Senate Bill 72

By: Senators Brass of the 6th, Kirkpatrick of the 32nd, Dolezal of the 27th, Strickland of the 42nd, Walker III of the 20th and others

A BILL TO BE ENTITLED

AN ACT

To amend Chapter 52 of Title 31 of the Official Code of Georgia Annotated, relating to terminally ill patient's right to try investigational drugs, biological products, and devices, so as to expand access to individualized investigational treatments to patients who have severely debilitating or life-threatening illnesses; to provide for definitions; to provide for eligibility criteria; to provide for written informed consent; to allow certain manufacturers or eligible facilities to make available individualized investigational treatments; to provide that coverage is not mandatory; to prohibit the sanctions against a physician's license; to provide exemption to liability for certain charges; to provide for statutory construction; to provide for related matters; to provide for a short title; to repeal conflicting laws; and for other purposes.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

SECTION 1.

This Act shall be known and may be cited as the "Hope for Georgia Patients Act."

SECTION 2.

Chapter 52 of Title 31 of the Official Code of Georgia Annotated, relating to terminally ill patient's right to try investigational drugs, biological products, and devices, is amended by designating Code Sections 31-52-1 through 31-52-10, the "Georgia Right to Try Act," as Article 1.

SECTION 3.

Said chapter is further amended by replacing "chapter" with "article" wherever the former appears in:

(1) Code Section 31-52-1, relating to short title;

(2) Code Section 31-52-4, relating to eligibility criteria;

(3) Code Section 31-52-6, relating to manufacturers permitted to make investigational drugs, biological products, or devices available;

(4) Code Section 31-52-7, relating to coverage under health benefit plan permitted but not required;

(5) Code Section 31-52-8, relating to physician immunity from sanction for recommending, prescribing, or treating with investigational drugs, biological products, or devices; and

(6) Code Section 31-52-10, relating to statutory construction.

SECTION 4.

Said chapter is further amended by revising Code Section 31-52-3, relating to definitions, as follows:

"31-52-3.

As used in this ~~chapter~~ article, the term:

(1) 'Eligible patient' means a person who meets the requirements of Code Section 31-52-4.

(2) 'Investigational drug, biological product, or device' means a drug, biological product, or device which has successfully completed Phase I of a federal Food and Drug Administration approved clinical trial but has not yet been approved for general use by the federal Food and Drug Administration and currently remains under investigation in a federal Food and Drug Administration approved clinical trial.

(3) 'Physician' means a person licensed to practice medicine pursuant to Article 2 of Chapter 34 of Title 43.

(4) 'Terminal illness' means a disease that, without life-sustaining procedures, will result in death in the near future and is not considered by a treating physician to be reversible even with administration of current federal Food and Drug Administration approved and available treatments.

(5) 'Written informed consent' means a written document that:

(A) Is signed by the patient; parent, if the patient is a minor; legal guardian; or ~~health care~~ healthcare agent designated by the patient in an advance directive for ~~health care~~ healthcare executed pursuant to Chapter 32 of ~~Title 31~~ this title;

(B) Is attested to by the patient's physician and a witness; and

(C) Meets the requirements of Code Section 31-52-5.″

SECTION 5.

Said chapter is further amended by adding a new article to read as follows:

″ARTICLE 2

31-52-20.

As used in this article, the term:

(1) 'Eligible facility' means an institution that is currently operating under the Federalwide Assurance for the Protection of Human Subjects under 42 U.S.C.

Section 289(a) and 45 C.F.R. Part 46 and is subject to federal laws, regulations, policies, and guidelines, including renewals and updates.

(2) 'Eligible patient' means a person who meets the requirements of Code Section 31-52-21.

(3) 'Individualized investigational treatment' means a drug, biological product, or device that is unique to and produced exclusively for an individual patient based on his or her own genetic profile. Such term includes, but is not limited to, individualized gene therapy, individualized investigational antisense oligonucleotides, and individualized neoantigen vaccines or individualized neoantigen therapy. Such term includes any drug, biological product, or device derived from human perinatal tissues, cells, and secreted factors, provided that such substances are not obtained from an abortion. Such term does not include any drug, biological product, or device derived from human primary or secondary embryonic stem cells or cell lines.

(4) 'Life-threatening illness' means a disease or condition where the likelihood of death is high unless the course of the disease is interrupted or a disease or condition with a potentially fatal outcome, where the end point of clinical trial analysis is survival. Such term shall not include the natural process of aging.

(5) 'Manufacturer' means a person or entity engaged in the manufacturing of individualized investigational treatments in an eligible facility.

(6) 'Physician' means a person licensed to practice medicine pursuant to Article 2 of Chapter 34 of Title 43.

(7) 'Severely debilitating illness' means a disease or condition that causes major irreversible morbidity.

(8) 'Written informed consent' means a written document that:

(A) Is signed by the patient; parent, if the patient is a minor; legal guardian; or healthcare agent designated by the patient in an advance directive for healthcare executed pursuant to Chapter 32 of this title;

(B) Is attested to by the patient's physician and a witness; and

(C) Meets the requirements of Code Section 31-52-22.

