MISSISSIPPI LEGISLATURE REGULAR SESSION 2024

By: Senator(s) Harkins, Hill, McLendon

To: Public Health and Welfare

SENATE BILL NO. 2858

AN ACT TO PROVIDE THAT A MANUFACTURER MAY MAKE AN INDIVIDUALIZED INVESTIGATIVE TREATMENT, AND AN ELIGIBLE PATIENT WHO HAS A LIFE-THREATENING OR SEVERELY DEBILITATING ILLNESS MAY RECEIVE SUCH TREATMENT IF THE PATIENT HAS GIVEN WRITTEN, INFORMED CONSENT; TO PROVIDE THAT A HEALTH PLAN, THIRD PARTY ADMINISTRATOR, OR GOVERNMENTAL AGENCY MAY PROVIDE COVERAGE FOR THE COST OF AN INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE, OR THE COST OF SERVICES RELATED TO THE USE OF AN INDIVIDUALIZED INVESTIGATIONAL DRUG, OR BIOLOGICAL PRODUCT; TO PROHIBIT A LICENSING BOARD OR DISCIPLINARY SUBCOMMITTEE FROM REVOKING, FAILING TO RENEW, SUSPENDING, OR TAKING ANY ACTION AGAINST A HEALTH CARE PROVIDER'S LICENSE BASED SOLELY ON THE HEALTH CARE PROVIDER'S RECOMMENDATIONS TO AN ELIGIBLE PATIENT REGARDING ACCESS TO OR TREATMENT WITH AN INDIVIDUALIZED INVESTIGATIONAL DRUG; TO SET CERTAIN PROVISIONS RELATED TO CIVIL CAUSES OF ACTION AND LIABILITY RELATED TO THE ACT; TO PROHIBIT AN OFFICIAL, EMPLOYEE, OR AGENT OF THIS STATE FROM BLOCKING OR ATTEMPTING TO BLOCK AN ELIGIBLE PATIENT'S ACCESS TO AN INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE; TO PROVIDE FOR THE SEVERABILITY OF THE ACT; TO BRING FORWARD SECTION 41-41-3, MISSISSIPPI CODE OF 1972, FOR THE PURPOSE OF POSSIBLE AMENDMENT; AND FOR RELATED PURPOSES.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MISSISSIPPI:

SECTION 1. As used in this act, the following terms shall have the meanings ascribed herein:

(a) "Life-threatening or severely debilitating illness," means as it is defined in Section 312.81 of Title 21, Code of

Federal Regulations (or any successor law or regulation, as applicable).

(b) "Eligible patient" means an individual who meets the following conditions:

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

(ii) Has received a recommendation from his or her 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;

(iii) Has a life-threatening or severely debilitating illness, or serious disease or condition associated with morbidity that has a substantial impact on day-to-day functioning, attested to by the patient's treating physician;

(iv) Has given written, informed consent for the use of the investigational drug, biological product, or device; and

(v) Has documentation from his or her physician that he or she meets the requirements of this subdivision.

(c) "Individualized investigational treatment" means drugs, biological products, or devices that are unique to and produced exclusively for use for an individual patient, based on their own genetic profile.

(d) "Individualized investigational treatment" includes, but is not limited to, individualized gene therapy antisense oligonucleotides (ASO) and individualized neoantigen vaccines. Individualized investigational treatment" does not include any drug, biological product, or device derived from human primary or secondary embryonic stem cells or cell lines, or tissues or cells derived from abortion, but does include any drug, biological product, or device derived from human perinatal tissues, cells, and secreted factors not obtained from an abortion.

(e) "Written, informed consent" means a written document that is signed by the patient; or if the patient is a minor, by any person authorized to consent under Section 41-41-3; and attested to by the patient's physician and a witness and that, at a minimum, includes all of the following:

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

(ii) 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;

(iii) Clear identification of the specific proposed individualized investigational drug, biological product or device that the patient is seeking to use;

(iv) A description of the potentially best and worst outcomes of using the individualized investigational drug, biological product, or device 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;

(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 drug, biological product, or device, unless they 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 begins curative treatment with the individualized investigational drug, biological product, or device and that care may be reinstated if this 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 drug, biological product, or device and that this liability extends to the patient's estate, unless a

contract between the patient and the manufacturer of the drug, biological product, or device states otherwise.

(f) "Eligible facility" means an institution that is operating under a Federal-wide Assurance (FWA) for the Protection of Human Subjects under 42 U.S.C. 289(a) and 45 CFR Part 46. and eligible facility is subject to the FWA laws, regulations, policies, and guidelines including renewals or updates.

