

By the Committee on Health Policy; and Senator Hutson

588-03836-20

2020714c1

1 A bill to be entitled
2 An act relating to the testing for and treatment of
3 influenza; amending s. 381.0031, F.S.; requiring
4 specified licensed pharmacists to report certain
5 information to the Department of Health; amending s.
6 465.003, F.S.; revising the definition of the term
7 "practice of the profession of pharmacy"; creating s.
8 465.1895, F.S.; authorizing pharmacists to test for
9 and treat influenza and providing requirements
10 relating thereto; requiring the written protocol
11 between a pharmacist and a supervising physician to
12 contain certain information, terms, and conditions;
13 requiring the Board of Medicine, in consultation with
14 the Board of Pharmacy and the Board of Osteopathic
15 Medicine, to develop a specified certification program
16 for pharmacists within a specified timeframe;
17 requiring a pharmacist to collect a medical history
18 before testing and treating a patient; requiring a
19 pharmacy in which a pharmacist tests for and treats
20 influenza to display and distribute specified
21 information; providing limitations on the medications
22 a pharmacist may administer to treat influenza;
23 requiring pharmacists to review certain information
24 for a specified purpose before testing and treating
25 patients; requiring a pharmacist who tests for and
26 treats influenza to maintain professional liability
27 insurance in a specified amount; providing
28 recordkeeping requirements for pharmacists who test
29 for and treat influenza; providing that a person may

588-03836-20

2020714c1

30 not interfere with a physician's professional decision
31 to enter into a written protocol with a pharmacist;
32 providing that a pharmacist may not enter into a
33 written protocol under certain circumstances;
34 requiring the Board of Medicine, in consultation with
35 the Board of Pharmacy and the Board of Osteopathic
36 Medicine, to adopt rules within a specified timeframe;
37 requiring pharmacists to notify a patient's primary
38 care provider and follow up with the treated patient
39 within specified timeframes; prohibiting a pharmacist
40 from testing or treating patients under certain
41 circumstances; specifying circumstances under which a
42 physician may supervise a pharmacist under a written
43 protocol; providing a contingency on implementation;
44 providing an effective date.

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

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48 Section 1. Subsection (2) of section 381.0031, Florida
49 Statutes, is amended to read:

50 381.0031 Epidemiological research; report of diseases of
51 public health significance to department.-

52 (2) Any practitioner licensed in this state to practice
53 medicine, osteopathic medicine, chiropractic medicine,
54 naturopathy, or veterinary medicine; any licensed pharmacist
55 authorized pursuant to a written protocol to order and evaluate
56 laboratory and clinical tests; any hospital licensed under part
57 I of chapter 395; or any laboratory appropriately certified by
58 the Centers for Medicare and Medicaid Services under the federal

588-03836-20

2020714c1

59 Clinical Laboratory Improvement Amendments, and the federal
60 rules adopted thereunder, which diagnoses or suspects the
61 existence of a disease of public health significance shall
62 immediately report the fact to the Department of Health.

63 Section 2. Subsection (13) of section 465.003, Florida
64 Statutes, is amended to read:

65 465.003 Definitions.—As used in this chapter, the term:

66 (13) "Practice of the profession of pharmacy" includes
67 compounding, dispensing, and consulting concerning contents,
68 therapeutic values, and uses of any medicinal drug; consulting
69 concerning therapeutic values and interactions of patent or
70 proprietary preparations, whether pursuant to prescriptions or
71 in the absence and entirely independent of such prescriptions or
72 orders; and conducting other pharmaceutical services. For
73 purposes of this subsection, "other pharmaceutical services"
74 means the monitoring of the patient's drug therapy and assisting
75 the patient in the management of his or her drug therapy, and
76 includes review of the patient's drug therapy and communication
77 with the patient's prescribing health care provider as licensed
78 under chapter 458, chapter 459, chapter 461, or chapter 466, or
79 similar statutory provision in another jurisdiction, or such
80 provider's agent or such other persons as specifically
81 authorized by the patient, regarding the drug therapy. However,
82 nothing in this subsection may be interpreted to permit an
83 alteration of a prescriber's directions, the diagnosis or
84 treatment of any disease, the initiation of any drug therapy,
85 the practice of medicine, or the practice of osteopathic
86 medicine, unless otherwise permitted by law. "Practice of the
87 profession of pharmacy" also includes any other act, service,

