

House Bill 1275 (COMMITTEE SUBSTITUTE)

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

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 human stem cell therapies are used to  
3 advance medical treatments and improve patient outcomes in an ethical manner that does not  
4 involve human stem cells derived from aborted fetuses; to provide for definitions; to provide  
5 for the designation of a physician assistant or nurse practitioner; to provide for certain  
6 requirements and patient protections; to provide for notice; to provide for consent; to provide  
7 for certain exceptions; to provide for the use of Georgia facilities; to provide for related  
8 matters; to provide for legislative findings; to repeal conflicting laws; and for other purposes.

9 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

10 **SECTION 1.**

11 The General Assembly finds that:

- 12 (1) Significant potential of human 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 human stem cells obtained in an ethical manner that does not involve human  
16 stem cells derived from aborted fetuses;

H. B. 1275 (SUB)

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 human stem cell sources such as adult human stem cells;  
20 umbilical cord Wharton's jelly mesenchymal human stem cells; and other ethically obtained  
21 human cells, tissues, or cellular or tissue based products, the state will advance regenerative  
22 medicine in a 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) 'Human stem cell therapy' means a treatment involving the use of afterbirth placental  
38 perinatal human stem cells, or human cells, tissues, or cellular or tissue based products,  
39 which complies with the regulatory requirements provided in this Code section. Such  
40 term shall not include treatment or research using human cells or tissues that were  
41 derived from an aborted fetus or embryo.

42 (4) 'Minimally manipulated' means:

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

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

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

51 (6) 'Physician' means a physician licensed under this article acting in the course and  
52 scope of his or her employment.

53 (7) 'Physician assistant' means a person licensed as a physician assistant pursuant to  
54 Article 4 of this chapter, the 'Physician Assistant Act.'

55 (8) 'Umbilical cord Wharton's jelly mesenchymal human stem cells' or 'Wharton's jelly'  
56 means highly potent, multipotent human stem cells derived from gelatinous connective  
57 tissue 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 human stem cell therapy that is not approved  
60 by the 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 human stem cells used  
64 for therapies conducted under this Code section meet the highest standards, any human  
65 stem cells used must fall under one of the following categories:

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

68 (2) Be retrieved, manufactured, and stored in a facility located in Georgia, another state  
69 in the United States, or another country and that is certified and accredited by one of the  
70 following entities:

71 (A) National Marrow Donor Program;

72 (B) World Marrow Donor Association;

73 (C) Association for the Advancement of Blood and Biotherapies;

74 (D) American Association of Tissue Banks; or

75 (E) Such other entity as the Department of Public Health may determine appropriate.

76 (d) A physician or his or her designee performing human stem cell therapy shall not obtain  
77 human stem cells for therapies from a facility engaging in the retrieval, manufacture, or  
78 storage of human stem cells intended for human use under this Code section unless the  
79 facility maintains a valid certification or accreditation as required by subsection (c) of this  
80 Code section.

81 (e) The facility described in this Code section shall notify the physician within 30 days  
82 after any change in certification or accreditation status, including renewal, suspension,  
83 revocation, or expiration, occurs.

84 (f) In the performance of any procedure using or purporting to use human stem cells or  
85 products containing human stem cells, the physician or his or her designee shall use human  
86 stem cell therapy products obtained from facilities that adhere to the applicable current  
87 good manufacturing practices for the collection, removal, processing, implantation, and  
88 transfer of human stem cells, or products containing human stem cells, pursuant to the  
89 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. Section 301, et seq.; 52 Stat. 1040 et  
90 seq.; and 21 C.F.R. Part 1271, Human Cells, Tissues, and Cellular and Tissue-Based  
91 Products.

92 (g) A physician or his or her designee who conducts human stem cell therapy pursuant to  
93 this Code section shall include the following in any form of advertisement:

- 94 'THIS NOTICE MUST BE PROVIDED TO YOU UNDER GEORGIA LAW. This  
95 physician or his or her designee performs one or more human stem cell therapies that  
96 have not yet been approved by the FDA. You are encouraged to consult with your  
97 primary care provider before undergoing any human stem cell therapy.'
- 98 (h) The notice required under subsection (g) of this Code section must be clearly legible  
99 and in a type size no smaller than the largest type size used in the advertisement of the  
100 human stem cell therapy services being offered.
- 101 (i) A physician or his or her designee who conducts human stem cell therapy pursuant to  
102 this Code section shall obtain a signed consent form from the patient before performing  
103 such human stem cell therapy.
- 104 (j) The consent form shall be signed by the patient or if the patient is not legally  
105 competent, the patient's representative, and shall state all of the following in a language the  
106 patient or his or her representative may reasonably be expected to understand:
- 107 (1) The nature and character of the proposed treatment;  
108 (2) The fact that the proposed human stem cell therapy has not yet been approved by the  
109 FDA if it has not been approved at such time; and  
110 (3) The anticipated results of the proposed treatment.
- 111 (k) This Code section does not apply to the following:
- 112 (1) A physician who has obtained approval for an investigational new drug or device  
113 from the FDA for the use of human cells, tissues, or cellular or tissue based products and  
114 is operating under such approval; or  
115 (2) A physician or his or her designee who performs human stem cell therapy under an  
116 employment or other contract on behalf of an institution certified or accredited by any of  
117 the following:
- 118 (A) The Foundation for the Accreditation of Cellular Therapy;  
119 (B) The Blood and Marrow Transplant Clinical Trials Network;  
120 (C) The Association for the Advancement of Blood and Biotherapies; or

- 121        (D) An entity with expertise in human stem cell therapy as determined by the  
122        Department of Public Health.
- 123        (I) A violation of this Code section may subject the physician or his or her designee to  
124        disciplinary action by the licensee's respective professional board."

125

**SECTION 3.**

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