Amendment No.

CHAMBER ACTION

Senate House

.

Representative Boyd offered the following:

2
 3

4

5

6

7

8

9

10

11

12

13

Amendment to Amendment (872398) (with title amendment)

Remove lines 2264-2641 of the amendment and insert:

- (b) An employee of the United States Department of
 Veterans Affairs, the United States Department of Defense, or
 the Indian Health Service who provides health care services
 pursuant to such employment and who has the authority to
 prescribe or dispense controlled substances shall have access to
 the information in the program's system upon verification of
 employment.
- (c) The program manager or designated program and support staff to administer the system.

165513

Approved For Filing: 3/9/2018 9:15:50 PM

Page 1 of 17

1. In order to calculate performance measures pursuant to
subsection (14), the program manager or program and support
staff members who have been directed by the program manager to
calculate performance measures may have direct access to
information that contains no identifying information of any
patient, physician, health care practitioner, prescriber, or
dispenser.

- 2. The program manager or designated program and support staff must provide the department, upon request, data that does not contain patient, physician, health care practitioner, prescriber, or dispenser identifying information for public health care and safety initiatives purposes.
- 3. The program manager, upon determining a pattern consistent with the department's rules established under subsection (16), may provide relevant information to the prescriber and dispenser.
- 4. The program manager, upon determining a pattern consistent with the rules established under subsection (16) and having cause to believe a violation of s. 893.13(7)(a)8.,

 (8)(a), or (8)(b) has occurred, may provide relevant information to the applicable law enforcement agency.

The program manager and designated program and support staff must complete a level II background screening.

	(5)	Tł	ne f	follo	wing	ent	iti	es ma	ay r	ot c	direc	tly	acces	SS	
info	rmat	ion	in	the	syste	∋m,	but	may	rec	quest	inf	orma	tion	from	the
progi	ram	mana	agei	or	desi	gnat	ed	prog	cam	and	supp	ort	stafi	f:	

- (a) The department and its health care regulatory boards, as appropriate, for investigations involving licensees authorized to prescribe or dispense controlled substances.
- (b) The Attorney General for Medicaid fraud cases involving prescribed controlled substances.
- (c) A law enforcement agency during active investigations of potential criminal activity, fraud, or theft regarding prescribed controlled substances.
- (d) A medical examiner when conducting an authorized investigation under s. 406.11, to determine the cause of death of an individual.
- (e) An impaired practitioner consultant who is retained by the department under s. 456.076 to review the system information of an impaired practitioner program participant or a referral who has agreed to be evaluated or monitored through the program and who has separately agreed in writing to the consultant's access to and review of such information.
- (f) A patient or the legal guardian or designated health care surrogate of an incapacitated patient who submits a written and notarized request that includes the patient's full name, address, phone number, date of birth, and a copy of a government-issued photo identification.

(6) The department may enter into one or more reciprocal
agreements or contracts to share prescription drug monitoring
information with other states, districts, or territories if the
prescription drug monitoring programs of such other states,
districts, or territories are compatible with the Florida
program.

- (a) In determining compatibility, the department shall
 consider:
- 1. The safeguards for privacy of patient records and the success of the program in protecting patient privacy.
- 2. The persons authorized to view the data collected by the program. Comparable entities and licensed health care practitioners in other states, districts, or territories of the United States, law enforcement agencies, the Attorney General's Medicaid Fraud Control Unit, medical regulatory boards, and, as needed, management staff that have similar duties as management staff who work with the prescription drug monitoring program as authorized in s. 893.0551 are authorized access upon approval by the department.
- 3. The schedules of the controlled substances that are monitored by the program.
- 4. The data reported to or included in the program's system.
- 5. Any implementing criteria deemed essential for a thorough comparison.

- 6. The costs and benefits to the state of sharing prescription information.
- (b) The department shall assess the prescription drug monitoring program's continued compatibility with other states', districts', or territories' programs every 4 years.
- (c) Any agreements or contracts for sharing of prescription drug monitoring information between the department and other states, districts, or territories shall contain the same restrictions and requirements as this section or s.

