

House Bill 1275

By: Representatives Newton of the 127th, Hawkins of the 27th, Cooper of the 45th, Au of the 50th, and Taylor of the 173rd

A BILL TO BE ENTITLED
AN ACT

1 To amend Article 2 of Chapter 34 of Title 43 of the Official Code of Georgia Annotated,
2 relating to medical practice, so as to ensure that stem cell therapies are used to advance
3 medical treatments and improve patient outcomes in an ethical manner that does not involve
4 stem cells derived from aborted fetuses; to provide for definitions; to provide for the
5 designation of a physician assistant or nurse practitioner; to provide for certain requirements
6 and patient protections; to provide for notice; to provide for consent; to provide for certain
7 exceptions; to provide for the use of Georgia facilities; to provide for related matters; to
8 provide for legislative findings; to repeal conflicting laws; and for other purposes.

9 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

10 style="text-align:center">**SECTION 1.**

11 The General Assembly finds that:

- 12 (1) Significant potential of stem cell therapies in advancing medical treatments and
13 improving patient outcomes exists;
- 14 (2) Protections need to be established to ensure that such therapies are provided using
15 umbilical cord stem cells obtained in an ethical manner that does not involve stem cells
16 derived from aborted fetuses;

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17 (3) Medical innovation should be fostered while upholding ethical standards that respect
18 the sanctity of life; and

19 (4) By encouraging the use of stem cell sources such as adult stem cells; umbilical cord
20 Wharton's jelly mesenchymal stem cells; and other ethically obtained human cells, tissues,
21 or cellular or tissue based products, the state will advance regenerative medicine in a
22 manner consistent with the values of this state.

23 **SECTION 2.**

24 Article 2 of Chapter 34 of Title 43 of the Official Code of Georgia Annotated, relating to
25 medical practice, is amended by adding a new Code section to read as follows:

26 "43-34-49.

27 (a) As used in this Code section, the term:

28 (1) 'FDA' means the United States Food and Drug Administration.

29 (2) 'Human cells, tissues, or cellular or tissue based products' means articles containing
30 or consisting of human cells or tissues that are intended for implantation, transplantation,
31 infusion, or transfer into a human recipient. Such term does not include:

32 (A) Vascularized human organs for transplantation;

33 (B) Whole blood or blood components or blood derivative products;

34 (C) Secreted or extracted human products, such as milk, collagen, and cell factors,
35 other than semen; or

36 (D) Wharton's jelly extracted from donated umbilical cords.

37 (3) 'Minimally manipulated' means:

38 (A) For structural tissue, processing that does not alter the original relevant
39 characteristics of such tissue relating to the tissue's utility for reconstruction, repair, or
40 replacement; and

41 (B) For cells or nonstructural tissues, processing that does not alter the relevant
42 biological characteristics of such cells or tissues.

43 (4) 'Nurse practitioner' means a registered professional nurse licensed pursuant to
44 Article 1 of Chapter 26 of this title and authorized by the Georgia Board of Nursing to
45 engage in advanced practice registered nursing as a nurse practitioner.

46 (5) 'Physician' means a physician licensed under this article acting in the course and
47 scope of his or her employment.

48 (6) 'Physician assistant' means a person licensed as a physician assistant pursuant to
49 Article 4 of this chapter, the 'Physician Assistant Act.'

50 (7) 'Stem cell therapy' means a treatment involving the use of afterbirth placental
51 perinatal stem cells, or human cells, tissues, or cellular or tissue based products, which
52 complies with the regulatory requirements provided in this Code section. Such term shall
53 not include treatment or research using human cells or tissues that were derived from an
54 aborted fetus or embryo.

55 (8) 'Umbilical cord Wharton's jelly mesenchymal stem cells' or 'Wharton's jelly' means
56 highly potent, multipotent stem cells derived from gelatinous connective tissue
57 surrounding the umbilical cord vessels.

58 (b) A physician or, following a lawful designation from such physician, a physician
59 assistant or nurse practitioner, may perform stem cell therapy that is not approved by the
60 FDA if such therapy is used for treatment or procedures that are within the scope of
61 practice of the physician, physician assistant, or nurse practitioner, so long as the patient
62 is advised and signs a consent form.

63 (c) To ensure that the retrieval, manufacture, storage, and use of stem cells used for
64 therapies conducted under this Code section meet the highest standards, any stem cells used
65 must fall under one of the following categories:

66 (1) Be retrieved, manufactured, and stored in a facility that is located in Georgia and
67 registered with the FDA; or

68 (2) Be retrieved, manufactured, and stored in a facility located in Georgia that is certified
69 and accredited by one of the following entities:

- 70 (A) National Marrow Donor Program;
71 (B) World Marrow Donor Association;
72 (C) Association for the Advancement of Blood and Biotherapies;
73 (D) American Association of Tissue Banks; or
74 (E) Such other entity as the Department of Public Health may determine appropriate.
- 75 (d) A physician or his or her designee performing stem cell therapy shall not obtain stem
76 cells for therapies from a facility engaging in the retrieval, manufacture, or storage of stem
77 cells intended for human use under this Code section unless the facility maintains a valid
78 certification or accreditation as required by subsection (c) of this Code section.
- 79 (e) The facility described in this Code section shall notify the physician within 30 days
80 after any change in certification or accreditation status, including renewal, suspension,
81 revocation, or expiration, occurs.
- 82 (f) In the performance of any procedure using or purporting to use stem cells or products
83 containing stem cells, the physician or his or her designee shall use stem cell therapy
84 products obtained from facilities that adhere to the applicable current good manufacturing
85 practices for the collection, removal, processing, implantation, and transfer of stem cells,
86 or products containing stem cells, pursuant to the Federal Food, Drug, and Cosmetic Act,
87 21 U.S.C. Section 301, et seq.; 52 Stat. 1040 et seq.; and 21 C.F.R. Part 1271, Human
88 Cells, Tissues, and Cellular and Tissue-Based Products.
- 89 (g) A physician or his or her designee who conducts stem cell therapy pursuant to this
90 Code section shall include the following in any form of advertisement:
91 'THIS NOTICE MUST BE PROVIDED TO YOU UNDER GEORGIA LAW. This
92 physician or his or her designee performs one or more stem cell therapies that have not
93 yet been approved by the FDA. You are encouraged to consult with your primary care
94 provider before undergoing any stem cell therapy.'

- 95 (h) The notice required under subsection (g) of this Code section must be clearly legible
96 and in a type size no smaller than the largest type size used in the advertisement of the stem
97 cell therapy services being offered.
- 98 (i) A physician or his or her designee who conducts stem cell therapy pursuant to this Code
99 section shall obtain a signed consent form from the patient before performing such stem
100 cell therapy.
- 101 (j) The consent form shall be signed by the patient or if the patient is not legally
102 competent, the patient's representative, and shall state all of the following in a language the
103 patient or his or her representative may reasonably be expected to understand:
- 104 (1) The nature and character of the proposed treatment;
105 (2) The fact that the proposed stem cell therapy has not yet been approved by the FDA
106 if it has not been approved at such time; and
107 (3) The anticipated results of the proposed treatment.
- 108 (k) This Code section does not apply to the following:
- 109 (1) A physician who has obtained approval for an investigational new drug or device
110 from the FDA for the use of human cells, tissues, or cellular or tissue based products and
111 is operating under such approval; or
112 (2) A physician or his or her designee who performs stem cell therapy under an
113 employment or other contract on behalf of an institution certified or accredited by any of
114 the following:
- 115 (A) The Foundation for the Accreditation of Cellular Therapy;
116 (B) The Blood and Marrow Transplant Clinical Trials Network;
117 (C) The Association for the Advancement of Blood and Biotherapies; or
118 (D) An entity with expertise in stem cell therapy as determined by the Department of
119 Public Health.
- 120 (l) A violation of this Code section may subject the physician or his or her designee to
121 disciplinary action by the licensee's respective professional board."

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SECTION 3.

123 All laws and parts of laws in conflict with this Act are repealed.