

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 Fiscal Policy

BILL: CS/SB 792

INTRODUCER: Health Policy Committee and Senator Bean

SUBJECT: Pharmacy

DATE: April 14, 2015

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Stovall	HP	Fav/CS
2.	Brown	Pigott	AHS	Recommend: Favorable
3.	Jones	Hrdlicka	FP	Pre-meeting

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 792 authorizes a registered pharmacy intern, who is certified, to administer certain immunizations or vaccines to adults under the supervision of a certified pharmacist. The bill requires a ratio of one pharmacist to one intern when a registered intern is administering vaccines. The certification program for a registered pharmacy intern to administer vaccines must consist of at least 20 hours of course work.

The bill also expands the specified list of vaccines that a certified pharmacist or registered intern may administer, to include:

- Immunizations or vaccines listed in schedules established by the Centers for Disease Control and Prevention; and
- Immunizations or vaccines approved by the board in response to a state of emergency declared by the Governor.

The Board of Pharmacy is authorized to update the immunizations or vaccines by rule.

The Medical Quality Assurance Trust Fund within the Department of Health will receive estimated revenues of approximately \$259,820 and will incur estimated costs of approximately \$36,328 over the first two years of the bill's implementation.

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). 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 DOH.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; and
- Administering vaccines to adults.³

To be licensed as a pharmacist in Florida, a person must:

- 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 be a graduate of a 4-year undergraduate pharmacy program of a school or college of pharmacy located outside the United States, demonstrate proficiency in English, pass the board-approved Foreign Pharmacy Graduate Equivalency Examination, and complete a minimum of 500 hours in a supervised work activity program within Florida under the supervision of a DOH-licensed pharmacist;
- Have completed an internship program of 2,080 hours; and
- Successfully completed the board-approved examination.⁴

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

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 Rule 64B16-26.2032(5), F.A.C.

course of a year so as to afford an intern with a broad experience in the filling, compounding, and dispensing of prescription drugs.⁶

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 FY 2013-14, 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. 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. Vaccines are usually administered through needle injections, but some can be administered by mouth or sprayed into the nose.⁹

Authorization in Florida

Currently, a licensed pharmacist 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 Centers for Disease Control and Prevention (CDC).¹⁰ A pharmacist may also administer epinephrine using an auto-injector delivery system to address any unforeseen allergic reaction to an administered vaccine.¹¹

Prior to administering vaccines, a pharmacist must complete a 20-hour board approved certification program and maintain 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 to address the authorization for pharmacists to administer vaccines. In 2007, the framework for pharmacists to administer vaccines was established. At that time, the only vaccination authorized was influenza.¹³ 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.¹⁴ In 2014, the Legislature added meningococcal to the list of vaccines and eliminated

⁶ Rule 64B16-26.2032(6)(c), F.A.C.

⁷ Rule 64B16-26.2032(4), F.A.C.

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

⁹ 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 April 10, 2015)

¹⁰ Section 465.189(1), F.S.

¹¹ Section 468.189(2), F.S.

¹² *Supra* note 8.

¹³ Chapter 2007-152, L.O.F.

¹⁴ Chapter 2012-60, L.O.F.

the requirement for a physician's prescription as the basis for a pharmacist to administer the shingles vaccine.¹⁵

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.¹⁶ Florida is one of a handful of states that do not authorize pharmacists to administer a more expansive list of vaccines, including Td/Tdap and HPV.¹⁷

Recommended Adult Immunization Schedule

Annually, the CDC publishes a recommended schedule of immunizations for adults (anyone 19 years of age or older). 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.¹⁸

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

- 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; and
- Haemophilus influenza type b (Hib).¹⁹

* Currently authorized for administration by certified pharmacists in Florida.

