



- Submit to the board a copy of the protocol to administer the vaccines or epinephrine autoinjection (pharmacist only).

This bill also amends the definition of the term “practice of the profession of pharmacy” to include the administration of certain vaccines and epinephrine autoinjections to adults.

The department estimates that the costs for the first year will be \$22,955, but the revenues generated from the \$55 initial application fee from the pharmacy interns will be about \$151,000.

This bill substantially amends the following sections of the Florida Statutes: 465.189 and 465.003.

The effective date of this legislation is July 1, 2012.

## II. Present Situation:

### Pharmacists and Pharmacy Interns

Pharmacists and pharmacy interns are regulated under ch. 465, F.S., the Florida Pharmacy Act (Act), by the board within the Department of Health (DOH). A “pharmacist” is any person licensed under the Act to practice the profession of pharmacy.<sup>1</sup> A “pharmacy intern” is a person who is currently registered in and attending a duly accredited college or school of pharmacy, or who is a graduate of such a school or college of pharmacy, and who is duly and properly registered with the DOH as provided for under the DOH’s rules.<sup>2</sup>

The practice of the profession of pharmacy includes: compounding, dispensing, and consulting concerning contents, 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. Other pharmaceutical services include the monitoring of a patient’s drug therapy, assisting the patient in the management of his or her drug therapy, and review of the patient’s drug therapy and communication with the patient’s prescribing health care provider or the provider’s agent or other persons as specifically authorized by the patient, regarding the drug therapy. However, a person practicing pharmacy is not authorized to alter a prescriber’s directions, diagnoses or treat any disease, initiate any drug therapy, or practice medicine or osteopathic medicine, unless specifically permitted by law. A pharmacist is authorized 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 influenza virus immunizations to adults.<sup>3</sup>

Any person desiring to be licensed as a pharmacist must apply to the DOH to take the licensure examination. The DOH must examine each applicant who the board certifies has:

- Completed an application form and remitted an examination fee set by the board not to exceed \$100 plus the actual per-applicant cost to the DOH for purchase of portions of the

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<sup>1</sup> Section 465.003(10), F.S.

<sup>2</sup> Section 465.003(12), F.S.

<sup>3</sup> Section 465.003(13), F.S.

examination from the National Association of Boards of Pharmacy or a similar national organization.

- Submitted satisfactory proof that the applicant is not less than 18 years of age and is a recipient of a degree from a school or college of pharmacy accredited by an accrediting agency recognized and approved by the United States Office of Education; or is a graduate of a 4-year undergraduate pharmacy program of a school or college of pharmacy located outside the United States, has demonstrated proficiency in English by passing two English-speaking competency tests, has passed the Foreign Pharmacy Graduate Equivalency Examination that is approved by rule of the board, and has completed a minimum of 500 hours in a supervised work activity program within Florida under the supervision of a pharmacist licensed by the DOH, which program is approved by the board.
- Submitted satisfactory proof that the applicant has completed an internship program approved by the board, which must not exceed 2,080 hours.

The passing of the examination does not automatically confer rights or privileges upon the applicant in connection with the practice of pharmacy in Florida. To obtain such rights or privileges, the DOH must issue a license to practice pharmacy to the applicant who successfully completed the examination.

For pharmacy interns, the board may refuse to certify to the DOH or may revoke the registration of any intern for good cause, including grounds enumerated in ch. 465, F.S., for revocation of pharmacists' licenses. A pharmacy student or graduate is required to be registered by the DOH before being employed as an intern in a pharmacy in Florida. An intern may not perform any acts relating to the filling, compounding, or dispensing of medicinal drugs unless it is done under the direct and immediate personal supervision of a person actively licensed to practice pharmacy in Florida.<sup>4</sup>

Pharmacies utilized for the obtaining of internship experience must meet the following minimum requirements:

