

SB299 INTRODUCED



1 SB299
2 7BT6XE2-1
3 By Senator Melson
4 RFD: Healthcare
5 First Read: 03-Apr-25



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SYNOPSIS:

This bill would permit a health care provider whose scope of practice includes stem cell therapy to perform stem cell therapy that is not approved by the United States Food and Drug Administration (FDA), provided the health care provider gives the patient written notice about the nature, anticipated results, and recognized risks of the stem cell therapy and obtains written consent before performing the therapy.

This bill would require health care providers who offer stem cell therapy in accordance with this bill to post a notice in the health care provider's office and accompanying any advertisement for the therapy stating that the therapy has not been approved by the FDA.

This bill would define the term "stem cell therapy" to include the use of afterbirth placental perinatal stem cells or human cells, tissues, or cellular or tissue-based products, but not any treatment or research using human cells or tissues that were derived from a fetus or embryo after an abortion.

This bill would provide exemptions for certain therapies which are approved for investigational use by the FDA or performed under an employment or other contract with certain entities.



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29 This bill would provide that a violation is
30 unprofessional conduct for purposes of licensure with
31 the State Board of Medical Examiners.

32 This bill would also require the State Board of
33 Medical Examiners to adopt rules.

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A BILL

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TO BE ENTITLED

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AN ACT

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40 Relating to stem cell therapy; to permit certain health
41 care providers to perform stem cell therapy that is not
42 approved by the United States Food and Drug Administration,
43 provided the health care provider meets certain notice and
44 consent requirements; to provide exceptions; to provide that a
45 violation is unprofessional conduct; and to require the State
46 Board of Medical Examiners to adopt rules.

47 BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

48 Section 1. For the purposes of this act, the following
49 terms have the following meanings:

50 (1) BOARD. The State Board of Medical Examiners.

51 (2) FDA. The United States Food and Drug
52 Administration.

53 (3) HEALTH CARE PROVIDER. An individual licensed to
54 practice medicine in this state.

55 (4) HUMAN CELLS, TISSUES, OR CELLULAR OR TISSUE-BASED
56 PRODUCTS. The same meaning as provided in 21 C.F.R. Part



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57 1271.3.

58 (5) STEM CELL THERAPY. Treatment involving the use of
59 afterbirth placental perinatal stem cells or human cells,
60 tissues, or cellular or tissue-based products. The term does
61 not include treatment or research using human cells or tissues
62 that were derived from a fetus or embryo after an abortion.

63 Section 2. (a) A health care provider whose scope of
64 practice includes the use of stem cell therapy may perform a
65 stem cell therapy that is not approved by the FDA if the
66 health care provider satisfies both of the following
67 requirements before performing the stem cell therapy:

68 (1) Provides the patient with written notice as
69 provided in Section 3.

70 (2) Obtains a signed consent form from the patient.

71 (b) The consent form required by subsection (a) shall
72 be signed by the patient or, if the patient is legally not
73 competent, the patient's representative and shall state all of
74 the following in language the patient could reasonably be
75 expected to understand:

76 (1) The nature and character of the proposed treatment,
77 including the treatment's FDA approval status.

78 (2) The anticipated results of the proposed treatment.

79 (3) The recognized possible alternative forms of
80 treatment.

81 (4) The recognized serious possible risks,
82 complications, and anticipated benefits involved in the: (i)
83 treatment; (ii) recognized possible alternative forms of
84 treatment; and (iii) nontreatment.



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85 Section 3. (a) The written notice required by Section 2
86 shall read as follows: "THIS NOTICE MUST BE PROVIDED TO YOU
87 UNDER ALABAMA LAW. This health care provider performs one or
88 more stem cell therapies that have not yet been approved by
89 the United States Food and Drug Administration. You are
90 encouraged to consult with your primary care provider before
91 undergoing a stem cell therapy."

92 (b) A health care provider required to provide the
93 written notice shall comply with each of the following:

94 (1) Prominently display the written notice in the
95 entrance and in an area visible to patients in the health care
96 provider's office on paper that is at least eight and one-half
97 inches by 11 inches and written in no less than 40-point type.

98 (2) Include the written notice in any advertisement for
99 the stem cell therapy, subject to the following requirements:

100 a. In a print advertisement, the notice must be clearly
101 legible and in a font size no smaller than the largest font
102 size otherwise used in the advertisement.

103 b. In any other advertisement, the notice must be
104 clearly legible and in a font size no smaller than the largest
105 font size used in the advertisement or clearly spoken.

106 Section 4. This act does not apply to either of the
107 following:

108 (1) A health care provider who has obtained approval
109 for an investigational new drug or device from the United
110 States Food and Drug Administration for the use of human
111 cells, tissues, or cellular or tissue-based products.

112 (2) A health care provider who performs a stem cell



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113 therapy under an employment or other contract on behalf of an
114 institution certified by any of the following:

115 a. The Foundation for the Accreditation of Cellular
116 Therapy.

117 b. The Blood and Marrow Transplant Clinical Trials
118 Network.

119 c. The Association for the Advancement of Blood and
120 Biotherapies.

121 d. An entity with expertise regarding stem cell therapy
122 as determined by the board.

123 Section 5. (a) A violation of this section is deemed
124 unprofessional conduct for the purposes of Chapter 24 of Title
125 34, Code of Alabama 1975.

126 (b) The board shall adopt rules to implement and
127 enforce this act.

128 Section 6. This act shall become effective on October
129 1, 2025.