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COMMITTEE REPORT

May 20, 2015

**S. 413**

Introduced by Senators Cleary, Leatherman, Bryant, Johnson, Campbell, Peeler, Fair and Shealy

S. Printed 5/20/15--H.

Read the first time March 17, 2015.

**THE COMMITTEE ON MEDICAL,**

**MILITARY, PUBLIC AND MUNICIPAL AFFAIRS**

To whom was referred a Bill (S. 413) to amend Section 40‑43‑190, Code of Laws of South Carolina, 1976, relating to protocol for pharmacists to administer influenza vaccines and certain medications, etc., respectfully

**REPORT:**

That they have duly and carefully considered the same and recommend that the same do pass:

LEON HOWARD for Committee.

**STATEMENT OF ESTIMATED FISCAL IMPACT**

**Fiscal Impact Summary**

The Department of Labor, Licensing and Regulation reports that this bill would have no expenditure impact on the general fund, federal funds, or other funds.

**Explanation of Fiscal Impact**

**State Expenditure**

Senate Bill 413 amends Section 40-43-190 and Section 40-43-200 relating to the administration of vaccines by pharmacists. The bill creates the Joint Pharmacist Administered Vaccines Committee and prescribes its membership, duties, and responsibilities. The committee is to recommend which specific vaccines are appropriate for administration by a pharmacist without a written prescription, and to submit proposed written protocols for the administration of each recommended vaccine. The bill authorizes the Board of Medical Examiners to issue protocols for vaccine administration and further specifies the requirements for pharmacists seeking authorization to administer approved vaccines.

The Department of Labor, Licensing and Regulation reports that this bill would have no expenditure impact on the general fund, federal funds, or other funds.

Frank A. Rainwater, Executive Director

Revenue and Fiscal Affairs Office

**A** **BILL**

TO AMEND SECTION 40‑43‑190, CODE OF LAWS OF SOUTH CAROLINA, 1976, RELATING TO PROTOCOL FOR PHARMACISTS TO ADMINISTER INFLUENZA VACCINES AND CERTAIN MEDICATIONS, SO AS TO PROVIDE A PROCEDURE FOR CREATING PROTOCOL THROUGH WHICH PHARMACISTS MAY ADMINISTER CERTAIN VACCINES WITHOUT A WRITTEN ORDER OR PRESCRIPTION FROM A PRACTITIONER, TO PROVIDE CIRCUMSTANCES IN WHICH A PHARMACY INTERN MAY ADMINISTER VACCINATIONS, TO REVISE RECORDKEEPING REQUIREMENTS TO EXTEND THE PERIOD FOR MAINTAINING RECORDS AND SPECIFY THE MANNER OF DETERMINING THE DATE FROM WHICH THIS PERIOD IS MEASURED, AND TO PROVIDE FOR THE ELECTRONIC STORAGE OF CERTAIN DOCUMENTS, RECORDS, AND COPIES; AND TO AMEND SECTION 40‑43‑200, RELATING TO THE JOINT PHARMACIST ADMINISTERED INFLUENZA VACCINES COMMITTEE, SO AS TO MAKE CONFORMING CHANGES.

Be it enacted by the General Assembly of the State of South Carolina:

SECTION 1. Section 40‑43‑190 of the 1976 Code, as added by Act 224 of 2010, is amended to read:

“Section 40‑43‑190. (A)(1) Upon recommendation of the Joint Pharmacist Administered Vaccines Committee, the Board of Medical Examiners shall determine whether a specific vaccine is appropriate for administration by a pharmacist without a written order or prescription of a practitioner pursuant to this section. If a vaccine is approved, the Board of Medical Examiners shall issue a written protocol for the administration of ~~influenza~~ vaccines by pharmacists without an order or prescription of a practitioner.

(2) The administration of ~~influenza~~ vaccines as authorized in this section must not be to ~~persons~~ a person under the age of eighteen years; provided, however, that:

(a) the influenza vaccine may be administered to a person twelve years of age or older pursuant to protocol issued by the Board of Medical Examiners; and

(b) a pharmacist who has completed the training described in subsection (B)(1) may administer a vaccine approved by the Centers for Disease Control to a person of any age pursuant to a written order or prescription of a practitioner for a specific patient of that practitioner.

(~~2~~3) The written protocol must further authorize pharmacists to administer without an order or prescription of a practitioner those medications necessary in the treatment of adverse events. These medications must be used only in the treatment of adverse events and must be limited to those delineated within the written protocol.

(~~3~~4) The Board of Medical Examiners must issue the written protocol ~~must be issued no later than January 1, 2011~~ upon its approval of the vaccine for administration pursuant to this section.

(5) A pharmacist who has completed the training described in subsection (B)(1) may administer a vaccine approved by the Centers for Disease Control pursuant to written order or prescription of a practitioner for a specific patient of that practitioner.

