

1 A bill to be entitled
2 An act relating to stem cells; creating s. 385.301,
3 F.S.; defining terms; requiring the Department of
4 Health to adopt rules by a specified date; providing
5 patient eligibility; requiring eligible patients to
6 sign a written informed consent prior to receiving an
7 investigational stem cell treatment; authorizing the
8 department to adopt a form by rule for the informed
9 consent; requiring an investigational stem cell
10 treatment to be administered directly by a licensed
11 and certified physician, overseen by an institutional
12 review board, and provided at a certain facility;
13 providing construction; prohibiting a licensing board
14 from taking action against a physician's license under
15 certain circumstances; prohibiting a state entity
16 responsible for Medicare certification from taking
17 action against a physician's Medicare certification
18 under certain circumstances; prohibiting a state
19 entity from interfering with an eligible patient's
20 access to or use of a stem cell treatment; requiring
21 institutional review boards to keep records on the
22 treatment of each patient; requiring each
23 institutional review board to submit an annual report
24 analyzing patient records to the Board of Medicine and
25 the Board of Osteopathic Medicine; requiring that the

26 | report exclude the personal identifying information of
 27 | patients and that it be made available to the public
 28 | in both written and electronic form; amending s.
 29 | 873.01, F.S; clarifying that the purchase or sale of
 30 | stem cells is a felony; providing an effective date.
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32 | Be It Enacted by the Legislature of the State of Florida:
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34 | Section 1. Section 385.301, Florida Statutes, is created
 35 | to read:

36 | 385.301 Investigational stem cell treatments.-

37 | (1) DEFINITIONS.-As used in this section, the term:

38 | (a) "Department" means the Department of Health.

39 | (b) "Institutional review board" means a board that:

40 | 1. Is affiliated with a hospital licensed under chapter
 41 | 395 which has at least 150 beds or an accredited medical school;

42 | and

43 | 2. Has been approved by the department to certify the
 44 | physician administration of and to oversee an investigational
 45 | stem cell treatment in compliance with this section.

46 | (c) "Investigational stem cell treatment" means an adult
 47 | stem cell treatment that:

48 | 1. Is under an investigation in a clinical trial approved
 49 | by the United States Food and Drug Administration;

50 | 2. Is being administered to human participants in the

51 clinical trial; and

52 3. Has not been approved for general use by the United
53 States Food and Drug Administration.

54 (d) "Severe chronic disease" means a condition, injury, or
55 illness that:

56 1. May be treated;

57 2. Is never cured or eliminated; and

58 3. Entails significant functional impairment or severe
59 pain.

60 (e) "Terminal illness" means an advanced stage of a
61 disease with an unfavorable prognosis that, without life-
62 sustaining procedures, will soon result in death or a state of
63 permanent unconsciousness from which recovery is unlikely.

64 (2) RULEMAKING.—No later than January 1, 2020, the
65 department shall adopt rules designating the medical conditions
66 that constitute a severe chronic disease or terminal illness for
67 purposes of this section, rules regarding institutional review
68 boards, and any other rules necessary to administer this
69 section.

70 (3) PATIENT ELIGIBILITY.—A patient is eligible to access
71 and use an investigational stem cell treatment under this
72 section if:

73 (a) The patient has been diagnosed by his or her treating
74 physician with a severe chronic disease or terminal illness;

75 (b) The physician, in consultation with the patient, has

76 considered all other treatment options currently approved by the
77 United States Food and Drug Administration and determined that
78 those treatment options are unavailable or unlikely to alleviate
79 the significant impairment or severe pain associated with the
80 severe chronic disease or terminal illness; and

81 (c) The physician has recommended or prescribed in writing
82 that the patient use a specific class of investigational stem
83 cell treatment.

84 (4) INFORMED CONSENT.—

85 (a) An eligible patient must sign a written informed
86 consent before receiving an investigational stem cell treatment.

87 (b) If the eligible patient is a minor or lacks the mental
88 capacity to provide informed consent, a parent, guardian, or
89 conservator may provide informed consent on the patient's
90 behalf.

91 (c) The department may adopt a form by rule for the
92 informed consent required under this section.

93 (5) TREATMENT REQUIREMENTS.—

94 (a) Treatment provided under this section must be:

95 1. Administered directly by a physician licensed under
96 chapter 458 or chapter 459 who is certified by an institutional
97 review board to provide such treatment;

98 2. Overseen by an institutional review board; and

99 3. Provided at a hospital or ambulatory surgical center
100 licensed under chapter 395 or an accredited medical school.

101 (b) A physician administering an investigational stem cell
102 treatment under this section shall comply with all applicable
103 Board of Medicine or Board of Osteopathic Medicine rules.

104 (6) EFFECT ON OTHER LAW.—

105 (a) This section does not expand the coverage that an
106 insurer must provide under the Florida Insurance Code and does
107 not affect mandatory health coverage for participation in
108 clinical trials.

109 (b) This section does not authorize a person to sell a
110 human organ or tissue in violation of s. 873.01.

111 (7) ACTION AGAINST PHYSICIAN'S LICENSE PROHIBITED;
112 MEDICARE.—A licensing board may not revoke, fail to renew,
113 suspend, or take any action against a physician's license issued
114 under chapter 458 or chapter 459 based solely on the physician's
115 recommendations to an eligible patient regarding access to or
116 use of an investigational stem cell treatment. A state entity
117 responsible for Medicare certification may not take action
118 against a physician's Medicare certification based solely on the
119 physician's recommendation that an eligible patient access or
120 use an investigational stem cell treatment.

121 (8) GOVERNMENTAL INTERFERENCE PROHIBITED.—A state entity
122 or an officer, employee, or agent of a governmental entity may
123 not interfere with an eligible patient's access to or use of a
124 stem cell treatment authorized under this section.

125 (9) INSTITUTIONAL REVIEW BOARD RECORDS; REPORT.—

126 (a) An institutional review board overseeing an
127 investigational stem cell treatment under this section shall
128 keep a record on each patient to whom a physician administers
129 the treatment and document in the record the provision of each
130 treatment and the effects of the treatment on the patient
131 throughout the period the treatment is administered to the
132 patient.

133 (b) Each institutional review board overseeing an
134 investigational stem cell treatment under this section shall
135 submit an annual report to the Board of Medicine and the Board
136 of Osteopathic Medicine which analyzes the patient records
137 described in paragraph (a). A report may not include the
138 personal identifying information of any patient and must be made
139 available to the public in both written and electronic form.

140 Section 2. Subsection (3) of section 873.01, Florida
141 Statutes, is amended, and subsections (1), (2), and (4) of that
142 section are republished, to read:

143 873.01 Purchase or sale of human organs and tissue
144 prohibited.—

145 (1) No person shall knowingly offer to purchase or sell,
146 or purchase, sell, or otherwise transfer, any human organ or
147 tissue for valuable consideration.

148 (2) No for-profit corporation or any employee thereof
149 shall transfer or arrange for the transfer of any human body
150 part for valuable consideration.

151 (3) (a) The human organs and tissues subject to the
152 provisions of this section are the eye, cornea, kidney, liver,
153 heart, lung, pancreas, bone, stem cells, and skin or any other
154 organ or tissue adopted by rule by the Agency for Health Care
155 Administration for this purpose.

156 (b) As used in this section, the term "valuable
157 consideration" does not include the reasonable costs associated
158 with the removal, storage, and transportation of a human organ
159 or tissue.

160 (4) A person who violates the provisions of this section
161 is guilty of a felony of the second degree, punishable as
162 provided in s. 775.082, s. 775.083, or s. 775.084.

163 Section 3. This act shall take effect July 1, 2019.