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LEGISLATIVE ACTION

| Senate | . | House |
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| Comm: RCS | . | |
| 02/11/2026 | . | |
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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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11 (3) (a) A podiatric physician may perform stem cell therapy
12 that is not approved by the United States Food and Drug
13 Administration if such therapy is used for treatment or
14 procedures that are within the scope of practice for such
15 podiatric physician and the therapies are related to
16 orthopedics, wound care, or pain management.

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

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

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

28 a. The National Marrow Donor Program.

29 b. The World Marrow Donor Association.

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

32 d. The American Association of Tissue Banks.

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

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



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

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

47 a. The name and address of the facility.

48 b. The certifying or accrediting organization.

49 c. The type and scope of certification or accreditation.

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

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

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

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

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



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

71
72 THIS NOTICE MUST BE PROVIDED TO YOU UNDER FLORIDA LAW.
73 This podiatric physician performs one or more stem
74 cell therapies that have not yet been approved by the
75 United States Food and Drug Administration. You are
76 encouraged to consult with your primary care provider
77 before undergoing any stem cell therapy.

78
79 (b) The notice required under paragraph (a) must be clearly
80 legible and in a type size no smaller than the largest type size
81 used in the advertisement.

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

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

90 1. The nature and character of the proposed treatment.

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

93 3. The anticipated results of the proposed treatment.

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



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

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

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

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

109 1. The Foundation for the Accreditation of Cellular
110 Therapy.

111 2. The Blood and Marrow Transplant Clinical Trials Network.

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

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

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

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

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

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



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127 section.

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