- The pharmacy must hold a current license or permit issued by the state in which it is operating and must have available all necessary equipment for professional services, including necessary reference works, official standards, and current professional journals.
- The pharmacy must be operated at all times under the supervision of a pharmacist and must be willing to train persons desiring to obtain professional experience.
- The pharmacy must establish to the program's satisfaction that the pharmacy fills, compounds, and dispenses a sufficient number, kind, and variety of prescriptions during the course of a year so as to afford to an intern a broad experience in the filling, compounding, and dispensing of prescription drugs.
- The pharmacy must have a clear record as to observance of federal, state, and municipal laws and ordinances covering any phase of activity in which it is engaged.
- A pharmacist may not be responsible for the supervision of more than one intern at any one time.<sup>5</sup>

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<sup>4</sup> Rule 64B16-26.2032, F.A.C.

<sup>5</sup> *Id.*

### **Administration of Influenza Virus Immunizations by Pharmacists**

In Florida, pharmacists may administer influenza virus immunizations to adults within the framework of an established protocol under a supervisory practitioner who is an allopathic or osteopathic physician. Each protocol must contain specific procedures for addressing any unforeseen allergic reaction to influenza virus immunizations.<sup>6</sup>

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 influenza virus immunizations.

A pharmacist administering influenza virus immunizations must maintain and make available patient records using the same standards for confidentiality and maintenance of such records as those that are imposed on health care practitioners under s. 456.057, F.S. These records are required to be maintained for a minimum of 5 years.<sup>7</sup>

The decision by a supervisory practitioner to enter into a protocol is a professional decision on the part of the practitioner, and a person may not interfere with a supervisory practitioner's 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.<sup>8</sup>

Any pharmacist seeking to administer influenza virus immunizations to adults must be certified to administer influenza virus immunizations pursuant to a certification program approved by the board in consultation with the Board of Medicine and the Board of Osteopathic Medicine. The certification program must, at a minimum, require that the pharmacist attend at least 20 hours of continuing education classes approved by the board and the program must have a curriculum of instruction concerning the safe and effective administration of influenza virus immunizations, including, but not limited to, potential allergic reactions to influenza virus immunizations.<sup>9</sup> The fee for influenza immunization certification is \$55.<sup>10</sup>

The written protocol between the pharmacist and supervising physician must include particular terms and conditions imposed by the supervising physician upon the pharmacist, relating to the administration of influenza virus immunizations by the pharmacist. Supervising physicians are required to review the administration of influenza virus immunizations by the pharmacists under such physician's supervision pursuant to the written protocol, and this review must take place as outlined in the written protocol. The pharmacist must submit to the board a copy of his or her protocol or written agreement to administer influenza virus immunizations.<sup>11</sup>

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<sup>6</sup> Section 465.189, F.S.

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*

<sup>9</sup> *Id.*

<sup>10</sup> Rule 64B16-26.1001, F.A.C.

<sup>11</sup> *Supra* fn. 6.

## Vaccines and Epinephrine Autoinjections

All 50 states authorize pharmacists to vaccinate people.<sup>12</sup> Therefore, the most accessible healthcare provider can positively impact public health and prevent disease by making vaccinations more readily available and less expensive.

Although every state allows pharmacists to administer immunizations, each state approaches immunizations differently. Some states require specific education or certification. Some limit the types of immunizations that can be administered, while other states limit the age of patients. Some states require pharmacists to have a prescription before administering an immunization, while others allow administration pursuant to protocol. Finally, some states limit the routes of immunization administration.<sup>13</sup>

Before being permitted to administer immunizations, most states require pharmacists to receive education in immunization administration. The most common educational requirements include completing state-specific courses in immunization administration, certificate programs in immunization administration, and immunization administration continuing education. Most states also require basic life support or cardiopulmonary resuscitation certification. Some states require ongoing continuing education and list specific timeframes for completion of the education, while other states require continuing education but give no specific guidelines for completion. Other states do not require any continuing education.<sup>14</sup>

The formulary of vaccines that can be administered by pharmacists also varies by state. Many states limit the formulary to the influenza and pneumococcal vaccines. Other states, such as Delaware, allow pharmacists to administer any injectable immunization or biologic contained in the *Orange Book*<sup>15</sup> that is administered in accordance with its Food and Drug Administration-approved indications. Still other states expand the scope of administration to include other routes of administration in addition to injection, such as oral or intranasal administration, while others allow pharmacists to administer immunizations by all routes of administration. Many states' laws limit administration to subcutaneous injection.<sup>16</sup>

Another variance between states is the minimum age restriction for which patients may receive the immunization in the protocol for a specific immunization. New York law allows pharmacists to administer the influenza or pneumococcal vaccines to patients 18 years of age or older. Oregon allows pharmacists to administer a large formulary of vaccines to patients older than 11 years of age. Some states do not set a minimum age limit.<sup>17</sup>

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<sup>12</sup> Immunization Action Coalition, *Vaccination Information for Healthcare Professionals*, July 21, 2009, available at: <http://www.immunize.org/laws/pharm.asp> (Last visited on December 8, 2011).

<sup>13</sup> Laura Carpenter, RPh, JD; *Pharmacist-administered immunizations: Trends in state laws*; September 2009, available at: [http://www.cedrugstorenews.com/userapp/lessons/page\\_view\\_ui.cfm?lessonuid=&pageid=B923321F24938AEE0854C1225838355F](http://www.cedrugstorenews.com/userapp/lessons/page_view_ui.cfm?lessonuid=&pageid=B923321F24938AEE0854C1225838355F) (Last visited on December 8, 2011).

<sup>14</sup> *Id.*

<sup>15</sup> The Electronic Orange Book for Approved Drug Products with Therapeutic Equivalence Evaluations is available on the U.S. Food and Drug Administration's website at: <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm> (Last visited on December 8, 2011).

<sup>16</sup> *Supra* fn. 12.

<sup>17</sup> *Id.*

### ***Influenza Vaccine***

There are two types of vaccines to protect people from influenza (the flu):

- The “flu shot” — an inactivated vaccine (containing killed virus) that is given with a needle, usually in the arm. The flu shot is approved for use in people older than 6 months, including healthy people and people with chronic medical conditions.
- The nasal-spray flu vaccine —a vaccine made with live, weakened flu viruses that do not cause the flu is approved for use in healthy people 2 to 49 years of age who are not pregnant.<sup>18</sup>

The seasonal flu vaccine protects against three influenza viruses that research indicates will be most common during the upcoming season.<sup>19</sup> The viruses in the vaccine change each year based on international surveillance and scientists’ estimations about which types and strains of viruses will circulate in a given year. About 2 weeks after vaccination, antibodies that provide protection against influenza virus infection develop in the body.

### ***Varicella-Zoster Vaccine***

Varicella-zoster virus is one of eight herpes viruses known to infect humans. The initial infection of any person with this virus leads to varicella, or chickenpox. Once infected, the person carries the virus in his or her body for life, although this often does not lead to any further symptoms. As a person’s immune system declines either from normal aging or disease, however, the virus can reactivate to cause zoster, or shingles, a condition in which painful sores erupt on the skin over a person’s rib cage. Although these diseases are two forms of the same virus, they are treated differently and have different vaccines.

The varicella vaccine is the best way to prevent chickenpox and can be administered to patients of any age. Vaccination not only protects vaccinated persons, it also reduces the risk for exposure in the community for persons unable to be vaccinated because of illness or other conditions, including those who may be at greater risk for severe disease. While no vaccine is 100 percent effective in preventing disease, the chickenpox vaccine is very effective: about 8 to 9 of every 10 people who are vaccinated are completely protected from chickenpox. In addition, the vaccine almost always prevents severe disease. If a vaccinated person does get chickenpox, it is usually a very mild case lasting only a few days and involving fewer skin lesions (usually less than 50), mild or no fever, and few other symptoms.<sup>20</sup>

Almost one out of every three people in the United States will develop shingles. There are an estimated 1 million cases each year in the United States, about half of which occur among men and women 60 years old or older.<sup>21</sup> The only way to reduce the risk of developing shingles and

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<sup>18</sup> Centers for Disease Control and Prevention (CDC), *Seasonal Influenza (Flu)*, available at: <http://www.cdc.gov/flu/protect/keyfacts.htm> (Last visited on December 8, 2011).

<sup>19</sup> CDC, *Vaccine Selection for the 2011-2012 Influenza Season*, available at: <http://www.cdc.gov/flu/about/qa/vaccine-selection.htm> (Last visited on December 8, 2011).

<sup>20</sup> CDC, *Varicella (Chickenpox) Vaccination*, available at: <http://www.cdc.gov/vaccines/vpd-vac/varicella/default.htm> (Last visited on December 8, 2011).

<sup>21</sup> CDC, *Shingles (Herpes Zoster): Overview*, available at: <http://www.cdc.gov/shingles/about/overview.html> (Last visited on December 8, 2011).

the long-term pain that can follow shingles is to get the zoster vaccine. The vaccine is licensed for persons aged 60 years and older.<sup>22</sup>

The zoster vaccine is approximately 14 times as powerful as the varicella vaccine, and the two cannot be interchanged.<sup>23</sup>

### ***Pneumococcal Vaccine***

Pneumococcal disease is an infection caused by a type of bacteria called *Streptococcus pneumoniae* (pneumococcus). The bacteria can lead to various types of disease, depending on what part of the body is infected and the state of the person's immune system. Diseases that can be caused by pneumococcus include lung infections (pneumonia), blood infections (bacteremia), ear infections (otitis media), and brain infections (meningitis). Pneumococcus is in many people's noses and throats and is spread by coughing, sneezing, or contact with respiratory secretions. Why it suddenly invades the body and causes disease is unknown.<sup>24</sup>

The symptoms of pneumococcal pneumonia include fever, cough, shortness of breath, and chest pain. The symptoms of pneumococcal meningitis include stiff neck, fever, mental confusion and disorientation, and visual sensitivity to light (photophobia). The symptoms of pneumococcal bacteremia may be similar to some of the symptoms of pneumonia and meningitis, along with joint pain and chills. The symptoms of otitis media typically include a painful ear, a red or swollen eardrum, and sometimes sleeplessness, fever and irritability.<sup>25</sup>

Pneumococcal vaccine is very good at preventing severe disease, hospitalization, and death. However, it is not guaranteed to prevent infection and symptoms in all people. The pneumococcal vaccine is recommended for certain categories of children, all adults over age 65, and people between ages 2 and 65 who have long-term health problems.<sup>26</sup>

### ***Epinephrine Autoinjection***

Epinephrine may be administered by a one-dose autoinjector, known as an EpiPen or Twinject. Epinephrine is used in emergencies to treat very serious allergic reactions (anaphylactic reactions) to insect stings or bites, foods, drugs, or other substances. Epinephrine acts quickly to improve breathing, stimulate the heart, raise a dropping blood pressure, reverse hives, and reduce swelling of the face, lips, and throat.<sup>27</sup>

Epinephrine autoinjectors should be only used on the thigh, through clothing if necessary. To avoid injecting into a vein, which would cause a dangerous reaction, the medicine should be injected into the front outer thigh and never into the buttocks. The effects of epinephrine are

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<sup>22</sup> CDC, *Shingles (Herpes Zoster): Prevention and Treatment*, available at: <http://www.cdc.gov/shingles/about/prevention-treatment.html> (Last visited on December 8, 2011).

<sup>23</sup> CDC, *Herpes Zoster Vaccination for Health Care Professionals*, available at: <http://www.cdc.gov/vaccines/vpd-vac/shingles/hcp-vaccination.htm> (Last visited on December 9, 2011).

<sup>24</sup> CDC, *Vaccines and Immunizations: Pneumococcal Disease In-Short*, available at: <http://www.cdc.gov/vaccines/vpd-vac/pneumo/in-short-both.htm> (December 8, 2011).

<sup>25</sup> *Id.*

<sup>26</sup> *Id.*

<sup>27</sup> MedicineNet.com, *Epinephrine Auto-Injector*, available at: [http://www.medicinenet.com/epinephrine\\_auto-injector/article.htm](http://www.medicinenet.com/epinephrine_auto-injector/article.htm) (Last visited on December 8, 2011).

rapid, but not long-lasting. After injecting epinephrine, a person should seek immediate medical attention.<sup>28</sup>

### III. Effect of Proposed Changes:

This bill authorizes a pharmacist or a pharmacy intern, having proper certification and working under a pharmacist's supervision, to administer within the framework of an established protocol under a supervising physician licensed under ch. 458, F.S. (allopathic physician) or licensed under ch. 459, F.S. (osteopathic physician) the following:

- Influenza vaccines to adults 18 years of age or older. (The bill authorizes a pharmacy intern to administer the influenza vaccine since pharmacists already may administer influenza vaccines.)
- Varicella zoster vaccines to adults 60 years of age or older.
- Pneumococcal vaccines to adults 65 years of age or older.
- Epinephrine using an autoinjector delivery system to adults 18 years of age or older who are suffering from an anaphylactic reaction.

However, in order to administer a vaccine or an epinephrine autoinjection, the pharmacist and pharmacy intern must:

- Maintain at least \$200,000 of professional liability insurance (pharmacist only);
- Maintain and make available patient records for a minimum of 5 years, using the same standards for confidentiality and maintenance of such records as those that are imposed on health care practitioners under s. 456.057, F.S.;
- Be certified to administer the vaccines or epinephrine autoinjection pursuant to a certification program approved by the board, and proof of such certification must be shown to the supervising physician. The program must require that the pharmacist or pharmacy intern attend at least 20 hours of continuing education classes approved by the board and must include instruction concerning the safe and effective administration of the influenza, varicella zoster, and pneumococcal vaccines and the epinephrine autoinjection, including potential adverse reactions; and
- Have a supervising physician review the administration of the vaccines or epinephrine autoinjections.

The pharmacist or pharmacy intern must also follow a written protocol for the administration of vaccines or epinephrine autoinjections. The protocol must include particular terms and conditions imposed by a supervising allopathic or osteopathic physician, which must be appropriate to the pharmacist's or the pharmacy intern's training and certification for the vaccine or epinephrine autoinjection; include specific categories and conditions among patients for whom the supervising physician authorizes the pharmacist or pharmacy intern to administer a vaccine or epinephrine autoinjection; be approved by the owner of the pharmacy employing the pharmacist; and contain specific procedures for addressing any unforeseen adverse reaction to the vaccine or epinephrine autoinjection. The pharmacist must submit to the board a copy of the protocol to administer the vaccines or epinephrine autoinjections.

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<sup>28</sup> *Id.*



This bill also amends the definition of the term “practice of the profession of pharmacy” to include the administration of influenza, varicella zoster, and pneumococcal vaccines and the epinephrine autoinjection to adults.

The bill provides an effective date of July 1, 2012.

#### **IV. Constitutional Issues:**

##### **A. Municipality/County Mandates Restrictions:**

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

##### **B. Public Records/Open Meetings Issues:**

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

##### **C. Trust Funds Restrictions:**

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

#### **V. Fiscal Impact Statement:**

##### **A. Tax/Fee Issues:**

None.

##### **B. Private Sector Impact:**

Pharmacies may generate additional revenue because they will be able to offer more vaccination services to customers. Pharmacy interns will be able to administer certain vaccines and epinephrine autoinjections.

##### **C. Government Sector Impact:**

The board will experience a recurring increase in workload related to processing certifications for the administration of vaccines or epinephrine autoinjections from pharmacists and pharmacy interns. Licensed pharmacists who are already certified to provide influenza vaccines will be able to provide additional vaccines and epinephrine autoinjections for no additional fee upon completion of a board-approved training course. A \$55 fee is required for initial vaccine administration certification, and the board will experience a positive fiscal impact related to this as pharmacy interns apply for certification.

Estimated processing costs will be \$22,955 in the first fiscal year after implementation and \$3,122 in the second year, although these costs do not include processing of extended

certifications for pharmacists already permitted to administer influenza vaccines. Estimated fee revenues are \$151,041 for the first fiscal year after implementation and \$20,544 for the second.<sup>29</sup>

## VI. Technical Deficiencies:

The term “varicella zoster vaccine” in lines 30-31 is incorrect. The varicella vaccine and the zoster vaccine are two separate entities and cannot be combined or interchanged. The varicella vaccine is recommended for all persons who have not had chickenpox, while the zoster vaccine is recommended for persons over age 60.

The term “supervision” is used in lines 24, 86, 96, and 104 to require a pharmacist to supervise a pharmacy intern. It is not clear whether the pharmacist is required to provide “direct supervision.” Rule 64B16-26.2032, F.A.C., relating to pharmacy interns, requires an intern to perform certain acts under the “direct and immediate personal supervision” of a pharmacist. If the intent of the bill is to require direct supervision by a pharmacist over a pharmacy intern, the language in this rule should be used for consistency.

## VII. Related Issues:

It is unclear in lines 32-33 why the bill authorizes pharmacists and pharmacy interns to provide pneumococcal vaccines only to adults aged 65 and older when this vaccine is also recommended for adults under age 65 with certain chronic medical conditions.

The relationship between the physician and the pharmacy intern is unclear. For example, is the pharmacy intern required to enter into a protocol with the supervising physician? The pharmacy intern is not required to maintain professional liability insurance, and it is not clear whether the intern would be covered under the pharmacist’s policy or the physician’s policy.

Similarly, there is no statute or rule which states how the supervising physician is to supervise the pharmacist. It is unclear whether direct or indirect supervision is required and whether the pharmacist or the supervising physician will ultimately be held liable for adverse events related to vaccine administration.

Issues concerning amendment barcode 741504:

Anaphylactic reactions are medical emergencies which can lead to the death of patients within minutes. Obtaining a prescription before a pharmacist administers an epinephrine autoinjection might be impracticable.

Physician assistants and nurse practitioners are also authorized to prescribe vaccines, but no provision is made to accept their prescriptions in this bill. Vaccines are an important element of primary care, and physician assistants and nurse practitioners constitute a large proportion of the primary care providers in the state.

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<sup>29</sup> Department of Health, *Bill Analysis, Economic Statement, and Fiscal Note for SB 850*. A copy is on file with the Senate Health Regulation Committee.

**VIII. Additional Information:**

- A. **Committee Substitute – Statement of Substantial Changes:**  
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

- B. **Amendments:**

**Barcode 741504 by Health Regulation on January 25, 2012:**

This amendment removes all reference to pharmacy interns from the bill and corrects a technical error in the name of one of the vaccines. The amendment also requires pharmacists may only administer vaccines or epinephrine autoinjections pursuant to a prescription from a licensed allopathic or osteopathic physician. Provisions concerning vaccine and epinephrine autoinjection administration certification programs are changed to require completion of a ten-hour program offered by a statewide professional organization of physicians which is accredited as AMA PRA Category 1.

This amendment would remove all fiscal impact relating to the pharmacy interns. The department estimates that the mailing cost of notifying providers of the remaining changes would cost about \$17,530.