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LEGISLATIVE ACTION

Senate . House

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The Committee on Health Policy (Massullo) recommended the following:

Senate Amendment

Delete lines 87 - 216

and insert:

(c) "Stem cell therapy" means a treatment involving the use of human cells, tissues, or cellular or tissue-based products which complies with the regulatory requirements provided in this section. The term does not include treatment or research using human cells or tissues that were derived from a fetus or an embryo after an abortion.

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(3)(a) A podiatric physician may perform stem cell therapy that is not approved by the United States Food and Drug Administration if such therapy is used for treatment or procedures that are within the scope of practice for such podiatric physician and the therapies are related to orthopedics, wound care, or pain management.

(b) To ensure that the retrieval, manufacture, storage, and use of stem cells used for therapies conducted under this section meet the highest standards, any stem cells used by a podiatric physician for therapy provided under this section must meet all of the following conditions:

1. Be retrieved, manufactured, and stored in a facility that is registered and regulated by the United States Food and Drug Administration.

2. Be retrieved, manufactured, and stored in a facility that is certified or accredited by one of the following entities:

a. The National Marrow Donor Program.

b. The World Marrow Donor Association.

c. The Association for the Advancement of Blood and Biotherapies.

d. The American Association of Tissue Banks.

3. Contain viable or live cells upon post-thaw analysis and be included in a post-thaw viability analysis report for the product lot which will be sent to the podiatric physician before use with the podiatric physician’s patient.

(c) A podiatric physician performing stem cell therapy may obtain stem cells for therapies from a facility engaging in the retrieval, manufacture, or storage of stem cells intended for

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human use under this section only if the facility maintains valid certification or accreditation as required by this subsection. Any contract or other agreement by which a podiatric physician obtains stem cells for therapies from such a facility must include the following:

1. A requirement that the facility provide all of the following information to the podiatric physician:

a. The name and address of the facility.

b. The certifying or accrediting organization.

c. The type and scope of certification or accreditation.

d. The effective and expiration dates of the certification or accreditation.

e. Any limitations or conditions imposed by the certifying or accrediting organization.

2. A requirement that the facility notify the podiatric physician within 30 days after any change in certification or accreditation status, including renewal, suspension, revocation, or expiration.

(4) In the performance of any procedure using or purporting to use stem cells or products containing stem cells, the podiatric physician shall use stem cell therapy products obtained from facilities that adhere to the applicable current good manufacturing practices for the collection, removal, processing, implantation, and transfer of stem cells, or products containing stem cells, pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.; and 21 C.F.R. part 1271, Human Cells, Tissues, and Cellular and Tissue-Based Products.

(5)(a) A podiatric physician who conducts stem cell therapy

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pursuant to this section shall include the following in any form of advertisement:

THIS NOTICE MUST BE PROVIDED TO YOU UNDER FLORIDA LAW. This podiatric physician performs one or more stem cell therapies that have not yet been approved by the United States Food and Drug Administration. You are encouraged to consult with your primary care provider before undergoing any stem cell therapy.

(b) The notice required under paragraph (a) must be clearly legible and in a type size no smaller than the largest type size used in the advertisement.

(6)(a) A podiatric physician who conducts stem cell therapy pursuant to this section shall obtain a signed consent form from the patient before performing the stem cell therapy.

(b) The consent form must be signed by the patient or, if the patient is not legally competent, the patient's representative and must state all of the following in language the patient or his or her representative may reasonably be expected to understand:

1. The nature and character of the proposed treatment.

2. That the proposed stem cell therapy has not yet been approved by the United States Food and Drug Administration.

3. The anticipated results of the proposed treatment.

4. The recognized serious possible risks, complications, and anticipated benefits involved in the treatment and in the recognized possible alternative forms of treatment, including nontreatment.

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5. That the patient is encouraged to consult with his or her primary care provider before undergoing any stem cell therapy.

(7) This section does not apply to the following:

(a) A podiatric physician who has obtained approval for an investigational new drug or device from the United States Food and Drug Administration for the use of human cells, tissues, or cellular or tissue-based products; or

(b) A podiatric physician who performs stem cell therapy under an employment or other contract on behalf of an institution certified or accredited by any of the following:

1. The Foundation for the Accreditation of Cellular Therapy.

2. The Blood and Marrow Transplant Clinical Trials Network.

3. The Association for the Advancement of Blood and Biotherapies.

(8) A violation of this section may subject the podiatric physician to disciplinary action by the board.

(9) A podiatric physician who willfully performs, or actively participates in, the following commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, and is subject to disciplinary action under this chapter and s. 456.072:

(a) Treatment or research using human cells or tissues derived from a fetus or an embryo after an abortion; or

(b) The sale, manufacture, or distribution of computer products created using human cells, tissues, or cellular or tissue-based products.

(10) The board may adopt rules necessary to implement this

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section.

Section 3. This act shall take effect upon becoming a law.