588-03836-20

2020714c1

88 operation, research, or transaction incidental to, or forming a
89 part of, any of the foregoing acts, requiring, involving, or
90 employing the science or art of any branch of the pharmaceutical
91 profession, study, or training, and shall expressly permit a
92 pharmacist to transmit information from persons authorized to
93 prescribe medicinal drugs to their patients. The practice of the
94 profession of pharmacy also includes the administration of
95 vaccines to adults pursuant to s. 465.189, the testing for and
96 treatment of influenza pursuant to s. 465.1895, and the
97 preparation of prepackaged drug products in facilities holding
98 Class III institutional pharmacy permits.

99 Section 3. Section 465.1895, Florida Statutes, is created
100 to read:

101 465.1895 Testing for and treatment of influenza.-

102 (1) A pharmacist may test for and treat influenza if all of
103 the following criteria are met:

104 (a) The pharmacist has entered into a written protocol with
105 a supervising physician licensed under chapter 458 or chapter
106 459, and such protocol complies with the requirements in
107 subsection (5) and the Board of Medicine's rules.

108 (b) The pharmacist uses an instrument and a waived test, as
109 that term is defined in 42 C.F.R. s. 493.2.

110 (c) The pharmacist uses a testing system that:

111 1. Provides automated readings in order to reduce user
112 subjectivity or interpretation of results.

113 2. Is capable of directly or indirectly interfacing with
114 electronic medical records systems.

115 3. Is capable of electronically reporting daily
116 deidentified test results to the appropriate agencies.

588-03836-20

2020714c1

117 4. Uses an instrument that incorporates both internal and
118 external controls and external calibration that show the reagent
119 and assay procedure is performing properly. External controls
120 must be used in accordance with local, state, and federal
121 regulations and accreditation requirements.

122 (d) The pharmacist is certified to test for and treat
123 influenza pursuant to a certification program approved by the
124 Board of Medicine, in consultation with the board and the Board
125 of Osteopathic Medicine. The certification program must be
126 developed and implemented within 90 days after the date upon
127 which this section becomes effective and must require that the
128 pharmacist attend, on a one-time basis, 8 hours of continuing
129 education courses approved by the Board of Medicine. The
130 continuing education curriculum must be provided by an
131 organization that is approved by the Accreditation Council for
132 Pharmacy Education to provide instructional services and must
133 include, at a minimum, point-of-care testing for influenza and
134 the safe and effective treatment of influenza.

135 (e) The pharmacist collects from the patient a full history
136 of the patient's past and present medical conditions on a form
137 adopted by the Board of Medicine by rule which allows the
138 patient to check off medical conditions from a list and add
139 other conditions that are not listed. The history must be
140 maintained as part of the patient's records in accordance with
141 subsection (3).

142 (f) The pharmacy in which a pharmacist tests for and treats
143 influenza prominently displays signage indicating that any
144 patient tested and treated at the pharmacy is advised to seek
145 followup care from his or her primary care physician or, if the

588-03836-20

2020714c1

146 patient has no primary care physician, from the pharmacist's
147 supervising physician.

148 (g) The pharmacist who tests for or treats influenza
149 provides the patient with the name and contact information for
150 the pharmacist's supervising physician and a pamphlet or
151 brochure that meets criteria established by the Board of
152 Medicine by rule informing the patient that:

153 1. If the test indicates that the patient has influenza,
154 the patient is advised to seek followup care from the patient's
155 primary care physician or, if the patient has no primary care
156 physician, from the pharmacist's supervising physician; and

157 2. If the pharmacist treats the patient for influenza, the
158 pharmacist and the pharmacy where the testing and treating
159 occurred are liable for damages the patient suffers as a result
160 of an adverse reaction to the treatment.

161 (h) The pharmacist's treatment is limited to medications
162 designed to treat influenza which are approved by the Board of
163 Medicine and which the Board of Medicine shall review annually.

164 (i) The pharmacist, prior to treating the patient, reviews
165 the patient's current prescriptions and recent prescription
166 history to check for relative contraindications involving the
167 pharmacist's intended treatment.

168 (2) A pharmacist may not enter into a written protocol
169 under this section unless he or she maintains at least \$250,000
170 of professional liability insurance and is certified as required
171 in paragraph (1) (d).

172 (3) A pharmacist who tests for and treats influenza shall
173 maintain and make available patient records using the same
174 standards for confidentiality and maintenance of such records as

588-03836-20

2020714c1

175 those that are imposed on health care practitioners under s.
176 456.057. Each patient's records maintained under this subsection
177 must include confirmation that the requirements of paragraphs
178 (1) (e) and (1) (g) were fulfilled. Such records shall be
179 maintained for at least 5 years.

180 (4) The decision by a supervising physician licensed under
181 chapter 458 or chapter 459 to enter into a written protocol
182 under this section is a professional decision on the part of the
183 physician and a person may not interfere with a physician's
184 decision regarding entering into such a protocol. A pharmacist
185 may not enter into a written protocol that is to be performed
186 while acting as an employee without the written approval of the
187 owner of the pharmacy.

188 (5) The Board of Medicine, in consultation with the board
189 and the Board of Osteopathic Medicine, shall adopt rules
190 establishing requirements for the written protocol within 90
191 days after the date upon which this section becomes effective.
192 At a minimum, the written protocol shall include:

193 (a) The terms and conditions required in s. 465.189(7).

194 (b) Specific categories of patients for whom the
195 supervising physician authorizes the pharmacist to test for and
196 treat influenza.

197 (c) The supervising physician's instructions for the
198 treatment of influenza based on the patient's age, symptoms, and
199 test results, including negative results.

200 (d) A process and schedule for the supervising physician to
201 review the pharmacist's actions under the written protocol.

202 (e) A process and schedule for the pharmacist to notify the
203 supervising physician of the patient's condition, tests

588-03836-20

2020714c1

204 administered, test results, and course of treatment.

205 (6) When the patient has a primary care provider, a
206 pharmacist who provides testing for or treatment of influenza
207 under this section shall notify the patient's primary care
208 provider within 2 business days after providing any such testing
209 or treatment.

210 (7) If a pharmacist tests for and treats influenza for a
211 patient under this section, the pharmacist or his or her
212 designee must follow up with the patient 3 days later to
213 determine whether the patient's condition has improved, and if
214 the patient informs the pharmacist that his or her condition has
215 not improved, the pharmacist shall do all of the following:

216 (a) Recommend that the patient seek treatment from the
217 patient's primary care physician or, if the patient has no
218 primary care physician, from the pharmacist's supervising
219 physician.

220 (b) Inform the patient's primary care physician that the
221 patient's condition failed to improve 3 days after treatment or,
222 if the patient has no primary care physician, the pharmacist
223 shall so inform the pharmacist's supervising physician.

224 (c) Document in the patient's record maintained under
225 subsection (3) whether the followup required under this
226 subsection occurred or whether attempts to contact the patient
227 were unsuccessful.

228 (8) A pharmacist may not test for or treat influenza under
229 this section for a patient who:

230 (a) Is younger than 18 years of age;

231 (b) Is older than 75 years of age;

232 (c) Refuses to provide a medical history under paragraph

588-03836-20

2020714c1

233 (1) (e); or

234 (d) Provides a medical history under paragraph (1) (e)
235 indicating a history of conditions relating to heart disease,
236 bronchial disorders, pneumonia, chronic obstructive pulmonary
237 disease, asthma, or any other medical conditions as determined
238 by the Board of Medicine by rule on an annual basis.

239 (9) A supervising physician who enters into a written
240 protocol with a pharmacist under this section must be a primary
241 care physician who is actively practicing in the community in
242 which the pharmacist tests and treats under this section
243 according to Board of Medicine rule. A supervising physician may
244 not enter into such a protocol with pharmacists employed at more
245 than four pharmacy locations.

246 (10) Implementation of this section is contingent upon the
247 enactment of an appropriation within the General Appropriations
248 Act which is sufficient to fund the Board of Medicine's efforts
249 to carry out its duties as required under this section.

250 Section 4. This act shall take effect upon becoming a law.