HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 547 Practice of Pharmacy
SPONSOR(S): Narain
TIED BILLS: **IDEN./SIM. BILLS:** SB 692

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Siples	O'Callaghan
2) Appropriations Committee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

In the practice of the profession of pharmacy, a pharmacist provides a number of services to his or her consumers, including the dispensing of drugs, consultation, monitoring of drug therapy, and administration of vaccines to adults. The bill creates the "Access to Pharmacist Services Act" and revises the definition of the "practice of the profession of pharmacy" to include the provision of health and wellness assessments and patient care relating to medication therapy management and the dispensing and administration of medications.

A consultant pharmacist provides expert advice on the use of medication by individuals or on the provision of pharmacy services to institutions. In addition to the training a consultant pharmacist may receive as part of a pharmacy degree program, he or she must complete a consultant pharmacy education course and participate in additional practical training. A doctor of pharmacy is an advanced professional degree that provides instruction on advanced pharmacy practice. The bill authorizes a consultant pharmacist or a doctor of pharmacy to perform certain services, and requires each to meet certain educational and training requirements.

Specifically, the bill allows a consultant pharmacist or a doctor of pharmacy to provide medication management, patient health and wellness assessments, counseling, and referrals related to medication and health care services, in accordance with the law and Board of Pharmacy standards.

Currently, a consultant pharmacist may order laboratory or clinical testing, if needed by the consultant pharmacist to properly perform his or her duties. The bill extends this authority to a doctor of pharmacy and also permits the ordering of diagnostic tests by a consultant pharmacist or doctor of pharmacy, if needed for the proper performance of his or her duties. The bill allows a consultant pharmacist or doctor of pharmacy to order clinical testing for a patient without authorization from a physician or nursing home medical director. Current law limits the ability to order clinical testing to patients residing in nursing homes or receiving home health care services and requires approval of a nursing home medical director or physician.

The bill authorizes a licensed consultant pharmacist or a doctor of pharmacy to initiate, modify, discontinue, and administer drugs within the framework of a drug management therapy order or protocol with one or more health care providers.

The bill provides that a health insurer or health benefit plan may pay or reimburse for a pharmacist's patient care services separate and apart from the payment for prescription medications, if the services provided are within the pharmacist's lawful scope of practice.

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

The bill provides an effective date of July 1, 2016.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Regulation of Pharmacists

Pharmacists are regulated under the Florida Pharmacy Act (act) in ch. 465, F.S. The Board of Pharmacy (board), within the Department of Health (DOH), has the authority to adopt rules to implement the provisions of ch. 465, F.S.[1] A pharmacist is a person who is licensed under the act to practice the profession of pharmacy.[2] To be licensed as a pharmacist in Florida, a person must:

- Complete an application and remit an examination fee;
- Be at least 18 years of age;
- Have received a degree from an accredited and approved school or college of pharmacy; or be a graduate of a 4-year undergraduate pharmacy program of a school or college of pharmacy located outside the United States, 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;
- Have completed a board-approved internship; and
- Successfully complete the board-approved examination.[3]

The practice of the profession of pharmacy includes:

- Compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any 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 the provider's agent or other persons specifically authorized by the patient, regarding drug therapy;
- Transmitting information from persons authorized to prescribe medicinal drugs to their patients; and
- Administering vaccines to adults.[4]

Doctor of Pharmacy Degree

The Accreditation Council for Pharmacy Education (ACPE) is the national agency for accreditation of professional degree programs in pharmacy.[5] The ACPE establishes minimum standards and guidelines for professional programs in pharmacy that lead to a Doctor of Pharmacy degree.[6] The accreditation standards require the education curriculum to include instruction on pharmaceutical science, social and behavioral pharmacy sciences, and clinical sciences.[7] Clinical sciences includes instruction in

[1] Sections 465.004 and 465.005, F.S.
[2] Section 465.003(10), 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] Section 465.003(13), F.S. Pharmacists are expressly prohibited from altering a prescriber's directions, diagnosing or treating any disease, initiating drug therapies, or practicing medicine, unless otherwise permitted by law.
[5] Accreditation Council for Pharmacy Education, *About ACPE*, *available at* https://www.acpe-accredit.org/about/default.asp (last visited Nov. 20, 2015).
[6] Accreditation Council for Pharmacy Education, *Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree*, (Adopted Jan. 15, 2006, Rev. Jan. 23, 2011, Eff. Feb. 14, 2011), *available at* https://www.acpe-accredit.org/students/standards.asp (last visited Nov. 20, 2015).
[7] *Id*.

pharmacy practice, medication dispensing and distribution systems, pharmacotherapy, care for special populations, medication safety, literature evaluation and research design, and a patient assessment laboratory.

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.[8] The advanced pharmacy experience must include primary, acute, chronic, and preventive care among patients of all ages. It must also include experiences in a community pharmacy, hospital or health-system pharmacy, ambulatory care, and inpatient/acute care general medicine.[9]

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.[10] However, pharmacists who were licensed prior to the change in the educational standards may not hold a doctor of pharmacy degree.

Consultant Pharmacists

A consultant pharmacist is a pharmacist who provides expert advice on the use of medications by individuals or on the provision of pharmacy services to institutions.[11] To be licensed as a consultant pharmacist, a person must:

- 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;[12] 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.[13]

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 enumerated a number of 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:

- 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:

[8] *Id* at 27.
[9] *Id*.
[10] *Id* at i. *See also* DOH, *House Bill 547 Agency Legislative Bill Analysis* (Nov. 13, 2015), on file with Health Quality Subcommittee.
[11] American Society of Consultant Pharmacists, *Frequently Asked Questions, available at* https://www.ascp.com/articles/about-ascp/frequently-asked-questions (last visited Nov. 17, 2015).
[12] Rule 64B16-26.300, F.A.C., requires the course to be sponsored by an accredited college of pharmacy located within the state of Florida, 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.
[13] Section 465.003(3), F.S., and Rule 64B16-26(3), F.A.C.

    - 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
- 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.[14]

The course must include a cognitive test on which the applicant must score a passing grade for certification of successful completion.

Within one year of completing the consultant pharmacy educational course, a period of assessment and evaluation, under the supervision of a qualified preceptor, must be successfully completed. 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, 60% of which must occur on-site at an institution that holds a pharmacy license. The training must include, at a minimum:

- 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.[15]

Scope of Practice

In addition to the services provided within the practice of the profession of pharmacy, a consultant pharmacist may 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.[16]

A consultant pharmacist and a pharmacist holding a Doctor of Pharmacy degree 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.[17] To qualify to order such testing, the consultant pharmacist must complete 3 hours of board-approved training, related to laboratory and clinical testing.[18]

[14] Rules 64B16-26.300 and 64B16-26.301, F.A.C.
[15] Rule 64B16-26.300(c), F.A.C. To act 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.
[16] Section 465.0125(1), F.S.
[17] Section 465.0125(2), F.S.
[18] *Id*.

Effect of Proposed Changes

The bill creates the "Access to Pharmacist Services Act."

The Practice of Pharmacy

The bill revises the definition of "practice of the profession of pharmacy" to allow a pharmacist to:

- Consult on the therapeutic values and interactions of patent or proprietary products and health and wellness assessments and patient care relating to medication therapy management;
- Manage, in addition to monitor and review, a patient's drug therapy;
- Collaborate with a patient's health care provider, the provider's authorized agent, or other persons specifically authorized by the patient regarding the patient's health care status, in addition to the patient's drug therapy; and
- Dispense medications, including vaccines, in addition to the administration of such medications.

Consultant Pharmacists and Doctors of Pharmacy

In addition to the drug records a consultant pharmacist is currently required to keep, the bill requires the consultant pharmacist to also maintain patient care and quality assurance records.

The bill authorizes a licensed consultant pharmacist or a doctor of pharmacy to perform medication management, patient health and wellness assessments, counseling, and referrals related to medications and health care services, in accordance with the law and the standards of practice adopted by the board.

Currently, a consultant pharmacist may order and evaluate laboratory or clinical testing when the consultant pharmacist determines it is needed for the proper performance of his or her duties. The bill authorizes a doctor of pharmacy to perform those same tests, but also authorizes a consultant pharmacist or a doctor of pharmacy to order and evaluate diagnostic testing when, in his or her judgment, such testing is necessary to properly perform his or her duties.

The bill repeals the requirement that a consultant pharmacist only order clinical testing for a patient residing in a nursing home or receiving home health services, and upon authorization by the medical director of the nursing home or physician, respectively. Consequently, the bill allows a consultant pharmacist or a doctor of pharmacy to order clinical testing for any patient for which he or she deems it necessary for the proper performance of his or her duties.

The bill allows a licensed consultant pharmacist or a doctor of pharmacy to initiate, modify, discontinue, and administer drugs within the framework of a drug management therapy order or protocol with one or more health care providers.

The bill authorizes a doctor of pharmacy to perform the same duties as a consultant pharmacist and subjects a doctor of pharmacy to the same additional training and experience requirement as a consultant pharmacist. The bill expands the training requirements to include instruction on the practice of pharmacy in community or other settings, in addition to institutional settings.

Reimbursement for a Pharmacist's Patient Care Services

The bill provides that a health insurer or health benefit plan may pay or reimburse for a pharmacist's patient care services separate and apart from the payment for prescription medications, if the services provided are within the pharmacist's lawful scope of practice. Pharmacists providing patient care services are not covered in the Medicare Part B portion of the Social Security Act.[19] According the American Pharmacists Association, this omission has been cited as a rationale to exclude patient care

[19] DOH, *House Bill 547 Agency Legislative Bill Analysis* (Nov. 13, 2015), on file with Health Quality Subcommittee.

services provided by a pharmacist from reimbursement by private health insurance companies.[20] However, health plans will reimburse pharmacists providing patient care services, such as medication review or smoking cessation counseling, as separate and distinct services.[21]

B. SECTION DIRECTORY:

Section 1. Provides that the act may be cited as the "Access to Pharmacist Services Act."
Section 2. Amends s. 465.003, F.S., relating to definitions.
Section 3. Amends s. 465.0125, F.S., relating to consultant pharmacist license; application, renewal, fees; responsibilities; rules.
Section 4. Allows a health benefit plan or insurer to pay or reimburse a pharmacist for patient care services separate and apart from the prescription medications, as long as the services are within the pharmacist's lawful scope of practice.
Section 5. Provides an effective date of July 1, 2016.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The bill may have an insignificant negative fiscal impact on the Department of Health associated with revisions to rules, which can be absorbed in the current budget authority. DOH indicates that it may incur an indeterminate, negative fiscal impact due to workload impacts related to potential additional practitioner complaints and investigations.[22]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Patients may see reduced health care costs as a result of being able to access certain medication management services and associated clinical laboratory tests without the necessity of a physician visit. Any such impacts are indeterminate.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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[20] *Id*.
[21] Houle, Sherilyn et al., *Paying Pharmacists for Patient Care: A Systematic Review of Remunerated Pharmacy Clinical Care Services*," Can. Pharm. J. (July 2014), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4212445/ (last visited Nov. 19, 2015).
[22] *Supra* note 19.

Not applicable. This 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 provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The term “health and wellness assessments” is not defined.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES