

LEGISLATIVE ACTION

Senate	•	House
Comm: RCS		
03/04/2009	•	
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The Committee on Health Regulation (Jones) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause

and insert:

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Section 1. Section 893.055, Florida Statutes, is created to read:

893.055 Prescription drug validation program.-

(1) As used in this section, the term:

(a) "Advisory report" means information provided by the

10 department in writing to a prescriber, dispenser, pharmacy, or

11 patient concerning the dispensing of controlled substances. All

12	advisory reports are for informational purposes only and impose
13	no obligations of any nature or any legal duty on a prescriber,
14	dispenser, pharmacy, or patient. The advisory reports issued by
15	the department are not subject to discovery or introduction into
16	evidence in any civil or administrative action against a
17	prescriber, dispenser, pharmacy, or patient arising out of the
18	matters that are the subject of the report, and no person who
19	participates in preparing an advisory report is permitted or
20	required to testify in any such civil action as to any findings,
21	recommendations, evaluations, opinions, or other actions taken
22	in connection with preparing such a report.
23	(b) "Controlled substance" means a controlled substance
24	listed in Schedule II, Schedule III, or Schedule IV in s.
25	893.03.
26	(c) "Department" means the Department of Health.
27	(d) "Dispenser" means a dispensing pharmacist or dispensing
28	health care practitioner.
29	(e) "Health care practitioner" or "practitioner" means any
30	practitioner subject to licensure or regulation by the
31	department under chapter 458, chapter 459, chapter 461, or
32	chapter 466.
33	(f) "Health care regulatory board" means any board that
34	licenses a practitioner or health care practitioner who is
35	regulated by the department.
36	(g) "Pharmacy" means any pharmacy subject to licensure or
37	regulation by the department under chapter 465 which dispenses
38	or delivers a controlled substance to a patient in this state.
39	(h) "Prescriber" means a prescribing physician, prescribing
40	practitioner, or other prescribing health care practitioner.



41 (2) (a) By December 1, 2010, the department shall design and 42 establish a comprehensive electronic system that has controlled 43 substance prescriptions provided to it and that provides 44 prescription information to a patient's health care practitioner 45 and, as determined by the department, may provide advisory reports to authorized pharmacists, pharmacies, prescribing 46 47 practitioners, and dispensing health care practitioners. The system shall be designed to provide information regarding 48 dispensed prescriptions of controlled substances in order to 49 50 prevent the inadvertent, improper, or illegal use of controlled 51 substances and shall not infringe upon the legitimate 52 prescribing of a controlled substance by a prescribing 53 practitioner, dispensing pharmacist, or dispensing practitioner 54 acting in good faith and in the course of professional practice. The system shall be consistent with standards of the American 55 56 Society for Automation in Pharmacy for the validation of 57 prescribing and dispensing controlled substances to an individual. The electronic system shall also comply with the 58 59 Health Insurance Portability and Accountability Act (HIPAA) as 60 it pertains to protected health information (PHI), electronic 61 protected health information (EPHI), and all other relevant 62 state and federal privacy and security laws and regulations. The 63 validating of prescribed controlled substances shall include a 64 dispensing transaction with a dispenser not located in this 65 state but which is otherwise subject to the jurisdiction of this 66 state as to that dispensing transaction. 67 (b) The department shall adopt rules concerning the 68 reporting, evaluation, management, and storage of information 69 within the system, including rules for when information is



