

HOUSE BILL 2246

By Hurt

AN ACT to amend Tennessee Code Annotated, Title 63
and Title 68, relative to stem cell therapies.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 63, Chapter 6, Part 2, is amended by
adding the following as a new section:

(a) As used in this section:

(1) "Human cells, tissues, or cellular or tissue-based products":

(A) Means articles containing or consisting of human cells or
tissues that are intended for implantation, transplantation, infusion, or
transfer into a human recipient; and

(B) Does not include:

(i) Vascularized human organs for transplantation;

(ii) Whole blood, blood components, or blood derivative
products;

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

(iv) Minimally manipulated bone marrow for homologous
use and not combined with another article other than water,
crystalloids, or a sterilizing, preserving, or storage agent, if the
addition of the agent does not raise new clinical safety concerns
with respect to the bone marrow;

(v) Ancillary products used in the manufacture of human
cells, tissues, or cellular or tissue-based products;

(vi) Cells, tissues, and organs derived from an animal;

(vii) In vitro diagnostic products; and

(viii) Blood vessels recovered with an organ that is intended for use in organ transplantation and clearly labeled "For use in organ transplantation only";

(2) "Minimally manipulated" means:

(A) For structural tissue, processing that does not alter the original relevant characteristics of the 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 cells or tissues;

(3) "Physician" means a person licensed pursuant to chapter 6 or 9 of this title; and

(4) "Stem cell therapy":

(A) Means a treatment involving the use of afterbirth placental perinatal stem cells or human cells, tissues, or cellular or tissue-based products, which complies with the regulatory requirements provided in this section; and

(B) Does not include treatment or research using human cells or tissues that were derived from a fetus or an embryo after an abortion.

(b)

(1) A physician may perform stem cell therapy that is not approved by the United States food and drug administration if the therapy is used for treatment or a procedure that is within the scope of practice for the physician and the therapy is related to orthopedics, wound care, or pain management.

(2) To ensure that the retrieval, manufacture, storage, and use of stem cells used for stem cell therapy meet the highest standard, stem cells used by a physician for stem cell therapy must:

(A) Be retrieved, manufactured, and stored in a facility that is registered and regulated by the United States food and drug administration;

(B) Be retrieved, manufactured, and stored in a facility that is certified or accredited by one (1) of the following entities:

(i) National Marrow Donor Program;

(ii) World Marrow Donor Association;

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

(iv) American Association of Tissue Banks; and

(C) Contain viable or live cells upon post-thaw analysis and be included in a post-thaw viability analysis report for the product lot which must be sent to the physician before use with the physician's patient.

(c) A physician performing stem cell therapy shall not obtain stem cells for a therapy from a facility engaging in the retrieval, manufacture, or storage of stem cells intended for human use, unless the facility maintains valid certification or accreditation as required by this section. Any contract or other agreement through which a physician obtains stem cells for a therapy from such a facility must include the following:

(1) A requirement that the facility provide all of the following information to the physician:

(A) The name and address of the facility;

(B) The certifying or accrediting organization;

(C) The type and scope of certification or accreditation;

(D) The effective and expiration dates of the certification or accreditation; and

(E) Any limitations or conditions imposed by the certifying or accrediting organization; and

(2) A requirement that the facility notify the physician within thirty (30) days after a change in certification or accreditation status, including renewal, suspension, revocation, or expiration.

(d) In the performance of a procedure using or purporting to use stem cells or products containing stem cells, the physician must use 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 stem cells, or products containing stem cells, pursuant to the federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.) and 21 CFR 1271.

(e)

(1) A physician who conducts stem cell therapy pursuant to this section must include the following in any form of advertisement:

THIS NOTICE MUST BE PROVIDED TO YOU UNDER TENNESSEE LAW. This physician performs one or more stem cell therapies that have not yet been approved by the United States Food and Drug Administration. You are encouraged to consult with your primary care provider before undergoing any stem cell therapy.

(2) The notice required under subdivision (e)(1) must be clearly legible and in a type size no smaller than the largest type size used in the advertisement.

(f)

(1) A physician who conducts stem cell therapy pursuant to this section must obtain a signed consent form from the patient before performing the stem cell therapy.

(2) The signed consent form must be signed by the patient or, if the patient is not legally competent, the patient's representative and must contain the following:

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

(B) A statement that the proposed stem cell therapy has not been approved by the United States food and drug administration;

(C) The anticipated results of the proposed treatment; and

(D) The recognized serious possible risks, complications, and anticipated benefits involved in the treatment and the recognized possible alternative forms of treatment, including nontreatment.

(g) This section does not apply to the following:

(1) A physician who has obtained approval for an investigational new drug or device from the United States food and drug administration for the use of human cells, tissues, or cellular or tissue-based products; or

(2) A physician who performs 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 stem cell therapy as determined by the department.

(h) A violation of this section may subject the physician to disciplinary action by the physician's respective board.

(i) A physician commits a Class E felony who intentionally performs or actively participates in the following:

(1) Treatment or research using human cells or tissues derived from a fetus or an embryo after an abortion; or

(2) The sale, manufacture, or distribution of computer products created using human cells, tissues, or cellular or tissue-based products.

(j)

(1) The board of medical examiners is authorized to promulgate rules effectuate this section. The rules must be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

(2) The board of osteopathic examination is authorized to promulgate rules to effectuate this section. The rules must be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

SECTION 2. For the purposes of promulgating rules, this act takes effect upon becoming a law, the public welfare requiring it. For all other purposes, this act takes effect July 1, 2026, the public welfare requiring it.

Amendment No. 1 to HB2246

Terry
Signature of Sponsor

AMEND Senate Bill No. 2586

House Bill No. 2246*

by deleting all language after the enacting clause and substituting:

SECTION 1. Tennessee Code Annotated, Title 63, Chapter 6, Part 2, is amended by adding the following as a new section:

(a) As used in this section:

(1) "Human cells, tissues, or cellular or tissue-based products":

(A) Means articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient; and

(B) Does not include:

(i) Vascularized human organs for transplantation;

(ii) Ancillary products used in the manufacture of human cells, tissues, or cellular or tissue-based products;

(iii) Cells, tissues, media, serums, and organs derived from an animal;

(iv) In vitro diagnostic products; and

(v) Blood vessels recovered with an organ that is intended for use in organ transplantation and are clearly labeled "For use in organ transplantation only";

(2) "Physician" means a person licensed pursuant to chapter 6 or 9 of this title;

(3) "Regenerative medicine therapy":

(A) Means the use of products that:

(i) Are supplied by a manufacturer that validates its isolation techniques by including cell viability and surface marker reports for cellular products, a viscosity report for Wharton's jelly, and particle counts for exosome-based regenerative products;

(ii) Contain a lot-specific sterility report and certificate of analysis for each product before the product is used on a patient; and

(iii) Are supplied by a manufacturer that retrieves, manufactures, and stores the product in a facility that is registered with the United States food and drug administration or accredited or certified by a recognized third-party accrediting organization, including:

(a) American Association of Tissue Banks;

(b) American Academy of Stem Cell Medicine;

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

(d) Foundation for the Accreditation of Cellular Therapy; and

(e) World Marrow Donor Program; and

(B) Does not include treatment or research using human cells or tissues that were derived from a fetus or an embryo after an abortion; and

(4) "Stem cell therapy":

(A) Means a treatment involving the use of cellular or tissue-based products that:

(i) Are retrieved, manufactured, and stored in a facility that provides the physician proof of registration from the United States food and drug administration for allogeneic therapy or are retrieved, manufactured, and stored in a facility with a Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate of compliance for autologous therapy;

(ii) Are stored in a freezer that maintains a temperature no higher than negative eighty degrees centigrade (-80° C), unless the cellular or tissue-based products are for autologous therapy;

(iii) Contain viable or live cells greater than ninety percent (90%), as indicated in a pre-thaw certificate of analysis report, and contain no less than eighty percent (80%) viable or live cells, as indicated in a post-thaw viability analysis report for the product lot sent before use on the patient, unless the cellular or tissue-based products are for autologous therapy; and

(iv) Contain documentation that the cellular or tissue-based products meet acceptance criteria established by validated manufacturing procedures, if used for allogeneic therapy, and consistent with applicable regulatory standards before cell administration, unless the cellular or tissue-based products are used for same-day autologous therapy; and

(B) Does not include:

(i) Treatment or research using human cells or tissues that were derived from a fetus or an embryo after an abortion;

(ii) Whole blood, blood components, or blood derivative products; and

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

(b) A physician may perform stem cell therapy or regenerative medicine therapy that is not approved by the United States food and drug administration if the therapy is used for a treatment or procedure that is within the scope of practice of the physician.

(c) A physician who performs stem cell therapy or regenerative medicine therapy shall obtain human cells, tissues, or cellular or tissue-based products for the therapy only from a facility that complies with this section.

(d)

(1) A physician who conducts stem cell therapy or regenerative medicine therapy under this section must include the following notice in each advertisement for therapy:

THIS NOTICE MUST BE PROVIDED TO YOU UNDER TENNESSEE LAW. This physician performs one (1) or more stem cell or regenerative medicine therapies that have not yet been approved by the United States food and drug administration. You are encouraged to consult with your primary care provider before undergoing any stem cell or regenerative medicine therapy.

(2) The notice required by subdivision (d)(1) must be clearly legible and in a type size no smaller than the largest type size used in the advertisement.

(e) Before performing stem cell therapy or regenerative medicine therapy under this section, a physician must obtain a written consent form signed by the patient or, if the patient is not legally competent, the patient's representative.

(f) This section does not apply to:

(1) A physician who performs therapy approved for an investigational new drug or device by the United States food and drug administration for the use of human cells, tissues, or cellular or tissue-based products;

(2) A hospital as defined in § 68-11-201(31), or an affiliated hospital outpatient clinic; or

(3) A therapy performed pursuant to the Phil Timp-Amanda Wilcox Right to Try Act, compiled in chapter 6, part 3 of this title.

(g) A physician who violates this section may be subject to disciplinary action by the physician's licensing authority.

(h)

(1) A physician who performs allogeneic stem cell therapy or regenerative medicine therapy under this section shall report an adverse event associated with such therapy to the manufacturer and, if applicable, to an accrediting organization as described in subdivision (a)(3)(A)(iii) within thirty (30) days after the physician becomes aware of such adverse event.

(2) A physician who performs stem cell therapy or regenerative medicine therapy under this section is encouraged to participate in clinical outcomes registries maintained by an accredited organization for purposes of ongoing safety monitoring, quality improvement, and evidence-based practice development.

(3) A physician who performs stem cell therapy or regenerative medicine therapy under this section shall report an adverse event associated with such therapy to the physician's licensing authority.

(4) As used in this subsection (h), "adverse event" means any untoward medical occurrence associated with the use of stem cell therapy or regenerative medicine therapy, regardless of whether such event is considered related to the therapy, including infection, allergic reaction, disease transmission, or an unanticipated clinical outcome.

(i)

(1) The board of medical examiners may promulgate rules to effectuate this section. The rules must be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

(2) The board of osteopathic examination may promulgate rules to effectuate this section. The rules must be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

SECTION 2. For purposes of promulgating rules, this act takes effect upon becoming a law, the public welfare requiring it. For all other purposes, this act takes effect July 1, 2026, the public welfare requiring it.