HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 833 Consultant Pharmacists
SPONSOR(S): Health Quality Subcommittee, Byrd
TIED BILLS: **IDEN./SIM. BILLS:** SB 1050

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	10 Y, 0 N, As CS	Siples	McElroy
2) Health & Human Services Committee	18 Y, 0 N	Siples	Calamas

SUMMARY ANALYSIS

A consultant pharmacist obtains specialized education above that which is required for licensure as a pharmacist and has a broader scope of practice. A consultant pharmacist may order and evaluate clinical and laboratory testing in addition to the services provided by a pharmacist in two settings: for a patient residing in a nursing home upon authorization by the medical director of the nursing home; and for individuals under the care of a licensed home health agency, if authorized by a licensed physician, podiatrist, or dentist.

CS/HB 883 expands the consultant pharmacist's scope of practice by authorizing a consultant pharmacist to enter into a collaborative practice agreement with a health care facility medical director or Florida-licensed allopathic physician, osteopathic physician, podiatric physician, or dentist to:

- Order and evaluate laboratory and clinical testing;
- Conduct patient assessments;
- Administer medications; and
- Initiate, modify, or discontinue medicinal drugs pursuant to a patient-specific order or treatment protocol; however, a consultant pharmacist may not modify or discontinue a medicinal drug if he or she does not have a collaborative practice agreement with the prescribing health care practitioner.

The bill authorizes a consultant pharmacist to provide these services in any setting, rather than limiting such services to nursing home or home health patients. The bill also authorizes a pharmacist to make recommendations regarding the patient's health care status with the patient's prescribing health care practitioner or others specifically authorized by the patient. The bill clarifies that a consultant pharmacist is not authorized to diagnose any disease or condition.

The bill requires both the consultant pharmacist and health care practitioner to maintain a copy of the collaborative agreement and make it available upon request or during an inspection. The bill also requires the consultant pharmacist to maintain all drug, patient care, and quality assurance records.

The bill authorized the Board of Pharmacy to establish additional education requirements for licensure as a consultant pharmacist.

The bill has no fiscal impact on state or local government.

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, 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 March 8, 2019).
[2] Sections 465.004 and 465.005, F.S.
[3] Section 465.007, F.S. 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 symptoms 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.

<u>Consultant Pharmacists</u>

A consultant pharmacist is a pharmacist who provides expert advice on the use of medications to individuals or older adults, wherever they live.[16] To be licensed as a consultant pharmacist, an applicant must:[17]

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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.

- Hold a license as a pharmacist that is active and in good standing;
- Successfully complete an approved consultant pharmacist course of at least 12 hours;[18] and
- Successfully complete a 40-hour period of assessment and evaluation under the supervision of a preceptor within one year of completion of an approved consultant pharmacist course.

Education and Training Requirements for Consultant Pharmacists

In addition to the training and education received as a part of a degree program in pharmacy, a consultant pharmacist is required to complete a consultant pharmacy course and a period of assessment and evaluation under the supervision of a preceptor. The Board has general rulemaking authority to adopt rules to implement the pharmacy practice act and specific authority to adopt rules related to the licensure of consultant pharmacists.[19] The Board does not have specific authority to adopt rules related to the educational requirements for consultant pharmacists. Regardless, the Board has, by rule, established the minimum educational and training requirements for licensure as a consultant.[20]

The Board has specified the topics on which a consultant pharmacist may be trained in order to qualify for the designation. The consultant pharmacy course must provide at least 12 hours of education in the following areas:[21]

- Jurisprudence; including state and federal laws and regulations pertaining to health care facilities, institutional pharmacy, safe and controlled storage of alcohol and other related substances, and fire and health-hazard control;
- Policies and procedures outlining the medication system in effect and record-keeping for controlled substances control and record of usage, medication use evaluation, medication errors, statistical reports, etc.;
- Fiscal controls;
- Personnel management, including intra-professional relations pertaining to medication use and intra-professional relations with other members of the institutional health care team to develop formularies, review medication use and prescribing, and the provision of in-service training of other members of the institutional health care team;
- Professional responsibilities, including:
    - Drug information retrieval and methods of dispersal;
    - Development of pharmacy practice;
    - Development of an IV Admixture service;
    - Procedures to enhance medication safety, including availability of equipment and techniques to prepare special dosage forms for pediatric and geriatric patients, safety of patient self-medication and control of drugs at bedside, reporting and trending adverse drug reactions, screening for potential drug interactions, and proper writing, initiating, transcribing and/or transferring patient medication orders;
    - Maintenance of drug quality and safe storage; and
    - Maintenance of drug identity;
- The institutional environment, including the institution's pharmacy function and purpose, understanding the scope of service and in-patient care mission of the institution, and interpersonal relationships important to the institutional pharmacy; and

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[16] American Society of Consultant Pharmacists, *What is a Senior Care Pharmacist,* available at http://www.ascp.com/page/whatisacp (last visited March 8, 2019). Consultant pharmacists are often referred to as "senior care pharmacist."
[17] Rule 64B16-26(3), F.A.C.
[18] Rule 64B16-26.300, F.A.C., requires the course to be sponsored by an accredited college of pharmacy and approved by the Florida Board of Pharmacy Tripartite Continuing Education Committee which is based on the Statement of the Competencies Required in Institutional Pharmacy Practice and subject matter set forth in Rule 64B16-26.301, F.A.C.
[19] Section 465.005, F.S.
[20] Rule 64B16-26.300, F.A.C.
[21] Rules 64B16-26.300 and 64B16-26.301, F.A.C.

- Nuclear pharmacy, including procurement, compounding, quality control procedures, dispensing, distribution, basic radiation protection and practices, consultation and education to the nuclear medical community, record-keeping, reporting adverse reactions and medical errors, and screening for potential drug interactions.

The applicant must score a passing grade on the course examination for certification of successful completion.[22]

A consultant pharmacist must successfully complete a period of assessment and evaluation, under the supervision of a qualified preceptor, within one year of completing the consultant pharmacy educational course.[23] The period of assessment and evaluation must be completed within three consecutive months and include at least 40 hours of training in the following practice areas:[24]

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

At least 60 percent of this training must occur on-site at an institution that holds a pharmacy license.[25]

Scope of Practice

The scope of practice for a consultant pharmacist is broader than that of a pharmacist. A consultant pharmacist may order and evaluate laboratory testing in addition to the services provided by a pharmacist. For example, a consultant pharmacist can order and evaluate clinical and laboratory testing for a patient residing in a nursing home upon authorization by the medical director of the nursing home.[26] 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.[27]

Pharmacist Collaborative Practice Agreements

A collaborative practice agreement (CPA) is a formal agreement in which a licensed practitioner makes a diagnosis, supervises patient care, and refers patients to a pharmacist under a protocol that allows the pharmacist to perform specific patient care functions.[28] A CPA specifies what functions beyond the pharmacist's typical scope of practice can be delegated to the pharmacist by the collaborating health

[22] Id.
[23] Rule 64B16-26.300(3)(c), F.A.C.
[24] Id. To act as a preceptor, a person must be a consultant of record at an institutional pharmacy, have a minimum of one year experience as a consultant pharmacist of record, and be licensed, in good standing, with the board. A preceptor may not supervise more than two applicants at the same time.
[25] Id.
[26] Section 465.0125(1), F.S.
[27] 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.
[28] U.S. Center for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division for Heart Disease and Stroke Prevention, *Collaborative Practice Agreements and Pharmacists' Patient Care Services: A Resource for Pharmacists*, (2013), available at https://www.cdc.gov/dhdsp/pubs/docs/translational_tools_pharmacists.pdf (last visited March 8, 2019)

care practitioner.[29] Common tasks include initiating, modifying, or discontinuing medication therapy and ordering and evaluating tests.[30]

