Page and Line Citings for areas of concern in the Prescription Drug Monitoring Legislation, signed by the Governor, Summer, 2009, also referred to as Senate Bill 462.

There are three parts to the law:

For the actual PDMP part which is the first part of this law, questions and concerns are:

1. Will this be required for all your patients, or will you be able to access the system on a patient by patient basis? What is the implementation date?

2. Who doesn't have to comply? *Page 12, Line 334*

3. If you are a dispensing physician, you need a reporting format that works for you. *P 13, L 361*

4. How is the data going to be made available? Who is going to get it? *P 13, L 371*

5. There is some good language in the bill: information into the PDMP is not discoverable or admissible in any civil or administration action, except in investigation (i.e., law enforcement)……*P 15, L 424-8*

6. Some bad language: failure to access the database could be used in a malpractice case against you. Better language would be: failure to access the database is not discoverable or admissible in any civil or administration action, except in investigation (i.e., law enforcement)……*P 22, L 634-45*

7. The Office of Drug Control is going to be a direct supporting organization for implementing this legislation. (http://www.flgov.com/drugcontrol/index.html for Governor's Office of Drug Control and http://www.flgov.com/drugcontrol/odc_director.html for introduction to the Director of the Office of Drug Control) What is it going to do? Can FAPM try to get a representation on the Board of this supporting organization?

8. There will be a Program Implementation and Oversight Task Force. *P 24, Lines 696-715*. The Governor is to appoint 12 people, 2 of whom are Florida-licensed, fellowship-trained pain physicians. *P 25, L 710*. Suggested that FAPM try to get representation on this Task Force. *P 25, Lines 704 -715* are related to this Task Force.

9. Scope of exceptions are of concern. *P 13, L 350-4*

The second part of the law deals with the inspection of pain clinics, questions and concerns are: For the second part of the law, inspection of pain clinics, questions and concerns are:

1. The Department of Health is to inspect pain clinics annually unless the clinic is accredited by a national agency approved by the Board of Medicine. Will the inspections be announced or unannounced? *P 27, L 781*. Specifically, what national organizations does the BOM approve? Drs Ray and Monzon noted that at previous meetings, the American Academy of Pain Management was "pushed away." We will talk with the American Academy of Pain Medicine to see if this is an avenue that they might like to pursue, to compete with existing bodies, such as CARF which charge $5,000 – 6,000 to credential pain clinics.

2. *P 27 or 28, L 826* – "if the majority of patients are dispensed controlled substance." That means more than 50%. So if your patients are prescribed narcotics in the early phases of treatment, while you teach them other ways to deal with their pain, the State will see this as the majority of your patients being dispensed controlled substances. This could be an example of legitimate pain practice being unduly burdened by the State. Will pain physicians have to develop strategies to keep themselves out of the State's annual inspection routine? For example, control your patient population so that less than half get narcotic analgesics.

2. *L 806-8* speaks to the financial requirements of compliance with this law.

For the third part of the law, standards of pain medicine practice, questions and concerns are:

P 809-843 deal with allopathic medicine. *P 844* begins the same information for osteopathic medicine.

There are 9 criteria listed that must be checked annually. However, the law reads "but need not be limited to"….these 9 subjects. This is problematic because of the potential for the State telling physicians how to practice medicine. You could potentially have a malpractice case for noncompliance. Keep this list limited to the 9 criteria to reduce the risk of being told how to practice medicine. FAPM should advocate for the rules and regs to be written in a way in which it is easier to comply. Advocate that these criteria not be strictly written, that onerous quality assurance requirements and excessive patient records requirements be avoided. These types of requirements result in administrative overload and expense for physicians.

FAPM should:

1. Ask to be involved in the formulation of draft rules. <u>Above all, FAPM wants to work with the Committee in developing rules in a way that makes sense</u>. *P 10, L 277* states the Department of Health shall work with the Board of Medicine, the FMA and FOMA. FAPM is a pertinent part of the FMA related to these issues.

2. Ask if there is an entity interested in being approved by the BOM to credential pain clinics (in lieu of annual State inspection), what is the process by which they apply?

3. Make the point that if rules are too stringent and expensive, the cost of healthcare will be driven up because legitimate pain practitioners will close, access for pain patients will be limited. Unlike many legitimate practitioners, pill mills have plenty of money to pay to stay in business. We were assured this legislation would lead to the shut down of pill mills and NOT hamper legitimate practitioners.

