

By the Committee on Health Policy

588-02037-16

20167038__

1 A bill to be entitled
2 An act relating to controlled substances; amending s.
3 456.42, F.S.; authorizing certain controlled
4 substances to be electronically prescribed; amending
5 s. 499.0121, F.S.; deleting a specified requirement in
6 the performance of due diligence of purchasers by
7 prescription drug wholesalers; amending s. 893.055,
8 F.S.; authorizing the designee of a pharmacy,
9 prescriber, or dispenser to access a patient's record
10 in the prescription drug monitoring program's database
11 for a specified purpose; authorizing an impaired
12 practitioner consultant to access an impaired
13 practitioner program participant's or referral's
14 record in the prescription drug monitoring program's
15 database; reenacting and amending s. 893.0551, F.S.;
16 authorizing the designee of a health care
17 practitioner, pharmacist, pharmacy, prescriber, or
18 dispenser and an impaired practitioner consultant to
19 receive certain information from the prescription drug
20 monitoring program; providing an effective date.

21
22 Be It Enacted by the Legislature of the State of Florida:

23
24 Section 1. Subsection (2) of section 456.42, Florida
25 Statutes, is amended to read:

26 456.42 Written prescriptions for medicinal drugs.—

27 (2) A written prescription for a controlled substance
28 listed in chapter 893 must have the quantity of the drug
29 prescribed in both textual and numerical formats, must be dated
30 in numerical, month/day/year format, or with the abbreviated
31 month written out, or the month written out in whole, and must
32 be either written on a standardized counterfeit-proof

588-02037-16

20167038__

33 prescription pad produced by a vendor approved by the department
34 or electronically prescribed as that term is used in s.
35 408.0611. All controlled substances listed in Schedule II,
36 Schedule III, Schedule IV, and Schedule V may be electronically
37 prescribed pursuant to applicable federal law. As a condition of
38 being an approved vendor, a prescription pad vendor must submit
39 a monthly report to the department that, at a minimum, documents
40 the number of prescription pads sold and identifies the
41 purchasers. The department may, by rule, require the reporting
42 of additional information.

43 Section 2. Paragraph (b) of subsection (15) of section
44 499.0121, Florida Statutes, is amended to read:

45 499.0121 Storage and handling of prescription drugs;
46 recordkeeping.—The department shall adopt rules to implement
47 this section as necessary to protect the public health, safety,
48 and welfare. Such rules shall include, but not be limited to,
49 requirements for the storage and handling of prescription drugs
50 and for the establishment and maintenance of prescription drug
51 distribution records.

52 (15) DUE DILIGENCE OF PURCHASERS.—

53 (b) A wholesale distributor must take reasonable measures
54 to identify its customers, understand the normal and expected
55 transactions conducted by those customers, and identify those
56 transactions that are suspicious in nature. A wholesale
57 distributor must establish internal policies and procedures for
58 identifying suspicious orders and preventing suspicious
59 transactions. ~~A wholesale distributor must assess orders for~~
60 ~~greater than 5,000 unit doses of any one controlled substance in~~
61 ~~any one month to determine whether the purchase is reasonable.~~

588-02037-16

20167038__

62 In making such assessments, a wholesale distributor may consider
63 the purchasing entity's clinical business needs, location, and
64 population served, in addition to other factors established in
65 the distributor's policies and procedures. A wholesale
66 distributor must report to the department any regulated
67 transaction involving an extraordinary quantity of a listed
68 chemical, an uncommon method of payment or delivery, or any
69 other circumstance that the regulated person believes may
70 indicate that the listed chemical will be used in violation of
71 the law. The wholesale distributor shall maintain records that
72 document the report submitted to the department in compliance
73 with this paragraph.

