

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 279 Pharmacy

SPONSOR(S): Pigman

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

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee		Castagna	Poche
2) Health & Human Services Committee			

SUMMARY ANALYSIS

Section 465.189, F.S., authorizes pharmacists to administer the influenza, pneumococcal, meningococcal, and shingles vaccines to adults within an established protocol with a supervising physician. Before administering a vaccine, a pharmacist must apply to the Board of Pharmacy (Board), under the Department of Health's (DOH) Division of Medical Quality Assurance, for immunization certification and pay a \$55 fee. To obtain certification, a pharmacist must demonstrate that he or she has successfully completed a Board-approved 20-hour vaccine administration certification program regarding the safe and effective administration of vaccines.

HB 279 adds the following vaccines to the list of vaccines a certified pharmacist may provide:

- Vaccines listed in the Centers for Disease Control and Prevention's (CDC) Adult Immunization Schedule (Schedule);
- Vaccines listed in the CDC's Health Information for International Travel; and
- Vaccines approved by the Board in response to a state of emergency declared by the Governor.

The bill authorizes pharmacy interns to administer vaccines upon completion of a 20-hour Board-approved vaccine administration certification program and payment of a \$55 fee. A pharmacy intern must be under the supervision of a pharmacist to be authorized to administer vaccines.

The bill has a significant positive fiscal impact on the DOH.

The bill provides an effective date of July 1, 2015.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current situation

Department of Health – Division of Medical Quality Assurance

The Department of Health's (DOH) Division of Medical Quality Assurance (MQA) regulates health care practitioners to ensure the health, safety and welfare of the public. There are 22 boards and 8 councils under the MQA, and the MQA licenses 7 types of facilities and 200-plus occupations in more than 40 health care professions.¹ MQA is responsible for the licensure of health care practitioners and facilities, the enforcement of law and rules governing practitioners and facilities, and providing information and data to the public.²

Boards

A board is a statutorily created entity that is authorized to exercise regulatory or rulemaking authority over practitioners within the MQA.³ A board is responsible for approving or denying applications for licensure and making disciplinary decisions on whether a health care practitioner is acting within the authority of the applicable practice act. Practice acts refer to the legal authority in state statute that grants a profession the authority to provide services to the public. The range of disciplinary actions taken by a board includes citations, suspensions, reprimands, probations, and revocations.

Pharmacy Practice in Florida

Chapter 465, F.S., governs the practice of pharmacy in Florida. The Board of Pharmacy (Board) is authorized to adopt rules to implement the provisions of the Florida Pharmacy Act.⁴

Section 465.003(13), F.S., defines the "practice of the profession of pharmacy" to include:

- Compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug;
- Consulting concerning therapeutic values and interactions of patent and proprietary preparations, whether pursuant to prescriptions or in the absence and entirely independent of such prescriptions or orders;
- Any other act, service, operation, research, or transaction incidental to any authorized acts involving or employing the practice or science of the pharmaceutical profession, study, or training; and
- Transmitting information from persons authorized to prescribe medicinal drugs to their patients.

To become a licensed pharmacist, a person must submit:

- An application form and the required fees to DOH;
- Satisfactory proof that the applicant:
 - Is at least 18 years of age;
 - Received a degree from an accredited school or college of pharmacy; or
 - Graduated from 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 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;

¹ Florida Department of Health, *Florida Health Source*, accessible at <http://www.flhealthsource.gov/> (last visited February 20, 2015).

² Id.

³ S. 456.001, F.S.

⁴ S. 465.005, F.S.

- Satisfactory proof that the applicant has completed an internship program, which must not exceed 2,080 hours; and
- Proof of successful completion of the licensure examination.⁵

A pharmacy license is renewed every two years by submitting an application, paying a \$205 renewal fee,⁶⁷ and submitting proof of completion of at least 30 hours of continuing professional pharmaceutical education during the two years prior to application for renewal.⁸ If a pharmacist is certified to administer vaccines, 3 completed continuing education hours must cover the safe and effective administration of vaccines and epinephrine autoinjection.⁹