4. Object to the adoption of the Office Surgery Rules template.

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An act relating to prescription drugs; creating s. 893.055, F.S.; providing definitions; requiring the Department of Health to establish a comprehensive electronic database system to monitor the prescribing and dispensing of certain controlled substances; requiring specified prescribing and dispensing information to be reported to the electronic database system; requiring the department to establish policies and procedures for the system; requiring the department, in consultation with the Office of Drug Control and specified organizations, to adopt by rules appropriate for the prescription drug monitoring program; providing reporting requirements; providing a reporting period; providing exemptions from participation in the system; authorizing the department to establish when to suspend and when to resume reporting requirements during declared emergencies; requiring all nonexempt, dispensing pharmacists and practitioners to submit information in a specified format; providing that the cost to the dispenser in submitting the required information may not be material or extraordinary; specifying costs that are not material or extraordinary; providing access to information reported to the system under certain circumstances; providing that information in the database for the electronic prescription drug monitoring system is not discoverable or admissible in any civil or administrative action; providing

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exceptions; providing for the use of data for specified purposes; providing requirements for verification of information requested; requiring data transmission to comply with state and federal privacy and security laws; authorizing an agency or person to

maintain the data for a specified period if the data is pertinent to active health care or law enforcement investigation or prosecution; requiring the annual reporting of certain performance measures to the Governor and Legislature; providing performance measure criteria; providing criminal penalties for violations; requiring that all costs incurred by the department for the program be funded through federal grants or available private funding sources; providing requirements for seeking funding and procuring goods or services; authorizing the Office of Drug Control, in coordination with the department, to establish a direct-support organization; providing a definition; providing for a board of directors appointed by the director of the office; requiring the director to provide guidance to the board regarding acceptance of moneys from appropriate sources; requiring the direct support organization to operate under written contract with the office; providing contract requirements; providing requirements for the direct-support organization's collecting, expending, and providing of funds; requiring department approval of activities of the direct-support organization; authorizing the office to adopt rules for the use of certain

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facilities and services; providing for audits; prohibiting the direct-support organization from exercising certain powers; establishing that a prescriber or dispenser is not liable for good faith use of the department-provided controlled substance prescription information of a patient; requiring the department, in collaboration with the office, to study the feasibility of enhancing the prescription drug monitoring program for specified purposes to the extent that funding is provided for such purpose; requiring certain persons to present specified identification in order to obtain controlled substances; providing for recordkeeping for certain transactions; requiring the Agency for Health Care Administration to continue the promotion of electronic prescribing and an electronic prescribing

clearinghouse; requiring the department to adopt rules; establishing a Program Implementation and Oversight Task Force; providing for membership; providing for reimbursement of certain member expenses; providing for meetings; providing the purpose of the task force; requiring reports to the Governor and Legislature; providing for the creation, membership, and duties of subcommittees; authorizing the direct-support organization to collect, expend, and provide funds and other assistance to the department; providing for a final report and the termination of the task force; amending ss. 458.309 and 459.005, F.S.; requiring certain physicians who

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engage in pain management to register their clinics with the department by a specified date; providing an exception; prohibiting certain physicians from practicing in a pain-management clinic that has not registered with the department; requiring the department to inspect each facility; providing for exceptions; requiring the physician seeking to register the clinic to pay the costs of registration and inspection or accreditation; requiring the Board of Medicine and the Board of Osteopathic Medicine to adopt rules setting forth standards of practice for certain physicians who engage in pain management; providing criteria for the rules; providing an effective date.

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

WHEREAS, while the importance and necessity of the proper prescribing, dispensing, and monitoring of controlled substances, particularly pain medication, have been established, controlled prescription drugs are too often diverted in this state, often through fraudulent means, including outright theft,

115 phony pharmacy fronts, loose Internet medical evaluations, and
116 inappropriate importation; in addition, there is a criminal

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

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146 prevent the abuse or diversion of prescribed controlled
147 substances; and to ensure that those who need prescribed
148 controlled substances receive them in a manner that protects

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
WHEREAS, it is the intent of the Legislature to encourage patient safety, responsible pain management, and proper access to useful prescription drugs that are prescribed by a knowledgeable, properly licensed health care practitioner who dispenses prescription drugs and that are dispensed by a pharmacist who is made aware of the patient's prescription drug medication history, thus preventing, in some cases, an abuse or addiction problem from developing or worsening, making such a problem possible or easier to identify, and facilitating the order of appropriate medical treatment or referral, and
WHEREAS, such an electronic system will also aid administrative and law enforcement agencies in an active controlled substance-related investigation and will allow decisions and recommendations for pursuing appropriate administrative or criminal actions while maintaining such information for any such investigation with a reasonable, good faith anticipation of securing an arrest or prosecution in the foreseeable future, and
WHEREAS, a Program Implementation and Oversight Task Force will provide information to the Governor and Legislature regarding the implementation of the program and ensure that

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privacy and confidentiality of the patient's prescription history is respected, NOW, THEREFORE,

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

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

<u>893.055 Prescription drug monitoring program.—</u>
<u>(1) As used in this section, the term:</u>
<u>(a) "Patient advisory report" or "advisory report" means information provided by the department in writing, or as determined by the department, to a prescriber, dispenser, pharmacy, or patient concerning the dispensing of controlled substances. All advisory reports are for informational purposes</u>

189 only and impose no obligations of any nature or any legal duty
190 on a prescriber, dispenser, pharmacy, or patient. The patient
191 advisory report shall be provided in accordance with s.
192 893.13(7)(a)8. The advisory reports issued by the department are
193 not subject to discovery or introduction into evidence in any
194 civil or administrative action against a prescriber, dispenser,
195 pharmacy, or patient arising out of matters that are the subject
196 of the report, and a person who participates in preparing,
197 reviewing, issuing, or any other activity related to an advisory
198 report may not be permitted or required to testify in any such
199 civil action as to any findings, recommendations, evaluations,
200 opinions, or other actions taken in connection with preparing,
201 reviewing, or issuing such a report.
202 (b) “Controlled substance” means a controlled substance
203 listed in Schedule II, Schedule III, or Schedule IV in s.

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204 893.03.
205 (c) “Dispenser” means a pharmacy, dispensing pharmacist, or
206 dispensing health care practitioner.
207 (d) “Health care practitioner” or “practitioner” means any
208 practitioner who is subject to licensure or regulation by the
209 department under chapter 458, chapter 459, chapter 461, chapter
210 462, chapter 464, chapter 465, or chapter 466.
211 (e) “Health care regulatory board” means any board for a
212 practitioner or health care practitioner who is licensed or
213 regulated by the department.
214 (f) “Pharmacy” means any pharmacy that is subject to
215 licensure or regulation by the department under chapter 465 and
216 that dispenses or delivers a controlled substance to an
217 individual or address in this state.
218 (g) “Prescriber” means a prescribing physician, prescribing
219 practitioner, or other prescribing health care practitioner.
220 (h) “Active investigation” means an investigation that is
221 being conducted with a reasonable, good faith belief that it
222 could lead to the filing of administrative, civil, or criminal
223 proceedings, or that is ongoing and continuing and for which
224 there is a reasonable, good faith anticipation of securing an
225 arrest or prosecution in the foreseeable future.
226 (i) “Law enforcement agency” means the Department of Law
227 Enforcement, a Florida sheriff’s department, a Florida police
228 department, or a law enforcement agency of the Federal

229 Government which enforces the laws of this state or the United
230 States relating to controlled substances, and which its agents
231 and officers are empowered by law to conduct criminal
232 investigations and make arrests.

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

262 advisory reports refers only to reports to patients, pharmacies,

263 and practitioners. Separate reports that contain patient
264 prescription history information and that are not patient
265 advisory reports are provided to persons and entities as
266 authorized in paragraphs (7)(b) and (c) and s. 893.0551.
267 (b) The department, when the direct support organization
268 receives at least $20,000 in nonstate moneys or the state
269 receives at least $20,000 in federal grants for the prescription
270 drug monitoring program, and in consultation with the Office of
271 Drug Control, shall adopt rules as necessary concerning the
272 reporting, accessing the database, evaluation, management,
273 development, implementation, operation, security, and storage of
274 information within the system, including rules for when patient
275 advisory reports are provided to pharmacies and prescribers. The
276 patient advisory report shall be provided in accordance with s.
277 893.13(7)(a)8. The department shall work with the professional
278 health care licensure boards, such as the Board of Medicine, the
279 Board of Osteopathic Medicine, and the Board of Pharmacy; other
280 appropriate organizations, such as the Florida Pharmacy
281 Association, the Office of Drug Control, the Florida Medical
282 Association, the Florida Retail Federation and the Florida
283 Osteopathic Medical Association, including those relating to
284 pain management; and the Attorney General, the Department of Law
285 Enforcement, and the Agency for Health Care Administration to
286 develop rules appropriate for the prescription drug monitoring
287 program.
288 (c) All dispensers and prescribers subject to these
289 reporting requirements shall be notified by the department of
290 the implementation date for such reporting requirements.

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291 (3) The pharmacy dispensing the controlled substance and
292 each prescriber who directly dispenses a controlled substance
293 shall submit to the electronic system, by a procedure and in a
294 format established by the department and consistent with an
295 ASAP-approved format, the following information for inclusion in
296 the database:
297 (a) The name of the prescribing practitioner, the
298 practitioner’s federal Drug Enforcement Administration
299 registration number, the practitioner’s National Provider
300 Identification (NPI) or other appropriate identifier, and the
301 date of the prescription.
302 (b) The date the prescription was filled and the method of

303 payment, such as cash by an individual, insurance coverage
304 through a third party, or Medicaid payment. This paragraph does
305 not authorize the department to include individual credit card
306 numbers or other account numbers in the database.
307 (c) The full name, address, and date of birth of the person
308 for whom the prescription was written.
309 (d) The name, national drug code, quantity, and strength of
310 the controlled substance dispensed.
311 (e) The full name, federal Drug Enforcement Administration
312 registration number, and address of the pharmacy or other
313 location from which the controlled substance was dispensed. If
314 the controlled substance was dispensed by a practitioner other
315 than a pharmacist, the practitioner's full name, federal Drug
316 Enforcement Administration registration number, and address.
317 (f) The name of the pharmacy or practitioner, other than a
318 pharmacist, dispensing the controlled substance and the
319 practitioner's National Provider Identification (NPI).

