

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.

28 |  
 29 | Be It Enacted by the Legislature of the State of Florida:

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

33 |       381.4017 Nonembryonic stem cells; stem cell bank  
 34 | registration.—

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

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

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

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

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

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

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

51           2. Whose members are registered with the department.  
 52           (e) "Nonembryonic stem cells" means autologous or  
 53 allogeneic cellular material that:  
 54           1. Has not been isolated or obtained directly from human  
 55 embryos; and  
 56           2. May have been or may be combined with one or more:  
 57           a. Naturally occurring biomaterials; or  
 58           b. Materials approved or cleared by the United States Food  
 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  
 63 person 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  
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  
 104 stem 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:

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

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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.