

As Introduced

**136th General Assembly
Regular Session
2025-2026**

S. B. No. 170

Senators Huffman, Roegner

A BILL

To enact sections 4729.891, 4731.971, 4731.972,
4731.973, 4731.975, 4731.976, 4731.977,
4731.978, 4731.979, and 4731.9710 of the Revised
Code regarding individualized investigational
treatments for life-threatening or severely
debilitating illnesses.

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

Section 1. That sections 4729.891, 4731.971, 4731.972,
4731.973, 4731.975, 4731.976, 4731.977, 4731.978, 4731.979, and
4731.9710 of the Revised Code be enacted to read as follows:

Sec. 4729.891. (A) As used in this section:

(1) "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 and
is subject to the federalwide assurance laws, regulations,
policies, and guidelines.

(2) "Eligible patient" and "individualized investigational
treatment" have the same meanings as in section 4731.971 of the
Revised Code.

(B) A manufacturer operating within an eligible facility 19
and pursuant to all applicable federalwide assurance laws and 20
regulations may make available an individualized investigational 21
treatment, and an eligible patient may request an individualized 22
investigational drug, biological product, or device from an 23
eligible facility or manufacturer operating within an eligible 24
facility. Nothing in this section requires a manufacturer to 25
make available an individualized investigational treatment to an 26
eligible patient. 27

(C) An eligible facility or a manufacturer operating 28
within an eligible facility may do both of the following: 29

(1) Provide an individualized investigational treatment to 30
an eligible patient without receiving compensation; 31

(2) Require an eligible patient to pay the costs of, or 32
associated with, the manufacture of the investigational drug, 33
biological product, or device. 34

Sec. 4731.971. As used in sections 4731.971 to 4731.9710 35
of the Revised Code: 36

(A) "Eligible patient" means an individual who meets all 37
of the requirements of section 4731.972 of the Revised Code. 38

(B) "Health benefit plan" and "health plan issuer" have 39
the same meanings as in section 3922.01 of the Revised Code. 40

(C) "Individualized investigational treatment" means a 41
drug, biological product, or device that is unique to and 42
produced exclusively for use by an individual patient, based on 43
the patient's own genetic profile, including individualized gene 44
therapy antisense oligonucleotides and individualized neoantigen 45
vaccines. 46

(D) "Life-threatening or severely debilitating illness" 47
means diseases or conditions that meet one or more of the 48
following: 49

(1) The likelihood of death is high unless the course of 50
the disease is interrupted. 51

(2) The outcome is potentially fatal and the end point of 52
clinical trial analysis is survival. 53

(3) Cause major irreversible morbidity. 54

Sec. 4731.972. An individual is an eligible patient for 55
purposes of sections 4731.971 to 4731.9710 and section 4729.891 56
of the Revised Code if the individual meets all of the 57
following: 58

(A) The individual has a life-threatening or severely 59
debilitating illness, as attested to by the individual's 60
treating physician. 61

(B) The individual has considered all treatment options 62
for the illness that are approved by the United States food and 63
drug administration. 64

(C) The individual has received a recommendation from the 65
individual's treating physician for an individualized 66
investigational treatment, based on an analysis of the 67
individual's genomic sequence; human chromosomes; 68
deoxyribonucleic acid; ribonucleic acid; genes; gene products, 69
such as enzymes and other types of proteins; or metabolites. 70

(D) Written, informed consent has been executed in 71
accordance with section 4731.973 of the Revised Code for the use 72
of the individualized investigational treatment. 73

(E) The individual has documentation from the individual's 74

treating physician that the individual meets the requirements of 75
divisions (A) to (D) of this section. 76

Sec. 4731.973. (A) A treating physician may treat an 77
eligible patient with an individualized investigational 78
treatment after securing the patient's written, informed consent 79
in a signed document that includes all of the provisions 80
described in division (B) of this section. The document shall be 81
signed by the patient's treating physician and one of the 82
following, in the presence of a witness who must also sign the 83
document: 84

(1) The patient; 85

(2) If the patient is a minor, the patient's parent, legal 86
custodian, or guardian; 87

(3) If the patient has designated an individual as the 88
patient's attorney in fact under a durable power of attorney for 89
health care in accordance with section 1337.12 of the Revised 90
Code, by the attorney in fact; 91

(4) If an individual has been appointed by a court to act 92
as the patient's guardian, by the guardian. 93

(B) Written, informed consent shall include all of the 94
following: 95

(1) An explanation of the currently approved products and 96
treatments for the life-threatening or severely debilitating 97
illness from which the patient suffers; 98

(2) Clear identification of the specific proposed 99
individualized investigational treatment that the patient is 100
seeking to use; 101

