

Representative Gage Froerer proposes the following substitute bill:

**INVESTIGATIONAL DRUG AND DEVICE ACCESS FOR
TERMINALLY ILL PATIENTS**

2015 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Gage Froerer

Senate Sponsor: Evan J. Vickers

LONG TITLE

General Description:

This bill amends provisions related to investigational drugs and devices.

Highlighted Provisions:

This bill:

- ▶ provides that a terminally ill patient may obtain an investigational drug or device from the drug's or device's manufacturer under certain circumstances; and
- ▶ exempts certain conduct from the definition of unlawful and unprofessional conduct for a physician who administers an investigational drug or uses an investigational device to treat a terminally ill patient.

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

58-67-501, as last amended by Laws of Utah 2001, Chapter 116

58-67-502, as last amended by Laws of Utah 2014, Chapter 72



26 **58-68-501**, as last amended by Laws of Utah 2001, Chapter 116

27 **58-68-502**, as last amended by Laws of Utah 2014, Chapter 72

28 ENACTS:

29 **58-85-101**, Utah Code Annotated 1953

30 **58-85-102**, Utah Code Annotated 1953

31 **58-85-103**, Utah Code Annotated 1953

32 **58-85-104**, Utah Code Annotated 1953

33 **58-85-105**, Utah Code Annotated 1953



35 *Be it enacted by the Legislature of the state of Utah:*

36 Section 1. Section **58-67-501** is amended to read:

37 **58-67-501. Unlawful conduct.**

38 (1) "Unlawful conduct" includes, in addition to the definition in Section **58-1-501**:

39 (a) buying, selling, or fraudulently obtaining, any medical diploma, license, certificate,
40 or registration;

41 (b) aiding or abetting the buying, selling, or fraudulently obtaining of any medical
42 diploma, license, certificate, or registration;

43 (c) substantially interfering with a licensee's lawful and competent practice of medicine
44 in accordance with this chapter by:

45 (i) any person or entity that manages, owns, operates, or conducts a business having a
46 direct or indirect financial interest in the licensee's professional practice; or

47 (ii) anyone other than another physician licensed under this title, who is engaged in
48 direct clinical care or consultation with the licensee in accordance with the standards and ethics
49 of the profession of medicine; or

50 (d) entering into a contract that limits a licensee's ability to advise the licensee's
51 patients fully about treatment options or other issues that affect the health care of the licensee's
52 patients.

53 (2) "Unlawful conduct" does not include:

54 (a) establishing, administering, or enforcing the provisions of a policy of accident and
55 health insurance by an insurer doing business in this state in accordance with Title 31A,
56 Insurance Code;

57 (b) adopting, implementing, or enforcing utilization management standards related to
58 payment for a licensee's services, provided that:

59 (i) utilization management standards adopted, implemented, and enforced by the payer
60 have been approved by a physician or by a committee that contains one or more physicians; and

61 (ii) the utilization management standards does not preclude a licensee from exercising
62 independent professional judgment on behalf of the licensee's patients in a manner that is
63 independent of payment considerations;

64 (c) developing and implementing clinical practice standards that are intended to reduce
65 morbidity and mortality or developing and implementing other medical or surgical practice
66 standards related to the standardization of effective health care practices, provided that:

67 (i) the practice standards and recommendations have been approved by a physician or
68 by a committee that contains one or more physicians; and

69 (ii) the practice standards do not preclude a licensee from exercising independent
70 professional judgment on behalf of the licensee's patients in a manner that is independent of
71 payment considerations;

72 (d) requesting or recommending that a patient obtain a second opinion from a licensee;

73 (e) conducting peer review, quality evaluation, quality improvement, risk management,
74 or similar activities designed to identify and address practice deficiencies with health care
75 providers, health care facilities, or the delivery of health care;

76 (f) providing employment supervision or adopting employment requirements that do
77 not interfere with the licensee's ability to exercise independent professional judgment on behalf
78 of the licensee's patients, provided that employment requirements that may not be considered to
79 interfere with an employed licensee's exercise of independent professional judgment include:

80 (i) an employment requirement that restricts the licensee's access to patients with
81 whom the licensee's employer does not have a contractual relationship, either directly or
82 through contracts with one or more third-party payers; or

