

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL: CS/SB 792

INTRODUCER: Health Policy Committee and Senator Bean

SUBJECT: Pharmacy

DATE: March 11, 2015

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Stovall	HP	Fav/CS
2.			AHS	
3.			FP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 792 authorizes a registered pharmacy intern to administer certain immunizations or vaccines to adults under the supervision of a pharmacist who is certified to administer vaccines and within the framework of a protocol under a supervising physician. The bill requires a ratio of one pharmacist to one intern when a registered intern is administering vaccines. Prior to administering vaccines, a pharmacy intern will need to obtain certification which is based on at least 20 hours of coursework that has been approved by the Board of Pharmacy.

The bill also expands the specified list of vaccines that a pharmacist may administer, which may also be administered by a registered intern, to include immunizations or vaccines listed in schedules established by the United States Centers for Disease Control and Prevention, any additional updates to those lists which are authorized by rules of the Board of Pharmacy, and immunizations or vaccines approved by the board in response to a state of emergency declared by the Governor.

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 of Pharmacy (board) within the Department of Health (DOH or department).

A “pharmacist” is a person licensed under the Act to practice the profession of pharmacy.¹ A “pharmacy intern” is a person who is currently registered in and attending an accredited college or school of pharmacy, or who is a graduate of such a school or college of pharmacy, and who is registered as a pharmacy intern with the department.²

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.
- Monitoring a patient’s drug therapy, assisting the patient in managing his or her drug therapy, and reviewing the patient’s drug therapy and communicating 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.
- Transmitting information from persons authorized to prescribe medicinal drugs to their patients.
- Administering vaccines to adults.³

To be licensed as a pharmacist in Florida, one must:⁴

- Complete an application and remit an examination fee;
- Be at least 18 years of age;
- Have received a degree from an accredited and approved school or college of pharmacy; 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, has passed the board-approved Foreign Pharmacy Graduate Equivalency Examination, 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;
- Have completed an internship program of 2,080 hours, approved by the board; and
- Successfully completed the board-approved examination.

The internship experience for the purposes of qualifying for the examination must be obtained in a community pharmacy, institutional pharmacy, or any board-approved pharmacy practice which includes significant aspects of the practice of pharmacy.⁵ One of many requirements for a pharmacy in which an approved internship may occur is that the pharmacy establish that it 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.⁶ Proponents of the bill contend that in order to more fully fulfill the educational objectives of an internship, an intern should be authorized to administer vaccines

¹ Section 465.003(10), F.S.

² Section 465.003(12), F.S.

³ Section 465.003(13), F.S.

⁴ Section 465.007, F.S. The department may also issue a license by endorsement to a pharmacist who is licensed in another state upon meeting the applicable requirements that are set forth in law and rule. *See* s. 465.0075, F.S.

⁵ Fla. Admin. Code R. 64B16-26.2032(5).

⁶ Fla. Admin. Code R. 64B16-26.2032(6)(c).

to adults under appropriate supervision since the administration of vaccines to adults is a component of the practice of pharmacy.

An intern may not perform any acts relating to filing, 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.⁷ Neither the Act nor the board's rules limit the number of interns a pharmacist may supervise. A pharmacy student or graduate is required to be registered by the DOH before being employed as an intern in a pharmacy in Florida. In Fiscal Year 2013-2014, there were 10,914 registered pharmacy interns actively practicing in the state.⁸

Vaccines and Immunizations

A vaccine is a product that stimulates a person's immune system to produce immunity to a specific disease, protecting the person from that disease. Vaccines are usually administered through needle injections, but can also be administered by mouth or sprayed into the nose. Immunization is a process by which a person becomes protected against a disease through vaccination. This term is often used interchangeably with vaccination or inoculation.⁹

Authorization in Florida

Currently, a pharmacist licensed in Florida may administer vaccines for influenza, pneumococcal, meningococcal, and shingles to an adult in accordance with a protocol under a supervising physician and guidelines of the U.S. Centers for Disease Control and Prevention (CDC). A pharmacist may also administer epinephrine using an autoinjector delivery system to address any unforeseen allergic reaction to an administered vaccine.¹⁰

