

The Senate Committee on Health and Human Services offered the following substitute to SB 72:

A BILL TO BE ENTITLED
AN ACT

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

11 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

12 **SECTION 1.**

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

14

SECTION 2.

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

19

SECTION 3.

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

- 22 (1) Code Section 31-52-1, relating to short title;
- 23 (2) Code Section 31-52-4, relating to eligibility criteria;
- 24 (3) Code Section 31-52-6, relating to manufacturers permitted to make investigational
25 drugs, biological products, or devices available;
- 26 (4) Code Section 31-52-7, relating to coverage under health benefit plan permitted but not
27 required;
- 28 (5) Code Section 31-52-8, relating to physician immunity from sanction for
29 recommending, prescribing, or treating with investigational drugs, biological products, or
30 devices; and
- 31 (6) Code Section 31-52-10, relating to statutory construction.

32

SECTION 4.

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

35 "31-52-3.

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

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

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

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

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

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

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

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

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

56 **SECTION 5.**

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

58 "ARTICLE 2

59 31-52-20.

60 As used in this article, the term:

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

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

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

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

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

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

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

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

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

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

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

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

92 31-52-21.

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

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

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

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

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

105 31-52-22.

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

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

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

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

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

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

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

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

135 31-52-23.

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

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

143 (1) Without receiving compensation; or

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

146 31-52-24.

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

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

156 31-52-25.

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

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

164 31-52-26.

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

169 31-52-27.

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

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

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

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

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

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

193

SECTION 6.

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