### HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 351 Podiatric Medicine

SPONSOR(S): Health Quality Subcommittee, Ponder and others

TIED BILLS: IDEN./SIM. BILLS:

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	13 Y, 1 N, As CS	Siples	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

# **SUMMARY ANALYSIS**

A podiatric physician diagnoses or provides medical, surgical, palliative, and mechanical treatment of ailments affecting the human foot and leg. Podiatric medicine also includes the amputation of toes and other parts of the foot, but does not include amputation of the entire leg or foot.

A physician assistant (PA) is licensed to perform health care services delegated by a supervising physician, in the specialty areas in which he or she has been trained. PAs are governed by the respective physician practice acts for allopathic physicians (MDs) and osteopathic physicians (DOs). A physician is responsible and liable for the performance and the acts and omissions of a PA he or she supervises. Currently, podiatric physicians may not delegate health care services to PAs.

Medical assistants are non-licensed personal that may assist a physician in all aspects of a medical practice under the direct supervision and responsibility of a physician. Current law does not specifically authorize podiatric physicians to utilize medical assistants in their practices.

HB 351 authorizes podiatric physician to delegate the performance of health care services to PAs in the same manner as MDs and DOs. The bill also authorizes podiatric physicians to employ and supervise medical assistants in the same manner as physicians.

Section 456.0301, F.S., requires health care practitioners with authority to prescribe controlled substances to take a board-approved 2-hour continuing education course on safe and effective prescribing of controlled substances biennially offered by certain statewide professional organizations of physicians. However, if a licensee's practice act requires the licensee to complete a 2-hour course on safe and effective prescribing of controlled substances, the licensee is exempt from the requirements of s. 456.0301, F.S. Podiatric physicians are required to complete 40 hours of continuing professional education biennially, but their practice act does not specifically require continuing education on controlled substances.

The bill requires podiatric physicians to complete a 2-hour continuing education course on safe and effective prescribing of controlled substances as a part of the 30 hours of continuing professional education required for biennial licensure renewal. Podiatric physicians will no longer be subject to the requirements of s. 456.0301, F.S., including the requirement that the course be offered only by certain physician organizations.

Currently, individuals may enter into direct health care agreements with allopathic physicians, osteopathic physicians, chiropractic physicians, nurses, or dentists, or a group or a health care group practice for the provision of health care services. The bill adds podiatric physicians to the list of health care providers who may offer such agreements.

The bill has an insignificant, negative fiscal impact on the Department of Health, which current resources are adequate to absorb. The bill has no fiscal impact on local governments.

The bill provides an effective date of July 1, 2020.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives.

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#### **FULL ANALYSIS**

#### I. SUBSTANTIVE ANALYSIS

## A. EFFECT OF PROPOSED CHANGES:

#### **Present Situation**

### Podiatric Medicine

Podiatric medicine is the diagnosis or medical, surgical, palliative, and mechanical treatment of ailments of the human foot or leg.<sup>1</sup> It also includes the amputation of toes or other parts of the foot, but does not include the amputation of the entire foot or leg. A podiatric physician is authorized to prescribe drugs specifically related to his or her scope of practice.<sup>2</sup>

### Licensure Requirements

Florida law requires a podiatric physician to meet the following requirements for licensure:<sup>3</sup>

- Be at least 18 years of age;
- Hold a degree from a school or college of podiatric medicine or chiropody recognized and approved by the Council on Podiatry Education of the American Podiatric Medical Association;
- Have successfully completed one of the following clinical experience requirements:
  - One year of residency in a residency program approved by the board;<sup>4</sup> or
  - Ten years of continuous, active licensed practice of podiatric medicine in another state immediately preceding application and completion of at least the same continuing education requirements during those ten years as are required of podiatric physicians licensed in this state:
- Successfully complete a background screening; and
- Obtain passing scores on the national examinations administered by the National Board of Podiatric Medical Examiners.<sup>5</sup>

A license to practice podiatric medicine must be renewed biennially.

#### Continuing Education

A podiatric physician must complete 40 hours of continuing education as a part of the biennial licensure renewal, which must include:<sup>6</sup>

- One hour on risk management;
- One hour on the laws and rules related to podiatric medicine;
- Two hours on the prevention of medical errors;
- Two hours on HIV/AIDS (due for the first renewal only); and
- One hour on human trafficking (beginning January 1, 2021).<sup>7</sup>

#### Controlled Substance Prescribers

Effective July 1, 2018, every person registered with the United States Drug Enforcement Administration and authorized to prescribe controlled substances, must complete a 2-hour continuing education

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<sup>&</sup>lt;sup>1</sup> Section 461.003(5), F.S.

<sup>&</sup>lt;sup>2</sup> ld.

<sup>&</sup>lt;sup>3</sup> Section 461.006, F.S.

<sup>&</sup>lt;sup>4</sup> If it has been more than four years since the completion of the residency, an applicant must have two years of active, licensed practice of podiatric medicine in another jurisdiction in the four years immediately preceding application or successfully complete a board-approved postgraduate program or board-approved course within the year preceding application.

<sup>&</sup>lt;sup>5</sup> Rule 64B18-11.002, F.A.C.

<sup>&</sup>lt;sup>6</sup> Section 461.007(3), F.S., and r. 64B18-17, F.A.C.

<sup>&</sup>lt;sup>7</sup> Section 456.0341. F.S.

course on prescribing controlled substances.8 The course must include information on the current standards for prescribing controlled substances, particularly opiates; alternatives to these standards; non-pharmacological therapies; prescribing emergency opioid antagonists; and the risks of opioid addiction following all stages of treatment in the management of acute pain.

The course can only be offered by a statewide professional association of physicians in this state that is accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category 1 Credit or the American Osteopathic Category 1-A medical continuing education on the safe and effective prescribing of controlled substances each biennial license renewal.<sup>9</sup> Currently the course is provided by the:<sup>10</sup>

- Florida Medical Association;
- Florida Osteopathic Medical Association;
- Informed Independent Physician Association:
- Emergency Medicine Learning and Resource Center; and
- Florida Academy of Family Physicians.

This requirement does not apply to a licensee who is required by his or her applicable practice act to complete a minimum of two hours of continuing education on the safe and effective prescribing of controlled substances. 11 This requirement applies to podiatric physicians because their practice act does not specifically require a two hours of continuing education on the safe and effective prescribing of controlled substances.

#### Physician Assistants

Physician assistants (PAs) are regulated by the Florida Council on Physician Assistants (Council) in conjunction with either the Board of Medicine for PAs licensed under ch. 458, F.S., or the Board of Osteopathic Medicine for PAs licensed under ch. 459, F.S. The boards are responsible for adopting the principles that a supervising physician must use for developing a PA's scope of practice, developing a formulary of drugs that may be prescribed by a PA, and approving educational programs.<sup>12</sup>

#### Council on Physician Assistants

The Council consists of five members including three physicians who are members of the Board of Medicine, one physician who is a member of the Board of Osteopathic Medicine, and one licensed PA appointed by the Surgeon General. 13 Two of the physicians must be physicians who supervise physician assistants in their practice. The Council is responsible for:<sup>14</sup>

- Making recommendations to DOH regarding the licensure of PAs;
- Developing rules for the regulation of PAs for consideration for adoption by the boards;
- Making recommendations to the boards regarding all matters relating to PAs;
- Addressing concerns and problems of practicing PAs to ensure patient safety; and
- Denying, restricting, or placing conditions on the license of PA who fails to meet the licensing requirements.

<sup>11</sup> Supra note 8.

<sup>&</sup>lt;sup>8</sup> Section 1, ch. 2018-13, Laws of Fla., codified at s. 456.0301, F.S.

<sup>&</sup>lt;sup>10</sup> Department of Health, Take Control of Controlled Substances, available at http://www.flhealthsource.gov/FloridaTakeControl/ (last visited November 4, 2019). To access a list of providers, select Podiatric Medicine.

<sup>&</sup>lt;sup>12</sup> Sections 458.347(4) and (6), F.S., and 459.022(4) and (6), F.S.

<sup>13</sup> Sections 458.347(9), F.S., and 459.022(9), F.S. Members of the Board of Medicine and the Board of Osteopathic Medicine are appointed by the Governor and confirmed by the Senate. See ss. 458.307, F.S., and 459.004, F.S., respectively. <sup>14</sup> Id.

## Licensure and Regulation of PAs

An applicant for a PA license must apply to the Department of Health (DOH). DOH must issue a license to a person certified by the Council as having met all of the following requirements:<sup>15</sup>

- Completed an approved PA training program;
- Obtained a passing score on the National Commission on Certification of Physician Assistants examination:
- Acknowledged any prior felony convictions;
- Submitted to a background screening and have no disqualifying offenses;<sup>16</sup>
- Acknowledged any previous revocation or denial of licensure in any state; and
- Provided a copy of course transcripts and a copy of the course description from a PA training program describing the course content in pharmacotherapy if the applicant is seeking prescribing authority.

PAs must renew their licenses biennially. During each biennial renewal cycle a PA must complete 100 hours of continuing medical education or must demonstrate current certification issued by the National Commission on Certification of Physician Assistants. 17 To maintain certification, a PA must earn at least 100 hours of continuing medical education biennially and must take a re-certification examination every 10 years. 18

# PA Scope of Practice

PAs may only practice under the direct or indirect supervision of an allopathic or osteopathic physician with whom they have a clinical relationship. 19 A supervising physician may only delegate tasks and procedures to the PA that are within the supervising physician's scope of practice. 20 The supervising physician is responsible and liable for any acts or omissions of the PA and may not supervise more than four PAs at any time.21

The Boards have established by rule that "responsible supervision" of a PA means the ability of the supervising physician to exercise control and provide direction over the services or tasks performed by the PA. Whether the supervision of a PA is adequate, is dependent upon 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.<sup>22</sup>

A supervising physician decides whether to permit a PA to perform a task or procedure under direct or indirect supervision based on reasonable medical judgment regarding the probability of morbidity and mortality to the patient.<sup>23</sup> A supervising physician may delegate the authority for a PA to:

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<sup>&</sup>lt;sup>15</sup> Sections 458.347(7), F.S., and 459.022(7), F.S.

<sup>&</sup>lt;sup>16</sup> Section 456.0135, F.S.

<sup>&</sup>lt;sup>17</sup> Sections 458.347(7)(c), F.S., and 459.022(7)(c), F.S.

<sup>&</sup>lt;sup>18</sup> National Commission on Certification of Physician Assistants, Maintaining Certification, available at https://www.nccpa.net/CertificationProcess (last visited November 4, 2019).

<sup>19</sup> Sections 458.347(2)(f), F.S., and 459.022(2)(f), F.S., define supervision as responsible supervision and control which requires the easy availability or physical presence of the licensed physician for consultation and direction of the PA.

<sup>&</sup>lt;sup>20</sup> Rules 64B8-30.012, F.A.C., and 64B15-6.010, F.A.C.

<sup>&</sup>lt;sup>21</sup> Sections 458.347(15), F.S., and 459.022(15), F.S.

<sup>&</sup>lt;sup>22</sup> Rules 64B8-30.001, F.A.C., and 64B15-6.001, F.A.C.

<sup>&</sup>lt;sup>23</sup> "Direct supervision" refers to the physical presence of the supervising physician so that the physician is immediately available to the PA when needed. "Indirect supervision" refers to the reasonable physical proximity of the supervising physician to the PA or availability by telecommunication. Supra note 22.

- Prescribe or dispense any medicinal drug used in the supervising physician's practice unless such medication is listed in the formulary established by the Council;<sup>24</sup>
- Order any medication for administration to the supervising physician's patient in a hospital or other facility licensed under chapter 395, F.S., or a nursing homes licensed under part II of chapter 400, F.S.;<sup>25</sup> and
- Any other service that are is not expressly prohibited in ch. 458, F.S., ch. 459, F.S., or the rules adopted thereunder.<sup>26</sup>

Currently, podiatric physicians are not authorized to supervise or delegate tasks and procedures to PAs.

# Medical Assistants

A medical assistant is a multi-skilled person that assists in all aspects of a medical practice under the direct supervision and responsibility of a physician.<sup>27</sup> There are no formal educational for becoming a medical assistant in most states, including Florida.<sup>28</sup> Most medical assistants have postsecondary education, such as a certificate; however, others enter the occupation with a high school diploma and learn through on-the-job training.<sup>29</sup>

A medical assistant assists with patient care management, executes administrative and clinical procedures, and performs managerial and supervisory functions. In Florida, a medical assistant may perform the following duties under the direct supervision of a physician: 30

- Clinical procedures, including:
  - Performing aseptic procedures;
  - Taking vital signs;
  - Preparing patients for physician care;
  - o Performing venipunctures and nonintravenous injections; and
  - Observing and reporting patients' signs and symptoms;
- Administering basic first aid:
- Assisting with patient examinations or treatments;
- Operating office medical equipment;
- Collecting routine laboratory specimens as directed by the physician;
- Administering medication as directed by the physician;
- Performing basic laboratory procedures;
- Performing office procedures and general administrative duties required by the physician; and
- Performing dialysis procedures, including home dialysis.

Medical assistants are not required to be licensed, certified, or registered to practice in Florida.

## **Direct Health Care Agreements**

<sup>&</sup>lt;sup>24</sup> Sections 458.347(4)(f), F.S., and 459.022(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, F.A.C., and 64B15-6.0038, F.A.C., prohibits PAs from prescribing; general, spinal or epidural anesthetics; radiographic contrast materials; and psychiatric mental health controlled substances for children younger than 18 years of age. It also restricts the prescribing of Schedule II controlled substances to a 7-day supply. However, the rules authorize physicians to delegate to PAs the authority to order controlled substances in hospitals and other facilities licensed under ch. 395, F.S. <sup>25</sup> Chapter 395, F.S., provides for the regulation and the licensure of hospitals and trauma centers, part II of ch. 400, F.S., provides for the regulation and licensure of nursing home facilities.

<sup>&</sup>lt;sup>26</sup> Sections 458.347(4), F.S., and 459.022(e), F.S.

<sup>&</sup>lt;sup>27</sup> Section 458.3485, F.S.

<sup>&</sup>lt;sup>28</sup> United States Department of Labor, *Occupational Outlook Handbook: Medical Assistants*, (last rev. Sept. 4, 2019), available at <a href="https://www.bls.gov/ooh/healthcare/medical-assistants.htm#tab-4">https://www.bls.gov/ooh/healthcare/medical-assistants.htm#tab-4</a> (last visited November 4, 2019).
<a href="https://www.bls.gov/ooh/healthcare/medical-assistants.htm#tab-4">https://www.bls.gov/ooh/healthcare/medical-assistants.htm#tab-4</a> (last visited November 4, 2019).

<sup>30</sup> Supra note 27.

Under current law, individuals may contract directly with certain health care providers, outside the scope of insurance, for the provision of health care services.<sup>31</sup> Since a direct health care agreement is not considered health insurance, it is exempt from the Florida Insurance Code and the Office of Insurance Regulation does not have authority to regulate such agreements.<sup>32</sup> These direct health care agreements must:<sup>33</sup>

- Be in writing;
- Be signed by the health care provider, or his or her agent, and the patient, the patient's legal representative, or the patient's employer;
- Allow either party to terminate the agreement by giving the other party 30 days' advance written notice:
- Allow immediate termination of the agreement for a violation of physician-patient relationship or a breach of the terms of the agreement;
- Describe the scope of health care services that are covered by the monthly fee;
- Specify the monthly fee and any fees for health care services not covered under the agreement;
- Specify the duration of the agreement and any automatic renewal provisions;
- Offer a refund to the patient of monthly fees paid in advance if the health care provider stops offering health care services for any reason;
- State that the agreement is not health insurance and that the health care provider will not bill the patient's health insurance policy or plan for services covered under the agreement;
- State that the agreement does not qualify as minimum essential coverage to satisfy the individual responsibility provision of the Patient Protection and Affordable Care Act; and
- State that the agreement is not workers' compensation insurance and may not replace the employer's workers' compensation obligations.

Currently, individuals may only contract with allopathic physicians, osteopathic physicians, chiropractic physicians, nurses, or dentists, or a health care group practice, for health care services that are within the competency and training of the health care provider.<sup>34</sup> An individual may not directly contract with a podiatric physician for the provision of health care services.

### **Effect of Proposed Bill**

### Continuing Education

HB 351 requires podiatric physicians to complete two hours of continuing education on safe and effective prescribing of controlled substances, as a part of the 40 hours of continuing professional education required for each biennial licensure renewal. This will exempt podiatric physicians from the requirement in s. 456.0301, F.S., including the requirement that the course be offered only by certain physician organizations.

#### Physician Assistants

The bill authorizes podiatric physicians to supervise and delegate tasks to physician assistants in the same manner as allopathic physicians and osteopathic physicians. The bill retains existing law relating to PA licensure and practice requirements. Under the bill, the Board of Podiatric Medicine has the same authority and responsibilities as the Board of Medicine and Board of Osteopathic Medicine to develop the PA's scope of practice, develop a formulary of drugs that may be prescribed by a PA, and approve educational programs.

As with allopathic and osteopathic physicians, a podiatric physician may only supervise up to four PAs and is responsible and liable for the performance and the acts and omissions of a PA under his or her

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<sup>&</sup>lt;sup>31</sup> Section 624.27, F.S. Health care services means the screening, assessment, diagnosis, and treatment of a patient conducted within the competency and training of the health care provider for the purpose of promoting health or detecting and managing disease or injury.

<sup>32</sup> Section 624.27(2), F.S.

<sup>33</sup> Section 624.27(3), F.S.

<sup>&</sup>lt;sup>34</sup> Supra note 31.

supervision. A PA supervised by a podiatric physician must be qualified in the medical areas in which the PA is to perform.

The bill also revises the definition of "continuing medical education" to include those courses approved by the Board of Podiatric Medicine and the American Board of Podiatric Medicine.

## **Medical Assistants**

The bill authorizes podiatric physicians to use medical assistants in the same manner and under the same conditions as an allopathic physician.

# **Direct Health Care Agreements**

The bill authorizes individuals to directly contract with podiatric physicians for the provision of health care services. The bill retains the contract requirements that are currently required for other health care practitioners offering direct health care agreements.

The bill provides and effective date of July 1, 2020.

### **B. SECTION DIRECTORY:**

Section 1: Amends s. 458.347, F.S., relating to physician assistants.
Section 2: Amends s. 458.3485, F.S., relating to medical assistants.
Section 3: Amends s. 459.022, F.S., relating to physician assistants.
Section 4: Amends s. 461.007, F.S., relating to renewal of license.
Section 5: Creates s. 461.0145, F.S., relating to physician assistants.

**Section 6:** Creates s. 461.0155, F.S., relating to medical assistants.

Section 7: Amends s. 624.27, F.S., relating to direct health care agreements; exemption from code.

**Section 8:** Provides an effective date of July 1, 2020.

#### II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

#### A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

DOH, the Board of Medicine, the Board of Osteopathic Medicine, and the Board of Podiatric Medicine may incur costs to amend and adopt rules to implement the bill's provisions.

#### B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

## C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Since additional organizations may be eligible to provide the controlled substances continuing education course, organizations currently authorized to offer the course may experience a loss in revenue.

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Podiatric physicians may establish practices that use direct health care agreements to provide health care services without concern of facing regulatory action, which may increase access to podiatric care.

### D. FISCAL COMMENTS:

None.

#### III. COMMENTS

#### A. CONSTITUTIONAL ISSUES:

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 Podiatric Medicine has sufficient rulemaking authority to implement the bill under s. 461.005, F.S.

### C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

#### IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On November 13, 2019, the Health Quality Subcommittee adopted an amendment that removed proposed changes to the duties and composition of the Council on Physician Assistants and reported HB 351 favorably as a committee substitute. The analysis is drafted to the committee substitute as passed by the Health Quality Subcommittee.

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