

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 431 Testing for and Treatment of Influenza and Streptococcus
SPONSOR(S): Health Quality Subcommittee; Plasencia
TIED BILLS: **IDEN./SIM. BILLS:** SB 524

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	12 Y, 2 N, As CS	Siples	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Pharmacists are valuable members of the health care team. A pharmacist provides a number of services to his or her consumers, including the dispensing of medications and counseling patients on the use of both prescription and over the counter medications. Over the last few years, the scope of practice for pharmacists has expanded to include the administration of vaccines and immunizations, assistance with medication management, as well as the injection of certain medications within an established protocol with a physician.

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

CS/HB 431 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 be eligible to provide such services, a pharmacist must:

- Complete an approved certification program;
- Maintain at least \$200,000 of professional liability insurance;
- Act within the framework of an established written protocol under a supervising physician that, at a minimum specifies the categories of patients the pharmacist is authorized to test for and treat the flu and strep, the supervising physician's instructions for treatment, and a process for reporting and reviewing the pharmacist's actions under the protocol;
- Obtain written approval of the owner of the pharmacy, if the pharmacist is acting as an employee of such pharmacy;
- Maintain patient records as required under state law for at least five years after the provision of services;
- Submit a copy of his or her protocol to the Board of Pharmacy;
- Use a test for which the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) has been waived;
- Use a test system that integrates with certified electronic health record technology;
- Provides the results of the test to any health care practitioner designated by the patient to receive such results; and
- Reports the diagnosis or suspected existence of a disease as required by the Department of Health.

The supervising physician must review the actions taken by the pharmacist in the manner outlined in the protocol.

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.

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

The bill takes effect upon becoming law.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives.

STORAGE NAME: h0431a.HQS

DATE: 1/18/2018

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Regulation of Pharmacists

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

Scope of Practice

In Florida, the practice of the profession of pharmacy includes:⁷

- 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;
- Administering vaccines to adults;⁸
- Administering epinephrine injections;⁹ and

¹ American Association of Colleges of Pharmacy, *About AACP*, available at <https://www.aacp.org/about-aacp> (last visited December 5, 2017).

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 465.003(13), F.S.

⁸ See s. 465.189, F.S.

⁹ *Id.*

- Administering antipsychotic medications by injection.¹⁰

Pharmacists are specifically prohibited from altering a prescriber's directions, diagnosing or treating any disease, initiating any drug therapy, and practicing medicine or osteopathic medicine, unless permitted by law.¹¹

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, 2015.¹² 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.,¹³ which must:¹⁴
 - 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;¹⁵
- Pass an examination and demonstrate vaccine administration technique;¹⁶ and
- Maintain at least \$200,000 of professional liability insurance.¹⁷

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.¹⁸ A pharmacist administering vaccines must provide DOH with vaccination records for inclusion in the state's registry of immunization information.¹⁹

Pharmacist Administration of Antipsychotic Medication by Injection

In 2017, the Legislature authorized a licensed pharmacist to administer an injection of a long-acting antipsychotic medication²⁰ approved by the United States Food and Drug Administration.²¹ To be eligible to administer such injections, a pharmacist must:²²

- Be authorized by and acting within the framework of a protocol with the prescribing physician;

¹⁰ Section 465.1893, F.S.

¹¹ *Supra* note 7

¹² Section 465.189, F.S. A registered intern may also administer immunizations or vaccinations under the supervision of a certified pharmacist.

¹³ Section 465.189(1), F.S.

¹⁴ Section 465.189(7), F.S.

¹⁵ 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.

¹⁶ *Id.*

¹⁷ Section 465.189(3), F.S.

¹⁸ Section 465.189(2), F.S.

¹⁹ Section 465.189(5), F.S.

²⁰ A long-acting injectable antipsychotic medication may be prescribed to treat symptoms of psychosis associated with schizophrenia and schizoaffective disorder and provided once or twice a month. 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, *Mental Health Medications*, available at <https://www.nami.org/Learn-More/Treatment/Mental-Health-Medications> (last visited December 8, 2017).

²¹ Chapter 2017-134, Laws of Fla., codified at s. 465.1893, F.S.

²² *Id.*

- 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;²³ 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 injection a pharmacist administers.

Consultant Pharmacists

A consultant pharmacist is a pharmacist who provides expert advice on the use of medications to individuals or older adults, wherever they live.²⁴ To be licensed as a consultant pharmacist, an applicant must:²⁵

- Hold a license as a pharmacist that is active and in good standing;
- Successfully complete an approved consultant pharmacist course of at least 12 hours;²⁶ and
- Successfully complete a 40-hour period of assessment and evaluation under the supervision of a preceptor within one year of completion of an approved consultant pharmacist course.

Education and Training Requirements for Consultant Pharmacists

In addition to the training and education received as a part of a degree program in pharmacy, a consultant pharmacist is required to complete a consultant pharmacy course and a period of assessment and evaluation under the supervision of a preceptor.

The Board of Pharmacy has enumerated a number of topics on which a consultant pharmacist may be trained in order to qualify for the designation. The consultant pharmacy course must provide at least 12 hours of education in the following areas:²⁷

- Jurisprudence; including state and federal laws and regulations pertaining to health care facilities, institutional pharmacy, safe and controlled storage of alcohol and other related substances, and fire and health-hazard control;
- Policies and procedures outlining the medication system in effect and record-keeping for controlled substances control and record of usage, medication use evaluation, medication errors, statistical reports, etc.;
- Fiscal controls;
- Personnel management, including intra-professional relations pertaining to medication use and intra-professional relations with other members of the institutional health care team to develop formularies, review medication use and prescribing, and the provision of in-service training of other members of the institutional health care team;
- Professional responsibilities, including:
 - Drug information retrieval and methods of dispersal;
 - Development of pharmacy practice;
 - Development of an IV Admixture service;
 - Procedures to enhance medication safety, including availability of equipment and techniques to prepare special dosage forms for pediatric and geriatric patients, safety of

²³ Section 381.0098, F.S., and r. 64E-16, F.A.C., regulate the disposal of biomedical waste.

²⁴ American Society of Consultant Pharmacists, *What is a Consultant Pharmacist*, available at <http://www.ascp.com/page/whatisacp> (last visited December 8, 2017).

²⁵ Rule 64B16-26(3), F.A.C.

²⁶ Rule 64B16-26.300, F.A.C., requires the course to be sponsored by an accredited college of pharmacy and approved by the Florida Board of Pharmacy Tripartite Continuing Education Committee which is based on the Statement of the Competencies Required in Institutional Pharmacy Practice and subject matter set forth in Rule 64B16-26.301, F.A.C.

²⁷ Rules 64B16-26.300 and 64B16-26.301, F.A.C.

- patient self-medication and control of drugs at bedside, reporting and trending adverse drug reactions, screening for potential drug interactions, and proper writing, initiating, transcribing and/or transferring patient medication orders;
- Maintenance of drug quality and safe storage; and
- Maintenance of drug identity;
- The institutional environment, including the institution's pharmacy function and purpose, understanding the scope of service and in-patient care mission of the institution, and interpersonal relationships important to the institutional pharmacy; and
- Nuclear pharmacy, including procurement, compounding, quality control procedures, dispensing, distribution, basic radiation protection and practices, consultation and education to the nuclear medical community, record-keeping, reporting adverse reactions and medical errors, and screening for potential drug interactions.

The applicant must score a passing grade on the course examination for certification of successful completion.

A consultant pharmacist must successfully complete a period of assessment and evaluation, under the supervision of a qualified preceptor, within one year of completing the consultant pharmacy educational course. The period of assessment and evaluation must be completed within three consecutive months and include at least 40 hours of training in the following practice areas:²⁸

- 24 hours on regimen review, documentation, and communication;
- 8 hours on facility review, including the ability to demonstrate areas that should be evaluated, documentation, and reporting procedures;
- 2 hours on committee and reports, including the review of quarterly Quality of Care committee minutes and preparation and delivery of the pharmacist quarterly report;
- 2 hours on policy and procedures, including preparation, review, and updating Policy and Methods;
- 2 hours on principles of formulary management; and
- 2 hours on professional relationships, including knowledge and interaction of facility administration and professional staff.

At least 60 percent of this training must occur on-site at an institution that holds a pharmacy license.²⁹

Scope of Practice

The scope of practice for a consultant pharmacist is broader than that of a pharmacist. 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.³⁰ 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.³¹

²⁸ Rule 64B16-26.300(c), F.A.C. To act a preceptor, a person must be a consultant of record at an institutional pharmacy, have a minimum of one year experience as a consultant pharmacist of record, and be licensed, in good standing, with the board. A preceptor may not supervise more than two applicants at the same time.

²⁹ Id.

³⁰ Section 465.0125(1), F.S.

³¹ 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.

Diagnostic Tests for Influenza and Streptococcus

Influenza Tests

Influenza (flu) is a viral, contagious respiratory illness.³² Although the flu virus may be detected at any time of the year, the flu virus is most common during the fall and winter.³³ Each year, on average 5 to 20 percent of the United States population gets the flu, tens of thousands are hospitalized, and thousands die from flu-related illnesses.³⁴ It is estimated that the flu results in \$10.4 billion in direct medical expenses and an additional \$16.3 billion in lost earnings annually.³⁵

A person who has contracted the flu virus is typically contagious for the first 3-4 days after the illness begins.³⁶ However, some individuals may be able to infect others beginning one day before symptoms develop and up to 5 to 7 days after becoming sick.³⁷ According to the CDC, most people infected with the flu will have a mild illness and do not need medical care or antiviral medication.³⁸ However, the CDC advises individuals who develop flu symptoms and are at higher risk of complications to contact a health care practitioner as early as possible to begin antiviral treatment.³⁹ The CDC recommends an annual vaccination as the best way to prevent flu.⁴⁰

Individuals with weakened immune systems, the elderly, young children, or those with certain health conditions, may be at high risk of serious flu complications.⁴¹ Complications of the flu may include bacterial pneumonia, ear infections, sinus infections, and worsening of chronic medical conditions, such as congestive heart failure, asthma, or diabetes.⁴² Serious flu infections can result in hospitalizations or death.

In recent years, the Food and Drug Administration has approved more than 10 rapid influenza diagnostic tests (RIDTs) to screen for influenza virus infection.⁴³ These tests can provide results within approximately 15 minutes and may be used to help with diagnosis and treatment decisions for patients.⁴⁴ However, a variety of factors can influence the accuracy of an RIDT, including the type of specimen tested, whether the specimen is collected within 72 hours of the onset of the illness, and the prevalence of flu activity in the area.⁴⁵ False positive results are more likely at the beginning or end of the flu season or during periods when the flu virus is not circulating, such as the summer. False negative results are more likely at the peak of the flu season.⁴⁶ 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.⁴⁷

³² CDC, *About Flu*, (Oct. 5, 2017), available at <https://www.cdc.gov/flu/about/index.html> (last visited December 8, 2017).

³³ Id.

³⁴ CDC Foundation, *Flu Prevention*, available at <https://www.cdcfoundation.org/businesspulse/flu-prevention-infographic> (last visited December 8, 2017).

³⁵ Id.

³⁶ CDC, *Key Facts about Influenza (Flu)*, (Oct. 5, 2017), available at <https://www.cdc.gov/flu/keyfacts.htm> (last visited December 8, 2017).

³⁷ Id.

³⁸ CDC, *The Flu: What to Do if You Get Sick*, (Feb. 14, 2017), available at <https://www.cdc.gov/flu/takingcare.htm> (last visited December 8, 2017).

³⁹ Id.

⁴⁰ Id.

⁴¹ *Supra* note 32.

⁴² *Supra* note 37.

⁴³ CDC, *Rapid Diagnostic Testing for Influenza: Information for Clinical Laboratory Directors*, (Oct. 26, 2016), available at <https://www.cdc.gov/flu/professionals/diagnosis/rapidlab.htm> (last visited December 8, 2017).

⁴⁴ Id.

⁴⁵ CDC, *Guidance for Clinicians on the Use of Rapid Influenza Diagnostic Tests*, available at https://www.cdc.gov/flu/pdf/professionals/diagnosis/clinician_guidance_ridt.pdf (last visited December 8, 2017).

⁴⁶ Id.

⁴⁷ CDC, *Diagnosing Flu: Questions and Answers*, (Oct. 3, 2017), available at <https://www.cdc.gov/flu/about/ga/testing.htm> (last visited December 8, 2017).

Some pharmacies may currently provide flu testing, as well as other health screenings.⁴⁸ 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. Group A strep infections include strep throat, scarlet fever, impetigo, toxic shock syndrome and cellulitis and necrotizing fasciitis.⁴⁹ Group B strep may cause blood infections, pneumonia, and meningitis in newborns, as well as urinary tract infections, blood infections, skin infections, and pneumonia in adults.⁵⁰ Strep throat, along with minor skin infections, are the most common infection.⁵¹

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.⁵² Strep throat is passed through person-to-person contact. A person who has been treated with antibiotics for 24 hours or longer however, can generally no longer transmit the bacteria.⁵³ 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.⁵⁴

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.⁵⁵ Results are generally available within 10-20 minutes; however, some tests may be able to detect the presence of Group A strep bacteria within 8 minutes.⁵⁶ RADTs, in general, have high diagnostic accuracy, with tests using newer techniques providing the greatest accuracy.⁵⁷

