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LEGISLATIVE ACTION

Senate

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House

The Committee on Health Policy (Hutson) recommended the following:

Senate Amendment (with title amendment)

Delete lines 70 - 148

and insert:

treatment of influenza pursuant to s. 465.1895, and the preparation of prepackaged drug products in facilities holding Class III institutional pharmacy permits.

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

465.1895 Testing for and treatment of influenza.-



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

13 (a) The pharmacist has entered into a written protocol with
14 a supervising physician licensed under chapter 458 or chapter
15 459, and such protocol complies with the requirements in
16 subsection (5) and the Board of Medicine's rules.

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

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

20 1. Provides automated readings in order to reduce user
21 subjectivity or interpretation of results.

22 2. Is capable of directly or indirectly interfacing with
23 electronic medical records systems.

24 3. Is capable of electronically reporting daily
25 deidentified test results to the appropriate agencies.

26 4. Uses an instrument that incorporates both internal and
27 external controls and external calibration that show the reagent
28 and assay procedure is performing properly. External controls
29 must be used in accordance with local, state, and federal
30 regulations and accreditation requirements.

31 (d) The pharmacist is certified to test for and treat
32 influenza pursuant to a certification program approved by the
33 Board of Medicine, in consultation with the board and the Board
34 of Osteopathic Medicine. The certification program must be
35 developed and implemented within 90 days after the date upon
36 which this section becomes effective and must require that the
37 pharmacist attend, on a one-time basis, 8 hours of continuing
38 education courses approved by the Board of Medicine. The
39 continuing education curriculum must be provided by an



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40 organization of instruction approved by the Accreditation
41 Council for Pharmacy Education and must include, at a minimum,
42 point-of-care testing for influenza and the safe and effective
43 treatment of influenza.

44 (e) The pharmacist collects from the patient a full history
45 of the patient's past and present medical conditions on a form
46 adopted by the Board of Medicine in rule which allows the
47 patient to check off medical conditions from a list and add
48 other conditions that are not listed. The history must be
49 maintained as part of the patient's records in accordance with
50 subsection (3).

51 (f) The pharmacy in which a pharmacist tests for and treats
52 influenza prominently displays signage indicating that any
53 patient tested and treated at the pharmacy is advised to seek
54 followup care from his or her primary care physician or, if the
55 patient has no primary care physician, from the pharmacist's
56 supervising physician.

57 (g) The pharmacist who tests for or treats influenza
58 provides the patient with the name and contact information for
59 the pharmacist's supervising physician and a pamphlet or
60 brochure that meets criteria established by the Board of
61 Medicine in rule informing the patient that:

62 1. If the test indicates that the patient has influenza,
63 the patient is advised to seek followup care from the patient's
64 primary care physician or, if the patient has no primary care
65 physician, from the pharmacist's supervising physician; and

66 2. If the pharmacist treats the patient for influenza, the
67 pharmacist and the pharmacy where the testing and treating
68 occurred are liable for damages the patient suffers as a result



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69 of an adverse reaction to the treatment.

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

73 (i) The pharmacist, prior to treating the patient, reviews
74 the patient's current prescriptions and recent prescription
75 history to check for relative contraindications involving the
76 pharmacist's intended treatment.

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

81 (3) A pharmacist who tests for and treats influenza shall
82 maintain and make available patient records using the same
83 standards for confidentiality and maintenance of such records as
84 those that are imposed on health care practitioners under s.
85 456.057. Each patient's records maintained under this subsection
86 must include confirmation that the requirements of paragraphs
87 (1) (e) and (1) (g) were fulfilled. Such records shall be
88 maintained for at least 5 years.

89 (4) The decision by a supervising physician licensed under
90 chapter 458 or chapter 459 to enter into a written protocol
91 under this section is a professional decision on the part of the
92 physician and a person may not interfere with a physician's
93 decision regarding entering into such a protocol. A pharmacist
94 may not enter into a written protocol that is to be performed
95 while acting as an employee without the written approval of the
96 owner of the pharmacy.

97 (5) The Board of Medicine, in consultation with the board



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98 and the Board of Osteopathic Medicine, shall adopt rules
99 establishing requirements for the written protocol within 90
100 days after the date upon which this section becomes effective.

101 At a minimum, the written protocol shall include:

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

103 (b) Specific categories of patients for whom the
104 supervising physician authorizes the pharmacist to test for and
105 treat influenza.

