

Amendment No. 5

COMMITTEE/SUBCOMMITTEE ACTION

| | | |
|-----------------------|---|-------|
| ADOPTED | — | (Y/N) |
| ADOPTED AS AMENDED | — | (Y/N) |
| ADOPTED W/O OBJECTION | — | (Y/N) |
| FAILED TO ADOPT | — | (Y/N) |
| WITHDRAWN | — | (Y/N) |
| OTHER | — | |

1 Committee/Subcommittee hearing PCB: Health & Human Services
2 Committee

3 Representative Brodeur offered the following:

4
5 **Amendment (with title amendment)**

6 Between lines 1043 and 1044, insert:

7 Section 4. Paragraph (oo) is added to subsection (1) of
8 section 456.072, Florida Statutes, to read:

9 456.072 Grounds for discipline; penalties; enforcement.—

10 (1) The following acts shall constitute grounds for which
11 the disciplinary actions specified in subsection (2) may be
12 taken:

13 (oo) Failing to comply with the requirements of s.
14 893.055(8) by failing to access the prescription drug monitoring
15 program database upon an initial visit with a patient and view
16 her or his prescription drug history before issuing a

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17 prescription for a controlled substance listed in s. 893.03(2),
18 (3), or (4) to the patient.

19 Section 5. Section 893.055, Florida Statutes, is amended
20 to read:

21 (Substantial rewording of section. See
22 s. 893.055, F.S., for present text.)

23 893.055 Prescription drug monitoring program.—

24 (1) As used in this section and s. 893.0551, the term:

25 (a) "Active investigation" means an open investigation
26 conducted by a law enforcement agency with a reasonable, good
27 faith belief that it will lead to the filing of criminal charges
28 or that is ongoing and for which there is a reasonable, good
29 faith anticipation of obtaining an arrest or prosecution in the
30 foreseeable future.

31 (b) "Administer" means to obtain and give a single dose of
32 a medicinal drug to a patient for her or his consumption.

33 (c) "Controlled substance" means a substance named or
34 described in s. 893.03(2), (3), or (4).

35 (d) "Dispense" means to transfer possession of one or more
36 doses of a medicinal drug to the ultimate consumer or her or his
37 agent.

38 (e) "Dispenser" means a pharmacist or dispensing health
39 care practitioner.

40 (f) "Health care practitioner" means a person licensed as
41 a physician or physician assistant under chapter 458, as an
42 osteopathic physician or physician assistant under chapter 459,

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43 as a podiatric physician under chapter 461, as an optometrist
44 under chapter 463, as an advanced registered nurse practitioner
45 under chapter 464, as a pharmacist under chapter 465, or as a
46 dentist under chapter 466.

47 (g) "Law enforcement agency" means the Department of Law
48 Enforcement, a Florida sheriff's department, a Florida police
49 department, or a law enforcement agency of the Federal
50 Government which enforces the laws of this state or the United
51 States relating to controlled substances, and the agents and
52 officers of which are empowered by law to conduct criminal
53 investigations and make arrests.

54 (h) "Patient advisory report" means information provided
55 by the program to a health care practitioner, dispenser, or
56 patient concerning the dispensing of a controlled substance to a
57 patient.

58 (i) "Pharmacy" means an entity permitted under chapter 465
59 as a pharmacy, as defined in s. 465.003(11), and a nonresident
60 pharmacy registered under s. 465.0156.

61 (j) "Program" means the prescription drug monitoring
62 program created under this section.

63 (2)(a) The department shall establish and maintain a
64 database of controlled substance dispensing information. The
65 database shall be used to provide information regarding
66 dispensed prescriptions of controlled substances to persons with
67 direct and indirect access to such information pursuant to this
68 section. The database must meet the standards of the American

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69 Society for Automation in Pharmacy and must comply with the
70 Health Insurance Portability and Accountability Act and all
71 other relevant state and federal privacy and security laws and
72 regulations. A transmission of information required by this
73 section must comply with relevant state and federal privacy and
74 security laws and regulations.

