

By the Committee on Health Regulation; and Senator Aronberg

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1 A bill to be entitled

2 An act relating to monitoring the dispensing of
3 controlled substances; creating s. 893.055, F.S.;
4 providing definitions; requiring the Department of
5 Health to issue a competitive procurement for the
6 adoption of a comprehensive electronic system to
7 monitor the dispensing of certain controlled
8 substances and to collect biometric identifiers of
9 recipients; requiring health care practitioners and
10 pharmacies who dispense certain controlled substances
11 to have an active and operational biometric scanning
12 device connected to a database and to submit specified
13 information to the database before dispensing such
14 substances; requiring the database to assign a unique
15 identifier to each prescription and to provide
16 specified information concerning any conflicting or
17 overlapping prescriptions to the prescribing
18 practitioner; providing exceptions to reporting
19 requirements; requiring that data be submitted in an
20 approved electronic format; providing for data
21 retention; requiring that data transmissions comply
22 with privacy and security laws; providing for
23 rulemaking concerning data to be reported and for
24 reporting formats; providing criminal penalties for
25 violations; specifying an effective date for criminal
26 penalties; providing an effective date.

27
28 Be It Enacted by the Legislature of the State of Florida:
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30 Section 1. Section 893.055, Florida Statutes, is created to
31 read:

32 893.055 Electronic system for monitoring the dispensing of
33 certain controlled substances.—

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

35 (a) "Biometric identifier" means an established unique form
36 of biological identification readily compared and matched, such
37 as a fingerprint, retinal scan, or other means of similar
38 biometric identification approved by the department and
39 authorized for retention in a database.

40 (b) "Biometric scan" means an electronic scan of a
41 biometric identifier.

42 (c) "Biometric scanning device" means an electronic
43 scanning device approved by the department that is designed to
44 accurately capture a biometric identifier.

45 (d) "Database" means an electronic database, or network of
46 databases, that is maintained by or contracted for by the
47 department and that maintains and compares each biometric scan
48 and the information contained therewith in conformity with the
49 provisions of this section.

50 (e) "Health care practitioner" or "practitioner" means any
51 practitioner subject to licensure or regulation by the
52 department under chapter 458, chapter 459, chapter 461, or
53 chapter 466.

54 (f) "Pharmacy" means a pharmacy subject to licensure or
55 regulation by the department under chapter 465.

56 (2) By March 1, 2011, the department shall adopt an
57 electronic monitoring system. If, after complying with the
58 requirements of ss. 287.0571-287.0574, the department determines

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59 that it is cost-effective to contract for any system components
60 or services, the department must issue a competitive
61 solicitation for those components or services, notwithstanding
62 s. 287.057(5) (f). The department may not award a contract for
63 any components or services related to biometrics unless it
64 receives a minimum of three responses to its competitive
65 solicitation for such components or services. The purpose of the
66 electronic monitoring system is to monitor the collection of
67 biometric identifiers and to record and store, in a secure
68 database, the following:

69 (a) The dispensing of controlled substances listed in
70 Schedule II, Schedule III, and Schedule IV by health care
71 practitioners within the state.

72 (b) The dispensing or delivering of controlled substances
73 listed in Schedule II, Schedule III, and Schedule IV to
74 individuals in this state by any pharmacy licensed in this state
75 and by any health care practitioner registered with the
76 department as a dispensing practitioner.

77 (3) Any health care practitioner who dispenses or delivers
78 a controlled substance listed in Schedule II, Schedule III, or
79 Schedule IV must have in the practitioner's office an active and
80 operational biometric scanning device connected to the database.
81 Any such practitioner who dispenses or delivers such a
82 controlled substance to a person in this state must first obtain
83 a biometric scan of an approved biometric identifier of the
84 person through use of the biometric scanning device and submit
85 the same to the database.

86 (4) Any pharmacy that dispenses or delivers a prescription
87 for a controlled substance listed in Schedule II, Schedule III,

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88 or Schedule IV must have in the pharmacy an active and
89 operational biometric scanning device connected to the database.
90 Any pharmacy that dispenses or delivers a prescription for such
91 a controlled substance to a person in this state must first
92 obtain a biometric scan of an approved biometric identifier of
93 the person through use of the biometric scanning device and
94 submit the same to the database.

95 (5) Prior to dispensing or delivering a controlled
96 substance listed in Schedule II, Schedule III, or Schedule IV to
97 a person in this state, every health care practitioner and
98 prescribing pharmacy must submit the following information to
99 the database:

100 (a) The biometric scan of the person's biometric
101 identifier.

102 (b) The full name and address of the prescribing
103 practitioner.

104 (c) The date of each prescription.

105 (d) The name of the controlled substance prescribed and the
106 strength, quantity, and directions for use thereof.