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320 (g) Other appropriate identifying information as determined
321 by department rule.
322 (4) Each time a controlled substance is dispensed to an
323 individual, the controlled substance shall be reported to the
324 department through the system as soon thereafter as possible,
325 but not more than 15 days after the date the controlled
326 substance is dispensed unless an extension is approved by the
327 department for cause as determined by rule. A dispenser must
328 meet the reporting requirements of this section by providing the
329 required information concerning each controlled substance that
330 it dispensed in a department-approved, secure methodology and
331 format. Such approved formats may include, but are not limited
332 to, submission via the Internet, on a disc, or by use of regular
333 mail.
334 (5) When the following acts of dispensing or administering
335 occur, the following are exempt from reporting under this
336 section for that specific act of dispensing or administration:
337 (a) A health care practitioner when administering a
338 controlled substance directly to a patient if the amount of the
339 controlled substance is adequate to treat the patient during
340 that particular treatment session.
341 (b) A pharmacist or health care practitioner when
342 administering a controlled substance to a patient or resident

343 receiving care as a patient at a hospital, nursing home,
344 ambulatory surgical center, hospice, or intermediate care
345 facility for the developmentally disabled which is licensed in
346 this state.
347 (c) A practitioner when administering or dispensing a
348 controlled substance in the health care system of the Department

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349 of Corrections.
350 (d) A practitioner when administering a controlled
351 substance in the emergency room of a licensed hospital.
352 (e) A health care practitioner when administering or
353 dispensing a controlled substance to a person under the age of
354 16.
355 (f) A pharmacist or a dispensing practitioner when
356 dispensing a one-time, 72-hour emergency resupply of a
357 controlled substance to a patient.
358 (6) The department may establish when to suspend and when
359 to resume reporting information during a state-declared or
360 nationally declared disaster.
361 (7)(a) A practitioner or pharmacist who dispenses a
362 controlled substance must submit the information required by
363 this section in an electronic or other method in an ASAP format
364 approved by rule of the department unless otherwise provided in
365 this section. The cost to the dispenser in submitting the
366 information required by this section may not be material or
367 extraordinary. Costs not considered to be material or
368 extraordinary include, but are not limited to, regular postage,
369 electronic media, regular electronic mail, and facsimile
370 charges.
371 (b) A pharmacy, prescriber, or dispenser shall have access
372 to information in the prescription drug monitoring program's
373 database which relates to a patient of that pharmacy,
374 prescriber, or dispenser in a manner established by the
375 department as needed for the purpose of reviewing the patient's
376 controlled substance prescription history. Other access to the
377 program's database shall be limited to the program's manager and

to the designated program and support staff, who may act only at the direction of the program manager or, in the absence of the program manager, as authorized. Access by the program manager or such designated staff is for prescription drug program management only or for management of the program's database and its system in support of the requirements of this section and in furtherance of the prescription drug monitoring program. Confidential and exempt information in the database shall be released only as provided in paragraph (c) and s. 893.0551.

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

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

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

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

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

be validated by the department to verify the identity of the patient and the legal guardian or health care surrogate, if the patient's legal guardian or health care surrogate is the requestor. Such verification is also required for any request to change a patient's prescription history or other information related to his or her information in the electronic database.

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

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

confidential and exempt:

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

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

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

(8) To assist in fulfilling program responsibilities, performance measures shall be reported annually to the Governor, the President of the Senate, and the Speaker of the House of Representatives by the department each December 1, beginning in 2011. Data that does not contain patient, physician, health care

457 practitioner, prescriber, or dispenser identifying information
458 may be requested during the year by department employees so that
459 the department may undertake public health care and safety
460 initiatives that take advantage of observed trends. Performance
461 measures may include, but are not limited to, efforts to achieve
462 the following outcomes:
463 (a) Reduction of the rate of inappropriate use of
464 prescription drugs through department education and safety

