

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 389 Testing for and Treatment of Influenza and Streptococcus

SPONSOR(S): Sirois

TIED BILLS: **IDEN./SIM. BILLS:** SB 714

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	11 Y, 3 N	Siples	McElroy
2) Health Care Appropriations Subcommittee	10 Y, 1 N	Mielke	Clark
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Pharmacy is the third largest health profession behind nursing and medicine and, for many people, the most accessible. A pharmacist dispenses medications and counsels patients on the use of both prescription and over the counter medications. In Florida, the scope of practice for pharmacists has expanded to include administration of vaccines and immunizations, assistance with medication management, as well as injection of certain medications within an established protocol with a physician. Other states have expanded the scope of pharmacists to include prescribing medications, either independently or pursuant to a statewide or health care practitioner protocol.

The influenza virus (flu) and streptococcal bacteria (strep) are infectious and, if not diagnosed and treated timely, can lead to serious and even fatal health conditions. Rapid diagnostic tests are available for both the flu and strep, providing results within minutes.

HB 389 authorizes pharmacists to tests for and treat the flu and strep within the framework of an established written protocol with a physician licensed in this state. To provide such services, a pharmacist must meet certain criteria, including education, proof of liability insurance, and employer approval. The bill also establishes standards of practice for pharmacists providing these services.

The bill requires a supervising physician to review the actions taken by a pharmacist. The bill also prohibits any person from interfering with a physician's professional decision of whether to enter into a protocol to supervise a pharmacist to provide testing for and the treatment of the flu and strep.

The bill has an insignificant, negative fiscal impact on the Department of Health, which current resources are sufficient to absorb. The bill has no fiscal impact on local governments.

The bill takes effect upon becoming a law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Pharmacist Licensure

Pharmacy is the third largest health profession behind nursing and medicine.¹ The Board of Pharmacy (board), in conjunction with the Department of Health (DOH), regulates the practice of pharmacists pursuant to ch. 465, F.S.² To be licensed as a pharmacist in Florida, a person must:³

- 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;⁴
- Have completed a board-approved internship; and
- Successfully complete the board-approved examination.

A pharmacist must complete at least 30 hours of board-approved continuing education during each biennial renewal period.⁵ Pharmacists who are certified to administer vaccines or epinephrine autoinjections must complete a 3-hour continuing education course on the safe and effective administration of vaccines and epinephrine injections as a part of the biennial licensure renewal.⁶ Pharmacists who administer long-acting antipsychotic medications must complete an approved 8-hour continuing education course as a part of the continuing education for biennial licensure renewal.⁷

Pharmacist Scope of Practice

In Florida, the practice of the profession of pharmacy includes:⁸

- Compounding, dispensing, and consulting concerning 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;⁹
- Administering vaccines to adults;¹⁰
- Administering epinephrine injections;¹¹ and
- Administering antipsychotic medications by injection.¹²

¹ American Association of Colleges of Pharmacy, *About AACP*, available at <https://www.aacp.org/about-aacp> (last visited October 30, 2019).

² Sections 465.004 and 465.005, F.S.

³ 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.

⁴ 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

⁵ Section 465.009, F.S.

⁶ Section 465.009(6), F.S.

⁷ Section 465.1893, F.S.

⁸ Section 465.003(13), F.S.

⁹ A Class III institutional pharmacy are those pharmacies affiliated with a hospital. See s. 465.019(2)(d), F.S.

¹⁰ See s. 465.189, F.S.

¹¹ *Id.*

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.¹³

Pharmacists may order and dispense drugs that are included in a formulary developed by a committee composed of members of the Boards of Medicine, Osteopathic Medicine, and Pharmacy.¹⁴ The formulary may only include:¹⁵

- 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 United States Food and Drug Administration;
- Medicinal drugs recommended by the United States Food and Drug Administration Advisory Panel for transfer to over-the-counter status pending approval by the United States Food and Drug Administration;
- 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:¹⁶

- 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;
- Certain urinary analgesics;
- Certain otic analgesics;
- Anti-nausea preparations;
- Certain antihistamines and decongestants;
- Certain topical antifungal/antibacterials.
- Certain topical anti-inflammatory products;
- Certain otic antifungal/antibacterial preparations;
- Certain keratolytics;
- 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;
- Certain ophthalmic solutions;
- Certain histamine H2 antagonists;
- Certain acne products;
- Topical Antiviral for herpes simplex infections of the lips; and
- Penciclovir.

One category of pharmacist has a broader scope of practice. 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.¹⁷ 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.¹⁸

¹² Section 465.1893, F.S.

¹³ *Supra* note 8.

¹⁴ Section 465.186, F.S.

¹⁵ *Id.*

¹⁶ Rule 64B16-27.220, F.A.C.

¹⁷ American Society of Consultant Pharmacists, *What is a Consultant Pharmacist*, available at <http://www.ascp.com/page/whatisacp> (last visited October 30, 2019).

¹⁸ Rule 64B16-26.300(3), F.A.C.

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.¹⁹ 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.²⁰

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, 2015.²¹ 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.;²² which must:²³
 - 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 Board of Pharmacy;
- Successfully complete a board-approved vaccine administration certification program that consists of at least 20 hours of continuing education;²⁴
- Pass an examination and demonstrate vaccine administration technique;²⁵
- 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;²⁶ and
- Maintain at least \$200,000 of professional liability insurance.²⁷

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.²⁸ A pharmacist administering vaccines must provide DOH with vaccination records for inclusion in the state's registry of immunization information.²⁹

¹⁹ Section 465.0125(1), F.S.

²⁰ 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.

²¹ Section 465.189, F.S. A registered intern may also administer immunizations or vaccinations under the supervision of a certified pharmacist.

²² Section 465.189(1), F.S.

²³ Section 465.189(7), F.S.

²⁴ Section 465.189(6), F.S. Rule 64B16-26.1031, F.A.C., provides more detail regarding subject matter that must be included in the certification course.

²⁵ Id.

²⁶ 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.

²⁷ Section 465.189(3), F.S.

²⁸ Section 465.189(2), F.S.

²⁹ Section 465.189(5), F.S.

In 2017, the Legislature authorized a licensed pharmacist to administer an injection of a long-acting antipsychotic medication³⁰ approved by the United States Food and Drug Administration.³¹ To be eligible to administer such injections, a pharmacist must:³²

- 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;³³ and
- Complete an approved 8-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.³⁴

Diagnostic Tests for Influenza and Streptococcus

Influenza

Influenza (flu) is a viral, contagious respiratory illness that infect the nose, throat, and sometimes the lungs.³⁵ Although the flu virus may be detected at any time of the year, the flu virus is most common during the fall and winter.³⁶ Each year, on average 3 to 11 percent of the United States population gets sick from the flu, hundreds of thousands are hospitalized, and thousands die from flu-related illnesses.³⁷ Annually, the flu costs businesses and employers \$10.4 billion in direct costs for hospitalizations and outpatient visits for adults.³⁸

A person who has contracted the flu virus is most contagious in the first three to four days after the illness begins.³⁹ However, some individuals may be able to infect others beginning one day before symptoms develop and up to five to seven days after becoming sick.⁴⁰ According to the CDC, most people infected with the flu will have a mild illness and do not need medical care or antiviral medication.⁴¹ The CDC recommends an annual vaccination as the best way to prevent flu.⁴²

Individuals with weakened immune systems, the elderly, young children, pregnant women, people living in nursing homes or other long-term care facilities, or those with certain health conditions, may be at high risk of serious flu complications.⁴³ Complications of the flu may include bacterial pneumonia, ear

³⁰ 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 October 30, 2019).

³¹ Chapter 2017-134, Laws of Fla., codified at s. 465.1893, F.S.

³² *Id.*

³³ Section 381.0098, F.S., and r. 64E-16, F.A.C., regulate the disposal of biomedical waste.

³⁴ Section 465.1893(1)(b), F.S.

³⁵ Centers for Disease Control and Prevention, *Key Facts about Influenza (Flu)*, (last rev. Sept. 13, 2019), available at <https://www.cdc.gov/flu/about/keyfacts.htm> (last visited October 30, 2019).

³⁶ Centers for Disease Control and Prevention, *The Flu Season*, (last rev. July 12, 2018), available at <https://www.cdc.gov/flu/about/season/flu-season.htm> (last visited October 30, 2019).

³⁷ *Supra* note 35, and Centers for Disease Control and Prevention, *Key Facts about Seasonal Flu Vaccine*, (last rev. Oct. 21, 2019), available at <https://www.cdc.gov/flu/prevent/keyfacts.htm> (last visited October 30, 2019).

³⁸ Centers for Disease Control and Prevention, *Make It Your Business to Fight the Flu*, available at https://www.cdc.gov/flu/pdf/business/toolkit_seasonal_flu_for_businesses_and_employers.pdf (last visited October 30, 2019).

³⁹ *Supra* note 35.

⁴⁰ *Id.*

⁴¹ Centers for Disease Control and Prevention, *People at High Risk for Flu Complications*, (last rev. Aug. 27, 2018), available at <https://www.cdc.gov/flu/takingcare.htm> (last visited February 21, 2019).

⁴² *Supra* note 35.

⁴³ *Supra* note 41.

infections, sinus infections, and worsening of chronic medical conditions, such as congestive heart failure, asthma, or diabetes.⁴⁴ Serious flu infections can result in hospitalizations or death.

In recent years, the Food and Drug Administration has approved several rapid influenza diagnostic tests (RIDTs) to identify the influenza virus in respiratory specimens.⁴⁵ These tests can provide results within approximately 15 minutes and may be used to help with diagnosis and treatment decisions for patients.⁴⁶ Some RIDTs use an analyzer reader device to standardize the result interpretations.⁴⁷ However, a variety of factors can influence the accuracy of an 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.⁴⁸ 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 type of diagnostic test to detect viral flu and provide results in 15-30 minutes.⁵⁰ 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.⁵¹ 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.⁵² 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.⁵³ Although a false positive is rare, it can occur through lab contamination or other factors.⁵⁴

Testing is not needed for all patients with signs and symptoms of flu to make antiviral treatment conditions.⁵⁵ 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.

Some pharmacies may currently provide flu testing, as well as other health screenings.⁵⁶ 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 Testing

Streptococcus (strep) is a bacteria that causes a variety of infections. There are two types of strep that cause most of the strep infections in people: group A and group B. Group A strep infections include strep throat, scarlet fever, impetigo, toxic shock syndrome and cellulitis and necrotizing fasciitis (flesh-eating disease).⁵⁷ Group B strep may cause blood infections, pneumonia, and meningitis in newborns,

⁴⁴ *Supra* note 35.

⁴⁵ Center for Disease Control and Prevention, *Rapid Influenza Diagnostic Tests*, (last rev. Oct. 25, 2016), available at https://www.cdc.gov/flu/professionals/diagnosis/clinician_guidance_ridt.htm (last visited October 30, 2019).

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ *Id.*

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 rev. Oct. 21, 2019), available at <https://www.cdc.gov/flu/professionals/diagnosis/molecular-assays.htm> (last visited October 30, 2019).

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ *Id.*, and *supra* note 45.

⁵⁶ For example, 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 October 30, 2019)), and Walgreens offers services through its Healthcare Clinic, which offers services by licensed healthcare professionals to patients 18 months or older (see Walgreens, *Healthcare Clinic*, available at <https://www.walgreens.com/topic/pharmacy/healthcare-clinic.jsp> (last visited October 30, 2019)).

⁵⁷ U.S. National Library of Medicine, Medline Plus, *Streptococcal Infections*, (last rev. Sept. 27, 2019), available at <https://medlineplus.gov/streptococcalinfections.html> (last visited October 31, 2019).

as well as urinary tract infections, blood infections, skin infections, and pneumonia in adults.⁵⁸ Strep throat, along with minor skin infections, are the most common group A strep infection.⁵⁹

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.⁶⁰ 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.⁶¹ 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 kidney.⁶²

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.⁶³ Results are generally available in 7 to 15 minutes.⁶⁴ RADTs, in general, have high diagnostic accuracy, with tests using newer techniques providing the greatest accuracy.⁶⁵

Reporting of Diseases to DOH

Any licensed physician, chiropractic physician, nurse, midwife, or veterinarian licensed in this state must immediately report the diagnosis or suspected diagnosis of a disease of public health importance to DOH.⁶⁶ DOH, by rule, has designated the diseases and conditions that must be reported, as well as the timeframes for such reports.⁶⁷ A suspected or confirmed diagnosis of flu that is caused by a novel or pandemic strain must be reported immediately.⁶⁸ 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 DOH, which includes information such as the patient's name, demographic information, diagnosis, test procedure used, and treatment given.⁶⁹ The practitioner must make the patient's medical records for such diseases available for onsite inspection by DOH.⁷⁰

Effect of Proposed Changes

HB 389 authorizes a pharmacist to test for and treat flu and strep, under certain conditions. To be eligible to provide such services, a pharmacist must:

- Complete a certification program approved by the Board of Pharmacy, in consultation with the Board of Medicine and the Board of Osteopathic Medicine, which consists of at least 8 hours of continuing education course approved by the board. The curriculum must be provided by an organization approved by the Accreditation Council for Pharmacy Education and must include instruction on point-of-care flu and strep testing and the safe and effective treatment of flu and strep infections;

⁵⁸ Id.

⁵⁹ National Institute of Allergy and Infectious Diseases, *Group A Streptococcal Infections*, (last rev. Sept. 29, 2015), available at <https://www.niaid.nih.gov/diseases-conditions/group-streptococcal-infections> (last visited October 31, 2019).

⁶⁰ CDC, *Strep Throat: All You Need to Know*, (last rev. Nov. 1, 2018), available at <https://www.cdc.gov/groupastrep/diseases-public/strep-throat.html> (last visited October 31, 2019).

⁶¹ CDC, *Pharyngitis (Strep Throat)*, (last rev. Jan. 22, 2019), available at <https://www.cdc.gov/groupastrep/diseases-hcp/strep-throat.html> (last visited October 31, 2019).

⁶² *Supra* note 57.

⁶³ John Mersch, MD, FAAP, MedicineNet.Com, *Rapid Strep Test*, available at https://www.medicinenet.com/rapid_strep_test/article.htm (last visited February 21, 2019).

⁶⁴ American Academy of Family Physicians, *Rapid Strep Test*, available at <https://familydoctor.org/rapid-strep-test/?adfree=true> (last visited October 31, 2019).

⁶⁵ 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 October 31, 2019).

⁶⁶ Section 381.0031, F.S. and r. 64D-3.030, F.A.C. Medical examiners, hospitals, and laboratories are also required to report the diagnosis or suspected existence of such diseases to DOH.

⁶⁷ Rule 64D-3.029, F.A.C. See also <http://www.floridahealth.gov/diseases-and-conditions/disease-reporting-and-management/documents/reportable-diseases/documents/reportable-diseases-list-practitioners.pdf> (last visited October 31, 2019).

⁶⁸ Id.

⁶⁹ Rule 64D-3.030, F.A.C.

⁷⁰ Id.

- Maintain at least \$200,000 of professional liability insurance;
- Act within the framework of a written protocol with a supervising physician that, at a minimum, includes:
 - The terms and conditions required in s. 489.189(7), F.S., which includes:
 - The specific categories and conditions among patients for whom the pharmacist is authorized to administer vaccines;
 - Limiting the terms, scope, and conditions to those that are appropriate for the pharmacist's training and certification for administering such vaccines;
 - Providing proof of current certification by the board to the supervising physician;
 - Requiring the supervising physician to review the administration of vaccines by the pharmacist as provided by the protocol; and
 - A process and schedule for the review;
 - The specific categories of patients the pharmacist is authorized to test for and treat flu and strep;
 - The supervising physician's instructions for treatment 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 protocol; and
 - 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
- Obtain the written approval of the owner of the pharmacy, if the pharmacist is acting as an employee of such pharmacy.

A pharmacist who is authorized to test for and treat flu and strep must use a test system that:

- Is waived from meeting the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA);⁷¹
- Provides automated readings to reduce user subjectivity in interpretation of results;
- Is capable of interfacing with electronic health record systems;
- Is capable of providing de-identified test results to the appropriate agencies; and
- Incorporates both internal and external controls and external calibration that show the reagent and assay procedure is performing properly.

The bill prohibits any person from interfering with a physician's professional decision of whether to enter into a protocol to supervise a pharmacist to provide testing for and the treatment of the flu and strep.

A pharmacist must also notify a patient's primary care provider within two business days after providing flu or strep testing or treatment. Each pharmacist who provides testing and treatment for flu and strep must maintain and make available patient records in the same manner as required under s. 457.057, F.S.⁷² The clinical record created by the pharmacist under this bill must be maintained for at least 5 years.

Within 90 days of the bill becoming effective, the board must adopt rules establishing the requirements for the written protocol and approve the 8-hour certification course.

The bill revises the definition of "the practice of the profession of pharmacy" to include the testing for and treatment of influenza and streptococcus.

The bill takes effect upon becoming a law.

⁷¹ CLIA regulates all facilities performing laboratory tests on human specimens for health assessment or the diagnosis, prevention, or treatment of a disease. Waived tests are those that have been cleared for home use and approved for waiver under CLIA criteria. CLIA requires waived test to be simple and have a low risk for erroneous results. See Centers for Disease Control and Prevention, *Clinical Laboratory Improvement Amendments (CLIA) – Waived Tests*, available at <https://www.cdc.gov/clia/resources/waivedtests/default.aspx> (last visited February 21, 2019).

⁷² Section 456.057, F.S., provides requirements on the maintenance and disclosure of medical records by a health care practitioner.

B. SECTION DIRECTORY:

- Section 1:** Amends s. 381.0031, F.S., relating to epidemiological research; report of diseases of public health significance to the department.
- Section 2:** Amends s. 465.003, F.S., relating to definitions.
- Section 3:** Creates s. 465.1895, F.S., relating to testing for and treatment of influenza and streptococcus.
- Section 4:** Provides an effective date of upon becoming a law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

DOH will incur insignificant, nonrecurring costs related to rulemaking, which current resources are adequate to absorb.

DOH will incur insignificant, nonrecurring costs related to updating the LEIDS licensing system to include a new modifier to identify pharmacist certification, which current resources are adequate to absorb.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Pharmacists who provide flu and strep testing and treatment as authorized by the bill will incur costs associated with obtaining the required continuing education, maintaining liability insurance, and entering into a supervisory protocol.

Individuals with limited access to health care practitioner services may be able to more easily access testing for and treatment of the flu and strep.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The Board of Pharmacy has broad rulemaking authority under its practice act; therefore, no additional rulemaking authority is needed.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill requires the written protocol to meet the terms and conditions specified in s. 465.189(7), F.S.; however, those terms and conditions are specific to the administration of vaccinations. Since the bill explicitly states the requirements of 465.189(7), F.S., the reference to that provision should be deleted.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES