

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 509 Pharmacy

SPONSOR(S): Health & Human Services Committee; Health & Human Services Quality Subcommittee;
Logan

TIED BILLS: **IDEN./SIM. BILLS:** SB 850

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health & Human Services Quality Subcommittee	10 Y, 5 N, As CS	Holt	Calamas
2) Health & Human Services Committee	16 Y, 1 N, As CS	Holt	Gormley

SUMMARY ANALYSIS

In 2007, pharmacists were granted the authority to administer influenza vaccines (flu shots) to an adult under a written protocol with a supervising physician. Currently, a pharmacist who wishes to administer the flu shot must complete a 20-hour influenza immunization certification program (certification program) approved by the Board of Medicine and the Board of Osteopathic Medicine.

The bill expands the current pharmacist's flu vaccine administration certification program by authorizing a pharmacist to administer the pneumococcal vaccine. Furthermore, the bill allows a pharmacist to administer the shingles vaccine, but the patient must possess a prescription issued by a licensed physician. The bill allows a pharmacist to administer epinephrine, in the event of an allergic reaction, using an autoinjector delivery system. The bill requires that all authorized vaccines, and epinephrine, must be administered under a written protocol with a physician licensed under ch. 458 or 459. The bill specifies that all authorized vaccines must be administered in accordance with the CDC guidelines.

The bill requires pharmacists who are certified to administer a vaccine or epinephrine autoinjection to complete a 3-hour continuing education course on the safe and effective administration of vaccines. The 3-hour course must be offered by a statewide professional association of physicians in this state and is considered part of the 30-hour continuing education requirement for biennial licensure renewal and recertification. If a pharmacist fails to take the 3-hour course, the authorization to administer vaccines or epinephrine autoinjection system is revoked.

The bill has no fiscal impact on state or local governments.

The bill will take effect July 1, 2012.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Influenza Vaccine Certification Program

In 2007, the Florida Legislature granted pharmacists the authority to administer influenza vaccines (flu shots) to adults.¹ Section 465.189, F.S., sets out the terms and conditions under which a pharmacist may administer a flu shot to an adult.² Florida is the only state that uses the terminology “adult” instead of specifying a numerical age, such as 18 years or older. Fifteen states and territories limit the administration to 18 years or older.³ Thirteen states authorize administration to individuals at any age.⁴

A pharmacist who wishes to administer the flu shot must enter into a written protocol with a supervising physician licensed under chapter 458 or chapter 459, F.S.⁵ However, the pharmacist may not enter into a protocol while acting as an employee without the written approval of the owner of the pharmacy.⁶

Through the protocol the supervising physician dictates which types and categories of patients to whom the pharmacist may administer the flu shot.⁷ The terms, scope, and conditions set forth in the protocol must be appropriate to the pharmacist’s training and certification.⁸ The pharmacist is required to provide the Board of Pharmacy a copy of the protocol.⁹

The pharmacist is required to maintain at least \$200,000 of professional liability insurance.¹⁰ The pharmacist is required for 5 years to maintain and make available patient records using the same standards for confidentiality and maintenance required of other healthcare practitioners. The pharmacist must forward all immunization records to the DOH for inclusion in the state immunization registry called, “Florida SHOTS”.¹¹ Florida SHOTS is a free, statewide, centralized online immunization registry available to physicians, hospitals, pharmacies, schools and licensed child care facilities to help track of immunization records.¹²

Additionally, the pharmacist must successfully complete a certification program, which includes 20 hours of coursework in the form of continuing education hours that require the successful passage of a cognitive examination and proficient demonstration of administration technique.¹³ The pharmacist is

¹ Ch. 2007-152, L.O.F.

² Section 465.189, F.S.

³ The states and territories are: Connecticut, District of Columbia, Hawaii, Iowa, Massachusetts, North Carolina, New Hampshire, New Jersey, New York, Pennsylvania, Puerto Rico, South Carolina, Vermont, and West Virginia. *See* American Pharmacist Association, Pharmacist Immunization Center, States authorizing pharmacists to administer influenza vaccine & pharmacists trained to administer vaccines, *available at:* http://www.pharmacist.com/AM/Template.cfm?Section=Pharmacist_Immunization_Center1 (last viewed January 19, 2012).