Florida Pharmacy Interns

To become a pharmacy intern, a person must be certified by the Board as enrolled in an intern program at an accredited school or college of pharmacy or as a graduate of an accredited school or college of pharmacy and not yet licensed as a pharmacist in Florida.¹⁰ The Board's rules outline the registration process for pharmacy interns and the internship program requirements for U.S. pharmacy students or graduates and foreign pharmacy graduates.¹¹ There were 10,319 registered pharmacy interns in 2014.¹²

A pharmacist is responsible for any delegated act performed by a registered pharmacy intern employed or supervised by the pharmacist.¹³

Requirements for Pharmacist Vaccine Administration

A pharmacist may become certified to administer the influenza, pneumococcal, meningococcal, and shingles vaccine to adults within an established protocol under a licensed supervising physician. A pharmacist is permitted to administer epinephrine to treat any allergic reaction resulting from a vaccine. The protocol between the pharmacist and the supervising physician dictates which types of patients to whom the pharmacist may administer allowable vaccines.¹⁴ The terms, scope, and conditions set forth in the protocol must be appropriate to the pharmacist's training and certification. A supervising physician must review the administration of vaccines by the pharmacist.¹⁵ A pharmacist is required to provide the Board a copy of the protocol.¹⁶

To be certified to administer vaccines, a pharmacist must successfully complete a Board-approved vaccine administration certification program. The certification program requires pharmacists to submit an application, pay a \$55 fee to the Board, and complete 20 hours of Board-approved continuing education classes.¹⁷ The continuing education classes must cover:

- 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;

⁵ S. 465.007, F.S.

⁶ Florida Board of Pharmacy, *Pharmacist*, available at <http://floridaspharmacy.gov/renewals/pharmacist/> (last visited March 7, 2015).

⁷ S. 465.008(1), F.S.

⁸ S. 465.009, F.S.

⁹ S. 465.009(6)(a), F.S.

¹⁰ S. 465.013, F.S.

¹¹ Rule 64B16-26.2032, F.A.C. (U.S. pharmacy students/graduates); Rule 64B16-26.2033, F.A.C. (foreign pharmacy graduates).

¹² Florida Dep't of Health, *2015 Agency Legislative Bill Analysis HB 279*, February 9, 2015 (on file with committee staff).

¹³ Rule 64B16-27.430, F.A.C.

¹⁴ S. 465.189(7), F.S.

¹⁵ Id.

¹⁶ Id.

¹⁷ Rule 64B16-26.1031, F.A.C.

- 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 payers;
- Administration techniques;
- Administration of epinephrine using an autoinjector delivery system;
- Current CDC immunization guidelines and recommendations for influenza, pneumococcal, meningococcal, and shingles vaccinations;
- Review of the current law permitting a pharmacist to administer vaccinations and epinephrine; and
- CPR training.¹⁸

A pharmacist must also pass an examination and demonstrate vaccine administration technique.¹⁹

Pharmacists who are certified to administer vaccines must also maintain at least \$200,000 of professional liability insurance.²⁰ A certified pharmacist is required to report all administered vaccinations to the state registry of immunization information, Florida SHOTS.²¹ Approximately 11,323, or 37 percent, of active licensed pharmacists in Florida are certified to administer vaccines.²²

Other State Laws on Pharmacist Vaccination

In the United States pharmacists are authorized to administer vaccinations in addition to traditional roles such as medication preparation and dispensing. Pharmacists are typically required to complete specific certification or training in the administration of vaccines prior to authorization. Depending on patient age and vaccine type, most states require pharmacists to have formal permission to administer certain vaccines.²³ Some states require a patient-specific prescription, a protocol with a supervising physician or public health official, or both, before a pharmacist can administer certain vaccinations.²⁴

All 50 states have laws authorizing pharmacists to administer vaccines to adults.²⁵ Forty two states authorize pharmacists to administer all Centers for Disease Control and Prevention (CDC) recommended vaccines.^{26,27} Eight states, including Florida, limit pharmacists' vaccination authority to only a few CDC recommended vaccines. In addition, 39 states and U.S. territories allow pharmacy interns to administer vaccines under the supervision of a pharmacist.²⁸

¹⁸ Id.

¹⁹ Id.

²⁰ S. 465.189(3), F.S.

²¹ Florida SHOTS is a statewide centralized online immunization registry that assists health-care providers and schools in keeping track of immunization records administered by the Florida Dep't of Health. Florida Shots, *Florida SHOTS Facts*, accessible at <http://www.flshots.com/what/> (last visited March 4, 2015).

²² Supra at FN 12.

²³ Association of State and Territorial Health Officials, *Pharmacy Legal Toolkit*, accessible at <http://www.astho.org/infectious-disease/pharmacy-legal-toolkit/> (last visited March 2, 2015).

²⁴ Id.

²⁵ Id.

²⁶ Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, District of Columbia, Delaware, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Massachusetts, Maryland, Maine, Michigan, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Jersey, New Mexico, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, Washington, and Wisconsin allow pharmacists to administer any CDC recommended vaccine. American Pharmacists Association, *Pharmacist Administered Vaccines*, available at <http://www.pharmacist.com/types-vaccines-pharmacists-are-authorized-administer> (last visited March 3, 2015).

²⁷ Association of State and Territorial Health Officials, *2013 State Immunization Legislation Summary*, available at <http://www.astho.org/Programs/Immunization/Legislative-Tracking/> (last visited March 3, 2015).

²⁸ Supra at FN 26.

Advisory Committee on Immunization Practices

Since 1964, the Advisory Committee on Immunization Practices (ACIP) has provided guidance on immunization policy to the CDC. ACIP members are selected by the Secretary of the U.S. Department of Health and Human Services and have expertise in fields such as vaccinology, immunology, pediatrics, internal medicine, and infectious disease. ACIP guidance includes scheduling of vaccine doses, specific risk groups for whom vaccinations are recommended, and vaccine contraindications and precautions.²⁹

Adult Immunization Schedule

ACIP annually issues the Adult Immunization Schedule (Schedule) which is the official federal guideline for the use of vaccines in the United States.³⁰ The Schedule provides a summary of ACIP³¹ recommendations for vaccines routinely administered to adults and ensures current vaccination practices for specific indications such as age, immunosuppressant medical conditions, pregnancy, and chronic diseases.

Although some vaccines listed on the Schedule have been recommended since the 1940s, the official, annually endorsed Schedule was not introduced until 1995.³² The Schedule has been continuously updated as more vaccines are developed. The current version of the Schedule, issued February 2015, includes the following vaccines:³³

- Influenza;
- Tetanus, diphtheria, pertussis (Td/Tdap), a combination vaccine, which prevents disease complications such as:³⁴
 - Whooping cough, a highly contagious infection that can lead to pneumonia;
 - Lockjaw and muscle spasms; and
 - Breathing problems;
- Varicella, which prevents chickenpox;³⁵
- Human Papillomavirus (for females and males), which prevents cervical cancer in women;
- Zoster, which prevents shingles;³⁶
- Measles, Mumps, and Rubella (MMR), a combination vaccine, which prevents viral infections;³⁷
- Pneumococcal,³⁸ which prevents pneumococcal bacterial disease and resulting complications such as:
 - Pneumonia, which causes inflammation in the lungs; and
 - Bacteremia, which causes bacteria to enter the blood stream;

²⁹ Centers for Disease Control and Prevention, *Structure, Role, and Procedures of the ACIP*, available at <http://www.cdc.gov/vaccines/acip/committee/structure-role.html> (last visited March 5, 2015).

³⁰ Immunization Action Coalition, *Vaccine Policy and Licensing*, available at <http://www.immunize.org/vacpolicy/> (last visited February 13, 2015).

³¹ The Schedule is also endorsed by the American Academy of Family Physicians, The American College of Physicians, American College of Obstetricians and Gynecologists and American College of Nurse-Midwives.

³² College of Physicians of Philadelphia, *The History of Vaccines, The Development of the Immunization Schedule*, available at <http://www.historyofvaccines.org/content/articles/development-immunization-schedule> (last visited February 13, 2015).

³³ Centers for Disease Control and Prevention, *Adult Immunization Schedules*, available at <http://www.cdc.gov/vaccines/schedules/hcp/adult.html> (last visited March 4, 2015).

³⁴ There are 4 combination vaccines used to prevent diphtheria, tetanus, and pertussis. DTap and DT are given to children under 7 and Tdap and Td are given to older children and adults. Centers for Disease Control and Prevention, *Tetanus (Lockjaw) Vaccination*, available at <http://www.cdc.gov/vaccines/vpd-vac/tetanus/> (last visited March 4, 2015).

³⁵ Varicella vaccines are recommended for adults who have never had chickenpox or shingles. Supra at FN 33.

³⁶ A single dose of zoster vaccine is recommended for adults aged 60 years or older regardless of whether they report a prior episode of zoster (shingles). Id.

³⁷ Children are the primary recipients of the MMR vaccine, but it is also recommended for adults, born after 1956, who have not been previously vaccinated as these diseases can cause serious health complications. Id.

³⁸ Two types of pneumococcal vaccines are recommended by the CDC for adults aged 65 and older, the pneumococcal13-valent conjugate and the pneumococcal polysaccharide vaccines. Id.

- Meningococcal, which prevents meningococcal bacterial disease and resulting complications such as meningitis;
- Hepatitis A and Hepatitis B;³⁹ and
- Haemophilus influenza type b (Hib).⁴⁰

New vaccines are considered for addition to the schedule after licensure by the United States Food and Drug Administration. Not all newly licensed vaccines are added to the Schedule. Some licensed vaccines are only recommended for people who are traveling to areas where other vaccine preventable diseases, such as typhoid fever, occur.⁴¹

CDC Health Information for International Travel

CDC's Health Information for International Travel, commonly called the Yellow Book (Book), is published biannually by the CDC as a reference for those who advise international travelers about health risks.⁴² The Book includes a complete catalog of travel-related diseases, up-to-date vaccine and booster recommendations, and destination specific environmental health information. The Book also includes advice on preventing and treating common travel-related ailments and tips for individuals traveling with special needs.⁴³ A team of approximately 200 experts update the Book to provide the latest CDC recommendations.⁴⁴

Vaccinations are recommended by the CDC to protect international travelers from illness and prevent the importation of infectious diseases across international borders. The Book recommends that persons traveling internationally should be up to date on all CDC recommended vaccines.⁴⁵ The Book includes an immunization schedule that recommends additional vaccines that are not listed in the Schedule, including yellow fever, rotavirus, and polio vaccines.⁴⁶ The specific vaccinations recommended depend on the traveler's destination and other factors. Some of the most common vaccinations considered for travelers include hepatitis A, hepatitis B, meningococcal, polio (adult booster), rabies, typhoid fever, and yellow fever.⁴⁷

State of Emergency

The scope of practice of certain regulated healthcare practitioners may be modified for emergency situations to meet the increased demand for services.⁴⁸ The legal authorities and mechanisms for modifying health care scope of practice for a state of emergency vary among states. Various states have permanently authorized modified scopes of practice during emergencies for pharmacists and other health care practitioners, either by statute or regulation. In this instance, these provisions may be activated by an emergency declaration by a governor, state health officer, or other authorized officials.⁴⁹

Florida State of Emergency

³⁹ Hepatitis A causes an acute, treatable infection while Hepatitis B can cause chronic and serious health complications such as cirrhosis, liver cancer, and death. A combination vaccine is available for Hepatitis A and B. Centers for Disease Control and Prevention, *Hepatitis A FAQs for the Public*, available at <http://www.cdc.gov/hepatitis/A/aFAQ.htm#overview> (last visited March 4, 2015).

⁴⁰ The Meningococcal vaccine, along with Hepatitis A and B, pneumococcal, and Hib are recommended for subgroups of the adult population based on pre-existing medical conditions, occupation, or lifestyle. Supra at FN 33.

⁴¹ Supra at FN 32.

⁴² Centers for Disease Control and Prevention. *CDC Health Information for International Travel 2014* (online version). New York: Oxford University Press; 2014. available at <http://wwwnc.cdc.gov/travel/yellowbook/2014/table-of-contents> (last visited March 4, 2015).

⁴³ Centers for Disease Control and Prevention, *CDC Releases 2014 Edition of the "Yellow Book"* available at <http://www.cdc.gov/media/releases/2013/p0806-2014-yellow-book.html> (last visited March 4, 2015).

⁴⁴ Id.

⁴⁵ Supra at FN 42, ch. 2.

⁴⁶ Id. at ch. 2, Table 2-04.

⁴⁷ Id. At ch. 4.

⁴⁸ Association of State and Territorial Health Officials, *Scope of Practice Issues in Public Health Emergencies*, available at <http://www.astho.org/Programs/Preparedness/Public-Health-Emergency-Law/Scope-of-Practice-Toolkit/Scope-of-Practice-Issues-in-Public-Health-Emergencies-Fact-Sheet/> (last viewed March 4, 2015).

⁴⁹ Id.

Section 252.36, F.S., describes the powers of the Governor in a state of emergency. In the event an emergency or disaster is beyond local control, the Governor may assume direct operational control over all or any part of the emergency management functions within the state.⁵⁰ The Governor is authorized to delegate such powers as he or she may deem prudent.⁵¹ A state of emergency must be declared by executive order or proclamation by the Governor when an emergency or disaster has occurred or the threat of occurrence is imminent.⁵²

Effect of Proposed Changes

HB 279 amends s.465.189, F.S., to authorize licensed pharmacists and registered pharmacy interns, who are certified with the Board to administer vaccines, to administer those vaccines:

- Listed in the CDC's Adult Immunization Schedule;
- Recommended in the CDC's Health Information for International Travel; and
- Approved by the Board in response to a state of emergency declared by the Governor.

A registered pharmacy intern who is authorized to administer vaccinations must be under the supervision of a pharmacist.

The bill requires a pharmacy intern to meet the same vaccine administration certification requirements as a pharmacist. To be certified, a pharmacy intern must complete 20 hours of coursework approved by the Board concerning the safe and effective administration of the vaccines listed in the bill and pay a fee of \$55.

In addition to the vaccines that pharmacists are currently authorized to administer in s. 465.189, F.S., the inclusion of the CDC's official immunization recommendations in s. 465.189, F.S., also authorizes:

- Measles, mumps, rubella (MMR);
- Tetanus, diphtheria, pertussis (Td/Tdap);
- Varicella;
- Human Papillomavirus (HPV);
- Hepatitis A;
- Hepatitis B;
- Haemophilus influenza type b (Hib); and
- Vaccines recommended for international travel such as yellow fever and typhoid fever.

The bill provides an effective date of July 1, 2015.

B. SECTION DIRECTORY:

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

Section 2: Provides an effective date of July 1, 2015.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

Based on Fiscal Year 2013-14 data, there are 30,636 pharmacists registered by the Board, and 11,323, or 37 percent, are currently certified to administer vaccines. There are 10,914 registered pharmacy interns. It is assumed that 4,038 (10,914 X 37 percent) of the current registered

⁵⁰ S. 252.36(1)(a), F.S.

⁵¹ Id.

⁵² S. 252.36(1)(b), F.S.

pharmacy interns will apply for certification to administer vaccines. There were 1,855 applications seeking intern registration in the Fiscal Year 2013-14. It is assumed that 686 (1,855 x 37 percent) pharmacy interns will apply for vaccine administration certification.

Revenues collected from the \$55 certification fee are calculated based on an estimated 4,724 (4,038 current registered interns + 686 newly registered interns) applications for certification totaling \$259,820 (4,724 x \$55). The fees collected are subject to the 8 percent general revenue surcharge and \$20,786 (\$259,820 x .08) is deducted from the estimated amounts to be collected by DOH to be deposited in the General Revenue Fund. The total estimated revenue for the DOH for first biennium is \$239,034 (\$259,820 - \$20,786).⁵³

2. Expenditures:

The bill will cause the DOH to experience a recurring increase in workload, associated with processing applications for vaccine certification for pharmacy interns, which can be absorbed within current resources.

DOH will incur a non-recurring increase in workload, associated with updating the Licensing and Enforcement Information Database System, modifying the pharmacy intern application, updating the Pharmacy website, and rulemaking. This can be absorbed within current resources.

DOH may experience an increase in workload costs associated with the receipt and processing of certification applications for registered pharmacy interns. The processing cost per application is \$7.69. It is estimated that 4,724 applicants for certification will be submitted for processing equating to a cost of \$36,328.⁵⁴

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Pharmacies that opt to allow pharmacists and pharmacy interns to administer the vaccinations may see an increase in customers seeking vaccinations.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

⁵³ Supra at FN 12

⁵⁴ Id.

The bill gives the DOH rulemaking authority to authorize additional immunizations or vaccines as they are added to the CDC Adult Immunization Schedule and to approve immunizations in response to a state of emergency declared by the Governor.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES