

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: SB 714

INTRODUCER: Senator Hutson

SUBJECT: Testing for and Treatment of Influenza and Streptococcus

DATE: February 17, 2020

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Brown	HP	Pre-meeting
2.	_____	_____	AHS	_____
3.	_____	_____	AP	_____

I. Summary:

SB 714 amends the definition of the “practice of the profession of pharmacy” to include the testing for and treatment of influenza and streptococcus by a pharmacist under a written protocol with a supervising physician that includes specific criteria. The bill requires the pharmacist to:

- Complete a certification program developed by the Board of Pharmacy (BOP), in consultation with the Board of Medicine (BOM) and the Board of Osteopathic Medicine (BOOM), with specific requirements;
- Maintain at least \$200,000 of professional liability insurance;
- Maintain and make available patient records that meet certain confidentiality standards for at least five years;
- Notify a patient’s primary care provider within two business days after providing testing or treatment; and
- Report any diagnoses or suspected existence of a disease of public health significance to the Department of Health (DOH).

The bill prohibits a pharmacist who is a pharmacy employee from entering into a written protocol that is to be performed while acting as a pharmacy employee without the written approval of the owner of the pharmacy and provides that the supervising physician’s decision to enter into a written protocol is a professional decision that no person may interfere with.

The bill takes effect upon becoming a law.

II. Present Situation:

The Practice of Pharmacy

Pharmacy is the third largest health profession behind nursing and medicine.¹ The BOP, in conjunction with the DOH, regulates the practice of pharmacists and pharmacies pursuant to ch. 465, F.S.² There are seven types of pharmacies eligible for various operating permits issued by the DOH:

- Community pharmacy;
- Institutional pharmacy;³
- Nuclear pharmacy;⁴
- Special pharmacy;⁵
- Internet pharmacy;⁶
- Non-resident sterile compounding pharmacy;⁷ and
- Special sterile compounding pharmacy.⁸

Pharmacist Licensure

To be licensed as a pharmacist in Florida, a person must:⁹

- 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;¹⁰
- Have completed a BOP-approved internship; and
- Successfully complete the BOP-approved examination.

¹ American Association of Colleges of Pharmacy, *About AACP*, available at <https://www.aacp.org/about-aacp> (last visited Feb. 13, 2020).

² Sections 465.004 and 465.005, F.S.

³ See ss. 465.003(11)(a)2. and 465.019, F.S.

⁴ The term “nuclear pharmacy” includes every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The term “nuclear pharmacy” does not include hospitals licensed under ch. 395, F.S., or the nuclear medicine facilities of such hospitals. See ss. 465.003(11)(a)3. and 465.0193, F.S.

⁵ The term “special pharmacy” includes every location where medicinal drugs are compounded, dispensed, stored, or sold if such locations are not otherwise defined in this subsection. See ss. 465.003(11)(a)4. and 465.0196, F.S.

⁶ The term “internet pharmacy” includes locations not otherwise licensed or issued a permit under this chapter, within or outside this state, which use the Internet to communicate with or obtain information from consumers in this state and use such communication or information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state. See ss. 465.003(11)(a)5. and 465.0197, F.S.

⁷ The term “nonresident sterile compounding pharmacy” includes a pharmacy that ships, mails, delivers, or dispenses, in any manner, a compounded sterile product into Florida, a nonresident pharmacy registered under s. 465.0156, F.S., or an outsourcing facility, must hold a nonresident sterile compounding permit See s. 465.0158, F.S.

⁸ See Fla. Admin. Code R. 64B16-2.100 and 64B16-28.802 (2019). An outsourcing facility is considered a pharmacy and needs to hold a special sterile compounding permit if it engages in sterile compounding.

⁹ 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.

¹⁰ If the applicant has graduated from a 4-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 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.

