 registered in subsection (1). 489 (c) An osteopathic physician must perform a physical 490 examination of a patient on the same day that he or she 491 dispenses or prescribes a controlled substance to a patient at a 492 pain-management clinic. If the osteopathic physician prescribes 493 or dispenses more than a 72-hour dose of controlled substances 494 for the treatment of chronic nonmalignant pain, the osteopathic 495 physician must document in the patient's record the reason for 496 which prescribing or dispensing a dosage in excess of a 72-hour 497 dose of controlled substances for the treatment of chronic 498 nonmalignant pain is within the standard of care for prescribing 499 or dispensing that quantity. 500 (5) PENALTIES; ENFORCEMENT.-501 (f) A licensee or other person who serves as the designated 502 physician of a pain-management clinic as defined in s. 458.3265 503 or s. 459.0137 and registers a pain-management clinic through 504 intentional misrepresentation or fraud or procures or attempts 505 to procure the registration of a pain-management clinic for any

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506	other person by making or causing to be made any false or
507	fraudulent representation commits a felony of the third degree,
508	punishable as provided in s. 775.082, s. 775.083, or s. 775.084.
509	(g) Any person who registers a pain-management clinic
510	through misrepresentation or fraud or who procures or attempts
511	to procure the registration of a pain-management clinic for any
512	other person by making or causing to be made any false or
513	fraudulent representation, commits a felony of the third degree,
514	punishable as provided in s. 775.082, s. 775.083, or s. 775.084.
515	Section 13. Subsection (11) is added to section 459.015,
516	Florida Statutes, to read:
517	459.015 Grounds for disciplinary action; action by the
518	board and department
519	(11) Notwithstanding subsection (2), upon finding that an
520	osteopathic physician has prescribed or dispensed, or caused to
521	be prescribed or dispensed, a controlled substance in a pain-
522	management clinic in a manner that violates the standard of
523	practice as set forth in chapter 459 or rules adopted pursuant
524	to chapter 459, the board shall, at a minimum, suspend the
525	osteopathic physician's license for at least 6 months and impose
526	a fine of at least \$10,000 per count. Repeated violations shall
527	result in increased penalties.
528	Section 14. Subsections (3) and (4) of section 465.015,
529	Florida Statutes, are renumbered as subsections (4) and (5),
530	respectively, and subsection (3) is added to that section, to
531	read:
532	465.015 Violations and penalties
533	(3)(a) A licensed pharmacist, pharmacy technician, or any
534	person working under the direction or supervision of a

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535	pharmacist or pharmacy technician, may not knowingly fail to
536	timely report to the local county sheriff's office the name of
537	any person who obtains or attempts to obtain a substance
538	controlled by s. 893.03 which the pharmacist, pharmacy intern,
539	or other person employed by or at a pharmacy knows or reasonably
540	should have known was obtained or attempted to be obtained from
541	the pharmacy through any fraudulent method or representation. A
542	pharmacist, pharmacy intern, or other person employed by or at a
543	pharmacy who fails to make such a report within 24 hours after
544	learning of the fraud or attempted fraud commits a misdemeanor
545	of the first degree, punishable as provided in s. 775.082 or s.
546	775.083.
547	(b) A sufficient report of the fraudulent obtaining of or
548	attempt to obtain a controlled substance under this section must
549	contain, at a minimum, a copy of the prescription used or
550	presented and a narrative, including all information available
551	to the pharmacy regarding:
552	1. The transaction, such as the name and telephone number
553	of the prescribing physician;
554	2. The name, description, and any personal identification
555	information pertaining to the person presenting the
556	prescription; and
557	3. All other material information, such as photographic or
558	video surveillance of the transaction.
559	
560	A pharmacist, pharmacy intern, or other person employed by or at
561	a pharmacy is not subject to disciplinary action for reporting
562	under this subsection.
563	Section 15. Subsection (6) is added to section 465.0276,
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564	Florida Statutes, to read:
565	465.0276 Dispensing practitioner
566	(6) In order to dispense a controlled substance listed in
567	Schedule II, Schedule III, or Schedule IV in s. 893.03, a
568	practitioner authorized by law to prescribe a controlled
569	substance shall register with the Board of Pharmacy as a
570	dispensing practitioner who dispenses controlled substances and
571	pay a fee not to exceed \$100. The department shall adopt rules
572	establishing procedures for renewal of the registration every 4
573	years.
574	Section 16. Paragraph (a) of subsection (1) of section
575	766.101, Florida Statutes, is amended to read:
576	766.101 Medical review committee, immunity from liability
577	(1) As used in this section:
578	(a) The term "medical review committee" or "committee"
579	means:
580	1.a. A committee of a hospital or ambulatory surgical
581	center licensed under chapter 395 or a health maintenance
582	organization certificated under part I of chapter 641,
583	b. A committee of a physician-hospital organization, a
584	provider-sponsored organization, or an integrated delivery
585	system,
586	c. A committee of a state or local professional society of
587	health care providers,
588	d. A committee of a medical staff of a licensed hospital or
589	nursing home, provided the medical staff operates pursuant to
590	written bylaws that have been approved by the governing board of
591	the hospital or nursing home,
592	e. A committee of the Department of Corrections or the



593 Correctional Medical Authority as created under s. 945.602, or 594 employees, agents, or consultants of either the department or 595 the authority or both,

596 f. A committee of a professional service corporation formed 597 under chapter 621 or a corporation organized under chapter 607 598 or chapter 617, which is formed and operated for the practice of 599 medicine as defined in <u>s. 458.305(4)</u> s. 458.305(3), and which 600 has at least 25 health care providers who routinely provide 601 health care services directly to patients,

g. A committee of the Department of Children and Family
Services which includes employees, agents, or consultants to the
department as deemed necessary to provide peer review,
utilization review, and mortality review of treatment services
provided pursuant to chapters 394, 397, and 916,

h. A committee of a mental health treatment facility
licensed under chapter 394 or a community mental health center
as defined in s. 394.907, provided the quality assurance program
operates pursuant to the guidelines which have been approved by
the governing board of the agency,

i. A committee of a substance abuse treatment and education
prevention program licensed under chapter 397 provided the
quality assurance program operates pursuant to the guidelines
which have been approved by the governing board of the agency,

j. A peer review or utilization review committee organizedunder chapter 440,

618 k. A committee of the Department of Health, a county health 619 department, healthy start coalition, or certified rural health 620 network, when reviewing quality of care, or employees of these 621 entities when reviewing mortality records, or

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622 1. A continuous quality improvement committee of a pharmacy 623 licensed pursuant to chapter 465, 624 625 which committee is formed to evaluate and improve the quality of 626 health care rendered by providers of health service, to 627 determine that health services rendered were professionally 628 indicated or were performed in compliance with the applicable 629 standard of care, or that the cost of health care rendered was 630 considered reasonable by the providers of professional health 631 services in the area; or 632 2. A committee of an insurer, self-insurer, or joint 633 underwriting association of medical malpractice insurance, or other persons conducting review under s. 766.106. 634 635 Section 17. Subsection (3) of section 810.02, Florida 636 Statutes, is amended to read: 637 810.02 Burglary.-638 (3) Burglary is a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, if, in the 639 640 course of committing the offense, the offender does not make an assault or battery and is not and does not become armed with a 641 642 dangerous weapon or explosive, and the offender enters or 643 remains in a: 644 (a) Dwelling, and there is another person in the dwelling at the time the offender enters or remains; 645 646 (b) Dwelling, and there is not another person in the 647 dwelling at the time the offender enters or remains; 648 (c) Structure, and there is another person in the structure

at the time the offender enters or remains;

(d) Conveyance, and there is another person in the

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651 conveyance at the time the offender enters or remains; or 652 (e) Authorized emergency vehicle, as defined in s. 316.003; 653 or. 654 (f) Structure or conveyance when the offense intended to be 655 committed is theft of a substance controlled by s. 893.03. 656 Notwithstanding any contrary provisions of law, separate 657 judgments and sentences for burglary with the intent to commit 658 theft of a controlled substance under this paragraph and for any 659 applicable offense for possession of a controlled substance 660 under s. 893.13, or an offense for trafficking in a controlled 661 substance under s. 893.135, may be imposed if all such offenses 662 involve the same amount or amounts of a controlled substance. 663

664 However, if the burglary is committed within a county that is 665 subject to a state of emergency declared by the Governor under 666 chapter 252 after the declaration of emergency is made and the 667 perpetration of the burglary is facilitated by conditions 668 arising from the emergency, the burglary is a felony of the 669 first degree, punishable as provided in s. 775.082, s. 775.083, 670 or s. 775.084. As used in this subsection, the term "conditions 671 arising from the emergency" means civil unrest, power outages, 672 curfews, voluntary or mandatory evacuations, or a reduction in 673 the presence of or response time for first responders or 674 homeland security personnel. A person arrested for committing a 675 burglary within a county that is subject to such a state of 676 emergency may not be released until the person appears before a 677 committing magistrate at a first appearance hearing. For purposes of sentencing under chapter 921, a felony offense that 678 is reclassified under this subsection is ranked one level above 679