107 (6) After receiving the information required under
108 subsection (5), the database shall assign the prescription a
109 unique identifying number and shall immediately transmit the
110 following to the prescribing practitioner:

111 (a) The unique identifying number.

112 (b) The names of controlled substances listed in Schedule
113 II, Schedule III, and Schedule IV that have been prescribed in
114 connection with the biometric scan submitted that may conflict
115 with or overlap the prescribing practitioner's prescription.

116 (c) The full name and address of the practitioner whose

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117 prescription may conflict with or overlap the prescribing
118 practitioner's prescription and the full name and address of the
119 practitioner or pharmacy that dispensed or delivered the
120 conflicting or overlapping prescription.

121 (7) Prior to dispensing or delivering a prescription for a
122 controlled substance listed in Schedule II, Schedule III, or
123 Schedule IV, the pharmacist or dispensing health care
124 practitioner shall submit the biometric scan of the person's
125 biometric identifier to the database and the database shall
126 immediately transmit the following to the pharmacy or dispensing
127 health care practitioner:

128 (a) The names of controlled substances listed in Schedule
129 II, Schedule III, and Schedule IV which have been prescribed in
130 connection with the biometric scan submitted that may conflict
131 with or overlap the prescription to be dispensed or delivered.

132 (b) The full name and address of the practitioner whose
133 prescription may conflict with or overlap the prescription to be
134 dispensed or delivered and the full name and address of the
135 practitioner or pharmacy that dispensed or delivered the
136 conflicting or overlapping prescription.

137 (8) The database shall not retain personal protected health
138 care information other than the biometric scans and the
139 prescription information provided to the database pursuant to
140 subsections (6) and (7). This section does not preclude health
141 care practitioners and pharmacies from retaining personal
142 information on their patients which is collected and maintained
143 in their regular course of business in compliance with
144 applicable law.

145 (9) This section does not apply to controlled substances

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146 listed in Schedule II, Schedule III, or Schedule IV:

147 (a) Administered by a health care practitioner directly to
148 his or her patient;

149 (b) Dispensed or delivered by a health care practitioner
150 authorized to prescribe controlled substances directly to a
151 patient and limited to an amount adequate to treat the patient
152 for a period of no more than 72 hours;

153 (c) Dispensed or delivered by a health care practitioner or
154 a pharmacist to an inpatient of a facility that holds an
155 institutional pharmacy permit;

156 (d) Ordered from an institutional pharmacy licensed under
157 s. 465.019 in accordance with internal policy and procedure for
158 controlled substances listed in Schedule II, Schedule III, and
159 Schedule IV;

160 (e) Dispensed or delivered by a pharmacist or administered
161 by a health care practitioner to a patient or resident receiving
162 care from a hospital, nursing home, assisted living facility,
163 home health care agency, hospice, or intermediate care facility
164 for the developmentally disabled that is licensed in this state;

165 (f) Prescribed by a health care practitioner for a patient
166 younger than 16 years of age;

167 (g) Prescribed or dispensed pursuant to rule adopted by the
168 department; or

169 (h) Administered, prescribed, dispensed, or delivered under
170 circumstances in which the pharmacist or practitioner cannot, in
171 good faith, comply with the provisions of this section.

172 (10) A dispensing practitioner or pharmacist who dispenses
173 or delivers a controlled substance listed in Schedule II,
174 Schedule III, or Schedule IV shall submit the information

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175 required under this section to the department, or any person or
176 agency authorized by the department, in an electronic format
177 approved by the department. The department, or the person or
178 agency authorized by the department, shall maintain the
179 information for no longer than 24 months from the date of
180 receipt and shall thereafter expunge the information unless
181 otherwise directed by a court of competent jurisdiction.

182 (11) All transmissions required by this section must comply
183 with relevant federal and state privacy and security laws.

184 (12) By March 1, 2010, the department, together with the
185 Board of Pharmacy and the Board of Medicine, shall adopt rules
186 pursuant to ss. 120.536(1) and 120.54 governing the
187 administration of this section, including rules governing access
188 to the database by practitioners and pharmacists and
189 implementing procedures to be employed when a biometric scanning
190 device is inoperable or the database is inaccessible.

191 (13) Any person who knowingly fails to comply with any
192 provision of this section commits a misdemeanor of the first
193 degree, punishable as provided in s. 775.082 or s. 775.083.

194 Section 2. The penalties in s. 893.055(13), Florida
195 Statutes, as created by this act, shall take effect March 1,
196 2011, or upon the adoption of the rules pursuant to s.
197 893.055(12), Florida Statutes, as created by this act, whichever
198 occurs first, and shall apply to acts or omissions on or after
199 that date.

200 Section 3. This act shall take effect July 1, 2009.