

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL: CS/SB 1324

INTRODUCER: Health Policy Committee and Senator Garcia

SUBJECT: Hair Restoration or Transplant

DATE: March 28, 2017

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Stovall	HP	Fav/CS
2.	_____	_____	AHS	_____
3.	_____	_____	AP	_____

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1324 prohibits anyone other than a physician or physician assistant (PA), licensed under the medical or osteopathic practice act, or an advanced registered nurse practitioner (ARNP) from performing a hair restoration or transplant, or making incisions for the purpose of performing a hair restoration or transplant.

The bill defines “hair restoration or transplant” as a surgical procedure that removes hair follicles from one location on a living human body to another location on the same body by:

- Coring with a hollow punch or a robotic instrument and removing the tissue,
- Removing or dissecting a strip of tissue from the body containing hair follicles that may be dissected off the strip, or
- Extracting or removing hair follicles.

The bill affirmatively states that it does not restrict a physician’s ability to delegate or supervise an ARNP or a PA in the performance of hair restoration or transplant services.

The bill has no fiscal impact on state government.

The bill provides an effective date of July 1, 2017.

II. Present Situation:

Hair Restoration Procedures

There are several techniques a physician can employ to restore hair to bald or balding portions of the human scalp. The most recently developed procedure is the follicular unit transplant. This procedure involves the removal of a strip of tissue from the donor area of a patient's scalp, which is then divided into a number of individual follicular units. The physician then grafts the individual follicular units into tiny holes made in the bald area of the scalp, called recipient sites.¹

Another type of hair restoration procedure is the bald scalp reduction procedure. As implied by the name, a bald scalp reduction procedure entails the removal of a bald area of the patient's scalp, and hair-producing areas of the scalp are stretched to cover the area removed. A similar procedure, the scalp flap surgery, involves the cutting and grafting of an entire flap of hair-producing scalp onto a bald area of the scalp. Both bald scalp reduction and scalp flap surgeries can have rapid results, but the follicular unit transplant surgery is generally preferred due to the more natural look produced and the risk of scarring or failure inherent with bald scalp reduction and scalp flap surgeries.²

Tissue or scalp expansion procedures can also be used to restore bald areas of the scalp. Tissue expansion uses a balloon, called an expander, to stretch the skin in order to create extra skin, which can be removed and grafted onto the bald area. Tissue expansion can be used for scalp repair since the stretched skin on the scalp retains normal hair growth.³

Regulation of Physician Assistants in Florida

Chapter 458, F.S., provides for the regulation of the practice of medicine by the Board of Medicine. Chapter 459, F.S., similarly provides for the regulation of the practice of osteopathic medicine by the Board of Osteopathic Medicine. Physician assistants are regulated by both boards. Licensure of PAs is overseen jointly by the boards through the Council on Physician Assistants.⁴

Physician assistants are trained and required by statute to work under the supervision and control of medical physicians or osteopathic physicians.⁵ The Board of Medicine and the Board of Osteopathic Medicine have adopted rules that set out the general principles a supervising

¹ Bernstein Medical Center for Hair Restoration, *Follicular Unit Transplant* (updated June 6, 2014) available at <http://www.bernsteinmedical.com/fut-hair-transplant/>, (last visited on March 21, 2017).

² Foundation for Hair Restoration, *Bald Scalp Reduction and Scalp Flap Surgery: A Historical Perspective* <http://www.foundhair.com/pages/baldScalp.shtml>, (last visited on Mar. 21, 2017).

³ University of Pittsburgh Medical Center, Children's Hospital of Pittsburgh, *Tissue Expansion* <http://www.chp.edu/our-services/plastic-surgery/patient-procedures/tissue-expansion>, (last visited on Mar. 17, 2017).

⁴ The council on Physician Assistants consists of three physicians who are members of the Board of Medicine; one physician who is a member of the Board of Osteopathic Medicine; and a physician assistant appointed by the State Surgeon General. See ss. 458.347(9) and 459.022(9), F.S.

⁵ Sections 458.347(4) and 459.022(4), F.S.

physician must use in developing the scope of practice of the PA under both direct⁶ and indirect⁷ supervision.

A supervising physician's decision to permit a PA to perform a task or procedure under direct or indirect supervision must be based on reasonable medical judgment regarding the probability of morbidity and mortality to the patient. The supervising physician must be certain that the PA is knowledgeable and skilled in performing the tasks and procedures assigned.⁸ Each physician or group of physicians supervising a licensed PA must be qualified in the medical areas in which the PA is to perform and must be individually or collectively responsible and liable for the performance and the acts and omissions of the PA.⁹

Regulation of Advanced Registered Nurse Practitioners in Florida

Chapter 464, F.S., governs the licensure and regulation of nurses in Florida. Nurses are licensed by the Department of Health and are regulated by the Board of Nursing (BON).¹⁰ An ARNP is a licensed nurse who is certified in advanced or specialized nursing.¹¹ Florida recognizes three types of ARNPs: nurse practitioner (NP), certified registered nurse anesthetist (CRNA), and certified nurse midwife (CNM).¹²

To be certified as an ARNP, a nurse must hold a current license as a registered nurse¹³ and submit proof to the BON that he or she meets one of the following requirements:¹⁴

- Satisfactory completion of a formal post-basic educational program of specialized or advanced nursing practice;
- Certification by an appropriate specialty board;¹⁵ or
- Graduation from a master's degree program in a nursing clinical specialty area with preparation in specialized practitioner skills.

Advanced or specialized nursing functions may only be performed under a protocol with a supervising physician or dentist. Within the established framework of the protocol, an ARNP may:¹⁶

⁶ "Direct supervision" requires the physician to be on the premises and immediately available. See Rules 64B8-30.001(4) and 64B15-6.001(4), F.A.C.

⁷ "Indirect supervision" refers to the easy availability of the supervising physician to the PA, which includes the ability to communicate by telecommunications, and requires the physician to be within reasonable physical proximity. See Rules 64B8-30.001(5) and 64B15-6.001(5), F.A.C.

⁸ Rules 64B8-30.012(2) and 64B15-6.010(2), F.A.C.

⁹ Sections 458.347(3) and 459.022(3), F.S.

¹⁰ The BON is comprised of 13 members appointed by the Governor and confirmed by the Senate who serve 4-year terms. See s. 464.004, F.S.

¹¹ "Advanced or specialized nursing practice" is defined as the performance of advanced-level nursing acts approved by the BON, which by virtue of post-basic specialized education, training, and experience, are appropriately performed by an advanced registered nurse practitioner. See s. 464.003(2) and (3), F.S.

¹² Section 464.003(3), F.S. Florida certifies clinical nurse specialists as a category distinct from advanced registered nurse practitioners. See ss. 464.003(7) and 464.0115, F.S.

¹³ Also referred to as "practice of professional nursing," which is defined in s. 464.003(20), F.S.

¹⁴ Section 464.012(1), F.S.

¹⁵ Specialty boards expressly recognized by the BON are set forth in Rule 64B9-4.002(2), F.A.C.

¹⁶ Section 464.012(3), F.S.

- Prescribe, dispense, administer or order any drug;¹⁷
- Initiate appropriate therapies for certain conditions;
- Perform additional functions as may be determined by rule;¹⁸
- Order diagnostic tests and physical and occupational therapy; and
- Order any medication for a patient in a hospital, ambulatory surgical center, or nursing home.

Chapter 464, F.S., further describes additional functions that may be performed within an ARNP's specialty certification (CRNA, CNM, and NP).¹⁹

An ARNP must meet financial responsibility requirements, as determined by rule of the BON, and the practitioner profiling requirements.²⁰ The BON requires 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 in the same amounts payable to the ARNP.²¹

Regulation of Hair Restoration Procedures in Florida

Currently, there are no provisions under chs. 458 or 459, F.S., that define "hair restoration or transplant" or provide guidelines on who may perform a hair restoration or transplant procedure.

III. Effect of Proposed Changes:

This bill creates new sections of Florida Statutes relating to hair restoration or transplant in the medical practice act, ch. 458, F.S., and the osteopathic medical practice act, ch. 459, F.S. The bill defines hair restoration or transplant to mean a surgical procedure that removes hair follicles from the body by coring with a hollow punch and removing the tissue²² or robotic instrument,²³ by removing or dissecting a strip of tissue from the body containing hair follicles that may be dissected off the strip,²⁴ or by extracting or removing hair follicles from one location on a living person's body to another location on that person's body.

The bill prohibits anyone other than a physician, PA, or an ARNP from performing a hair restoration or transplant or making incisions for the purpose of performing a hair restoration or transplant. The bill affirmatively states that it does not restrict a physician's ability to delegate or supervise an ARNP or a PA in the performance of hair restoration or transplant services.

¹⁷ However, an ARNP may prescribe or dispense controlled substances as defined in s. 893.03, F.S., only if he or she has graduated from a program leading to a master's or doctoral degree in a clinical nursing specialty area with training in specialized practitioner skills. *See* s. 464.012(3)(a), F.S.

¹⁸ An ARNP may perform acts of nursing diagnosis and nursing treatment for alterations in a patient's health status. The ARNP may also perform acts of medical diagnosis and treatment, prescription, and operation as authorized within the framework of his or her established supervisory protocol. *See* s. 464.003(2), F.S.

¹⁹ Section 464.012(4), F.S.

²⁰ Sections 456.0391, 456.041, and 456.048, F.S.

²¹ Rule 64B9-4.002(5), F.A.C.

²² *See* Bernstein Medical Center for Hair Restoration, *Follicular Unit Transplantation (FUT)*, available at <https://www.bernsteinmedical.com/robotic-hair-transplant/> (last visited March 27, 2017), describing coring with hollow punch and dissection of follicles off a tissue strip.

²³ Coring with a hollow punch or robotic instrument are two surgical methods of harvesting hair plugs from one area of the body to be transplanted to another part of the human body. *See* Bernstein Medical Center for Hair Restoration, *Robotic FUE Hair Transplants*, available at: <https://www.bernsteinmedical.com/robotic-hair-transplant/>, (last visited March 27, 2017).

²⁴ *Supra* note 22.

However, the effect of the bill is to restrict a physician from delegating certain aspects of a hair transplant or hair restoration surgery to anyone other than a licensed PA or an ARNP.

The bill has no fiscal impact on state government.

The effective date of the bill is July 1, 2017.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Only licensed physicians, or PAs under the medical practice act or osteopathic practice act, and ARNPs, may perform a hair restoration or transplant. This may impact operations for some medical practices.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates the following sections of the Florida Statutes: 458.352 and 459.027.

IX. Additional Information:

- A. **Committee Substitute – Substantial :**
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on March 27, 2017:

The CS expands the definition of hair restoration or transplant to include surgical procedures that removes hair follicles from the body by coring with a hollow punch and removing the tissue or robotic instrument, or by removing or dissecting a strip of tissue from the body containing hair follicles that may be dissected off the strip of tissue.

The CS affirmatively states that it does not restrict a physician’s ability to delegate or supervise an ARNP or a PA in the performance of hair restoration or transplant services.

- B. **Amendments:**

None.