The Senate Committee on Health and Human Services offered the following substitute to HB 1275:

A BILL TO BE ENTITLED
AN ACT

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

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

SECTION 1.

The General Assembly finds that:

(1) Significant potential of human stem cell therapies in advancing medical treatments and improving patient outcomes exists;

(2) Protections need to be established to ensure that such therapies are provided using umbilical cord human stem cells obtained in an ethical manner that does not involve human stem cells derived from aborted fetuses;

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

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

SECTION 2.

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

"43-34-49.

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

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

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

(A) Vascularized human organs for transplantation;

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

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

(3) 'Human stem cell therapy' means a treatment involving the use of afterbirth placental perinatal human stem cells, or human cells, tissues, or cellular or tissue based products, which complies with the regulatory requirements provided in this Code section. Such

term shall not include treatment or research using human cells or tissues that were derived from an aborted fetus or embryo.

(4) 'Minimally manipulated' means:

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

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

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

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

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

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

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

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

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

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

(A) World Marrow Donor Association;

(B) Association for the Advancement of Blood and Biotherapies;

(C) American Association of Tissue Banks; or

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

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

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

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

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

'THIS NOTICE MUST BE PROVIDED TO YOU UNDER GEORGIA LAW. This physician or his or her designee performs one or more human stem cell therapies that have not yet been approved by the FDA. You are encouraged to consult with your primary care provider before undergoing any human stem cell therapy.'

(h) The notice required under subsection (g) of this Code section must be clearly legible and in a type size no smaller than the largest type size used in the advertisement of the human stem cell therapy services being offered.

(i) A physician or his or her designee who conducts human stem cell therapy pursuant to this Code section shall obtain a signed consent form from the patient before performing such human stem cell therapy.

(j) The consent form shall be signed by the patient or if the patient is not legally competent, the patient's representative, and shall state all of the following in a language the patient or his or her representative may reasonably be expected to understand:

(1) The nature and character of the proposed treatment;

(2) The fact that the proposed human stem cell therapy has not yet been approved by the FDA if it has not been approved at such time; and

(3) The anticipated results of the proposed treatment.

(k) This Code section does not apply to the following:

(1) A physician who has obtained approval for an investigational new drug or device from the FDA for the use of human cells, tissues, or cellular or tissue based products and is operating under such approval; or

(2) A physician or his or her designee who performs human stem cell therapy under an employment or other contract on behalf of an institution certified or accredited by any of the following:

(A) The Foundation for the Accreditation of Cellular Therapy;

(B) The Blood and Marrow Transplant Clinical Trials Network;

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

(D) An entity with expertise in human stem cell therapy as determined by the Department of Public Health.

(l) A violation of this Code section may subject the physician or his or her designee to disciplinary action by the licensee's respective professional board.

(m) Nothing in this Code section shall be construed to regulate, restrict, or prohibit stem cell research or the derivation, banking, or use of human stem cell lines for research or therapeutic research purposes, conducted in accordance with federal law, including research overseen by an institutional review board or embryonic stem cell research oversight committee."

SECTION 3.

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