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.⁵⁸ DOH, by rule, has designated the diseases or conditions which must be reported, as well as the timeframes for such reports.⁵⁹ A suspected or confirmed diagnosis of flu that is caused by a novel or pandemic strain must be reported immediately.⁶⁰ However, strep throat is not among the diseases or conditions that must be reported. The practitioner must report the disease or condition on

⁴⁸ For example, CVS Pharmacy offers services through its MinuteClinic®, which is staffed by nurse practitioners or physician assistants (see CVS, *Want to Learn More about MinuteClinic®?*, available at <https://www.cvs.com/minuteclinic/info> (last visited December 11, 2017)), and Walgreens offers services through its Healthcare Clinic, which is staffed by professional healthcare professionals (see Walgreens, *Healthcare Clinic*, available at <https://www.walgreens.com/topic/pharmacy/healthcare-clinic.jsp> (last visited December 11, 2017)).

⁴⁹ U.S. National Library of Medicine, Medline Plus, *Streptococcal Infections*, (Oct. 3, 2017), available at <https://medlineplus.gov/streptococcalinfections.html> (last visited December 11, 2017).

⁵⁰ *Id.*

⁵¹ 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 December 11, 2017).

⁵² *Supra* note 49.

⁵³ CDC, *Pharyngitis (Strep Throat)*, (Sept. 16, 2016), available at <https://www.cdc.gov/groupastrep/diseases-hcp/strep-throat.html#resources> (last visited December 11, 2017).

⁵⁴ Lab Tests Online, *Strep Throat Test*, available at <https://labtestsonline.org/understanding/analytes/strep/tab/sample/> (last visited December 11, 2017).

⁵⁵ John Mersch, MD, FAAP, MedicineNet.Com, *Rapid Strep Test*, available at https://www.medicinenet.com/rapid_strep_test/article.htm (last visited December 11, 2017).

⁵⁶ *Supra* note 54.

⁵⁷ 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 December 11, 2017).

⁵⁸ 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.

⁵⁹ 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 January 17, 2018).

⁶⁰ *Id.*

a form developed by DOH, which includes information such as the patient's name, demographic information, diagnosis, test procedure used, and treatment given.⁶¹ The practitioner must make the patient's medical records for such diseases available for onsite inspection by DOH.⁶²

Effect of Proposed Changes

CS/HB 431 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 on point-of-care flu and strep testing and the safe and effective treatment of flu and strep infections;
- Maintain at least \$200,000 of professional liability insurance;
- Act within the framework of an established written protocol under a supervising physician that, at a minimum, includes:
 - 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;
- Obtain the written approval of the owner of the pharmacy, if the pharmacist is acting as an employee of such pharmacy;
- Submit a copy of his or her protocol to the Board of Pharmacy;
- Uses a test that is waived from meeting the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA);⁶³
- Use a test system that is capable of interfacing with electronic health record technology;
- Provides results to any health care practitioner designated by the patient; and
- Reports any diagnosed or suspected cases of diseases of public health importance as defined by DOH.

The supervising physician must review the actions taken by the pharmacist pursuant to the protocol, in the manner outlined in the protocol.

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. The pharmacist must provide a current copy of his or her certification by the Board of Pharmacy to provide such services to the supervising physician.

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.⁶⁴ The clinical record created by the pharmacist under this bill must be maintained for at least 5 years.

⁶¹ Rule 64D-3.030, F.A.C.

⁶² Id.

⁶³ 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 January 17, 2018).

⁶⁴ Section 456.057, F.S., provides requirements on the maintenance and disclosure of medical records by a health care practitioner.

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.

B. SECTION DIRECTORY:

Section 1: Amends s. 381.0031, F.S., relating to epidemiological research; report of diseases of public health significance to 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 that the act shall take effect upon becoming a law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

DOH will incur non-recurring costs related to rulemaking and experience a workload increase related to the review of the written protocol between a pharmacist and a supervising physician, for which current resources are sufficient to absorb.⁶⁵

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 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 and treatment for the flu and strep.

D. FISCAL COMMENTS:

None.

⁶⁵ Department of Health, *2018 Agency Legislative Bill Analysis for House Bill 431*, (Oct. 25, 2017), (on file with the Health Quality Subcommittee).

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:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On January 16, 2018, the Health Quality Subcommittee adopted two amendments to the bill. The amendments require any pharmacist who tests for or treats flu or strep to:

- Use of a strep or flu test that has qualified for a waiver under the Clinical Laboratory Improvement Amendments of 1988 (CLIA);
- Use a test system that interfaces with electronic health records;
- Provide test results to any health care practitioner designated by the patient; and
- Report the diagnosis or suspected existence of a disease of public health significance to the Department of Health.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute.