By the Committee on Budget Subcommittee on Health and Human Services Appropriations; and Senator Oelrich

603-03209-12 2012850c1

A bill to be entitled

An act relating to pharmacy; amending s. 465.189, F.S.; revising the types of vaccines that pharmacists may administer under certain circumstances; authorizing pharmacists to administer an influenza vaccine, an epinephrine autoinjection, or a shingles vaccine within the framework of an established protocol under certain circumstances; amending s. 465.003, F.S.; revising the definition of the term "practice of the profession of pharmacy" to conform to changes made by the act; amending s. 465.009, F.S.; revising continuing professional pharmaceutical educational requirements with respect to administering such vaccines or autoinjection; providing effective dates.

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

Section 1. Subsections (2) through (7) of section 465.189, Florida Statutes, are renumbered as subsections (4) through (9), respectively, and new subsections (1), (2), and (3) are added to that section, to read:

465.189 Administration of <u>vaccines and epinephrine</u> autoinjection <u>influenza virus immunizations</u>.

(1) In accordance with guidelines of the Centers for

Disease Control and Prevention for each recommended immunization
or vaccine, a pharmacist may administer the following vaccines
to an adult within the framework of an established protocol
under a supervising physician licensed under chapter 458 or

603-03209-12 2012850c1

chapter 459:

- (a) Influenza vaccine.
- (b) Pneumococcal vaccine.
- (2) In accordance with guidelines of the Centers for Disease Control and Prevention, a pharmacist may administer the shingles vaccine within the framework of an established protocol and pursuant to a written or electronic prescription issued to the patient by a physician licensed under chapter 458 or chapter 459.
- (3) In order to address any unforeseen allergic reaction, a pharmacist may administer epinephrine using an autoinjector delivery system within the framework of an established protocol under a supervising physician licensed under chapter 458 or chapter 459.
- (1) Pharmacists may administer influenza virus immunizations to adults within the framework of an established protocol under a supervisory practitioner who is a physician licensed under chapter 458 or chapter 459. Each protocol shall contain specific procedures for addressing any unforeseen allergic reaction to influenza virus immunizations.
- (4) (2) A pharmacist may not enter into a protocol unless he or she maintains at least \$200,000 of professional liability insurance and has completed training in administering vaccines authorized under influenza virus immunizations as provided in this section.
- (5)(3) A pharmacist administering vaccines under this section influenza virus immunizations shall maintain and make available patient records using the same standards for confidentiality and maintenance of such records as those that

603-03209-12 2012850c1

are imposed on health care practitioners under s. 456.057. These records shall be maintained for a minimum of 5 years.

(6)(4) The decision by a <u>supervising physician licensed</u> under chapter 458 or chapter 459 supervisory practitioner to enter into a protocol under this section is a professional decision on the part of the practitioner, and a person may not interfere with a <u>physician's supervisory practitioner's</u> decision as to entering into such a protocol. A pharmacist may not enter into a protocol that is to be performed while acting as an employee without the written approval of the owner of the pharmacy. Pharmacists shall forward <u>vaccination</u> immunization records to the department for inclusion in the state registry of immunization information.

(7)-(5) Any pharmacist seeking to administer vaccines influenza virus immunizations to adults under this section must be certified to administer such vaccines influenza virus immunizations pursuant to a certification program approved by the Board of Pharmacy in consultation with the Board of Medicine and the Board of Osteopathic Medicine. The certification program shall, at a minimum, require that the pharmacist attend at least 20 hours of continuing education classes approved by the board. The program shall have a curriculum of instruction concerning the safe and effective administration of such vaccines influenza virus immunizations, including, but not limited to, potential allergic reactions to such vaccines influenza virus immunizations.

(8) (6) The written protocol between the pharmacist and supervising physician <u>under this section</u> must include particular terms and conditions imposed by the supervising physician upon

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603-03209-12 2012850c1

the pharmacist relating to the administration of vaccines influenza virus immunizations by the pharmacist pursuant to this section. The written protocol shall include, at a minimum, specific categories and conditions among patients for whom the supervising physician authorizes the pharmacist to administer such vaccines influenza virus immunizations. The terms, scope, and conditions set forth in the written protocol between the pharmacist and the supervising physician must be appropriate to the pharmacist's training and certification for administering such vaccines immunization. Pharmacists who have been delegated the authority to administer vaccines under this section influenza virus immunizations by the supervising physician under the protocol shall provide evidence of current certification by the Board of Pharmacy to the supervising physician. A supervising physician physicians shall review the administration of such vaccines influenza virus immunizations by the pharmacist pharmacists under such physician's supervision pursuant to the written protocol between them, and this review shall take place as outlined in the written protocol. The process and schedule for the review shall be outlined in the written protocol between the pharmacist and the supervising physician.

(9) (7) The pharmacist shall submit to the Board of Pharmacy a copy of his or her protocol or written agreement to administer vaccines under this section influenza virus immunizations.

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

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

(13) "Practice of the profession of pharmacy" includes compounding, dispensing, and consulting concerning contents,

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603-03209-12 2012850c1

therapeutic values, and uses of any medicinal drug; consulting concerning therapeutic values and interactions of patent or proprietary preparations, whether pursuant to prescriptions or in the absence and entirely independent of such prescriptions or orders; and other pharmaceutical services. For purposes of this subsection, "other pharmaceutical services" means the monitoring of the patient's drug therapy and assisting the patient in the management of his or her drug therapy, and includes review of the patient's drug therapy and communication with the patient's prescribing health care provider as licensed under chapter 458, chapter 459, chapter 461, or chapter 466, or similar statutory provision in another jurisdiction, or such provider's agent or such other persons as specifically authorized by the patient, regarding the drug therapy. However, nothing in this subsection may be interpreted to permit an alteration of a prescriber's directions, the diagnosis or treatment of any disease, the initiation of any drug therapy, the practice of medicine, or the practice of osteopathic medicine, unless otherwise permitted by law. "Practice of the profession of pharmacy" also includes any other act, service, operation, research, or transaction incidental to, or forming a part of, any of the foregoing acts, requiring, involving, or employing the science or art of any branch of the pharmaceutical profession, study, or training, and shall expressly permit a pharmacist to transmit information from persons authorized to prescribe medicinal drugs to their patients. The practice of the profession of pharmacy also includes the administration of vaccines influenza virus immunizations to adults pursuant to s. 465.189.

Section 3. Effective October 1, 2012, subsection (6) is

603-03209-12 2012850c1

added to section 465.009, Florida Statutes, to read:

- 465.009 Continuing professional pharmaceutical education.
- (6) Notwithstanding subsections (1)-(5):
 - (a) Each pharmacist certified to administer a vaccine or epinephrine autoinjection under s. 465.189 must complete a 3-hour continuing education course, which shall be offered by a statewide professional association of physicians in this state accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award (AMA PRA) Category 1 credit, on the safe and effective administration of vaccines and epinephrine autoinjection as part of biennial relicensure or recertification. This course may be offered in a distance-learning format and must be included in the 30 hours of continuing professional pharmaceutical education specified in subsection (1).
 - (b) Each pharmacist must submit confirmation of having completed the course specified in paragraph (a) on a form provided by the board when submitting fees for license renewal.
 - (c) Failure to comply with paragraphs (a) and (b) results in the revocation of the authorization for a pharmacist to administer a vaccine or epinephrine autoinjection under s.

 465.189. Such authorization may be restored upon completion of such requirements.
 - Section 4. Except as otherwise expressly provided in this act, this act shall take effect July 1, 2012.