⁴ The states are: Alabama, Alaska, California, Colorado, Michigan, Mississippi, Nebraska, New England, New Mexico, Oklahoma, Tennessee, Texas, Virginia, and Washington. *See* American Pharmacist Association, Pharmacist Immunization Center, States authorizing pharmacists to administer influenza vaccine & pharmacists trained to administer vaccines, *available at:* http://www.pharmacist.com/AM/Template.cfm?Section=Pharmacist_Immunization_Center1 (last viewed January 19, 2012).

⁵ Section 465.189(1), F.S.

⁶ Section 465.189(4), F.S.

⁷ Section 465.189(6), F.S.

⁸ *Id.*

⁹ Section 465.189(7), F.S.

¹⁰ Section 465.189(2), F.S.

¹¹ Section 465.189(4), F.S.

¹² Florida Shots, *available at:* <http://www.flshots.com/what/> (last viewed January 25, 2012)

¹³ Chapter 64B16-26.1031, F.A.C.

required to provide the Board of Pharmacy proof of possessing a current certification to administer the flu shot.¹⁴ The coursework must include instruction in the following:¹⁵

- Mechanisms of action for vaccines, contraindications, drug interactions, and monitoring after vaccine administration;
- Immunization schedules;
- Immunization screening questions, provision of risk/benefit information, informed consent, recordkeeping, and electronic reporting into the statewide immunization registry maintained by DOH;
- Vaccine storage and handling;
- Bio-hazardous waste disposal and sterile technique;
- Entering, negotiating, and performing pursuant to physician oversight protocols;
- Community immunization resources and programs;
- Identifying, managing and responding to adverse incidents including but not limited to potential allergic reactions associated with vaccine administration;
- Procedures and policies for reporting adverse incidents to the Vaccine Adverse Event Reporting System;
- Reimbursement procedures and vaccine coverage by federal, state, and local governmental jurisdictions and private third party payors;
- Administration techniques;
- Current influenza immunization guidelines and recommendations of the CDC published in the Morbidity Weekly Report;
- Review of the current law permitting pharmacist to administer influenza vaccine (s. 465.189, F.S.); and
- CPR training.

The certification program is approved by the Board of Medicine and the Board of Osteopathic Medicine, as required by law.¹⁶

As of June 2009, all states allow pharmacists to immunize patients.¹⁷ However, there is variability by states as to what vaccines pharmacists are authorized to administer. Thirty-seven states and territories¹⁸ allow pharmacists to administer any vaccine, of which, 15 require a prescription.¹⁹ Florida, Maine, and Puerto Rico are more restrictive and only allow pharmacist to administer the flu shot.²⁰

In addition to Florida-licensed medical physicians, osteopathic physicians, physician assistants, and nurses, paramedics may administer immunizations. Section 401.272, F.S., authorizes a paramedic to administer immunizations after his or her medical director has verified and documented that the paramedic has received sufficient training and experience to administer immunizations.

¹⁴ Section 465.189(6), F.S.

¹⁵ Chapter 64B16-26.1031(2), F.A.C.

¹⁶ Section 465.189(7), F.S.

¹⁷ American Pharmacist Association, States Where Pharmacists Can Immunize, *See* map available at:

<http://www.pharmacist.com/AM/TemplateRedirect.cfm?Template=/CM/ContentDisplay.cfm&ContentID=21623> (last viewed January 19, 2012).

¹⁸ Alabama*, Alaska*, Arizona*, Arkansas*, California, Colorado, District of Columbia*, Delaware*, Georgia*, Hawaii*, Idaho, Illinois, Indiana*, Iowa*, Kansas, Kentucky, Louisiana*, Michigan*, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Jersey*, New Mexico, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina*, Tennessee, Texas, Vermont, Virginia*, Washington, and Wisconsin (*states that require a prescription).

¹⁹ American Pharmacist Association, Pharmacist Immunization Center, States authorizing pharmacists to administer influenza vaccine & pharmacists trained to administer vaccines, *available at*:

http://www.pharmacist.com/AM/Template.cfm?Section=Pharmacist_Immunization_Center1 (last viewed January 19, 2012).