International Travel

Some types of international travel, especially to developing countries and rural areas, have higher health risks. Vaccine-preventable diseases that are rarely seen in the United States, like polio, can still be found in other parts of the world. The CDC recommends seeing one's healthcare professional or visiting a travel clinic at least four-to-six weeks prior to any

¹⁵ Chapter 2014-113, L.O.F.

¹⁶ American Pharmacists Association, *Pharmacist Administered Vaccines*, slide 6 (updated Jan. 31, 2015), available at http://www.pharmacist.com/sites/default/files/files/Pharmacist_IZ_Authority_1_31_15.pdf (last visited April 10, 2015).

¹⁷ *Id.* slides 1, 9, and 11.

¹⁸ Centers for Disease Control and Prevention, *Adult Immunization Schedules* (2015), (last updated April 6, 2015) available at <http://www.cdc.gov/vaccines/schedules/hcp/adult.html> (last visited April 10, 2015).

¹⁹ *Id.*

international travel, since not all primary care physicians stock travel vaccines. This allows time to complete any vaccine series and gives the body time to build up immunity.²⁰

Vaccine Information Statement and Adverse Incident Reporting

A Vaccine Information Statement (VIS) is a CDC produced document that informs vaccine recipients, or their parents or legal representatives, about the benefits and risks of a vaccine they are receiving.²¹ The National Vaccine Childhood Injury Act²² requires all vaccine providers to give the appropriate VIS to the patient, or parent or legal representative, prior to every dose of a vaccine.²³

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.²⁴

The Vaccine Adverse Event Reporting System (VAERS) accepts and monitors all of the reports concerning any significant adverse events after a vaccination. It is in the discretion of the healthcare professionals to decide whether to report a medical error. The VAERS accepts reports online, by facsimile, or by mail.²⁵

III. Effect of Proposed Changes:

The bill expands access and availability of certain immunizations for adults by expanding the list of vaccines a pharmacist may administer and authorizing a registered pharmacy intern, once certified, to administer vaccines under the supervision of a certified pharmacist.

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 CDC adult immunization schedule as of February 2015. Currently, the statute authorizes the administration of vaccines for influenza, pneumococcal, meningococcal and shingles to adults (19 years of age or older).²⁶ 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;

²⁰ Centers for Disease Control and Prevention, *Travel Smart: Get Vaccinated*, (last updated April 9, 2015) available at <http://www.cdc.gov/Features/vaccines-travel/index.html> (last visited April 10, 2015).

²¹ Centers for Disease Control and Prevention, *Vaccine Information Statements*, (updated June 18, 2013) available at <http://www.cdc.gov/vaccines/hcp/vis/about/facts-vis.html> (last visited April 10, 2015).

²² 42 U.S.C. s. 300aa-26

²³ *Supra* note 21.

²⁴ *Id.*

²⁵ Vaccine Adverse Events Reporting System, *Report an Adverse Event*, available at <http://vaers.hhs.gov/esub/index> (last visited April 10, 2015).

²⁶ 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.

- Hepatitis B; and
- Haemophilus influenza type b (Hib).²⁷

The bill specifies that 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 be administered.

The bill requires a registered pharmacy intern to take a certification program consisting of at least 20 hours of course work to become certified to administer vaccines. Additionally, the bill requires a supervision ratio of one registered intern to one pharmacist when the intern is administering immunizations.

The bill is effective 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:

Under the bill, 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 are indeterminate.

²⁷ *Supra* note 18.

C. Government Sector Impact:

The DOH estimates potential increase of \$259,820 in certification fees.²⁸ The DOH 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 DOH 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:

The bill grants rulemaking authority for the board to authorize additional immunizations or vaccines that the CDC adds to the adult immunization schedule or recommends additional immunizations or vaccines for international travel. The board must also adopt rules for a certification program for interns.

VIII. Statutes Affected:

This bill substantially amends 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.

²⁸ *Supra* note 8. The certification fee estimate of \$259,820 is based on 4,038 currently registered interns (calculated as 10,914 total registered interns X 37%, the 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.