SECTION 2. (1) A manufacturer operating within an eligible facility and pursuant to all applicable FWA laws and regulations may make available an individualized investigative treatment and an eligible patient may request an individualized investigational drug, biological product or device from an eligible facility or manufacturer operating within an eligible facility under this act. This act does not require that a manufacturer make available an individualized investigational drug, biological product, or device to an eligible patient.

(2) An eligible facility or manufacturer operating within an eligible facility may do all of the following:

(a) Provide an individualized investigational drug, biological product, or device to an eligible patient without receiving compensation; and

(b) Require an eligible patient to pay the costs of, or the costs associated with, the manufacture of the investigational drug, biological product, or device.

SECTION 3. (1) This act shall not be construed to expand the coverage required of an insurer under Title 83 of the Mississippi Code.

(2) A health plan, third party administrator, or governmental agency may, but is not required to, provide coverage for the cost of an individualized investigational drug, biological product, or device, or the cost of services related to the use of an individualized investigational drug, biological product, or device under this act.

(3) This act shall not be construed to require any governmental agency to pay costs associated with the use, care, or treatment of a patient with an individualized investigational drug, biological product, or device.

(4) This act shall not be construed to require a licensed hospital or facility to provide new or additional services, unless approved by the hospital or facility.

SECTION 4. If a patient's death is proximately caused by treatment with an individualized investigational drug, biological product, or device, the patient's estate, heirs, or devisees are not liable for any debt remaining after payment by insurance for charges directly incurred for said treatment. However, this provision does not provide an exemption to liability for charges for non-experimental treatments provided to the patient, including non-experimental treatments rendered to the patient due to complications or consequences of the experimental treatment.

SECTION 5. (1) A licensing board or disciplinary subcommittee shall not revoke, fail to renew, suspend, or take any action against a health care provider's license, and based solely on the health care provider's recommendations to an eligible patient regarding access to or treatment with an individualized investigational drug, biological product or device.

(2) An entity responsible for Medicare certification shall not take action against a health care provider's Medicare certification based solely on the health care provider's recommendation that a patient have access to an individualized investigational drug, biological product, or device.

SECTION 6. (1) An official, employee, or agent of this state shall not block or attempt to block an eligible patient's access to an individualized investigational drug, biological product, or device.

(2) Counseling, advice, or a recommendation consistent with medical standards of care from a licensed health care provider shall not be considered a violation of this section.

SECTION 7. This act does not create a private cause of action against a manufacturer of an individualized investigational drug, biological product, or device or against any other person or entity involved in the care of an eligible patient using the individualized investigational drug, biological product, or device for any harm done to the eligible patient resulting from the individualized investigational drug, biological product, or

device, if the manufacturer or other person or entity is complying in good faith with the terms of this act and has exercised reasonable care.

SECTION 8. If any one or more provisions, sections, subsections, sentences, clauses, phrases or words of this act or the application thereof to any person or circumstance is found to be unconstitutional, the same is hereby declared to be severable, and the balance of this act shall remain effective notwithstanding such unconstitutionality. The Legislature hereby declares that it would have passed this act, and each provision, section, subsection, sentence, clause, phrase or word thereof, irrespective of the fact that any one or more provisions, sections, subsections, sentences, clauses, phrases or words be declared unconstitutional.

SECTION 9. Section 41-41-3, Mississippi Code of 1972, is brought forward as follows:

41-41-3. (1) It is hereby recognized and established that, in addition to such other persons as may be so authorized and empowered, any one (1) of the following persons who is reasonably available, in descending order of priority, is authorized and empowered to consent on behalf of an unemancipated minor, either orally or otherwise, to any surgical or medical treatment or procedures not prohibited by law which may be suggested, recommended, prescribed or directed by a duly licensed physician:

(a) The minor's guardian or custodian.

(b) The minor's parent.

(c) An adult brother or sister of the minor.

(d) The minor's grandparent.

(2) If none of the individuals eligible to act under subsection (1) is reasonably available, an adult who has exhibited special care and concern for the minor and who is reasonably available may act; the adult shall communicate the assumption of authority as promptly as practicable to the individuals specified in subsection (1) who can be readily contacted.

(3) Any female, regardless of age or marital status, is empowered to give consent for herself in connection with pregnancy or childbirth.

SECTION 10. This act shall take effect and be in force from and after July 1, 2024.