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 Appropriations Subcommittee on Health and Human Services

BILL:	CS/SB 714
INTRODUCER:	Health Policy Committee and Senator Hutson
SUBJECT:	Testing for and Treatment of Influenza
DATE:	February 24, 2020 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Brown	HP	**Fav/CS**
2.	Howard	Kidd	AHS	**Recommend: Favorable**
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 714 amends the definition of the "practice of the profession of pharmacy" to include the testing for and treatment of influenza by a pharmacist under a written protocol with a primary care supervising physician that includes specific terms and conditions.

The bill authorizes a pharmacist to test for and treatment influenza, if the pharmacist:

- Completes a certification program with specific requirements approved by the Board of Medicine (BOM), in consultation with the Board of Osteopathic Medicine (BOOM) and the Board of Pharmacy (BOP), that must be developed and implemented within 90 days after the bill's effective date;
- Uses a specific instrument and a waived test;
- Uses a specific testing system that meets certain criteria;
- Obtains a complete medical history on a BOM-approved form;
- Provides pharmacy signage recommending follow-up for patients tested;
- Provides the patient with the name and contact information of the pharmacist's supervising physician;
- Provides the patient with a BOM-approved pamphlet or brochure that includes advising the patient:
  - To seek follow-up care if the test is positive; and
  - That the pharmacist and pharmacy are liable for damages from adverse reactions to the treatment;

- Treats patients only with medications approved by the BOM and reviewed annually;
- Reviews the patient's prescription history for contraindications;
- Maintains at least $250,000 of professional liability insurance; and
- Maintains, and makes available, medical records for five years using prescribed standards.

The bill also specifies certain persons whom a pharmacist may not test or treat for influenza and that a supervising physician may not supervise pharmacists employed at more than four pharmacy locations.

The Department of Health (department) will experience an increase in workload and costs associated with the requirements of the bill; however, the department anticipates existing resources are adequate to absorb the impact of the bill.

The bill includes language that implementation of the Board of Medicine's (BOM) efforts to carry out the duties required by the bill is contingent upon the enactment of an appropriation within the General Appropriations Act.

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 Board of Pharmacy (BOP), in conjunction with the Department of Health (department), 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 department:

- Community pharmacy;
- Institutional pharmacy;[3]
- Nuclear pharmacy;[4]
- Special pharmacy;[5]
- Internet pharmacy;[6]

[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.

- 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.

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;

[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 department 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 department-licensed pharmacist.
[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.

- 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);
- 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

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

  - 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 then 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 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:

[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).
[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 administers immunizations or vaccinations under the supervision of a certified pharmacist.

- 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
- 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 department 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 medication[37] approved by the United States Food and Drug Administration.[38] To be eligible to administer such injections, a pharmacist must:[39]

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[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.
[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.

- 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 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]

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[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).
[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.

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;
- 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

[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.

- 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 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.

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[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).
[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)

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 department. The department, 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 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 department, which includes information such as the patient's name, demographic 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 department.[53]

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 diagnose or suspect the existence of a disease of public health significance to report that fact to the Department of Health (department). 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 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 if the pharmacist meets all of the following requirements:

- Enters into a written protocol with a supervising physician licensed under chapters 458 or 459, F.S., which meets the requirements for a written protocol pursuant to Board of Medicine (BOM) rules, adopted in consultation with the Board of Osteopathic Medicine (BOOM) and the Board of Pharmacy (BOP), that includes, at a minimum:
  - Terms and conditions required by s. 465.189(7), F.S., which includes;
  - That the pharmacist, or his designee, must follow up with the patient three days after treatment to determine whether the patient's condition has improved; and
  - If the patient's condition has not improved, the pharmacist must do all of the following:
    - Recommend that the patient seek treatment from the patient's primary care physician or, if the patient has no primary care physician, from the pharmacist's supervising physician;
    - Inform the patient's primary care physician that the patient's condition failed to improve three days after treatment or, if the patient has no primary care physician, the pharmacist must so inform the pharmacist's supervising physician; and
    - Document in the patient's records whether the follow-up occurred or whether attempts to contact the patient were unsuccessful.

[53] 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).