31-52-21.

In order for a person to be considered an eligible patient to access an individualized investigational treatment pursuant to this article, a physician must document in writing that the person:

(1) Has a life-threatening or severely debilitating illness;

(2) Has, in consultation with the physician, considered all other treatment options currently approved by the United States Food and Drug Administration;

(3) Has been given a recommendation by the physician for an individualized investigational treatment based on an analysis of such patient's genomic sequence, human chromosomes, deoxyribonucleic acid, ribonucleic acid, genes, gene products such as enzymes and other types of proteins, or metabolites; and

(4) Has given written informed consent for the use of the individualized investigational treatment.

31-52-22.

Written informed consent shall, at a minimum, include the following:

(1) A description of the currently approved products and treatments for the life-threatening or severely debilitating illness from which the patient suffers;

(2) An attestation that the patient concurs with his or her physician in believing that all currently approved and conventionally recognized treatments are unlikely to prolong the patient's life, and the known risks of the individualized investigational treatment are not greater than the probable outcome of the patient's illness;

(3) Clear identification of the specific proposed individualized investigational treatment that the patient is seeking to use;

(4) A description of the potential best and worst outcomes of using the individualized investigational treatment and a realistic description of the most likely outcome. The description shall include the possibility that new, unanticipated, different, or worse symptoms might result and that death could be hastened by the proposed treatment. The description shall be based on the physician's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition;

(5) A statement that the patient understands that his or her health benefit plan or third-party administrator is not obligated to pay for the individualized investigational treatment, or any care or treatment consequent to the use of such treatment, unless such health benefit plan or third-party administrator is specifically required to do so by law or contract;

(6) A statement that the patient understands that his or her eligibility for hospice care may be withdrawn if he or she begins treatment with the individualized investigational treatment but that such hospice care may be reinstated if such treatment ends and he or she meets hospice eligibility requirements; and

(7) A statement that the patient understands that he or she is liable for all expenses consequent to the use of the individualized investigational treatment and that such liability extends to the patient's estate, unless a contract between the patient and the manufacturer of the individualized investigational treatment states otherwise, except as provided for in Code Section 31-52-27.

31-52-23.

(a) A manufacturer or an eligible entity may make available an individualized investigational treatment to an eligible patient, and an eligible patient may request such treatment from such manufacturer or facility pursuant to this article; provided, however, that nothing in this article shall be construed to require that such manufacturer or facility make available such treatment to such patient.

(b) A manufacturer or an eligible facility may provide an individualized investigational treatment to an eligible patient:

(1) Without receiving compensation; or

(2) With the requirement that the eligible patient pays the costs of or the costs associated with the manufacture of the individualized investigational treatment.

31-52-24.

(a) A health benefit plan or governmental agency may provide coverage for the cost of any individualized investigational treatment pursuant to this article; provided, however, that nothing in this article shall be construed to require a health benefit plan or governmental agency to provide coverage for the cost of any individualized investigational treatment or related cost of services associated with the use, care, or treatment of an eligible patient associated with such individualized investigational treatment pursuant to this article.

(b) A hospital or other healthcare facility is not required to provide new or additional services associated with any individualized investigational treatment unless approved by such hospital or facility.

31-52-25.

(a) The Georgia Composite Medical Board shall not revoke, suspend, sanction, fail to renew, or take any other action against a physician's license solely based on such physician's recommendation, prescription, or treatment of an eligible patient with an individualized investigational treatment pursuant to this article.

(b) The department shall not take action against a healthcare provider's Medicare certification based solely on such provider's recommendation that an eligible patient have access to an individualized investigational treatment.

31-52-26.

No official, employee, or agent of the state shall block or attempt to block an eligible patient's access to an individualized investigational treatment. Counseling, advice, or a recommendation for treatment consistent with medical standards of care shall not be construed as a violation of this Code section.

31-52-27.

(a) This article shall not be construed to create a private cause of action against a manufacturer, eligible facility, or any other person or entity involved in the care of an eligible patient using any individualized investigational treatment for any harm done to such patient resulting from the individualized investigational treatment if such manufacturer, facility, person, or entity complied in good faith with the terms of this article and exercised reasonable care.

(b) This article shall not be construed to create a private cause of action against a physician who refuses to recommend an individualized investigational treatment for any otherwise eligible patient.

(c) Any person or entity involved in the care of an eligible patient using an individualized investigational treatment shall not be liable for injury or death to such patient as a result of such treatment under Code Section 51-1-27 or Chapter 4 of Title 51, unless it is shown that the person or entity failed to obtain written informed consent in compliance with Code Section 31-52-22.

(d) This article shall not be construed to affect any required healthcare coverage under Title 33 for patients in clinical trials.

(e) If an eligible patient's death is proximately caused by an individualized investigational treatment, such patient's estate, heirs, or devisees are not liable for any debt remaining after payment by insurance for charges directly incurred for such treatment; provided, however, that this subsection does not provide an exemption to liability for charges for

nonexperimental treatments provided to the patient, including nonexperimental treatments rendered to the patient due to complications or consequences of the individualized investigational treatment."

SECTION 6.

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