75 (b) The department shall designate a program manager to
76 administer the program and ensure the program's integrity and
77 compliance with this section. The program manager and each
78 member of the authorized program and support staff must undergo
79 a level 2 background screening pursuant to s. 435.04 as a
80 condition of employment.

81 (c) The program shall be funded only by federal grants or
82 private funding received by the state. The department may not
83 commit funds for the program without ensuring that funding is
84 available. The department shall cooperate with the direct-
85 support organization established in subsection (16) in seeking
86 federal grant funds, other nonstate grant funds, gifts,
87 donations, or other private funds for the program if the costs
88 of doing so are nonmaterial. For purposes of this paragraph,
89 nonmaterial costs include, but are not limited to, costs for
90 postage and department personnel assigned to research or apply
91 for a grant. Funds provided by prescription drug manufacturers
92 may not be used to establish or administer the program.

93 (d) To the extent that funding is provided for the program
94 through federal grant funds, other nonstate grant funds, gifts,

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95 donations, or other private funds, the department shall study
96 the feasibility of enhancing the program for the purposes of
97 supporting public health initiatives and improving statistical
98 reporting. The study shall be conducted to reduce drug abuse and
99 further the safety and quality of health care services by
100 improving prescribing and dispensing practices related to
101 controlled substances and incorporating advances in technology.

102 (e) The department shall comply with s. 287.057 for the
103 procurement of any goods or services required by this section.

104 (3) Within 7 days after the date that a prescription
105 substance is dispensed, a dispenser shall submit to the database
106 the following information:

107 (a) The prescribing health care practitioner's full name,
108 federal Drug Enforcement Administration registration number, and
109 National Provider Identifier or other appropriate identifier.

110 (b) The full name, address, and date of birth of the
111 person for whom the prescription was written.

112 (c) The date that the prescription was written.

113 (d) The date that the prescription was filled and the
114 method of payment. The department may not include credit card
115 numbers or other account numbers in the database.

116 (e) The name, national drug code, quantity, and strength
117 of the controlled substance dispensed.

118 (f) The full name, federal Drug Enforcement Administration
119 number, and address of the pharmacy or other location from which
120 the controlled substance was dispensed or, if the controlled

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121 substance was dispensed by a health care practitioner other than
122 a pharmacist, the health care practitioner's full name, federal
123 Drug Enforcement Administration registration number, National
124 Provider Identifier or other appropriate identifier, and
125 address.

126 (g) Other appropriate identifying information as
127 determined by rule.

128 (4) A dispenser shall submit the information required by
129 this section electronically, or by another method established by
130 rule, in a format approved by the department. The cost to the
131 dispenser to submit the information required by this section may
132 not be material or extraordinary. The department shall
133 establish a reporting procedure and format by rule and may
134 authorize an extension of time to report such information for
135 cause as defined by rule.

136 (5) The following acts of a health care practitioner or
137 dispenser are exempt from reporting under this section:

138 (a) Administering or dispensing a controlled substance to
139 a patient in a hospital, nursing home, ambulatory surgical
140 center, hospice, or intermediate care facility for the
141 developmentally disabled.

142 (b) Administering or dispensing a controlled substance
143 within the Department of Corrections health care system.

144 (c) Administering or dispensing a controlled substance to
145 a person under the age of 16.

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146 (d) Dispensing a one-time, 72-hour emergency supply of a
147 controlled substance to a patient.

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

152 (7) A dispenser or her or his agent, before dispensing a
153 controlled substance to a person not known to the dispenser,
154 shall require the person purchasing or receiving the controlled
155 substance to present identification issued by the state or the
156 Federal Government that contains the person's photograph,
157 printed name, and signature, or a document considered acceptable
158 identification under 8 C.F.R. s. 274a.2(b)(1)(v)(A) and (B).

159 (a) If the person does not have such identification, the
160 dispenser may verify the validity of the prescription and the
161 identity of the patient with the prescribing health care
162 practitioner or her or his agent. Verification of health plan
163 eligibility of the person purchasing or receiving the controlled
164 substance satisfies the requirement of this subsection.