74 Section 3. Paragraphs (b) and (c) of subsection (7) and
75 subsection (12) of section 893.055, Florida Statutes, are
76 amended to read:

77 893.055 Prescription drug monitoring program.—

78 (7)

79 (b) A pharmacy, prescriber, or dispenser, or the designee
80 of a pharmacy, prescriber, or dispenser, shall have access to
81 information in the prescription drug monitoring program's
82 database which relates to a patient of that pharmacy,
83 prescriber, or dispenser in a manner established by the
84 department as needed for the purpose of reviewing the patient's
85 controlled substance prescription history. Other access to the
86 program's database shall be limited to the program's manager and
87 to the designated program and support staff, who may act only at
88 the direction of the program manager or, in the absence of the
89 program manager, as authorized. Access by the program manager or
90 such designated staff is for prescription drug program

588-02037-16

20167038__

91 management only or for management of the program's database and
92 its system in support of the requirements of this section and in
93 furtherance of the prescription drug monitoring program.

94 Confidential and exempt information in the database shall be
95 released only as provided in paragraph (c) and s. 893.0551. The
96 program manager, designated program and support staff who act at
97 the direction of or in the absence of the program manager, and
98 any individual who has similar access regarding the management
99 of the database from the prescription drug monitoring program
100 shall submit fingerprints to the department for background
101 screening. The department shall follow the procedure established
102 by the Department of Law Enforcement to request a statewide
103 criminal history record check and to request that the Department
104 of Law Enforcement forward the fingerprints to the Federal
105 Bureau of Investigation for a national criminal history record
106 check.

107 (c) The following entities are ~~shall~~ not be allowed direct
108 access to information in the prescription drug monitoring
109 program database but may request from the program manager and,
110 when authorized by the program manager, the program manager's
111 program and support staff, information that is confidential and
112 exempt under s. 893.0551. Before ~~Prior to~~ release, a ~~the~~ request
113 by the following entities shall be verified as authentic and
114 authorized with the requesting organization by the program
115 manager, the program manager's program and support staff, or as
116 determined in rules by the department as being authentic and as
117 having been authorized by the requesting entity:

118 1. The department or its relevant health care regulatory
119 boards responsible for the licensure, regulation, or discipline

588-02037-16

20167038__

120 of practitioners, pharmacists, or other persons who are
121 authorized to prescribe, administer, or dispense controlled
122 substances and who are involved in a specific controlled
123 substance investigation involving a designated person for one or
124 more prescribed controlled substances.

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

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

130 4. A patient or the legal guardian or designated health
131 care surrogate of an incapacitated patient as described in s.
132 893.0551 who, for the purpose of verifying the accuracy of the
133 database information, submits a written and notarized request
134 that includes the patient's full name, address, and date of
135 birth, and includes the same information if the legal guardian
136 or health care surrogate submits the request. The request shall
137 be validated by the department to verify the identity of the
138 patient and the legal guardian or health care surrogate, if the
139 patient's legal guardian or health care surrogate is the
140 requestor. Such verification is also required for any request to
141 change a patient's prescription history or other information
142 related to his or her information in the electronic database.

143 5. An impaired practitioner consultant who is retained by
144 the department under s. 456.076 for the purpose of reviewing the
145 database information of an impaired practitioner program
146 participant or a referral who has agreed to be evaluated or
147 monitored through the program and who has separately agreed in
148 writing to the consultant's access to and review of such

588-02037-16

20167038__

149 information.

150

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

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

168 Section 4. Section 893.0551, Florida Statutes, is reenacted
169 and amended to read:

170 893.0551 Public records exemption for the prescription drug
171 monitoring program.—

172 (1) For purposes of this section, the terms used in this
173 section have the same meanings as provided in s. 893.055.

174 (2) The following information of a patient or patient's
175 agent, a health care practitioner, a dispenser, an employee of
176 the practitioner who is acting on behalf of and at the direction
177 of the practitioner, a pharmacist, or a pharmacy that is

588-02037-16

20167038__

178 contained in records held by the department under s. 893.055 is
179 confidential and exempt from s. 119.07(1) and s. 24(a), Art. I
180 of the State Constitution:

181 (a) Name.

182 (b) Address.

183 (c) Telephone number.

184 (d) Insurance plan number.

185 (e) Government-issued identification number.

186 (f) Provider number.

187 (g) Drug Enforcement Administration number.

188 (h) Any other unique identifying information or number.

189 (3) The department shall disclose such confidential and
190 exempt information to the following persons or entities upon
191 request and after using a verification process to ensure the
192 legitimacy of the request as provided in s. 893.055:

193 (a) The Attorney General, or his or her designee, when
194 working on Medicaid fraud cases involving prescription drugs or
195 when the Attorney General has initiated a review of specific
196 identifiers of Medicaid fraud regarding prescription drugs. The
197 Attorney General's Medicaid fraud investigators may not have
198 direct access to the department's database. The Attorney
199 General, or his or her designee, may disclose to a criminal
200 justice agency, as defined in s. 119.011, only the confidential
201 and exempt information received from the department that is
202 relevant to an identified active investigation that prompted the
203 request for the information.

204 (b) The department's relevant health care regulatory boards
205 responsible for the licensure, regulation, or discipline of a
206 practitioner, pharmacist, or other person who is authorized to

588-02037-16

20167038__

207 prescribe, administer, or dispense controlled substances and who
208 is involved in a specific controlled substances investigation
209 for prescription drugs involving a designated person. The health
210 care regulatory boards may request information from the
211 department but may not have direct access to its database. The
212 health care regulatory boards may provide to a law enforcement
213 agency pursuant to ss. 456.066 and 456.073 only information that
214 is relevant to the specific controlled substances investigation
215 that prompted the request for the information.

216 (c) A law enforcement agency that has initiated an active
217 investigation involving a specific violation of law regarding
218 prescription drug abuse or diversion of prescribed controlled
219 substances and that has entered into a user agreement with the
220 department. A law enforcement agency may request information
221 from the department but may not have direct access to its
222 database. The law enforcement agency may disclose to a criminal
223 justice agency, as defined in s. 119.011, only confidential and
224 exempt information received from the department that is relevant
225 to an identified active investigation that prompted the request
226 for such information.

227 (d) A health care practitioner, or his or her designee, who
228 certifies that the information is necessary to provide medical
229 treatment to a current patient in accordance with ss. 893.05 and
230 893.055.

231 (e) A pharmacist, or his or her designee, who certifies
232 that the requested information will be used to dispense
233 controlled substances to a current patient in accordance with
234 ss. 893.04 and 893.055.

235 (f) A patient or the legal guardian or designated health

588-02037-16

20167038__

236 care surrogate for an incapacitated patient, if applicable,
237 making a request as provided in s. 893.055(7)(c)4.

238 (g) The patient's pharmacy, prescriber, or dispenser, or
239 the designee of the pharmacy, prescriber, or dispenser, who
240 certifies that the information is necessary to provide medical
241 treatment to his or her current patient in accordance with s.
242 893.055.

243 (h) An impaired practitioner consultant who has been
244 authorized in writing by a participant in or referral to the
245 impaired practitioner program to access and review information
246 as provided in s. 893.055(7)(c)5.

247 (4) If the department determines consistent with its rules
248 that a pattern of controlled substance abuse exists, the
249 department may disclose such confidential and exempt information
250 to the applicable law enforcement agency in accordance with s.
251 893.055. The law enforcement agency may disclose to a criminal
252 justice agency, as defined in s. 119.011, only confidential and
253 exempt information received from the department that is relevant
254 to an identified active investigation that is specific to a
255 violation of s. 893.13(7)(a)8., s. 893.13(8)(a), or s.
256 893.13(8)(b).

257 (5) Before disclosing confidential and exempt information
258 to a criminal justice agency or a law enforcement agency
259 pursuant to this section, the disclosing person or entity must
260 take steps to ensure the continued confidentiality of all
261 confidential and exempt information. At a minimum, these steps
262 must include redacting any nonrelevant information.

263 (6) An agency or person who obtains any confidential and
264 exempt information pursuant to this section must maintain the

588-02037-16

20167038__

265 confidential and exempt status of that information and may not
266 disclose such information unless authorized by law. Information
267 shared with a state attorney pursuant to paragraph (3)(a) or
268 paragraph (3)(c) may be released only in response to a discovery
269 demand if such information is directly related to the criminal
270 case for which the information was requested. Unrelated
271 information may be released only upon an order of a court of
272 competent jurisdiction.

273 (7) A person who willfully and knowingly violates this
274 section commits a felony of the third degree, punishable as
275 provided in s. 775.082, s. 775.083, or s. 775.084.

276 Section 5. This act shall take effect upon becoming a law.