(3) A description, based on the treating physician's 102

knowledge of the proposed treatment in conjunction with an 103
awareness of the patient's condition, of the potentially best 104
and worst outcomes of using the individualized investigational 105
treatment and a realistic description of the most likely 106
outcome, including the possibility that new, unanticipated, 107
different, or worse symptoms might result and that death could 108
be hastened by the proposed treatment; 109

(4) A statement that the patient's health plan issuer and 110
provider are not obligated to pay for any care or treatment 111
directly related to the use of the individualized 112
investigational treatment, unless the entity is specifically 113
required to do so by law or contract; 114

(5) A statement that the patient's eligibility for hospice 115
care may be withdrawn if the patient begins curative treatment 116
with the individualized investigational treatment and that 117
hospice care may be reinstated if this treatment ends and the 118
patient meets hospice eligibility requirements; 119

(6) A statement that the patient understands that the 120
patient is liable for all expenses directly related to the use 121
of the individualized investigational treatment and that this 122
liability extends to the patient's estate, unless a contract 123
between the patient and the manufacturer of the drug, biological 124
product, or device states otherwise. 125

(7) An attestation that the patient has a life-threatening 126
or severely debilitating illness and the physician believes that 127
all approved and conventionally recognized products and 128
treatments are unlikely to prolong the patient's life. 129

(8) An attestation that the patient, or the patient's 130
representative, agrees with the physician's attestation under 131

division (B) (7) of this section. 132

Sec. 4731.975. (A) A health benefit plan or governmental 133
agency may provide coverage for the cost of an individualized 134
investigational treatment or the cost of services related to the 135
use of an individualized investigational treatment. 136

(B) Nothing in section 4729.891 or sections 4731.971 to 137
4731.9710 of the Revised Code shall not be construed to do any 138
of the following: 139

(1) Expand the coverage required under a health benefit 140
plan; 141

(2) Require any governmental agency to pay costs 142
associated with the use by an eligible patient of an 143
individualized investigational drug, biological product, or 144
device, including any related care or treatment of that patient; 145

(3) Require a hospital or facility to provide new or 146
additional services, unless approved by the hospital or 147
facility; 148

(4) Authorize a health benefit plan or governmental agency 149
to exclude coverage for a covered person receiving an individual 150
investigational treatment for health services that are not 151
related to an individual investigational treatment and that are 152
otherwise covered by the health benefit plan or governmental 153
agency; 154

(5) Negate, abrogate, or in any way affect any mandatory 155
coverage for participation in clinical trials required in 156
sections 1739.05, 1751.01, and 3923.80 of the Revised Code. 157

Sec. 4731.976. If a patient dies while being treated by an 158
individualized investigational treatment, the patient's heirs 159

are not liable for any outstanding debt related to the treatment 160
or lack of coverage due to the treatment. 161

Sec. 4731.977. (A) The state medical board shall not 162
limit, revoke, or suspend; refuse to grant, renew, or reinstate; 163
or take any other action against a physician's license or 164
certificate to practice based solely on the physician's 165
recommendations to an eligible patient regarding an 166
individualized investigational treatment. 167

(B) To the extent permitted under federal law, an entity 168
responsible for medicare certification shall not take action 169
against a physician's medicare certification based solely on the 170
physician's recommendation that an eligible patient have access 171
to an individualized investigational treatment. 172

Sec. 4731.978. (A) An official, employee, or agent of this 173
state shall not prevent or attempt to prevent access by an 174
eligible patient or eligible patient's treating physician to an 175
individualized investigational treatment that is being provided 176
or is to be provided in accordance with sections 4731.971 to 177
4731.977 and section 4729.891 of the Revised Code. 178

(B) Counseling, advice, or a recommendation consistent 179
with medical standards of care from a treating physician shall 180
not be considered a violation of this section. 181

Sec. 4731.979. Nothing in sections 4731.971 to 4731.978 182
and section 4729.891 of the Revised Code shall be construed to 183
create a private cause of action against a manufacturer of an 184
individualized investigational treatment or against any other 185
person or entity involved in the care of an eligible patient 186
using the individualized investigational treatment for any harm 187
to the patient resulting from the individualized investigational 188

treatment, if the manufacturer or other person or entity has 189
complied in good faith with sections 4731.971 to 4731.978 and 190
section 4729.891 of the Revised Code and has exercised 191
reasonable care. 192

Sec. 4731.9710. A patient who is an eligible patient under 193
section 4731.97 and sections 4731.971 to 4731.979 of the Revised 194
Code may elect to receive treatment in accordance with either or 195
both section 4731.97 and sections 4731.971 to 4731.979 of the 196
Revised Code. 197