As of May 2016, 48 states, including Florida, permit some type of collaborative practice between a pharmacist and a prescriber.[31] However, the laws and regulations of these states vary in areas such as the functions that may be authorized, the requirements for collaborative agreements, and the qualifications for participants.[32]

Effect of Proposed Changes

Consultant Pharmacists

CS/HB 833 authorizes a consultant pharmacist to enter into a collaborative practice agreement with a health care facility[33] medical director or a Florida-licensed allopathic physician, osteopathic physician, podiatric physician, or dentist, who is authorized to prescribe medication, to provide medication management services, which may include:

- Ordering and evaluating laboratory and clinical tests[34] to monitor medication therapy and treatment outcomes, as well as promote and evaluate patient health and wellness;
- Conducting patient assessments to evaluate and monitor drug therapy;
- Initiating, modifying, or discontinuing medications as outlined in a patient-specific order or pre-approved treatment protocol; and
- Administering medication.

The bill prohibits a consultant pharmacist from modifying or discontinuing a medication if the consultant pharmacist does not have a collaborative practice agreement with the prescribing practitioner. The bill also clarifies that a consultant pharmacist is not authorized to diagnose any disease or condition.

The bill eliminates the restriction on the setting in which a consultant pharmacist's services may be offered that is in current law, and allows such services to be provided in any setting. The consultant pharmacist and the collaborating health care practitioner must maintain the collaborative practice agreement, which must be available upon request or during an inspection. The consultant pharmacist must maintain all drug, patient care, and quality assurance records as required by law.

The Board previously established, by rule, the additional training required for licensure as a consultant pharmacist under its general rulemaking authority.[35] The bill gives the Board express authority to establish additional education requirements for licensure as a consultant pharmacist.

The bill revises the definition of "practice of pharmacy" to authorize a pharmacist consult with a prescribing health care practitioner or others specifically authorized by the patient on a patient's health care status; and to authorize consultant pharmacists to:

- Order and evaluate any laboratory or clinical testing;

[29] U.S. Center for Disease Control and Prevention, *Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team*, (2017), available at https://www.cdc.gov/dhdsp/pubs/docs/CPA-Team-Based-Care.pdf (last visited March 8, 2019).
[30] *Supra* note 28.
[31] *Supra* note 29.
[32] Id.
[33] The bill defines a health care facility as an ambulatory surgery center licensed under ch. 395, F.S., an inpatient hospice licensed under part IV of ch. 400, F.S., a hospital licensed under ch. 395, F.S., an alcohol or chemical dependency center licensed under ch. 397, F.S., an ambulatory care center as defined in s. 408.07, F.S., or a nursing home component under ch. 400, F.S., within a continuing care facility licensed under ch. 651, F.S.
[34] Under current law, a consultant pharmacist may only order and evaluate laboratory and clinical tests for patients residing in a nursing home or who are under the care of a home health agency.
[35] *Supra* note 21.

- Conduct patient assessments; and
- Initiate, modify, discontinue, or administer medication.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 465.003, F.S., regarding definitions.
Section 2: Amends s. 465.0125, F.S., regarding consultant pharmacist license; application, renewal, fees; responsibilities; rules.
Section 3: 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:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

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 implement the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 12, 2019, the Health Quality Subcommittee adopted a strike-all amendment and reported HB 883 favorably as a committee substitute. The strike-all amendment:

- Prohibited a consultant pharmacist from modifying or discontinuing a medication if he or she does not have a collaborative practice agreement with the prescribing health care practitioner;
- Provided that consultant pharmacists may not diagnose any disease or condition;
- Revised the definition of health care facility to remove home health agencies and narrowed hospice facilities to inpatient facilities; and
- Restored current law related to consultant pharmacy practice in home health agencies.

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