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465 efforts.
466 (b) Reduction of the quantity of pharmaceutical controlled
467 substances obtained by individuals attempting to engage in fraud
468 and deceit.
469 (c) Increased coordination among partners participating in
470 the prescription drug monitoring program.
471 (d) Involvement of stakeholders in achieving improved
472 patient health care and safety and reduction of prescription
473 drug abuse and prescription drug diversion.
474 (9) Any person who willfully and knowingly fails to report
475 the dispensing of a controlled substance as required by this
476 section commits a misdemeanor of the first degree, punishable as
477 provided in s. 775.082 or s. 775.083.
478 (10) All costs incurred by the department in administering
479 the prescription drug monitoring program shall be funded through
480 federal grants or private funding applied for or received by the
481 state. The department may not commit funds for the monitoring
482 program without ensuring funding is available. The prescription
483 drug monitoring program and the implementation thereof are
484 contingent upon receipt of the nonstate funding. The department
485 and state government shall cooperate with the direct-support
486 organization established pursuant to subsection (11) in seeking
487 federal grant funds, other nonstate grant funds, gifts,
488 donations, or other private moneys for the department so long as
489 the costs of doing so are not considered material. Nonmaterial
490 costs for this purpose include, but are not limited to, the
491 costs of mailing and personnel assigned to research or apply for
492 a grant. Notwithstanding the exemptions to competitive493
solicitation requirements under s. 287.057(5)(f), the department

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494 shall comply with the competitive-solicitation requirements
495 under s. 287.057 for the procurement of any goods or services
496 required by this section.
497 (11) The Office of Drug Control, in coordination with the
498 department, may establish a direct-support organization that has
499 a board consisting of at least five members to provide
500 assistance, funding, and promotional support for the activities
501 authorized for the prescription drug monitoring program.
502 (a) As used in this subsection, the term “direct-support
503 organization” means an organization that is:
504 1. A Florida corporation not for profit incorporated under
505 chapter 617, exempted from filing fees, and approved by the
506 Department of State.
507 2. Organized and operated to conduct programs and
508 activities; raise funds; request and receive grants, gifts, and
509 bequests of money; acquire, receive, hold, and invest, in its
510 own name, securities, funds, objects of value, or other
511 property, either real or personal; and make expenditures or
512 provide funding to or for the direct or indirect benefit of the
513 department in the furtherance of the prescription drug
514 monitoring program.
515 (b) The direct-support organization is not considered a
516 lobbying firm within the meaning of s. 11.045.
517 (c) The director of the Office of Drug Control shall
518 appoint a board of directors for the direct-support
519 organization. The director may designate employees of the Office
520 of Drug Control, state employees other than state employees from
521 the department, and any other nonstate employees as appropriate,
522 to serve on the board. Members of the board shall serve at the

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523 pleasure of the director of the Office of Drug Control. The
524 director shall provide guidance to members of the board to
525 ensure that moneys received by the direct-support organization
526 are not received from inappropriate sources. Inappropriate
527 sources include, but are not limited to, donors, grantors,
528 persons, or organizations that may monetarily or substantively
529 benefit from the purchase of goods or services by the department
530 in furtherance of the prescription drug monitoring program.

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

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

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

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

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

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

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

7. The direct-support organization's collecting, expending, and providing of funds to the department for the development, implementation, and operation of the prescription drug monitoring program as described in this section and section 2 of this act as long as the task force is authorized. The direct-support organization may collect and expend funds to be used for the functions of the direct-support organization's board of directors, as necessary and approved by the director of the Office of Drug Control. In addition, the direct-support organization may collect and provide funding to the department

571 in furtherance of the prescription drug monitoring program by:
572 a. Establishing and administering the prescription drug
573 monitoring program's electronic database, including hardware and
574 software.
575 b. Conducting studies on the efficiency and effectiveness
576 of the program to include feasibility studies as described in
577 subsection (13).
578 c. Providing funds for future enhancements of the program
579 within the intent of this section.
580 d. Providing user training of the prescription drug

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581 monitoring program, including distribution of materials to
582 promote public awareness and education and conducting workshops
583 or other meetings, for health care practitioners, pharmacists,
584 and others as appropriate.
585 e. Providing funds for travel expenses.
586 f. Providing funds for administrative costs, including
587 personnel, audits, facilities, and equipment.
588 g. Fulfilling all other requirements necessary to implement
589 and operate the program as outlined in this section.
590 (e) The activities of the direct-support organization must
591 be consistent with the goals and mission of the Office of Drug
592 Control, as determined by the office in consultation with the
593 department, and in the best interests of the state. The direct594
support organization must obtain a written approval from the
595 director of the Office of Drug Control for any activities in
596 support of the prescription drug monitoring program before
597 undertaking those activities.
598 (f) The Office of Drug Control, in consultation with the
599 department, may permit, without charge, appropriate use of
600 administrative services, property, and facilities of the Office
601 of Drug Control and the department by the direct-support
602 organization, subject to this section. The use must be directly
603 in keeping with the approved purposes of the direct-support
604 organization and may not be made at times or places that would
605 unreasonably interfere with opportunities for the public to use
606 such facilities for established purposes. Any moneys received
607 from rentals of facilities and properties managed by the Office
608 of Drug Control and the department may be held by the Office of
609 Drug Control or in a separate depository account in the name of

610 the direct-support organization and subject to the provisions of
611 the letter of agreement with the Office of Drug Control. The
612 letter of agreement must provide that any funds held in the
613 separate depository account in the name of the direct-support
614 organization must revert to the Office of Drug Control if the
615 direct-support organization is no longer approved by the Office
616 of Drug Control to operate in the best interests of the state.
617 (g) The Office of Drug Control, in consultation with the
618 department, may adopt rules under s. 120.54 to govern the use of
619 administrative services, property, or facilities of the
620 department or office by the direct-support organization.
621 (h) The Office of Drug Control may not permit the use of
622 any administrative services, property, or facilities of the
623 state by a direct-support organization if that organization does
624 not provide equal membership and employment opportunities to all
625 persons regardless of race, color, religion, gender, age, or
626 national origin.
627 (i) The direct-support organization shall provide for an
628 independent annual financial audit in accordance with s.
629 215.981. Copies of the audit shall be provided to the Office of
630 Drug Control and the Office of Policy and Budget in the
631 Executive Office of the Governor.
632 (j) The direct-support organization may not exercise any
633 power under s. 617.0302(12) or (16).
634 (12) A prescriber or dispenser may have access to the
635 information under this section which relates to a patient of
636 that prescriber or dispenser as needed for the purpose of
637 reviewing the patient's controlled drug prescription history. A
638 prescriber or dispenser acting in good faith is immune from any

639 civil, criminal, or administrative liability that might
640 otherwise be incurred or imposed for receiving or using
641 information from the prescription drug monitoring program. This
642 subsection does not create a private cause of action, and a
643 person may not recover damages against a prescriber or dispenser
644 authorized to access information under this subsection for

645 accessing or failing to access such information.
646 (13) To the extent that funding is provided for such
647 purpose through federal or private grants or gifts and other
648 types of available moneys, the department, in collaboration with
649 the Office of Drug Control, shall study the feasibility of
650 enhancing the prescription drug monitoring program for the
651 purposes of public health initiatives and statistical reporting
652 that respects the privacy of the patient, the prescriber, and
653 the dispenser. Such a study shall be conducted in order to
654 further improve the quality of health care services and safety
655 by improving the prescribing and dispensing practices for
656 prescription drugs, taking advantage of advances in technology,
657 reducing duplicative prescriptions and the overprescribing of
658 prescription drugs, and reducing drug abuse. The requirements of
659 the National All Schedules Prescription Electronic Reporting
660 (NASPER) Act are authorized in order to apply for federal NASPER
661 funding. In addition, the direct-support organization shall
662 provide funding for the department, in collaboration with the
663 Office of Drug Control, to conduct training for health care
664 practitioners and other appropriate persons in using the
665 monitoring program to support the program enhancements.
666 (14) A pharmacist, pharmacy, or dispensing health care
667 practitioner or his or her agent, before releasing a controlled

668 substance to any person not known to such dispenser, shall
669 require the person purchasing, receiving, or otherwise acquiring
670 the controlled substance to present valid photographic
671 identification or other verification of his or her identity to
672 the dispenser. If the person does not have proper
673 identification, the dispenser may verify the validity of the
674 prescription and the identity of the patient with the prescriber
675 or his or her authorized agent. Verification of health plan
676 eligibility through a real-time inquiry or adjudication system
677 will be considered to be proper identification. This subsection
678 does not apply in an institutional setting or to a long-term
679 care facility, including, but not limited to, an assisted living
680 facility or a hospital to which patients are admitted. As used
681 in this subsection, the term “proper identification” means an
682 identification that is issued by a state or the Federal
683 Government containing the person’s photograph, printed name, and
684 signature or a document considered acceptable under 8 C.F.R.

685 274a.2(b)(1)(v)(A) and (B).
686 (15) The Agency for Health Care Administration shall
687 continue the promotion of electronic prescribing by health care
688 practitioners, health care facilities, and pharmacies under s.
689 408.0611.
690 (16) By October 1, 2010, the department shall adopt rules
691 pursuant to ss. 120.536(1) and 120.54 to administer the
692 provisions of this section, which shall include as necessary the
693 reporting, accessing, evaluation, management, development,
694 implementation, operation, and storage of information within the
695 monitoring program's system.
696 Section 2. (1) The Program Implementation and Oversight

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697 Task Force is created within the Executive Office of the
698 Governor. The director of the Office of Drug Control shall be a
699 nonvoting, ex officio member of the task force and shall act as
700 chair. The Office of Drug Control and the Department of Health
701 shall provide staff support for the task force.
702 (a) The following state officials shall serve on the task
703 force:
704 1. The Attorney General or his or her designee.
705 2. The Secretary of Children and Family Services or his or
706 her designee.
707 3. The Secretary of Health Care Administration or his or
708 her designee
709 4. The State Surgeon General or his or her designee.
710 (b) In addition, the Governor shall appoint 12 members of
711 the public to serve on the task force. Of these 12 appointed
712 members, one member must have professional or occupational
713 expertise in computer security; one member must be a Florida714
licensed, board-certified oncologist; two members must be
715 Florida-licensed, fellowship-trained, pain-medicine physicians
716 one member must be a Florida-licensed primary care physician who
717 has experience in prescribing scheduled prescription drugs; one
718 member must have professional or occupational expertise in e-
719 Prescribing or prescription drug monitoring programs; two
720 members must be a Florida-licensed pharmacists; one member must
721 have professional or occupational expertise in the area of law
722 enforcement and have experience in prescription drug
723 investigations; one member must have professional or
724 occupational expertise as an epidemiologist and have a

725 background in tracking and analyzing drug trends; and two

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726 members must have professional or occupational expertise as
727 providers of substance abuse treatment, with priority given to a
728 member who is a former substance abuser.
729 (c) Members appointed by the Governor shall be appointed to
730 a term of 3 years each. Any vacancy on the task force shall be
731 filled in the same manner as the original appointment, and any
732 member appointed to fill a vacancy shall serve only for the
733 unexpired term of the member's predecessor.
734 (d) Members of the task force and members of subcommittees
735 appointed under subsection (4) shall serve without compensation,
736 but are entitled to reimbursement for per diem and travel
737 expenses as provided in s. 112.061, Florida Statutes.
738 (e) The task force shall meet at least quarterly or upon
739 the call of the chair.
740 (2) The purpose of the task force is to monitor the
741 implementation and safeguarding of the electronic system
742 established for the prescription drug monitoring program under
743 s. 893.055, Florida Statutes, and to ensure privacy, protection
744 of individual medication history, and the electronic system's
745 appropriate use by physicians, dispensers, pharmacies, law
746 enforcement agencies, and those authorized to request
747 information from the electronic system.
748 (3) The Office of Drug Control shall submit a report to the
749 Governor, the President of the Senate, and the Speaker of the
750 House of Representatives by December 1 of each year which
751 contains a summary of the work of the task force during that
752 year and the recommendations developed in accordance with the
753 task force's purpose as provided in subsection (2). Interim
754 reports may be submitted at the discretion of the chair.

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755 (4) The chair of the task force may appoint subcommittees
756 that include members of state agencies that are not represented
757 on the task force for the purpose of soliciting input and
758 recommendations from those state agencies as needed by the task

759 force to accomplish its purpose as provided in subsection (2).
760 In addition, the chair may appoint subcommittees as necessary
761 from among the members of the task force in order to efficiently
762 address specific issues. If a state agency is to be represented
763 on any subcommittee, the representative shall be the head of the
764 agency or his or her designee. The chair may designate lead and
765 contributing agencies within a subcommittee.
766 (5) The direct-support organization created in s. 893.055,
767 Florida Statutes, may collect, expend, and provide funds and
768 other assistance to the department for the development,
769 implementation, and operation of the task force.
770 (6) The task force shall provide a final report in
771 accordance with the task force's purpose as provided in
772 subsection (2) on July 1, 2012, to the Governor, the President
773 of the Senate, and the Speaker of the House of Representatives.
774 Such report shall be prepared using only data that does not
775 identify a patient, a prescriber, or a dispenser. The task force
776 shall expire and this section is repealed on that date unless
777 reenacted by the Legislature.
778 Section 3. Subsections (4), (5), and (6) are added to
779 section 458.309, Florida Statutes, to read:
780 458.309 Rulemaking authority.—
781 (4) All privately owned pain-management clinics,
782 facilities, or offices, hereinafter referred to as "clinics,"
783 which advertise in any medium for any type of pain-management

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784 services, or employ a physician who is primarily engaged in the
785 treatment of pain by prescribing or dispensing controlled
786 substance medications, must register with the department by
787 January 4, 2010, unless that clinic is licensed as a facility
788 pursuant to chapter 395. A physician may not practice medicine
789 in a pain-management clinic that is required to but has not
790 registered with the department. Each clinic location shall be
791 registered separately regardless of whether the clinic is
792 operated under the same business name or management as another
793 clinic. If the clinic is licensed as a health care clinic under
794 chapter 400, the medical director is responsible for registering
795 the facility with the department. If the clinic is not
796 registered pursuant to chapter 395 or chapter 400, the clinic
797 shall, upon registration with the department, designate a
798 physician who is responsible for complying with all requirements