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

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

111 (e) A process and schedule for the pharmacist to notify the
112 supervising physician of the patient's condition, tests
113 administered, test results, and course of treatment.

114 (6) When the patient has a primary care provider, a
115 pharmacist who provides testing for or treatment of influenza
116 under this section shall notify the patient's primary care
117 provider within 2 business days after providing any such testing
118 or treatment.

119 (7) If a pharmacist tests for and treats influenza for a
120 patient under this section, the pharmacist or his or her
121 designee must follow up with the patient 3 days later to
122 determine whether the patient's condition has improved, and if
123 the patient informs the pharmacist that his or her condition has
124 not improved, the pharmacist shall do all of the following:

125 (a) Recommend that the patient seek treatment from the
126 patient's primary care physician or, if the patient has no



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127 primary care physician, from the pharmacist's supervising
128 physician.

129 (b) Inform the patient's primary care physician that the
130 patient's condition failed to improve 3 days after treatment or,
131 if the patient has no primary care physician, the pharmacist
132 shall so inform the pharmacist's supervising physician.

133 (c) Document in the patient's record maintained under
134 subsection (3) whether the followup required under this
135 subsection occurred or whether attempts to contact the patient
136 were unsuccessful.

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

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

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

141 (c) Refuses to provide a medical history under paragraph
142 (1) (e); or

143 (d) Provides a medical history under paragraph (1) (e)
144 indicating a history of conditions relating to heart disease,
145 bronchial disorders, pneumonia, chronic obstructive pulmonary
146 disease, asthma, or any other medical conditions as determined
147 by the Board of Medicine in rule on an annual basis.

148 (9) A supervising physician who enters into a written
149 protocol with a pharmacist under this section must be a primary
150 care physician who is actively practicing in the community in
151 which the pharmacist tests and treats under this section
152 according to Board of Medicine rule. A supervising physician may
153 not enter into such a protocol with pharmacists employed at more
154 than four pharmacy locations.

155 (10) Implementation of this section is contingent upon the



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156 enactment of an appropriation within the General Appropriations
157 Act which is sufficient to fund the Board of Medicine's efforts
158 to carry out its duties as required under this section.

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160 ===== T I T L E A M E N D M E N T =====

161 And the title is amended as follows:

162 Delete lines 3 - 18

163 and insert:

164 of influenza; amending s. 381.0031, F.S.; requiring
165 specified licensed pharmacists to report certain
166 information to the Department of Health; amending s.
167 465.003, F.S.; revising the definition of the term
168 "practice of the profession of pharmacy"; creating s.
169 465.1895, F.S.; authorizing pharmacists to test for
170 and treat influenza and providing requirements
171 relating thereto; requiring the written protocol
172 between a pharmacist and a supervising physician to
173 contain certain information, terms, and conditions;
174 requiring the Board of Medicine, in consultation with
175 the Board of Pharmacy and the Board of Osteopathic
176 Medicine, to develop a specified certification program
177 for pharmacists within a specified timeframe;
178 requiring a pharmacist to collect a medical history
179 before testing and treating a patient; requiring a
180 pharmacy in which a pharmacist tests for and treats
181 influenza to display and distribute specified
182 information; providing limitations on the medications
183 a pharmacist may administer to treat influenza;
184 requiring pharmacists to review certain information



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185 for a specified purpose before testing and treating
186 patients; requiring a pharmacist who tests for and
187 treats influenza to maintain professional liability
188 insurance in a specified amount; providing
189 recordkeeping requirements for pharmacists who test
190 for and treat influenza; providing that a person may
191 not interfere with a physician's professional decision
192 to enter into a written protocol with a pharmacist;
193 providing that a pharmacist may not enter into a
194 written protocol under certain circumstances;
195 requiring the Board of Medicine, in consultation with
196 the Board of Pharmacy and the Board of Osteopathic
197 Medicine, to adopt rules within a specified timeframe;
198 requiring pharmacists to notify a patient's primary
199 care provider and follow up with the treated patient
200 within specified timeframes; prohibiting a pharmacist
201 from testing or treating patients under certain
202 circumstances; specifying circumstances under which a
203 physician may supervise a pharmacist under a written
204 protocol; providing a contingency on implementation;
205 providing an effective date.