

By Senator Hutson

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1 A bill to be entitled
2 An act relating to nonembryonic stem cells; creating
3 s. 381.4017, F.S.; providing legislative findings and
4 intent; providing definitions; authorizing the
5 administration of nonembryonic stem cells and the use
6 of such cells in health care products; authorizing the
7 ownership and operation of a pharmacy in the state
8 which compounds a drug, medicine, or health care
9 product using nonembryonic stem cells; authorizing the
10 importation of any sterile compound, drug, or other
11 treatment containing nonembryonic stem cells under
12 certain circumstances; authorizing certain licensed
13 persons to administer or assist in the administration
14 of such compounds, drugs, or other treatment;
15 authorizing the operation of stem cell banks in the
16 state; requiring a stem cell bank to register with the
17 Department of Health; providing requirements for a
18 department-approved registration form; requiring a
19 stem cell bank to notify the department of any changes
20 in information within a specified time period;
21 requiring a stem cell bank to obtain or otherwise
22 carry professional liability insurance; providing that
23 a professional licensing board is not limited in its
24 duties; providing liability for persons who fail to
25 use reasonable care; requiring that the department
26 adopt by rule standards developed by an independent
27 third party; providing an effective date.

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29 Be It Enacted by the Legislature of the State of Florida:

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Section 1. Section 381.4017, Florida Statutes, is created to read:

381.4017 Nonembryonic stem cells; stem cell bank registration.-

(1) The Legislature finds that access to safe and high-quality health care services and products is of concern to all persons and regenerative medicine, including the use of nonembryonic stem cells, is a promising area of health care. It is the intent of the Legislature to encourage and facilitate the safety of all health care services and products.

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

(a) "Allogeneic" means originating from the body of another person.

(b) "Autologous" means originating from within a person's own body.

(c) "Department" means the Department of Health.

(d) "Independent third party" means an organization:

1. That provides industry safety standards, relevant research, and an industry-specific database in association with one or more stem cell banks; and

2. Whose members are registered with the department.

(e) "Nonembryonic stem cells" means autologous or allogeneic cellular material that:

1. Has not been isolated or obtained directly from human embryos; and

2. May have been or may be combined with one or more:

a. Naturally occurring biomaterials; or

b. Materials approved or cleared by the United States Food

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59 and Drug Administration or other applicable agency or authority.

60 (f) "Stem cell bank" means a facility that stores
61 nonembryonic stem cells.

62 (3) Nonembryonic stem cells may be administered to a person
63 by:

64 (a) Himself or herself; or

65 (b) A person licensed or authorized in this state to
66 administer or assist in the administration of medicine or health
67 care if such person administers or assists in the administration
68 of the nonembryonic stem cells using a mode of administration
69 permitted under his or her license or authorization.

70 (4) A health care product may be compounded using
71 nonembryonic stem cells as a sterile ingredient either by
72 themselves or in combination with other sterile ingredients. A
73 pharmacy that compounds a drug, medicine, or health care product
74 using nonembryonic stem cells may be owned or operated, or both,
75 in this state.

76 (5) (a) A person may import into this state any sterile
77 compound, drug, or other treatment containing nonembryonic stem
78 cells if such compound, drug, or other treatment:

79 1. Was obtained without violating the laws of the
80 jurisdiction in which it was obtained; and

81 2. Is for personal use.

82 (b) A person licensed or authorized in this state to
83 administer or assist in the administration of medicine or health
84 care may administer or assist in the administration of the
85 imported sterile compound, drug, or other treatment containing
86 nonembryonic stem cells if such person administers or assists in
87 the administration of such compound, drug, or other treatment

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88 using a mode of administration permitted under his or her
89 license or authorization.

90 (6) (a) Notwithstanding any other provision of law, a stem
91 cell bank may operate in this state.

92 (b) Before organizing or arranging for the operation of a
93 stem cell bank in this state, a stem cell bank must register
94 with the department by submitting a department-approved
95 registration form that contains:

96 1. The name, street address, and telephone number of the
97 stem cell bank.

98 2. The name, street address, and telephone number of each
99 officer, director, or organizational official of the stem cell
100 bank who is responsible for the operation of the stem cell bank.

101 3. Identification of the types of human tissue used in
102 business or research at the stem cell bank.

103 4. Identification of the product names produced at the stem
104 cell bank for distribution.

105 5. Any other information required for registration by the
106 department.

107 (c) Each stem cell bank shall notify the department in
108 writing of any change in the information required for
109 registration not later than 10 days after such change goes into
110 effect.

111 (d) Each stem cell bank that operates in this state must
112 obtain or otherwise carry, before engaging in such business, a
113 policy of professional liability insurance that insures the stem
114 cell bank against any liability arising from the operation of
115 such business.

116 (7) This section does not absolve:

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117 (a) A professional licensing board of the duty to regulate
118 licenses or otherwise prohibit or limit the powers and duties of
119 a licensing board to regulate the procedures used to administer
120 nonembryonic stem cells.

121 (b) Any person of civil or criminal liability or penalty
122 for failure to use the reasonable care, skill, or knowledge
123 ordinarily used in rendering health care services or
124 administering health care products under similar circumstances.

125 (8) The department shall adopt by rule standards developed
126 by an independent third party to ensure public safety and to
127 implement this section.

128 Section 2. This act shall take effect July 1, 2020.