²⁰ *Id.*

Pneumococcal Disease and Immunization

According to the American Pharmacist Association, Florida is one of three states and Puerto Rico that do not authorize pharmacist to administer the pneumococcal vaccine.²¹

Pneumococcal disease is an infection caused by the bacteria called *Streptococcus pneumoniae*.²² Pneumococcal disease is the leading cause of serious illness in children and adults throughout the world.²³ Bacteria can invade different organs of the body, causing pneumonia in the lungs, bacteremia in the bloodstream, meningitis in the brain, middle ear infections, and sinusitis.²⁴ There are more than 90 known pneumococcal types; the ten most common types cause 62 percent of invasive disease worldwide.²⁵

Each year in the U.S., there are 175,000 cases of pneumococcal pneumonia, more than 50,000 cases of bacteremia, and between 3,000 and 6,000 cases of meningitis.²⁶ According to the Centers for Disease Control and Prevention, invasive pneumococcal disease causes 6,000 deaths each year.²⁷

Symptoms of pneumococcal infection, depending on the location of the infection, include fever, cough, shortness of breath and chest pain; stiff neck, fever, mental confusion, disorientation and sensitivity to light (meningitis); joint pains and chills (bacteremia); and a painful ear, a red or swollen eardrum, sleeplessness, fever and irritability (middle ear infection).²⁸ Pneumococcal disease can result in long term damage, such as hearing loss, loss of a limb, and brain damage; pneumococcal disease can also result in death.²⁹

The best way to protect against pneumococcal disease is through vaccination. The vaccination is very good at preventing severe pneumococcal disease, but it is not guaranteed to protect against infection and symptoms in all people.³⁰ Persons aged 65 years or older are considered to be at high risk for pneumococcal disease or its complications. It is recommended that persons 65 years old or older be vaccinated against pneumococcal disease.³¹ Currently, there is only one vaccine on the market, called Pneumovax®, which is currently recommended for use in adults who are older than 65 years of age.³² About half of people who get the vaccine have mild side effects, such as redness or pain where the shot is given and less than 1 percent develop a fever, muscle aches, or more severe local reactions.³³

Shingles and Immunization

Shingles, a painful localized skin rash often with blisters, is caused by the reactivation of the varicella zoster virus (virus), which causes chicken pox. Anyone who has had chickenpox can develop shingles years later because the virus remains in the nerve cells of the body after the chickenpox infection clears and virus can reappear years later causing shingles. Shingles most commonly occurs in people 50

²¹ The 3 states are: Florida, Massachusetts, and South Carolina. *See*, American Pharmacist Association, Pharmacist Immunization Center, States authorizing pharmacists to administer influenza vaccine & pharmacists trained to administer vaccines , *available at*: http://www.pharmacist.com/AM/Template.cfm?Section=Pharmacist_Immunization_Center1 (last viewed January 19, 2012).

²² Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, Pneumococcal Disease In-Short, *available at*: <http://www.cdc.gov/vaccines/vpd-vac/pneumo/in-short-both.htm> (last viewed January 19, 2012).

²³ National Foundation for Infectious Diseases, Pneumococcal Disease, *available at*: <http://www.nfid.org/factsheets/pneumofacts.shtml> (last viewed January 19, 2012).

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.*

³² Centers for Disease Control and Prevention, Vaccines & Immunizations, Pneumococcal Vaccination, *available at*: <http://www.cdc.gov/vaccines/vpd-vac/pneumo/default.htm> (last viewed January 25, 2012).