799 related to registration of the clinic. The designated physician
800 shall be licensed under this chapter or chapter 459 and shall
801 practice at the office location for which the physician has
802 assumed responsibility. The department shall inspect the clinic
803 annually to ensure that it complies with rules of the Board of
804 Medicine adopted pursuant to this subsection and subsection (5)
805 unless the office is accredited by a nationally recognized
806 accrediting agency approved by the Board of Medicine. The actual
807 costs for registration and inspection or accreditation shall be
808 paid by the physician seeking to register the clinic.
809 (5) The Board of Medicine shall adopt rules setting forth
810 standards of practice for physicians practicing in privately
811 owned pain-management clinics that primarily engage in the
812 treatment of pain by prescribing or dispensing controlled

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813 substance medications. Such rules shall address, but need not be
814 limited to, the following subjects:
815 (a) Facility operations;
816 (b) Physical operations;
817 (c) Infection control requirements;
818 (d) Health and safety requirements;
819 (e) Quality assurance requirements;
820 (f) Patient records;
821 (g) Training requirements for all facility health care
822 practitioners who are not regulated by another board;
823 (h) Inspections; and
824 (i) Data collection and reporting requirements.
825
826 A physician is primarily engaged in the treatment of pain by
827 prescribing or dispensing controlled substance medications when
828 the majority of the patients seen are prescribed or dispensed
829 controlled substance medications for the treatment of chronic
830 nonmalignant pain. Chronic nonmalignant pain is pain unrelated
831 to cancer which persists beyond the usual course of the disease
832 or the injury that is the cause of the pain or more than 90 days
833 after surgery.
834 (6) A privately owned clinic, facility, or office that
835 advertises in any medium for any type of pain-management
836 services or employs one or more physicians who are primarily
837 engaged in the treatment of pain by prescribing or dispensing
838 controlled substances is exempt from the registration provisions

839 in subsection (4) if the majority of the physicians who provide
840 services in the clinic, facility, or office primarily provide
841 surgical services.

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842 Section 4. Subsections (3), (4), and (5) are added to
843 section 459.005, Florida Statutes, to read:
844 459.005 Rulemaking authority.—
845 (3) All privately owned pain-management clinics,
846 facilities, or offices, hereinafter referred to as “clinics,”
847 which advertise in any medium for any type of pain-management
848 services, or employ a physician who is licensed under this
849 chapter and who is primarily engaged in the treatment of pain by
850 prescribing or dispensing controlled substance medications, must
851 register with the department by January 4, 2010, unless that
852 clinic is licensed as a facility under chapter 395. A physician
853 may not practice osteopathic medicine in a pain-management
854 clinic that is required to but has not registered with the
855 department. Each clinic location shall be registered separately
856 regardless of whether the clinic is operated under the same
857 business name or management as another clinic. If the clinic is
858 licensed as a health care clinic under chapter 400, the medical
859 director is responsible for registering the facility with the
860 department. If the clinic is not registered under chapter 395 or
861 chapter 400, the clinic shall, upon registration with the
862 department, designate a physician who is responsible for
863 complying with all requirements related to registration of the
864 clinic. The designated physician shall be licensed under chapter
865 458 or this chapter and shall practice at the office location
866 for which the physician has assumed responsibility. The
867 department shall inspect the clinic annually to ensure that it
868 complies with rules of the Board of Osteopathic Medicine adopted
869 pursuant to this subsection and subsection (4) unless the office
870 is accredited by a nationally recognized accrediting agency

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871 approved by the Board of Osteopathic Medicine. The actual costs
872 for registration and inspection or accreditation shall be paid

873 by the physician seeking to register the clinic.
874 (4) The Board of Osteopathic Medicine shall adopt rules
875 setting forth standards of practice for physicians who practice
876 in privately owned pain-management clinics that primarily engage
877 in the treatment of pain by prescribing or dispensing controlled
878 substance medications. Such rules shall address, but need not be
879 limited to, the following subjects:
880 (a) Facility operations;
881 (b) Physical operations;
882 (c) Infection control requirements;
883 (d) Health and safety requirements;
884 (e) Quality assurance requirements;
885 (f) Patient records;
886 (g) Training requirements for all facility health care
887 practitioners who are not regulated by another board;
888 (h) Inspections; and
889 (i) Data collection and reporting requirements.
890
891 A physician is primarily engaged in the treatment of pain by
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894 controlled substance medications for the treatment of chronic
895 nonmalignant pain. Chronic nonmalignant pain is pain unrelated
896 to cancer which persists beyond the usual course of the disease
897 or the injury that is the cause of the pain or more than 90 days
898 after surgery.
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901 services or employs one or more physicians who are primarily
902 engaged in the treatment of pain by prescribing or dispensing
903 controlled substances is exempt from the registration provisions
904 in subsection (3) if the majority of the physicians who provide
905 services in the clinic, facility, or office primarily provide
906 surgical services .
907 Section 5. This act shall take effect July 1, 2009.