

1                   A bill to be entitled  
2           An act relating to prescription drugs; creating s.  
3           893.055, F.S.; providing definitions; requiring the  
4           Department of Health to establish a comprehensive  
5           electronic database system to monitor the prescribing and  
6           dispensing of certain controlled substances; requiring  
7           specified prescribing and dispensing information to be  
8           reported to the electronic database system; requiring the  
9           department to establish policies and procedures for the  
10          system; requiring the department, upon receipt of certain  
11          funds and in coordination with the Office of Drug Control  
12          and specified organizations, to adopt rules appropriate  
13          for the prescription drug monitoring program; providing  
14          reporting requirements; providing a reporting period;  
15          providing exemptions from participation in the system;  
16          authorizing the department to establish when to suspend  
17          and when to resume reporting requirements during declared  
18          emergencies; requiring all nonexempt, dispensing  
19          pharmacists and practitioners to submit information in a  
20          specified format; providing that the cost to the dispenser  
21          in submitting the required information may not be material  
22          or extraordinary; specifying costs that are not material  
23          or extraordinary; providing access to information reported  
24          to the system under certain circumstances; providing that  
25          information in the database for the electronic  
26          prescription drug monitoring system is not discoverable or  
27          admissible in any civil or administrative action;  
28          providing exceptions; providing for the use of data for

29 | specified purposes; providing requirements for  
30 | verification of information requested; requiring data  
31 | transmission to comply with state and federal privacy and  
32 | security laws; authorizing an agency or person to maintain  
33 | the data for a specified period if the data is pertinent  
34 | to ongoing health care or an active law enforcement  
35 | investigation or prosecution; requiring the annual  
36 | reporting of certain performance measures to the Governor  
37 | and Legislature; providing performance measure criteria;  
38 | providing criminal penalties for violations; requiring  
39 | that all costs incurred by the department for the program  
40 | be funded through federal grants or available private  
41 | funding sources; providing requirements for seeking  
42 | funding and procuring goods or services; authorizing the  
43 | Office of Drug Control, in coordination with the  
44 | department, to establish a direct-support organization;  
45 | providing a definition; providing for a board of directors  
46 | appointed by the director of the office; requiring the  
47 | director to provide guidance to the board regarding  
48 | acceptance of moneys from appropriate sources; requiring  
49 | the direct-support organization to operate under written  
50 | contract with the office; providing contract requirements;  
51 | providing requirements for the direct-support  
52 | organization's collecting, expending, and providing of  
53 | funds; requiring department approval of activities of the  
54 | direct-support organization; authorizing the office to  
55 | adopt rules for the use of certain facilities and  
56 | services; providing for audits; prohibiting the direct-

57 | support organization from exercising certain powers;  
58 | establishing that a prescriber or dispenser is not liable  
59 | for good faith use of the department-provided controlled  
60 | substance prescription information of a patient; requiring  
61 | the department, in collaboration with the office, to study  
62 | the feasibility of enhancing the prescription drug  
63 | monitoring program for specified purposes to the extent  
64 | that funding is provided for such purpose; requiring  
65 | certain persons to present specified identification in  
66 | order to obtain controlled substances; providing for  
67 | recordkeeping for certain transactions; requiring the  
68 | Agency for Health Care Administration to continue the  
69 | promotion of electronic prescribing and an electronic  
70 | prescribing clearinghouse; requiring the department to  
71 | adopt rules; establishing a Program Implementation and  
72 | Oversight Task Force; providing for membership; providing  
73 | for reimbursement of certain member expenses; providing  
74 | for meetings; providing the purpose of the task force;  
75 | requiring reports to the Governor and Legislature;  
76 | providing for the creation, membership, and duties of  
77 | subcommittees; authorizing the direct-support organization  
78 | to collect, expend, and provide funds and other assistance  
79 | to the department; providing for a final report and the  
80 | termination of the task force; amending ss. 458.309 and  
81 | 459.005, F.S.; requiring certain physicians who engage in  
82 | pain management to register their clinics with the  
83 | department by a specified date; prohibiting certain  
84 | physicians from practicing in a pain-management clinic

85 that has not registered with the department; requiring the  
86 department to inspect each facility; providing for  
87 exceptions; requiring the physician seeking to register  
88 the clinic to pay the costs of registration and inspection  
89 or accreditation; requiring the Board of Medicine and the  
90 Board of Osteopathic Medicine to adopt rules setting forth  
91 standards of practice for certain physicians who engage in  
92 pain management; providing criteria for the rules;  
93 providing exceptions for certain clinics in which the  
94 majority of the physicians who provide services primarily  
95 provide surgical services; providing an effective date.

96  
97 WHEREAS, as has been advocated by numerous pain management  
98 experts, addiction medicine experts, pharmacists, and law  
99 enforcement personnel, a prescription drug monitoring program  
100 that provides for reporting and advisory information and other  
101 specified information is established pursuant to this act to  
102 serve as a means to promote the public health and welfare and to  
103 detect and prevent controlled substance abuse and diversion, and

104 WHEREAS, while the importance and necessity of the proper  
105 prescribing, dispensing, and monitoring of controlled  
106 substances, particularly pain medication, have been established,  
107 controlled prescription drugs are too often diverted in this  
108 state, often through fraudulent means, including outright theft,  
109 phony pharmacy fronts, loose Internet medical evaluations, and  
110 inappropriate importation; in addition, there is a criminal  
111 element that facilitates the prescription drug abuse epidemic  
112 through illegal profitmaking from the diversion of certain

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113 controlled substances that are prescribed or dispensed by  
114 physicians, health care practitioners, and pharmacists, and  
115 WHEREAS, in 2007, 8,620 drug-related deaths occurred in  
116 this state, 3,159 of which were caused by prescription drugs, an  
117 average of nearly 9 Floridians dying each day from prescription  
118 drugs; Schedule IV benzodiazepines, such as Xanax and Valium,  
119 were found to be present in more drug-related deaths than  
120 cocaine; and opiate pain medications were found to be  
121 contributing to increasing numbers of drug-related deaths, and  
122 WHEREAS, pharmaceutical drug diversion hurts this state  
123 significantly in terms of lost lives, increased crime, human  
124 misery from addiction, and ballooning health care costs  
125 connected to treatment, medical expenses, and Medicaid fraud  
126 that all Floridians ultimately bear, and  
127 WHEREAS, the intent of this act is not to interfere with  
128 the legitimate medical use of controlled substances; however,  
129 the people of this state are in need of and will benefit from a  
130 secure and privacy-protected statewide electronic system of  
131 specified prescription drug medication information created  
132 primarily to encourage safer controlled substance prescription  
133 decisions that reduce the number of prescription drug overdoses  
134 and the number of drug overdose deaths; to educate and inform  
135 health care practitioners and provide an added tool in patient  
136 care, including appropriate treatment for patients who have  
137 become addicted; to guide public health initiatives to educate  
138 the population on the dangers of misusing prescription drugs; to  
139 prevent the abuse or diversion of prescribed controlled  
140 substances; and to ensure that those who need prescribed

141 controlled substances receive them in a manner that protects  
 142 patient confidentiality, and

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

147 WHEREAS, it is the intent of the Legislature to encourage  
 148 patient safety, responsible pain management, and proper access  
 149 to useful prescription drugs that are prescribed by a  
 150 knowledgeable, properly licensed health care practitioner who  
 151 dispenses prescription drugs and that are dispensed by a  
 152 pharmacist who is made aware of the patient's prescription drug  
 153 medication history, thus preventing, in some cases, an abuse or  
 154 addiction problem from developing or worsening, making such a  
 155 problem possible or easier to identify, and facilitating the  
 156 order of appropriate medical treatment or referral, and

157 WHEREAS, such an electronic system will also aid  
 158 administrative and law enforcement agencies in an active  
 159 controlled substance-related investigation by facilitating  
 160 decisions and recommendations for pursuing appropriate  
 161 administrative or criminal justice actions while maintaining  
 162 such information for any such investigation with a reasonable,  
 163 good faith anticipation of securing an arrest or prosecution in  
 164 the foreseeable future, and

165 WHEREAS, a Program Implementation and Oversight Task Force  
 166 will provide information to the Governor and Legislature  
 167 regarding the implementation of the program and ensure that  
 168 privacy and confidentiality of the patient's prescription

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169 history is respected, NOW, THEREFORE,

170

171 Be It Enacted by the Legislature of the State of Florida:

172

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

175 893.055 Prescription drug monitoring program.--

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

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

183 (b) "Controlled substance" means a controlled substance  
184 listed in Schedule II, Schedule III, or Schedule IV in s.  
185 893.03.

186 (c) "Dispenser" means a pharmacy, dispensing pharmacist,  
187 or dispensing health care practitioner.

188 (d) "Health care practitioner" or "practitioner" means any  
189 practitioner who is subject to licensure or regulation by the  
190 department under chapter 458, chapter 459, chapter 461, chapter  
191 462, chapter 464, chapter 465, or chapter 466.

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

195 (f) "Law enforcement agency" means the Department of Law  
196 Enforcement, a Florida sheriff's department, a Florida police

197 department, or a law enforcement agency of the Federal  
198 Government which enforces the laws of this state or the United  
199 States relating to controlled substances and the agents and  
200 officers of which are empowered by law to conduct criminal  
201 investigations and make arrests.

202 (g) "Patient advisory report" or "advisory report" means  
203 information provided by the department in writing, or as  
204 determined by the department, to a prescriber, dispenser,  
205 pharmacy, or patient concerning the dispensing of controlled  
206 substances. All advisory reports are for informational purposes  
207 only and impose no obligations of any nature or any legal duty  
208 on a prescriber, dispenser, pharmacy, or patient. The patient  
209 advisory report shall be provided in accordance with s.  
210 893.13(7)(a)8. The advisory reports issued by the department are  
211 not subject to discovery or introduction into evidence in any  
212 civil or administrative action against a prescriber, dispenser,  
213 pharmacy, or patient arising out of matters that are the subject  
214 of the report, and a person who participates in preparing,  
215 reviewing, issuing, or any other activity related to an advisory  
216 report may not be permitted or required to testify in any such  
217 civil action as to any findings, recommendations, evaluations,  
218 opinions, or other actions taken in connection with preparing,  
219 reviewing, or issuing such a report.

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

224 (i) "Prescriber" means a prescribing physician,



225 prescribing practitioner, or other prescribing health care  
226 practitioner.

227 (2) (a) By December 1, 2010, the department shall design  
228 and establish a comprehensive electronic database system that  
229 has controlled substance prescriptions provided to it and that  
230 provides prescription information to a patient's health care  
231 practitioner and pharmacist who inform the department that they  
232 wish the patient advisory report provided to them. Otherwise,  
233 the patient advisory report will not be sent to the  
234 practitioner, pharmacy, or pharmacist. The system shall be  
235 designed to provide information regarding dispensed  
236 prescriptions of controlled substances and shall not infringe  
237 upon the legitimate prescribing or dispensing of a controlled  
238 substance by a prescriber or dispenser acting in good faith and  
239 in the course of professional practice. The system shall be  
240 consistent with standards of the American Society for Automation  
241 in Pharmacy (ASAP). The electronic system shall also comply with  
242 the Health Insurance Portability and Accountability Act (HIPAA)  
243 as it pertains to protected health information (PHI), electronic  
244 protected health information (EPHI), and all other relevant  
245 state and federal privacy and security laws and regulations. The  
246 department shall establish policies and procedures as  
247 appropriate regarding the reporting, accessing, evaluation,  
248 management, development, implementation, operation, storage, and  
249 security of information within the system. The reporting of  
250 prescribed controlled substances shall include a dispensing  
251 transaction with a dispenser pursuant to chapter 465 or through  
252 a dispensing transaction to an individual or address in this

253 state with a pharmacy that is not located in this state but that  
254 is otherwise subject to the jurisdiction of this state as to  
255 that dispensing transaction. The reporting of patient advisory  
256 reports refers only to reports to patients, pharmacies, and  
257 practitioners. Separate reports that contain patient  
258 prescription history information and that are not patient  
259 advisory reports are provided to persons and entities as  
260 authorized in paragraphs (7) (b) and (c) and s. 893.0551.

261 (b) The department, when the direct support organization  
262 receives at least \$20,000 in nonstate moneys or the state  
263 receives at least \$20,000 in federal grants for the prescription  
264 drug monitoring program, and in coordination with the Office of  
265 Drug Control, shall adopt rules as necessary concerning the  
266 reporting, accessing, evaluation, management, development,  
267 implementation, operation, security, and storage of information  
268 within the system, including rules for when patient advisory  
269 reports are provided to pharmacies and prescribers. The patient  
270 advisory report shall be provided in accordance with s.  
271 893.13(7) (a)8. The department shall work with the professional  
272 health care licensure boards, such as the Board of Medicine, the  
273 Board of Osteopathic Medicine, and the Board of Pharmacy; other  
274 appropriate organizations, such as the Florida Pharmacy  
275 Association, the Office of Drug Control, the Florida Medical  
276 Association, the Florida Retail Federation, and the Florida  
277 Osteopathic Medical Association, including those relating to  
278 pain management; and the Attorney General, the Department of Law  
279 Enforcement, and the Agency for Health Care Administration to  
280 develop rules appropriate for the prescription drug monitoring

281 program.

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

285 (3) The pharmacy dispensing the controlled substance and  
286 each prescriber who directly dispenses a controlled substance  
287 shall submit to the electronic system, by a procedure and in a  
288 format established by the department and consistent with an  
289 ASAP-approved format, the following information for inclusion in  
290 the database:

291 (a) The name of the prescribing practitioner, the  
292 practitioner's federal Drug Enforcement Administration  
293 registration number, the practitioner's National Provider  
294 Identification (NPI) or other appropriate identifier, and the  
295 date of the prescription.

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

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

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

305 (e) The full name, federal Drug Enforcement Administration  
306 registration number, and address of the pharmacy or other  
307 location from which the controlled substance was dispensed. If  
308 the controlled substance was dispensed by a practitioner other

309 than a pharmacist, the practitioner's full name, federal Drug  
310 Enforcement Administration registration number, and address.

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

314 (g) Other appropriate identifying information as  
315 determined by department rule.

316 (4) Each time a controlled substance is dispensed to an  
317 individual, the controlled substance shall be reported to the  
318 department through the system as soon thereafter as possible,  
319 but not more than 15 days after the date the controlled  
320 substance is dispensed unless an extension is approved by the  
321 department for cause as determined by rule. A dispenser must  
322 meet the reporting requirements of this section by providing the  
323 required information concerning each controlled substance that  
324 it dispensed in a department-approved, secure methodology and  
325 format. Such approved methodologies and formats may include, but  
326 are not limited to, submission via the Internet, on a disc, or  
327 by use of regular mail.

328 (5) When the following acts of dispensing or administering  
329 occur, the following are exempt from reporting under this  
330 section as to that specific act of dispensing or administration:

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

335 (b) A pharmacist or health care practitioner when  
336 administering a controlled substance to a patient or resident

337 receiving care as a patient at a hospital, nursing home,  
338 ambulatory surgical center, hospice, or intermediate care  
339 facility for the developmentally disabled which is licensed in  
340 this state.

341 (c) A practitioner when administering or dispensing a  
342 controlled substance in the health care system of the Department  
343 of Corrections.

344 (d) A practitioner when administering a controlled  
345 substance in the emergency room of a licensed hospital.

346 (e) A health care practitioner when administering or  
347 dispensing a controlled substance to a person under the age of  
348 16.

349 (f) A pharmacist or a dispensing practitioner when  
350 dispensing a one-time, 72-hour emergency resupply of a  
351 controlled substance to a patient.

352 (6) The department may establish when to suspend and when  
353 to resume reporting information during a state-declared or  
354 nationally declared disaster.

355 (7) (a) A practitioner or pharmacist who dispenses a  
356 controlled substance must submit the information required by  
357 this section in an electronic or other method in an ASAP format  
358 approved by rule of the department unless otherwise provided in  
359 this section. The cost to the dispenser in submitting the  
360 information required by this section may not be material or  
361 extraordinary. Costs not considered to be material or  
362 extraordinary include, but are not limited to, regular postage,  
363 electronic media, regular electronic mail, and facsimile  
364 charges.

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365       (b) A pharmacy, prescriber, or dispenser shall have access  
366 to information in the prescription drug monitoring program's  
367 database which relates to a patient of that pharmacy,  
368 prescriber, or dispenser in a manner established by the  
369 department as needed for the purpose of reviewing the patient's  
370 controlled substance prescription history. Other access to the  
371 program's database shall be limited to the program's manager and  
372 to the designated program and support staff, who may act only at  
373 the direction of the program manager or, in the absence of the  
374 program manager, as authorized. Access by the program manager or  
375 such designated staff is for prescription drug program  
376 management only or for management of the program's database and  
377 its system in support of the requirements of this section and in  
378 furtherance of the prescription drug monitoring program.  
379 Confidential and exempt information in the database shall be  
380 released only as provided in paragraph (c) and s. 893.0551.

381       (c) The following entities shall not be allowed direct  
382 access to information in the prescription drug monitoring  
383 program database but may request from the program manager and,  
384 when authorized by the program manager, the program manager's  
385 program and support staff, information that is confidential and  
386 exempt under s. 893.0551. Prior to release, the request shall be  
387 verified as authentic and authorized with the requesting  
388 organization by the program manager, the program manager's  
389 program and support staff, or as determined in rules by the  
390 department as being authentic and as having been authorized by  
391 the requesting entity:

392       1. The department or its relevant health care regulatory

393 boards responsible for the licensure, regulation, or discipline  
394 of practitioners, pharmacists, or other persons who are  
395 authorized to prescribe, administer, or dispense controlled  
396 substances and who are involved in a specific controlled  
397 substance investigation involving a designated person for one or  
398 more prescribed controlled substances.

399 2. The Attorney General for Medicaid fraud cases involving  
400 prescribed controlled substances.

401 3. A law enforcement agency during active investigations  
402 regarding potential criminal activity, fraud, or theft regarding  
403 prescribed controlled substances.

404 4. A patient or the legal guardian or designated health  
405 care surrogate of an incapacitated patient as described in s.  
406 893.0551 who, for the purpose of verifying the accuracy of the  
407 database information, submits a written and notarized request  
408 that includes the patient's full name, address, and date of  
409 birth, and includes the same information if the legal guardian  
410 or health care surrogate submits the request. The request shall  
411 be validated by the department to verify the identity of the  
412 patient and the legal guardian or health care surrogate, if the  
413 patient's legal guardian or health care surrogate is the  
414 requestor. Such verification is also required for any request to  
415 change a patient's prescription history or other information  
416 related to his or her information in the electronic database.

417  
418 Information in the database for the electronic prescription drug  
419 monitoring system is not discoverable or admissible in any civil  
420 or administrative action, except in an investigation and

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421 disciplinary proceeding by the department or the appropriate  
422 regulatory board.

423 (d) The following entities shall not be allowed direct  
424 access to information in the prescription drug monitoring  
425 program database but may request from the program manager and,  
426 when authorized by the program manager, the program manager's  
427 program and support staff information that contains no  
428 identifying information of any patient, physician, health care  
429 practitioner, prescriber, or dispenser and that is not  
430 confidential and exempt:

431 1. Department staff for the purpose of calculating  
432 performance measures pursuant to subsection (8).

433 2. The Program Implementation and Oversight Task Force for  
434 its reporting to the Governor, the President of the Senate, and  
435 the Speaker of the House of Representatives regarding the  
436 prescription drug monitoring program. This subparagraph expires  
437 July 1, 2012.

438 (e) All transmissions of data required by this section  
439 must comply with relevant state and federal privacy and security  
440 laws and regulations. However, any authorized agency or person  
441 under s. 893.0551 receiving such information as allowed by s.  
442 893.0551 may maintain the information received for up to 24  
443 months before purging it from his or her records or maintain it  
444 for longer than 24 months if the information is pertinent to  
445 ongoing health care or an active law enforcement investigation  
446 or prosecution.

447 (8) To assist in fulfilling program responsibilities,  
448 performance measures shall be reported annually to the Governor,



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449 the President of the Senate, and the Speaker of the House of  
450 Representatives by the department each December 1, beginning in  
451 2011. Data that does not contain patient, physician, health care  
452 practitioner, prescriber, or dispenser identifying information  
453 may be requested during the year by department employees so that  
454 the department may undertake public health care and safety  
455 initiatives that take advantage of observed trends. Performance  
456 measures may include, but are not limited to, efforts to achieve  
457 the following outcomes:

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

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

464 (c) Increased coordination among partners participating in  
465 the prescription drug monitoring program.

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

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

473 (10) All costs incurred by the department in administering  
474 the prescription drug monitoring program shall be funded through  
475 federal grants or private funding applied for or received by the  
476 state. The department may not commit funds for the monitoring

477 program without ensuring funding is available. The prescription  
478 drug monitoring program and the implementation thereof are  
479 contingent upon receipt of the nonstate funding. The department  
480 and state government shall cooperate with the direct-support  
481 organization established pursuant to subsection (11) in seeking  
482 federal grant funds, other nonstate grant funds, gifts,  
483 donations, or other private moneys for the department so long as  
484 the costs of doing so are not considered material. Nonmaterial  
485 costs for this purpose include, but are not limited to, the  
486 costs of mailing and personnel assigned to research or apply for  
487 a grant. Notwithstanding the exemptions to competitive-  
488 solicitation requirements under s. 287.057(5)(f), the department  
489 shall comply with the competitive-solicitation requirements  
490 under s. 287.057 for the procurement of any goods or services  
491 required by this section.

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

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

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

502 2. Organized and operated to conduct programs and  
503 activities; raise funds; request and receive grants, gifts, and  
504 bequests of money; acquire, receive, hold, and invest, in its

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505 own name, securities, funds, objects of value, or other  
506 property, either real or personal; and make expenditures or  
507 provide funding to or for the direct or indirect benefit of the  
508 department in the furtherance of the prescription drug  
509 monitoring program.

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

512 (c) The director of the Office of Drug Control shall  
513 appoint a board of directors for the direct-support  
514 organization. The director may designate employees of the Office  
515 of Drug Control, state employees other than state employees from  
516 the department, and any other nonstate employees, as  
517 appropriate, to serve on the board. Members of the board shall  
518 serve at the pleasure of the director of the Office of Drug  
519 Control. The director shall provide guidance to members of the  
520 board to ensure that moneys received by the direct-support  
521 organization are not received from inappropriate sources.  
522 Inappropriate sources include, but are not limited to, donors,  
523 grantors, persons, or organizations that may monetarily or  
524 substantively benefit from the purchase of goods or services by  
525 the department in furtherance of the prescription drug  
526 monitoring program.

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

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

532 2. Submission of an annual budget for the approval of the

533 Office of Drug Control.

534 3. Certification by the Office of Drug Control in  
535 consultation with the department that the direct-support  
536 organization is complying with the terms of the contract in a  
537 manner consistent with and in furtherance of the goals and  
538 purposes of the prescription drug monitoring program and in the  
539 best interests of the state. Such certification must be made  
540 annually and reported in the official minutes of a meeting of  
541 the direct-support organization.

542 4. The reversion, without penalty, to the Office of Drug  
543 Control, or to the state if the Office of Drug Control ceases to  
544 exist, of all moneys and property held in trust by the direct-  
545 support organization for the benefit of the prescription drug  
546 monitoring program if the direct-support organization ceases to  
547 exist or if the contract is terminated.

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

551 6. The disclosure of the material provisions of the  
552 contract to donors of gifts, contributions, or bequests,  
553 including such disclosure on all promotional and fundraising  
554 publications, and an explanation to such donors of the  
555 distinction between the Office of Drug Control and the direct-  
556 support organization.

557 7. The direct-support organization's collecting,  
558 expending, and providing of funds to the department for the  
559 development, implementation, and operation of the prescription  
560 drug monitoring program as described in this section and for the

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561 Program Implementation and Oversight Task Force under section 2  
562 of this act as long as the task force is authorized. The direct-  
563 support organization may collect and expend funds to be used for  
564 the functions of the direct-support organization's board of  
565 directors, as necessary and approved by the director of the  
566 Office of Drug Control. In addition, the direct-support  
567 organization may collect and provide funding to the department  
568 in furtherance of the prescription drug monitoring program by:

569 a. Establishing and administering the prescription drug  
570 monitoring program's electronic database, including hardware and  
571 software.

572 b. Conducting studies on the efficiency and effectiveness  
573 of the program to include feasibility studies as described in  
574 subsection (13).

575 c. Providing funds for future enhancements of the program  
576 within the intent of this section.

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

582 e. Providing funds for travel expenses.

583 f. Providing funds for administrative costs, including  
584 personnel, audits, facilities, and equipment.

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

587 (e) The activities of the direct-support organization must  
588 be consistent with the goals and mission of the Office of Drug

589 Control, as determined by the office in consultation with the  
590 department, and in the best interests of the state. The direct-  
591 support organization must obtain a written approval from the  
592 director of the Office of Drug Control for any activities in  
593 support of the prescription drug monitoring program before  
594 undertaking those activities.

595 (f) The Office of Drug Control, in consultation with the  
596 department, may permit, without charge, appropriate use of  
597 administrative services, property, and facilities of the Office  
598 of Drug Control and the department by the direct-support  
599 organization, subject to this section. The use must be directly  
600 in keeping with the approved purposes of the direct-support  
601 organization and may not be made at times or places that would  
602 unreasonably interfere with opportunities for the public to use  
603 such facilities for established purposes. Any moneys received  
604 from rentals of facilities and properties managed by the Office  
605 of Drug Control and the department may be held by the Office of  
606 Drug Control or in a separate depository account in the name of  
607 the direct-support organization and subject to the provisions of  
608 the letter of agreement with the Office of Drug Control. The  
609 letter of agreement must provide that any funds held in the  
610 separate depository account in the name of the direct-support  
611 organization must revert to the Office of Drug Control if the  
612 direct-support organization is no longer approved by the Office  
613 of Drug Control to operate in the best interests of the state.

614 (g) The Office of Drug Control, in consultation with the  
615 department, may adopt rules under s. 120.54 to govern the use of  
616 administrative services, property, or facilities of the

617 department or office by the direct-support organization.

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

624 (i) The direct-support organization shall provide for an  
625 independent annual financial audit in accordance with s.  
626 215.981. Copies of the audit shall be provided to the Office of  
627 Drug Control and the Office of Policy and Budget in the  
628 Executive Office of the Governor.

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

631 (12) A prescriber or dispenser may have access to the  
632 information under this section which relates to a patient of  
633 that prescriber or dispenser as needed for the purpose of  
634 reviewing the patient's controlled drug prescription history. A  
635 prescriber or dispenser acting in good faith is immune from any  
636 civil, criminal, or administrative liability that might  
637 otherwise be incurred or imposed for receiving or using  
638 information from the prescription drug monitoring program. This  
639 subsection does not create a private cause of action, and a  
640 person may not recover damages against a prescriber or dispenser  
641 authorized to access information under this subsection for  
642 accessing or failing to access such information.

643 (13) To the extent that funding is provided for such  
644 purpose through federal or private grants or gifts and other

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645 types of available moneys, the department, in collaboration with  
646 the Office of Drug Control, shall study the feasibility of  
647 enhancing the prescription drug monitoring program for the  
648 purposes of public health initiatives and statistical reporting  
649 that respects the privacy of the patient, the prescriber, and  
650 the dispenser. Such a study shall be conducted in order to  
651 further improve the quality of health care services and safety  
652 by improving the prescribing and dispensing practices for  
653 prescription drugs, taking advantage of advances in technology,  
654 reducing duplicative prescriptions and the overprescribing of  
655 prescription drugs, and reducing drug abuse. The requirements of  
656 the National All Schedules Prescription Electronic Reporting  
657 (NASPER) Act are authorized in order to apply for federal NASPER  
658 funding. In addition, the direct-support organization shall  
659 provide funding for the department, in collaboration with the  
660 Office of Drug Control, to conduct training for health care  
661 practitioners and other appropriate persons in using the  
662 monitoring program to support the program enhancements.

663 (14) A pharmacist, pharmacy, or dispensing health care  
664 practitioner or his or her agent, before releasing a controlled  
665 substance to any person not known to such dispenser, shall  
666 require the person purchasing, receiving, or otherwise acquiring  
667 the controlled substance to present valid photographic  
668 identification or other verification of his or her identity to  
669 the dispenser. If the person does not have proper  
670 identification, the dispenser may verify the validity of the  
671 prescription and the identity of the patient with the prescriber  
672 or his or her authorized agent. Verification of health plan



673 eligibility through a real-time inquiry or adjudication system  
 674 will be considered to be proper identification. This subsection  
 675 does not apply in an institutional setting or to a long-term  
 676 care facility, including, but not limited to, an assisted living  
 677 facility or a hospital to which patients are admitted. As used  
 678 in this subsection, the term "proper identification" means an  
 679 identification that is issued by a state or the Federal  
 680 Government containing the person's photograph, printed name, and  
 681 signature or a document considered acceptable under 8 C.F.R. s.  
 682 274a.2(b)(1)(v)(A) and (B).

683 (15) The Agency for Health Care Administration shall  
 684 continue the promotion of electronic prescribing by health care  
 685 practitioners, health care facilities, and pharmacies under s.  
 686 408.0611.

687 (16) By October 1, 2010, the department shall adopt rules  
 688 pursuant to ss. 120.536(1) and 120.54 to administer the  
 689 provisions of this section, which shall include as necessary the  
 690 reporting, accessing, evaluation, management, development,  
 691 implementation, operation, and storage of information within the  
 692 monitoring program's system.

693 Section 2. (1) The Program Implementation and Oversight  
 694 Task Force is created within the Executive Office of the  
 695 Governor. The director of the Office of Drug Control shall be a  
 696 nonvoting, ex officio member of the task force and shall act as  
 697 chair. The Office of Drug Control and the Department of Health  
 698 shall provide staff support for the task force.