A pharmacist must complete at least 30 hours of BOP-approved continuing education during each biennial renewal period.¹¹ Pharmacists who are certified to administer vaccines or epinephrine autoinjections must complete a three-hour continuing education course on the safe and effective administration of vaccines and epinephrine injections as a part of the biennial licensure renewal.¹² Pharmacists who administer long-acting antipsychotic medications must complete an approved eight-hour continuing education course as a part of the continuing education for biennial licensure renewal.¹³

Pharmacist Scope of Practice

In Florida, the practice of the profession of pharmacy includes:¹⁴

- Compounding, dispensing, and consulting concerning the contents, therapeutic values, and uses of a medicinal drug;
- Consulting concerning therapeutic values and interactions of patent or proprietary preparations;
- Monitoring a patient's drug therapy and assisting the patient in the management of his or her drug therapy, including the review of the patient's drug therapy and communication with the patient's prescribing health care provider or other persons specifically authorized by the patient, regarding the drug therapy;
- Transmitting information from prescribers to their patients;
- Preparing prepackaged drug products in facilities holding Class III institutional facility permits;¹⁵
- Administering vaccines to adults;¹⁶
- Administering epinephrine injections;¹⁷ and
- Administering antipsychotic medications by injection.¹⁸

A pharmacist may not alter a prescriber's directions, diagnosing or treating any disease, initiating any drug therapy, and practicing medicine or osteopathic medicine, unless permitted by law.¹⁹

Pharmacists may order and dispense drugs that are included in a formulary developed by a committee composed of members of the Boards of Medicine (BOM), Board of Osteopathic Medicine (BOOM), and the BOP.²⁰ The formulary may only include:²¹

- Medicinal drugs of single or multiple active ingredients in any strengths when such active ingredients have been approved individually or in combination for over-the-counter sale by the U.S. Food and Drug Administration (FDA);

¹¹ Section 465.009, F.S.

¹² Section 465.009(6), F.S.

¹³ Section 465.1893, F.S.

¹⁴ Section 465.003(13), F.S.

¹⁵ A Class III institutional pharmacy are those pharmacies affiliated with a hospital. *See* s. 465.019(2)(d), F.S.

¹⁶ *See* s. 465.189, F.S.

¹⁷ *Id.*

¹⁸ Section 465.1893, F.S.

¹⁹ Section 465.003(13), F.S.

²⁰ Section 465.186, F.S.

²¹ *Id.*

- Medicinal drugs recommended by the FDA’s Advisory Panel for transfer to over-the-counter status pending approval by the FDA;
- Medicinal drugs containing an antihistamine or decongestant as a single active ingredient or in combination;
- Medicinal drugs containing fluoride in any strength;
- Medicinal drugs containing lindane in any strength;
- Over-the-counter proprietary drugs under federal law that have been approved for reimbursement by the Florida Medicaid Program; and
- Topical anti-infectives, excluding eye and ear topical anti-infectives.

A pharmacist may order, within his or her professional judgment and subject to the stated conditions:²²

- Certain oral analgesics for mild to moderate pain. The pharmacist may order these drugs for minor pain and menstrual cramps for patients with no history of peptic ulcer disease. The prescription is limited to a six day supply for one treatment:
 - Magnesium salicylate/phenyltoloxamine citrate;
 - Acetylsalicylic acid (Zero order release, long acting tablets);
 - Choline salicylate and magnesium salicylate;
 - Naproxen sodium;
 - Naproxen;
 - Ibuprofen;
 - Phenazopyridine, for urinary pain; and
 - Antipyrine 5.4%, benzocaine 1.4%, glycerin, for ear pain if clinical signs or symptoms of tympanic membrane perforation are not present;
- Anti-nausea preparations;
- Certain antihistamines and decongestants;
- Certain topical antifungal/antibacterial;
- Topical anti-inflammatory preparations containing hydrocortisone not exceeding 2.5%;
- Otic antifungal/antibacterial;
- Salicylic acid 16.7% and lactic acid 16.7% in flexible collodion, to be applied to warts, except for patients under 2 years of age, and those with diabetes or impaired circulation;
- Vitamins with fluoride, excluding vitamins with folic acid in excess of 0.9 mg.;
- Medicinal drug shampoos containing Lindane for the treatment of head lice;
- Ophthalmics. Naphazoline 0.1% ophthalmic solution;
- Certain histamine H2 antagonists;
- Acne products; and
- Topical Antiviral for herpes simplex infections of the lips.²³

One category of pharmacist has a broader scope of practice than other pharmacists. A consultant pharmacist, also known as a senior care pharmacist, provides expert advice on the use of medications to individuals or older adults, wherever they live.²⁴ In addition to the training and

²² Fla. Admin. Code R. 64B16-27.220, (2019).

²³ Fla. Admin. Code R. 64B16-27.220 (2019).

²⁴ American Society of Consultant Pharmacists, *What is a Consultant Pharmacist*, available at <http://www.ascp.com/page/whatisacp> (last visited Feb. 13, 2020).

education received as a part of a degree program in pharmacy, a consultant pharmacist must complete a consultant pharmacy course and a period of assessment and evaluation under the supervision of a preceptor.²⁵

A consultant pharmacist may order and evaluate laboratory testing in addition to the services provided by a pharmacist. For example, a consultant pharmacist can order and evaluate clinical and laboratory testing for a patient residing in a nursing home upon authorization by the medical director of the nursing home.²⁶ Additionally, a consultant pharmacist may order and evaluate clinical and laboratory testing for individuals under the care of a licensed home health agency, if authorized by a licensed physician, podiatrist, or dentist.²⁷

Pharmacist Administration of Vaccines and Injections

A pharmacist may become certified to administer the immunizations or vaccines listed in the Centers for Disease Prevention and Control (CDC) Adult Immunization Schedule as of February 1, 2015, as well as those recommended for international travel as of July 1, 2015.²⁸ To be certified to administer vaccines, a pharmacist must:

- Enter into a written protocol under a supervising physician licensed under ch. 458, or ch. 459, F.S.;²⁹ which must:³⁰
 - Specify the categories and conditions among patients to whom the pharmacist may administer such vaccines;
 - Be appropriate to the pharmacist's training and certification for administering such vaccine;
 - Outline the process and schedule for the review of the administration of vaccines by the pharmacists pursuant to 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;³¹
- Pass an examination and demonstrate vaccine administration technique;³²
- Must maintain and make available patient records using the same standards for confidentiality and maintenance of such records as required by s. 456.057, F.S., and maintain the records for at least five years;³³ and

²⁵ Fla. Admin. Code R. 64B16-26.300(3), (2019).

²⁶ Section 465.0125(1), F.S.

²⁷ Section 465.0125(2), F.S. To qualify to order and evaluate such testing, the consultant pharmacist or doctor of pharmacy must complete 3 hours of board-approved training, related to laboratory and clinical testing.

²⁸ Section 465.189, F.S. A registered intern may also administer immunizations or vaccinations under the supervision of a certified pharmacist.

²⁹ Section 465.189(1), F.S.

³⁰ Section 465.189(7), F.S.

³¹ Section 465.189(6), F.S., Fla. Admin. Code R. 64B16-26.1031,(2019), provides more detail regarding subject matter that must be included in the certification course.

³² Id.

³³ 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 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.

- Maintain at least \$200,000 of professional liability insurance.³⁴

A pharmacist may also administer epinephrine using an autoinjector delivery system, within the framework of the established protocol with the supervising physician, to treat any allergic reaction resulting from a vaccine.³⁵ A pharmacist administering vaccines must provide the DOH with vaccination records for inclusion in the state's registry of immunization information.³⁶

Pharmacist Administration of Antipsychotic Medication by Injection

In 2017, the Legislature authorized a licensed pharmacist to administer an injection of a long-acting antipsychotic medication³⁷ approved by the United States Food and Drug Administration.³⁸ To be eligible to administer such injections, a pharmacist must:³⁹

- Be authorized by and acting within the framework of a protocol with the prescribing physician;
- Practice at a facility that accommodates privacy for nondeltoid injections and conforms with state rules and regulations for the appropriate and safe disposal of medication and medical waste;⁴⁰ and
- Complete an approved eight-hour continuing education course that includes instruction on the safe and effective administration of behavioral health and antipsychotic medications by injection, including potential allergic reactions.

A separate prescription from a physician is required for each injection a pharmacist administers.⁴¹

Diagnostic Tests for Influenza and Streptococcus

Influenza

Influenza (flu) is a contagious viral respiratory illness that infects the nose, throat, and sometimes the lungs. It can cause mild to severe illness, and at times can lead to death.⁴² There are four types of flu virus: Types A, B, C, and D. The influenza A and B viruses are responsible for seasonal flu epidemics each year.⁴³ Influenza type C infections generally cause mild illness and

³⁴ Section 465.189(3), F.S.

