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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/18/2026	.	
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The Appropriations Committee on Health and Human Services
(Massullo) recommended the following:

Senate Amendment (with title amendment)

Delete lines 43 - 188

and insert:

461.011 Cellular and tissue-based products.-

(1) The Legislature recognizes the significant potential of
cellular and tissue-based products in advancing medical
treatments and improving patient outcomes and further recognizes
the need to ensure that such treatments are provided using
cellular or tissue-based products obtained in an ethical manner



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11 that does not involve cells derived from aborted fetuses. It is
12 the intent of the Legislature to foster medical innovation while
13 upholding ethical standards that respect the sanctity of life.
14 By encouraging the use of cellular or tissue-based products, the
15 state will advance regenerative medicine in a manner consistent
16 with the values of the state.

17 (2) As used in this section, the term:

18 (a) "Cellular or tissue-based products" means products
19 containing or consisting of human cells or tissues which are
20 intended for implantation, transplantation, infusion, or
21 transfer into a human recipient. The term does not include:

22 1. Vascularized human organs for transplantation;

23 2. Whole blood or blood components or blood derivative
24 products;

25 3. Secreted or extracted human products, such as milk,
26 collagen, and cell factors, other than semen;

27 4. Minimally manipulated bone marrow for homologous use and
28 not combined with another article other than water,
29 crystalloids, or a sterilizing, preserving, or storage agent, if
30 the addition of the agent does not raise new clinical safety
31 concerns with respect to the bone marrow;

32 5. Ancillary products used in the manufacture of human
33 cells, tissues, or cellular or tissue-based products;

34 6. Cells, tissues, and organs derived from animals;

35 7. In vitro diagnostic products;

36 8. Blood vessels recovered with an organ which are intended
37 for use in organ transplantation and labeled "For use in organ
38 transplantation only"; or

39 9. Harvesting and reimplantation of autologous tissue.



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- 40 (b) "Minimally manipulated" means:
- 41 1. For structural tissue, processing that does not alter
- 42 the original relevant characteristics of the tissue relating to
- 43 the tissue's utility for reconstruction, repair, or replacement.
- 44 2. For cells or nonstructural tissues, processing that does
- 45 not alter the relevant biological characteristics of cells or
- 46 tissues.
- 47 (c) "Procedure using cellular or tissue-based products"
- 48 means a treatment involving the use of human cells, tissues, or
- 49 cellular or tissue-based products which complies with the
- 50 regulatory requirements provided in this section. The term does
- 51 not include treatment or research using human cells or tissues
- 52 derived from a fetus or an embryo after an abortion.
- 53 (3) (a) A podiatric physician may perform a procedure using
- 54 cellular or tissue-based products that are not approved by the
- 55 United States Food and Drug Administration if such products are
- 56 used for treatment or procedures within the scope of practice
- 57 for such podiatric physician and the treatment or procedures are
- 58 related to connective tissue, ligament, and tendon repair; wound
- 59 care; or pain management.
- 60 (b) To ensure that the retrieval, manufacture, storage, and
- 61 use of any cellular or tissue-based products pursuant to this
- 62 section meet the highest standards, any cellular or tissue-based
- 63 products used by a podiatric physician for a procedure provided
- 64 under this section must meet all of the following conditions:
- 65 1. Be retrieved, manufactured, and stored in a facility
- 66 that is registered and regulated by the United States Food and
- 67 Drug Administration.
- 68 2. Be retrieved, manufactured, and stored in a facility



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69 that is certified or accredited by one of the following
70 entities:

71 a. The National Marrow Donor Program.

72 b. The World Marrow Donor Association.

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

75 d. The American Association of Tissue Banks.

76 3. Contain viable or live cells upon post-thaw analysis and
77 be included in a post-thaw viability analysis report for the
78 product lot, which must be sent to the podiatric physician
79 before use with the podiatric physician's patient.

80 (4) (a) A podiatric physician who performs a procedure using
81 cellular or tissue-based products pursuant to this section shall
82 include the following in any form of advertisement:

83
84 THIS NOTICE MUST BE PROVIDED TO YOU UNDER FLORIDA LAW.
85 This podiatric physician performs procedures using
86 cellular or tissue-based products that have not yet
87 been approved by the United States Food and Drug
88 Administration. You are encouraged to consult with
89 your primary care provider before undergoing any
90 procedure using these products.

91
92 (b) The notice required under paragraph (a) must be clearly
93 legible and in a type size no smaller than the largest type size
94 used in the advertisement.

95 (5) (a) A podiatric physician who performs a procedure using
96 cellular or tissue-based products pursuant to this section shall
97 obtain a signed consent form from the patient before performing



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98 the procedure.

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

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

105 2. That the proposed procedure uses cellular or tissue-
106 based products that have not yet been approved by the United
107 States Food and Drug Administration.

108 3. The anticipated results of the proposed treatment.

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

113 5. That the patient is encouraged to consult with his or
114 her primary care provider before undergoing the procedure.

115 (6) This section does not apply to the following:

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

120 (b) A podiatric physician who performs procedures using
121 cellular or tissue-based products

122
123 ===== T I T L E A M E N D M E N T =====

124 And the title is amended as follows:

125 Delete lines 8 - 21

126 and insert:



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127 perform procedures using cellular or tissue-based
128 products not approved by the United States Food and
129 Drug Administration under certain circumstances;
130 specifying requirements for the cellular or tissue-
131 based products that may be used by such podiatric
132 physicians; requiring such podiatric physicians to
133 include a specified notice in any form of
134 advertisement; specifying requirements for such
135 notice; requiring podiatric physicians to obtain a
136 signed consent form from the patient or his or her
137 representative before performing procedures using
138 cellular or tissue-based products; specifying
139 requirements for the consent form;