HOUSE OF REPRESENTATIVES STAFF FINAL BILL ANALYSIS

BILL #: CS/HB 389 Practice of Pharmacy
SPONSOR(S): Health & Human Services Committee, Sirois and others
TIED BILLS: **IDEN./SIM. BILLS:**

FINAL HOUSE FLOOR ACTION: 98 **Y's** 17 **N's** **GOVERNOR'S ACTION:** Approved

SUMMARY ANALYSIS

CS/HB 389 passed the House on March 6, 2020. The bill was amended in the Senate on March 11, 2020, and returned to the House. The House concurred in the Senate amendment and subsequently passed the bill as amended on March 11, 2020.

A pharmacist dispenses medications and counsels patients on the use of both prescription and over the counter medications. In Florida, current law allows pharmacists to administer vaccines and immunizations, assist with medication management, as well as inject certain medications within an established protocol with a physician. Other states have expanded pharmacist scope of practice to include prescribing medications, either independently or pursuant to a statewide or health care practitioner protocol.

The 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 authorizes a pharmacist, who meets certain qualifications, to test or screen for and treat minor, non-chronic health conditions within the framework of a written protocol with a supervising physician. The conditions are limited to influenza, streptococcus, lice, skin conditions, and minor, uncomplicated infections. The protocol must specify the patients that may be seen, instructions for obtaining a patient's medical history, instructions for treatment, and a process and schedule for the pharmacist to provide patient information to the supervising physician and the supervising physician to review the pharmacist's actions under the protocol.

The bill requires the Board of Pharmacy 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 certain laboratory or clinical tests, as well as any established screening procedures for which no test is available.

A pharmacy in which a pharmacist provides services for minor, non-chronic health conditions must prominently display a sign advising a patient receiving such services to seek follow-up care from a physician. The Board of Pharmacy must adopt guidelines for advising a patient to seek follow-up care from a physician.

The bill has an insignificant, negative fiscal impact on the Department of Health, which can be absorbed with existing resources. The bill has no fiscal impact on local governments.

The bill was approved by the Governor on March 11, 2020, ch. 2020-7, L.O.F., and will become effective on July 1, 2020.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF 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 pharmacy under 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

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[1] American Association of Colleges of Pharmacy, *About AACP*, available at https://www.aacp.org/about-aacp (last visited February 26, 2020).
[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.*

- Administering antipsychotic medications by injection.[12]

A pharmacist may not alter a prescriber's directions, diagnose or treat any disease, initiate any drug therapy, or practice 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,

[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.

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]

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]

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.[21] Drug therapy management may include:[22]

- 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.[23] 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.;[24] which must:[25]
    - 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;[26]

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[17] American Society of Consultant Pharmacists, *What is a Consultant Pharmacist,* available at http://www.ascp.com/page/whatisacp (last visited February 26, 2020).
[18] Rule 64B16-26.300(3), F.A.C.
[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] Rule 64B16-27.830, F.A.C.
[22] *Id.*
[23] Section 465.189, F.S. A registered intern may also administers immunizations or vaccinations under the supervision of a certified pharmacist.
[24] Section 465.189(1), F.S.
[25] Section 465.189(7), F.S.
[26] 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.

- Pass an examination and demonstrate vaccine administration technique;[27]
- 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;[28] and
- Maintain at least $200,000 of professional liability insurance.[29]

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.[30] A pharmacist administering vaccines must submit vaccination records to DOH for inclusion in the state's registry of immunization information.[31] There are 13,115 Florida-licensed pharmacists and 2,627 pharmacy interns who are certified to administer vaccines.[32]

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[33] approved by the United States Food and Drug Administration.[34] To be eligible to administer such injections, a pharmacist must:[35]

- 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;[36] 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.[37]

Pharmacist Education

The Accreditation Council for Pharmacy Education (ACPE) is the national agency for accreditation of professional degree programs in pharmacy.[38] The ACPE establishes minimum standards and guidelines for professional programs in pharmacy that lead to a Doctor of Pharmacy degree.[39] The

[27] *Id.*
[28] 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.
[29] Section 465.189(3), F.S.
[30] Section 465.189(2), F.S.
[31] Section 465.189(5), F.S.
[32] E-mail correspondence with DOH, dated December 19, 2019, on file with the Health Quality Subcommittee.
[33] 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 February 26, 2020).
[34] Chapter 2017-134, Laws of Fla., codified at s. 465.1893, F.S.
[35] *Id.*
[36] Section 381.0098, F.S., and r. 64E-16, F.A.C., regulate the disposal of biomedical waste.
[37] Section 465.1893(1)(b), F.S.
[38] Accreditation Council for Pharmacy Education, *About ACPE*, available at https://www.acpe-accredit.org/about/ (last visited February 26, 2020).
[39] *Id.*

accreditation standards require the education curriculum to include the following educational outcomes:[40]

- 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.

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.[41] The advanced pharmacy experience must include acute, chronic, and preventive care among patients of all ages, genders, races, ethnicities, socioeconomic factors, and disease states.[42] It must also include experiences in a community pharmacy, hospital or health-system pharmacy, ambulatory patient care, and inpatient general medicine patient care.[43]

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.[44] 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 2015, the National Association of Boards of Pharmacy (NAPB) Task Force on Pharmacists Prescriptive Authority (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)[45] with health care practitioners, implementing and expanding limited prescriptive authority through formularies and protocols, and providing "provider status"[46] to pharmacists.[47]

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[40] 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 February 26, 2020).
[41] *Id*. at 9.
[42] *Id.*
[43] *Id*.
[44] *Supra* note 38.
[45] 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*.
[46] "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 February 26, 2020).
[47] 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 February 26, 2020).

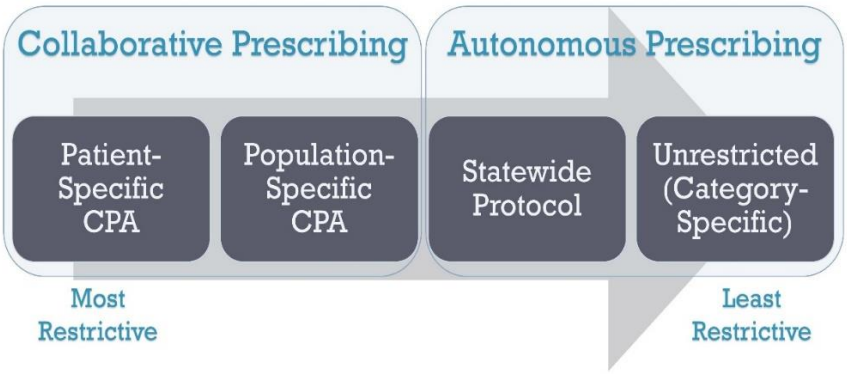
The task force recommended including the initiation of drug therapy in the definition of the practice of pharmacy and that boards of pharmacy limit such prescriptive authority using the following factors in developing parameters:[48]

- 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.

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.[49]

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.[50] The prescriptive authority states provides vary from limited to expansive and provided on a continuum:[51]



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.[52] A few states give pharmacists prescriptive authority to initiate prescriptions for naloxone.[53] Other medicinal drugs for which pharmacist are often give autonomous prescribing authority or may prescribe pursuant to a CPA or statewide protocol include:[54]

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

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[48] *Id.*
[49] *Id* at 6.
[50] 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 February 26, 2020).
[51] 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 February 26, 2020).
[52] *Id.*
[53] *Id.*
[54] 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 February 26, 2020).

Some states authorize autonomous prescribing for pharmacists; however, the authority provided by each state varies. Eight states allow pharmacists to prescribe controlled substances.[55] Several states (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.[56] 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:[57]

- 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.[58] 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 health assessment or the diagnosis, prevention, or treatment of diseases are regulated the Clinical Laboratory Improvement Amendments of 1988 (CLIA).[59] Waived tests are those that have been cleared by the Food and Drug Administration (FDA) for home use; such tests must be simple and have a low risk of erroneous results.[60] CLIA-waived tests includes those for:[61]

- 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.

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[55] U.S Drug Enforcement Administration, *Mid-Level Practitioners Authorization by State*, (Feb. 10, 2020), available at https://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf (last visited February 26, 2020). Those states include California; Idaho (CPA only) Massachusetts (institutional only, no retail); Montana (CPA only); New Mexico; North Carolina; Ohio; and Washington.

[56] *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.

[57] Based on research of committee staff.

[58] 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 February 26, 2020).

[59] 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 February 26, 2020).

[60] *Id.*

[61] 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 February 26, 2020).

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.[62] DOH, by rule, has designated the diseases or conditions which must be reported, as well as the timeframes for such reports.[63] 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.[64] The practitioner must make the patient's medical records for such diseases available for onsite inspection by DOH.[65]

Effect of Proposed Changes

Collaborative Pharmacy Practice

The bill authorizes pharmacists who meet certain criteria to enter in a collaborative pharmacy practice agreement (CPPA) with a physician for the management of chronic health conditions.[66] Under the bill, "chronic health condition" means:

- Arthritis
- Asthma;
- Chronic obstructive pulmonary diseases;
- Type 2 diabetes;
- HIV/AIDS;
- Obesity; or
- Any other chronic condition adopted into rule by the Board, in consultation with the Boards of Medicine and Osteopathic Medicine.

To qualify for Board certification for practice under a CPPA, a pharmacist must submit proof of meeting the following criteria:

- 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; and
- Any other qualification required by the Board.

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.

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[62] 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.
[63] Rule 64D-3.029, F.A.C. *See also* http://www.floridahealth.gov/diseases-and-conditions/disease-reporting-and-management/_documents/reportable-diseases-list-practitioners.pdf (last visited February 26, 2020).
[64] Rule 64D-3.030, F.A.C.
[65] *Id.*
[66] 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.

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 may 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.

A copy of the CPPA must be submitted to the Board.

The bill prohibits collaborating pharmacists from:

- Initiating or prescribing a controlled substance;[67]
- 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 that typically need a prescription to dispense, such as antibiotics.

The CPPA automatically terminates two years after execution, if not renewed. 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.

The bill requires the Board to consult with the Boards of Medicine and Osteopathic Medicine when developing the rules to implement the bill's provisions, including rules for the certification, the requirements for the 20-hour certification course, and the chronic conditions that may be managed under a CPPA.

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

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 within the framework of a written protocol with a supervising physician.[68] A minor, non-chronic health condition is one that is typically short-term and is generally managed with minimal treatment or self-care, and is limited to:

- Influenza;
- Streptococcus;
- 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 maintain at least $250,000 of liability coverage and hold a Board-issued certification that requires a pharmacist to 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.

The written protocol with the supervising physician must be tailored to the pharmacist's training and at a minimum, include:

- The categories of patients for which pharmacist may test or screen for and treat minor, non-chronic conditions
- The physician's instructions for obtaining relevant patient medical history to identify disqualifying health conditions, adverse reactions, and contraindications to the approved course of treatment;
- The physician's instructions for treatment based on the patient's age, symptoms, and test results, including negative results;
- A process and schedule for the physician to review the pharmacist's actions under the protocol;
- A process and schedule for the pharmacist to notify the supervising physician of the patient's condition, tests administered, test results, and course of treatment; and
- Any other requirements established by the Board, in consultation with the Boards of Medicine and Osteopathic Medicine.

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.

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.[69]

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

[68] The physician must be licensed in Florida as an allopathic or osteopathic physician.
[69] Centers for Disease Control and Prevention, *Diagnosis of Head Lice*, available at https://www.cdc.gov/parasites/lice/head/diagnosis.html (last visited February 26, 2020).

records for at least 5 years and furnish such records to a health care practitioner designated by the patient, upon the request of the patient.

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.

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

A pharmacy in which a pharmacist provides testing or screening for and treatment of minor, non-chronic health conditions must prominently display a sign advising a patient receiving such services to seek follow-up care from his or her primary care physician. The Board of Pharmacy must adopt guidelines for the circumstances under which a pharmacist providing such services must provide a patient with a written notice advising the patient to seek follow-up care from a primary care physician.

A pharmacist does not have to have a physician protocol to treat minor, non-chronic health conditions with over-the-counter medication.

The bill provides an effective date of July 1, 2020.

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.[70]

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:

[70] Department of Health, *2020 Agency Legislative Bill Analysis for House Bill 389*, (Oct. 22, 2019), on file with the Health Quality Subcommittee.

Pharmacists who engage in collaborative pharmacy practice of chronic conditions or testing and screening for and treatment of minor, non-chronic health conditions as authorized by the bill will incur costs associated with obtaining the required continuing education, maintaining liability insurance, and entering into a CPPA or supervisory protocol.

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

D. FISCAL COMMENTS:

None.