Prior to administering vaccines, a pharmacist must be certified to administer the vaccines pursuant to a 20-hour certification program approved by the board in consultation with the boards of medicine and osteopathic medicine.¹¹ Additionally, the pharmacist must submit to the board a copy of his or her protocol. A pharmacist may not enter into a protocol unless he or she maintains at least \$200,000 of professional liability insurance. A pharmacist who administers vaccines must also maintain applicable patient records. Approximately 11,323 or 37 percent of the actively licensed pharmacists are certified to administer vaccines.¹²

The Legislature has acted three times since 2007 addressing the authorization for pharmacists to administer vaccines. Chapter 2007-152, L.O.F., established the framework for pharmacists to administer vaccines. At that time, the only vaccination authorized was influenza. In 2012, the Legislature authorized the administration of the pneumococcal vaccine, the administration of the shingles vaccine pursuant to a physician's prescription, and the use of epinephrine for an allergic reaction.¹³ Then in 2014, the Legislature added meningococcal to the list of vaccines and

⁷ Fla. Admin. Code R. 64B16-26.2032(4).

⁸ Department of Health, *Senate Bill 792 Analysis* (Feb. 11, 2015) (on file with the Senate Committee on Health Policy).

⁹ See U.S. Centers for Disease Control and Prevention, *Immunizations: The Basics*, (updated Sept. 25, 2014) available at <http://www.cdc.gov/vaccines/vac-gen/imz-basics.htm>, (last visited Mar. 6, 2015)

¹⁰ Section 465.189, F.S.

¹¹ Section 465.189, F.S., and Fla. Admin. Code. R. 64B16-26.1031

¹² *Supra* note 8.

¹³ Ch. 2012-60, Laws of Fla.

eliminated the requirement for a physician's prescription as the basis for a pharmacist to administer the shingles vaccine.¹⁴

Authorizations in Other States

Forty-four states or territories currently authorize pharmacy interns to administer vaccines. Most commonly, the intern must be trained, such as having completed a certificate training program, and must operate under the supervision of a trained pharmacist.¹⁵ Florida is one of a handful of states that does not authorize pharmacists to administer a more expansive list of vaccines, including Td/Tdap and HPV.¹⁶

Recommended Adult Immunization Schedule

Annually, the CDC publishes a recommended schedule of immunizations for adults (anyone 19 years of age or older).¹⁷ The schedule includes the recommended age groups, number of doses, and medical indications for which administration of the currently licensed and listed vaccine is commonly indicated. Prior to being published each year, the Advisory Committee on Immunization Practices (ACIP) reviews the recommended adult immunization schedule to ensure that the schedule reflects current recommendations for the listed vaccines.¹⁸

The recommended adult immunization schedule is also approved by the ACIP, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, the American College of Physicians, and the American College of Nurse-Midwives.¹⁹

The adult immunization schedule as of February 2015, lists the following vaccines:²⁰

- Influenza (flu)*
- Tetanus, diphtheria, pertussis (Td/Tdap)
- Varicella (chickenpox)
- Human papillomavirus (HPV) Female
- Human papillomavirus (HPV) Male
- Zoster (shingles)*
- Measles, mumps, rubella (MMR)
- Pneumococcal 13-valent conjugate (PCV13)*
- Pneumococcal polysaccharide (PPSV23)*
- Meningococcal*
- Hepatitis A
- Hepatitis B

¹⁴ Ch. 2014-113, Laws of Fla.

¹⁵ American Pharmacists Association, *Pharmacist Administered Vaccines*, slide 6 (updated January 31, 2015), available at http://www.pharmacist.com/sites/default/files/files/Pharmacist_IZ_Authority_1_31_15.pdf, (last visited Mar. 6, 2015).

¹⁶ *Id.* slides 1, 9, and 11.

