

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1217 Hair Restoration or Transplant

SPONSOR(S): Geller

TIED BILLS: **IDEN./SIM. BILLS:** SB 974

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	9 Y, 2 N	Siples	O'Callaghan
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

An individual affected by hair loss may be treated with medication or by surgery, including hair transplantation, scalp reduction, scalp expansion, and scalp flaps. Each of these surgical interventions involves an incision to either harvest hair for transplantation or to redistribute sections of hair-bearing scalp.

Currently, Florida law does not delineate who may perform hair restoration or transplant services. The bill prohibits anyone who is not a licensed physician or physician assistant, under ch. 458 or ch. 459, F.S., or an advanced registered nurse practitioner, certified under s. 464.012, F.S., from performing hair restoration or transplant services or making an incision for the purpose of performing such services.

The bill defines "hair restoration or transplant" to mean a surgical procedure that extracts or removes hair follicles from one location on an individual living human body for the purpose of redistributing the hair follicles to another location on that body.

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

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Hair Transportation and Restoration

Hair loss, also known as alopecia, is experienced by millions of individuals, and may be caused by a number of conditions, diseases, medical regimens, or other factors, such as heredity or stress.¹ To determine the cause of hair loss, a health care practitioner may inquire about medications, nutrition, and allergies, among other things. The health care practitioner may also find it necessary to perform a scalp biopsy or order a blood test to determine the cause of hair loss.²

There are a number of treatments available to address hair loss, including prescription and nonprescription medications and surgical procedures. Hair transplantation is a surgical procedure in which hair is moved from a donor area of a patient's scalp to areas that are thinning or balding.³ This is accomplished by one of two methods: follicular unit transplantation, which involves removing a long, thin strip from the donor area that is dissected into follicular units⁴ under special microscopes; and follicular unit extraction, which involves removing follicular units one by one directly from the scalp. Once the follicular units are harvested, they are grafted into needle-sized holes made in the recipient area of the scalp by the health care practitioner.

Other surgical interventions for hair loss include scalp reduction, scalp expansion, and scalp flaps. A scalp reduction involves a health care practitioner surgically removing bald scalp and then stretching the hair-bearing scalp to cover the area removed.⁵ In a scalp expansion, devices are inserted under the scalp to stretch the skin; this may be done to relax the scalp prior to a scalp reduction or it may be done to stretch the hair-bearing areas in an effort to reduce balding. Scalp flaps involve surgically moving hair-bearing segments of the scalp and placing them where hair is needed.⁶

To determine the best course of treatment, a health care practitioner may assess the cause of the hair loss and the expected outcomes of treatment.

Licensure and Regulation of Physicians

Chapter 458, F.S., provides for the licensure and regulation of the practice of allopathic medicine by the Florida Board of Medicine (Board of Medicine), and ch. 459, F.S., addresses the licensure and regulation of the practice of osteopathic medicine by the Board of Osteopathic Medicine (Osteopathic Board). The boards work in conjunction with the Department of Health (DOH) to regulate the practice of allopathic and osteopathic physicians. The respective chapters provide, among other things, licensure requirements by examination for medical school graduates and licensure by endorsement requirements.

¹ American Academy of Dermatology, *Hair Loss*, available at <https://www.aad.org/public/diseases/hair-and-scalp-problems/hair-loss> (last visited January 28, 2016).

² *Id.*

³ Bernstein Medical Center for Hair Restoration, *Hair Transplant Surgery*, available at <http://www.bernsteinmedical.com/hair-transplant/> (last visited January 28, 2016).

⁴ A follicular unit is a tiny bundle of one to four hairs that occur in the human scalp. *Id.*

⁵ *Supra* note 1. This procedure may be done in conjunction with a hair transplant.

⁶ *Supra* note 1.

Licensure of Allopathic Physicians

An individual seeking to be licensed by examination as a medical doctor, must meet the following requirements:⁷

- Complete an application and pay an application fee;⁸
- Be at least 21 years of age;
- Be of good moral character;
- Has not committed an act or offense that would constitute the basis for disciplining a physician, pursuant to s. 458.331, F.S.;
- Complete 2 years of post-secondary education which includes, at a minimum, courses in fields such as anatomy, biology, and chemistry prior to entering medical school;
- Meets one of the following medical education and postgraduate training requirements:
 - Is a graduate of an allopathic medical school recognized and approved by an accrediting agency recognized by the U.S. Office of Education or recognized by an appropriate governmental body of a U.S. territorial jurisdiction, and has completed at least one year of approved residency training;
 - Is a graduate of an allopathic foreign medical school registered with the World Health Organization and certified pursuant to statute as meeting the standards required to accredit U.S. medical schools, and has completed at least one year of approved residency training; or
 - Is a graduate of an allopathic foreign medical school that has not been certified pursuant to statute; has an active, valid certificate issued by the Educational Commission for Foreign Medical Graduates (ECFMG),⁹ has passed that commission's examination; and has completed an approved residency or fellowship of at least 2 years in one specialty area;
- Has submitted to a background screening by the DOH; and
- Has obtained a passing score on:
 - The United States Medical Licensing Examination (USMLE);
 - A combination of the USMLE, the examination of the Federation of State Medical Boards of the United States, Inc. (FLEX), or the examination of the National Board of Medical Examiners up to the year 2000; or
 - The Special Purpose Examination of the Federation of State Medical Boards of the United States (SPEX), if the applicant was licensed on the basis of a state board examination, is currently licensed in at least one other jurisdiction of the United States or Canada, and has practiced for a period of at least 10 years.

An individual who holds an active license to practice medicine in another jurisdiction may seek licensure by endorsement to practice medicine in Florida.¹⁰ The applicant must meet the same basic requirements for licensure by examination. To qualify for licensure by endorsement, the applicant must also submit evidence of the licensed active practice of medicine in another jurisdiction for at least 2 of the preceding 4 years, or evidence of successful completion of either a board-approved postgraduate training program within 2 years preceding filing of an application or a board-approved clinical competency examination within the year preceding the filing of an application for licensure.¹¹

Licensure of Osteopathic Physicians

⁷ Section 458.311(1), F.S.

⁸ Pursuant to r. 64B8-3.002(5), F.A.C., the application fee for a person desiring to be licensed as a physician by examination is \$500. The applicant must pay an initial license fee of \$429. Section 766.314(4), F.S., assesses a fee to be paid with at time of an initial license to finance the Florida Birth-Related Neurological Injury Compensation Plan. The current assessment amount is \$250.

⁹ A graduate of a foreign medical school does not need to present an ECFMG certification or pass its exam if the graduate received his or bachelor's degree from an accredited U.S. college or university, studied at a medical school recognized by the World Health Organization, and has completed all but the internship or social service requirements, has passed parts I and II of the National Board Medical Examiners licensing examination or the ECFMG equivalent examination. (Section 458.311, F.S.)

¹⁰ Section 458.313, F.S.

¹¹ If an applicant for licensure by endorsement fails to meet all the requirements for licensure, the DOH may deny the application or may issue a license and impose additional requirements or restrictions on the applicant's license. See s. 458.311(8), F.S.

To be licensed as an osteopathic physician (DO), an applicant must:¹²

- Complete an application and pay an application fee;¹³
- Be of at least 21 years of age;
- Be of good moral character;
- Complete at least 3 years of pre-professional postsecondary education;
- Have not previously committed or be under investigation in any jurisdiction for any act that would constitute a violation of ch. 459, F.S., unless the Osteopathic Board determines that such act does not adversely affect the applicant's present ability and fitness to practice;
- Have not had an application for a license to practice osteopathic medicine denied, revoked, suspended, or acted against by any licensing authority unless the Osteopathic Board determines the grounds on which the action was taken do not adversely affect the applicant's present ability and fitness to practice;
- Have not received less than a satisfactory evaluation from an internship, residency, or fellowship training program, unless the Osteopathic Board determines that such act does not adversely affect the applicant's present ability and fitness to practice;
- Submit to a background screening by the DOH;
- Be a graduate of a medical college recognized and approved by the American Osteopathic Association;
- Successfully complete a resident internship of at least 12 months in an approved hospital or another approved internship program approved by the Osteopathic Board upon a good showing by the applicant; and
- Obtain a passing score on all parts of the examination conducted by the National Board of Osteopathic Medical Examiners (NBOME) or other approved examination within five years of application.

If an individual holds a valid DO license from another state and wishes to practice medicine in Florida, he or she is required to submit evidence to the board that they possess an active license in another state.¹⁴ The initial license from another jurisdiction must have occurred less than 5 years after receiving a passing score on the examination administered by the NBOME or other substantially similar examination approved by the Osteopathic Board.¹⁵ If the DO has not practiced for more than 2 years, then the Osteopathic Board has the discretion to determine if the lapse in time has adversely affected the DO's present ability and fitness to practice osteopathic medicine.¹⁶

Licensure and Regulation of 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.¹⁷ PAs licensure is governed by ss. 458.347(7) and 459.022(7), F.S. The DOH licenses PAs, and the Florida Council on Physician Assistants (Council) regulates the practice of PAs in conjunction with either the Board of Medicine for PAs licensed under ch. 458, F.S., or the Osteopathic Board for PAs licensed under ch. 459, F.S.

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

¹² Section 459.0055(1), F.S.

¹³ Pursuant to r. 64B15-10.002, F.A.C., the application fee is \$200. The applicant must also pay an initial license fee of \$300 upon the submission of the application. Section 766.314(4), F.S., assesses a fee to be paid with at time of an initial license to finance the Florida Birth-Related Neurological Injury Compensation Plan. The current assessment amount is \$250.

¹⁴ Section 459.0055(2), F.S.

¹⁵ Section 459.0055(1)(m), F.S.

¹⁶ *Supra* note 14. If the Osteopathic Board determines that the interruption in practice has adversely affected the applicant's ability and fitness to practice, the Osteopathic Board may deny the application or issue the license and impose additional requirements or restrictions on the license.

¹⁷ Sections 458.347(2)(e) and 459.022(2)(e), F.S.

- 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;¹⁸
- 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.¹⁹

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 scope of practice.²⁰ 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.²¹ A physician may not supervise more than four PAs at any time.²²

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.²³ 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.²⁴

Direct supervision refers to the physical presence of the supervising physician so that the physician is immediately available to the PA when needed.²⁵ Indirect supervision refers to the reasonable physical proximity of the supervising physician to the PA or availability by telecommunication.²⁶ 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.²⁷

Delegable Tasks

Rules of both the Board of Medicine and the Osteopathic Board place limitations on a supervising physician's ability to delegate certain tasks. Prescribing, dispensing, or compounding medicinal drugs

¹⁸ 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.

¹⁹ Sections 458.347(7) and 459.022(7), F.S.

²⁰ 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.

²¹ Sections 458.347(2)(f) and 459.022(2)(f), F.S.

²² Sections 458.347(3) and 459.022(3), F.S.

²³ Rules 64B8-30.001(3) and 64B15-6.001(3), F.A.C.

²⁴ *Id.*

²⁵ Rules 64B8-30.001(4) and 64B15-6.001(4), F.A.C.

²⁶ Rules 64B8-30.001(5) and 64B15-6.001(5), F.A.C.

²⁷ Rules 64B8-30.012(2) and 64B15-6.010(2), F.A.C.

and making a final diagnosis are not permitted to be delegated to a PA, except when specifically authorized by statute.²⁸

Regulation of Advanced Registered Nurse Practitioners

Part I of ch. 464, F.S., 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.²⁹

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.³⁰ 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.³¹

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.³² 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.³³

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.³⁴ Florida law allows a primary care physician to supervise ARNPs in up to four offices, in addition to the physician’s primary practice location.³⁵ 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.

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

²⁸ *Supra* note 12.

²⁹ 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.

³⁰ Section 464.003(3), F.S.

³¹ Section 464.003(2), F.S.

³² Section 464.012(2), F.S.

³³ 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.

³⁴ 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.

³⁵ Sections 458.348(4) and 459.025(3), F.S.

- 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
- Perform additional functions determined by rule.³⁷

All ARNPs must carry malpractice insurance or demonstrate proof of financial responsibility.³⁸ An applicant for certification is required to submit proof of coverage or financial responsibility within sixty days of certification and with each biennial renewal.³⁹ 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 \$300,000.⁴⁰

Effect of Proposed Changes

The bill prohibits anyone other than a licensed physician, PA, or ARNP from performing hair restoration or transplant services, or making any incision for the purpose of performing hair restoration or transplant services. The bill defines “hair restoration or transplant” as a surgical procedure that extracts or removes hair follicles from one location on an individual living human body for the purpose of redistributing the hair follicles to another location of the body.

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

B. SECTION DIRECTORY:

Section 1. Creates s. 458.352, F.S., relating to hair restoration or transplant.

Section 2. Creates s. 459.027, F.S., relating to hair restoration or transplant.

Section 3. 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:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

³⁶ Rule 64B9-4.010, F.A.C.

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 Section 456.048, F.S.

³⁹ Rule 64B9-4.002(5), F.A.C.

⁴⁰ *Id.*

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES