State of Arkansas
95th General Assembly
Regular Session, 2025

A Bill

SENATE BILL 136

By: Senator J. Boyd
By: Representative Gramlich

For An Act To Be Entitled

AN ACT TO CREATE THE RIGHT TO TRY INDIVIDUALIZED INVESTIGATIONAL TREATMENT ACT; TO ESTABLISH PROCEDURES FOR PATIENTS TO TRY INDIVIDUALIZED INVESTIGATIONAL TREATMENTS; TO ENSURE THAT PATIENTS WITH LIFE-THREATENING OR SEVERELY DEBILITATING ILLNESS HAVE ACCESS TO INDIVIDUALIZED INVESTIGATIONAL TREATMENT; AND FOR OTHER PURPOSES.

Subtitle

TO CREATE THE RIGHT TO TRY INDIVIDUALIZED INVESTIGATIONAL TREATMENT ACT; AND TO ENSURE THAT PATIENTS HAVE ACCESS TO INDIVIDUALIZED INVESTIGATIONAL TREATMENT.

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

SECTION 1. Arkansas Code Title 20, Chapter 15, is amended to add an additional subchapter to read as follows:

Subchapter 25 — Right to Try Individualized Investigational Treatment Act

20-15-2501. Title.

This subchapter shall be known and may be cited as the "Right to Try Individualized Investigational Treatment Act".

20-15-2502. Definitions.

As used in this subchapter:

(1) “Costs associated with the manufacture of the individualized investigational treatment” means the actual out-of-pocket costs incurred in providing the individualized investigational treatment to the patient in his or her specific case;

(2) "Eligible facility" means an institution that is operating under a Federalwide Assurance for the Protection of Human Subjects under 42 U.S.C. § 289(a) and 45 C.F.R. Part 46, as existing on January 1, 2025, and is subject to the laws, regulations, policies, and guidelines relating to Federalwide Assurance for the Protection of Human Subjects, including renewals or updates;

(3) “Eligible patient” means a person who meets the requirements of eligibility under § 20-15-2503;

(4) "Individualized investigational treatment" means a drug, biological product, or device that is unique to and produced exclusively for use for an individual patient, based on his or her own genetic profile, including without limitation an individualized gene therapy antisense oligonucleotide and individualized neoantigen vaccines;

(5) "Life-threatening" means a disease or condition:

(A) Where the likelihood of death is high unless the course of the disease or condition is interrupted; and

(B) With a potentially fatal outcome, where the endpoint of clinical trial analysis is survival;

(6) “Physician” means an individual licensed to practice medicine in the State of Arkansas under the Arkansas Medical Practices Act, § 17-95-201 et seq., § 17-95-301 et seq., and § 17-95-401 et seq.; and

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

20-15-2503. Eligibility.

In order for a patient to access an individualized investigational treatment under this subchapter, a physician shall document in the patient’s medical record and chart that the patient:

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

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

(3) Has received a recommendation from the physician for an

individualized investigational treatment based on analysis of the patient's genomic sequence, human chromosomes, deoxyribonucleic acid, ribonucleic acid, genes, gene products such as enzymes and other types of proteins, or metabolites;

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

(B) If the patient is a minor or lacks the mental capacity to provide informed consent, a parent or legal guardian may provide written, informed consent on the patient's behalf.

(C) The written, informed consent shall include at a minimum:

(i) An explanation of the currently approved products and treatments for the disease or condition of which the patient suffers;

(ii) An attestation that the patient, or if the patient is a minor or lacks the mental capacity to concur, a parent or legal guardian, concurs with his or her physician in believing that all currently approved and conventionally recognized treatments are unlikely to prolong the patient's life;

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

(iv) A description of the potentially best and worst outcomes of using the individualized investigational treatment and a realistic description of the most likely outcome, including without limitation the possibility that new, unanticipated, different, or worse symptoms might result, and that death could be hastened by the individualized investigational treatment, which is based on the physician's knowledge of the individualized investigational treatment in conjunction with an awareness of the patient's condition;

(v) A statement that the patient's health plan or third-party administrator and provider are not obligated to pay for any care or treatments consequent to the use of the individualized investigational treatment, unless the patient's health plan or third-party administrator and provider are specifically required to do so by law or contract;

(vi) A statement that the patient's eligibility for hospice care may be withdrawn if the patient receives an individualized

investigational treatment and that care may be reinstated if the individualized investigational treatment ends and the patient meets hospice eligibility requirements; and

(vii) 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 this liability extends to the patient's estate, unless a contract between the patient and the manufacturer of the individualized investigational treatment states otherwise; and

(5) Has received written documentation from a physician that the patient meets the requirements of this subchapter.

20-15-2504. Availability.

(a) A manufacturer of an individualized investigational treatment operating within an eligible facility may make available an individualized investigational treatment available to eligible patients under this subchapter.

(b) This section does not require that a manufacturer make available an individualized investigational treatment to an eligible patient.

20-15-2505. Costs.

(a) A manufacturer of an individualized investigational treatment or an eligible facility may:

(1) Provide an individualized investigational treatment to an eligible patient without receiving compensation; or

(2) Require an eligible patient to pay the costs associated with the manufacture of the individualized investigational treatment.

(b) If an eligible patient dies while receiving individualized investigational treatment, the eligible patient's heirs are not liable for any outstanding debt to the manufacturer related to the individualized investigational treatment.

20-15-2506. Insurance coverage.

(a) An insurance company:

(1) May, but is not required to, provide coverage for an individualized investigational treatment; and

(2) Shall not deny coverage for an item or service that is otherwise covered by an insurance contract between the eligible person and the insurance company.

(b) This subchapter does not affect any mandatory healthcare coverage for participation in clinical trials or expand the health care coverage required of an insurance company.

20-15-2507. Prohibited sanctions.

The recommendation, prescription, treatment, or participation in the treatment of a life-threatening or severely debilitating illness with an individualized investigational treatment shall not permit:

(1) A state agency or licensing board to revoke a license, fail to renew a license, or take any other action against a medical professional's license or a healthcare provider's license;

(2) A state agency, state official, or employee or agent of the state to block or attempt to block an eligible patient's access to an individualized investigational treatment; or

(3) An action against a hospital's Medicare certification.

20-15-2508. Counseling, advice, or recommendation not violation.

The counseling, advice, or recommendation consistent with medical standards of care by a medical professional licensed under state law is not a violation of this subchapter.

20-15-2509. Immunity.

(a) Except in the case of gross negligence or willful misconduct, a person or entity that manufacturers, imports, distributes, prescribes, dispenses, administers, or is otherwise involved in the care of an eligible patient using an individualized investigational treatment is immune from civil liability for any loss, damage, or injury arising out of, relating to, or resulting from the individualized investigational treatment if the person or entity is substantially complying in good faith with this subchapter and has exercised reasonable care.

(b) This subchapter does not require a medical professional who is licensed under the laws of this state to counsel, advise, prescribe, dispense, administer, or otherwise be involved in the care of an eligible

patient using an individualized investigational treatment.

(c) This subchapter does not require a hospital licensed under § 20-9-213 to provide any new or additional service related to an individualized investigational treatment, unless approved by the hospital.

20-15-2510. Medicaid coverage.

This subchapter does not require the Department of Human Services or the Arkansas Medicaid Program to provide additional coverage for an individualized investigational treatment.

APPROVED: 2/27/25