Health Quality Subcommittee

Tuesday, December 1, 2015
3:30 PM - 5:30 PM
306 HOB

Steve Crisafulli
Speaker

Cary Pigman
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Health Quality Subcommittee

Start Date and Time: Tuesday, December 01, 2015 03:30 pm

End Date and Time: Tuesday, December 01, 2015 05:30 pm

Location: 306 HOB

Duration: 2.00 hrs

Consideration of the following bill(s):

HB 315 Medical Examiners by Roberson, K.
HB 423 Drug Prescription by Advanced Registered Nurse Practitioners & Physician Assistants by Pigman
HB 517 Licensure of Life Support Services by Renner
HB 547 Practice of Pharmacy by Narain

Pursuant to rule 7.12, the deadline for amendments to bills on the agenda by non-appointed members is 6:00 p.m., Monday, November 30, 2015.

By request of the chair, all committee members are asked to have amendments to bills on the agenda submitted to staff by 6:00 p.m., Monday, November 30, 2015.

NOTICE FINALIZED on 11/24/2015 2:05PM by Iseminger.Bobbye

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 315 Medical Examiners
SPONSOR(S): Roberson
TIED BILLS: **IDEN./SIM. BILLS:** SB 620

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

SUMMARY ANALYSIS

Section 406.06, F.S., entitles a medical examiner to compensation, and a reasonable salary and fees as established by a board of county commissioners. A number of counties have interpreted this provision as authority for their board of county commissioners to authorize their district medical examiner to collect a user fee for a determination of cause of death performed when a body is to be cremated, dissected, or buried at sea pursuant to s. 406.11(1)(c), F.S. The bill amends s. 382.011, F.S., to prohibit a medical examiner from charging such user fees. However, the bill provides an exception to this prohibition which allows counties to enact an ordinance or resolution authorizing medical examiners to charge an approval fee of up to $50 when a determination of death is made for a body being cremated, buried at sea or dissected and the death is not related to circumstances set forth in s. 406.11(1)(a), F.S.

Section 382.011, F.S., requires any case in which a death or fetal death resulted from the causes or conditions listed in s. 406.011, F.S., to be referred to the district medical examiner for the determination of the cause of death. The bill corrects a citation in s. 382.011, F.S., to clarify that only deaths and fetal deaths involving circumstances set forth in subsection (1) of s. 406.11, F.S., are required to be referred to the district medical examiner for the determination of the cause of death. The remaining provisions in s. 406.11, F.S., are not related to causes or conditions of death upon which a medical examiner can make a determination.

The bill does not appear to have a fiscal impact on state or local governments.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Medical Examiners Act

The Medical Examiners Act (Act), ch. 406, F.S., establishes minimum and uniform requirements for statewide medical examiner services. The Act created the Medical Examiners Commission (Commission) which is composed of seven persons appointed by the Governor, the Attorney General and the State Surgeon General. The Commission is responsible for establishing, by rule, minimum and uniform standards of excellence, performance of duties, and maintenance of records requirements for medical examiners.[1] The Commission is additionally responsible for the creation of medical examiner districts throughout the state.[2] There are currently 24 medical examiner districts.[3]

Determination of Cause of Death

Each district medical examiner is responsible for conducting investigations, examinations and autopsies and reporting vital statistics to the Department of Health for their district. Section 382.011, F.S., currently requires that any case of death or fetal death due to causes or conditions listed in s. 406.11, F.S., be referred to the district medical examiner for investigation and determination of the cause of death.

The causes and conditions of death listed in s. 406.11(1), F.S., can be separated into two categories. Section 406.11(1)(a), F.S., sets forth causes and conditions related to the circumstances surrounding the death and requires a determination of the cause when any person dies in the state:

- Of criminal violence;
- By accident;
- By suicide;
- Suddenly, when in apparent good health;
- Unattended by a practicing physician or other recognized practitioner;
- In any prison or penal institution;
- In police custody;
- In any suspicious or unusual circumstance;
- By criminal abortion;
- By poison;
- By disease constituting a threat to public health; or
- By disease, injury, or toxic agent resulting from employment.

Sections 406.11(1)(b) and (c), F.S., relate to transport and disposal of the decedent's remains and require a determination of the cause of death when a dead body is:

- Brought into the state without proper medical certification; or
- To be cremated, dissected, or buried at sea.

[1] Section 406.04, F.S.
[2] Section 406.05, F.S.
[3] A map of the medical examiner districts in Florida is available at http://myfloridamedicalexaminer.com/ (last viewed on November 20, 2015).

Under s. 406.11(1) F.S., the district medical examiner is authorized to perform any such examinations, investigations, and autopsies as he or she deems necessary to determine the cause of death. The complexity of the determination of the cause of death, however, can differ greatly depending on whether the investigation is required pursuant to s. 406.11(1)(a), F.S., or s. 406.11(1)(c), F.S.

A determination pursuant to s. 406.11(1)(a), F.S., requires a comprehensive review to determine the cause of a death that occurred under unusual circumstances.[4] Physical inspection of the decedent's remains is typically required.[5] As such, a district medical examiner usually performs autopsies or other necessary physical examinations.[6] A district medical examiner also typically requests and reviews any pertinent documentation related to the person's death.[7]

When a death occurs under ordinary circumstances, the district medical examiner does not perform an autopsy or investigation.[8] The disposition of the remains occurs and no further issues arise. On occasion, issues arise after disposition which raise the question of whether a death actually occurred under ordinary circumstances. In these situations the body is exhumed and the district medical examiner performs a determination of cause of death. This examination cannot occur if the body has been cremated, dissected or buried at sea. Thus, s. 406.11(1)(c), F.S., requires the medical examiner to make a determination of cause of death in situations where there is an irretrievable disposal of the remains.

Determinations of the cause of death performed pursuant to s. 406.11(1)(c), F.S., are generally administrative in nature.[9] The process begins with the funeral director completing the death certificate and forwarding it to the decedent's attending or primary physician for signature.[10] Once the funeral director receives the signed death certificate, he or she forwards it to the district medical examiner for review. Unless the medical examiner identifies an issue on the face of the death certificate, he or she grants approval and the funeral director may proceed with the disposal of the remains.[11] The medical examiner may conduct a more thorough investigation if he or she identifies an issue on the face of the death certificate.[12] For example, if a secondary cause of death is a fractured hip, the medical examiner may request additional information to ensure that it was not related to abuse or neglect. Even in that situation, the investigation is generally less comprehensive than the investigation performed under s. 406.11(1)(a), F.S.

Prior to 2012, the approval process for a death certificate was a slow and arduous paper process.[13] It required the manual entry and the transmittal of information through numerous offices within county and state departments.[14] However, in 2012, Florida's Department of Health automated the process through the Electronic Death Registration System. The electronic transmittal of the information has made the approval process more efficient by reducing reporting time and allows for more timely issuances of death certificates.[15] In 2014, county health departments issued 1,267,336 certified death certificates for which $13,005,798 in fees were collected.[16]

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[4] In 2014, 187,944 death certificates were issued. Medical examiners investigation into these deaths consisted of 9,809 autopsies, 5,320 body inspections and 3,291 investigations (body was not viewed). *2014 Annual Report*, Medical Examiners Commission, August 2015.
[5] *Practice Guidelines for Florida Medical Examiners*, Florida Association of Medical Examiners, 2010.
[6] Id.
[7] Id.
[8] Id.
[9] Id.
[10] Section 382.008, F.S. In 2014, there were 187,944 death certificates issued of which 165,419 were issued by physicians. Correspondence from the Florida Department of Health to Florida House of Representatives Health Quality Subcommittee, dated October 21, 2015 (on file with the Health Quality Subcommittee).
[11] *Supra* footnote 5.
[12] Id.
[13] *Electronic Death Registration*, Florida Department of Health. http://www.floridahealth.gov/%5C/certificates/certificates/EDRS/index.html (last viewed on November 20, 2015).
[14] Id.
[15] Id.
[16] Death Sales Chart provided by the Department of Health on file with the House of Representatives Health Quality Subcommittee.

Medical Examiner User Fees

Pursuant to s. 406.06(3), F.S., district medical examiners and associate medical examiners are entitled to compensation and such reasonable salary and fees as are established by the board of county commissioners. There are currently 24 medical examiner districts but only 22 medical examiner offices, 19 of which have determined that this provision authorizes the collection of a user fee. The user fee is for the approval of a cremation, dissection, or burial at sea of a decedent's body as required by s. 406.11(1)(c), F.S. The user fees range from no charge in 24 counties to $63 per approval in Miami-Dade County. There are only two districts, District 11 and District 17 which charge more than $50 for the approval fee ($54 and $63 respectively).[17] The estimated revenue from these fees in 2014 was approximately $3.98 million.[18]

Effect of Proposed Changes

Pursuant to s. 406.06(3), F.S., district medical examiners and associate medical examiners are entitled to compensation and such reasonable salary and fees as are established by the board of county commissioners. A number of counties have interpreted this provision as authority for their board of county commissioners to authorize their district medical examiner to collect a user fee for a determination of cause of death performed when a body is to be cremated, dissected, or buried at sea pursuant to s. 406.11(1)(c), F.S. The bill amends s. 382.011, F.S., to prohibit a medical examiner from charging such user fees. However, the bill provides an exception to this prohibition in circumstances when:

- The county, by resolution or ordinance of the board of county commissioners, has approved charging a medical examiner approval fee;
- The fee does not exceed $50;
- The body is to be cremated, buried at sea or dissected; and
- The death does not involve the circumstances listed in s. 406.11(1)(a).

Section 382.011, F.S., requires any case in which a death or fetal death resulted from the causes or conditions listed in s. 406.11, F.S., to be referred to the district medical examiner for the determination of the cause of death. The bill corrects a citation in s. 382.011, F.S., to clarify that only deaths and fetal deaths involving circumstances set forth in subsection (1) of s. 406.11, F.S., are required to be referred to the district medical examiner for the determination of the cause of death. The remaining provisions in s. 406.11, F.S., are not related to causes or conditions of death upon which a medical examiner can make a determination. Instead, the remaining provisions:

- Grant medical examiners discretion to perform autopsies and other laboratory examinations necessary to determine the cause of death;
- Require the Commission to adopt rules to require a medical examiner to notify the decedent's next of kin of a medical examiner investigation;
- Prohibit a medical examiner from retaining or furnishing a body part of the deceased for research or other purposes without approval by the next of kin; and
- Provide rulemaking authority for the Commission.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 382.011, F.S., relating to medical examiner determination of cause of death.
Section 2: Provides an effective date of October 1, 2016.

[17] 2016 FDLE Legislative Bill Analysis for HB 315 dated October 7, 2015 (on file with the Florida House of Representatives Health Quality Subcommittee).
[18] Id.

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:

   Currently 19 of the 24 medical examiner districts, which represents 42 counties, charge user fees for any determination of the cause of death performed pursuant to s. 406.11(1)(c), F.S. The user fees vary from district to district. Assuming medical examiners charged a user fee for every death that occurred within their medical examiner districts in 2014, the medical examiners charges would have totaled approximately $3.98 million.[19] The bill amends s. 382.011, F.S., to prohibit a medical examiner from charging such user fees. However, the bill provides an exception to this prohibition which allows counties to enact an ordinance or resolution authorizing medical examiners to charge an approval fee of up to $50 when a determination of death is made for a body being cremated, buried at sea or dissected and the death is not related to circumstances set forth in s. 406.11(1)(a), F.S.

2. Expenditures:

   Indeterminate. The actual cost to the counties is unclear as there is a broad discrepancy in the user fees currently charged (fees range from no charge to $63 per approval), and there does not seem to be a correlation between the fees charged to services being provided by the medical examiner.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Because the bill prohibits medical examiners and counties from charging user fees, and only allows approval fees under certain limited circumstances, the private sector may achieve some cost-savings. However, consumers in counties which are not currently charging a user fee would experience a negative fiscal impact should any of those counties adopt an ordinance or resolution authorizing such fees to be collected.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not applicable. The bill does not appear to require counties or municipalities to spend funds or take action requiring the expenditures of funds; reduce the authority that counties or municipalities have

[19] *Supra* footnote 17.

to raise revenues in the aggregate; or reduce the percentage of state tax shared with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to medical examiners; amending s. 382.011, F.S.; providing that a member of the public may not be charged for certain examinations, investigations, or autopsies; authorizing a county to charge a medical examiner approval fee under certain circumstances; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (1) of section 382.011, Florida Statutes, is amended to read:

382.011 Medical examiner determination of cause of death.—

(1) In the case of any death or fetal death involving the circumstances ~~due to causes or conditions~~ listed in s. 406.11(1) ~~406.11~~, any death that occurred more than 12 months after the decedent was last treated by a primary or attending physician as defined in s. 382.008(3), or any death for which there is reason to believe that the death may have been due to an unlawful act or neglect, the funeral director or other person to whose attention the death may come shall refer the case to the district medical examiner of the county in which the death occurred or the body was found for investigation and determination of the cause of death. A county or district medical examiner may not charge a member of the public a fee for an examination, investigation, or autopsy performed to determine

the cause of death involving the circumstances listed in s. 406.11(1). However, a county, by resolution or ordinance of the board of county commissioners, may charge a medical examiner approval fee not to exceed $50 when a body is to be cremated, buried at sea, or dissected, provided the fee is not charged for a death under the jurisdiction of the medical examiner when such death involves the circumstances listed in s. 406.11(1)(a).

Section 2. This act shall take effect October 1, 2016.

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 315 (2016)

Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION	
ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Health Quality Subcommittee

Representative Roberson, K. offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Subsection (1) of section 382.011, Florida Statutes, is amended to read:

382.011 Medical examiner determination of cause of death.—

(1) In the case of any death or fetal death involving the circumstances ~~due to causes or conditions~~ listed in s. 406.11(1) ~~406.11~~, any death that occurred more than 12 months after the decedent was last treated by a primary or attending physician as defined in s. 382.008(3), or any death for which there is reason to believe that the death may have been due to an unlawful act or neglect, the funeral director or other person to whose

attention the death may come shall refer the case to the district medical examiner of the county in which the death.

Section 2. Subsection (3) of section 406.06, Florida Statutes, is amended to read:

406.06 District medical examiners; associates; suspension of medical examiners.—

(3) District medical examiners and associate medical examiners shall be entitled to compensation and such reasonable salary and fees as are established by the board of county commissioners in the respective districts. However, a medical examiner or a county may not charge a member of the public a fee for an examination, investigation, or autopsy performed pursuant to s. 406.11.

Section 3. This act shall take effect July 1, 2016.

T I T L E A M E N D M E N T

Remove everything before the enacting clause and insert: An act relating to medical examiners; amending s. 382.011, F.S.; clarifying the circumstances under which a case must be referred to the district medical examiner for the determination of cause of death; amending s. 406.06, F.S.; prohibiting fees for specified services; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 423 Drug Prescription by Advanced Registered Nurse Practitioners & Physician Assistants
SPONSOR(S): Pigman and others
TIED BILLS: **IDEN./SIM. BILLS:**

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

SUMMARY ANALYSIS

Unlike all other states in the U.S., Florida does not allow advanced registered nurse practitioners (ARNPs) to prescribe controlled substances and is one of two states that does not allow physician assistants (PAs) to prescribe controlled substances.

The bill authorizes ARNPs to prescribe, dispense, order, and administer controlled substances, but only to the extent authorized under a supervising physician's protocol. The bill also authorizes PAs to prescribe controlled substances that are not listed on the formulary established by the Council on Physician Assistants, under current supervisory standards. The bill subjects ARNPs and PAs to administrative disciplinary actions, such as fines or license suspensions, for violating standards of practice in law relating to prescribing and dispensing controlled substances. The bill adds specific prohibited acts related to the prescribing of controlled substances, which constitute grounds for denial of license or disciplinary action, into the Nurse Practice Act.

The bill requires ARNPs and PAs who prescribe controlled substances for the treatment of chronic nonmalignant pain to meet certain registration and prescribing requirements, but prevents ARNPs and PAs from prescribing controlled substances in registered pain management clinics.

The bill adds ARNPs and PAs into the definition of "practitioner" in the Florida Comprehensive Drug Abuse Prevention and Control Act (Act) requiring compliance with the prescribing and dispensing requirements and limitations under the Act.

The bill makes several technical and conforming changes throughout and amends several statutes to recognize that an ARNP or a PA may be a prescriber of controlled substances. These include statutes relating to pilot licensure, criminal probation, and the state employees' prescription drug program.

The bill may 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

Physician Assistants

Licensure and Regulation

A physician assistant (PA) is a person who has completed an approved medical training program and is licensed to perform medical services, as delegated by a supervising physician.[1] The licensure of PAs in Florida is governed by ss. 458.347(7) and 459.022(7), F.S. The Department of Health (DOH) licenses PAs, and the Florida Council on Physician Assistants (Council) regulates the practice of PAs in conjunction with either the Florida Board of Medicine (Board of Medicine) for PAs licensed under ch. 458, F.S., or the Board of Osteopathic Medicine (Osteopathic Board) for PAs licensed under ch. 459, F.S. There are currently 7,987 PAs who hold active licenses in Florida.[2]

To be licensed as a PA in Florida, an applicant must demonstrate to the Council that he or she has met the following requirements:

- Satisfactory passage of the proficiency examination administered by the National Commission on Certification of Physician Assistants;
- Completion of an application and remittance of the applicable fees to the DOH; [3]
- Completion of an approved PA training program;
- Submission of a sworn statement of any prior felony convictions;
- Submission of a sworn statement of any revocation or denial of licensure or certification in any state;
- Submission of two letters of recommendation; and
- If the applicant is seeking prescribing authority, a submission of a copy of course transcripts and the course description from a PA training program describing the course content in pharmacotherapy.[4]

Licenses are renewed biennially.[5] At the time of renewal, a PA must demonstrate that he or she has met the continuing medical education requirements of 100 hours and must submit a sworn statement that he or she has not been convicted of any felony in the previous two years.[6] If a PA is licensed as a prescribing PA, an additional 10 hours of continuing medical education in the specialty areas of his or her supervising physician must be completed.[7]

Supervision of PAs

A PA may only practice under the delegated authority of a supervising physician. A supervising physician may only delegate tasks and procedures to the PA that are within the supervising physician's

[1] Sections 458.347(2)(e) and 459.022(2)(e), F.S.
[2] Email correspondence with the Department of Health on November 9, 2015. The number of active-licensed PAs include both in-state and out-of-state licensees, as of November 9, 2015.
[3] The application fee is $100 and the initial license fee is $200. Applicants must also pay an unlicensed activity fee of $5. *See* Rules 64B8-30.019 and 64B15-6.013, F.A.C.
[4] Sections 458.347(7) and 459.022(7), F.S.
[5] For timely renewed licenses, the renewal fee is $275 and the prescribing registration fee is $150. Additionally, at the time of renewal, the PA must pay an unlicensed activity fee of $5. *See* Rules 64B8-30.019 and 64B15-6.013, F.A.C.
[6] Sections 458.347(7)(c)-(d) and 459.022(7)(c)-(d), F.S.
[7] Rules 64B8-30.005(6) and 64B15-6.0035(6), F.A.C.

scope of practice.[8] Supervision is defined as responsible supervision and control that requires the easy availability or physical presence of the licensed physician for consultation and direction of the PA.[9] A physician may not supervise more than four PAs at any time.[10]

The Board of Medicine and the Osteopathic Board have prescribed by rule what constitutes adequate responsible supervision. Responsible supervision is the ability of a supervising physician to reasonably exercise control and provide direction over the services or tasks performed by the PA.[11] Whether the supervision of the PA is adequate is dependent on the:

- Complexity of the task;
- Risk to the patient;
- Background, training, and skill of the PA;
- Adequacy of the direction in terms of its form;
- Setting in which the tasks are performed;
- Availability of the supervising physician;
- Necessity for immediate attention; and
- Number of other persons that the supervising physician must supervise.[12]

The decision to permit a PA to perform a task or procedure under direct or indirect supervision is made by the supervising physician based on reasonable medical judgment regarding the probability of morbidity and mortality to the patient.[13] Direct supervision refers to the physical presence of the supervising physician so that the physician is immediately available to the PA when needed.[14] Indirect supervision refers to the reasonable physical proximity of the supervising physician to the PA or availability by telecommunication.[15]

Delegable Tasks

Rules of both the Board of Medicine and the Osteopathic Board place limitations on a supervising physicians ability to delegate certain tasks. The following tasks are not permitted to be delegated to a PA, except when specifically authorized by statute:

- Prescribing, dispensing, or compounding medicinal drugs; and
- Final diagnosis.[16]

A supervising physician may delegate authority to a PA the authority to:

- Prescribe or dispense any medicinal drug used in the supervising physician's practice;[17]
- Order medicinal drugs for a hospitalized patient of the supervising physician;[18] and
- Administer a medicinal drug under the direction and supervision of the physician.

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[8] Rules 64B8-30.012(1) and 64B15-6.010(1), F.A.C. The term "scope of practice" refers to those tasks and procedures that the supervising physician is qualified by training or experience to support.
[9] Sections 458.347(2)(f) and 459.022(2)(f), F.S.
[10] Sections 458.347(3) and 459.022(3), F.S.
[11] Rules 64B8-30.001(3) and 64B15-6.001(3), F.A.C.
[12] *Id.*
[13] Rules 64B8-30.012(2) and 64B15-6.010(2), F.A.C.
[14] Rules 64B8-30.001(4) and 64B15-6.001(4), F.A.C.
[15] Rules 64B8-30.001(5) and 64B15-6.001(5), F.A.C.
[16] *Supra* note 12.
[17] Sections 458.347(4)(f)1., F.S., and 459.022(4)(e), F.S., directs the Council to establish a formulary listing the medical drugs that a PA may not prescribe. The formulary in Rules 64B8-30.008 and 64B15-6.0038, F.A.C., prohibits PAs from prescribing controlled substances, as defined in Chapter 893, F.S., general, spinal, or epidural anesthetics, and radiographic contrast materials.
[18] Sections 458.347(4)(g), and 459.022(4)(f), F.S., provides that an order is not a prescription.

Currently, PAs are prohibited from prescribing controlled substances, anesthetics, and radiographic contrast materials.[19] However, physicians may delegate the authority to order controlled substances in facilities licensed under ch. 395, F.S.[20]

Education of PAs

According to the American Academy of Physician Assistants, all accredited PA educational programs include pharmacology courses, and the average amount of formal classroom instruction in pharmacology is 75 hours.[21] Course topics, include pharmacokintetics, drug interactions, adverse effects, contraindications, indications, and dosage, generally by doctoral-level pharmacologists or clinical pharmacists.[22] Additionally, pharmacology education occurs on all clinical clerkships or rotations.[23]

Regulation of Advanced Registered Nurse Practitioners

Part I of ch. 464, F.S. (Nurse Practice Act), governs the licensure and regulation of advanced registered nurse practitioners (ARNPs) in Florida. Nurses are licensed by the DOH and are regulated by the Board of Nursing.[24] There are 22,003 actively licensed ARNPs in Florida.[25]

In Florida, an ARNP is a licensed nurse who is certified in advanced or specialized nursing practice and may practice as a certified registered nurse anesthetist, a certified nurse midwife, or a nurse practitioner.[26] Section 464.003(2), F.S., defines "advanced or specialized nursing practice" to include the performance of advanced-level nursing acts approved by the Board of Nursing, which by virtue of postbasic specialized education, training, and experience are appropriately performed by an ARNP.[27]

Florida recognizes three types of ARNPs: nurse anesthetist, certified nurse midwife, and nurse practitioner. The Board of Nursing, created by s. 464.004, F.S., establishes the eligibility criteria for an applicant to be certified as an ARNP and the applicable regulatory standards for ARNP nursing practices.[28] To be certified as an ARNP, the applicant must:

- Have a registered nurse license;
- Have earned, at least, a master's degree; and
- Submit proof to the Board of Nursing of holding a current national advanced practice certification obtained from a board-approved nursing specialty board.[29]

