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Alert | Health Care & FDA Practice

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New Florida Legislation Expands Pharmacist Scope of Practice

I. Overview of New Legislation

The Florida legislature, with approval from the governor, recently enacted amendments to Florida scope of practice laws that expand pharmacy practice to include certain drug therapy services pursuant to collaborative pharmacy practice agreements, and testing and treatment for certain minor, nonchronic health conditions pursuant to a written protocol with a supervising physician.

Expanded Scope of Practice

The new legislation amends subsection 13 of section 465.003, Florida Statutes, to include "initiating, modifying, or discontinuing drug therapy for a chronic health condition under a collaborative pharmacy practice agreement" and "the testing or screening for and treatment of minor, nonchronic health conditions pursuant to Section 465.1895" in the definition of the practice of the profession of pharmacy, and adds new language outlining the requirements practitioners, agreements and protocols must meet in order to provide these additional services.

Collaborative Pharmacy Practice Agreements

The legislation establishes Section 465.1865, Florida Statutes, to enable and regulate the provision of services pursuant to a collaborative pharmacy practice agreement – an agreement whereby a

collaborating physician authorizes a pharmacist to provide specified patient care services to the physician's patients. According to the new legislation, collaborative pharmacy practice agreements can allow a pharmacist to initiate, modify, or discontinue drug therapy for the following conditions:

- arthritis
- asthma
- chronic obstructive pulmonary diseases
- type 2 diabetes
- HIV or AIDS
- obesity
- any other chronic condition adopted in rule by the Florida Board of Pharmacy (the Board), in consultation with the Board of Medicine and Board of Osteopathic Medicine

Furthermore, the collaborating physician must be a Florida-licensed physician, and pharmacists must hold certain qualifications and meet certain requirements in order to provide these services. Pharmacists must satisfy the following:

- certification by the Board, which itself requires that a pharmacist hold an active and unencumbered license to practice pharmacy in Florida
- possess a degree of Doctor of Pharmacy or have completed five years of experience as a licensed pharmacist
- complete an initial 20-hour course approved by the Board that includes instruction on performance of patient assessments, ordering, performing, and interpreting clinical and laboratory tests related to collaborative pharmacy practice, evaluating and managing diseases and health conditions in collaboration with health care practitioners, and any other area required by the Board
- complete an eight-hour continuing education course approved by the Board each biennial licensure renewal that addresses issues related to collaborative pharmacy practice and submit confirmation of completion when applying for licensure renewal
- maintain at least $250,000 of professional liability insurance coverage or coverage pursuant to Section 465.1895, Florida Statutes
- establish a system to maintain records of all patients receiving services under a collaborative pharmacy practice agreement for a period of five years from each patient's most recent provision of services
- employed pharmacists must have written approval from the owner of the pharmacy in order to enter into a collaborative pharmacy practice agreement

The new legislation also requires that the terms of a valid collaborative pharmacy practice agreement meet the following requirements:

- The agreement must include (i) the name of the collaborating physician's patient or patients for whom a pharmacist may provide services, (ii) each chronic health condition to be collaboratively managed, (iii) the medicinal drugs to be managed by the pharmacist for each patient, (iv) the circumstances under which the pharmacist may order or perform and evaluate laboratory or clinical tests, (v) the

conditions and events upon which the pharmacist must notify the collaborating physician and the manner and timeframe in which such notification must occur, (vi) beginning and ending dates and termination procedures, including procedures for patient notification and medical records transfers, (vi) a statement that the agreement may be terminated, in writing, by either party at any time.

- A collaborative pharmacy practice agreement shall automatically terminate two years after execution if not renewed.
- The pharmacist and collaborating physician must maintain the agreement on file at their practice locations and must make the agreements available to the Department of Health or the Board upon request or inspection.
- The pharmacist must submit a copy of the signed agreement to the Board before the agreement may be implemented.

The legislation prohibits the modification or discontinuation by pharmacists of medicinal drugs prescribed by a health care practitioner with whom they do not have a collaborative pharmacy practice agreement, and a physician may not delegate the authority to initiate or prescribe certain controlled substances to a pharmacist.

Testing and Treatment of Minor, Nonchronic Health Conditions Under Written Protocols

The new legislation adds Section 465.1895, Florida Statutes, which allows pharmacists, pursuant to an established written protocol with a Florida-licensed supervising physician, to test, screen for, and treat the following minor, nonchronic health conditions:

- influenza
- streptococcus
- lice
- skin conditions, such as ringworm and athlete's foot
- minor, uncomplicated infections

Pharmacists who provide these services must meet the following requirements:

- Hold an active and unencumbered license to practice pharmacy in Florida.
- Hold a certification issued by the Board to test, screen for and treat minor, nonchronic health conditions and provide evidence of such certification to the supervising physician to be reviewed in accordance with the protocol. The certification must require completion of a 20-hour education course approved by the Board and must address patient assessments, point-of-care testing procedures, safe and effective treatment, and identification of contraindications.
- Maintain at least $250,000 of professional liability insurance coverage or coverage pursuant to Section 465.1895, Florida Statutes.
- Report diagnoses, or the suspected existence, of a disease of public health significance to the Department of Health.
- Furnish patient records to a health care practitioner at the request of a patient.

- Maintain patient records for at least five years from the most recent provision of services.
- Pharmacists may use any tests that may guide diagnosis or clinical decision-making which the Centers for Medicare and Medicaid Services has determined qualifies for a waiver under the federal Clinical Laboratory Improvement Amendments of 1988 (and the federal rules adopted thereunder), or any established screening procedures that can safely be performed by a pharmacist.
- An employed pharmacist must have the written approval of the owner of the pharmacy to provide such services.
- Complete a three-hour continuing education course approved by the Board each biennial license renewal, which addresses issues related to minor, nonchronic health conditions and submit confirmation when applying for licensure renewal.
- Provide patients with written information that advises the patient to seek follow up care from his or her primary care physician, according to guidelines established by the Board.
- The pharmacy in which a pharmacist provides these services must prominently display signage indicating that any patient receiving testing, screening, or treatment services under this section is advised to seek follow up care from his or her primary care physician.

As with the collaborative pharmacy practice agreements, the written protocols enabling pharmacists to test, screen for, and treat minor, nonchronic health conditions must include certain terms and conditions, must be appropriate to the pharmacists training, and must be submitted to the Board. Valid written protocols must include the following:

- the specific categories of patients for whom the pharmacist is authorized to provide these services
- the physician's instructions for obtaining relevant patient medical history in order to identify disqualifying health conditions, adverse reactions, and contraindications to the course of treatment
- the physician's instructions for treatment based on the patient's age, symptoms, and test 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 physician of the patient's condition, tests administered, test results, and course of treatment
- any other requirements as established by the Board, in consultation with the Board of Medicine and the Board of Osteopathic Medicine

II. Florida Board of Pharmacy Rules

The Board is currently drafting and considering proposed rules as required by the new legislation, which will implement and expand upon the requirements for collaborative pharmacy practice agreements and testing and treatment of minor, nonchronic health conditions pursuant to a written protocol with a supervising provision. Once approved, these rules will be published in the Florida Administrative Code and are expected to be effective July 1, 2020. The Joint Rules Committee of the Board has an upcoming meeting on June 25, 2020, to discuss the proposed rules. A draft version is available on the Board website and summarized below.

Collaborative Pharmacy Practice Agreement Proposals

The proposed rules for the collaborative pharmacy practice agreements require pharmacists to submit two application forms: the "Application for Pharmacist Collaborative Practice Certification" form and the "Application for Initial Collaborative Practice Certification Course" form, which will be available on the Board website. The application forms and the proposed rules require that pharmacists complete certification courses that meet the requirements in the new legislation and also discuss laws and rules applicable to the collaborative practice for the treatment of chronic health conditions, as well as writing and entering into a collaborative practice agreement. Additionally, the proposed rules require that a valid certification course may only be offered by a program provider accredited by the Association Council for Pharmacy Education (ACPE) or a program provider accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category 1 credit or the American Osteopathic Association Category 1-A continuing medical education credit. Furthermore, no less than 12 hours of the course shall be offered through a live seminar or a live video teleconference, and an approved course will count for 20 hours of general continuing education credits.

The proposed rules also require that, prior to providing services, or immediately after a renewal, the pharmacist shall submit an executed collaborative pharmacy practice agreement to the Board through the pharmacist's online licensure account (or via mail), and the pharmacist shall maintain a copy of any addendum to the agreement.

In addition to those conditions specified in the legislation, the proposed rules would also add the following conditions for which a pharmacist can provide specified services pursuant to a collaborative pharmacy practice agreement:

- Hyperlipidemia
- Hypertension
- Anti-coagulation management
- Smoking cessation
- Osteoporosis and osteo-arthritis
- Opioid use disorder
- Any disease state expected to last greater than one year or more and will require ongoing medical treatment and drug therapy services

Testing and Treatment of Minor, Nonchronic Health Conditions Proposals

The proposed rules covering testing and treatment of minor, nonchronic health conditions likewise require the submission of two application forms: "Application for Pharmacist Test and Treat Certification" and "Application for Initial Test and Treat Certification Course," and completion of a 20-hour certification course (at least 12 hours to be in a live seminar or a live video teleconference format) offered by an ACPE or an accredited provider that discusses areas required by the legislation, as well as laws and rules applicable to test and treat certifications and writing and entering into a written protocol.

The proposed rules require that within five days of entering into a written protocol with a supervising physician, the pharmacist shall submit a copy of the protocol to the Board office through the pharmacist's

online licensure account or via mail, and the pharmacist shall maintain a copy of any addendum to the agreement.

An important provision in the proposed rules requires a pharmacist to provide written information to a patient being treated pursuant to a written protocol that advises the patient when to seek follow-up care on three occasions: (i) immediately prior to performing services on a patient for the first time, (ii) as outlined in the written protocol, and (iii) when the pharmacist determines the patient should follow up with his or her primary care provider. The proposed rules also require that a pharmacist provide patient records within five business days of a patient request.

The new legislation requires the Board to designate a formulary of medicinal drugs a pharmacist may prescribe pursuant to a written protocol with a supervising physician, which is addressed in the proposed rules to include (i) all medicinal drugs approved by the United States Food and Drug Administration (FDA) and (ii) all compounded medicinal drugs that utilize only active pharmaceutical ingredients approved by the FDA. A pharmacist may not prescribe controlled substances as described in Section 893.03 or 21 U.S.C. § 812.

Finally, the proposed rules require that the Board review the rules and amend, modify or repeal any rule that creates barriers to entry for private business competition, is duplicative, outdated, obsolete, overly burdensome, or imposes excessive costs, no later than 90 days prior to Dec. 31, 2025.

Next Steps

The new legislation is effective July 1, 2020. Pharmacists interested in providing these services may wish to discuss these new opportunities with employers, begin building relationships with collaborating physicians, and start developing processes and procedures that meet the requirements. The Board rules are currently in the proposal stage, however, the meeting on June 25 is open to the public and pharmacists and pharmacist practices should keep abreast of the finalization of Board rulemaking.

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