³⁵ Section 465.189(2), F.S.

³⁶ Section 465.189(5), F.S.

³⁷ A long-acting injectable antipsychotic medication may be prescribed to treat symptoms of psychosis associated with schizophrenia or as a mood stabilizer in individuals with bipolar disorder. A long-acting injectable may last from two to 12 weeks. It may be prescribed for individuals who have difficulty remembering to take daily medications or who have a history of discontinuing medication. National Alliance on Mental Illness, *Long-Acting Injectables*, available at <https://www.nami.org/Learn-More/Treatment/Mental-Health-Medications/Long-Acting-Injectables> (last visited Feb 13, 2020).

³⁸ Chapter 2017-134, Laws of Fla., codified at s. 465.1893, F.S.

³⁹ Id.

⁴⁰ Section 381.0098, F.S., and Fla. Admin. Code R. 64E-16, (2019), regulate the disposal of biomedical waste.

⁴¹ Section 465.1893(1)(b), F.S.

⁴² Centers for Disease Control and Prevention, *Key Facts about Influenza (Flu)*, (last reviewed July 10, 2019) available at <https://www.cdc.gov/flu/about/keyfacts.htm> (last visited Feb 13, 2020).

⁴³ Center for Disease Control and Prevention, *Influenza (Flu)*, available at <https://www.cdc.gov/flu/about/viruses/index.htm> (last visited Feb. 13, 2020).

are not thought to cause human flu epidemics. Influenza D viruses primarily affect cattle and are not known to infect or cause illness in people. Influenza A viruses are the only influenza viruses known to cause flu pandemics, i.e., global epidemics of flu disease.⁴⁴

Flu Symptoms

Flu is different from a cold. Flu usually comes on suddenly. People who have flu often feel some, or all, of these symptoms:

- Fever or feeling feverish/chills;
- Cough;
- Sore throat;
- Runny or stuffy nose;
- Muscle or body aches;
- Headaches;
- Fatigue (tiredness); and

Some people may have vomiting and diarrhea, though this is more common in children than adults.⁴⁵

Flu Complications

Most people who get the flu will recover in a few days to less than two weeks, but some people will develop moderate complications as a result of flu, including:

- Ear infections;
- Sinus infections; and
- Worsening of chronic medical conditions, such as:
 - Congestive heart failure;
 - Asthma; or
 - Diabetes.⁴⁶

Serious complications can also be triggered by flu and can cause:

- Heart inflammation (myocarditis);
- Brain inflammation (encephalitis);
- Muscle tissue inflammation (myositis, rhabdomyolysis);
- Multi-organ failure (respiratory and kidney failure); and
- Death.⁴⁷

Most people who get sick with flu will have a mild illness, will not need medical care or antiviral drugs, and will recover in less than two weeks. However people with the following health and age factors are at a higher risk of experiencing serious flu complications:

- Adults 65 years and older;

⁴⁴ Center for Disease Control and Prevention, *Types of Influenza Viruses*, (November 18, 2019) available at <https://www.cdc.gov/flu/about/viruses/types.htm> (last visited Feb. 13, 2020).

⁴⁵ See note 43. It's important to note that not everyone with flu will have a fever.

⁴⁶ Center for Disease Control and Prevention, *Flu Symptoms & Complications*, (September 18, 2019) available at <https://www.cdc.gov/flu/symptoms/symptoms.htm> (last visited Feb. 13, 2020).

⁴⁷ Id.

- Children younger than two years old;
- Pregnant women and women up to two weeks after the end of pregnancy;
- American Indians and Alaska Natives;
- People who live in nursing homes and other long-term care facilities;
- People who are obese with a body mass index (BMI) of 40 or higher;
- People younger than 19 years of age on long-term aspirin or salicylate medications;
- People with a weakened immune system due to disease (HIV, some cancers like leukemia) or medications (such as those receiving chemotherapy or radiation treatment for cancer, or persons with chronic conditions requiring chronic corticosteroids or other drugs that suppress the immune system);
- People with:
 - Asthma;
 - Neurologic and neurodevelopment conditions;
 - Blood disorders (such as sickle cell disease);
 - Chronic lung disease (chronic obstructive pulmonary disease and cystic fibrosis);
 - Endocrine disorders (such as diabetes mellitus);
 - Heart disease (congenital heart disease, congestive heart failure and coronary artery disease);
 - Kidney disorders;
 - Liver disorders; and
 - Metabolic disorders (inherited metabolic disorders and mitochondrial disorders).⁴⁸

Diagnostic Tests for Flu

In recent years, the FDA has approved several rapid influenza diagnostic tests (RIDTs) to identify the influenza A and B virus nucleoprotein antigens in respiratory specimens and display the result as either positive or negative. These tests can provide results within approximately 15 minutes and may be used to help with diagnosis and treatment decisions for patients. Some RIDTs use an analyzer reader device to standardize the result interpretations. However, a variety of factors can influence the accuracy of a RIDT, including the type of specimen tested, time from illness onset to collection of respiratory specimen for testing, and the prevalence of flu activity in the area. False positive results are more likely at the beginning or end of the flu season or during the summer. False negative results are more likely at the peak of the flu season.⁴⁹

Rapid molecular assays are a new tests available to detect influenza virus infection and include the Reverse Transcription-Polymerase Chain Reaction (RT-PCR) test, and other nucleic acid amplification tests. These tests can detect influenza viral ribonucleic acid (RNA) or nucleic acids in respiratory specimens with high sensitivity and high specificity, but the detection does not necessarily indicate a live virus or ongoing viral replication. Rapid molecular assays can provide results in approximately 15-30 minutes. These tests are more accurate than RIDTs and the Infectious Diseases Society of America recommends the rapid molecular assays over RIDT for detecting the flu virus in outpatients. As with RIDTs, the accuracy of rapid molecular assays may be affected by the source of the specimen, specimen handling, and the timing of the collection of

⁴⁸ Center for Disease Control and Prevention, *People at High Risk For Flu Complications*, (last reviewed August 27, 2018), available at <https://www.cdc.gov/flu/highrisk/index.htm> (last visited Feb. 13, 2020).

⁴⁹ Center for Disease Control and Prevention, *Rapid Influenza Diagnostic Tests*, (last reviewed October 25, 2016), available at https://www.cdc.gov/flu/professionals/diagnosis/clinician_guidance_ridt.htm (last visited Feb. 13, 2020).

the specimen. False negative results may occur due to improper or clinical specimen collection or handling or if the specimen is collected when the patient is no longer shedding detectable flu virus. Although a false positive is rare, it can occur through lab contamination or other factors.⁵⁰

Testing is not needed for all patients with signs and symptoms of flu to make antiviral treatment conditions. A health care practitioner may diagnose an individual with the flu based on symptoms and his or her clinical judgment, irrespective of the test results.⁵¹

Some pharmacies may currently provide flu testing, as well as other health screenings.⁵² However, these pharmacies vary by the types of patients seen, the array of services offered, the type of health care practitioner available, and the type of medications prescribed.

Streptococcus

Streptococcus (strep) is a genus of bacteria that cause a variety of infections. The Streptococcus genus is divided into at least 49 species and eight subspecies, from which as many as 35 have been identified as sources of invasive infections in humans.⁵³

There are two types of strep that cause most of the strep infections in people: group A and group B.

Group A streptococci are gram positive, anaerobic organisms that represent one of the most formidable sets of human pathogens. The numerous virulence factors of group A allow it to produce a wide array of serious infections including, but not limited to:

- Sinusitis;
- Tonsillitis;
- Respiratory infections including pneumonia;
- Skin conditions including impetigo;
- Soft tissue infections;
- Pharyngitis;
- Scarlet fever;
- Toxic shock syndrome;
- Necrotizing fasciitis (flesh-eating disease);
- Erysipelas and other spreading infections;
- Rheumatic fever;
- Glomerulonephritis;
- Endocarditis;

⁵⁰ Centers for Disease Control and Prevention, *Information on Rapid Molecular Assays, RT-PCR, and other Molecular Assays for Diagnosis of Influenza Virus Infection*, (last reviewed October 21, 2019), available at <https://www.cdc.gov/flu/professionals/diagnosis/molecular-assays.htm> (last visited Feb. 13, 2020).

⁵¹ Id.

⁵² See examples: CVS Pharmacy offers services through its MinuteClinic®, which is staffed by nurse practitioners or physician assistants (see CVS, *MinuteClinic® Services*, available at <https://www.cvs.com/minuteclinic/services?WT.ac=MC-Home-Badge1-services> (last visited Feb. 13, 2020)

⁵³ National Institutes of Health, U.S. National Library of Medicine, European Journal of Clinical Microbiology & Infectious Diseases, *The pathogenicity of the Streptococcus genus*, (July 3, 2013) available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3824240/?report=classic> (last visited Feb. 13, 2020).

- Septicemias;
- Meningitis;
- Sinusitis; and
- Mastitis.⁵⁴

Group B streptococci are an important cause of neonatal infections characterized by sepsis and meningitis. Group B streptococcal infections can cause or exacerbate diabetes mellitus, cancer, and human immunodeficiency virus infection. Adult group B infections include bacteremia, endocarditis, skin and soft tissue infection, and osteomyelitis.⁵⁵

Strep throat is a highly contagious group A strep infection. It is most common in children between ages 5 and 15; however, anyone may contract it.⁵⁶ Strep throat is passed through person-to-person contact. However, a person who has been treated with antibiotics for 24 hours or longer can generally no longer transmit the bacteria.⁵⁷ If strep throat is not diagnosed and treated, it may lead to complications such as rheumatic fever, which can damage the heart, or glomerulonephritis, which affects the kidneys.⁵⁸

Rapid antigen diagnostic tests (RADTs) may be used to determine the presence of group A strep in a patient's throat or other infected areas.⁵⁹ Results are generally available in 7 to 15 minutes.⁶⁰ RADTs, in general, have high diagnostic accuracy, with tests using newer techniques providing the greatest accuracy.⁶¹

Reporting of Diseases to the Department of Health

Any licensed physician, chiropractic physician, nurse, midwife, medical examiners, hospitals, laboratories, or veterinarians licensed in this state must immediately report the diagnosis or suspected diagnosis of a disease of public health importance to the DOH. The DOH, by rule, has designated the diseases and conditions that must be reported, as well as the timeframes for such reports. A suspected or confirmed diagnosis of the flu that is caused by a by novel or pandemic strain must be reported immediately. However, strep throat is not among the diseases or conditions that must be reported. The practitioner must report the disease or condition on a form developed by the DOH, which includes information such as the patient's name, demographic

⁵⁴ Howard, B.J., et al. 1994. *Clinical and Pathogenic Microbiology*, 2nd ed. Mosby, St. Louis, IL.

⁵⁵ Id.

⁵⁶ Center for Disease Control and Prevention, *Strep Throat: All You Need to Know*, (last reviewed November 1, 2018), available at <https://www.cdc.gov/groupastrep/diseases-public/strep-throat.html> (last visited Feb. 13, 2020).

⁵⁷ Center for Disease Control and Prevention, *Pharyngitis (Strep Throat)*, (last reviewed January 22, 2019), available at <https://www.cdc.gov/groupastrep/diseases-hcp/strep-throat.html> (last visited Feb. 13, 2020).

⁵⁸ Id.

⁵⁹ John Mersch, MD, FAAP, MedicineNet.Com, *Rapid Strep Test*, (last reviewed November 30, 2018) available at https://www.medicinenet.com/rapid_strep_test/article.htm (last visited Feb. 13, 2020).

⁶⁰ American Academy of Family Physicians, *Rapid Strep Test*, (last updated January 14, 2017) available at <https://familydoctor.org/rapid-strep-test/?adfree=true> (last visited Feb. 13, 2020).