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[19] Rules 64B8-30.008, F.A.C., and 64B15-6.0038, F.A.C.
[20] Sections 458.347(4)(g), F.S., and 459.022(4)(f), F.S.; the facilities licensed in ch. 395, F.S., include hospitals, ambulatory surgical centers, and mobile surgical facilities.
[21] American Academy of Physician Assistants, *PAs as Prescribers of Controlled Medications*, Professional Issues – Issue Brief (Dec. 2013), *available at* https://www.aapa.org/workarea/downloadasset.aspx?id=2549 (last visited Nov. 19, 2015).
[22] *Id.*
[23] *Id.*
[24] Pursuant to s. 464.004, F.S., the Board of Nursing is comprised of 13 members appointed by the Governor and confirmed by the Senate who serve 4-year terms. The Board is comprised of three licensed practical nurses who have practiced for at least four years, seven members who are registered numbers who have practiced for at least 4 years; three Florida residents who have never been licensed as nurses, are not connected to the practice of nursing, and have no financial interest in any health care facility, agency, or insurer; and seven members who are registered nurses who have practiced at least four years. Among the seven members who are registered nurses, there must be at least one must be an ARNP, one nurse educator of an approved program, and one nurse executive.
[25] E-mail correspondence with the Department of Health (Nov. 9, 2015) (on file with committee staff). This number includes all active licenses, including out of state practitioners.
[26] Section 464.003(3), F.S.
[27] Section 464.003(2), F.S.
[28] Section 464.012(2), F.S.
[29] Section 464.012(1), F.S., and Rule 64B9-4.002, F.A.C. A nursing specialty board must attest to the competency of nurses in a clinical specialty area, require nurses to take a written examination prior to certification, require nurses to complete a formal program prior to eligibility of examination, maintain program accreditation, and identify standards or scope of practice statements appropriate for each nursing specialty.

All ARNPs must carry malpractice insurance or demonstrate proof of financial responsibility.[30] An applicant for certification is required to submit proof of coverage or financial responsibility within sixty days of certification and with each biennial renewal.[31] An ARNP must have professional liability coverage of at least $100,000 per claim with a minimum annual aggregate of at least $300,000, or an unexpired irrevocable letter of credit, which is payable to the ARNP as beneficiary, in the amount of at least $100,000 per claim with a minimum aggregate availability of at least $300,000.[32]

Supervision of ARNPs

Pursuant to s. 464.012(3), F.S., ARNPs may only perform nursing practices delineated in an established protocol filed with the Board of Nursing that is filed within 30 days of entering into a supervisory relationship with a physician and upon biennial license renewal.[33] Florida law allows a primary care physician to supervise ARNPs in up to four offices, in addition to the physician's primary practice location.[34] If the physician provides specialty health care services, then only two medical offices, in addition to the physician's primary practice location, may be supervised.

The supervision limitations do not apply in the following facilities:

- Hospitals;
- Colleges of medicine or nursing;
- Nonprofit family-planning clinics;
- Rural and federally qualified health centers;
- Nursing homes;
- Assisted living facilities;
- Student health care centers or school health clinics; and
- Other government facilities.[35]

To ensure appropriate medical care, the number of ARNPs a supervising physician may supervise is limited based on consideration of the following factors:

- Risk to the patient;
- Educational preparation, specialty, and experience in relation to the supervising physician's protocol;
- Complexity and risk of the procedures;
- Practice setting; and
- Availability of the supervising physician or dentist.[36]

Delegable Tasks

Within the framework of a written physician protocol, an ARNP may:

- Monitor and alter drug therapies;
- Initiate appropriate therapies for certain conditions;
- Order diagnostic tests and physical and occupational therapy;
- Perform certain acts within his or her specialty;
- Perform medical acts authorized by a joint committee; and

[30] Section 456.048, F.S.
[31] Rule 64B9-4.002(5), F.A.C.
[32] *Id.*
[33] Physicians are also required to provide notice of the written protocol and the supervisory relationship to the Board of Medicine or Board of Osteopathic Medicine, respectively. *See* ss. 458.348 and 459.025, F.S.
[34] Sections 458.348(4) and 459.025(3), F.S.
[35] Sections 458.348(4)(e), and 459.025(3)(e), F.S.
[36] Rule 64B9-4.010, F.A.C.

- Perform additional functions determined by rule. [37]

Florida law does not authorize ARNPs to prescribe, independently administer, or dispense controlled substances.[38]

Controlled Substances

Controlled substances are drugs with the potential for abuse. Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act (Act) and classifies controlled substances into five categories, known as schedules.[39] The distinguishing factors between the different drug schedules are the "potential for abuse" of the substance and whether there is a currently accepted medical use for the substance. Schedules are used to regulate the manufacture, distribution, preparation and dispensing of the substances. The Act provides requirements for the prescribing and administering of controlled substances by health care practitioners and proper dispensing by pharmacists and health care practitioners.[40]

Controlled Substance Prescribing for Nonmalignant Pain in Florida

As of January 1, 2012, every physician, podiatrist, or dentist, who prescribes controlled substances in the state for the treatment of chronic nonmalignant pain,[41] must register as a controlled substance prescribing practitioner and comply with certain practice standards specified in statute and rule.[42] Before prescribing controlled substances for the treatment of chronic nonmalignant pain, a practitioner must:

- Document certain characteristics about the nature of the patient's pain, success of past treatments, and a history of alcohol and substance abuse;
- Develop a written plan for assessing the patient's risk for aberrant drug-related behavior and monitor such behavior throughout the course of controlled substance treatment;
- Develop an written individualized treatment plan for each patient stating the objectives that will be used to determine treatment success; and
- Enter into a controlled substance agreement with each patient that must be signed by the patient or their legal representative and by the prescribing practitioner. Such agreements must include:
    - The number and frequency of prescriptions and refills;
    - A statement outlining expectations for patience compliance and reasons for which the drug therapy may be discontinued, such as violation of the agreement; and
    - An agreement that the patient's chronic nonmalignant pain only be treated by a single treating practitioner unless otherwise authorized and documented in the medical record.[43]

Patients being treated with controlled substances for chronic nonmalignant pain must be seen by their prescribing practitioners at least once every three months to monitor progress and compliance, and detailed medical records relating to such treatment must be maintained.[44] Patients at special risk for drug abuse or diversion may require consultation with or a referral to an addiction medicine physician or

[37] Section 464.012(3), F.S. Pursuant to s. 464.012(4), F.S., certified registered nurse anesthetists, certified nurse midwives, and certified nurse practitioners are authorized to perform additional acts that are within their specialty and authorized under an established supervisory protocol.
[38] Sections 893.02(21) and 893.05(1), F.S. The definition of practitioner does not include ARNPs.
[39] *See* s. 893.03, F.S.
[40] Sections 893.04 and 893.05, F.S.
[41] "Chronic nonmalignant pain" is defined as pain unrelated to cancer which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery. Section 456.44(1)(e), F.S.
[42] Chapter 2011-141, s. 3, Laws of Fla. (creating ss. 456.44, F.S., effective July 1, 2011).
[43] Section 465.44(3), F.S.
[44] Section 465.44(3)(d), F.S.

a psychiatrist.[45] Anyone with signs or symptoms of substance abuse must be immediately referred to a pain-management physician, an addiction medicine specialist, or an addiction medicine facility.[46]

Drug Enforcement Administration

The Drug Enforcement Administration (DEA), housed within the U.S. Department of Justice, enforces the controlled substances laws and regulations of the United States, including preventing and investigating the diversion of controlled pharmaceuticals.[47]

Any health care professional wishing to prescribe controlled substances must apply for a registration number from the DEA. Registration numbers are linked to state licenses and may be suspended or revoked upon any disciplinary action taken against a licensee.[48] The DEA will grant registration numbers to a wide range of health care professionals, including physicians, nurse practitioners, physician assistants, optometrists, dentists, and veterinarians, but such professionals may only prescribe controlled substances as authorized under state law.[49] The DEA provides that a controlled substance prescription may only be issued by a registered practitioner who is:

- Authorized to prescribe controlled substances by the jurisdiction in which the practitioner is licensed to practice; and
- Registered with the DEA, or exempt from registration (e.g., Public Health Service, Federal Bureau of Prisons, or military practitioners); or
- An qualified agent or employee of a hospital or other institution acting in the normal course of business or employment under the DEA registration number of the hospital or other institution which is registered in lieu of the individual practitioner being registered.[50]

The DEA's Practitioner Manual includes requirements for valid prescriptions. The DEA defines "prescription" as an order for medication which is dispensed to or for an ultimate user, but is not an order for a medication dispensed for immediate administration to the user, such as an order to dispense a drug to a patient in a hospital setting.[51]

Other States' Controlled Substance Prescriptive Authority for ARNPs and PAs

ARNPs

An ARNP's ability to prescribe, dispense, or administer controlled substances is dependent on his or her specific state's law. Forty-nine states authorize ARNPs to prescribe controlled substances.[52] Twenty-one states and the District of Columbia allow an ARNP to practice independently, including evaluating, diagnosing, ordering, and interpreting diagnostic tests, and managing treatment, including prescribing medications, of a patient without physician supervision.[53] Twenty-two states specifically prohibit certified registered nurse anesthetists from prescribing controlled substances.[54]

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[45] Section 465.44(3)(e), F.S.
[46] Section 456.44(3)(g), F.S.
[47] Drug Enforcement Administration, *About Us*, *available at* http://www.deadiversion.usdoj.gov/Inside.html (last visited Nov. 15, 2015).
[48] Registration numbers must be renewed every three years. Drug Enforcement Administration, *Practitioners Manual*, 7(2006), *available at* http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf (last visited Nov.19, 2015).
[49] *Id.* at 7.
[50] DEA, *Practitioner Manual*, 18.
[51] *Id.*
[52] Drug Enforcement Agency, *Mid-Level Practitioners Authorization by State* (Nov. 10, 2015), *available at* http://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf (last visited Nov. 19, 2015). The Commonwealth of Puerto Rico also prohibits ARNPs from prescribing controlled substances.
[53] Alaska, Arizona, Colorado, Connecticut, Hawaii, Idaho, Iowa, Maine, Maryland, Minnesota, Montana, Nebraska, Nevada, New Hampshire, New Mexico, North Dakota, Oregon, Rhode Island, Vermont, Washington, and Wyoming allow for independent practice. *See* American Association of Nurse Practitioners, *State Practice Environment*, *available at* https://www.aanp.org/legislation-regulation/state-legislation/state-practice-environment/66-legislation-regulation/state-practice-environment/1380-state-practice-by-type (last visited Nov. 19, 2015).
[54] American Association of Nurse Anesthetists, AANA Journal, June 2011; 79(3):235, on file with committee staff.

Some states have specific limitations regarding ARNPs prescribing authority for schedule II controlled substances,[55] for example, 7 states authorize ARNPs to prescribe all levels of scheduled drugs, except for schedule II. Some states have specific education requirements for those ARNPs who wish to prescribe schedule II substances or require additional registration for ARNPs to be authorized to prescribe.[56]

PAs

A PA's ability to prescribe, dispense, or administer controlled substances is dependent on their specific state's law. Forty-eight states authorize PAs to prescribe controlled substances within an agreement with a supervisory physician, with varying limitations on administration, dispensing, and independent prescribing.[57] Of the 48 states, some have specific restrictions on PAs' prescribing authority for schedule II controlled substances; for example, Texas and Hawaii only authorize PAs to order schedule II controlled substances in an inpatient hospital setting. Some states have medication quantity restrictions on prescriptions for schedule II drugs and some states give PAs' prescriptive authority for all levels of scheduled drugs except for schedule II.[58] Some states also have a formulary determined by the relevant PA licensing board which identifies the controlled substances that PAs are authorized to prescribe.

Effect of Proposed Changes

The bill authorizes PAs licensed under ch. 458, F.S., the Medical Practice Act or under ch. 459, F.S., the Osteopathic Medical Practice Act, and ARNPs certified under part I of ch. 464, F.S., the Nurse Practice Act, to prescribe controlled substances under current supervisory standards for PAs and protocols for ARNPs.