¹⁷ The most current recommended adult immunization schedule for 2015, is available at <http://www.cdc.gov/vaccines/schedules/hcp/adult.html>, (last visited Mar. 6, 2015). For past immunization schedules see <http://www.cdc.gov/vaccines/schedules/past.html>, (last visited Mar. 6, 2015).

¹⁸ U.S. Centers for Disease Control and Prevention, *Adult Immunization Schedules* (2015) available at <http://www.cdc.gov/vaccines/schedules/hcp/adult.html>, (last visited Mar. 11, 2015).

¹⁹ *Id.*

²⁰ *Id.*

- Haemophilus influenza type b (Hib)

* Currently authorized in Florida.

The recommended adult immunization schedule does change from year-to-year, typically with respect to the footnotes and full ACIP vaccine recommendations. For example, the list of 13 vaccines did not change from 2014 to 2015; however, the recommendation for PCV13 changed from “recommended if some other risk is present” for those aged 65 and older to “recommended.” The list for 2010 included 10 vaccines. Changes over the last few years include the addition of: HPV Male in 2012, PCV13 in 2013, and Hib in 2014.²¹

International Travel

Some types of international travel, especially to developing countries and rural areas, have higher health risks. These risks depend on a number of factors including where one is traveling, activities while traveling, current health status, and vaccination history. Vaccine-preventable diseases that are rarely seen in the United States, like polio, can still be found in other parts of the world.²²

The CDC recommends seeing one’s healthcare professional, or visiting a travel clinic since not all primary care physicians stock travel vaccines, at least 4-6 weeks prior to any international travel. This allows time to complete any vaccine series and gives the body time to build up immunity.

The CDC maintains an interactive website for both travelers and clinicians, by destination and certain traveler conditions, which provides recommendations on vaccines. Options for traveler conditions include, but is not limited to, pregnant, immune-compromised, or providing mission/disaster relief.²³

Vaccine Information Statement and Adverse Incident Reporting

A Vaccine Information Statement (VIS) is a document, produced by the CDC, which informs vaccine recipients, or their parents or legal representatives, about the benefits and risks of a vaccine they are receiving. All vaccine providers are required by the National Vaccine Childhood Injury Act²⁴ to give the appropriate VIS to the patient, or parent or legal representative, prior to every dose of specified vaccines. The CDC also requires providers of other vaccines to provide a VIS under certain conditions. The VIS must be given regardless of the age of the recipient.²⁵

²¹ Go to: <http://www.cdc.gov/vaccines/schedules/past.html>, and select the applicable year, (last visited Mar. 6, 2015).

²² U.S. Centers for Disease Control and Prevention, *Travel Smart: Get Vaccinated*, <http://www.cdc.gov/Features/vaccines-travel/index.html>, (last visited Mar. 6, 2015).

²³ U.S. Centers for Disease Control and Prevention, *Traveler’s Health: Destinations*, <http://wwwnc.cdc.gov/travel/destinations/list>, (last visited Feb. 23, 2015).

²⁴ NCVIA - 42 U.S.C. § 300aa-26

²⁵ U.S. Centers for Disease Control and Prevention, *Vaccine Information Statements*, (last update June 18, 2013) (last reviewed June 13, 2014) <http://www.cdc.gov/vaccines/hcp/vis/about/facts-vis.html>, (last visited Mar. 6, 2015).

In addition to distributing a VIS, providers are required to record specific information in the patient's medical record or in a permanent office log. The information that must be recorded is:²⁶

- The edition date of the VIS, (a VIS may be updated frequently);
- The date the VIS is provided, i.e., the date of the visit when the vaccine is administered;
- The office address and name and title of the person who administers the vaccine;
- The date the vaccine is administered; and
- The vaccine manufacturer and lot number.

The Vaccine Adverse Event Reporting System (VAERS) is primarily concerned with monitoring adverse health events following vaccination but it accepts all reports, including reports of vaccination errors. Using clinical judgment, healthcare professionals can decide whether or not to report a medical error at their own discretion. For example, a healthcare professional may elect to report vaccination errors that do not have an associated adverse health event, especially if they think the vaccination error may pose a safety risk (e.g., administering a live vaccine to an immunocompromised patient) or that the error would be preventable with public health action or education. There are three ways to report to VAERS – online, by facsimile, or by mail.²⁷

III. Effect of Proposed Changes:

CS/SB 792 expands access and availability of certain immunizations for adults by expanding the list of vaccines that a pharmacist may administer and authorizing a registered pharmacy intern, once certified, to administer those same vaccines under the supervision of a pharmacist who is certified to administer vaccines.

Rather than specifying individual immunizations or vaccines that may be administered by a pharmacist or registered intern, the bill authorizes administration of the immunizations or vaccines that are listed in the adult immunization schedule as of February 2015, by the U.S. Centers for Disease Control and Prevention. Currently, the statute authorizes the administration of vaccines for influenza, pneumococcal, meningococcal and shingles to adults (19 years of age or older).²⁸ By referencing the CDC adult immunization schedule as of February 2015, this bill adds:

- Tetanus, diphtheria, pertussis (Td/Tdap)
- Varicella (chickenpox)
- Human papillomavirus (HPV) Female
- Human papillomavirus (HPV) Male
- Measles, mumps, rubella (MMR)
- Hepatitis A
- Hepatitis B
- Haemophilus influenza type b (Hib)

²⁶ *Id.*

²⁷ See Vaccine Adverse Events Reporting System, <http://vaers.hhs.gov/esub/index> (last visited Mar. 6, 2015).

²⁸ Section 465.189, F.S., does not define an adult. However, this section of law authorizes administration in accordance with the guidelines of the CDC, which defines an adult as a person who is 19 years of age or older.

The administration of immunizations or vaccines that are recommended by the CDC for international travel as of July 1, 2015, as well as those approved by the board in response to a Governor-declared state of emergency may also be administered in accordance with the requirements in this section of law.

The bill grants rulemaking authority for the board to authorize additional immunizations or vaccines as the CDC adds to the adult immunization schedule or the CDC recommends additional immunizations or vaccines for international travel.

The bill requires a registered pharmacy intern to be certified to administer vaccines pursuant to a program approved by the board, and the boards of medicine and osteopathic medicine, which includes at least 20 hours of coursework. Additionally the bill sets a supervision ratio of one registered intern to one pharmacist when the intern is administering immunizations.

The effective date of the bill is July 1, 2015.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Pharmacy interns seeking certification to administer vaccinations will incur a \$55 initial application fee. The public may be able to obtain applicable vaccinations at their local pharmacy, which may be more expedient and possibly less expensive than scheduling an appointment at a physician's office, however any such savings is indeterminate.

C. Government Sector Impact:

The department²⁹ estimates potential certification fees of \$259,820³⁰ less the 8 percent general revenue surcharge of \$20,786, for a net revenue in the first biennium of \$239,034. The department estimates total expenditures of \$36,328 related to the costs for processing certification applications, based on the processing cost of \$7.69 per application.

The department indicates that the increase in workload associated with application and website modifications, updates to the Licensing and Enforcement Information Database System, and rulemaking can be absorbed within existing resources.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the section 465.189 of the Florida Statutes.

IX. Additional Information:**A. Committee Substitute – Statement of Substantial Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on March 10, 2015:

The CS requires the supervising pharmacist to be certified to administer vaccines, and references a more current recommended adult immunization list which is the one in effect as of February 2015. The CS also requires a one to one supervision ratio when the intern administers an immunization.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

²⁹ *Supra* note 8.

³⁰ The certification fee estimate of \$259,820 is based on 4,038 currently registered interns (calculated as 10,914 total registered inters X 37%, number of certified pharmacists) + 686 newly registering interns (calculated as 1,855 new registered intern applications X 37%) for 4,724 applications for certification X \$55 application fee.