⁶¹ W. L. Lean et al., *Rapid Diagnostic Tests for Group A Streptococcal Pharyngitis: A Meta-analysis*, 134 *Pediatrics* 771–781 (2014), available at <http://pediatrics.aappublications.org/content/pediatrics/early/2014/09/02/peds.2014-1094.full.pdf> (last visited Feb. 13, 2020).

information, diagnosis, test procedure used, and treatment given. The practitioner must make the patient's medical records for such diseases available for onsite inspection by the DOH.⁶²

III. Effect of Proposed Changes:

Section 1 amends s. 381.0031, F.S., which requires certain health care practitioners, hospitals, and federally-certified laboratories which diagnoses or suspects the existence of a disease of public health significance to report that fact to the DOH. The bill adds the licensed pharmacist with written protocol with a physician that includes ordering and evaluating laboratory and clinical tests to those required to report.

Section 2 amends the definition of the “practice of the profession of pharmacy” to include the testing for, and treatment of, influenza and streptococcus pursuant to s. 465.1895, F.S., which is created by the bill.

Section 3 creates s. 465.1895, F.S., which permits a pharmacist to test for and treat influenza and streptococcus if:

- The pharmacist as a written protocol with a supervising physician that, at a minimum, includes:
 - Particular terms and conditions imposed by the supervising physician upon the pharmacist relating to the administration of vaccines by the pharmacist;
 - Specific categories and conditions among patients for whom the supervising physician authorizes the pharmacist to administer such vaccines;
 - Provides proof of a current certification to administer vaccines from the BOP;
 - Scheduled Reviews of protocol between pharmacist and supervising physician process;
 - Specific categories of patients the supervising physician authorizes the pharmacist to test and treat for influenza and streptococcus;
 - Instructions from the supervising physician for the treatment of influenza and streptococcus based on the patient's age, symptoms, and test results, including negative results;
 - A process and schedule for the pharmacist to notify the supervising physician of the patient's condition, tests administered, test results, and course of treatment; and
 - A process and schedule for the supervising physician to review the pharmacist's actions under the written protocol.
- The pharmacist uses an instrument and a waived test, as that term is defined in 42 C.F.R. s. 493.2. The testing system must:
 - Provide automated readings to reduce user subjectivity or interpretation of results;
 - Be capable of directly or indirectly interfacing with electronic medical records systems;
 - Be capable of electronically reporting daily deidentified test results to the appropriate agencies; and
 - Use an instrument that incorporates both internal and external controls and external calibration that show the reagent and assay procedure is performing properly. External

⁶² Section 381.0031, F.S., and Fla. Admin. Code R. 64D-3.029 and 64D-3.030, (2019). See also Florida Department of Health, *Health Care Practitioner Reporting Guidelines for Reportable Diseases and Conditions in Florida*, (October 20, 2016), available at <http://www.floridahealth.gov/diseases-and-conditions/disease-reporting-and-management/documents/guidelines-health-care.pdf> (last visited Feb. 13, 2020).

controls must be used in accordance with local, state, and federal regulations and accreditation requirements;

- The pharmacist maintains at least \$200,000 of professional liability insurance; and
- The pharmacist completes a certification program developed by the BOP, in consultation with the BOM and the BOOM, that includes eight hours of BOP-approved continuing education with a curriculum approved by the Accreditation Council for Pharmacy Education and must provide, at a minimum, point-of-care testing for influenza and streptococcus and the safe and effective treatment of influenza and streptococcus.

Once the pharmacist has completed the initial requirements to test for and treat influenza and streptococcus, the bill requires the pharmacist to maintain patient records for at least five years and make them available using confidentiality and maintenance standards imposed on health care practitioners under Florida law.⁶³ The bill also requires the pharmacist to notify the patient's primary care provider within two business days after providing testing or treatment.

The bill prohibits a pharmacist who is an employee of a pharmacy from entering into a written protocol that is to be performed while acting as a pharmacy employee without the written approval of the owner of the pharmacy.

The bill provides that the supervising physician's decision to enter into a written protocol with a pharmacist for the testing and treatment of flu and strep is a professional decision and no person may interfere with that decision regarding entering into such a protocol.

Section 4 provides that the bill takes effect upon becoming a law.

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.

⁶³ Section 456.057, F.S.

V. Fiscal Impact Statement:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The Department of Health did not provide a fiscal impact estimate for this bill. The Board of Pharmacy may incur an unknown amount of recurring costs to carry out its responsibilities under SB 714.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 381.0031 and 465.003.

This bill creates section 465.1895 of the Florida Statutes.

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

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

None.

B. Amendments:

None.