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 committed. Section 18. Paragraph (c) of subsection (2) of section 812.014, Florida Statutes, is amended to read: 812.014 Theft (2) (c) It is grand theft of the third degree and a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, if the property stolen is: 1. Valued at \$300 or more, but less than \$5,000. 2. Valued at \$5,000 or more, but less than \$10,000. 3. Valued at \$10,000 or more, but less than \$20,000. 4. A will, codicil, or other testamentary instrument. 5. A firearm. 6. A motor vehicle, except as provided in paragraph (a). 7. Any commercially farmed animal, including any animal of the equine, bovine, or swine class, or other grazing animal, and including aquaculture species raised at a certified aquaculture facility. If the property stolen is aquaculture species raised at a certified aquaculture facility, then a \$10,000 fine shall be imposed. 8. Any fire extinguisher. 9. Any amount of citrus fruit consisting of 2,000 or more individual pieces of fruit. 10. Taken from a designated construction site identified by the posting of a sign as provided for in s. 810.09(2)(d). 11. Any stop sign. 12. Anhydrous ammonia. 13. Any amount of a substance controlled by s. 893.03. 	680	the ranking under s. 921.0022 or s. 921.0023 of the offense
 812.014, Florida Statutes, is amended to read: 812.014, Florida Statutes, is amended to read: 812.014 Theft (c) It is grand theft of the third degree and a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, if the property stolen is: 1. Valued at \$300 or more, but less than \$5,000. 2. Valued at \$5,000 or more, but less than \$10,000. 3. Valued at \$10,000 or more, but less than \$20,000. 4. A will, codicil, or other testamentary instrument. 5. A firearm. 6. A motor vehicle, except as provided in paragraph (a). 7. Any commercially farmed animal, including any animal of the equine, bovine, or swine class, or other grazing animal, and including aquaculture species raised at a certified aquaculture facility. If the property stolen is aquaculture species raised at a certified aquaculture facility, then a \$10,000 fine shall be imposed. 8. Any fire extinguisher. 9. Any amount of citrus fruit consisting of 2,000 or more individual pieces of fruit. 10. Taken from a designated construction site identified by the posting of a sign as provided for in s. 810.09(2)(d). 11. Any stop sign. 12. Anhydrous ammonia. 	681	committed.
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707 12. Anhydrous ammonia.	705	the posting of a sign as provided for in s. 810.09(2)(d).
-	706	11. Any stop sign.
708 13. Any amount of a substance controlled by s. 893.03.	707	12. Anhydrous ammonia.
	708	13. Any amount of a substance controlled by s. 893.03.

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Notwithstanding any contrary provisions of law, separate judgments and sentences for theft of a controlled substance under this subparagraph, and for any applicable offense for possession of a controlled substance under s. 893.13, or an offense for trafficking in a controlled substance under s. 893.135 may be imposed if all such offenses involve the same amount or amounts of controlled substance.

717 However, if the property is stolen within a county that is 718 subject to a state of emergency declared by the Governor under chapter 252, the property is stolen after the declaration of 719 720 emergency is made, and the perpetration of the theft is 721 facilitated by conditions arising from the emergency, the 722 offender commits a felony of the second degree, punishable as 723 provided in s. 775.082, s. 775.083, or s. 775.084, if the 724 property is valued at \$5,000 or more, but less than \$10,000, as 725 provided under subparagraph 2., or if the property is valued at 726 \$10,000 or more, but less than \$20,000, as provided under 727 subparagraph 3. As used in this paragraph, the term "conditions 728 arising from the emergency" means civil unrest, power outages, 729 curfews, voluntary or mandatory evacuations, or a reduction in 730 the presence of or the response time for first responders or 731 homeland security personnel. For purposes of sentencing under 732 chapter 921, a felony offense that is reclassified under this 733 paragraph is ranked one level above the ranking under s. 921.0022 or s. 921.0023 of the offense committed. 734

735 Section 19. Section 893.021, Florida Statutes, is created 736 to read:

893.021 Adulterated drug.-

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738	(1) As used in this chapter, a drug is adulterated if it is
739	a controlled substance that:
740	(a) Has been produced, prepared, packed, and marketed for
741	oral consumption by the manufacturer; and
742	(b) Has had any change to its integrity or composition for
743	use by means of inhalation, injection, or any other form of
744	ingestion not in accordance with the manufacturer's recommended
745	use, and such mode of use has not been previously directed and
746	approved by the prescribing physician.
747	(2) A physician is not prevented from directing or
748	prescribing a change to the recognized manufactured
749	recommendations for use in a patient who presents a medical need
750	for such a requirement change of any controlled substance. The
751	prescribing physician shall clearly indicate any deviation of
752	the recognized manufacturer's recommended use of a controlled
753	substance on the original prescription, and the licensed
754	pharmacist shall clearly indicate such deviation on the label of
755	the prescription upon dispensing the controlled substance.
756	Section 20. Paragraphs (c), (d), and (e) of subsection (1)
757	of section 893.04, Florida Statutes, are amended to read:
758	893.04 Pharmacist and practitioner
759	(1) A pharmacist, in good faith and in the course of
760	professional practice only, may dispense controlled substances
761	upon a written or oral prescription of a practitioner, under the
762	following conditions:
763	(c) The following information must There shall appear on
764	the face of the prescription or written record <u>of a</u> thereof for
765	the controlled substance the following information:
766	1. The full name and address of the person for whom, or the
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767 owner of the animal for which, the controlled substance is 768 dispensed. 769 2. The full name and address of the prescribing 770 practitioner and the practitioner's federal controlled substance 771 registry number shall be printed thereon. 772 3. If the prescription is for an animal, the species of 773 animal for which the controlled substance is prescribed. 774 4. The name of the controlled substance prescribed and the strength, quantity, and directions for use thereof. The 775 776 directions for use must specify the authorization by the 777 physician, any instructions requiring the adulteration of the 778 dispensed form of the medication, and the medical necessity for 779 the adulteration in accordance with s. 893.021. 780 5. The number of the prescription, as recorded in the 781 prescription files of the pharmacy in which it is filled. 782 6. The initials of the pharmacist filling the prescription 783 and the date filled. 784 (d) The prescription must shall be retained on file by the 785 proprietor of the pharmacy in which it is filled for a period of 786 2 years. 787 (e) A label bearing the following information must be 788 affixed to the original container in which a controlled 789 substance is delivered as upon a prescription or authorized refill thereof, as hereinafter provided, there shall be a label 790 791 bearing the following information: 792 1. The name and address of the pharmacy from which such 793 controlled substance was dispensed. 794 2. The date on which the prescription for such controlled 795 substance was filled.

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796 3. The number of such prescription, as recorded in the 797 prescription files of the pharmacy in which it is filled. 798 4. The name of the prescribing practitioner. 799 5. The name of the patient for whom, or of the owner and species of the animal for which, the controlled substance is 800 801 prescribed. 802 6. The directions for the use of the controlled substance 803 prescribed in the prescription. 804 7. A clear, concise warning that it is a crime to transfer 805 the controlled substance to any person other than the patient 806 for whom prescribed. 807 Section 21. Section 893.055, Florida Statutes, is amended to read: 808 809 893.055 Prescription drug monitoring program.-810 (1) As used in this section, the term: (a) "Patient advisory report" or "advisory report" means 811 812 information provided by the department in writing, or as determined by the department, to a prescriber, dispenser, 813 814 pharmacy, or patient concerning the dispensing of controlled 815 substances. All advisory reports are for informational purposes 816 only and impose no obligations of any nature or any legal duty on a prescriber, dispenser, pharmacy, or patient. The patient 817 818 advisory report shall be provided in accordance with s. 819 893.13(7)(a)8. The advisory reports issued by the department are 820 not subject to discovery or introduction into evidence in any 821 civil or administrative action against a prescriber, dispenser, 822 pharmacy, or patient arising out of matters that are the subject 823 of the report; and a person who participates in preparing, 824 reviewing, issuing, or any other activity related to an advisory



825 report may not be permitted or required to testify in any such 826 civil action as to any findings, recommendations, evaluations, 827 opinions, or other actions taken in connection with preparing, 828 reviewing, or issuing such a report.

(b) "Controlled substance" means a controlled substance
listed in Schedule II, Schedule III, or Schedule IV in s.
831 893.03.

832 (c) "Dispenser" means a pharmacy, dispensing pharmacist, or833 dispensing health care practitioner.

(d) "Health care practitioner" or "practitioner" means any
practitioner who is subject to licensure or regulation by the
department under chapter 458, chapter 459, chapter 461, chapter
462, chapter 464, chapter 465, or chapter 466.

(e) "Health care regulatory board" means any board for a
practitioner or health care practitioner who is licensed or
regulated by the department.

(f) "Pharmacy" means any pharmacy that is subject to licensure or regulation by the department under chapter 465 and that dispenses or delivers a controlled substance to an individual or address in this state.

(g) "Prescriber" means a prescribing physician, prescribingpractitioner, or other prescribing health care practitioner.

(h) "Active investigation" means an investigation that is being conducted with a reasonable, good faith belief that it could lead to the filing of administrative, civil, or criminal proceedings, or that is ongoing and continuing and for which there is a reasonable, good faith anticipation of securing an arrest or prosecution in the foreseeable future.

853

(i) "Law enforcement agency" means the Department of Law



Enforcement, a Florida sheriff's department, a Florida police department, or a law enforcement agency of the Federal Government which enforces the laws of this state or the United States relating to controlled substances, and which its agents and officers are empowered by law to conduct criminal investigations and make arrests.

(j) "Program manager" means an employee of or a person contracted by the Department of Health who is designated to ensure the integrity of the prescription drug monitoring program in accordance with the requirements established in paragraphs (2) (a) and (b).

865 (2) (a) By December 1, 2010, the department shall design and establish a comprehensive electronic database system that has 866 867 controlled substance prescriptions provided to it and that provides prescription information to a patient's health care 868 869 practitioner and pharmacist who inform the department that they 870 wish the patient advisory report provided to them. Otherwise, the patient advisory report will not be sent to the 871 872 practitioner, pharmacy, or pharmacist. The system shall be 873 designed to provide information regarding dispensed 874 prescriptions of controlled substances and shall not infringe 875 upon the legitimate prescribing or dispensing of a controlled 876 substance by a prescriber or dispenser acting in good faith and 877 in the course of professional practice. The system shall be consistent with standards of the American Society for Automation 878 in Pharmacy (ASAP). The electronic system shall also comply with 879 880 the Health Insurance Portability and Accountability Act (HIPAA) as it pertains to protected health information (PHI), electronic 881 protected health information (EPHI), the National All Schedules 882



883 Prescription Electronic Reporting (NASPER) Act's minimum 884 requirements for authentication of a practitioner who requests 885 information in the prescription drug monitoring program database 886 and certification of the purpose for which information is 887 requested, and all other relevant state and federal privacy and 888 security laws and regulations. The department shall establish 889 policies and procedures as appropriate regarding the reporting, 890 accessing the database, evaluation, management, development, 891 implementation, operation, storage, and security of information 892 within the system. The reporting of prescribed controlled 893 substances shall include a dispensing transaction with a 894 dispenser pursuant to chapter 465 or through a dispensing 895 transaction to an individual or address in this state with a 896 pharmacy that is not located in this state but that is otherwise 897 subject to the jurisdiction of this state as to that dispensing 898 transaction. The reporting of patient advisory reports refers 899 only to reports to patients, pharmacies, and practitioners. 900 Separate reports that contain patient prescription history 901 information and that are not patient advisory reports are 902 provided to persons and entities as authorized in paragraphs 903 (7) (b) and (c) and s. 893.0551.

904 (b) The department, when the direct support organization 905 receives at least \$20,000 in nonstate moneys or the state 906 receives at least \$20,000 in federal grants for the prescription 907 drug monitoring program, and in consultation with the Office of 908 Drug Control, shall adopt rules as necessary concerning the 909 reporting, accessing the database, evaluation, management, development, implementation, operation, security, and storage of 910 information within the system, including rules for when patient 911



912 advisory reports are provided to pharmacies and prescribers. The 913 patient advisory report shall be provided in accordance with s. 914 893.13(7)(a)8. The department shall work with the professional 915 health care licensure boards, such as the Board of Medicine, the 916 Board of Osteopathic Medicine, and the Board of Pharmacy; other 917 appropriate organizations, such as the Florida Pharmacy 918 Association, the Office of Drug Control, the Florida Medical Association, the Florida Retail Federation, and the Florida 919 920 Osteopathic Medical Association, including those relating to 921 pain management; and the Attorney General, the Department of Law 922 Enforcement, and the Agency for Health Care Administration to 923 develop rules appropriate for the prescription drug monitoring 924 program.

925 (c) All dispensers and prescribers subject to these
926 reporting requirements shall be notified by the department of
927 the implementation date for such reporting requirements.

928 (d) The program manager shall work with professional health
929 care licensure boards and the stakeholders listed in paragraph
930 (b) to develop rules appropriate for identifying indicators of
931 controlled substance abuse.

932 (e) The department shall establish a method to allow 933 corrections to the database when notified by a health care 934 practitioner or pharmacist.

935 (3) The pharmacy dispensing the controlled substance and 936 each prescriber who directly dispenses a controlled substance 937 shall submit to the electronic system, by a procedure and in a 938 format established by the department and consistent with an 939 ASAP-approved format, the following information for inclusion in 940 the database:



941 (a) The name of the prescribing practitioner, the
942 practitioner's federal Drug Enforcement Administration
943 registration number, the practitioner's National Provider
944 Identification (NPI) or other appropriate identifier, and the
945 date of the prescription.

(b) The date the prescription was filled and the method of
payment, such as cash by an individual, insurance coverage
through a third party, or Medicaid payment. This paragraph does
not authorize the department to include individual credit card
numbers or other account numbers in the database.

951 (c) The full name, address, and date of birth of the person 952 for whom the prescription was written.

953 (d) The name, national drug code, quantity, and strength of 954 the controlled substance dispensed.

955 (e) The full name, federal Drug Enforcement Administration 956 registration number, and address of the pharmacy or other 957 location from which the controlled substance was dispensed. If 958 the controlled substance was dispensed by a practitioner other 959 than a pharmacist, the practitioner's full name, federal Drug 960 Enforcement Administration registration number, and address.

961 (f) The name of the pharmacy or practitioner, other than a 962 pharmacist, dispensing the controlled substance and the 963 practitioner's National Provider Identification (NPI).

964 (g) Other appropriate identifying information as determined 965 by department rule.

966 (h) The number of refills ordered and whether the drug was 967 dispensed as a refill of a prescription or was a first-time 968 request.

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(4) Each time a controlled substance is dispensed to an



970 individual, the controlled substance shall be reported to the 971 department through the system as soon thereafter as possible, 972 but not more than 7 $\frac{15}{15}$ days after the date the controlled 973 substance is dispensed unless an extension is approved by the 974 department for cause as determined by rule. A dispenser must 975 meet the reporting requirements of this section by providing the 976 required information concerning each controlled substance that 977 it dispensed in a department-approved, secure methodology and 978 format. Such approved formats may include, but are not limited 979 to, submission via the Internet, on a disc, or by use of regular 980 mail.

981 (5) When the following acts of dispensing or administering
982 occur, the following are exempt from reporting under this
983 section for that specific act of dispensing or administration:

(a) A health care practitioner when administering a
controlled substance directly to a patient if the amount of the
controlled substance is adequate to treat the patient during
that particular treatment session.

(b) A pharmacist or health care practitioner when administering a controlled substance to a patient or resident receiving care as a patient at a hospital, nursing home, ambulatory surgical center, hospice, or intermediate care facility for the developmentally disabled which is licensed in this state.

994 (c) A practitioner when administering or dispensing a 995 controlled substance in the health care system of the Department 996 of Corrections.

997 <u>(c) (d)</u> A practitioner when administering a controlled 998 substance in the emergency room of a licensed hospital.

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999 <u>(d) (e)</u> A health care practitioner when administering or 1000 dispensing a controlled substance to a person under the age of 1001 16 if the amount of the controlled substance is adequate to 1002 treat the patient during that particular treatment session.

1003 (e) (f) A pharmacist or a dispensing practitioner when 1004 dispensing a one-time, <u>48-hour</u> 72-hour emergency resupply of a 1005 controlled substance to a patient.

1006 (6) The department may establish when to suspend and when 1007 to resume reporting information during a state-declared or 1008 nationally declared disaster.

1009 (7) (a) A practitioner or pharmacist who dispenses a 1010 controlled substance must submit the information required by this section in an electronic or other method in an ASAP format 1011 1012 approved by rule of the department unless otherwise provided in 1013 this section. The cost to the dispenser in submitting the 1014 information required by this section may not be material or 1015 extraordinary. Costs not considered to be material or extraordinary include, but are not limited to, regular postage, 1016 1017 electronic media, regular electronic mail, and facsimile 1018 charges.

1019 (b)1. In order for a pharmacy, prescriber, practitioner, or 1020 dispenser to shall have access to information in the prescription drug monitoring program's database which relates to 1021 1022 a patient of that pharmacy, prescriber, practitioner, or 1023 dispenser, the pharmacy, prescriber, practitioner, or dispenser 1024 shall register with the department by submitting a registering 1025 document provided by the department. The document and validation 1026 of that document shall be determined by the department. Before a 1027 pharmacy, prescriber, practitioner, or dispenser is granted

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1028 access to information in the database from the prescription drug 1029 monitoring program, the department shall approve the submitted document. Upon approval, the department shall grant the 1030 1031 registrant access to the appropriate information in the 1032 prescription drug monitoring program's database in a manner established by the department as needed for the purpose of 1033 1034 reviewing the patient's controlled substance prescription 1035 history.

1036 2. Other access to the program's database shall be limited 1037 to the program's manager and to the designated program and 1038 support staff, who may act only at the direction of the program 1039 manager or, in the absence of the program manager, as 1040 authorized. Access by the program manager or such designated 1041 staff is for prescription drug program management only or for management of the program's database and its system in support 1042 1043 of the requirements of this section and in furtherance of the prescription drug monitoring program. Confidential and exempt 1044 1045 information in the database shall be released only as provided 1046 in paragraph (c) and s. 893.0551. The program manager, 1047 designated program and support staff who act at the direction of 1048 or in the absence of the program manager, and any individual who 1049 has similar access regarding the management of the database from 1050 the prescription drug monitoring program shall submit 1051 fingerprints to the department for background screening. The 1052 department shall follow the procedure established by the 1053 Department of Law Enforcement to request a statewide criminal 1054 history record check and to request that the Department of Law 1055 Enforcement forward the fingerprints to the Federal Bureau of 1056 Investigation for a national criminal history record check.

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1057 (c) The following entities may shall not have be allowed direct access to information in the prescription drug monitoring 1058 1059 program database but may request from the program manager and, 1060 when authorized by the program manager, the program manager's program and support staff, information that is confidential and 1061 1062 exempt under s. 893.0551. Prior to release, the request shall be 1063 verified as authentic and authorized with the requesting 1064 organization by the program manager, the program manager's 1065 program and support staff, or as determined in rules by the 1066 department as being authentic and as having been authorized by 1067 the requesting entity:

1068 1. The department or its relevant health care regulatory 1069 boards responsible for the licensure, regulation, or discipline 1070 of practitioners, pharmacists, or other persons who are 1071 authorized to prescribe, administer, or dispense controlled 1072 substances and who are involved in a specific controlled 1073 substance investigation involving a designated person for one or 1074 more prescribed controlled substances.

1075 2. The Attorney General for Medicaid fraud cases or 1076 <u>Medicaid investigations</u> involving prescribed controlled 1077 substances.

1078 3. A law enforcement agency during active investigations
1079 regarding potential criminal activity, fraud, or theft regarding
1080 prescribed controlled substances.

4. A patient or the legal guardian or designated health
care surrogate of an incapacitated patient as described in s.
893.0551 who, for the purpose of verifying the accuracy of the
database information, submits a written and notarized request
that includes the patient's full name, address, and date of



1086 birth, and includes the same information if the legal guardian 1087 or health care surrogate submits the request. The patient's 1088 phone number, current address, and a copy of a government-issued photo identification must be provided in person to the program 1089 1090 manager along with the notarized request. The request shall be 1091 validated by the department to verify the identity of the 1092 patient and the legal guardian or health care surrogate, if the 1093 patient's legal quardian or health care surrogate is the 1094 requestor. Such verification is also required for any request to 1095 change a patient's prescription history or other information 1096 related to his or her information in the electronic database.

5. The Agency for Health Care Administration for Medicaid fraud cases or Medicaid investigations involving prescribed controlled substances.

Information in the database for the electronic prescription drug monitoring system is not discoverable or admissible in any civil or administrative action, except in an investigation and disciplinary proceeding by the department or the appropriate regulatory board.

1106 (d) The following entities may shall not have be allowed 1107 direct access to information in the prescription drug monitoring 1108 program database but may request from the program manager and, 1109 when authorized by the program manager, the program manager's 1110 program and support staff, information that contains no 1111 identifying information of any patient, physician, health care 1112 practitioner, prescriber, or dispenser and that is not 1113 confidential and exempt:

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1. Department staff for the purpose of calculating



1115 performance measures pursuant to subsection (8).

1116 2. The Program Implementation and Oversight Task Force for 1117 its reporting to the Governor, the President of the Senate, and 1118 the Speaker of the House of Representatives regarding the 1119 prescription drug monitoring program. This subparagraph expires 1120 July 1, 2012.

1121 (e) All transmissions of data required by this section must comply with relevant state and federal privacy and security laws 1122 1123 and regulations. However, any authorized agency or person under 1124 s. 893.0551 receiving such information as allowed by s. 893.0551 1125 may maintain the information received for up to 24 months before 1126 purging it from his or her records or maintain it for longer 1127 than 24 months if the information is pertinent to ongoing health 1128 care or an active law enforcement investigation or prosecution.

(f) The program manager, upon determining a pattern consistent with the rules established under paragraph (2) (d) and having cause to believe a violation of s. 893.13(7) (a)8., (8) (a), or (8) (b) has occurred, may provide relevant information to the applicable law enforcement agency.

1134 (8) To assist in fulfilling program responsibilities, 1135 performance measures shall be reported annually to the Governor, the President of the Senate, and the Speaker of the House of 1136 1137 Representatives by the department each December 1, beginning in 11.38 2011. Data that does not contain patient, physician, health care 1139 practitioner, prescriber, or dispenser identifying information 1140 may be requested during the year by department employees so that 1141 the department may undertake public health care and safety initiatives that take advantage of observed trends. Performance 1142 1143 measures may include, but are not limited to, efforts to achieve

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1144 the following outcomes:

(a) Reduction of the rate of inappropriate use of prescription drugs through department education and safety efforts.

(b) Reduction of the quantity of pharmaceutical controlled substances obtained by individuals attempting to engage in fraud and deceit.

1151 (c) Increased coordination among partners participating in 1152 the prescription drug monitoring program.

(d) Involvement of stakeholders in achieving improved patient health care and safety and reduction of prescription drug abuse and prescription drug diversion.

(9) Any person who willfully and knowingly fails to report the dispensing of a controlled substance as required by this section commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

1160 (10) All costs incurred by the department in administering the prescription drug monitoring program shall be funded through 1161 1162 federal grants or private funding applied for or received by the 1163 state. The department may not commit funds for the monitoring program without ensuring funding is available. The prescription 1164 drug monitoring program and the implementation thereof are 1165 contingent upon receipt of the nonstate funding. The department 1166 1167 and state government shall cooperate with the direct-support 1168 organization established pursuant to subsection (11) in seeking 1169 federal grant funds, other nonstate grant funds, gifts, 1170 donations, or other private moneys for the department so long as the costs of doing so are not considered material. Nonmaterial 1171 1172 costs for this purpose include, but are not limited to, the

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1173 costs of mailing and personnel assigned to research or apply for 1174 a grant. Notwithstanding the exemptions to competitive-1175 solicitation requirements under s. 287.057(3)(f), the department 1176 shall comply with the competitive-solicitation requirements 1177 under s. 287.057 for the procurement of any goods or services 1178 required by this section.

(11) The Office of Drug Control, in coordination with the department, may establish a direct-support organization that has a board consisting of at least five members to provide assistance, funding, and promotional support for the activities authorized for the prescription drug monitoring program.

(a) As used in this subsection, the term "direct-support organization" means an organization that is:

1186 1. A Florida corporation not for profit incorporated under 1187 chapter 617, exempted from filing fees, and approved by the 1188 Department of State.

1189 2. Organized and operated to conduct programs and activities; raise funds; request and receive grants, gifts, and 1190 1191 bequests of money; acquire, receive, hold, and invest, in its 1192 own name, securities, funds, objects of value, or other 1193 property, either real or personal; and make expenditures or 1194 provide funding to or for the direct or indirect benefit of the 1195 department in the furtherance of the prescription drug 1196 monitoring program.

(b) The direct-support organization is not considered a lobbying firm within the meaning of s. 11.045.

(c) The director of the Office of Drug Control shall
appoint a board of directors for the direct-support
organization. The director may designate employees of the Office

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1202 of Drug Control, state employees other than state employees from 1203 the department, and any other nonstate employees as appropriate, 1204 to serve on the board. Members of the board shall serve at the 1205 pleasure of the director of the Office of Drug Control. The 1206 director shall provide guidance to members of the board to 1207 ensure that moneys received by the direct-support organization 1208 are not received from inappropriate sources. Inappropriate 1209 sources include, but are not limited to, donors, grantors, 1210 persons, or organizations that may monetarily or substantively 1211 benefit from the purchase of goods or services by the department 1212 in furtherance of the prescription drug monitoring program.

(d) The direct-support organization shall operate under written contract with the Office of Drug Control. The contract must, at a minimum, provide for:

1216 1. Approval of the articles of incorporation and bylaws of 1217 the direct-support organization by the Office of Drug Control.

1218 2. Submission of an annual budget for the approval of the1219 Office of Drug Control.

1220 3. Certification by the Office of Drug Control in 1221 consultation with the department that the direct-support 1222 organization is complying with the terms of the contract in a 1223 manner consistent with and in furtherance of the goals and 1224 purposes of the prescription drug monitoring program and in the best interests of the state. Such certification must be made 1225 1226 annually and reported in the official minutes of a meeting of 1227 the direct-support organization.

4. The reversion, without penalty, to the Office of Drug
Control, or to the state if the Office of Drug Control ceases to
exist, of all moneys and property held in trust by the direct-



1231 support organization for the benefit of the prescription drug 1232 monitoring program if the direct-support organization ceases to 1233 exist or if the contract is terminated.

5. The fiscal year of the direct-support organization, which must begin July 1 of each year and end June 30 of the following year.

1237 6. The disclosure of the material provisions of the
1238 contract to donors of gifts, contributions, or bequests,
1239 including such disclosure on all promotional and fundraising
1240 publications, and an explanation to such donors of the
1241 distinction between the Office of Drug Control and the direct1242 support organization.

1243 7. The direct-support organization's collecting, expending, 1244 and providing of funds to the department for the development, 1245 implementation, and operation of the prescription drug 1246 monitoring program as described in this section and s. 2, 1247 chapter 2009-198, Laws of Florida, as long as the task force is 1248 authorized. The direct-support organization may collect and 1249 expend funds to be used for the functions of the direct-support 1250 organization's board of directors, as necessary and approved by 1251 the director of the Office of Drug Control. In addition, the 1252 direct-support organization may collect and provide funding to 1253 the department in furtherance of the prescription drug 1254 monitoring program by:

1255 a. Establishing and administering the prescription drug 1256 monitoring program's electronic database, including hardware and 1257 software.

b. Conducting studies on the efficiency and effectivenessof the program to include feasibility studies as described in



1260 subsection (13).

1261 c. Providing funds for future enhancements of the program
1262 within the intent of this section.

d. Providing user training of the prescription drug monitoring program, including distribution of materials to promote public awareness and education and conducting workshops or other meetings, for health care practitioners, pharmacists, and others as appropriate.

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e. Providing funds for travel expenses.

1269 f. Providing funds for administrative costs, including 1270 personnel, audits, facilities, and equipment.

g. Fulfilling all other requirements necessary to implement and operate the program as outlined in this section.

1273 (e) The activities of the direct-support organization must 1274 be consistent with the goals and mission of the Office of Drug 1275 Control, as determined by the office in consultation with the 1276 department, and in the best interests of the state. The direct-1277 support organization must obtain a written approval from the 1278 director of the Office of Drug Control for any activities in 1279 support of the prescription drug monitoring program before 1280 undertaking those activities.

1281 (f) The Office of Drug Control, in consultation with the 1282 department, may permit, without charge, appropriate use of 1283 administrative services, property, and facilities of the Office 1284 of Drug Control and the department by the direct-support 1285 organization, subject to this section. The use must be directly 1286 in keeping with the approved purposes of the direct-support organization and may not be made at times or places that would 1287 1288 unreasonably interfere with opportunities for the public to use



1289 such facilities for established purposes. Any moneys received 1290 from rentals of facilities and properties managed by the Office 1291 of Drug Control and the department may be held by the Office of 1292 Drug Control or in a separate depository account in the name of 1293 the direct-support organization and subject to the provisions of 1294 the letter of agreement with the Office of Drug Control. The 1295 letter of agreement must provide that any funds held in the 1296 separate depository account in the name of the direct-support 1297 organization must revert to the Office of Drug Control if the 1298 direct-support organization is no longer approved by the Office 1299 of Drug Control to operate in the best interests of the state.

(g) The Office of Drug Control, in consultation with the department, may adopt rules under s. 120.54 to govern the use of administrative services, property, or facilities of the department or office by the direct-support organization.

(h) The Office of Drug Control may not permit the use of any administrative services, property, or facilities of the state by a direct-support organization if that organization does not provide equal membership and employment opportunities to all persons regardless of race, color, religion, gender, age, or national origin.

(i) The direct-support organization shall provide for an
independent annual financial audit in accordance with s.
215.981. Copies of the audit shall be provided to the Office of
Drug Control and the Office of Policy and Budget in the
Executive Office of the Governor.

1315 (j) The direct-support organization may not exercise any 1316 power under s. 617.0302(12) or (16).

(12) A prescriber or dispenser may have access to the

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1318 information under this section which relates to a patient of 1319 that prescriber or dispenser as needed for the purpose of 1320 reviewing the patient's controlled drug prescription history. A 1321 prescriber or dispenser acting in good faith is immune from any 1322 civil, criminal, or administrative liability that might 1323 otherwise be incurred or imposed for receiving or using 1324 information from the prescription drug monitoring program. This 1325 subsection does not create a private cause of action, and a 1326 person may not recover damages against a prescriber or dispenser 1327 authorized to access information under this subsection for 1328 accessing or failing to access such information.

1329 (13) To the extent that funding is provided for such 1330 purpose through federal or private grants or gifts and other 1331 types of available moneys, the department, in collaboration with the Office of Drug Control, shall study the feasibility of 1332 1333 enhancing the prescription drug monitoring program for the 1334 purposes of public health initiatives and statistical reporting 1335 that respects the privacy of the patient, the prescriber, and 1336 the dispenser. Such a study shall be conducted in order to 1337 further improve the quality of health care services and safety 1338 by improving the prescribing and dispensing practices for 1339 prescription drugs, taking advantage of advances in technology, reducing duplicative prescriptions and the overprescribing of 1340 1341 prescription drugs, and reducing drug abuse. The requirements of 1342 the National All Schedules Prescription Electronic Reporting 1343 (NASPER) Act are authorized in order to apply for federal NASPER 1344 funding. In addition, the direct-support organization shall provide funding for the department, in collaboration with the 1345 1346 Office of Drug Control, to conduct training for health care



1347 practitioners and other appropriate persons in using the 1348 monitoring program to support the program enhancements.

1349 (14) A pharmacist, pharmacy, or dispensing health care 1350 practitioner or his or her agent, before releasing a controlled 1351 substance to any person not known to such dispenser, shall 1352 require the person purchasing, receiving, or otherwise acquiring 1353 the controlled substance to present valid photographic 1354 identification or other verification of his or her identity to 1355 the dispenser. If the person does not have proper 1356 identification, the dispenser may verify the validity of the 1357 prescription and the identity of the patient with the prescriber 1358 or his or her authorized agent. Verification of health plan 1359 eligibility through a real-time inquiry or adjudication system 1360 will be considered to be proper identification. This subsection 1361 does not apply in an institutional setting or to a long-term 1362 care facility, including, but not limited to, an assisted living 1363 facility or a hospital to which patients are admitted. As used 1364 in this subsection, the term "proper identification" means an 1365 identification that is issued by a state or the Federal 1366 Government containing the person's photograph, printed name, and 1367 signature or a document considered acceptable under 8 C.F.R. s. 1368 274a.2(b)(1)(v)(A) and (B).

(15) The Agency for Health Care Administration shall continue the promotion of electronic prescribing by health care practitioners, health care facilities, and pharmacies under s. 408.0611.

(16) By October 1, 2010, the department shall adopt rules pursuant to ss. 120.536(1) and 120.54 to administer the provisions of this section, which shall include as necessary the

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1376	reporting, accessing, evaluation, management, development,
1377	implementation, operation, and storage of information within the
1378	monitoring program's system.
1379	(17) After the prescription drug monitoring program has
1380	been operational for 12 months, the State Surgeon General shall
1381	enter into reciprocal agreements for the sharing of prescription
1382	drug monitoring information with any other state that has a
1383	compatible prescription drug monitoring program. If the State
1384	Surgeon General evaluates the prescription drug monitoring
1385	program of another state as authorized in this subsection,
1386	priority shall be given to a state that is contiguous with the
1387	borders of this state.
1388	(a) In determining compatibility, the State Surgeon General
1389	shall consider:
1390	1. The essential purposes of the program and the success of
1391	the program in fulfilling those purposes.
1392	2. The safeguards for privacy of patient records and the
1393	success of the program in protecting patient privacy.
1394	3. The persons authorized to view the data collected by the
1395	program. Comparable organizations and professions for
1396	practitioners in other states, law enforcement agencies, the
1397	Attorney General's Medicaid Fraud Unit, medical regulatory
1398	boards, and, as needed, management staff who have similar duties
1399	as management staff who work with the prescription drug
1400	monitoring program as authorized in s. 893.0551 are authorized
1401	access upon approval by the State Surgeon General.
1402	4. The schedules of the controlled substances that are
1403	monitored.
1404	5. The data required to be submitted for each prescription.

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6. Any implementing criteria deemed essential for a
thorough comparison.
(b) The State Surgeon General shall annually review any
agreement to determine its continued compatibility with the
prescription drug monitoring program in this state.
(c) Any agreement between the State Surgeon General and
another state shall prohibit the sharing of information
concerning a resident of this state or a practitioner,
pharmacist, or other prescriber for any purpose that is not
otherwise authorized by this section or s. 893.0551.
Section 22. Present subsections (4), (5), (6), and (7) of
section 893.0551, Florida Statutes, are redesignated as
subsections (5), (6), (7), and (8), respectively, and a new
subsection (4) is added to that section, to read:
893.0551 Public records exemption for the prescription drug
monitoring program
(4) The department may disclose confidential and exempt
information contained in records held by the department under s.
893.055 if the State Surgeon General has entered into a
reciprocal agreement for the sharing of prescription drug
monitoring information with any other state that has a
compatible prescription drug monitoring program.
(a) The reciprocal agreement may allow the following
persons from another state to receive information from the
prescription drug monitoring program if approved by the State
Surgeon General:
1. A designated representative of a state professional
licensing, certification, or regulatory agency charged with
oversight of those persons authorized to prescribe or dispense



1434	controlled substances for the purpose of a bona fide, specific
1435	investigation of a prescription of a controlled substance which
1436	involves a designated person. As required in s. 893.055, this
1437	authorization does not preclude the requirement for the program
1438	manager to review the request for information and validate it.
1439	2. A health care practitioner or pharmacist licensed in the
1440	state from which the request originates. Such health care
1441	practitioner or pharmacist shall certify that the requested
1442	information is for the purpose of providing medical or
1443	pharmaceutical treatment to a bona fide, current patient. The
1444	health care practitioner or pharmacist shall follow all the
1445	procedures required in s. 893.055 and rules established by the
1446	department for a health care practitioner or pharmacist to
1447	request information from the database.
1448	3. A law enforcement officer from another state:
1449	a. Who is a member of a sheriff's department or a police
1450	department;
1451	b. Who is authorized by law to conduct criminal
1452	investigations and make arrests;
1453	c. Whose duty it is to enforce the laws of his or her state
1454	relating to controlled substances; and
1455	d. Who is engaged in a bona fide specific, active
1456	investigation involving a designated person regarding
1457	prescriptions for controlled substances.
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1459	As required in s. 893.055, this authorization does not preclude
1460	the requirement for the program manager to review the request
1461	for information and validate it. This authorization also does
1462	not preclude the ability to provide a report to a law
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1463 enforcement agency in another state under s. 893.055(7) or this
1464 subsection.

1465 (b) Any agreement between the State Surgeon General and 1466 another state shall prohibit the sharing of information 1467 concerning a resident of this state, a patient whose information 1468 is in the program's database, or a practitioner, pharmacy, 1469 pharmacist, health care practitioner, or other prescriber for 1470 any purpose that is not otherwise authorized by this section or 1471 s. 893.055, and the information must be provided according to 1472 the State Surgeon General's determination of compatibility as 1473 described in s. 893.055(17).

1474 Section 23. Subsections (1), (4), and (5) of section 1475 893.07, Florida Statutes, are amended, and a new subsection (6) 1476 is added to that section to read:

893.07 Records.-

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1478 (1) Notwithstanding any other provision of law and in 1479 consonance with the authority of State v. Carter, 23 So. 3d 798 1480 (Fla. 1st DCA 2009) and State v. Tamulonis, 39 So. 3d 524 (Fla. 1481 2nd DCA 2010), every person who engages in the manufacture, 1482 compounding, mixing, cultivating, growing, or by any other 1483 process producing or preparing, or in the dispensing, 1484 importation, or, as a wholesaler, distribution, of controlled 1485 substances shall:

(a) On January 1, 1974, or as soon thereafter as any person
first engages in such activity, and every second year
thereafter, make a complete and accurate record of all stocks of
controlled substances on hand. The inventory may be prepared on
the regular physical inventory date which is nearest to, and
does not vary by more than 6 months from, the biennial date that

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1492 would otherwise apply. As additional substances are designated 1493 for control under this chapter, they shall be inventoried as 1494 provided for in this subsection.

(b) On and after January 1, 1974, maintain, on a current basis, a complete and accurate record of each substance manufactured, received, sold, delivered, or otherwise disposed of by him or her, except that this subsection shall not require the maintenance of a perpetual inventory.

1501 Compliance with the provisions of federal law pertaining to the 1502 keeping of records of controlled substances shall be deemed a 1503 compliance with the requirements of this subsection.

1504 (4) Every inventory or record required by this chapter,1505 including prescription records, shall be maintained:

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(a) Separately from all other records of the registrant, or

(b) Alternatively, in the case of Schedule III, IV, or V controlled substances, in such form that information required by this chapter is readily retrievable from the ordinary business records of the registrant.

1512 In either case, <u>such</u> records <u>described in this subsection</u> shall 1513 be kept and made available for a period of at least 2 years for 1514 inspection and copying by law enforcement officers whose duty it 1515 is to enforce the laws of this state relating to controlled 1516 substances. <u>This subsection does not require a law enforcement</u> 1517 <u>officer to obtain a subpoena, court order, or search warrant in</u> 1518 order to obtain access to or copies of such records.

1519 (5) Each person shall maintain a record <u>that contains</u> which
 1520 shall contain a detailed list of controlled substances lost,



1521 destroyed, or stolen, if any; the kind and quantity of such 1522 controlled substances; and the date of the discovering of such 1523 loss, destruction, or theft. If a person discovers the theft or 1524 loss of a controlled substance, such person shall report the 1525 theft or loss to a local county sheriff's office within 48 hours 1526 after the discovery of such theft or loss. A person who fails to 1527 report the theft or loss of a controlled substance under this 1528 subsection commits a misdemeanor of the second degree, 1529 punishable as provided in s. 775.082 or s. 775.083. However, a 1530 person who fails to report the theft or loss of a Schedule II 1531 controlled substance commits a misdemeanor of the first degree, 1532 punishable as provided in s. 775.082 or s. 775.083. 1533 (6) The Legislature finds that the opinions rendered in 1534 State v. Carter, 23 So. 3d 798 (Fla. 1st DCA 2009), and State v. 1535 Tamulonis, 39 So. 3d 524 (Fla. 2nd DCA 2010), correctly construe 1536 this Legislature's intent that the inspection powers previously 1537 conferred upon law enforcement officers which allow such 1538 officers to access and review pharmacy records concerning 1539 controlled substances are to be exercised properly by such law 1540 enforcement officers without the requirement of a subpoena or 1541 search warrant being sought or issued to examine and copy such 1542 records, and without the requirement that those persons to whom 1543 particular pharmacy records refer be given notice of the 1544 records' examination and copying under this section. 1545 Section 24. Subsections (7) and (8) of section 893.13, 1546 Florida Statutes, are amended to read: 1547 893.13 Prohibited acts; penalties.-(7) (a) A It is unlawful for any person may not: 1548 1549 1. To Distribute or dispense a controlled substance in



1550 violation of this chapter.

1551 2. To Refuse or fail to make, keep, or furnish any record,
1552 notification, order form, statement, invoice, or information
1553 required under this chapter.

1554 3. To Refuse an entry into any premises for any inspection
1555 or to refuse to allow any inspection authorized by this chapter.

1556 4. To Distribute a controlled substance named or described 1557 in s. 893.03(1) or (2) except pursuant to an order form as 1558 required by s. 893.06.

1559 5. To Keep or maintain any store, shop, warehouse, 1560 dwelling, building, vehicle, boat, aircraft, or other structure 1561 or place which is resorted to by persons using controlled 1562 substances in violation of this chapter for the purpose of using 1563 these substances, or which is used for keeping or selling them 1564 in violation of this chapter.

1565 6. To Use to his or her own personal advantage, or to 1566 reveal, any information obtained in enforcement of this chapter 1567 except in a prosecution or administrative hearing for a 1568 violation of this chapter.

1569 7. To Possess a prescription form which has not been 1570 completed and signed by the practitioner whose name appears 1571 printed thereon, unless the person is that practitioner, is an 1572 agent or employee of that practitioner, is a pharmacist, or is a 1573 supplier of prescription forms who is authorized by that 1574 practitioner to possess those forms.

1575 8. To Withhold information from a practitioner from whom 1576 the person seeks to obtain a controlled substance or a 1577 prescription for a controlled substance that the person making 1578 the request has received a controlled substance or a

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1579 prescription for a controlled substance of like therapeutic use 1580 from another practitioner within the previous 30 days.

9. To Acquire or obtain, or attempt to acquire or obtain,
possession of a controlled substance by misrepresentation,
fraud, forgery, deception, or subterfuge.

1584 10. To Affix any false or forged label to a package or 1585 receptacle containing a controlled substance.

1586 11. To Furnish false or fraudulent material information in, 1587 or omit any material information from, any report or other 1588 document required to be kept or filed under this chapter or any 1589 record required to be kept by this chapter.

1590 12. To Store anhydrous ammonia in a container that is not 1591 approved by the United States Department of Transportation to 1592 hold anhydrous ammonia or is not constructed in accordance with 1593 sound engineering, agricultural, or commercial practices.

1594 13. With the intent to obtain a controlled substance or 1595 combination of controlled substances that are not medically 1596 necessary for the person or an amount of a controlled substance 1597 or substances that are not medically necessary for the person, 1598 obtain or attempt to obtain from a practitioner a controlled 1599 substance or a prescription for a controlled substance by 1600 misrepresentation, fraud, forgery, deception, subterfuge, or 1601 concealment of a material fact. For purposes of this 1602 subparagraph, a material fact includes whether the person has an 1603 existing prescription for a controlled substance issued for the 1604 same period of time by another practitioner or as described in 1605 subparagraph 8.

1606 (b) A health care practitioner, with the intent to provide 1607 a controlled substance or combination of controlled substances

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1608	that are not medically necessary to his or her patient or an
1609	amount of controlled substances that are not medically necessary
1610	for his or her patient, may not provide a controlled substance
1611	or a prescription for a controlled substance by
1612	misrepresentation, fraud, forgery, deception, subterfuge, or
1613	concealment of a material fact. For purposes of this paragraph,
1614	a material fact includes whether the patient has an existing
1615	prescription for a controlled substance issued for the same
1616	period of time by another practitioner or as described in
1617	subparagraph (a)8.
1618	(c) Any person who adulterates a controlled substance for
1619	directed off-label use without authorization by a prescribing
1620	physician violates the provisions of subparagraph (a)1. and
1621	causes the issuance of the entire prescription for the
1622	controlled substance to become invalid. A law enforcement
1623	officer in the performance of his or her official duties may
1624	seize the adulterated or off-label prescribed controlled
1625	substance as evidence. The controlled substance may be returned
1626	to the owner only with a notarized affidavit from the original
1627	prescribing practitioner who has knowledge and gave
1628	authorization and explicit directions for the adulteration or
1629	off-label use of the controlled substance.
1630	(d) (b) Any person who violates the provisions of
1631	subparagraphs (a)17. commits a misdemeanor of the first
1632	degree, punishable as provided in s. 775.082 or s. 775.083;

1633 except that, upon a second or subsequent violation, the person 1634 commits a felony of the third degree, punishable as provided in 1635 s. 775.082, s. 775.083, or s. 775.084.

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(e) (c) Any person who violates the provisions of

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1637 subparagraphs (a)8.-12. commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. 1638 1639 (f) A person or health care practitioner who violates the 1640 provisions of paragraph (b) or subparagraph (a)13. commits a 1641 felony of the third degree, punishable as provided in s. 1642 775.082, s. 775.083, or s. 775.084, if any controlled substance 1643 that is the subject of the offense is listed in Schedule II, 1644 Schedule III, or Schedule IV. 1645 (8) (a) Notwithstanding subsection (9), a prescribing 1646 practitioner may not: 1647 1. Knowingly assist a patient, other person, or the owner 1648 of an animal in obtaining a controlled substance through 1649 deceptive, untrue, or fraudulent representations in or related 1650 to the practice of the prescribing practitioner's professional 1651 practice; 2. Employ a trick or scheme in the practice of the 1652 prescribing practitioner's professional practice to assist a 1653 patient, other person, or the owner of an animal in obtaining a 1654 1655 controlled substance; 3. Knowingly write a prescription for a controlled 1656 1657 substance for a fictitious person; or 1658 4. Write a prescription for a controlled substance for a 1659 patient, other person, or an animal if the sole purpose of 1660 writing such prescription is to provide a monetary benefit to, 1661 or obtain a monetary benefit for, the prescribing practitioner; 1662 or. 1663 5. Write a prescription for a controlled substance for a 1664 patient, other person, or an animal and authorize or direct the 1665 adulteration of the dispensed form of the controlled substance

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1666 for the purpose of ingestion by means of inhalation, injection, 1667 or any other means that is not medically necessary for the 1668 treatment of the patient.

1669 (b) If the prescribing practitioner wrote a prescription or 1670 multiple prescriptions for a controlled substance for the 1671 patient, other person, or animal for which there was no medical 1672 necessity, or which was in excess of what was medically 1673 necessary to treat the patient, other person, or animal, that 1674 fact does not give rise to any presumption that the prescribing 1675 practitioner violated subparagraph (a)1., but may be considered 1676 with other competent evidence in determining whether the 1677 prescribing practitioner knowingly assisted a patient, other 1678 person, or the owner of an animal to obtain a controlled 1679 substance in violation of subparagraph (a)1.

1680 (c) A person who violates paragraph (a) commits a felony of 1681 the third degree, punishable as provided in s. 775.082, s. 1682 775.083, or s. 775.084.

1683 (d) Notwithstanding paragraph (c), if a prescribing 1684 practitioner has violated paragraph (a) and received \$1,000 or 1685 more in payment for writing one or more prescriptions or, in the 1686 case of a prescription written for a controlled substance described in s. 893.135, has written one or more prescriptions 1687 1688 for a quantity of a controlled substance which, individually or 1689 in the aggregate, meets the threshold for the offense of 1690 trafficking in a controlled substance under s. 893.15, the 1691 violation is reclassified as a felony of the second degree and 1692 ranked in level 4 of the Criminal Punishment Code.

1693Section 25. Present subsections (3) through (10) of section1694893.138, Florida Statutes, are redesignated as subsections (4)

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COMMITTEE AMENDMENT

Florida Senate - 2011 Bill No. SB 818

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1695	through (11), respectively, and a new subsection (3) is added to
1696	that section, to read:
1697	893.138 Local administrative action to abate drug-related,
1698	prostitution-related, or stolen-property-related public
1699	nuisances and criminal gang activity
1700	(3) Any pain-management clinic, as described in s. 458.3265
1701	or s. 459.0137, which has been used on more than two occasions
1702	within a 6-month period as the site of a violation of:
1703	(a) Section 784.011, s. 784.021, s. 784.03, or s. 784.045,
1704	relating to assault and battery;
1705	(b) Section 810.02, relating to burglary;
1706	(c) Section 812.014, relating to dealing in theft;
1707	(d) Section 812.131, relating to robbery by sudden
1708	snatching; or
1709	(e) Section 893.13, relating to the unlawful distribution
1710	of controlled substances,
1711	
1712	may be declared to be a public nuisance, and such nuisance may
1713	be abated pursuant to the procedures provided in this section.
1714	Section 26. (1) DEFINITIONS.—As used in this section, the
1715	term:
1716	(a) "Interchange or substitution of an opioid analgesic
1717	drug" means the substitution of any opioid analgesic drug, brand
1718	or generic, for the opioid analgesic drug incorporating a
1719	tamper-resistance technology originally prescribed, irrespective
1720	of whether the substituted drug is rated as pharmaceutically and
1721	therapeutically equivalent by the United States Food and Drug
1722	Administration or the Board of Pharmacy or whether the opioid
1723	analgesic drug with tamper-resistance technology bears a

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1724	labeling claim with respect to reduction of tampering, abuse, or
1725	abuse potential.
1726	(b) "Opioid analgesic drug" means a drug in the opioid
1727	analgesic drug class prescribed to treat moderate to severe pain
1728	or other conditions, whether in immediate release or extended
1729	release form and whether or not combined with other drug
1730	substances to form a single tablet or other dosage form.
1731	(c) "Opioid analgesic drug incorporating a tamper-
1732	resistance technology" means an opioid analgesic drug listed as
1733	such by the Board of Pharmacy based on a submission of evidence
1734	by the drug manufacturer or distributor that the drug:
1735	1. Incorporates a tamper-resistance technology; and
1736	2. Has been approved by the United States Food and Drug
1737	Administration pursuant to an application that includes at least
1738	one study on human tampering or abuse potential or a laboratory
1739	study comparing the tamper- or abuse-resistance properties of
1740	the drug to one or more opioid analgesic drugs that:
1741	a. Have been approved by the United States Food and Drug
1742	Administration; and
1743	b. Serve as a positive control.
1744	(d) "Pharmacist" means any person licensed under chapter
1745	465, Florida Statutes, to practice the profession of pharmacy,
1746	including, but not limited to, a community pharmacist and a
1747	pharmacist in a hospital-based pharmacy, when filling
1748	prescriptions for inpatient or outpatient care.
1749	(2) LIST OF OPIOID ANALGESIC DRUGS INCORPORATING A TAMPER-
1750	RESISTANCE TECHNOLOGYThe Board of Pharmacy shall create a list
1751	of opioid analgesic drugs for which information has been
1752	submitted consistent with paragraph (1)(c). Inclusion of a drug
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1753	on such list does not require that the drug bear a labeling
1754	claim with respect to reduction of tampering, abuse, or abuse
1755	potential at the time of listing. Such list must also include a
1756	determination by the Board of Pharmacy as to which listed opioid
1757	analgesic drugs incorporating tamper-resistance technologies
1758	provide substantially similar tamper-resistance properties,
1759	based solely on studies submitted by the drug manufacturer
1760	consistent with paragraph (1)(c).
1761	(3) PROHIBITIONNotwithstanding s. 465.025, Florida
1762	Statutes, a pharmacist may not interchange or substitute an
1763	opioid analgesic drug, brand or generic, for an opioid analgesic
1764	drug incorporating a tamper-resistance technology which is
1765	listed pursuant to subsection (2) without:
1766	(a) Verifying that the opioid analgesic drug has been
1767	listed by the Board of Pharmacy under subsection (2) as
1768	providing tamper-resistance properties substantially similar to
1769	the prescribed opioid analgesic drug incorporating a tamper-
1770	resistance technology; or
1771	(b) Obtaining written, signed consent from the prescribing
1772	physician for such interchange or substitution.
1773	Section 27. This act shall take effect October 1, 2011.
1774	
1775	=========== TITLE AMENDMENT=============
1776	And the title is amended as follows:
1777	Delete everything before the enacting clause
1778	and insert:
1779	A bill to be entitled
1780	An act relating to controlled substances; amending s.
1781	400.9905, F.S.; redefining the terms "clinic" and
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1782 "portable equipment provider" within the Health Care 1783 Clinic Act; amending s. 456.013, F.S.; authorizing 1784 certain health care practitioners to complete a 1785 continuing education course relating to the 1786 prescription drug monitoring program; providing 1787 requirements for the course; requiring the Department of Health or a board that is authorized to exercise 1788 1789 regulatory or rulemaking functions within the 1790 department to approve the course offered through a 1791 facility licensed under ch. 395, F.S., under certain 1792 circumstances; providing application of the course 1793 requirements; requiring a board or the Department of 1794 Health to adopt rules; amending s. 458.305, F.S.; 1795 defining the term "dispensing physician" as it relates 1796 to the practice of medicine in this state; prohibiting 1797 certain persons from using titles or displaying signs 1798 that would lead the public to believe that they engage 1799 in the dispensing of controlled substances; 1800 prohibiting certain persons, firms, or corporations 1801 from using a trade name, sign, letter, or 1802 advertisement that implies that the persons, firms, or 1803 corporations are licensed or registered to dispense 1804 prescription drugs; prohibiting certain persons, 1805 firms, or corporations from holding themselves out to 1806 the public as licensed or registered to dispense 1807 controlled substances; prohibiting certain persons 1808 from performing the functions of a dispensing 1809 physician; providing penalties; amending s. 458.3191, 1810 F.S.; revising the information in the physician survey

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1811 that is submitted by persons who apply for licensure renewal as a physician under ch. 458 or ch. 459, F.S.; 1812 1813 amending s. 458.3192, F.S.; requiring the Department 1814 of Health to provide nonidentifying information to the 1815 prescription drug monitoring program's Implementation 1816 and Oversight Task Force regarding the number of 1817 physicians that are registered with the prescription 1818 drug monitoring program and that use the database from 1819 the program in their practice; amending s. 458.3265, 1820 F.S.; revising the list of entities that are not 1821 required to register as a pain-management clinic; 1822 deleting certain requirements for a physician to 1823 practice medicine in a pain-management clinic; 1824 requiring a physician who works in a pain-management 1825 clinic to document the reason a prescription for a 1826 certain dosage of a controlled substance is within the 1827 proper standard of care; creating a felony of the 1828 third-degree for any person to register or attempt to 1829 register a pain-management clinic through 1830 misrepresentation or fraud; amending s. 458.327, F.S.; 1831 providing additional penalties; amending s. 458.331, 1832 F.S.; providing additional grounds for disciplinary 1833 action by the Board of Medicine; amending s. 459.003, 1834 F.S.; defining the term "dispensing physician" as it 1835 relates to the practice of osteopathic medicine in 1836 this state; amending s. 459.013, F.S.; providing 1837 additional penalties; amending s. 459.0137, F.S.; 1838 requiring an osteopathic physician who works in a 1839 pain-management clinic to document the reason a

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1840 prescription for a certain dosage of a controlled 1841 substance is within the proper standard of care; 1842 creating a felony of the third-degree for a licensee 1843 or other person who serves as the designated physician 1844 of a pain-management clinic to register a pain-1845 management clinic through misrepresentation or fraud; 1846 amending s. 459.015, F.S.; providing additional 1847 grounds for disciplinary action by the Board of 1848 Osteopathic Medicine; amending s. 465.015, F.S.; 1849 prohibiting certain persons from knowingly failing to 1850 report to the local county sheriff's office and the 1851 Department of Law Enforcement the commission of a 1852 felony involving a person who acquires or obtains 1853 possession of a controlled substance by 1854 misrepresentation, fraud, forgery, deception, or 1855 subterfuge under certain conditions; providing 1856 penalties; providing requirements for reporting the 1857 commission of the felony that involves a person who 1858 acquires or obtains possession of a controlled 1859 substance by misrepresentation, fraud, forgery, 1860 deception, or subterfuge; providing that a pharmacist, 1861 pharmacy intern, or other person employed by or at a 1862 pharmacy is not subject to disciplinary action for 1863 reporting; amending s. 465.0276, F.S.; requiring a 1864 practitioner to register as a dispensing practitioner 1865 in order to dispense controlled substances; amending 1866 s. 766.101, F.S.; conforming a cross-reference; amending s. 810.02, F.S.; redefining the offense of 1867 1868 burglary to include the theft of a controlled



1869 substance within a dwelling, structure, or conveyance; 1870 amending s. 812.014, F.S.; redefining the offense of 1871 theft to include the theft of a controlled substance; 1872 creating s. 893.021, F.S.; providing conditions in 1873 which a drug is considered adulterated; providing that 1874 a physician is not prevented from directing or 1875 prescribing a change to the recognized manufactured 1876 recommendations for use of any controlled substance in 1877 a patient under certain circumstances; requiring a 1878 prescribing physician to indicate any deviation of the 1879 recognized manufacturer's recommended use of a 1880 controlled substance on the original prescription; 1881 requiring a pharmacist or physician to indicate such 1882 deviation on the label of the prescription upon 1883 dispensing; amending s. 893.04, F.S.; revising the 1884 required information that must appear on the face of a 1885 prescription or written record of a controlled 1886 substance before it is dispensed by a pharmacist; 1887 amending s. 893.055, F.S.; requiring that the 1888 prescription drug monitoring program comply with the 1889 minimum requirements of the National All Schedules 1890 Prescription Electronic Reporting Act; requiring the 1891 Department of Health to establish a method to allow 1892 corrections to the database of the prescription drug 1893 monitoring program; requiring the number of refills 1894 ordered and whether the drug was dispensed as a refill 1895 or a first-time request to be included in the database of the prescription drug monitoring program; revising 1896 1897 the number of days in which a dispensed controlled



1898 substance must be reported to the department through 1899 the prescription drug monitoring program; revising the 1900 list of acts of dispensing or administering which are 1901 exempt from reporting; requiring a pharmacy, 1902 prescriber, practitioner, or dispenser to register 1903 with the department by submitting a registering 1904 document in order to have access to certain 1905 information in the prescription drug monitoring 1906 program's database; requiring the department to 1907 approve the registering document before granting 1908 access to information in the prescription drug 1909 monitoring program's database; requiring criminal 1910 background screening for those persons who have direct 1911 access to the prescription drug monitoring program's 1912 database; authorizing the Attorney General to obtain 1913 confidential and exempt information for Medicaid fraud 1914 cases and Medicaid investigations; requiring certain 1915 documentation to be provided to the program manager in 1916 order to release confidential and exempt information 1917 from the prescription drug monitoring program's 1918 database to a patient, legal guardian, or a designated 1919 health care surrogate; authorizing the Agency for 1920 Health Care Administration to obtain confidential and 1921 exempt information from the prescription drug 1922 monitoring program's database for Medicaid fraud cases 1923 and Medicaid investigations involving controlled 1924 substances; deleting the provision that administrative 1925 costs of the prescription drug monitoring program are 1926 funded through federal grants and private sources;

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1927 requiring the State Surgeon General to enter into 1928 reciprocal agreements for the sharing of information 1929 in the prescription drug monitoring program with other 1930 states that have a similar prescription drug 1931 monitoring program; requiring the State Surgeon 1932 General to annually review a reciprocal agreement to 1933 determine its compatibility; providing requirements 1934 for compatibility; prohibiting the sharing of certain 1935 information; amending s. 893.0551, F.S.; authorizing 1936 the Department of Health to disclose certain 1937 confidential and exempt information in the 1938 prescription drug monitoring program's database under 1939 certain circumstances involving reciprocal agreements 1940 with other states; prohibiting the sharing of 1941 information from the prescription drug monitoring 1942 program's database which is not for the purpose that 1943 is statutorily authorized or according to the State Surgeon General's determination of compatibility; 1944 1945 amending s. 893.07, F.S.; requiring that a person 1946 report to the Department of Law Enforcement and the 1947 local sheriff's office the theft or loss of a controlled substance within a specified time; 1948 1949 providing penalties; providing legislative intent; 1950 amending s. 893.13, F.S.; prohibiting a person from 1951 obtaining or attempting to obtain from a practitioner 1952 a controlled substance or a prescription for a 1953 controlled substance by misrepresentation, fraud, 1954 forgery, deception, subterfuge, or concealment of a 1955 material fact; prohibiting a health care provider from



1956 providing a controlled substance or a prescription for 1957 a controlled substance by misrepresentation, fraud, 1958 forgery, deception, subterfuge, or concealment of a 1959 material fact; prohibiting a person from adulterating 1960 a controlled substance for certain use without 1961 authorization by a prescribing physician; authorizing 1962 a law enforcement officer to seize as evidence the 1963 adulteration or off-label use of a prescribed 1964 controlled substance; providing that such adulterated 1965 or off-label use of the controlled substance may be 1966 returned to its owner only under certain conditions; 1967 providing penalties; prohibiting a prescribing 1968 practitioner from writing a prescription for a 1969 controlled substance and authorizing or directing the 1970 adulteration of the dispensed form of the controlled 1971 substance for the purpose of ingestion by means that 1972 is not medically necessary; amending s. 893.138, F.S.; 1973 providing circumstances in which a pain-management 1974 clinic may be declared a public nuisance; providing 1975 definitions; requiring the Board of Pharmacy to create 1976 a list of opioid analgesic drugs; providing 1977 requirements for the list of opioid analgesic drugs; 1978 prohibiting a pharmacist from interchanging or 1979 substituting an opioid analgesic drug, brand, or 1980 generic, for an opioid analgesic drug incorporating a 1981 tamper-resistance technology unless certain 1982 requirements are met; providing an effective date.