165 (b) This subsection does not apply in an institutional
166 setting or in a long-term care facility, including, but not
167 limited to, an assisted living facility or a hospital to which
168 patients are admitted.

169 (8) (a) The program manager, and program and support staff
170 only as directed or authorized by the program manager, shall

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171 have direct access to the database for program management in
172 support of the requirements of this section.

173 (b) A health care practitioner or dispenser shall have
174 direct access to information in the database which relates to a
175 patient of that health care practitioner or dispenser for the
176 purpose of reviewing the patient's controlled substance
177 prescription history. A prescribing health care practitioner
178 must access the database and view a patient's prescription drug
179 history before issuing a prescription for a controlled substance
180 to the patient upon her or his initial visit. A health care
181 practitioner or dispenser acting in good faith is immune from
182 any civil, criminal, or administrative liability for receiving
183 or using information from the database. This section does not
184 create a private cause of action and a person may not recover
185 damages against a health care practitioner or dispenser who is
186 authorized to access information from the database for accessing
187 or failing to access such information. A prescribing health
188 care practitioner is exempt from the access and viewing
189 requirement of this paragraph if the database is inaccessible
190 for any reason not due to the fault of the practitioner before
191 she or he issues a prescription for a controlled substance at a
192 patient's initial visit. A prescribing health care practitioner
193 must access the database and view the patient's prescription
194 drug history when database accessibility is restored following
195 the patient's initial visit.

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196 (9) The following entities may not have direct access to
197 information in the database but may request information from the
198 program:

199 (a) The department for the purpose of an active
200 investigation of a health care practitioner or dispenser who is
201 authorized to prescribe, administer, or dispense controlled
202 substances.

203 (b) The Attorney General for the purpose of an active
204 investigation of Medicaid fraud involving prescriptions of
205 controlled substances.

206 (c) A law enforcement agency for the purpose of an active
207 investigation regarding potential criminal activity, fraud, or
208 theft involving prescriptions of controlled substances.

209 (d) A patient or the legal guardian or health care
210 surrogate, as defined in s. 765.101(16), of an incapacitated
211 patient. The department shall verify the identity of the
212 incapacitated patient or the legal guardian or health care
213 surrogate. Verification is also required for a request to change
214 an incapacitated patient's prescription drug history or other
215 information in the database.

216 (10) Before releasing information pursuant to paragraph
217 (9)(c), the department shall enter into a user agreement with
218 the law enforcement agency requesting information from the
219 database. At a minimum, the user agreement must:

220 (a) Provide for access control and information security in
221 order to ensure the confidentiality of the information.

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222 (b) Contain training requirements.

223 (c) Require each law enforcement agency head to submit an
224 annual attestation to the program manager stating that the law
225 enforcement agency is complying with the user agreement and
226 disclosing any findings made and actions taken to maintain
227 compliance. Any findings of noncompliance must be reported
228 immediately to the program manager by the law enforcement agency
229 head.

230 (d) Require each law enforcement agency that receives
231 information from the database to electronically update the
232 database biennially with the status of the case for which
233 information was received, in accordance with procedures
234 established by department rule.

235 (e) Require each law enforcement agency head to appoint
236 one agency administrator who is responsible for appointing
237 authorized users to request and receive information from the
238 database and ensure the law enforcement agency maintains
239 compliance with the user agreement and the laws governing
240 access, use, and dissemination of the information.

241 (f) Require each authorized user to attest that each
242 request for information from the database is predicated on and
243 related to an active investigation.

244 (g) Require the law enforcement agency to conduct an
245 annual audit of the agency administrator and each authorized
246 user to ensure compliance with the user agreement. Such an
247 audit must be conducted by the internal affairs or professional

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248 standards division within the law enforcement agency. The
249 review must include any allegation of noncompliance, potential
250 security violations, and a report on user compliance with the
251 user agreement and applicable laws and rules. The law
252 enforcement agency shall also conduct a routine audit on access
253 to and dissemination of information received from the database.
254 The result of each audit shall be submitted to the program
255 manager within 7 days after completion of the audit.

256 (h) Allow the program manager to restrict, suspend, or
257 terminate an agency administrator's or authorized user's access
258 to the database if the administrator or user has failed to
259 comply with the user agreement. If a law enforcement agency
260 does not comply with the audit requirements in paragraph (g),
261 the program manager shall suspend the law enforcement agency's
262 access to the database until the agency complies with such
263 requirements.

264 (11) The program manager, upon determining a pattern
265 consistent with the rules established under subsection (17)
266 evidencing controlled substance abuse or diversion and having
267 cause to believe a violation of ss. 893.13(7)(a)8., (8)(a), or
268 (8)(b) has occurred, may provide relevant information to the
269 appropriate law enforcement agency.

270 (12) An authorized person or entity receiving information
271 from the database under subsection (9) may maintain the
272 information for no more than 24 months before purging the
273 information from official records. Information may be maintained

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274 for more than 24 months if it is pertinent to an active
275 investigation or criminal prosecution.

276 (13) Information contained in the database is not
277 discoverable or admissible in any civil or administrative
278 action, except in an investigation or disciplinary proceeding
279 conducted by the department. Information shared with a state
280 attorney pursuant to ss. 893.0551(3)(a) or (c) may be released
281 only in response to a discovery demand if such information is
282 directly related to the criminal case for which the information
283 was requested. If additional information is shared with the
284 state attorney which is not directly related to the criminal
285 case, the state attorney shall inform the inquirer that such
286 information exists. Unrelated information may not be released
287 except upon an order of a court of competent jurisdiction.

288 (14) A person who participates in preparing, reviewing,
289 issuing, or any other activity related to a patient advisory
290 report may not be permitted or required to testify in any civil
291 action as to any finding, recommendation, evaluation, opinion,
292 or other action taken in connection with preparing, reviewing,
293 or issuing such a report.

294 (15) The department shall report performance measures
295 annually to the Governor, the President of the Senate, and the
296 Speaker of the House of Representatives by December 1.
297 Department staff may not have direct access to information in
298 the database for the purpose of reporting performance measures.
299 To measure performance and undertake public health care and

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300 safety initiatives, department staff may request data from the
301 database that does not contain patient, health care
302 practitioner, or dispenser identifying information. Performance
303 measures may include, but are not limited to:

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

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

310 (c) Increased coordination among partners participating in
311 the program.

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

315 (16) The department may establish a direct-support
316 organization to provide assistance, funding, and promotional
317 support for the activities authorized for the program.

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

320 1. A Florida not-for-profit corporation incorporated under
321 chapter 617, exempted from filing fees, and approved by the
322 Department of State.

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

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326 own name, securities, funds, objects of value, or other
327 property, either real or personal; and make expenditures or
328 provide funding to or for the benefit of the program.

329 (b) The State Surgeon General shall appoint a board of
330 directors for the direct-support organization consisting of at
331 least five members. Members of the board shall serve at the
332 pleasure of the State Surgeon General. The State Surgeon General
333 shall provide guidance to members of the board to ensure that
334 funds received by the direct-support organization are not from
335 inappropriate sources. An inappropriate source includes, but is
336 not limited to, a donor, grantor, person, or organization that
337 may benefit from the purchase of goods or services by the
338 department for the program.

339 (c) The direct-support organization shall operate under
340 written contract with the department. The contract must, at a
341 minimum, provide for:

342 1. Department approval of the articles of incorporation,
343 bylaws, and annual budgets.

344 2. Department certification that the direct-support
345 organization is complying with the terms of the contract in a
346 manner consistent with and in furtherance of the program. Such
347 certification must be made annually and reported in the official
348 minutes of a direct-support organization board meeting.

349 3. The reversion, without penalty, to the state of all
350 funds and property held in trust by the direct-support
351 organization for the benefit of the program if the direct-

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352 support organization ceases to exist or if the contract is
353 terminated. The state shall use all funds and property reverted
354 to it to support the program.

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

358 5. The disclosure of the material provisions of the
359 contract to a donor of a gift, contribution, or bequest,
360 including such disclosure on all promotional and fundraising
361 publications, and an explanation to the donor of the distinction
362 between the department and the direct-support organization.

363 6. The direct-support organization's collecting,
364 expending, and providing of funds to the department for the
365 operation of the program.

366 7. The reversion to the department of any funds of the
367 direct-support organization held by the department in a separate
368 depository account received from rentals of facilities and
369 properties managed by the department for use by the direct-
370 support organization.

371 (d) The direct-support organization may collect and expend
372 funds for the function of its board of directors, as approved by
373 the department, and provide funds to the department for:

374 1. Establishing and administering the database, including
375 hardware and software.

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376 2. Conducting studies on the efficiency and effectiveness
377 of the program, including the feasibility study described in
378 paragraph (2) (d).

379 3. Future enhancements of the program.

380 4. User training for the program, including the
381 distribution of materials to promote public awareness and
382 education and conducting workshops or other meetings for health
383 care practitioners, pharmacists, and others.

384 5. Travel expenses incurred by the board.

385 6. Administrative costs.

386 7. Fulfilling all other requirements necessary to operate
387 the program.

388 (e) The department may authorize, without charge,
389 appropriate use of its administrative services, property, and
390 facilities by the direct-support organization.

391 (f) The department may not authorize the use of any of its
392 administrative services, property, or facilities by a direct-
393 support organization if the organization does not provide equal
394 membership and employment opportunities to all persons
395 regardless of race, color, religion, gender, age, or national
396 origin.

397 (g) The direct-support organization shall provide for an
398 independent annual financial audit in accordance with s.
399 215.981. A copy of the audit shall be provided to the department
400 and the Office of Policy and Budget in the Executive Office of
401 the Governor.

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402 (h) The direct-support organization is not a lobbying firm
403 for purposes of s. 11.045.

404 (17) (a) The department shall adopt rules to administer
405 this section. Such rules shall include, but not be limited to:

406 1. Procedures for reporting information to the database
407 and accessing information in the database.

408 2. Indicators which identify controlled substance abuse or
409 diversion.

410 3. By October 1, 2014, practices to ensure a law
411 enforcement agency is in compliance with the audit requirements
412 in paragraph (10) (g).

413 4. The form and content of a user agreement pursuant to
414 subsection (10).

415 (b) The department may adopt rules to govern the use of
416 its administrative services, property, or facilities by the
417 direct-support organization established under subsection (16).

418 Section 6. Notwithstanding s. 893.055, Florida Statutes,
419 for the 2014-2015 fiscal year, the sum of \$500,000 in
420 nonrecurring funds is appropriated from the General Revenue Fund
421 to the Department of Health for the general administration of
422 the prescription drug monitoring program.

423 Section 7. This act shall take effect July 1, 2014.

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428 **T I T L E A M E N D M E N T**

429 Remove line 109 and insert:

430 independent nurse practitioners; amending s. 456.072, F.S.;

431 providing additional grounds for discipline of a licensee of the

432 department by a regulatory board; amending s. 893.055, F.S.;

433 revising definitions; revising provisions relating to the

434 database of controlled substance dispensing information;

435 revising program funding requirements; requiring a prescriber to

436 access and view certain patient information in the database

437 before initially prescribing a controlled substance; providing

438 requirements related to the release of identifying information;

439 providing requirements for the release of information shared;

440 with a state attorney in response to a discovery demand;

441 providing procedures for the release of information to a law

442 enforcement agency during an active investigation; requiring the

443 department to enter into a user agreement with a law enforcement

444 agency requesting the release of information; providing

445 requirements for the user agreement; requiring a law enforcement

446 agency under a user agreement to conduct annual audits;

447 providing for the restriction, suspension, or termination of a

448 user agreement; revising information retention requirements;

449 revising provisions required in a contract with a direct-support

450 organization; requiring the state to use certain properties and

451 funds to support the program; providing for the adoption of

452 specific rules by the department; providing an appropriation to

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COMMITTEE/SUBCOMMITTEE AMENDMENT

PCB Name: PCS for CS/HB 7113 (2014)

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453 | the Department of Health to fund the administration of the
454 | prescription drug monitoring program; providing an
455 |

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