  - A supervising physician's instructions for the treatment of influenza based on the patient's age, symptoms, and test results, including negative results;
  - A process and schedule for the supervising physician to review the pharmacist's actions under the written protocol;
  - 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 procedure to notify the patient's primary care provider within two business days after providing any such testing or treatment, when the patient has a primary care provider.
- Uses instruments and waived tests, as defined in 42 C.F.R. s. 493.2.
- Uses a testing system that:
  - Provides automated readings in order to reduce user subjectivity or interpretation of results;
  - Is capable of directly or indirectly interfacing with electronic medical records systems;
  - Is capable of electronically reporting daily deidentified test results to the appropriate agencies; and
  - Uses an instrument that incorporates both internal and external controls and external calibration that show the reagent and assay procedure is performing properly. External controls must be used in accordance with local, state, and federal regulations and accreditation requirements.
- Is certified through a certification program approved by the BOM, in consultation with the BOOM and the BOP. The program must:
  - Be developed and implemented within 90 days after the effective date of the bill.
  - Required to attend eight hours of BOM-approved continuing education with a curriculum approved by the Accreditation Council for Pharmacy Education; and
  - Provide instructional services, including at a minimum, point-of-care testing for influenza and the safe and effective treatment of influenza.
- Has obtained a full past and present history from the patient on a form promulgated and adopted by rule of the BOM which allows the patient to check off medical conditions from a list and add other conditions that are not listed.
- Prominently displays signage indicating that any patient tested and treated at the pharmacy is advised to seek follow-up care from his or her primary care physician or, if the patient has no primary care physician, from the pharmacist's supervising physician.
- Provides the patient with the name and contact information of the pharmacist's supervising physician and a pamphlet or brochure that meets criteria established by BOM rule informing the patient that:
  - If the test indicates that the patient has influenza, the patient is advised to seek follow-up care from the patient's primary care physician or, if the patient has no primary care physician, from the pharmacist's supervising physician; and
  - If the pharmacist treats the patient for influenza, the pharmacist and the pharmacy where the testing and treating occurred are liable for damages the patient suffers as a result of an adverse reaction to the treatment.
- Treats only with limited medications designed to treat influenza which are approved by the BOM and which the BOM reviews annually.
- Reviews the patient's current prescriptions and recent prescription history to check for relative contraindications involving the intended treatment.
- Maintains at least $250,000 of professional liability insurance.

- Maintains, and makes available, patient records, including the required patient history, test results, and the name and contact information of the pharmacist's supervising physician, for at least five years, using the same standards for confidentiality and record maintenance as required under s. 456.057, F.S.

The bill specifies that a pharmacist may not test for or treat influenza for a patient who:

- Is younger than 18 years of age;
- Is older than 75 years of age;
- Refuses to provide a medical history; or
- Provides a medical history indicating a history of conditions relating to:
  - Heart disease;
  - Bronchial disorders;
  - Pneumonia;
  - Chronic obstructive pulmonary disease;
  - Asthma; or
  - Any other medical conditions the BOM specifies annually by rule.

The bill requires that a supervising physician who enters into a written protocol with a pharmacist must be a primary care physician who is actively practicing in the community in which the pharmacist tests and treats according to BOM rule. A supervising physician may not supervise pharmacists employed at more than four pharmacy locations.

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. A pharmacist may not enter into a written protocol that is to be performed while acting as an employee without the written approval of the owner of the pharmacy.

Implementation of s. 465.1895, F.S., as created by the bill, is contingent on the enactment of an appropriation within the General Appropriations Act which is sufficient to fund the BOM's required duties under the bill.

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.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The CS/SB 714 would increase the Department of Health's workload associated with the submission and tracking of written protocols between pharmacists and supervising physicians, additional complaints, investigations, and prosecution for non-compliance with the requirements of the bill, updating the Licensing and Enforcement Information Database System to include a new modifier to identify certification, and rulemaking. However, the department anticipates current resources are adequate to absorb the impact of the bill.

The bill includes language that implementation of the Board of Medicine's (BOM) efforts to carry out the duties required by the bill is contingent upon the enactment of an appropriation within the General Appropriations Act.

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.)

CS by Health Policy on February 18, 2020:
The CS:

- Removes from the definition of the "practice of professional pharmacy" the testing for and treatment of streptococcus from the underlying bill;
- Changes the underlying bill's rulemaking authority from the BOP to the BOM for rules to:
  - Establish requirements for pharmacist's written protocol with supervising physician to test and treat for influenza;
  - Approve pharmacist's required certification program to test for and treat influenza; and
  - Approve the pharmacist's required one-time, one hour continuing education course required by the certification program.
- Adds the following additional requirements for a pharmacist to test for and treat influenza:
  - Obtain a complete medical history on a BOM approved form;
  - Provide pharmacy signage recommending follow-up for patients tested;
  - Provide the patient with the name and contact information of the supervising physician; and
  - Provide the patient with a BOM approved pamphlet or brochure that includes advising the patient:
- To seek follow-up care if the test is positive; and
  - That the pharmacist and pharmacy are liable for damages from adverse reactions.
  - Treat patients only with medications approved by the BOM, and reviewed annually; and
  - Review the patient's prescription history for contraindications.
- Specifies patients the pharmacist may not test for or treat for influenza.

B. Amendments:

None.