70	provided to pharmacies, prescribers, health care practitioners,
71	health care regulatory boards, and law enforcement agencies, and
72	such rules shall be developed with a reasonable-person standard
73	for prescription drug dispensers, prescribers, and patients. The
74	department shall work with the professional health care
75	licensure boards, such as the Board of Medicine and the Board of
76	Pharmacy and other appropriate organizations, such as the
77	Florida Pharmacy Association and the Florida Medical
78	Association, including those relating to pain management, the
79	the Attorney General, the Department of Law Enforcement, and the
80	Agency for Health Care Administration, to develop the
81	reasonable-person standard for rules appropriate for the
82	prescription drug validation program.
83	(c) All dispensers and prescribers subject to such
84	reporting requirements shall be notified by the department of
85	the implementation date for such reporting requirements.
86	(3) The pharmacist in charge of each pharmacy, regarding
87	each controlled substance dispensed by a pharmacist under the
88	supervision of the pharmacist in charge, and each prescriber who
89	directly dispenses a controlled substance shall submit to the
90	electronic system, by a procedure and in a format established by
91	the department, the following minimum information for inclusion
92	in the database:
93	(a) The name of the prescribing practitioner and the
94	practitioner's federal Drug Enforcement Administration
95	registration number, the practitioner's National Provider
96	Identification (NPI) or other appropriate identifier, and the
97	date of the prescription.
98	(b) The date the prescription was filled and the method of
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99	payment therefor, including cash. This paragraph does not
100	authorize the department to include individual credit card or
101	other account numbers in the database.
102	(c) The name, address, and date of birth of the person for
103	whom the prescription was written.
104	(d) The name, national drug code, quantity, and strength of
105	the controlled substance dispensed.
106	(e) The name and address of the pharmacy or other location
107	from which the controlled substance was dispensed.
108	(f) The name of the pharmacist or practitioner dispensing
109	the controlled substance, the practitioner's National Provider
110	Identification (NPI), and other appropriate identifying
111	information as determined by department rule.
112	(4) Each time a controlled substance is dispensed to an
113	individual, the controlled substance shall be reported to the
114	department through the system as soon thereafter as possible,
115	but not more than 15 days after the date the controlled
116	substance is dispensed. A dispenser must meet the reporting
117	requirements of this section by providing the required
118	information concerning each controlled substance that it
119	dispensed in a department-approved, secure methodology and
120	format. Such approved formats may include, but are not limited
121	to, submission via the Internet, on a disc, or by use of regular
122	mail.
123	(5) The following are exempt from this section when
124	administering controlled substances:
125	(a) A health care practitioner administering a controlled
126	substance directly to a patient if the amount of the controlled
127	substance is adequate to treat the patient during that

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128	particular treatment session.
129	(b) A pharmacist or health care practitioner administering
130	a controlled substance to a patient or resident receiving care
131	as an admitted patient at a hospital, nursing home, hospice, or
132	intermediate care facility for the developmentally disabled
133	which is licensed in this state.
134	(c) A person administering a controlled substance in the
135	health care system of the Department of Corrections.
136	(d) A person administering a controlled substance in the
137	emergency room of a licensed hospital.
138	(e) A pharmacist or health care practitioner administering
139	a controlled substance to a person under the age of 16.
140	(6) The department may establish when to suspend and when
141	to resume requirements for reporting dispensing information to
142	the electronic system of controlled prescription drugs during a
143	state-declared or nationally declared disaster.
144	(7)(a) A practitioner or pharmacist who dispenses a
145	controlled substance must submit the information required by
146	this section in an electronic or other format approved by rule
147	of the department. The cost to the dispenser in submitting the
148	information required by this section may not be material or
149	extraordinary. Costs not considered to be material or
150	extraordinary include, but are not limited to, regular postage,
151	electronic media, regular electronic mail, and facsimile
152	charges.
153	(b) A pharmacy, prescriber, or dispenser may access
154	information in the prescription drug validation program's
155	electronic system which relates to a patient of that pharmacy,
156	prescriber, or dispenser for the purpose of reviewing the

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157	patient's controlled drug prescription history to ensure a
158	proper standard of care. Other access to the program's
159	electronic system shall be limited to the program's manager and
160	designated program staff, who may act only in the absence of the
161	program manager. Access by the program manager or such
162	designated staff is only for prescription drug management and
163	for management of the database. Confidential and exempt
164	information in the database shall be released only as provided
165	in s. 893.0551. The individual who requests his or her own
166	information, the attorney general, a health care regulatory
167	board, any law enforcement agency, or any criminal justice
168	agency may request this information from the program manager and
169	may not directly access the database for this information.
170	(c) All transmissions of data required by this section must
171	comply with relevant state and federal privacy and security laws
172	and regulations. However, any authorized agency or person
173	receiving such information may maintain the information received
174	for up to 24 months before purging it from his or her records or
175	maintain it for longer than 24 months if the information is
176	pertinent to an ongoing health care or active law enforcement
177	investigation or prosecution.
178	(8) To assist in fulfilling the program responsibilities,
179	performance measures shall be reported annually by the
180	department each December 1, beginning in 2011. Data that does
181	not contain patient, physician, health care practitioner, or
182	dispenser identifying information may be requested during the
183	year by department employees so that the department may
184	undertake public health care and safety initiatives that take
185	advantage of observed trends. Performance measures may include,
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186	but are not limited to, efforts to achieve the following
187	outcomes:
188	(a) Reduction of the rate of inappropriate use of
189	prescription drugs through department education and safety
190	efforts.
191	(b) Reduction of the quantity of pharmaceutical controlled
192	substances obtained by individuals attempting to engage in fraud
193	and deceit.
194	(c) Increased coordination among prescription drug
195	validation program partners.
196	(d) Involvement of stakeholders in achieving improved
197	patient health care and reduction of prescription drug abuse and
198	prescription drug diversion.
199	(9) Any person who knowingly fails to report the dispensing
200	of a controlled substance as required by this section commits a
201	misdemeanor of the first degree, punishable as provided in s.
202	<u>775.082 or s. 775.083.</u>
203	(10) All costs incurred by the department in administering
204	the prescription drug validation program shall be reimbursed
205	through federal grants or private funding applied for or
206	received by the state. The department and state government shall
207	cooperate in seeking federal grant funds, other nonstate grant
208	funds, gifts, donations, or other private moneys for the
209	department so long as the costs of doing so are not considered
210	material. Nonmaterial costs for this purpose include, but are
211	not limited to, the costs of mailing and personnel assigned to
212	research or apply for a grant. Notwithstanding the exemptions to
213	competitive-solicitation requirements under s. 287.057(5)(f),
214	the Department of Health shall comply with the competitive-

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215	solicitation requirements for the procurement of any goods or
216	services required by this section.
217	(11) The Office of Drug Control, in coordination with the
218	department, may establish a direct-support organization that has
219	a board consisting of at least five members to provide
220	assistance, funding, and promotional support for the activities
221	authorized for the prescription drug validation program.
222	(a) As used in this subsection, the term "direct-support
223	organization" means an organization that is:
224	1. A Florida corporation not for profit incorporated under
225	chapter 617, exempted from filing fees, and approved by the
226	Department of State.
227	2. Organized and operated to conduct programs and
228	activities; raise funds; request and receive grants, gifts, and
229	bequests of money; acquire, receive, hold, and invest, in its
230	own name, securities, funds, objects of value, or other
231	property, either real or personal; and make expenditures to or
232	for the direct or indirect benefit of the department in the
233	furtherance of the prescription drug validation program.
234	(b) The direct-support organization is not considered a
235	lobbying firm within the meaning of s. 11.045.
236	(c) The director of the Office of Drug Control shall
237	appoint a board of directors for the direct-support
238	organization. The director may designate employees of the Office
239	of Drug Control; state employees other than state employees from
240	the Department of Health; members of provider associations, such
241	as the Florida Pharmacy Association or the Florida Medical
242	Association; and any other nonstate employees as appropriate, to
243	serve on such board. Members of the board shall serve at the
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244 245 246 247	<pre>pleasure of the director of the Office of Drug Control. (d) The direct-support organization may operate under written contract with the Office of Drug Control. The contract must provide for:</pre>
246	written contract with the Office of Drug Control. The contract
247	must provide for:
248	1. Approval of the articles of incorporation and bylaws of
249	the direct-support organization by the Office of Drug Control.
250	2. Submission of an annual budget for the approval of the
251	Office of Drug Control.
252	3. Certification by the Office of Drug Control in
253	consultation with the department that the direct-support
254	organization is complying with the terms of the contract in a
255	manner consistent with and in furtherance of the goals and
256	purposes of the prescription drug validation program and in the
257	best interest of the state. Such certification must be made
258	annually and reported in the official minutes of a meeting of
259	the direct-support organization.
260	4. The reversion, without penalty, to the Office of Drug
261	Control, or to the state if the Office of Drug Control ceases to
262	exist, of all moneys and property held in trust by the direct-
263	support organization for the benefit of the prescription drug
264	validation program if the direct-support organization ceases to
265	exist or if the contract is terminated.
266	5. The fiscal year of the direct-support organization,
267	which must begin July 1 of each year and end June 30 of the
268	following year.
269	6. The disclosure of the material provisions of the
270	contract to donors of gifts, contributions, or bequests,
271	including such disclosure on all promotional and fundraising
272	publications, and an explanation to such donors of the

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273 distinction between the Office of Drug Control and the direct-274 support organization. 275 (e) The direct-support organization is specifically 276 authorized to collect and expend funds to be used for the 277 functions of the direct-support organization's board of 278 directors, as necessary; establishing and administering the 279 prescription drug validation program's electronic database, 280 including hardware, software, and personnel; conducting studies 2.81 on the efficiency and effectiveness of the program; providing 282 funds for future enhancements of the program within the intent 283 of this section; providing health care practitioner education, 284 including distribution of materials to promote public awareness 285 and education and conducting workshops or other meetings; travel 286 expenses; administrative costs, including personnel, audits, 287 facilities, and equipment; and all other requirements necessary 288 to establish the program as outlined in this section. 289 (f) The activities of the direct-support organization must 290 be consistent with the goals and mission of the Office of Drug

290 <u>be consistent with the goals and mission of the Office of Drug</u> 291 <u>Control, as determined by the office in consultation with the</u> 292 <u>department, and in the best interests of the state. The direct-</u> 293 <u>support organization must obtain a written approval from the</u> 294 <u>director of the Office of Drug Control for any activities in</u> 295 <u>support of the prescription drug validation program before</u> 296 <u>undertaking those activities.</u>

(g) The Office of Drug Control, in consultation with the department, may permit, without charge, appropriate use of administrative services, property, and facilities of the Office of Drug Control and the department by the direct-support organization, subject to this section. The use must be directly

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302	in keeping with the approved purposes of the direct-support
303	organization and may not be made at times or places that would
304	unreasonably interfere with opportunities for the public to use
305	such facilities for established purposes. Any moneys received
306	from rentals of facilities and properties managed by the Office
307	of Drug Control and the department may be held by the Office of
308	Drug Control or in a separate depository account in the name of
309	the direct-support organization and subject to the provisions of
310	the letter of agreement with the Office of Drug Control. The
311	letter of agreement must provide that any funds held in the
312	separate depository account in the name of the direct-support
313	organization must revert to the Office of Drug Control if the
314	direct-support organization is no longer approved by the Office
315	of Drug Control to operate in the best interests of the state.
316	(h) The Office of Drug Control, in consultation with the
317	department, may adopt requirements with which a direct-support
318	organization must comply in order to use department and Office
319	of Drug Control administrative services, property, or
320	facilities.
321	(i) The Office of Drug Control may not permit the use of
322	any administrative services, property, or facilities of the
323	state by a direct-support organization if that organization does
324	not provide equal membership and employment opportunities to all
325	persons regardless of race, color, religion, gender, age, or
326	national origin.
327	(j) The direct-support organization shall provide for an
328	independent annual financial audit in accordance with s.
329	215.981. Copies of the audit shall be provided to the Office of
330	Drug Control and the Office of Policy and Budget in the

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331	Executive Office of the Governor.
332	(k) The direct-support organization may not exercise any
333	power under s. 617.0302(12) or (16).
334	(12) A prescriber or dispenser is authorized access to the
335	information under this section for his or her patient for his or
336	her review of the patient's controlled drug prescription history
337	to ensure a proper standard of care. A prescriber or dispenser
338	acting in good faith is immune from any civil, criminal, or
339	administrative liability that might otherwise be incurred or
340	imposed for receiving or using information from the prescription
341	drug validation program. This subsection does not create a
342	private cause of action, and a person may not recover damages
343	against a prescriber or dispenser authorized to access
344	information under this subsection for accessing or failing to
345	access such information.
346	(13) To the extent that funding is provided for such
347	purpose through federal or private grants or gifts and other
348	types of available moneys, the department, in collaboration with
349	the Office of Drug Control, shall study the feasibility of
350	enhancing the prescription drug validation program for the
351	purposes of public health initiatives and statistical reporting
352	that respects the privacy of the patient, the prescriber, and
353	the dispenser. Such a study shall be conducted in order to
354	further improve the quality of health care services and safety
355	by improving prescription drug prescribing practices, taking
356	advantage of advances in technology, reducing duplicative
357	prescriptions and the overprescribing of prescription drugs, and
358	reducing drug abuse. In addition, the direct-support
359	organization shall provide funding for the department, in
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360	collaboration with the Office of Drug Control, to conduct
361	training for health care practitioners and other appropriate
362	persons in using the program to support the program
363	enhancements.
364	(14) A pharmacist, pharmacy, or dispensing health care
365	practitioner or his or her agent, prior to releasing a
366	controlled substance to any person not known to such dispenser,
367	shall require the person purchasing, receiving, or otherwise
368	acquiring the controlled substance to present valid photographic
369	identification or other verification of his or her identity to
370	the dispenser. If the person does not have proper
371	identification, the dispenser may verify the validity of the
372	prescription and the identity of the patient with the prescriber
373	or his or her authorized agent, or by a method determined by the
374	department, before dispensing the controlled substance. The
375	person purchasing, receiving, or otherwise acquiring the
376	controlled substance does not have to be the specific patient to
377	whom the prescription is prescribed. A record shall be
378	maintained for 2 years of the person acquiring the controlled
379	substance, which record shall include the person's name and
380	signature using the proper identification. This subsection does
381	not apply in an institutional setting or to a long-term care
382	facility, including, but not limited to, an assisted living
383	facility or a hospital to which patients are admitted. As used
384	in this subsection, the term "proper identification" means a
385	government-issued identification containing the person's
386	picture, printed name, and signature.
387	(15) The Agency for Health Care Administration shall
388	continue the implementation of electronic prescribing by health

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389	care practitioners, health care facilities, and pharmacies under
390	s. 408.061 and the electronic prescribing clearinghouse
391	collaboration with the private sector under s. 408.0611.
392	(16) By October 1, 2010, the department shall adopt rules
393	pursuant to ss. 120.536(1) and 120.54 to implement the
394	provisions of this section.
395	Section 2. (1) The Program Implementation and Oversight
396	Workgroup is created within the Executive Office of the
397	Governor. The director of the Office of Drug Control shall be a
398	nonvoting, ex officio member of the workgroup and shall act as
399	chair. The Office of Drug Control and the Department of Health
400	shall provide staff support for the workgroup.
401	(a) The following state officials shall serve on the
402	workgroup:
403	1. The Attorney General or his or her designee.
404	2. The Secretary of Children and Family Services or his or
405	her designee.
406	3. The Secretary of Health Care Administration or his or
407	her designee.
408	4. The State Surgeon General or his or her designee.
409	(b) In addition, the Governor shall appoint 10 members of
410	the public to serve on the workgroup. Of these 10 appointed
411	members, one member must have professional or occupational
412	expertise in computer security; one member must be a Florida-
413	licensed, board-certified oncologist; two members must be
414	Florida-licensed, board-certified, fellowship-trained physicians
415	who have experience in pain management; one member must have
416	professional or occupational expertise in e-Prescribing or
417	prescription drug validation programs; one member must be a

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418	Florida-licensed pharmacist; one member must have professional
419	or occupational expertise in law enforcement with experience in
420	prescription drug investigations; one member must have
421	professional or occupational expertise as an epidemiologist with
422	a background in tracking and analyzing drug trends; and two
423	members must have professional or occupational expertise as
424	providers of substance abuse treatment, with priority given to a
425	member who is a former substance abuser.
426	(c) Members appointed by the Governor shall be appointed to
427	a term of 3 years each. Any vacancy on the workgroup shall be
428	filled in the same manner as the original appointment, and any
429	member appointed to fill a vacancy shall serve only for the
430	unexpired term of the member's predecessor.
431	(d) Members of the workgroup and members of subcommittees
432	appointed under subsection (4) shall serve without compensation,
433	but are entitled to reimbursement for per diem and travel
434	expenses as provided in s. 112.061, Florida Statutes.
435	(e) The workgroup shall meet at least quarterly or upon the
436	call of the chair.
437	(2) The purpose of the workgroup is to monitor the
438	implementation and safeguarding of the electronic system
439	established for the prescription drug validation program under
440	s. 893.055, Florida Statutes, and to ensure privacy, protection
441	of individual medication history, and the electronic system's
442	appropriate use by physicians, dispensers, pharmacies, law
443	enforcement agencies, and those authorized to request
444	information from the electronic system.
445	(3) The Office of Drug Control shall submit a report to the
446	Governor, the President of the Senate, and the Speaker of the

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447	House of Representatives by December 1 of each year which
448	contains a summary of the work of the workgroup during that year
449	and the recommendations developed in accordance with the
450	workgroup's purpose as provided in subsection (2). Interim
451	reports may be submitted at the discretion of the chair.
452	(4) The chair of the workgroup shall appoint subcommittees
453	that include members of state agencies that are not represented
454	on the workgroup for the purpose of soliciting input and
455	recommendations from those state agencies as needed by the
456	workgroup to accomplish its purposes. In addition, the chair may
457	appoint subcommittees as necessary from among the members of the
458	workgroup in order to efficiently address specific issues. If a
459	state agency is to be represented on any subcommittee, the
460	representative shall be the head of the agency or his or her
461	designee. The chair may designate lead and contributing agencies
462	within a subcommittee.
463	(5) The workgroup shall provide a final report in
464	accordance with the workgroup's purpose as provided in
465	subsection (2) on July 1, 2012, to the Governor, the President
466	of the Senate, and the Speaker of the House of Representatives.
467	Such report shall be prepared using only data that does not
468	identify a patient or dispenser. The workgroup shall expire and
469	this section is repealed on that date.
470	Section 3. Subsections (4) and (5) are added to section
471	458.309, Florida Statutes, to read:
472	458.309 Rulemaking authority
473	(4) Each physician who practices in a privately owned pain-
474	management facility that primarily engages in the treatment of
475	pain by prescribing narcotic medications shall register the

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476	facility with the department unless it is licensed as a facility
477	under chapter 395. The department shall inspect the facility
478	annually to ensure that it complies with board rules adopted
479	pursuant to s. 458.309(4) and (5) unless the facility is
480	accredited by a nationally recognized accrediting agency
481	approved by the board. The actual costs for registration and
482	inspection or accreditation shall be paid by the physician
483	seeking to register the facility.
484	(5) The board shall adopt rules setting forth standards of
485	practice for physicians practicing in privately owned pain-
486	management facilities that primarily engage in the treatment of
487	pain by prescribing controlled substance medications. These
488	rules shall address, but need not be limited to, the following
489	subjects:
490	(a) Facility operations;
491	(b) Physical operations;
492	(c) Infection control requirements;
493	(d) Health and safety requirements;
494	(e) Quality assurance requirements;
495	(f) Patient records;
496	(g) Training requirements for all facility health care
497	practitioners; and
498	(h) Inspections.
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500	A physician is primarily engaged in the treatment of pain by
501	prescribing narcotic medications when the majority of the
502	patients seen on any day the facility is open are issued
503	narcotic prescriptions for the treatment of nonmalignant pain.
504	Section 4. This act shall take effect July 1, 2009.
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507	And the title is amended as follows:
508	Delete everything before the enacting clause
509	and insert:
510	A bill to be entitled
511	An act relating to a prescription drug validation
512	program (PDVP); creating s. 893.055, F.S.; providing
513	definitions; requiring the Department of Health to
514	establish a comprehensive electronic system to
515	validate the prescribing and dispensing of certain
516	controlled substances; requiring specified prescribing
517	and dispensing information to be reported to the
518	electronic system; requiring the department, in
519	conjunction with specified organizations, to adopt by
520	rule a reasonable-person standard appropriate for the
521	prescription drug validation program; providing a
522	reporting period; providing for implementation of a
523	shorter reporting period; providing exemptions from
524	participation in the system; authorizing the
525	Department of Health to establish when to suspend and
526	when to resume requirements for reporting dispensing
527	information during declared emergencies; requiring all
528	nonexempt pharmacists, pharmacies, dispensing
529	physicians, or prescribing and dispensing health care
530	practitioners to submit information in a specified
531	format; providing that the cost to the dispenser in
532	submitting the required information may not be
533	material or extraordinary; providing that specified



534 costs are not material or extraordinary; limiting 535 access to the system; providing for the use of data 536 for specified purposes; requiring compliance with 537 state and federal privacy and security laws; 538 authorizing an agency or person to maintain the data 539 for a specified period if the data is pertinent to an 540 ongoing health care or active law enforcement 541 investigation or prosecution; requiring the reporting 542 of certain performance measures; providing criminal 543 penalties for violations; requiring that all costs 544 incurred by the department for the program be paid 545 through a federal grant or through available private 546 funding sources; authorizing the Office of Drug 547 Control, in coordination with the Department of 548 Health, to establish a direct-support organization; 549 providing a definition; providing for a board of 550 directors appointed by the director of the Office of Drug Control; authorizing the direct-support 551 552 organization to operate under written contract with 553 the Office of Drug Control; authorizing certain 554 activities and expenditures of the direct-support 555 organization; providing requirements for the use of 556 certain facilities and services; providing for audits; 557 prohibiting the direct-support organization from 558 exercising certain powers; establishing that a 559 prescribing health care practitioner, dispensing 560 physician, or pharmacist is not liable for use of the 561 department-provided controlled substances prescription 562 information of a patient; requiring a study of the



563 feasibility of enhancing the prescription drug 564 validation program for specified purposes; requiring 565 certain persons to present specified identification to 566 obtain prescriptions; providing for recordkeeping for 567 certain transactions; requiring the Agency for Health 568 Care Administration to continue implementation of 569 electronic prescribing and an electronic prescribing 570 clearinghouse; requiring the Department of Health to 571 adopt rules; establishing a Program Implementation and 572 Oversight Workgroup; providing for membership; 573 providing for reimbursement of certain member 574 expenses; providing for meetings; providing purposes; 575 requiring reports; providing for the creation, 576 membership, and duties of subcommittees; providing for 577 a final report and termination of the workgroup; amending s. 458.309, F.S.; requiring certain 578 579 physicians who engage in pain management to register their facility with the department; requiring the 580 581 department to inspect the facility; requiring the 582 Board of Medicine to adopt rules setting forth 583 standards of practice for certain physicians who 584 engage in pain management; providing criteria for the 585 rules; providing an effective date.

586

587 WHEREAS, as has been advocated by numerous pain management 588 experts, addiction medicine experts, pharmacists, and law 589 enforcement personnel, a prescription drug validation program 590 that provides for reporting and advisory information is 591 established pursuant to this act to serve as a means to promote



592 the public health and welfare and to detect and prevent 593 controlled substance abuse and diversion, and

594 WHEREAS, while the importance and necessity of the proper 595 prescribing, dispensing, and monitoring of controlled 596 substances, particularly pain medication, have been established, 597 controlled prescription drugs are too often diverted in this 598 state, often through fraudulent means, including outright theft, 599 phony pharmacy fronts, loose Internet medical evaluations, and 600 inappropriate importation; in addition, there is a criminal 601 element that facilitates the prescription drug abuse epidemic 602 through illegal profitmaking from the diversion of certain 603 controlled substances that are prescribed or dispensed by 604 physicians, health care practitioners, and pharmacists, and

WHEREAS, in 2007, 8,620 drug-related deaths occurred in this state, 3,159 of which were caused by prescription drugs, an average of nearly 9 Floridians dying each day from prescription drugs; Schedule IV benzodiazepines, such as Xanax and Valium, were found to be present in more drug-related deaths than cocaine; and opiate pain medications contribute to increasing numbers of drug-related deaths, and

612 WHEREAS, pharmaceutical drug diversion hurts this state 613 significantly in terms of lost lives, increased crime, human 614 misery from addiction, and ballooning health care costs 615 connected to treatment, medical expenses, and Medicaid fraud 616 that all Floridians ultimately bear, and

617 WHEREAS, the intent of this act is not to interfere with 618 the legitimate medical use of controlled substances; however, 619 the people of this state are in need of and will benefit from a 620 secure and privacy-protected statewide electronic system of



621 specified prescription drug medication information created 622 primarily to encourage safer controlled substance prescription 623 decisions that reduce the number of prescription drug overdoses 624 and the number of drug overdose deaths; to educate and inform 625 health care practitioners and provide an added tool in patient 626 care, including appropriate treatment for patients who have 627 become addicted; to quide public health initiatives to educate 628 the population on the dangers of misusing prescription drugs; to 62.9 prevent the abuse or diversion of prescribed controlled 630 substances; and to ensure that those who need prescribed 631 controlled substances receive them in a manner that protects 632 patient confidentiality, and

WHEREAS, while certain medicines are very helpful if
properly prescribed to a patient in need and then used as
prescribed, they may be dangerous or even deadly if improperly
dispensed, misused, or diverted, and

637 WHEREAS, it is the intent of the Legislature to encourage 638 patient safety, responsible pain management, and proper access 639 to useful prescription drugs that are prescribed by a 640 knowledgeable, properly licensed health care practitioner who 641 dispenses prescription drugs and that are dispensed by a 642 pharmacist who is made aware of the patient's prescription drug 643 medication history, thus preventing, in some cases, an abuse or 644 addiction problem from developing or worsening, making such a 645 problem possible or easier to identify, and facilitating the 646 order of appropriate medical treatment or referral, and

647 WHEREAS, such an electronic system will also aid
648 administrative and law enforcement agencies in an active and
649 ongoing controlled drug-related investigation, maintaining such



650 information for any such investigation with a reasonable, good 651 faith anticipation of securing an arrest or prosecution in the 652 foreseeable future, and

653 WHEREAS, a Program Implementation and Oversight Workgroup 654 will provide information to the Governor and Legislature 655 regarding the implementation of the program and ensure that 656 privacy and confidentiality of the patient's prescription 657 history is respected, NOW, THEREFORE,