 893.0551, and the information must be provided according to the department's determination of compatibility.
- (7) The department may enter into agreements or contracts to establish secure connections between the system and a prescribing or dispensing health care practitioner's electronic health recordkeeping system. The electronic health recordkeeping system owner or license holder will be responsible for ensuring that only authorized individuals have access to prescription drug monitoring program information.
- (8) A prescriber or dispenser or a designee of a prescriber or dispenser must consult the system to review a patient's controlled substance dispensing history before prescribing or dispensing a controlled substance for a patient age 16 or older. This requirement does not apply when prescribing or dispensing a nonopioid controlled substance listed in Schedule V of s. 893.03 or 21 U.S.C. 812. For purposes

113	of this subsection, a "nonopioid controlled substance" is a
114	controlled substance that does not contain any amount of a
115	substance listed as an opioid in s. 893.03 or 21 U.S.C. 812.

- (a) The duty to consult the system does not apply when the
 system:
- 1. Is determined by the department to be nonoperational; or
- 2. Cannot be accessed by the prescriber or dispenser or a designee of the prescriber or dispenser because of a temporary technological or electrical failure.
- (b) A prescriber or dispenser or designee of a prescriber or dispenser who does not consult the system under this subsection shall document the reason he or she did not consult the system in the patient's medical record or prescription record and shall not prescribe or dispense greater than a 3-day supply of a controlled substance to the patient.
- (c) The department shall issue a nondisciplinary citation to any prescriber or dispenser who fails to consult the system as required by this subsection for an initial offense. Each subsequent offense is subject to disciplinary action pursuant to s. 456.073.
- (9) A person who willfully and knowingly fails to report the dispensing of a controlled substance as required by this section commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

content of the system may be released only as provided in this section and s. 893.0551. The content of the system is intended to be informational only. Information in the system is not subject to discovery or introduction into evidence in any civil or administrative action against a prescriber, dispenser, pharmacy, or patient arising out of matters that are the subject of information in the system. The program manager and authorized persons who participate in preparing, reviewing, issuing, or any other activity related to management of the system may not be permitted or required to testify in any such civil or administrative action as to any findings, recommendations, evaluations, opinions, or other actions taken in connection with management of the system.

(11) A prescriber or dispenser, or his or her designee, may have access to the information under this section which relates to a patient of that prescriber or dispenser as needed for the purpose of reviewing the patient's controlled drug prescription history. A prescriber or dispenser acting in good faith is immune from any civil, criminal, or administrative liability that might otherwise be incurred or imposed for receiving or using information from the prescription drug monitoring program. This subsection does not create a private cause of action, and a person may not recover damages against a prescriber or dispenser authorized to access information under

Amendment No.

L63	this	subsection	for	accessing	or	failing	to	access	such
L64	info	rmation.							

- (12) (a) All costs incurred by the department in administering the prescription drug monitoring program shall be funded through federal grants, private funding applied for or received by the state, or state funds appropriated in the General Appropriations Act. The department may not:
- 1. Commit funds for the monitoring program without ensuring funding is available; or
- 2. Use funds provided, directly or indirectly, by prescription drug manufacturers to implement the program.
- (b) The department shall cooperate with the direct-support organization established under subsection (15) in seeking federal grant funds, other nonstate grant funds, gifts, donations, or other private moneys for the department if the costs of doing so are immaterial. Immaterial costs include, but are not limited to, the costs of mailing and personnel assigned to research or apply for a grant. The department may competitively procure and contract pursuant to s. 287.057 for any goods and services required by this section.
- (13) The department shall conduct or participate in studies to examine the feasibility of enhancing the prescription drug monitoring program for the purposes of public health initiatives and statistical reporting. Such studies shall respect the privacy of the patient, the prescriber, and the