Physician Assistants

The bill authorizes PAs to prescribe controlled substances by removing the requirement that the formulary of medicinal drugs that a PA may not prescribe include controlled substances. However, because the formulary is determined by the Council on Physician Assistants pursuant to s. 458.347(4)(f)1., F.S.,[59] the Council may elect to add controlled substances to the formulary, prohibiting PAs from prescribing them.

The bill subjects PAs to administrative disciplinary actions in s. 456.072, F.S., such as fines or license suspensions for violating standards of practice in law relating to prescribing and dispensing controlled substances.[60]

Advanced Registered Nurse Practitioners

The bill authorizes ARNPs, regulated under s. 464.012(3), F.S., to prescribe, dispense, order, or administer controlled substances, if allowed under a supervising physician's protocol. The bill adds additional acts related to the prescribing of controlled substances into s. 464.018, F.S., which an ARNP is prohibited from performing and which, if performed, constitute grounds for denial of license or disciplinary actions.

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[55] *Supra* note 51.
[56] *Id.*
[57] *Id.* Every state, except Florida and Kentucky, has some form of controlled substance prescriptive authority for PAs.
[58] *Id.*
[59] Section 459.022(4)(e), F.S., of the Osteopathic Medical Practice Act refers to the formulary in the Medical Practice Act.
[60] Disciplinary sanctions against physicians apply to PAs. Sections 458.347(7)(g) and 459.022(7)(g), F.S., state that the Board of Medicine or the Board of Osteopathic Medicine may impose any penalty authorized under ss. 456.072, 458.332(2), and 459.015(2), F.S., on a PA if the PA or the supervising physician has been found guilty of any prohibited acts.

Section 456.072(7), F.S., is revised to include disciplinary actions against ARNPs including specific fines and license suspension, which mirror actions against physicians for prescribing or dispensing a controlled substance other than in the course of professional practice or for failing to meet practice standards.

Controlled Substances

The bill adds PAs and ARNPs to the definition of practitioner in ch. 893, F.S., the Florida Comprehensive Drug Abuse Prevention and Control Act (Act), thus requiring these practitioners to comply with the prescribing and dispensing requirements and limitations under the Act. This definition also requires practitioners to hold a valid federal DEA controlled substance registry number.

The bill amends s. 456.44, F.S., to require a PA or ARNP who prescribes any controlled substance that is listed in schedule II, schedule III, or schedule IV, for the treatment of chronic nonmalignant pain to register himself or herself as a controlled substance prescribing practitioner on his or her practitioner profile maintained by the DOH and to meet other statutory requirements for such registrants.[61] The bill also replaces the terms physician and clinician with registrant throughout this section of law. The bill specifies that this registration is not required to prescribe medication in a facility licensed under ch. 395, F.S.[62]

The bill amends sections regulating pain-management clinics under the Medical Practice Act and the Osteopathic Medical Practice Act to only authorize physicians licensed under ch. 458, F.S., or ch. 459, F.S., to prescribe controlled substances in a pain-management clinic. Accordingly, PAs and ARNPs are prohibited from prescribing controlled substances in pain-management clinics.

The bill makes several conforming changes to various statutes to recognize the new prescribing authority for PAs and ARNPs.

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

B. SECTION DIRECTORY:

Section 1. Amends s. 110.12315, F.S., relating to prescription drug program.
Section 2. Amends s. 310.071, F.S., relating to deputy pilot certification.
Section 3. Amends s. 310.073, F.S., relating to state pilot licensing.
Section 4. Amends s. 310.081, F.S., relating to department examination and licensure of state pilots and certification of deputy pilots; vacancies.
Section 5. Amends s. 456.072, F.S., relating to grounds for discipline; penalties; enforcement.
Section 6. Amends s. 456.44, F.S., relating to controlled substance prescribing.
Section 7. Amends s. 458.3265, F.S., relating to pain-management clinics.
Section 8. Amends s. 458.347, F.S., relating to physician assistants.
Section 9. Amends s. 459.0137, F.S., relating to pain-management clinics.
Section 10. Amends s. 464.012, relating to certification of advanced registered nurse practitioners; fees; controlled substance prescribing.
Section 11. Amends s. 464.018, F.S., relating to disciplinary actions.
Section 12. Amends s. 893.02, F.S., relating to definitions.
Section 13. Amends s. 948.03, F.S., relating to terms and conditions of probation.
Section 14. Reenacts s. 310.071, F.S., relating to deputy pilot certification.
Section 15. Reenacts s. 458.331, F.S., relating to ground for discipline; action by the board and department; s. 458.347, F.S., relating to physician assistants; s. 459.022, F.S., relating to physician assistants; and s. 465.0158, relating to nonresident sterile compounding permit.

[61] Currently, PAs do not have practitioner profiles. Practitioner profiles contain information about a practitioner's education, training, and practice and are accessible to the public. If the bill is enacted, the Department will need to develop a profile for PAs.
[62] The facilities licensed under ch. 395, F.S., include hospitals, ambulatory surgical centers, and mobile surgical facilities.

Section 16. Reenacts s. 456.072, F.S., relating to grounds for discipline; penalties; enforcement and s. 466.02751, F.S., relating to establishment of practitioner profile for designation as a controlled substance prescribing practitioner.
Section 17. Reenacts s. 458.303, F.S., relating to provisions not applicable to other practitioners; exceptions, etc.; s. 458.347, F.S., relating to physician assistants; s. 458.3475, F.S., relating to anesthesiologist assistants; s. 459.022, F.S., relating to physician assistants; and s. 459.023, F.S., relating to relating to anesthesiologist assistants.
Section 18. Reenacts s. 456.041, F.S., relating to practitioner profile; creation; s. 458.348, F.S., relating to formal supervisory relationships, standing orders, and established protocols; notice; standards; and s. 459.025, F.S., relating to relating to formal supervisory relationships, standing orders, and established protocols; notice; standards.
Section 19. Reenacts s. 464.008, F.S., relating to licensure by examination; s. 464.009, F.S., relating to licensure by endorsement; s. 464.018, F.S., relating to disciplinary actions; and s. 464.0205, F.S., relating to retired volunteer nurse certificate.
Section 20. Reenacts s. 775.051, F.S., relating to voluntary intoxication; not a defense; evidence not admissible for certain purposes; exceptions.
Section 21. Reenacts s. 944.17, F.S., relating to commitments and classification; transfers; s. 948.001, F.S., relating to definitions; and s. 948.101, F.S., relating to terms and conditions of community control.
Section 22. 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 rulemaking, the creation of practitioner profiles for PAs, and workload impacts related to potential additional practitioner complaints and investigations.

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 and efficiencies in health care delivery as a result of having their health care needs more fully addressed by the PA or ARNP without specific additional involvement of a physician prescribing a needed controlled substance for treatment. Any such impacts are indeterminate.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The Board of Nursing, Board of Medicine, Board of Osteopathic Medicine, the Department of Health, and the Department of Management Services have sufficient rule-making authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to drug prescription by advanced registered nurse practitioners and physician assistants; amending s. 110.12315, F.S.; expanding the categories of persons who may prescribe brand drugs under the prescription drug program when medically necessary; amending ss. 310.071, 310.073, and 310.081, F.S.; exempting controlled substances prescribed by an advanced registered nurse practitioner or a physician assistant from the disqualifications for certification or licensure, and for continued certification or licensure, as a deputy or state pilot; amending s. 456.072, F.S.; applying existing penalties for violations relating to the prescribing or dispensing of controlled substances to an advanced registered nurse practitioner; amending s. 456.44, F.S.; deleting an obsolete date; requiring advanced registered nurse practitioners and physician assistants who prescribe controlled substances for certain pain to make a certain designation, comply with registration requirements, and follow specified standards of practice; providing applicability; amending ss. 458.3265 and 459.0137, F.S.; limiting the authority to prescribe a controlled substance in a pain-management clinic to a physician licensed under chapter 458 or chapter 459, F.S.; amending s. 458.347, F.S.;

expanding the prescribing authority of a licensed physician assistant; amending s. 464.012, F.S.; authorizing an advanced registered nurse practitioner to prescribe, dispense, administer, or order drugs, rather than to monitor and alter drug therapies; amending s. 464.018, F.S.; specifying acts that constitute grounds for denial of a license for or disciplinary action against an advanced registered nurse practitioner; amending s. 893.02, F.S.; redefining the term "practitioner" to include advanced registered nurse practitioners and physician assistants under the Florida Comprehensive Drug Abuse Prevention and Control Act; amending s. 948.03, F.S.; providing that possession of drugs or narcotics prescribed by an advanced registered nurse practitioner or physician assistant is an exception from a prohibition relating to the possession of drugs or narcotics during probation; reenacting s. 310.071(3), F.S., relating to deputy pilot certification, to incorporate the amendment made by the act to s. 310.071, F.S., in a reference thereto; reenacting ss. 458.331(10), 458.347(7)(g), 459.015(10), 459.022(7)(f), and 465.0158(5)(b), F.S., relating to grounds for disciplinary action against certain licensed health care practitioners or applicants, physician assistant licensure, the

imposition of penalties upon physician assistants by the Board of Osteopathic Medicine, and nonresident sterile compounding permits, respectively, to incorporate the amendment made by the act to s. 456.072, F.S., in references thereto; reenacting ss. 456.072(1)(mm) and 466.02751, F.S., relating to grounds for discipline of certain licensed health care practitioners or applicants and dentist practitioner profiles, respectively, to incorporate the amendment made by the act to s. 456.44, F.S., in references thereto; reenacting ss. 458.303, 458.347(4)(e) and (9)(c), 458.3475(7)(b), 459.022(4)(e) and (9)(c), and 459.023(7)(b), F.S., relating to the nonapplicability of certain provisions to specified health care practitioners, the prescribing or dispensing of medications by physician assistants, the duties of the Council on Physician Assistants, and the duties of the Board of Medicine and the Board of Osteopathic Medicine with respect to anesthesiologist assistants, respectively, to incorporate the amendment made by the act to s. 458.347, F.S., in references thereto; reenacting ss. 456.041(1)(a), 458.348(1) and (2), and 459.025(1), F.S., relating to practitioner profiles and notice and standards for formal supervisory relationships, standing orders, and established protocols, respectively, to incorporate the amendment

made by the act to s. 464.012, F.S., in references thereto; reenacting ss. 464.008(2), 464.009(5), 464.018(2), and 464.0205(1)(b), (3), and (4)(b), F.S., relating to licensure by examination of registered nurses and licensed practical nurses, licensure by endorsement to practice professional or practical nursing, disciplinary actions against nursing applicants or licensees, and retired volunteer nurse certifications, respectively, to incorporate the amendment made by the act to s. 464.018, F.S., in references thereto; reenacting s. 775.051, F.S., relating to the exclusion as a defense and nonadmissibility as evidence of voluntary intoxication, to incorporate the amendment made by the act to s. 893.02, F.S., in a reference thereto; reenacting ss. 944.17(3)(a), 948.001(8), and 948.101(1)(e), F.S., relating to the receipt by the state correctional system of certain persons sentenced to incarceration, the definition of the term "probation," and the terms and conditions of community control, respectively, to incorporate the amendment made by the act to s. 948.03, F.S., in references thereto; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (7) of section 110.12315, Florida Statutes, is amended to read:

110.12315 Prescription drug program.—The state employees' prescription drug program is established. This program shall be administered by the Department of Management Services, according to the terms and conditions of the plan as established by the relevant provisions of the annual General Appropriations Act and implementing legislation, subject to the following conditions:

(7) The department shall establish the reimbursement schedule for prescription pharmaceuticals dispensed under the program. Reimbursement rates for a prescription pharmaceutical must be based on the cost of the generic equivalent drug if a generic equivalent exists, unless the physician, advanced registered nurse practitioner, or physician assistant prescribing the pharmaceutical clearly states on the prescription that the brand name drug is medically necessary or that the drug product is included on the formulary of drug products that may not be interchanged as provided in chapter 465, in which case reimbursement must be based on the cost of the brand name drug as specified in the reimbursement schedule adopted by the department.

Section 2. Paragraph (c) of subsection (1) of section 310.071, Florida Statutes, is amended to read:

310.071 Deputy pilot certification.—

(1) In addition to meeting other requirements specified in this chapter, each applicant for certification as a deputy pilot

must:

(c) Be in good physical and mental health, as evidenced by documentary proof of having satisfactorily passed a complete physical examination administered by a licensed physician within the preceding 6 months. The board shall adopt rules to establish requirements for passing the physical examination, which rules shall establish minimum standards for the physical or mental capabilities necessary to carry out the professional duties of a certificated deputy pilot. Such standards shall include zero tolerance for any controlled substance regulated under chapter 893 unless that individual is under the care of a physician, advanced registered nurse practitioner, or physician assistant and that controlled substance was prescribed by that physician, advanced registered nurse practitioner, or physician assistant. To maintain eligibility as a certificated deputy pilot, each certificated deputy pilot must annually provide documentary proof of having satisfactorily passed a complete physical examination administered by a licensed physician. The physician must know the minimum standards and certify that the certificateholder satisfactorily meets the standards. The standards for certificateholders shall include a drug test.

Section 3. Subsection (3) of section 310.073, Florida Statutes, is amended to read:

310.073 State pilot licensing.—In addition to meeting other requirements specified in this chapter, each applicant for license as a state pilot must:

(3) Be in good physical and mental health, as evidenced by documentary proof of having satisfactorily passed a complete physical examination administered by a licensed physician within the preceding 6 months. The board shall adopt rules to establish requirements for passing the physical examination, which rules shall establish minimum standards for the physical or mental capabilities necessary to carry out the professional duties of a licensed state pilot. Such standards shall include zero tolerance for any controlled substance regulated under chapter 893 unless that individual is under the care of a physician, advanced registered nurse practitioner, or physician assistant and that controlled substance was prescribed by that physician, advanced registered nurse practitioner, or physician assistant. To maintain eligibility as a licensed state pilot, each licensed state pilot must annually provide documentary proof of having satisfactorily passed a complete physical examination administered by a licensed physician. The physician must know the minimum standards and certify that the licensee satisfactorily meets the standards. The standards for licensees shall include a drug test.

Section 4. Paragraph (b) of subsection (3) of section 310.081, Florida Statutes, is amended to read:

310.081 Department to examine and license state pilots and certificate deputy pilots; vacancies.—

(3) Pilots shall hold their licenses or certificates pursuant to the requirements of this chapter so long as they:

(b) Are in good physical and mental health as evidenced by documentary proof of having satisfactorily passed a physical examination administered by a licensed physician or physician assistant within each calendar year. The board shall adopt rules to establish requirements for passing the physical examination, which rules shall establish minimum standards for the physical or mental capabilities necessary to carry out the professional duties of a licensed state pilot or a certificated deputy pilot. Such standards shall include zero tolerance for any controlled substance regulated under chapter 893 unless that individual is under the care of a physician, advanced registered nurse practitioner, or physician assistant and that controlled substance was prescribed by that physician, advanced registered nurse practitioner, or physician assistant. To maintain eligibility as a certificated deputy pilot or licensed state pilot, each certificated deputy pilot or licensed state pilot must annually provide documentary proof of having satisfactorily passed a complete physical examination administered by a licensed physician. The physician must know the minimum standards and certify that the certificateholder or licensee satisfactorily meets the standards. The standards for certificateholders and for licensees shall include a drug test.

Upon resignation or in the case of disability permanently affecting a pilot's ability to serve, the state license or certificate issued under this chapter shall be revoked by the

department.

Section 5. Subsection (7) of section 456.072, Florida Statutes, is amended to read:

456.072 Grounds for discipline; penalties; enforcement.—

(7) Notwithstanding subsection (2), upon a finding that a physician has prescribed or dispensed a controlled substance, or caused a controlled substance to be prescribed or dispensed, in a manner that violates the standard of practice set forth in s. 458.331(1)(q) or (t), s. 459.015(1)(t) or (x), s. 461.013(1)(o) or (s), or s. 466.028(1)(p) or (x), or that an advanced registered nurse practitioner has prescribed or dispensed a controlled substance, or caused a controlled substance to be prescribed or dispensed, in a manner that violates the standard of practice set forth in s. 464.018(1)(n) or (p)6., the physician or advanced registered nurse practitioner shall be suspended for a period of not less than 6 months and pay a fine of not less than $10,000 per count. Repeated violations shall result in increased penalties.

Section 6. Subsections (2) and (3) of section 456.44, Florida Statutes, are amended to read:

456.44 Controlled substance prescribing.—

(2) REGISTRATION. ~~Effective January 1, 2012,~~ A physician licensed under chapter 458, chapter 459, chapter 461, or chapter 466, a physician assistant licensed under chapter 458 or chapter 459, or an advanced registered nurse practitioner certified under part I of chapter 464 who prescribes any controlled

substance, listed in Schedule II, Schedule III, or Schedule IV as defined in s. 893.03, for the treatment of chronic nonmalignant pain, must:

(a) Designate himself or herself as a controlled substance prescribing practitioner on his or her ~~the physician's~~ practitioner profile.

(b) Comply with the requirements of this section and applicable board rules.

(3) STANDARDS OF PRACTICE.—The standards of practice in this section do not supersede the level of care, skill, and treatment recognized in general law related to health care licensure.

(a) A complete medical history and a physical examination must be conducted before beginning any treatment and must be documented in the medical record. The exact components of the physical examination shall be left to the judgment of the registrant ~~clinician~~ who is expected to perform a physical examination proportionate to the diagnosis that justifies a treatment. The medical record must, at a minimum, document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, a review of previous medical records, previous diagnostic studies, and history of alcohol and substance abuse. The medical record shall also document the presence of one or more recognized medical indications for the use of a controlled substance. Each

registrant must develop a written plan for assessing each patient's risk of aberrant drug-related behavior, which may include patient drug testing. Registrants must assess each patient's risk for aberrant drug-related behavior and monitor that risk on an ongoing basis in accordance with the plan.

(b) Each registrant must develop a written individualized treatment plan for each patient. The treatment plan shall state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and shall indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the registrant ~~physician~~ shall adjust drug therapy to the individual medical needs of each patient. Other treatment modalities, including a rehabilitation program, shall be considered depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment. The interdisciplinary nature of the treatment plan shall be documented.

(c) The registrant ~~physician~~ shall discuss the risks and benefits of the use of controlled substances, including the risks of abuse and addiction, as well as physical dependence and its consequences, with the patient, persons designated by the patient, or the patient's surrogate or guardian if the patient is incompetent. The registrant ~~physician~~ shall use a written controlled substance agreement between the registrant ~~physician~~ and the patient outlining the patient's responsibilities,

including, but not limited to:

1. Number and frequency of controlled substance prescriptions and refills.

2. Patient compliance and reasons for which drug therapy may be discontinued, such as a violation of the agreement.

3. An agreement that controlled substances for the treatment of chronic nonmalignant pain shall be prescribed by a single treating registrant ~~physician~~ unless otherwise authorized by the treating registrant ~~physician~~ and documented in the medical record.

(d) The patient shall be seen by the registrant ~~physician~~ at regular intervals, not to exceed 3 months, to assess the efficacy of treatment, ensure that controlled substance therapy remains indicated, evaluate the patient's progress toward treatment objectives, consider adverse drug effects, and review the etiology of the pain. Continuation or modification of therapy shall depend on the registrant's ~~physician's~~ evaluation of the patient's progress. If treatment goals are not being achieved, despite medication adjustments, the registrant ~~physician~~ shall reevaluate the appropriateness of continued treatment. The registrant ~~physician~~ shall monitor patient compliance in medication usage, related treatment plans, controlled substance agreements, and indications of substance abuse or diversion at a minimum of 3-month intervals.

(e) The registrant ~~physician~~ shall refer the patient as necessary for additional evaluation and treatment in order to

achieve treatment objectives. Special attention shall be given to those patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation and requires consultation with or referral to an addiction medicine specialist or psychiatrist.

(f) A registrant ~~physician~~ registered under this section must maintain accurate, current, and complete records that are accessible and readily available for review and comply with the requirements of this section, the applicable practice act, and applicable board rules. The medical records must include, but are not limited to:

1. The complete medical history and a physical examination, including history of drug abuse or dependence.

2. Diagnostic, therapeutic, and laboratory results.

3. Evaluations and consultations.

4. Treatment objectives.

5. Discussion of risks and benefits.

6. Treatments.

7. Medications, including date, type, dosage, and quantity prescribed.

8. Instructions and agreements.

9. Periodic reviews.

10. Results of any drug testing.

11. A photocopy of the patient's government-issued photo identification.

12. If a written prescription for a controlled substance is given to the patient, a duplicate of the prescription.

13. The registrant's ~~physician's~~ full name presented in a legible manner.

(g) Patients with signs or symptoms of substance abuse shall be immediately referred to a board-certified pain management physician, an addiction medicine specialist, or a mental health addiction facility as it pertains to drug abuse or addiction unless the registrant is a physician who is board certified ~~board-certified~~ or board eligible ~~board-eligible~~ in pain management. Throughout the period of time before receiving the consultant's report, a prescribing registrant ~~physician~~ shall clearly and completely document medical justification for continued treatment with controlled substances and those steps taken to ensure medically appropriate use of controlled substances by the patient. Upon receipt of the consultant's written report, the prescribing registrant ~~physician~~ shall incorporate the consultant's recommendations for continuing, modifying, or discontinuing controlled substance therapy. The resulting changes in treatment shall be specifically documented in the patient's medical record. Evidence or behavioral indications of diversion shall be followed by discontinuation of controlled substance therapy, and the patient shall be discharged, and all results of testing and actions taken by the

registrant ~~physician~~ shall be documented in the patient's medical record.

This subsection does not apply to a board-eligible or board-certified anesthesiologist, physiatrist, rheumatologist, or neurologist, or to a board-certified physician who has surgical privileges at a hospital or ambulatory surgery center and primarily provides surgical services. This subsection does not apply to a board-eligible or board-certified medical specialist who has also completed a fellowship in pain medicine approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, or who is board eligible or board certified in pain medicine by the American Board of Pain Medicine or a board approved by the American Board of Medical Specialties or the American Osteopathic Association and performs interventional pain procedures of the type routinely billed using surgical codes. This subsection does not apply to a registrant, physician, advanced registered nurse practitioner, or physician assistant who prescribes medically necessary controlled substances for a patient during an inpatient stay in a hospital licensed under chapter 395.

Section 7. Paragraph (b) of subsection (2) of section 458.3265, Florida Statutes, is amended to read:

458.3265 Pain-management clinics.—

(2) PHYSICIAN RESPONSIBILITIES.—These responsibilities apply to any physician who provides professional services in a

pain-management clinic that is required to be registered in subsection (1).

(b) A person may not dispense any medication on the premises of a registered pain-management clinic unless he or she is a physician licensed under this chapter or chapter 459. A person may not prescribe any controlled substance regulated under chapter 893 on the premises of a registered pain-management clinic unless he or she is a physician licensed under this chapter or chapter 459.

Section 8. Paragraph (f) of subsection (4) of section 458.347, Florida Statutes, is amended to read:

458.347 Physician assistants.—

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

(f)1. The council shall establish a formulary of medicinal drugs that a fully licensed physician assistant having prescribing authority under this section or s. 459.022 may not prescribe. The formulary must include ~~controlled substances as defined in chapter 893,~~ general anesthetics~~,~~ and radiographic contrast materials.

2. In establishing the formulary, the council shall consult with a pharmacist licensed under chapter 465, but not licensed under this chapter or chapter 459, who shall be selected by the State Surgeon General.

3. Only the council shall add to, delete from, or modify the formulary. Any person who requests an addition, deletion, or modification of a medicinal drug listed on such formulary has

the burden of proof to show cause why such addition, deletion, or modification should be made.

4. The boards shall adopt the formulary required by this paragraph, and each addition, deletion, or modification to the formulary, by rule. Notwithstanding any provision of chapter 120 to the contrary, the formulary rule shall be effective 60 days after the date it is filed with the Secretary of State. Upon adoption of the formulary, the department shall mail a copy of such formulary to each fully licensed physician assistant having prescribing authority under this section or s. 459.022, and to each pharmacy licensed by the state. The boards shall establish, by rule, a fee not to exceed $200 to fund the provisions of this paragraph and paragraph (e).

Section 9. Paragraph (b) of subsection (2) of section 459.0137, Florida Statutes, is amended to read:

459.0137 Pain-management clinics.—

(2) PHYSICIAN RESPONSIBILITIES.—These responsibilities apply to any osteopathic physician who provides professional services in a pain-management clinic that is required to be registered in subsection (1).

(b) A person may not dispense any medication on the premises of a registered pain-management clinic unless he or she is a physician licensed under this chapter or chapter 458. A person may not prescribe any controlled substance regulated under chapter 893 on the premises of a registered pain-management clinic unless he or she is a physician licensed under

this chapter or chapter 458.

Section 10. Section 464.012, Florida Statutes, is amended to read:

464.012 Certification of advanced registered nurse practitioners; fees; controlled substance prescribing.—

(1) Any nurse desiring to be certified as an advanced registered nurse practitioner shall apply to the department and submit proof that he or she holds a current license to practice professional nursing and that he or she meets one or more of the following requirements as determined by the board:

(a) Satisfactory completion of a formal postbasic educational program of at least one academic year, the primary purpose of which is to prepare nurses for advanced or specialized practice.

(b) Certification by an appropriate specialty board. Such certification shall be required for initial state certification and any recertification as a registered nurse anesthetist or nurse midwife. The board may by rule provide for provisional state certification of graduate nurse anesthetists and nurse midwives for a period of time determined to be appropriate for preparing for and passing the national certification examination.

(c) Graduation from a program leading to a master's degree in a nursing clinical specialty area with preparation in specialized practitioner skills. For applicants graduating on or after October 1, 1998, graduation from a master's degree program

shall be required for initial certification as a nurse practitioner under paragraph (4)(c). For applicants graduating on or after October 1, 2001, graduation from a master's degree program shall be required for initial certification as a registered nurse anesthetist under paragraph (4)(a).

(2) The board shall provide by rule the appropriate requirements for advanced registered nurse practitioners in the categories of certified registered nurse anesthetist, certified nurse midwife, and nurse practitioner.

(3) An advanced registered nurse practitioner shall perform those functions authorized in this section within the framework of an established protocol that is filed with the board upon biennial license renewal and within 30 days after entering into a supervisory relationship with a physician or changes to the protocol. The board shall review the protocol to ensure compliance with applicable regulatory standards for protocols. The board shall refer to the department licensees submitting protocols that are not compliant with the regulatory standards for protocols. A practitioner currently licensed under chapter 458, chapter 459, or chapter 466 shall maintain supervision for directing the specific course of medical treatment. Within the established framework, an advanced registered nurse practitioner may:

(a) Prescribe, dispense, administer, or order any ~~Monitor and alter~~ drug ~~therapies~~.

(b) Initiate appropriate therapies for certain conditions.

(c) Perform additional functions as may be determined by rule in accordance with s. 464.003(2).

(d) Order diagnostic tests and physical and occupational therapy.

(4) In addition to the general functions specified in subsection (3), an advanced registered nurse practitioner may perform the following acts within his or her specialty:

(a) The certified registered nurse anesthetist may, to the extent authorized by established protocol approved by the medical staff of the facility in which the anesthetic service is performed, perform any or all of the following:

1. Determine the health status of the patient as it relates to the risk factors and to the anesthetic management of the patient through the performance of the general functions.

2. Based on history, physical assessment, and supplemental laboratory results, determine, with the consent of the responsible physician, the appropriate type of anesthesia within the framework of the protocol.

3. Order under the protocol preanesthetic medication.

4. Perform under the protocol procedures commonly used to render the patient insensible to pain during the performance of surgical, obstetrical, therapeutic, or diagnostic clinical procedures. These procedures include ordering and administering regional, spinal, and general anesthesia; inhalation agents and techniques; intravenous agents and techniques; and techniques of hypnosis.

5. Order or perform monitoring procedures indicated as pertinent to the anesthetic health care management of the patient.

6. Support life functions during anesthesia health care, including induction and intubation procedures, the use of appropriate mechanical supportive devices, and the management of fluid, electrolyte, and blood component balances.

7. Recognize and take appropriate corrective action for abnormal patient responses to anesthesia, adjunctive medication, or other forms of therapy.

8. Recognize and treat a cardiac arrhythmia while the patient is under anesthetic care.

9. Participate in management of the patient while in the postanesthesia recovery area, including ordering the administration of fluids and drugs.

10. Place special peripheral and central venous and arterial lines for blood sampling and monitoring as appropriate.

(b) The certified nurse midwife may, to the extent authorized by an established protocol which has been approved by the medical staff of the health care facility in which the midwifery services are performed, or approved by the nurse midwife's physician backup when the delivery is performed in a patient's home, perform any or all of the following:

1. Perform superficial minor surgical procedures.

2. Manage the patient during labor and delivery to include amniotomy, episiotomy, and repair.

3. Order, initiate, and perform appropriate anesthetic procedures.

4. Perform postpartum examination.

5. Order appropriate medications.

6. Provide family-planning services and well-woman care.

7. Manage the medical care of the normal obstetrical patient and the initial care of a newborn patient.

(c) The nurse practitioner may perform any or all of the following acts within the framework of established protocol:

1. Manage selected medical problems.

2. Order physical and occupational therapy.

3. Initiate, monitor, or alter therapies for certain uncomplicated acute illnesses.

4. Monitor and manage patients with stable chronic diseases.

5. Establish behavioral problems and diagnosis and make treatment recommendations.

(5) The board shall certify, and the department shall issue a certificate to, any nurse meeting the qualifications in this section. The board shall establish an application fee not to exceed $100 and a biennial renewal fee not to exceed $50. The board is authorized to adopt such other rules as are necessary to implement the provisions of this section.

Section 11. Paragraph (p) is added to subsection (1) of section 464.018, Florida Statutes, to read:

464.018 Disciplinary actions.—

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(p) For an advanced registered nurse practitioner:

1. Presigning blank prescription forms.

2. Prescribing for office use any medicinal drug appearing on Schedule II in chapter 893.

3. Prescribing, ordering, dispensing, administering, supplying, selling, or giving a drug that is an amphetamine or a sympathomimetic amine drug, or a compound designated pursuant to chapter 893 as a Schedule II controlled substance, to or for any person except for:

a. The treatment of narcolepsy; hyperkinesis; behavioral syndrome in children characterized by the developmentally inappropriate symptoms of moderate to severe distractibility, short attention span, hyperactivity, emotional lability, and impulsivity; or drug-induced brain dysfunction.

b. The differential diagnostic psychiatric evaluation of depression or the treatment of depression shown to be refractory to other therapeutic modalities.

c. The clinical investigation of the effects of such drugs or compounds when an investigative protocol is submitted to, reviewed by, and approved by the department before such investigation is begun.

4. Prescribing, ordering, dispensing, administering, supplying, selling, or giving growth hormones, testosterone or its analogs, human chorionic gonadotropin (HCG), or other

hormones for the purpose of muscle building or to enhance athletic performance. As used in this subparagraph, the term "muscle building" does not include the treatment of injured muscle. A prescription written for the drug products listed in this paragraph may be dispensed by a pharmacist with the presumption that the prescription is for legitimate medical use.

5. Promoting or advertising on any prescription form a community pharmacy unless the form also states: "This prescription may be filled at any pharmacy of your choice."

6. Prescribing, dispensing, administering, mixing, or otherwise preparing a legend drug, including a controlled substance, other than in the course of his or her professional practice. For the purposes of this subparagraph, it is legally presumed that prescribing, dispensing, administering, mixing, or otherwise preparing legend drugs, including all controlled substances, inappropriately or in excessive or inappropriate quantities is not in the best interest of the patient and is not in the course of the advanced registered nurse practitioner's professional practice, without regard to his or her intent.

7. Prescribing, dispensing, or administering a medicinal drug appearing on any schedule set forth in chapter 893 to himself or herself, except a drug prescribed, dispensed, or administered to the advanced registered nurse practitioner by another practitioner authorized to prescribe, dispense, or administer medicinal drugs.

8. Prescribing, ordering, dispensing, administering,

supplying, selling, or giving amygdalin (laetrile) to any person.

9. Dispensing a controlled substance listed on Schedule II or Schedule III in chapter 893 in violation of s. 465.0276.

10. Promoting or advertising through any communication medium the use, sale, or dispensing of a controlled substance appearing on any schedule in chapter 893.

Section 12. Subsection (21) of section 893.02, Florida Statutes, is amended to read:

893.02 Definitions.—The following words and phrases as used in this chapter shall have the following meanings, unless the context otherwise requires:

(21) "Practitioner" means a physician licensed under ~~pursuant to~~ chapter 458, a dentist licensed under ~~pursuant to~~ chapter 466, a veterinarian licensed under ~~pursuant to~~ chapter 474, an osteopathic physician licensed under ~~pursuant to~~ chapter 459, an advanced registered nurse practitioner certified under chapter 464, a naturopath licensed under ~~pursuant to~~ chapter 462, a certified optometrist licensed under ~~pursuant to~~ chapter 463, ~~or~~ a podiatric physician licensed under ~~pursuant to~~ chapter 461, or a physician assistant licensed under chapter 458 or chapter 459, provided such practitioner holds a valid federal controlled substance registry number.

Section 13. Paragraph (n) of subsection (1) of section 948.03, Florida Statutes, is amended to read:

948.03 Terms and conditions of probation.—

(1) The court shall determine the terms and conditions of probation. Conditions specified in this section do not require oral pronouncement at the time of sentencing and may be considered standard conditions of probation. These conditions may include among them the following, that the probationer or offender in community control shall:

(n) Be prohibited from using intoxicants to excess or possessing any drugs or narcotics unless prescribed by a physician, advanced registered nurse practitioner, or physician assistant. The probationer or community controllee may ~~shall~~ not knowingly visit places where intoxicants, drugs, or other dangerous substances are unlawfully sold, dispensed, or used.

Section 14. Subsection (3) of s. 310.071, Florida Statutes, is reenacted for the purpose of incorporating the amendment made by this act to s. 310.071, Florida Statutes, in a reference thereto.

Section 15. Subsection (10) of s. 458.331, paragraph (g) of subsection (7) of s. 458.347, subsection (10) of s. 459.015, paragraph (f) of subsection (7) of s. 459.022, and paragraph (b) of subsection (5) of s. 465.0158, Florida Statutes, are reenacted for the purpose of incorporating the amendment made by this act to s. 456.072, Florida Statutes, in references thereto.

Section 16. Paragraph (mm) of subsection (1) of s. 456.072 and s. 466.02751, Florida Statutes, are reenacted for the purpose of incorporating the amendment made by this act to s. 456.44, Florida Statutes, in references thereto.

Section 17. Section 458.303, paragraph (e) of subsection (4) and paragraph (c) of subsection (9) of s. 458.347, paragraph (b) of subsection (7) of s. 458.3475, paragraph (e) of subsection (4) and paragraph (c) of subsection (9) of s. 459.022, and paragraph (b) of subsection (7) of s. 459.023, Florida Statutes, are reenacted for the purpose of incorporating the amendment made by this act to s. 458.347, Florida Statutes, in references thereto.

Section 18. Paragraph (a) of subsection (1) of s. 456.041, subsections (1) and (2) of s. 458.348, and subsection (1) of s. 459.025, Florida Statutes, are reenacted for the purpose of incorporating the amendment made by this act to s. 464.012, Florida Statutes, in references thereto.

Section 19. Subsection (2) of s. 464.008, subsection (5) of s. 464.009, subsection (2) of s. 464.018, and paragraph (b) of subsection (1), subsection (3), and paragraph (b) of subsection (4) of s. 464.0205, Florida Statutes, are reenacted for the purpose of incorporating the amendment made by this act to s. 464.018, Florida Statutes, in references thereto.

Section 20. Section 775.051, Florida Statutes, is reenacted for the purpose of incorporating the amendment made by this act to s. 893.02, Florida Statutes, in a reference thereto.

Section 21. Paragraph (a) of subsection (3) of s. 944.17, subsection (8) of s. 948.001, and paragraph (e) of subsection (1) of s. 948.101, Florida Statutes, are reenacted for the purpose of incorporating the amendment made by this act to s.

948.03, Florida Statutes, in references thereto.

Section 22. This act shall take effect July 1, 2016.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 517 Licensure of Life Support Services
SPONSOR(S): Renner
TIED BILLS: **IDEN./SIM. BILLS:**

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

SUMMARY ANALYSIS

The provision of emergency medical transportation services are governed by the Raymond H. Alexander, M.D., Emergency Medical Transportation Services Act, found in part III of ch. 401, F.S.

The Department of Health (DOH) is charged with licensing basic life support (BLS) service providers, advanced life support (ALS) service providers and air ambulances. All license applicants must meet the minimum standards regarding equipment, vehicles, personnel, services, and insurance established by the DOH. However, all BLS, ALS, and air ambulance service providers must also obtain a Certificate of Public Convenience and Necessity (COPCN) from the county government in which it plans to operate.

Pursuant to s. 401.25, F.S., each county may adopt an ordinance establishing the standards for the issuance of a COPCN. Currently, a county must consider state guidelines, recommendations of local and regional trauma centers, and recommendations of municipalities within its jurisdiction. The bill makes the adoption of such an ordinance mandatory and requires existing COPCN ordinances to be amended to comply with the bill's provisions. The new or amended ordinance must include standards regarding available equipment, available trained personnel, and the response time to life support calls. The bill also requires the county commissions to consider recommendations from fire control districts in establishing the standards for the COPCN.

Currently, if a COPCN is denied or revoked, an applicant usually appeals the decision to the county commission that denied or revoked the application. The bill allows an applicant for a COPCN whose application is denied to appeal the decision by writ of certiorari to the circuit court with jurisdiction over the county and the applicant to review the county commission's decision. The bill provides that the applicant must be awarded the COPCN if the court record demonstrates that the applicant will provide a superior level of service than the current provider. In determining service level, the court must take into account available equipment, available trained personnel, and the response time for life support calls at an equal or lesser cost than the current provider.

The bill may have an indeterminate, negative fiscal impact on the state court system related to the review of denied COPCN applications in the circuit court having jurisdiction over the county and applicant.

The bill may have an indeterminate, negative fiscal impact on those counties that have to defend denial of COPCN applications in circuit court.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Emergency Medical Services

Part III of ch. 401, F.S., governs the provision of emergency medical transportation services in Florida and is titled the "Raymond H. Alexander, M.D., Emergency Medical Transportation Services Act (Act)."[1] The Act establishes the licensing and operational requirements for emergency medical services.

Emergency Medical Services Advisory Council

The Act creates the Emergency Medical Services Advisory Council (Council)[2] to act as an advisory body the emergency medical services program within the Department of Health (DOH).[3] The Council's duties include:

- Identifying and making recommendations to the DOH regarding the appropriateness of suggested changes to statutes and administrative rules;
- Acting as a clearinghouse for information specific to changes in the provision of medical services and trauma care;
- Providing technical support to the DOH in the areas of emergency medical services and trauma systems design, required medical and rescue equipment, required drugs and dosages, medical treatment protocols and emergency medical services personnel education and training requirements;
- Providing a forum for discussing significant issues facing the emergency medical services and trauma care communities;
- Providing a forum for planning the continued development of the state's emergency medical services system through the joint production of the emergency medical services state plan;
- Assisting the DOH in developing the emergency medical services quality management program;
- Assisting the DOH in setting program priorities; and
- Providing feedback to the DOH on the administration and performance of the emergency medical services program.[4]

Emergency Medical Transportation Services

Basic life support (BLS) service refers to any emergency medical service that uses only basic life support techniques.[5] BLS includes basic non-invasive interventions to reduce morbidity and mortality associated with out-of-hospital medical and traumatic emergencies.[6] The services provided may include stabilization and maintenance of airway and breathing, pharmacological interventions, trauma care, and transportation to an appropriate medical facility.[7]

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[1] Section 401.2101, F.S.
[2] Pursuant to 401.245(2), F.S., the Council consists of 15 members appointed by the State Surgeon General, except that state agency representatives are appointed by the respective agency heads. Members are typically appointed for four year terms, with the chair being designated by the State Surgeon General and Secretary of Health. Additional members include six ex officio representatives appointed by various other state agency heads.
[3] Section 401.245(1), F.S.
[4] *Id.*
[5] Section 401.23(8), F.S.
[6] Section 401.23(7), F.S., and U.S. Department of Transportation, National Highway Safety Administration, *National EMS Scope of Practice Model* 23-24, *available at* www.nhtsa.gov/people/injury/ems/pub/emtbnsc.pdf (last visited Nov. 21, 2015).
[7] *Id.*

Advanced life support (ALS) service refers to any emergency medical or nontransport service that uses advanced life support techniques.[8] ALS includes the assessment or treatment of a person by a qualified individual, such as a paramedic, who is trained in the use of techniques such as the administration of drugs or intravenous fluid, endotracheal intubation, telemetry, cardiac monitoring, and cardiac defibrillation.[9]

Air ambulance services refers to a licensed publicly or privately owned service that operates air ambulances to transport persons requiring or likely to require medical attention during transport.[10] An air ambulance is a fixed-wing or rotary-wing aircraft used for, or intended to be used for, the air transportation of sick or injured persons that require or are likely to require medical attention during transport.[11]

Licensure

Current law requires providers of basic or advanced life support transportation services to be licensed as a BLS service.[12] Air ambulances must also be licensed by the DOH.[13] The provider must submit an application to the DOH and must include documentation that the applicant meets the requirements for a BLS service or an ALS service.[14] There are currently 233 licensed ALS providers, 8 licensed BLS providers, and 33 licensed air ambulance providers in this state.[15]

To be licensed as an BLS or ALS service, an applicant must comply with the following requirements:

- The ambulances, equipment, vehicles, personnel, communications systems, staffing patterns, and services of the applicant meet the statutory requirement and administrative rules for either a BLS service or an ALS service, whichever is applicable;
- Have adequate insurance coverage or certificate of self-insurance for claims arising out of injury to or death of persons and damage to the property of others resulting from any cause for which the owner of such business or service would be liable; and
- A Certificate of Public Convenience and Necessity from each county in which the applicant will operate.[16]

In addition to the general licensure requirement, the DOH has provided a list of the equipment and supplies that each BLS vehicle must contain and the equipment and medication each ALS vehicle must contain.[17] Additionally, each BLS and ALS service must employ or contract with a medical director who is a licensed physician to oversee the services it provides.[18]

To be licensed as an air ambulance service, an applicant must:

- Submit an application to the DOH with the appropriate fee;
- Specify the location of all required medical equipment and provide documentation that all such equipment is available and in good working order;
- Provide documentation that all aircraft and crew members meet applicable Federal Aviation Administration (FAA) regulations;

[8] Section 401.23(2), F.S.
[9] Section 401.23(1), F.S.
[10] Section 401.23(4), F.S.
[11] Section 401.23(3), F.S.
[12] Section 401.25(1), F.S.
[13] Section 401.251, F.S.
[14] *Id.*
[15] E-mail communication with staff of the Department of Health (Nov. 20, 2015) (on file with the Health Quality Subcommittee).
[16] Section 401.25(2), F.S.
[17] *See* Rule 64J-1.002(4) F.A.C., and Rule 64J-1.003(7), F.A.C., respectively.
[18] Rule 64J-1.004, F.A.C. The medical director must also be board certified, active in a broad-based clinical medical specialty with experience in prehospital care, and hold a certificate in Advanced Cardiac Life Support or its equivalent.

- Provide proof of adequate insurance coverage or certificate of self-insurance for claims arising out of injury to or death of persons and damage to the property of others resulting from any cause for which the owner of such business or service would be liable;
- Specify whether the service uses either fixed-winged or rotary-winged aircraft, or both; and
- Provide evidence that it has employed or contracted with a medical director, if the service provides interhospital air transport, air transport from one hospital to another facility, air transport from hospital to home, or other similar air transport.[19]

Additionally, the DOH has provided a list of structural, equipment, and supply requirements that air ambulances must meet for licensure.[20] An air ambulance service must also have a safety committee and emergency protocols to address, at minimum, emergency procedures when the aircraft is overdue, when radio communications cannot be established, or when aircraft location cannot be verified.[21]

Certificate of Public Convenience and Necessity

A Certificate of Public Convenience and Necessity (COPCN) is a written statement, issued by the governing board of a county, granting permission for an emergency medical service provider to provide authorized services for the benefit of the population of that county or the benefit of the population of some geographic area of that county.[22] At the time of licensure, each provider of life support transportation services must have a COPCN from the county in which it intends to operate.[23] Section 401.25(6), F.S., authorizes each county to adopt an ordinance establishing standards for issuing a COPCN.

The majority of counties, but not all counties, have adopted ordinances to establish a procedure and standards for obtaining a COPCN.[24] These ordinances generally provide instructions on the application process, criteria on which the application may be judged, and procedures for appealing a denial, suspension, or revocation of a COPCN with the county commission.

Effect of Proposed Changes

Each county has the authority to adopt an ordinance providing standards for a COPCN, which takes into account state guidelines, recommendations of local and regional trauma centers, and recommendations of municipalities within its jurisdiction. The bill requires each county to adopt such an ordinance or amend an existing ordinance to comply with the bill's provisions. The new or amended ordinance must include standards regarding available equipment, available trained personnel, and the response time to life support calls. The bill also requires the county commissions to consider recommendations from fire control districts in establishing the standards for the COPCN.

Currently, if a COPCN is denied or revoked, an applicant usually appeals the decision to the county commission that denied or revoked the application. The bill allows an applicant for a COPCN whose application is denied to appeal the decision by writ of certiorari to the circuit court with jurisdiction over the county and the applicant to review the county commission's decision. The bill provides that the applicant must be awarded the COPCN if the court record demonstrates that the applicant will provide a superior level of service than the current provider. In determining service level, the court must take into account available equipment, available trained personnel, and the response time for life support calls at an equal or lesser cost than the current provider.

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

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[19] Section 401.251, F.S.
[20] Rule 64J-1.005, F.S.
[21] *Id.*
[22] Rule 64J-1.001(4), F.A.C.
[23] Section 401.25(2)(d), F.S.
[24] Research by Health Quality Staff (on file with subcommittee). Some counties have policies or informal procedures in place for the award of a COPCN to an emergency transportation provider, but have not enacted an ordinance.

B. SECTION DIRECTORY:

Section 1. Amends s. 401.25, F.S., relating to licensure as a basic life support or an advanced life support service.
Section 2. Provides an effective date of July 1, 2016.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   The state court system may see an indeterminate, positive fiscal impact from the collection of filing fees associated with providers filing writs of certiorari to appeal the decision of a county commission to deny an application for a COPCN.

2. Expenditures:

   The state court system may see an indeterminate, negative fiscal impact from ALS, BLS, or air ambulance providers filing writs of certiorari to appeal the decision of a county commission to deny an application for a COPCN.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   A county that has not enacted an ordinance establishing standards for issuing a COPCN, as required by the bill, may incur expenses or use resources to enact or amend an ordinance to comply with the bill's provisions.

   To the extent that a county commission has to defend its decision to deny the award of a COPCN, a county may accrue legal fees associated with such a legal action.

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 require counties or municipalities to spend funds or take action requiring the expenditure of funds; reduce the authority that counties or municipalities have to raise revenues in the aggregate; or reduce the percentage of state tax shared with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to licensure of life support services; amending s. 401.25, F.S.; requiring county governing bodies to adopt or amend ordinances that provide standards for certificates of public convenience and necessity for life support and air ambulance services; providing for the filing of an appeal by an applicant for a certificate of public convenience and necessity under certain circumstances; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (6) of section 401.25, Florida Statutes, is amended to read:

401.25 Licensure as a basic life support or an advanced life support service.—

(6) The governing body of each county shall ~~may~~ adopt or amend ordinances to ~~that~~ provide reasonable standards for certificates of public convenience and necessity for basic or advanced life support services and air ambulance services, including, but not limited to, available equipment, available trained personnel, and response time to life support calls. In developing standards for certificates of public convenience and necessity, the governing body of each county must consider state guidelines, recommendations of the local or regional trauma

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

agency created under chapter 395, and the recommendations of municipalities and fire control districts within its jurisdiction. An applicant whose application for a certificate of public convenience and necessity to provide basic or advanced life support services pursuant to this chapter is denied may appeal the decision by certiorari to the circuit court with jurisdiction over the county and the applicant. An appellant shall be awarded the requested certificate if the record on appeal demonstrates that the applicant will provide a level of service that is superior than the level of service provided by the current provider, as measured by available equipment, available trained personnel, and response time to life support calls at an equal or lesser cost for the proposed service within the applicant's jurisdiction and applicable state guidelines.

Section 2. This act shall take effect July 1, 2016.

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 517 (2016)

Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION	
ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Health Quality Subcommittee

Representative Renner offered the following:

Amendment

Remove everything after the enacting clause and insert:

Section 1. Subsection (6) of section 401.25, Florida Statutes, is amended to read:

401.25 Licensure as a basic life support or an advanced life support service.—

(6) The governing body of each county shall ~~may~~ adopt or amend an ordinance ~~ordinances~~ that provides ~~provide~~ reasonable standards for certificates of public convenience and necessity for basic or advanced life support services and air ambulance services, including, but not limited to, objective standards that address the quality and cost of service, such as available equipment and trained personnel. In developing standards for

certificates of public convenience and necessity, the governing body of each county must consider state guidelines, recommendations of the local or regional trauma agency created under chapter 395, and the recommendations of municipalities and fire control districts within its jurisdiction. An applicant whose application for a certificate of public convenience and necessity to provide basic or advanced life support services or air ambulance services pursuant to this chapter is denied may appeal the decision by certiorari to the circuit court with jurisdiction over the county and the applicant. An appellant shall be awarded the requested certificate if the record on appeal demonstrates that the applicant will provide a service that is superior to the service provided by the current provider, as measured by the standards set forth in the ordinance enacted in the applicant's jurisdiction and applicable state guidelines.

Section 2. This act shall take effect July 1, 2016.

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 within institutions, 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 doctor of pharmacy to perform the same services, and requires the doctor of pharmacy to meet the same educational and training requirements, as a consultant pharmacist.

The bill expands the services that a consultant pharmacy or a doctor of pharmacy may provide. Under the bill's provisions, a consultant pharmacist or a doctor of pharmacy may 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

[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).

behavioral pharmacy sciences, and clinical sciences.[7] Clinical sciences includes instruction in 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]

Consultant Pharmacists

A consultant pharmacist is a pharmacist who provides expert advice on the use of medications by individuals, or within institutions, 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

[7] *Id.*
[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.

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
- 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,

[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.

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]

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.
- 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 for a consultant pharmacist. The bill expands the training requirements to include the practice of pharmacy in community or other settings, in addition to institutional settings.

Reimbursement for a Pharmacist's Patient Care Services

[17] Section 465.0125(2), F.S.
[18] *Id.*

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 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, 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 test without the necessity of a physician visit. Any such impacts are indeterminate.

D. FISCAL COMMENTS:

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[19] DOH, *House Bill 547 Agency Analysis.*
[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.

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   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

A bill to be entitled

An act relating to the practice of pharmacy; providing a short title; amending s. 465.003, F.S.; revising the definition of the term "practice of the profession of pharmacy"; amending s. 465.0125, F.S.; providing additional responsibilities for licensed consultant pharmacists and doctors of pharmacy; providing for payment or reimbursement for certain pharmacist patient care services; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. This act may be cited as the "Access to Pharmacist Services Act."

Section 2. Subsection (13) of section 465.003, Florida Statutes, is amended to read:

465.003 Definitions.—As used in this chapter, the term:

(13) "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, or other preparations and products, and health and wellness assessments and patient care relating to medication therapy management, whether pursuant to prescriptions or in the absence and entirely independent of such prescriptions or orders; and other pharmaceutical services. For purposes of this

subsection, "other pharmaceutical services" means the pharmacist's management and monitoring of the patient's drug therapy and assisting the patient in the management of his or her drug therapy, and includes review and management of the patient's drug therapy and collaboration ~~communication~~ with the patient's other ~~prescribing~~ health care providers ~~provider~~ as licensed under chapter 458, chapter 459, chapter 461, or chapter 466, or similar statutory provision in another jurisdiction, or such provider's agent or such other persons as specifically authorized by the patient, regarding the drug therapy and health care status. However, nothing in this subsection may be interpreted to permit ~~an alteration of a prescriber's directions, the diagnosis or treatment of any disease, the initiation of any drug therapy,~~ the practice of medicine~~,~~ or the practice of osteopathic medicine, unless otherwise permitted by law. "Practice of the profession of pharmacy" also includes any other act, service, operation, research, or transaction incidental to, or forming a part of, any of the foregoing acts, requiring, involving, or employing the science or art of any branch of the pharmaceutical profession, study, or training, and shall expressly permit a pharmacist to transmit information from persons authorized to prescribe medicinal drugs to their patients. The practice of the profession of pharmacy also includes the dispensing and administration of medications, including vaccines ~~to adults~~ pursuant to s. 465.189.

Section 3. Section 465.0125, Florida Statutes, is amended

to read:

465.0125 Consultant pharmacist license; application, renewal, fees; responsibilities; rules.—

(1) The department shall issue or renew a consultant pharmacist license upon receipt of an initial or renewal application which conforms to the requirements for consultant pharmacist initial licensure or renewal as promulgated by the board by rule and a fee set by the board not to exceed $250. The consultant pharmacist shall be responsible for maintaining all drug, patient care, and quality assurance records required by law and for establishing drug handling procedures for the safe handling and storage of drugs. A ~~The~~ consultant pharmacist or doctor of pharmacy licensed in this state may perform medication management, patient health and wellness assessments, counseling, and referrals relating to medications and health care services in accordance with this section and the standards of practice adopted by board rules pursuant to s. 465.0155. A consultant pharmacist or doctor of pharmacy licensed as a health care provider in this state may also be responsible for ordering and evaluating any laboratory, diagnostic, or clinical testing when, in the judgment of the consultant pharmacist or doctor of pharmacy, such activity is necessary for the proper performance of his or her ~~the consultant pharmacist's~~ responsibilities. A consultant pharmacist or doctor of pharmacy licensed in this state may initiate, modify, discontinue, and administer drugs within the context of a drug therapy management order or

protocol in collaboration with one or more health care providers. ~~Such laboratory or clinical testing may be ordered only with regard to patients residing in a nursing home facility, and then only when authorized by the medical director of the nursing home facility.~~ The consultant pharmacist or doctor of pharmacy must have completed such additional training and demonstrate such additional qualifications relating to ~~in~~ the practice of pharmacy in institutional, community, or other settings ~~pharmacy~~ as ~~shall be~~ required by the board in addition to licensure as a registered pharmacist and health care provider.

(2) Notwithstanding the provisions of subsection (1), a consultant pharmacist or a doctor of pharmacy licensed in this state may also be responsible for ordering and evaluating any laboratory, diagnostic, or clinical testing ~~for persons under the care of a licensed home health agency~~ when, in the judgment of the consultant pharmacist or doctor of pharmacy, such activity is necessary for the proper performance of his or her responsibilities ~~and only when authorized by a practitioner licensed under chapter 458, chapter 459, chapter 461, or chapter 466~~. In order for the consultant pharmacist or doctor of pharmacy to qualify and accept this authority, he or she must receive 3 hours of continuing education relating to medical records and laboratory, diagnostic, and clinical testing as established by the board.

(3) The board shall adopt ~~promulgate~~ rules necessary to

implement and administer this section.

Section 4. Notwithstanding any provisions of a patient's health benefit plan, a health benefit plan or insurer may provide payment or reimbursement for the pharmacist's patient care services, separate and apart from the prescription medications, when the services provided are within the pharmacist's lawful scope of practice.

Section 5. This act shall take effect July 1, 2016.

Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION	
ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Health Quality Subcommittee

Representative Narain offered the following:

Amendment (with title amendment)

Between lines 105 and 106, insert:

Section 4. Subsections (3), (4), (5), (6), (7), and (8) of section 465.189, Florida Statutes, are amended to read:

465.189 Administration of vaccines, ~~and~~ epinephrine autoinjection, and medication by injection.—

(3) A pharmacist may administer medication by injection to a patient if authorized by and within the framework of an established protocol under a supervising physician licensed under chapter 458 or chapter 459 and the supervising physician has prescribed such medication to the patient.

(4) A pharmacist may not enter into a protocol unless he or she maintains at least $200,000 of professional liability

insurance and has completed training in administering vaccines or in administering medications by injection, or both if applicable, as authorized under this section.

(5) ~~(4)~~ A pharmacist administering vaccines or medications by injection under this section shall maintain and make available patient records using the same standards for confidentiality and maintenance of such records as those that are imposed on health care practitioners under s. 456.057. These records shall be maintained for a minimum of 5 years.

(6) ~~(5)~~ The decision by a supervising physician licensed under chapter 458 or chapter 459 to enter into a protocol under this section is a professional decision on the part of the practitioner, and a person may not interfere with a physician's decision as to entering into such a protocol. A pharmacist may not enter into a protocol that is to be performed while acting as an employee without the written approval of the owner of the pharmacy. Pharmacists shall forward vaccination records to the department for inclusion in the state registry of immunization information.

(7) ~~(6)~~ Any pharmacist or registered intern seeking to administer vaccines to adults under this section must be certified to administer such vaccines pursuant to a certification program approved by the Board of Pharmacy in consultation with the Board of Medicine and the Board of Osteopathic Medicine. The certification program shall, at a minimum, require that the pharmacist attend at least 20 hours of

continuing education classes approved by the board and the registered intern complete at least 20 hours of coursework approved by the board. The program shall have a curriculum of instruction concerning the safe and effective administration of such vaccines, including, but not limited to, potential allergic reactions to such vaccines.

(8) ~~(7)~~ Any pharmacist seeking to administer medications by injection under this section must be certified to administer such medications by injection pursuant to a certification program approved by the Board of Pharmacy in consultation with the Board of Medicine and the Board of Osteopathic Medicine. The certification program shall, at a minimum, require that the pharmacist attend at least 20 hours of continuing education classes approved by the board. The program shall have a curriculum of instruction concerning the safe and effective administration of medications by injection, including, but not limited to, potential allergic reactions to such medications.

(9) The written protocol between the pharmacist and supervising physician under this section must include particular terms and conditions imposed by the supervising physician upon the pharmacist relating to the administration of vaccines or medications by injection by the pharmacist pursuant to this section. The written protocol shall include, at a minimum, specific categories and conditions among patients for whom the supervising physician authorizes the pharmacist to administer such vaccines or medications by injection. The terms, scope, and

conditions set forth in the written protocol between the pharmacist and the supervising physician must be appropriate to the pharmacist's training and certification for administering such vaccines or medications by injection. Pharmacists who have been delegated the authority to administer vaccines or medication by injection under this section by the supervising physician under the protocol shall provide evidence of current certification by the Board of Pharmacy to the supervising physician. A supervising physician shall review the administration of such vaccines or medications by injection by the pharmacist pursuant to the written protocol between them, and this review shall take place as outlined in the written protocol. The process and schedule for the review shall be outlined in the written protocol between the pharmacist and the supervising physician.

(10) ~~(8)~~ The pharmacist shall submit to the Board of Pharmacy a copy of his or her protocol or written agreement to administer vaccines or medications by injection, or to administer both, under this section.

T I T L E A M E N D M E N T

Remove line 7 and insert:

pharmacists and doctors of pharmacy; amending s. 465.189, F.S.; authorizing pharmacists to administer injectable medications;

providing standards and requiring certification for such administration authority; providing recordkeeping requirements; providing for