

By: Senator(s) Harkins, Hill, McLendon

To: Public Health and Welfare

SENATE BILL NO. 2858

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

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

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

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



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

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

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

35 (ii) Has received a recommendation from his or her  
36 physician for an individualized investigational treatment, based  
37 on analysis of the patient's genomic sequence, human chromosomes,  
38 deoxyribonucleic acid, ribonucleic acid, genes, gene products  
39 (such as enzymes and other types of proteins), or metabolites;

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

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

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

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



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

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

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

69 (ii) An attestation that the patient concurs with his  
70 or her physician in believing that all currently approved and  
71 conventionally recognized treatments are unlikely to prolong the  
72 patient's life;

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



76 (iv) A description of the potentially best and worst  
77 outcomes of using the individualized investigational drug,  
78 biological product, or device and a realistic description of the  
79 most likely outcome. The description shall include the  
80 possibility that new, unanticipated, different or worse symptoms  
81 might result and that death could be hastened by the proposed  
82 treatment. The description shall be based on the physician's  
83 knowledge of the proposed treatment in conjunction with an  
84 awareness of the patient's condition;

85 (v) A statement that the patient's health plan or third  
86 party administrator and provider are not obligated to pay for any  
87 care or treatments consequent to the use of the individualized  
88 investigational drug, biological product, or device, unless they  
89 are specifically required to do so by law or contract;

90 (vi) A statement that the patient's eligibility for  
91 hospice care may be withdrawn if the patient begins curative  
92 treatment with the individualized investigational drug, biological  
93 product, or device and that care may be reinstated if this  
94 treatment ends and the patient meets hospice eligibility  
95 requirements; and

96 (vii) A statement that the patient understands that he  
97 or she is liable for all expenses consequent to the use of the  
98 individualized investigational drug, biological product, or device  
99 and that this liability extends to the patient's estate, unless a



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

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

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

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

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

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



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

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

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

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

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



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

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

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

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

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



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

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

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

190       41-41-3. (1) It is hereby recognized and established that,  
191 in addition to such other persons as may be so authorized and  
192 empowered, any one (1) of the following persons who is reasonably  
193 available, in descending order of priority, is authorized and  
194 empowered to consent on behalf of an unemancipated minor, either  
195 orally or otherwise, to any surgical or medical treatment or  
196 procedures not prohibited by law which may be suggested,  
197 recommended, prescribed or directed by a duly licensed physician:

198           (a) The minor's guardian or custodian.





199 (b) The minor's parent.

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

201 (d) The minor's grandparent.

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

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

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