188	dispenser. Such studies may be conducted by the department or a
189	contracted vendor in order to:
190	(a) Improve the quality of health care services and safety
191	by improving prescribing and dispensing practices for controlled
192	substances;
193	(b) Take advantage of advances in technology;
194	(c) Reduce duplicative prescriptions and the
195	overprescribing of controlled substances; and
196	(d) Reduce drug abuse.
197	(14) The department shall annually report on performance
198	measures to the Governor, the President of the Senate, and the
199	Speaker of the House of Representatives by December 1.
200	Performance measures may include, but are not limited to, the
201	following outcomes:
202	(a) Reduction of the rate of inappropriate use of
203	controlled substances through department education and safety
204	efforts.
205	(b) Reduction of the quantity of controlled substances
206	obtained by individuals attempting to engage in fraud and
207	deceit.
208	(c) Increased coordination among partners participating in
209	the prescription drug monitoring program.
210	(d) Involvement of stakeholders in achieving improved
211	patient health care and safety and reduction of controlled

165513

212

Approved For Filing: 3/9/2018 9:15:50 PM

substance abuse and controlled substance diversion.

(15) The department may establish a direct-support	
organization to provide assistance, funding, and promotional	
support for the activities authorized for the prescription dru	ıg
monitoring program.	

- (a) As used in this subsection, the term "direct-support organization" means an organization that is:
- 1. A Florida corporation not for profit incorporated under chapter 617, exempted from filing fees, and approved by the Department of State.
- 2. Organized and operated to conduct programs and activities; raise funds; request and receive grants, gifts, and bequests of money; acquire, receive, hold, and invest, in its own name, securities, funds, objects of value, or other property, either real or personal; and make expenditures or provide funding to or for the direct or indirect benefit of the department in the furtherance of the prescription drug monitoring program.
- (b) The State Surgeon General shall appoint a board of directors for the direct-support organization.
- 1. The board of directors shall consist of no fewer than five members who shall serve at the pleasure of the State Surgeon General.
- 2. The State Surgeon General shall provide guidance to members of the board to ensure that moneys received by the direct-support organization are not received from inappropriate

sources. Inappropriate sources include, but are not limited to,
donors, grantors, persons, prescription drug manufacturers, or
organizations that may monetarily or substantively benefit from
the purchase of goods or services by the department in
furtherance of the prescription drug monitoring program.

- (c) The direct-support organization shall operate under written contract with the department. The contract must, at a minimum, provide for:
- 1. Approval of the articles of incorporation and bylaws of the direct-support organization by the department.
- 2. Submission of an annual budget for the approval of the department.
- 3. The reversion, without penalty, to the department's grants and donations trust fund for the administration of the prescription drug monitoring program 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.
- 4. The fiscal year of the direct-support organization, which must begin July 1 of each year and end June 30 of the following year.
- 5. The disclosure of the material provisions of the contract to donors of gifts, contributions, or bequests, including such disclosure on all promotional and fundraising

263	publications, and an explanation to such donors of the
264	distinction between the department and the direct-support
265	organization.

- 6. 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. 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 department. In addition, the direct-support organization may collect and provide funding to the department in furtherance of the prescription drug monitoring program by:
- a. Establishing and administering the prescription drug monitoring program's electronic system, including hardware and software.
- <u>b.</u> Conducting studies on the efficiency and effectiveness of the program to include feasibility studies as described in subsection (13).
- c. Providing funds for future enhancements of the program within the intent of this section.
- d. Providing user training of the prescription drug

 monitoring program, including distribution of materials to

 promote public awareness and education and conducting workshops

287	or	other	meeti	ngs	for	health	care	practition	ers,	pharmacists,
288	and	d othe	rs as	appr	opri	iate.				

- e. Providing funds for travel expenses.
- <u>f. Providing funds for administrative costs, including</u> personnel, audits, facilities, and equipment.
- g. Fulfilling all other requirements necessary to implement and operate the program as outlined in this section.
- 7. Certification by 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.
- (d) The activities of the direct-support organization must be consistent with the goals and mission of the department, as determined by the department, and in the best interests of the state. The direct-support organization must obtain written approval from the department for any activities in support of the prescription drug monitoring program before undertaking those activities.
- (e) The direct-support organization shall provide for an independent annual financial audit in accordance with s.

 215.981. Copies of the audit shall be provided to the department

Approved For Filing: 3/9/2018 9:15:50 PM
Page 13 of 17

Amendment No.

313

314

315

316

317

318

319

320

321

322

323

324

325

326

327

328

329

330

331

332

333

334

335

311	ć	and	the	Office	of	Policy	and	Budget	in	the	Executive	Office	of
312	t	the	Gove	ernor.									

- (f) The direct-support organization may not exercise any power under s. 617.0302(12) or (16).
- (g) The direct-support organization is not considered a lobbying firm within the meaning of s. 11.045.
- (h) The department may permit, without charge, appropriate use of administrative services, property, and facilities of the department by the direct-support organization, subject to this section. The use must be directly in keeping with the approved purposes of the direct-support organization and may not be made at times or places that would unreasonably interfere with opportunities for the public to use such facilities for established purposes. Any moneys received from rentals of facilities and properties managed by the department may be held in a separate depository account in the name of the directsupport organization and subject to the provisions of the letter of agreement with the department. The letter of agreement must provide that any funds held in the separate depository account in the name of the direct-support organization must revert to the department if the direct-support organization is no longer approved by the department to operate in the best interests of the state.
- (i) The department may adopt rules under s. 120.54 to govern the use of administrative services, property, or

165513

facilities	of	the	department	or	office	bу	the	direct-	support
organizatio	on.								

- (j) The department may not permit the use of any administrative services, property, or facilities of the state by a direct-support organization if that organization does not provide equal membership and employment opportunities to all persons regardless of race, color, religion, gender, age, or national origin.
- (k) This subsection is repealed October 1, 2027, unless reviewed and saved from repeal by the Legislature.
- (16) The department shall adopt rules necessary to implement this section.

Section 13. Section 893.0551, Florida Statutes, is amended to read:

- 893.0551 Public records exemption for the prescription drug monitoring program.—
- (1) For purposes of this section, the terms used in this section have the same meanings as provided in s. 893.055.
- (2) The following information of a patient or patient's agent, a health care practitioner, a dispenser, an employee of the practitioner who is acting on behalf of and at the direction of the practitioner, a pharmacist, or a pharmacy that is contained in records held by the department under s. 893.055 is confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution:

Approved For Filing: 3/9/2018 9:15:50 PM Page 15 of 17

Amendment No.

361	(a)	Name.	
362	(b)	Address.	
363	(c)	Telephone number.	
364	(d)	Insurance plan number.	
365	(e)	Government-issued identification number.	
366	(f)	Provider number.	
367	(g)	Drug Enforcement Administration number.	
368	(h)	Any other unique identifying information or number.	
369	(3)	The department shall disclose such confidential and	
370	exempt information to the following persons or entities upon		
371	request and after using a verification process to ensure the		
372	legitimacy of the request as provided in s. 893.055:		
373	(a) A health care practitioner, or his or her designee,		
374	who certifies that the information is necessary to provide		
375	medical treatment to a current patient in accordance with ss.		
376	893.04, 893.05, and 893.055.		
377	(b)	An employee of the United States Department of	
378	Veterans Affairs, the United States Department of Defense, or		
379	the Indian Health Service who provides health care services		
380	pursuant to such employment and who has the authority to		
381	prescribe or dispense controlled substances shall have access to		
382	the information in the program's system upon verification of		
383	such employment.		
384			
385			

165513

Approved For Filing: 3/9/2018 9:15:50 PM
Page 16 of 17

Amendment No.

386	TITLE AMENDMENT
387	Remove lines 3965-3966 of the amendment and insert:
388	system; providing a system for discipline of specified
389	persons for failing to meet such requirements; prohibiting
390	a

165513