HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 111 Testing for and Treatment of Influenza and Streptococcus
SPONSOR(S): Health Quality Subcommittee, Plasencia
TIED BILLS: **IDEN./SIM. BILLS:** HB 81

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	14 Y, 0 N, As CS	Siples	McElroy
2) Health Care Appropriations Subcommittee			
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.

CS/HB 111 bill authorizes a pharmacist to enter into a collaborative pharmacy practice agreement (CPPA) with a physician to manage chronic health conditions if the pharmacist meets certain qualifications. A CPPA must meet certain terms and specify the health conditions, treatments, and tests governed by the CPPA.

The bill prohibits a collaborating pharmacist from initiating or prescribing a controlled substance or modifying or discontinuing any medication that is prescribed by a health care practitioner who does not have a CPPA with the pharmacist.

The bill also authorizes a pharmacist to perform testing or screening for and testing of minor, non-chronic health conditions if the pharmacist meets and maintains certain qualifications.

The bill requires the board to adopt, by rule, a formulary of medicinal drugs that an authorized pharmacist may prescribe to treat minor, non-chronic health conditions. A pharmacist may not prescribe any controlled substance; however, the board-developed formulary may include any non-controlled substance, including those that typically need a prescription to dispense, such as antibiotics, and over-the-counter medications. The bill authorizes a pharmacist to use any CLIA-waived test that guides diagnosis or clinical decision-making, as well as any established screening procedures for which no test is available.

Although typically considered non-chronic conditions, the bill explicitly requires pharmacists who test for influenza and streptococcus to do so within the framework of a written protocol with a supervising physician, which must be submitted to the board. The bill establishes minimum criteria for the content of such protocols.

The bill will have an insignificant, negative fiscal impact on the Department of Health and appears to have no fiscal impact on local governments.

The bill provides an effective date of July 1, 2019.

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;
- Administering vaccines to adults;[9]
- Administering epinephrine injections;[10] and
- Administering antipsychotic medications by injection.[11]

[1] American Association of Colleges of Pharmacy, *About AACP*, available at https://www.aacp.org/about-aacp (last visited December 15, 2018).
[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] *See* s. 465.189, F.S.
[10] *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.[12]

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.[13] The formulary may only include:[14]

- Any medicinal drug 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;
- Any medicinal drug 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;
- Any medicinal drug containing any antihistamine or decongestant as a single active ingredient or in combination;
- Any medicinal drug containing fluoride in any strength;
- Any medicinal drug containing lindane in any strength;
- Any over-the-counter proprietary drug under federal law that has been approved for reimbursement by the Florida Medicaid Program; and
- Any 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:[15]

- 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 otic analgesics. Antipyrine 5.4%, benzocaine 1.4%, glycerin, if clinical signs or symptions of tympanic membrane perforation do not exist.
- Anti-nausea preparations.
- Certain antihistamines and decongestants.
- Certain topical antifungal/antibacterials.
- 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 two (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.
- Topical Antiviral for herpes simplex infections of the lips.

One category of pharmacist has a broader scope of practice. A provides expert advice on the use of medications to individuals or older adults, wherever they live.[16] In addition to the training and education received as a part of a degree program in pharmacy, a consultant pharmacist must complete a

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[11] Section 465.1893, F.S.
[12] *Supra* note 8.
[13] Section 465.186, F.S.
[14] Id.
[15] Rule 64B16-27.220, F.A.C.
[16] American Society of Consultant Pharmacists, *What is a Consultant Pharmacist,* available at http://www.ascp.com/page/whatisacp (last visited December 8, 2017).

consultant pharmacy course and a period of assessment and evaluation under the supervision of a preceptor.[17]

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.[18] 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.[19]

Collaborative Practice

Under current law, a pharmacist may provide drug therapy management to a patient pursuant to an individualized assessment and orders for specific drugs, laboratory tests, and other pharmaceutical services, written by a licensed physician.[20] Drug therapy management may include:[21]

- Drug therapy to be initiated by the pharmacist;
- Laboratory values or test to be ordered, monitored, and interpreted by the pharmacist;
- The conditions under which the licensed physician authorizes the execution of orders concerning drug therapy; and
- The conditions under which the pharmacist must contact the physician.

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.[22] 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.;[23] which must:[24]
    - 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;[25]
- Pass an examination and demonstrate vaccine administration technique;[26] and
- Maintain at least $200,000 of professional liability insurance.[27]

[17] Rule 64B16-26(3), F.A.C.
[18] Section 465.0125(1), F.S.
[19] 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.
[20] Rule 64B16-27.830, F.A.C.
[21] *Id.*
[22] Section 465.189, F.S. A registered intern may also administers immunizations or vaccinations under the supervision of a certified pharmacist.
[23] Section 465.189(1), F.S.
[24] Section 465.189(7), F.S.
[25] 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.
[26] *Id*.
[27] Section 465.189(3), F.S.

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]

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[30] 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]

Pharmacist Education

The Accreditation Council for Pharmacy Education (ACPE) is the national agency for accreditation of professional degree programs in pharmacy.[35] The ACPE establishes minimum standards and guidelines for professional programs in pharmacy that lead to a Doctor of Pharmacy degree.[36] The accreditation standards require the education curriculum to include the following educational outcomes:[37]

- Foundational knowledge, including biomedical, pharmaceutical, social/behavioral/administrative, and clinical sciences;
- Essentials for practice and care, including patient-centered care, medication use systems management, health and wellness, and population-based care;
- Approach to practice and care, including problem-solving, patient advocacy, patient education, interprofessional collaboration, cultural sensitivity, and communication; and
- Personal and professional development, including self-awareness, leadership, innovation and entrepreneurship, and professionalism.

[28] Section 465.189(2), F.S.
[29] Section 465.189(5), F.S.
[30] A long-acting injectable antipsychotic medication may be prescribed to treat symptoms of psychosis associated with schizophrenia and schizoaffective disorder and provided 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 December 10, 2018).
[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] Accreditation Council for Pharmacy Education, *About ACPE*, available at https://www.acpe-accredit.org/about/ (last visited December 10, 2018)
[36] *Id.*
[37] Accreditation Council for Pharmacy Education, *Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree* (Jan. 25, 2015), pp. 1-2, available at https://www.acpe-accredit.org/pdf/Standards2016FINAL.pdf (last visited December 10, 2018).

The accreditation guidelines also include an advanced pharmacy practice experience of at least 1,440 hours to be completed during the last academic year and after all practice experience requirements have been met.[38] The advanced pharmacy experience must include acute, chronic, and preventive care among patients of all ages, genders, races, ethnicities, socioeconomic factors, and disease states.[39] It must also include experiences in a community pharmacy, hospital or health-system pharmacy, ambulatory patient care, and inpatient general medicine patient care.[40]

There is no special licensure designation for doctor of pharmacy. Bachelor degree programs for pharmacy were phased out in the early 2000s and all newly licensed pharmacists hold a doctor of pharmacy degree.[41] However, pharmacists who were licensed prior to the change in the educational standards may be practicing and not hold a doctor of pharmacy degree.

Pharmacist Prescriptive Authority

In recent years, states have expanded the scope of practice for pharmacists, including the authority to prescribe drugs without a physician's prescription, perform laboratory and clinical testing, and practice, including initiating, modifying and terminating drug therapy, within the scope of a collaborative practice agreement.

National Association of Boards of Pharmacy Task Force on Pharmacists

In 2018, the National Association of Boards of Pharmacy (NAPB) revised its model state pharmacy to expand the scope of practice of pharmacists incorporating amendments offered by the NAPB's Task Force on Pharmacists Prescriptive Authority (task force).[42] The task force recommended the expansion of pharmacist's roles in a manner that is consistent with their education and training, including entering into collaborative practice agreements (CPAs)[43] with health care practitioners, implementing and expanding limited prescriptive authority through formularies and protocols, and providing "provider status"[44] to pharmacists.[45]

The task force recommends including the initiation of drug therapy in the definition of the practice of pharmacy and that boards of pharmacy limit such prescriptive authority using the following factors in developing parameters:[46]

- Limiting it to conditions in which no diagnosis is required or is easily assessed;
- Using a formulary or protocol established by the Board of Pharmacy or other state entity; and
- Requiring feedback and communication between the pharmacist, patient, and the patient's primary care when one exists or referral by pharmacist to an appropriate practitioner, if necessary.

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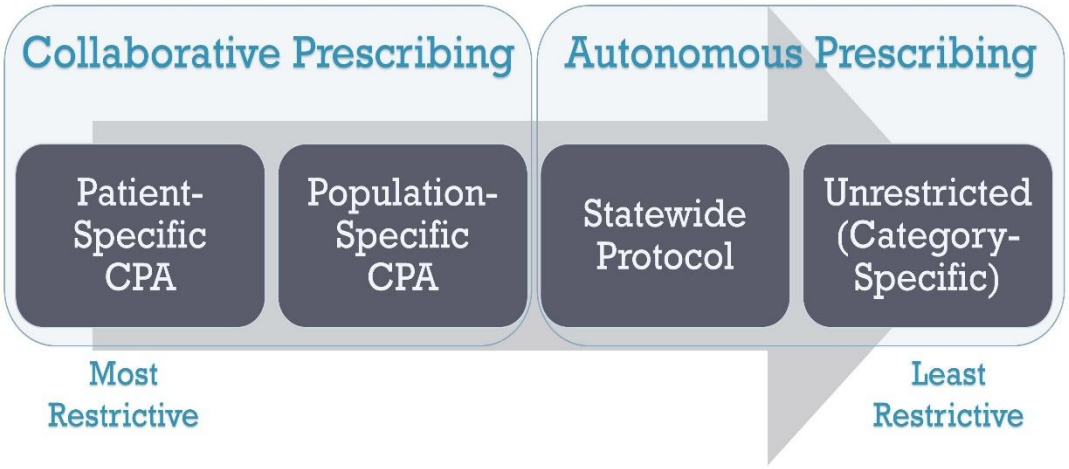
[38] *Id*. at 9.
[39] *Id.*
[40] *Id*.
[41] *Supra* note 35.
[42] National Association of Boards of Pharmacy, *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*, (Aug. 2018), available at https://nabp.pharmacy/publications-reports/resource-documents/model-pharmacy-act-rules/ (last visited December 17, 2018).
[43] A collaborative practice agreement is a written and signed agreement between one or more pharmacists and one or more practitioners that provides for collaborative pharmacy practice. Collaborative pharmacy practice is defined as the practice of pharmacy whereby one or more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more practitioners under protocol and in collaboration with practitioner(s) to provide patient care services to achieve optimal medication use and desired patient outcomes. *Id*.
[44] "Provider status" is recognition of pharmacist of patient care service which are eligible to be reimbursed by Medicare on a federal level and health insurance companies and managed health care plans on a state level. *See*, Rachel Balick, *The Latest on Provider Status at the Federal, State Levels*, Pharmacy Today, (Sept. 2017), available at https://www.pharmacytoday.org/article/S1042-0991(17)31336-1/fulltext (last visited December 17, 2018).
[45] National Association of Boards of Pharmacy, *Report of the Task Force on Pharmacist Prescriptive Authority*, (Jan. 2016), available at https://nabp.pharmacy/2015-report-of-the-task-force-on-pharmacist-prescriptive-authority/ (last visited December 17, 2018).
[46] *Id.*

The task force also recommended that boards of pharmacy review the requirements for collaborative practice and remove barriers that may hinder adoption of CPAs or interfere in the extent of collaborative practice, including the ability of a pharmacist to initiate drug therapy, the administration and interpretation of tests, the number of patients and disease states that can be treated, and the types of drugs that a pharmacist can initiate, discontinue, or modify.[47]

State Laws on Pharmacy Prescriptive Authority

Every state provides pharmacist some authority to dispense a medicinal drug without a physician prescription, either autonomously or pursuant to a protocol.[48] The prescriptive authority states provides vary from limited to expansive and provided on a continuum:[49]



For example, every state has enacted laws to increase access to naloxone. The majority of the states allow it to be dispensed pursuant to a standing order or a non-patient specific protocol or a collaborative practice agreement.[50] A few states give pharmacists prescriptive authority to initiate prescriptions for naloxone.[51] Other medicinal drugs for which pharmacist are often give autonomous prescribing authority or may prescribe pursuant to a CPA or statewide protocol include:[52]

- Immunizations;
- Smoking cessation products;
- Hormonal and emergency contraceptives;
- Travel medications; and
- Fluoride replacements.

Some states authorize autonomous prescribing for pharmacists; however, the authority provided by each state varies. Eight states allow pharmacists to prescribe controlled substances.[53] Several states

[47] *Id* at 6.
[48] Edward M. DeSimone II, et. al., *Expanding Access to Naloxone*, US Pharm. 2018;43(3):16-20, (March 16, 2018), available at https://www.uspharmacist.com/article/expanding-access-to-naloxone (last visited December 18, 2018).
[49] National Alliance of State Pharmacy Associations, *Pharmacist Statewide Protocols and Prescriptive Authority*, (Nov. 9, 2018), available at https://naspa.us/resource/swp/#unique-identifier-continuum (last visited December 18, 2018).
[50] *Id.*
[51] *Id.*
[52] National Alliance of State Pharmacy Associations, *Statewide Protocol Infographic*, (May 29, 2018), available at https://naspa.us/resource/statewide-protocols-for-pharmacist-prescribing/ (last visited December 18, 2018).
[53] U.S Drug Enforcement Administration, *Mid-Level Practitioners Authorization by State*, (Sept. 11, 2018), available at https://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf (last visited December 18, 2018). Those states include

(California, Montana, New Mexico, and North Carolina) created new licensure categories to provide additional scope of practice authority for pharmacists who meet certain education and experience requirements.[54] However, two of these states (Montana and North Carolina) still require such pharmacists to practice the expanded authority pursuant to a CPA.

Some states, such as California, Colorado, Idaho, New Mexico, and Oregon, have statewide protocols in place for the prescribing of medications for the treatment of certain conditions. Such statewide protocols address the prescribing of:[55]

- Hormonal contraceptive patches;
- Oral contraceptives;
- Emergency contraceptives;
- Smoking cessation products;
- Naloxone;
- Statins for diabetes;
- Short-acting beta antagonists for asthma patients; and
- Treatment of conditions such as:
    - Recurrent cold sores;
    - Seasonal flu in low risk patients;
    - Strep throat in low-risk patients; and
    - Uncomplicated urinary tract infections.

Laboratory and Clinical Testing

Numerous states authorize pharmacists to perform clinical and laboratory tests, either autonomously or under the auspices of a collaborative practice agreement.[56] The type of authority is often relative to the breadth of the prescriptive authority pharmacists have in the state.

All facilities that perform laboratory tests on human specimens for the diagnosis, prevention, or treatment of diseases are regulated the Clinical Laboratory Improvement Amendments of 1988 (CLIA).[57] Waived tests are those that have been cleared by the Food and Drug Administration (FDA) for home use; such tests must simple and have a low risk of erroneous results.[58] CLIA-waived tests includes those for:[59]

- Urine testing and diagnosis of various diseases, such as diabetes and urinary tract infections;
- Diagnosing pregnancy;
- Monitoring blood glucose levels;
- Screening for anemia;
- Measuring cholesterol in whole blood;
- Detection of influenza; and
- Detection of streptococcus group A.

California; Idaho (CPA only) Massachusetts (institutional only, no retail); Montana (CPA only); New Mexico; North Carolina; Ohio; and Washington.

[54] *See* CAL. BUS. PROF. CODE ss. 4052.6 and 4210, MONT. CODE ANN. s. 37-7-206, N.M. STAT. s. 16.19.4.17, and 21 NCAC s. 46.3101, respectively.

[55] Based on research of committee staff.

[56] At least 31 states authorize a pharmacist to order or interpret laboratory tests. *See* Centers for Disease Control and Preventions, *Select Features of State Pharmacist Collaborative Practice Laws*, available at https://www.cdc.gov/dhdsp/pubs/docs/pharmacist_state_law.pdf (last visited January 7, 2019).

[57] Centers for Disease Control and Prevention, *Clinical Laboratory Improvement Amendments (CLIA): Waived Tests*, available at https://wwwn.cdc.gov/CLIA/Resources/WaivedTests/default.aspx (last visited December 18, 2018).

[58] *Id.*

[59] Centers for Medicare and Medicaid Services, *Tests Granted Waived Status under CLIA*, available at https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/waivetbl.pdf (last visited December 18, 2018).

Disease Reporting 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.[60] DOH, by rule, has designated the diseases or conditions which must be reported, as well as the timeframes for such reports.[61] 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.[62] The practitioner must make the patient's medical records for such diseases available for onsite inspection by DOH.[63]

Effect of Proposed Changes

Collaborative Pharmacy Practice

CS/HB 111 authorizes pharmacists who meet certain criteria to enter in a collaborative pharmacy practice agreement (CPPA)[64] with a physician for the management of chronic health conditions. The bill defines a "chronic health condition" as a condition which typically lasts more than one year and requires ongoing medical attention, limits activities of daily living, or both, including, but not limited to:

- Arthritis
- Asthma;
- Congestive heart failure;
- Chronic obstructive pulmonary diseases;
- Diabetes;
- Emphysema;
- HIV/AIDS;
- Hypertension;
- Obesity;
- Renal disease; and
- Any other chronic condition or co-morbidity identified by the collaborating physician.

Prior to practicing under a CPPA, a pharmacist must:

- Hold and active and unencumbered license to practice pharmacy;
- Have a doctor of pharmacy degree or at least five years' experience as a licensed pharmacist;
- Complete an initial 20-hour board-approved course, which at a minimum, includes instruction on:
    - Performing patient assessments;
    - Ordering, performing, and interpreting clinical and laboratory tests;
    - Evaluating and managing diseases and health conditions in collaboration with other health care practitioners; and
    - Any other topic required by the board in rule.
- Maintain at least $250,000 in professional liability coverage;
- Any other qualification required by the board; and
- Submit, to the board, a copy of the signed CPPA and proof of meeting the criteria listed above.

[60] Section 381.0031, F.S. and r. 64D-3.030, FA.C. Medical examiners, hospitals, and laboratories are also required to report the diagnosis or suspected existence of such diseases to DOH.
[61] 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 December 18, 2018).
[62] Rule 64D-3.030, F.A.C.
[63] *Id.*
[64] The bill defines "collaborative practice agreement" as a written agreement between a qualified pharmacist and a physician that authorizes the pharmacist to provide patient care services, as authorized in the agreement.

To maintain authority to perform patient care services pursuant to a CPPA, a pharmacist must complete an 8-hour board approved continuing education course each biennial licensure renewal cycle. Such course is in addition to the 30-hours of continuing education that must be completed each biennium to maintain licensure. If the pharmacist fails to complete the required 8 hour course, the pharmacist may not provide any services authorized pursuant to a CPPA.

The CPPA must be tailored to the pharmacist's training and the services delegated to a pharmacist must be within the collaborating physician's scope of practice. The CPPA must include:

- The name of the patient or patients for which the pharmacist will provide services;
- Each chronic health condition to be collaboratively managed;
- The specific medicinal drug or drugs to be managed by the pharmacist;
- The circumstances under which the pharmacist may order or perform and evaluate laboratory or clinical tests;
- The conditions and events upon which the pharmacist must notify the collaborating physician and the manner and time frame in which such notification must occur;
- The date on which the CPPA begins and ends and termination procedures, including patient notification and medical records transfer procedures; and
- A statement that the collaborative pharmacy practice agreement may be terminated, in writing, by either party at any time.

The bill prohibits collaborating pharmacist from:

- Initiating or prescribing a controlled substance;[65]
- Modifying or discontinuing any medication that is prescribed by a health care practitioner who does not have a CPPA with the pharmacist; and
- Entering into a CPPA without the express, written approval of the owner of the pharmacy at which he or she is an employee.

However, a pharmacist may prescribe any non-controlled substance, including those typically need a prescription to dispense, such as antibiotics.

The bill requires the CPPA to be renewed every two years. Both the pharmacist and the collaborative physician must maintain a copy of the CPPA at their respective practice locations and make it available for inspection, upon request. All medical records generated pursuant to the pharmacist's practice under the CPPA must be maintained for five years.

Non-Chronic Health Conditions

The bill authorizes a pharmacist who meet certain criteria to perform clinical or laboratory testing or screening for and treating of minor, non-chronic health conditions. A minor, non-chronic health condition is one that is typically short-term and is generally managed with minimal treatment or self-care. Examples of minor, non-chronic health care include influenza (flu), streptococcus (strep), lice, skin conditions such as ringworm or athlete's foot, and minor, uncomplicated infections.

To screen or test and treat minor, non-chronic health conditions, a pharmacist must:

- Complete an initial 20-hour board-approved course, which at a minimum, includes instruction on:
    - Performing patient assessments;
    - Point-of-care testing procedures;
    - Safe and effective treatment of minor, non-chronic health conditions; and
    - Identification of contraindications; and

[65] For the schedule of controlled substance, see s. 893.03, F.S., and 21 U.S.C. s. 812.

- Maintain at least $250,000 of liability coverage.

The bill requires the board to adopt, by rule, a formulary of medicinal drugs approved by the U.S. Food and Drug Administration that a qualified pharmacist may prescribe for the treatment of minor, non-chronic health conditions. The bill prohibits a pharmacist from prescribing any controlled substance; however, the board-developed formulary may include any non-controlled substance, including those that typically need a prescription to dispense, such as antibiotics, and over-the-counter medications.

The bill authorizes a qualified pharmacist to use any CLIA-waived test that guides diagnosis or clinical decision-making, as well as any established screening procedures for which no test is available. For example, a clinical or laboratory test is not typically used to diagnose lice, since it may be visible by the naked eye or screened for by using a fine-tooth louse comb.[66]

The bill requires a pharmacist to report any disease of public health significance to DOH. The bill also requires that any pharmacist providing testing or screening and treatment services maintain patient records for at least 5 years and furnish such records to a health care practitioner designated by the patient or the patient's legal guardian.

To maintain authority to perform test or screen for minor, non-chronic health conditions, a pharmacist must complete a 3-hour board-approved continuing education course each biennial licensure renewal cycle. Such course is in addition to the 30-hours of continuing education that must be completed each biennium to maintain licensure. If the pharmacist fails to complete the required 3-hour course, the pharmacist may not provide the testing or screening and treatment of minor, non-chronic health conditions.

Influenza and Streptococcus

Although considered non-chronic conditions, the bill explicitly requires pharmacists who screen for the influenza (flu) and streptococcus (strep) to do so within the framework of a written protocol with a supervising physician. The bill authorizes the board to adopt rules establishing the requirements of a protocol; however, at a minimum a protocol must include:

- The categories of patients for which pharmacist may 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.

A copy of the protocol must be submitted to the board and requires that a pharmacist who is performing such actions while employed obtain written consent of the owner of the pharmacy.

The bill provides an effective date of July 1, 2019.

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. 465.1865, F.S., relating to collaborative pharmacy practice for chronic health conditions.

[66] Centers for Disease Control and Prevention, *Diagnosis of Head Lice*, available at https://www.cdc.gov/parasites/lice/head/diagnosis.html (last visited December 18, 2018).

Section 4: Creates s. 465.1895, F.S., relating to testing or screening for and treatment of minor, non-chronic health conditions.

Section 5: Provides an effective date of July 1, 2019.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   DOH may incur recurring, insignificant costs relating to verifying that all requirements are met to practice collaboratively or to test or screen and for minor, non-chronic health conditions. The enlarged scope of practice may increase regulatory costs due to additional complaints related to the additional duties a qualified pharmacists, as well as costs related to reviewing written protocols.

   DOH will incur non-recurring, insignificant costs related to rulemaking which current resources are sufficient 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 services authorized by the bill will incur costs associated with obtaining the required education, maintaining liability insurance, and entering into a supervisory protocol.

Individuals with chronic health conditions may achieve cost savings by having pharmacists perform necessary testing and adjustment to medication therapies. For some, who must travel longer distances to access health care, some cost savings related to travel may be achieved.

Individuals with limited access to health care practitioner services may be able to more easily access testing or screening for and treatment for minor, non-chronic health conditions.

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 sufficient rule-making authority to enact the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 5, 2019, the Health Quality Subcommittee adopted a strike-all amendment and reported the bill favorably as a committee substitute. The strike-all amendment:

- Authorized pharmacists who meet certain educational and experience criteria and who maintain at least $250,000 personal liability coverage to enter into a collaborative pharmacy practice agreement with a physician to manage the chronic health conditions of that physician's patients.
- Authorized pharmacists who meet certain educational and experience criteria and who maintain at least $250,000 personal liability coverage to test and screen for and treat minor, non-chronic health conditions.
- Authorized pharmacists to test for and treat influenza and streptococcus only within the framework of a protocol with a supervising physician.
- Required the board to adopt a formulary of drugs a pharmacist may prescribe for minor, non-chronic illnesses.
- Prohibited a pharmacist from initiating or prescribing a controlled substance.
- Change the bill's effective date to July 1, 2019.

The analysis is drafted to the committee substitute as passed by the Health Quality Subcommittee.