

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 494

INTRODUCER: Health Policy Committee and Senator Burgess

SUBJECT: Administration of Vaccines

DATE: February 4, 2021

REVISED: _____

| | ANALYST | STAFF DIRECTOR | REFERENCE | ACTION |
|----|---------------------|----------------|-----------|---------------|
| 1. | Rossitto-Van Winkle | Brown | HP | Fav/CS |
| 2. | _____ | _____ | RC | _____ |

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 494 revises the authority of pharmacists and pharmacy interns to administer immunizations and vaccines, within the framework of an established protocol with a supervising physician, by eliminating steps in the approval process for immunizations and vaccines that such practitioners may administer. The bill authorizes pharmacists and pharmacy interns to administer to an adult, under the protocol, any immunization or vaccine that is:

- Listed in the Adult Immunization Schedule by the federal Centers for Disease Control and Prevention (CDC), regardless of the date it was added to the schedule and without the need for authorization by rule of the Board of Pharmacy (BOP);
- Recommended by the CDC's Advisory Committee on Immunization Practices (ACIP); or
- Recommended by the CDC for international travel, regardless of the date of the recommendation and without the need for authorization by rule of the BOP.

The bill further requires a pharmacist, when administering epinephrine using an auto-injector delivery system in order to address an unforeseen allergic reaction, under a protocol with a supervising physician, to administer a weight-based dose of epinephrine.

The bill provides an effective date of July 1, 2021.

II. Present Situation:

Vaccinations – U. S. Department of Health and Human Services

The Office of Infectious Disease and HIV/AIDS Policy (Office), in the U. S. Department of Health and Human Services (HHS), oversees the National Vaccine Program, which provides strategic leadership for vaccine and immunization activities among federal agencies and to the states and other stakeholders, to help reduce the burden of preventable infectious diseases. The Office's services include the National Vaccine Strategic Plans (NVSP) and National Vaccine Advisory Committee (NVAC).¹ The NVSP for 2021-2025, released January 19, 2021, is the newest roadmap to coordinate vaccine development and use and is based on the NVAC's recommendations that revise the Standards for Adult Immunization Practices.²

The Centers for Disease Control and Prevention's Immunization Recommendations

The CDC, under the Secretary of HHS,³ sets the adult and childhood immunization and vaccination schedules based on the recommendations from the ACIP.⁴ The ACIP works with professional organizations, such as the American Academy of Pediatrics, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, and the American College of Physicians, to develop annual childhood and adult immunization schedules.⁵ The CDC reviews the ACIP's recommendations and, once approved, they are published as the CDC's official recommendations for immunizations for the population.⁶ The current recommended immunization schedule for persons 18 years of age and older includes:⁷

- Influenza (annually) (IIV,RIV or LAIV);
- Measles, mumps, rubella (MMR) (if patient is born in 1957 or later);
- Zoster (ZVL) or (RZV);
- Pneumococcal polysaccharide (PPSV23);
- Haemophilus influenza Type B (Hib);
- Hepatitis B (HepB);
- Varicella (VAR) (if patient is born 1980 or later);
- Tetanus, diphtheria, pertussis (Tdap or Td) (booster every 10 years);
- Human papillomavirus (HPV);
- Pneumococcal conjugate (PCV13);

¹ U.S. Department of Health & Human Services, *Vaccines & Immunizations*, available at <https://www.hhs.gov/vaccines/index.html> (last visited Feb. 1, 2021).

² U.S. Department of Health & Human Services, *Vaccines National Strategic Plan*, available at <https://www.hhs.gov/vaccines/vaccines-national-strategic-plan/index.html> (last visited Feb. 1, 2021).

³ U.S. Department of Health & Human Service, HHS Leadership, *Office of the Secretary Leaders*, available at <https://www.hhs.gov/about/leadership/index.html#opdiv> (last visited Feb. 1, 2021).

⁴ Center for Disease Control and Prevention, Advisory Committee on Immunization Practices (ACIP), *Role of the Advisory Committee on Immunization Practices in CDC's Vaccine Recommendations*, available at <https://www.cdc.gov/vaccines/acip/committee/role-vaccine-recommendations.html> (last visited Feb. 1, 2021).

⁵ Centers for Disease Control and Prevention, Advisory Committee on Immunization Practices (ACIP), *ACIP Recommendations*, available at <https://www.cdc.gov/vaccines/acip/recommendations.html> (last visited Feb. 1, 2021).

⁶ *Id.*

⁷ Centers for Disease Control and Prevention, *Recommended Adult Immunization Schedule for Ages 19 Years or Older, United States, 2020*, available at <https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html> (last visited Feb. 1, 2021). The schedule provides the recommended age, as well as the administration intervals for vaccines that require multiple doses. Some vaccines are recommended only for populations with special situations that put these individuals at higher risk.

- Hepatitis A (HepA);
- Meningococcal A, C, W, Y (MenACWY); and
- Meningococcal B (MenB).

New vaccines are considered for addition to the schedule after being licensed by the Food and Drug Administration (FDA).⁸ Not all newly licensed vaccines are added to the schedule. Some licensed vaccines are only recommended for people who are traveling to areas where certain vaccine-preventable diseases occur, such as yellow fever, cholera, dengue, Japanese encephalitis, plague, rabies, smallpox, and typhoid.⁹

CDC Health Information for International Travel

The CDC's *Health Information for International Travel*, commonly called the Yellow Book, is published biennially by the CDC as a reference to advise international travelers about health risks.¹⁰ The Yellow Book includes the CDC's most current travel health guidelines, including pre-travel vaccine recommendations and destination-specific health advice. The Yellow Book is authored by subject-matter experts both within and outside the CDC and its guidelines are evidence-based and supported by best practices.¹¹

Certain vaccinations are recommended by the CDC to protect international travelers from illness and prevent the importation of infectious diseases across international borders. The Yellow Book recommends that persons traveling internationally should be up to date on all CDC-recommended vaccines.¹² Additionally, the Yellow Book recommends additional vaccinations based on a traveler's destination and other factors.

Florida's Adult Vaccination Policy

Communicable Disease Prevention and Control

The Department of Health (DOH) is responsible for the state's public health system.¹³ As part of fulfilling its public health mission, the DOH is responsible for conducting a communicable disease prevention and control program. A communicable disease is any disease caused by the transmission of a specific infectious agent, or its toxic products, from an infected person, animal, or the environment to a susceptible host, either directly or indirectly.¹⁴

The DOH communicable disease program includes, but need not be limited to, programs for the prevention and control of:

- Tuberculosis;

⁸ 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 Feb. 1, 2021).

⁹ *Id.* For a complete list of FDA-licensed vaccines, see U.S. Food & Drug Administration, *Vaccines Licensed for Use in the United States*, (last rev. Apr. 24, 2020), available at <https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states> (last visited Feb. 1, 2021).

¹⁰ Centers for Disease Control and Prevention. *CDC Yellow Book 2020: Health Information for International Travel*, available at <https://wwwnc.cdc.gov/travel/page/yellowbook-home> (last visited Feb. 1, 2021).

¹¹ *Id.*

¹² *Supra*, note 10.

¹³ Section 381.001, F.S.

¹⁴ Section 381.003(1), F.S.

- Human immunodeficiency virus (HIV) infection;
- Acquired Immune Deficiency Syndrome (AIDS);
- Sexually transmissible diseases;
- Communicable diseases of public health significance; and
- Vaccine-preventable diseases,¹⁵ including programs to immunize school children¹⁶ and the development of an automated, electronic, and centralized database or registry for immunization records.¹⁷

The DOH may adopt rules related to the prevention and control of communicable diseases and the administration of the immunization registry. Such rules may include procedures for:

- Investigating disease;
- Timeframes for reporting disease;
- Definitions;
- Procedures for managing specific diseases;
- Requirements for follow-up reports on disease exposure; and
- Procedures for providing access to confidential information necessary for disease investigations.¹⁸

The DOH recommends the following vaccines for adults:¹⁹

- Human Papillomavirus (HPV);
- Tetanus-diphtheria-pertussis (Tdap);
- Tetanus-diphtheria (Td) booster every ten years;
- Hepatitis A;
- Meningococcal;
- Measles-mumps-rubella (MMR);
- Varicella (chickenpox);
- Seasonal influenza;
- Zoster (shingles); and
- Pneumococcal.

The Practice of Pharmacy

The Board of Pharmacy (BOP), in conjunction with the DOH, regulates the practice of pharmacists and registered pharmacist interns pursuant to ch. 465, F.S.²⁰

¹⁵ Measles, mumps, rubella, pertussis, diphtheria, tetanus, polio, varicella, pneumococcal disease, hepatitis A, hepatitis B, influenza, meningococcal and Haemophilus influenza type b (Hib) are all preventable by vaccine. See Department of Health, *Vaccine Preventable Diseases*, available at <http://www.floridahealth.gov/diseases-and-conditions/vaccine-preventable-disease/index.html> (last visited Feb. 1, 2021).

¹⁶ See s. 1003.22(3)-(11), F.S.

¹⁷ Section 381.003(1), F.S.

¹⁸ Section 381.003(2), F.S.

¹⁹ The Florida Department of Health, *Don't Miss Opportunities to Vaccinate!* available at http://www.floridahealth.gov/programs-and-services/immunization/publications/_documents/opportunities-to-vaccinate-adult.pdf (last visited Feb. 1, 2021).

²⁰ Sections 465.004 and 465.005, F.S.

Licensure

To be licensed as a pharmacist in Florida, a person must:²¹

- Complete an application and remit an examination fee;
- Be at least 18 years of age;
- Hold a degree from an accredited and approved school or college of pharmacy;²²
- Have completed a BOP-approved internship; and
- Successfully complete the BOP-approved examination.

A pharmacist must complete at least 30 hours of BOP-approved continuing education during each biennial licensure renewal period.²³ Pharmacists who are certified to administer vaccines or epinephrine auto-injections must complete a three-hour continuing education course on the safe and effective administration of vaccines and epinephrine injections as a part of their renewal.²⁴ Pharmacists who administer long-acting antipsychotic medications must complete an approved eight-hour continuing education course as a part of the continuing education for their renewal.²⁵

Scope of Pharmacy Practice

In Florida, the practice of the profession of pharmacy includes:²⁶

- Compounding, dispensing, and consulting concerning the contents, therapeutic values, and uses of a medicinal drug;
- Consultation concerning therapeutic values and interactions of patented or proprietary preparations;
- Monitoring a patient's drug therapy and assisting the patient in the management of his or her drug therapy;
- Reviewing, and making recommendations regarding the patient's drug therapy and health care status in communication with the patient's prescribing health care provider as authorized by the patient;
- Initiating, modifying, or discontinuing drug therapy for a chronic health condition under a collaborative pharmacy practice agreement;²⁷
- Transmitting information from prescribers to their patients;
- Administering vaccines to adults;²⁸
- Administering epinephrine injections;²⁹

²¹ Section 465.007, F.S. The DOH may also issue a license by endorsement to a pharmacist who is licensed in another state upon meeting the applicable requirements set forth in law and rule. *See* s. 465.0075, F.S.

²² If the applicant has graduated from a four-year undergraduate pharmacy program of a school or college of pharmacy located outside the United States, the applicant must demonstrate proficiency in English, pass the BOP-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.

²³ Section 465.009, F.S.

²⁴ Section 465.009(6), F.S.

²⁵ Section 465.1893, F.S.

²⁶ Section 465.003(13), F.S.

²⁷ Section 465.1865, F.S.

²⁸ *See* s. 465.189, F.S.

²⁹ *Id.*

- Preparing prepackaged drug products in facilities holding Class III institutional facility permits;³⁰
- Administering antipsychotic medications by injection;³¹
- Ordering and dispensing over-the-counter drugs approved by the FDA;³²
- Ordering and dispensing within his or her professional judgment, subject to specified conditions:³³
 - Certain oral analgesics for mild to moderate pain;
 - Anti-nausea preparations;
 - Certain antihistamines and decongestants;
 - Certain topical antifungal/antibacterial;
 - Topical anti-inflammatory preparations containing an amount of hydrocortisone not exceeding 2.5 percent;
 - Otic antifungal/antibacterial;
 - Salicylic acid;
 - Vitamins;
 - Ophthalmics;
 - Certain histamine H2 antagonists;
 - Acne products; and
 - Topical antivirals for herpes simplex infections of the lips.

Pharmacists with a Broader Scope of Practice

There are three categories of pharmacists that have broader scopes of practice than other pharmacists:

- The consultant pharmacist;³⁴
- The pharmacist working under a collaborative pharmacy practice agreement with a physician;³⁵ and
- The pharmacist working within the framework of an established written protocol with a supervising physician.³⁶

A consultant pharmacist works within the framework of a written collaborative practice agreement between the pharmacist and any of the following who are authorized to prescribe medicinal drugs:³⁷

- A health care facility medical director;
- A medical, osteopathic, or podiatric physician; or
- A dentist.³⁸

³⁰ A Class III institutional pharmacy are those pharmacies affiliated with a hospital. *See* s. 465.019(2)(d), F.S.

³¹ Section 465.1893, F.S.

³² Section 465.186, F.S.

³³ Fla. Admin. Code R. 64B16-27.220 (2020).

³⁴ Sections 465.003(3) and 465.0125, F.S.

³⁵ Section 465.1865, F.S.

³⁶ Section 465.1895, F.S.

³⁷ Section 465.0125, F.S.

³⁸ *Id.*

The consultant pharmacist may provide medication management services only in the following health care facilities:³⁹

- Ambulatory surgical centers;
- Hospitals;
- Alcohol or chemical dependency treatment centers;
- Inpatient hospices;
- Nursing homes;
- Ambulatory care centers; or
- Nursing homes within a continuing care facility.

The scope of practice of a consultant pharmacist includes providing the following medical management services to the patients of the health care practitioner with whom he or she has a written collaborative practice agreement:

- Patient assessments;
- Ordering and evaluating laboratory and clinical tests;
- Monitoring drug therapy and treatment outcomes, including modifying, discontinuing or administering medicinal drugs; and
- Maintaining drug, patient care, and quality assurance records.

A pharmacist, with the consent of his employer if employed at a pharmacy, may also expand his or her scope of practice by entering into a collaborative pharmacy practice agreement with a medical or osteopathic physician, to provide specific services to the physician's patients named in the agreement, which may include:⁴⁰

- Ordering and evaluating a patient's laboratory and clinical testing;
- Conducting patient assessments; and
- Modifying, discontinuing, or administering medicinal drugs.

The scope of practice for a pharmacist, within the framework of an established written protocol with a supervising medical or osteopathic physician, may also include the testing or screening for and treatment of minor, nonchronic health conditions, which are defined as short-term conditions that are generally managed with minimal treatment or self-care, and include:

- Influenza;
- Streptococcus;
- Lice;
- Skin conditions such as ring worm and athlete's foot; and
- Minor uncomplicated infections.

Pharmacy Interns

To become a pharmacy intern, a person must be certified by the BOP and enrolled in an intern program at an accredited school or college of pharmacy or as a graduate of an accredited school

³⁹ Section 465.1865, F.S.

⁴⁰ Section 465.0125, F.S. A pharmacist with a collaborative practice agreement with a physician, may not modify or discontinue any medications of any other health care practitioner he or she does not have a collaborative pharmacy practice agreement with.

or college of pharmacy and not yet licensed as a pharmacist in Florida.⁴¹ The BOP'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.⁴²

A pharmacist is responsible for any delegated act performed by a registered pharmacy intern employed or supervised by the pharmacist.⁴³

Administration of Vaccines by Pharmacists and Registered Pharmacy Interns

A pharmacist or pharmacy intern must become certified to administer immunizations and vaccines that are:

- Listed in the CDC Adult Immunization Schedule as of February 1, 2015;
- Listed in the Adult Immunization Schedule after February 1, 2015, and have been authorized by BOP rule;
- Recommended by the CDC for international travel as of July 1, 2015;
- Recommended by the CDC for international travel after July 1, 2015, and have been authorized by BOP rule;⁴⁴ or
- Approved by the BOP in response to an emergency declared by the Governor.⁴⁵

To be certified to administer vaccines, a pharmacist must:

- Enter into a written protocol with a supervising medical or osteopathic physician;⁴⁶ and the protocol must:⁴⁷
 - Specify the categories of patients and patient conditions for which the pharmacist may administer vaccines;
 - Be appropriate to the pharmacist's training and certification for administering the vaccine;
 - Outline the process and schedule for the review of the administration of vaccines by the pharmacist under the written protocol; and
 - Be submitted to the BOP;
- Successfully complete a BOP-approved vaccine administration certification program that consists of at least 20 hours of continuing education;⁴⁸
- Pass an examination and demonstrate vaccine administration technique;⁴⁹
- Maintain and make available patient records using the same standards for confidentiality and retention of such records as required by s. 456.057, F.S., and maintain the records for at least five years;⁵⁰ and

⁴¹ Section 465.013, F.S.

⁴² Fla. Admin. Code R. 64B16-26.2032 (U.S. pharmacy students/graduates); Fla. Admin. Code R. 64B16-26.2033 (foreign pharmacy graduates).

⁴³ Fla. Admin. Code R. 64B16-27.430

⁴⁴ Section 465.189(1)(b), F.S.

⁴⁵ Section 465.189, (1)(c), F.S.

⁴⁶ Section 465.189(1), F.S.

⁴⁷ Section 465.189(7), F.S.

⁴⁸ Section 465.189(6), F.S., Fla. Admin. Code R. 64B16-26.1031 (2020), provides more detail regarding subject matter that must be included in the certification course.

⁴⁹ *Id.*

⁵⁰ Section 456.057, F.S., requires certain health care practitioners to develop and implement policies, standards, and procedures to protect the confidentiality and security of medical records, provides conditions under which a medical record

- Maintain at least \$200,000 of professional liability insurance.⁵¹

To administer vaccines, a registered pharmacy intern must complete the same BOP-approved vaccine administration certification program as the pharmacist and also be supervised by a certified pharmacist, at a ratio of one pharmacist to one certified registered intern.⁵²

Current law restricts the vaccines a pharmacist may administer to those vaccines listed in the February 1, 2015, CDC Recommended Adult Immunization Schedule, which is the same as the 2020 list of recommended vaccines, except that the CDC has added the Meningococcal B vaccine to the list.⁵³ A pharmacist may also administer epinephrine using an auto-injector delivery system within the framework of an established protocol under a supervising physician in order to address any unforeseen allergic reactions.⁵⁴

III. Effect of Proposed Changes:

SB 494 expands the source lists for the immunizations and vaccines that certified pharmacists and certified registered pharmacy interns may administer to adults. Currently, pharmacists and pharmacy interns, under a protocol with a supervising physician, are limited to administering vaccines that are:

- Listed in the CDC's Adult Immunization Schedule as of February 1, 2015;
- Recommended by the CDC for international travel as of July 1, 2015;
- Authorized by BOP rule if listed or recommended, respectively, after those dates; or
- Approved by the BOP in response to a state of emergency declared by the Governor.⁵⁵

The bill authorizes certified pharmacists and certified registered pharmacy interns, still under a protocol with a supervising physician, to administer vaccines and immunizations to adults, without regard to date, that are:

- Listed in the CDC's Adult Immunization Schedule;
- Recommended by the ACIP;
- Recommended by the CDC for international travel; or
- Approved by the BOP in response to a state of emergency declared by the Governor.⁵⁶

Under the bill:

- Immunizations and vaccines added to the Adult Immunization Schedule after February 1, 2015, or recommended by the CDC for international travel after July 1, 2015, will no longer

may be disclosed without the express consent of the patient, provides procedures for disposing of records when a practice is closing or relocating, and provides for enforcement of its provisions.

⁵¹ Section 465.189(3), F.S.

⁵² Section 465.189(6), F.S.

⁵³ Centers for Disease Control and Prevention, *Recommended Adult Immunization Schedule, United States - 2015*, available at <https://www.cdc.gov/vaccines/schedules/downloads/past/2015-adult.pdf> (last visited Feb. 1, 2021). The schedule provides the recommended age, as well as the administration intervals for vaccines that require multiple doses. Some vaccines are recommended only for populations with special situations that put these individuals at higher risk. *Also supra*, note 7.

⁵⁴ Section 465.189(2), F.S.

⁵⁵ Section 465.186, F.S.

⁵⁶ *See* s. 252.36, F.S.

need authorization under BOP rule to be available for administration to adults by pharmacists and pharmacy interns; and

- An immunization or vaccine will no longer need to appear on the CDC's Adult Immunization Schedule to be available for administration by a pharmacist or pharmacy intern as long as the immunization or vaccine has been recommended by the ACIP.

The bill further requires a pharmacist, when administering epinephrine using an auto-injector delivery system in order to address an unforeseen allergic reaction, under a protocol with a supervising physician, to administer a weight-based dose of epinephrine.

The bill provides an effective date of July 1, 2021.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

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 February 4, 2021:

The CS amends s. 465.189(2), F.S., to require a pharmacist, when administering epinephrine using an auto injector delivery system to address an unforeseen allergic reaction, under a protocol with a supervising physician, to administer a weight-based dose of epinephrine.

B. Amendments:

None.