HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 689 Pharmacy
SPONSOR(S): Health & Human Services Committee; Health Quality Subcommittee; Byrd
TIED BILLS: **IDEN./SIM. BILLS:** SB 914

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	11 Y, 1 N, As CS	Siples	McElroy
2) Health & Human Services Committee	16 Y, 1 N, As CS	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 689 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 an individual health care practitioner 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 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 requires the consultant pharmacist to maintain all drug, patient care, and quality assurance records.

The Board of Pharmacy has adopted rules establishing the minimum education requirements for licensure as a consultant pharmacist. The bill codifies the authority of the Board of Pharmacy, within the Department of Health, 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, 2018.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Regulation of Pharmacists

Licensure

Pharmacy is the third largest health profession behind nursing and medicine.[1] The Board of Pharmacy (Board), in conjunction with the Department of Health (DOH), regulates the practice of pharmacists pursuant to ch. 465, F.S.[2] To be licensed as a pharmacist, a person must:[3]

- Complete an application and remit an examination fee;
- Be at least 18 years of age;
- Hold a degree from an accredited and approved school or college of pharmacy;[4]
- Have completed a Board-approved internship; and
- Successfully complete the Board-approved examination.

A pharmacist must complete at least 30 hours of Board-approved continuing education during each biennial renewal period.[5] Pharmacists who are certified to administer vaccines or epinephrine autoinjections must complete a 3-hour continuing education course on the safe and effective administration of vaccines and epinephrine injections as a part of the biennial licensure renewal.[6]

Scope of Practice

The practice of the profession of pharmacy includes:[7]

- Compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of a medicinal drug;
- Consulting concerning therapeutic values and interactions of patent or proprietary preparations;
- Monitoring a patient's drug therapy and assisting the patient in the management of his or her drug therapy, including the review of the patient's drug therapy and communication with the patient's prescribing health care provider or other persons specifically authorized by the patient, regarding the drug therapy;
- Transmitting information from prescribers to their patients;
- Administering vaccines to adults;[8]
- Administering epinephrine injections;[9] and
- Administering antipsychotic medications by injection.[10]

---

[1] American Association of Colleges of Pharmacy, *About AACP*, available at https://www.aacp.org/about-aacp (last visited December 5, 2017).
[2] Sections 465.004 and 465.005, F.S.
[3] Section 465.007, F.S. DOH may also issue a license by endorsement to a pharmacist who is licensed in another state upon meeting the applicable requirements set forth in law and rule. *See* s. 465.0075, F.S.
[4] If the applicant has graduated from a 4-year undergraduate pharmacy program of a school or college of pharmacy located outside the United States, the applicant must demonstrate proficiency in English, pass the board-approved Foreign Pharmacy Graduate Equivalency Examination, and complete a minimum of 500 hours in a supervised work activity program within Florida under the supervision of a DOH-licensed pharmacist
[5] Section 465.009, F.S.
[6] Section 465.009(6), F.S.
[7] Section 465.003(13), F.S.
[8] *See* s. 465.189, F.S.
[9] Id.
[10] Section 465.1893, F.S.

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

Consultant Pharmacists

A consultant pharmacist is a pharmacist who provides expert advice on the use of medications to individuals or older adults, wherever they live.[12] To be licensed as a consultant pharmacist, an applicant must:[13]

- 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;[14] 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.[15] 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.[16]

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:[17]

- 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;

[11] *Supra* note 7.
[12] American Society of Consultant Pharmacists, *What is a Consultant Pharmacist,* available at http://www.ascp.com/page/whatisacp (last visited December 8, 2017).
[13] Rule 64B16-26(3), F.A.C.
[14] 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.
[15] Section 465.005, F.S.
[16] Rule 64B16-26.300, F.A.C.
[17] Rules 64B16-26.300 and 64B16-26.301, F.A.C.

    - 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
- 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.[18]

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.[19] 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:[20]

- 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.[21]

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.[22] 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.[23]

[18] Id.
[19] Rule 64B16-26.300(3)(c), F.A.C.
[20] 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.
[21] Id.
[22] Section 465.0125(1), F.S.
[23] 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.

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.[24] A CPA specifies what functions beyond the pharmacist's typical scope of practice can be delegated to the pharmacist by the collaborating health care practitioner.[25] Common tasks include initiating, modifying, or discontinuing medication therapy and ordering and evaluating tests.[26]

As of May 2016, 48 states, including Florida, permit some type of collaborative practice between a pharmacist and a prescriber.[27] 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.[28]

Effect of Proposed Changes

Consultant Pharmacists

CS/HB 689 authorizes a consultant pharmacist to enter into a collaborative practice agreement with a health care facility[29] medical director or an individual health care practitioner, who is authorized to prescribe medication, to provide medication management services, which may include:

- Ordering and evaluating laboratory and clinical tests[30] 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 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 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.

---

[24] 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 January 11, 2018).

[25] 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 January 11, 2018).

[26] *Supra* note 24.

[27] *Supra* note 25.

[28] Id.

[29] The bill defines a health care facility as an ambulatory surgery center licensed under ch. 395, F.S., a hospice licensed under part IV of ch. 400, F.S., a hospital licensed under ch. 395, F.S., a home health agency licensed under part III of ch. 400, 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.

[30] 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.

The Board previously established, by rule, the additional training required for licensure as a consultant pharmacist under its general rulemaking authority.[31] The bill gives the Board express authority to establish additional education requirements for licensure as a consultant pharmacist.

The bill authorizes the Board to establish education requirements for consultant pharmacists and repeals a requirement that a consultant pharmacist complete 3 hours of continuing education to order and evaluate laboratory and clinical tests for individuals under the care of a home health agency.

The bill provides an effective date of July 1, 2018.

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, 2018.

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.

[31] *Supra* note 17.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The Board of Pharmacy has sufficient rule-making authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill authorizes a consultant pharmacist to enter into a collaborative practice agreement with a medical director of a health care facility. Since the bill does not define health care facility, it is unclear with which medical directors a consultant pharmacist may enter into a collaborative agreement.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On January 16, 2018, the Health Quality Subcommittee adopted a strike-all amendment and reported HB 689 favorably as a committee substitute. The strike-all amendment:

- Added ordering and evaluation of laboratory and clinical tests, conducting patient assessments, and administering, initiating, modifying, or discontinuing medicinal drugs as a consultant pharmacist to the definition of "practice of the profession of pharmacy;"
- Removed the consulting on health care products and services from the definition of the "practice of the profession of pharmacy;"
- Removed the authority of a pharmacist to order and evaluate tests and to administer, modify, and discontinue medications; and
- Changed "medications" to "medicinal drugs" throughout the bill.

On February 15, 2018, the Health and Human Services Committee adopted two amendments and reported CS/HB 689 favorably as a committee substitute. The amendments:

- 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; and
- Defined health care facility.

The analysis is drafted to the committee substitute as passed by the Health and Human Services Committee.