699 (a) The following state officials shall serve on the task  
 700 force:

701        1. The Attorney General or his or her designee.  
 702        2. The Secretary of Children and Family Services or his or  
 703 her designee.  
 704        3. The Secretary of Health Care Administration or his or  
 705 her designee.  
 706        4. The State Surgeon General or his or her designee.  
 707        (b) In addition, the Governor shall appoint 12 members of  
 708 the public to serve on the task force. Of these 12 appointed  
 709 members, one member must have professional or occupational  
 710 expertise in computer security; one member must be a Florida-  
 711 licensed, board-certified oncologist; two members must be  
 712 Florida-licensed, fellowship-trained, pain-medicine physicians;  
 713 one member must be a Florida-licensed primary care physician who  
 714 has experience in prescribing scheduled prescription drugs; one  
 715 member must have professional or occupational expertise in e-  
 716 Prescribing or prescription drug monitoring programs; two  
 717 members must be Florida-licensed pharmacists; one member must  
 718 have professional or occupational expertise in the area of law  
 719 enforcement and have experience in prescription drug  
 720 investigations; one member must have professional or  
 721 occupational expertise as an epidemiologist and have a  
 722 background in tracking and analyzing drug trends; and two  
 723 members must have professional or occupational expertise as  
 724 providers of substance abuse treatment, with priority given to a  
 725 member who is a former substance abuser.  
 726        (c) Members appointed by the Governor shall be appointed  
 727 to a term of 3 years each. Any vacancy on the task force shall  
 728 be filled in the same manner as the original appointment, and

729 any member appointed to fill a vacancy shall serve only for the  
730 unexpired term of the member's predecessor.

731 (d) Members of the task force and members of subcommittees  
732 appointed under subsection (4) shall serve without compensation,  
733 but are entitled to reimbursement for per diem and travel  
734 expenses as provided in s. 112.061, Florida Statutes.

735 (e) The task force shall meet at least quarterly or upon  
736 the call of the chair.

737 (2) The purpose of the task force is to monitor the  
738 implementation and safeguarding of the electronic system  
739 established for the prescription drug monitoring program under  
740 s. 893.055, Florida Statutes, and to ensure privacy, protection  
741 of individual medication history, and the electronic system's  
742 appropriate use by physicians, dispensers, pharmacies, law  
743 enforcement agencies, and those authorized to request  
744 information from the electronic system.

745 (3) The Office of Drug Control shall submit a report to  
746 the Governor, the President of the Senate, and the Speaker of  
747 the House of Representatives by December 1 of each year which  
748 contains a summary of the work of the task force during that  
749 year and the recommendations developed in accordance with the  
750 task force's purpose as provided in subsection (2). Interim  
751 reports may be submitted at the discretion of the chair.

752 (4) The chair of the task force may appoint subcommittees  
753 that include members of state agencies that are not represented  
754 on the task force for the purpose of soliciting input and  
755 recommendations from those state agencies as needed by the task  
756 force to accomplish its purpose as provided in subsection (2).

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757 In addition, the chair may appoint subcommittees as necessary  
758 from among the members of the task force in order to efficiently  
759 address specific issues. If a state agency is to be represented  
760 on any subcommittee, the representative shall be the head of the  
761 agency or his or her designee. The chair may designate lead and  
762 contributing agencies within a subcommittee.

763 (5) The direct-support organization created in s. 893.055,  
764 Florida Statutes, may collect, expend, and provide funds and  
765 other assistance to the department for the development,  
766 implementation, and operation of the task force.

767 (6) The task force shall provide a final report in  
768 accordance with the task force's purpose as provided in  
769 subsection (2) on July 1, 2012, to the Governor, the President  
770 of the Senate, and the Speaker of the House of Representatives.  
771 Such report shall be prepared using only data that does not  
772 identify a patient, a prescriber, or a dispenser. The task force  
773 shall expire and this section is repealed on that date unless  
774 reenacted by the Legislature.

775 Section 3. Subsections (4), (5), and (6) are added to  
776 section 458.309, Florida Statutes, to read:

777 458.309 Rulemaking authority.--

778 (4) All privately owned pain-management clinics,  
779 facilities, or offices, hereinafter referred to as "clinics,"  
780 which advertise in any medium for any type of pain-management  
781 services, or employ a physician who is primarily engaged in the  
782 treatment of pain by prescribing or dispensing controlled  
783 substance medications, must register with the department by  
784 January 4, 2010, unless that clinic is licensed as a facility

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785 pursuant to chapter 395. A physician may not practice medicine  
786 in a pain-management clinic that is required to but has not  
787 registered with the department. Each clinic location shall be  
788 registered separately regardless of whether the clinic is  
789 operated under the same business name or management as another  
790 clinic. If the clinic is licensed as a health care clinic under  
791 chapter 400, the medical director is responsible for registering  
792 the facility with the department. If the clinic is not  
793 registered pursuant to chapter 395 or chapter 400, the clinic  
794 shall, upon registration with the department, designate a  
795 physician who is responsible for complying with all requirements  
796 related to registration of the clinic. The designated physician  
797 shall be licensed under this chapter or chapter 459 and shall  
798 practice at the office location for which the physician has  
799 assumed responsibility. The department shall inspect the clinic  
800 annually to ensure that it complies with rules of the Board of  
801 Medicine adopted pursuant to this subsection and subsection (5)  
802 unless the office is accredited by a nationally recognized  
803 accrediting agency approved by the Board of Medicine. The actual  
804 costs for registration and inspection or accreditation shall be  
805 paid by the physician seeking to register the clinic.

806 (5) The Board of Medicine shall adopt rules setting forth  
807 standards of practice for physicians practicing in privately  
808 owned pain-management clinics that primarily engage in the  
809 treatment of pain by prescribing or dispensing controlled  
810 substance medications. Such rules shall address, but need not be  
811 limited to, the following subjects:

812 (a) Facility operations;

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- 813        (b) Physical operations;  
814        (c) Infection control requirements;  
815        (d) Health and safety requirements;  
816        (e) Quality assurance requirements;  
817        (f) Patient records;  
818        (g) Training requirements for all facility health care  
819 practitioners who are not regulated by another board;  
820        (h) Inspections; and  
821        (i) Data collection and reporting requirements.  
822

823 A physician is primarily engaged in the treatment of pain by  
824 prescribing or dispensing controlled substance medications when  
825 the majority of the patients seen are prescribed or dispensed  
826 controlled substance medications for the treatment of chronic  
827 nonmalignant pain. Chronic nonmalignant pain is pain unrelated  
828 to cancer which persists beyond the usual course of the disease  
829 or the injury that is the cause of the pain or more than 90 days  
830 after surgery.

831        (6) A privately owned clinic, facility, or office that  
832 advertises in any medium for any type of pain-management  
833 services or employs one or more physicians who are primarily  
834 engaged in the treatment of pain by prescribing or dispensing  
835 controlled substances is exempt from the registration provisions  
836 in subsection (4) if the majority of the physicians who provide  
837 services in the clinic, facility, or office primarily provide  
838 surgical services.

839        Section 4. Subsections (3), (4), and (5) are added to  
840 section 459.005, Florida Statutes, to read:

841 459.005 Rulemaking authority.--

842 (3) All privately owned pain-management clinics,

843 facilities, or offices, hereinafter referred to as "clinics,"

844 which advertise in any medium for any type of pain-management

845 services, or employ a physician who is licensed under this

846 chapter and who is primarily engaged in the treatment of pain by

847 prescribing or dispensing controlled substance medications, must

848 register with the department by January 4, 2010, unless that

849 clinic is licensed as a facility under chapter 395. A physician

850 may not practice osteopathic medicine in a pain-management

851 clinic that is required to but has not registered with the

852 department. Each clinic location shall be registered separately

853 regardless of whether the clinic is operated under the same

854 business name or management as another clinic. If the clinic is

855 licensed as a health care clinic under chapter 400, the medical

856 director is responsible for registering the facility with the

857 department. If the clinic is not registered under chapter 395 or

858 chapter 400, the clinic shall, upon registration with the

859 department, designate a physician who is responsible for

860 complying with all requirements related to registration of the

861 clinic. The designated physician shall be licensed under chapter

862 458 or this chapter and shall practice at the office location

863 for which the physician has assumed responsibility. The

864 department shall inspect the clinic annually to ensure that it

865 complies with rules of the Board of Osteopathic Medicine adopted

866 pursuant to this subsection and subsection (4) unless the office

867 is accredited by a nationally recognized accrediting agency

868 approved by the Board of Osteopathic Medicine. The actual costs

869 for registration and inspection or accreditation shall be paid  
 870 by the physician seeking to register the clinic.

871 (4) The Board of Osteopathic Medicine shall adopt rules  
 872 setting forth standards of practice for physicians who practice  
 873 in privately owned pain-management clinics that primarily engage  
 874 in the treatment of pain by prescribing or dispensing controlled  
 875 substance medications. Such rules shall address, but need not be  
 876 limited to, the following subjects:

- 877 (a) Facility operations;
- 878 (b) Physical operations;
- 879 (c) Infection control requirements;
- 880 (d) Health and safety requirements;
- 881 (e) Quality assurance requirements;
- 882 (f) Patient records;
- 883 (g) Training requirements for all facility health care  
 884 practitioners who are not regulated by another board;
- 885 (h) Inspections; and
- 886 (i) Data collection and reporting requirements.

887

888 A physician is primarily engaged in the treatment of pain by  
 889 prescribing or dispensing controlled substance medications when  
 890 the majority of the patients seen are prescribed or dispensed  
 891 controlled substance medications for the treatment of chronic  
 892 nonmalignant pain. Chronic nonmalignant pain is pain unrelated  
 893 to cancer which persists beyond the usual course of the disease  
 894 or the injury that is the cause of the pain or more than 90 days  
 895 after surgery.

896 (5) A privately owned clinic, facility, or office that



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897 advertises in any medium for any type of pain-management  
898 services or employs one or more physicians who are primarily  
899 engaged in the treatment of pain by prescribing or dispensing  
900 controlled substances is exempt from the registration provisions  
901 in subsection (3) if the majority of the physicians who provide  
902 services in the clinic, facility, or office primarily provide  
903 surgical services.

904 Section 5. This act shall take effect July 1, 2009.