³³ *Id.*

years old or older, people who have medical conditions that keep the immune system from working properly, or people who receive immunosuppressive drugs.³⁴

Shingles vaccine is recommended by the Advisory Committee on Immunization Practices (ACIP) to reduce the risk of shingles and its associated pain in anyone 60 years old or older, regardless of whether they recall having had chickenpox or not. Studies show that more than 99% of Americans ages 40 and older have had chickenpox, even if they don't remember getting the disease.³⁵

Almost one out of every three people in the U.S. will develop shingles.³⁶ There are 1 million estimated cases of shingles every year in the U.S., and half of those cases occur in persons over the age of 60.³⁷ The only way to reduce the risk of developing shingles is to get vaccinated.³⁸ Currently, there is only one vaccine on the market, called " Zostavax® " that is recommended to prevent the occurrence of shingles.³⁹ The most common side effects in people who got the vaccine were redness, soreness, swelling or itching at the shot site, and headache.⁴⁰

Anaphylaxis Epinephrine Auto-Injectors

Currently, a pharmacist who is eligible to administer the flu vaccine is not authorized to administer an epinephrine auto-injector system, commonly referred to as an EpiPen, to a person if they have an anaphylaxis reaction to the vaccine.

Many individuals with severe allergies that have resulted in, or can result in, anaphylaxis carry an EpiPen. The EpiPen consists of a syringe prefilled with an appropriate dose of epinephrine and a retractable needle that is protected by a safety guard to prevent injury or reuse. There are two dosages available for the EpiPen- for children weighing between 33 and 66 pounds, the dosage is .15 mg; for children and adults weighing more than 66 pounds, the dosage is .30 mg.⁴¹ When injected into the top of the thigh, epinephrine eases the symptoms of anaphylaxis until professional medical treatment is obtained.

Anaphylaxis is a severe, whole body allergic reaction to a chemical that has become an allergen.⁴² The human body releases chemicals during anaphylaxis that can cause shock, resulting in a sudden drop in blood pressure and the release of histamines, which restrict breathing.⁴³ Symptoms of anaphylaxis include a rapid, weak pulse, skin rash, nausea and vomiting.⁴⁴ Common causes include drug allergies, food allergies, insect bites or stings and exposure to latex.⁴⁵ The severely allergic population has increased significantly during that last ten years, with the current incidence rate estimated to be 49.8 per 100,000 person-years.⁴⁶

³⁴ Centers for Disease Control and Prevention, Vaccines & Immunizations, Shingles Vaccination: What You Need to Know, *available at*: <http://www.cdc.gov/vaccines/vpd-vac/shingles/vacc-need-know.htm> (last viewed January 25, 2012).

³⁵ *Id.*

³⁶ Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, Division of Viral Diseases, Shingles-Overview, *available at*: <http://www.cdc.gov/vaccines/vpd-vac/shingles/default.htm> (last viewed January 20, 2012).

³⁷ *Id.*

³⁸ Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, Shingles-Prevention & Treatment, *available at*: <http://www.cdc.gov/shingles/about/prevention-treatment.html> (last viewed January 19, 2012).

³⁹ Centers for Disease Control and Prevention, Vaccines & Immunizations, Shingles Vaccination: What You Need to Know, *available at*: <http://www.cdc.gov/vaccines/vpd-vac/shingles/vacc-need-know.htm> (last viewed January 25, 2012).

⁴⁰ *Id.*

⁴¹ Dey Pharma, L.P., EpiPen Prescribing Information, *available at*: <http://files.epipen.ghethifi.com/footer-pdfs/patient-packaging-insert-pdf/Prescribing-Information.pdf>. (last viewed January 20, 2012).

⁴² U.S. National Institute of Health, U.S. National Library of Medicine, National Center for Biotechnology Information, Anaphylaxis, *available at*: <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001847/> (last viewed January 19, 2012).

⁴³ Mayo Foundation for Medical Education and Research, First Aid: Anaphylaxis, *available at*: <http://www.mayoclinic.com/health/first-aid-anaphylaxis/FA00003> (last viewed January 20, 2012).

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ Stephanie Guerlain, PhD, et al., *A comparison of 4 epinephrine autoinjector delivery systems: usability and patient preference*, NIH Public Access Author Manuscript, *available at* <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2892620/>, citing Decker WW,

Anaphylaxis is an emergency situation that requires immediate medical attention. If anaphylaxis is not treated, it will lead to unconsciousness and possible death. Initial treatment of anaphylaxis includes the administration of epinephrine, also known as adrenaline, to improve breathing by relaxing muscles in the airways, stimulate the heart, and tighten the blood vessels to reduce swelling. Epinephrine is classified as a sympathomimetic drug, meaning its effects mimic those of the stimulated sympathetic nervous system, which stimulates the heart and narrows the blood vessels. It is available through a prescription from a physician.

Effect of Proposed Changes

The bill expands the current pharmacist's flu vaccine administration certification program by authorizing a pharmacist to administer the pneumococcal vaccine under a protocol with a physician. Furthermore, the bill allows a pharmacist to administer the shingles vaccine pursuant to a prescription issued by a licensed physician. The bill specifies that all authorized vaccines must be administered in accordance with the CDC guidelines.

The bill also authorizes pharmacists to administer, in the event of an allergic reaction, epinephrine using an autoinjector delivery system within the framework of the established protocol with a physician.

The bill amends the continuing education requirements for pharmacists by requiring pharmacists who are certified to administer a vaccine or epinephrine autoinjection to complete a 3-hour continuing education course on the safe and effective administration of vaccines offered by a statewide professional association of physicians in this state (i.e., the Florida Medical Association), as part of biennial licensure renewal and recertification. The 3-hour course may be offered in a distance-learning format and must be included within the required 30 hours of biennial continuing professional pharmaceutical education. The pharmacist is required to submit confirmation to the board of having completed the 3-course at the time of licensure renewal. If a pharmacist fails to complete the 3-hour course the certification to administer vaccines or epinephrine autoinjector systems is revoked and may be reinstated once the pharmacist submits confirmation of completing the course.

The bill makes conforming changes to the section to incorporate the additional vaccines and epinephrine autoinjector authorized by the bill.

B. SECTION DIRECTORY:

Section 1. Amends s. 465.189, F.S., relating to administration of vaccines and epinephrine autoinjection.

Section 2. Amends s. 465.003, F.S., relating to definitions.

Section 3. Amends s. 465.009, F.S., relating to continuing professional pharmaceutical education.

Section 4. Provides an effective date of July 1, 2012.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None identified.

2. Expenditures:

None identified.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

See Fiscal Comments.

2. Expenditures:

See Fiscal Comments.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Pharmacies that opt to allow its pharmacists and pharmacy interns to administer the vaccines specified in the bill will realize positive fiscal impact from the revenue generated from offering vaccinations.

D. FISCAL COMMENTS:

DOH has promulgated a rule requiring applicants for the influenza immunization certificate program to pay a non-refundable \$55 fee to the Board of Pharmacy.⁴⁷ However, s. 465.189, F.S., does not authorize DOH to charge a fee for the certification program.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

None identified.

B. RULE-MAKING AUTHORITY:

DOH has sufficient rule-making authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On January 25, 2012, the Health & Human Services Quality Subcommittee adopted a strike-all amendment and reported the bill favorably as a committee substitute. The strike-all removes the provision authorizing pharmacy interns to administer vaccines and the EpiPen. Additionally, the strike-all removes the authorization to administer the varicella vaccine and authorizes the administration of the shingles vaccine.

One February 7, 2012, the Health & Human Services Committee adopted a strike-all amendment and reported the bill favorably as a committee substitute. The strike-all:

- Allows a pharmacist to administer the pneumococcal vaccines under a protocol with a physician.
- Places a restriction on the administration of the shingles vaccine such that the patient requires a prescription issued by a physician prior to the pharmacists administering the vaccine, and requires its administration to be under a protocol with a physician.
- Clarifies that a pharmacist may administer epinephrine with an autoinjector system in the event of an allergic reaction.
- Requires a pharmacist who administers vaccines or epinephrine to complete a 3-hour education course in the safe and effective administration of vaccines. The course:

⁴⁷ 64B16-26.1001, F.A.C.

- May be offered in a distance-learning format.
- Must be offered by a statewide physician professional association that meets certain criteria (i.e., the Florida Medical Association).
- Each pharmacist is required to submit confirmation of having completed the 3-hour course at the time of licensure renewal. Failure to comply results in the revocation of authorization to administer vaccines or epinephrine autoinjector systems. The authorization may be restored upon submission of confirmation of completing the 3-hour course.

This analysis is drafted to the committee substitute.