(B) The written protocol must provide that:

(1) A pharmacist seeking authorization to administer ~~influenza vaccines as authorized in~~ a vaccine approved pursuant to this section shall successfully complete a course of training accredited by the Accreditation Council for Pharmacy Education or a similar health authority or professional body approved by the Board of Pharmacy and the Board of Medical Examiners. Training must comply with current Centers for Disease Control guidelines and must include study materials, hands‑on training, and techniques for administering ~~influenza~~ vaccines and must provide instruction and experiential training in the following content areas:

(a) mechanisms of action for ~~influenza~~ vaccines, contraindications, drug interactions, and monitoring after vaccine administration;

(b) standards for adult ~~immunization~~ vaccination practices;

(c) basic immunology and vaccine protection;

(d) vaccine‑preventable diseases;

(e) recommended ~~immunization~~ vaccination schedules;

(f) vaccine storage management;

(g) biohazard waste disposal and sterile techniques;

(h) informed consent;

(i) physiology and techniques for vaccine administration;

(j) prevaccine and postvaccine assessment and counseling;

(k) ~~immunization~~ vaccination record management;

(l) management of adverse events, including identification, appropriate response, emergency procedures, documentation, and reporting;

(m) understanding of vaccine coverage by federal, state, and local entities;

(n) needle stick management.

(2) A pharmacist administering ~~an influenza vaccine~~ vaccinations without an order or prescription of a practitioner pursuant to this section shall:

(a) obtain the signed written consent of the person being vaccinated or that person’s guardian;

(b) maintain a copy of the vaccine administration in that person’s record and provide a copy to the person or the person’s guardian;

(c) notify that person’s designated physician or primary care provider of ~~any influenza~~ a vaccine administered;

(d) report administration of ~~an influenza vaccine to any statewide immunization registry~~ all vaccinations to the South Carolina Immunization Registry in compliance with regulations established by the Department of Health and Environmental Control as the department may require; provided, however, that the phase‑in schedule provided in Regulation 61‑120 for reporting vaccinations does not apply to vaccinations administered pursuant to this section;

(e) maintain a current copy of the written protocol at each location at which a ~~pharmacist administers an influenza vaccine~~ vaccination is administered pursuant to this section.

(3) A pharmacist may not delegate the administration of ~~influenza~~ vaccines to a pharmacy technician ~~as defined in Section 40‑43‑30 or any other person who is not a pharmacist~~ or certified pharmacy technician.

(4) A pharmacy intern may administer vaccinations under the direct supervision, as defined in Section 40‑43‑84(C), of a pharmacist who has completed vaccination training as required by item (1) if the pharmacy intern:

(a) is certified through a basic life support or CPR provider‑level course that is jointly approved by the Board of Medical Examiners and the Board of Pharmacy; and

(b) completes this course of training described in item (1).

(~~4~~5) A pharmacist administering ~~influenza vaccines~~ vaccinations shall, as part of the current continuing education requirements pursuant to Section 40‑43‑130, complete no less than one hour of continuing education each license year regarding administration of ~~influenza vaccines~~ vaccinations.

(C) Informed consent must be documented in accordance with the written protocol for ~~influenza~~ vaccine administration issued pursuant to this section.

(D) All records required by this section must be maintained in the pharmacy for a period of at least ~~six~~ ten years from the date of the last vaccination for adults and at least thirteen years from the date of the last vaccination for minors.

(E) All documentation, records, and copies required by this section may be stored electronically.”

SECTION 2. Section 40‑43‑200 of the 1976 Code, as added by Act 224 of 2010, is amended to read:

“Section 40‑43‑200. (A) There is created a Joint Pharmacist Administered ~~Influenza~~ Vaccines Committee as a committee to the Board of Medical Examiners which consists of seven members with experience regarding ~~influenza~~ vaccines. The committee is comprised of two physicians selected by the Board of Medical Examiners, two pharmacists selected by the Board of Pharmacy, and two advanced practice nurse practitioners selected by the Board of Nursing. One member of the Department of Health and Environmental Control designated by the ~~commissioner~~ director of the department also shall serve on the committee. Members of the committee may not be compensated for their service on the board and may not receive mileage, per diem, and subsistence as otherwise authorized by law for members of state boards, committees, and commissions.

(B) The committee shall meet at least once annually and at other times as may be necessary. Five members constitute a quorum for all meetings. At its initial meeting, and at the beginning of each year thereafter, the committee shall elect from its membership a chairperson to serve for a one year term.

(C) The committee shall assist and advise the Board of Medical Examiners in ~~establishing a~~ determining whether a specific vaccine is appropriate for administration by a pharmacist without a written order or prescription of a practitioner pursuant to Section 40‑43‑190. For a specific vaccine recommended by the committee to the Board of Medical Examiners, the committee also must submit a proposed written protocol for the purpose of authorizing pharmacists to administer ~~influenza vaccines without an order of a practitioner~~ the vaccine as authorized by Section 40‑43‑190 ~~and shall provide a suggested written protocol~~. The committee must submit its initial recommendations to the board no later than four months after the passage of this act, and periodically thereafter as determined by the committee.”

SECTION 3. This act takes effect upon approval by the Governor.

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