83 (ii) providing compensation incentives that are not related to the treatment of any
84 particular patient;

85 (g) providing benefit coverage information, giving advice, or expressing opinions to a
86 patient or to a family member of a patient to assist the patient or family member in making a
87 decision about health care that has been recommended by a licensee; [or]

- 88 (h) in compliance with Section 58-85-103:
- 89 (i) obtaining an investigational drug or investigational device;
- 90 (ii) administering the investigational drug to an eligible patient; or
- 91 (iii) treating an eligible patient with the investigational drug or investigational device;

92 or

93 ~~[(h)]~~ (i) any otherwise lawful conduct that does not substantially interfere with the
94 licensee's ability to exercise independent professional judgment on behalf of the licensee's
95 patients and that does not constitute the practice of medicine as defined in this chapter.

96 Section 2. Section 58-67-502 is amended to read:

97 **58-67-502. Unprofessional conduct.**

98 (1) "Unprofessional conduct" includes, in addition to the definition in Section
99 58-1-501:

100 ~~[(+)]~~ (a) using or employing the services of any individual to assist a licensee in any
101 manner not in accordance with the generally recognized practices, standards, or ethics of the
102 profession, state law, or division rule;

103 ~~[(2)]~~ (b) making a material misrepresentation regarding the qualifications for licensure
104 under Section 58-67-302.7; or

105 ~~[(3)]~~ (c) violating the dispensing requirements of Section 58-17b-309 or Chapter 17b,
106 Part 8, Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy,
107 if applicable.

108 (2) "Unprofessional conduct" does not include, in compliance with Section 58-85-103:

109 (a) obtaining an investigational drug or investigational device;

110 (b) administering the investigational drug to an eligible patient; or

111 (c) treating an eligible patient with the investigational drug or investigational device.

112 Section 3. Section 58-68-501 is amended to read:

113 **58-68-501. Unlawful conduct.**

114 (1) "Unlawful conduct" includes, in addition to the definition in Section 58-1-501:

115 (a) buying, selling, or fraudulently obtaining any osteopathic medical diploma, license,
116 certificate, or registration; and

117 (b) aiding or abetting the buying, selling, or fraudulently obtaining of any osteopathic
118 medical diploma, license, certificate, or registration;

119 (c) substantially interfering with a licensee's lawful and competent practice of medicine
120 in accordance with this chapter by:

121 (i) any person or entity that manages, owns, operates, or conducts a business having a
122 direct or indirect financial interest in the licensee's professional practice; or

123 (ii) anyone other than another physician licensed under this title, who is engaged in
124 direct clinical care or consultation with the licensee in accordance with the standards and ethics
125 of the profession of medicine; or

126 (d) entering into a contract that limits a licensee's ability to advise the licensee's
127 patients fully about treatment options or other issues that affect the health care of the licensee's
128 patients.

129 (2) "Unlawful conduct" does not include:

130 (a) establishing, administering, or enforcing the provisions of a policy of accident and
131 health insurance by an insurer doing business in this state in accordance with Title 31A,
132 Insurance Code;

133 (b) adopting, implementing, or enforcing utilization management standards related to
134 payment for a licensee's services, provided that:

135 (i) utilization management standards adopted, implemented, and enforced by the payer
136 have been approved by a physician or by a committee that contains one or more physicians; and

137 (ii) the utilization management standards does not preclude a licensee from exercising
138 independent professional judgment on behalf of the licensee's patients in a manner that is
139 independent of payment considerations;

140 (c) developing and implementing clinical practice standards that are intended to reduce
141 morbidity and mortality or developing and implementing other medical or surgical practice
142 standards related to the standardization of effective health care practices, provided that:

143 (i) the practice standards and recommendations have been approved by a physician or
144 by a committee that contains one or more physicians; and

145 (ii) the practice standards do not preclude a licensee from exercising independent
146 professional judgment on behalf of the licensee's patients in a manner that is independent of
147 payment considerations;

148 (d) requesting or recommending that a patient obtain a second opinion from a licensee;

149 (e) conducting peer review, quality evaluation, quality improvement, risk management,

150 or similar activities designed to identify and address practice deficiencies with health care
151 providers, health care facilities, or the delivery of health care;

152 (f) providing employment supervision or adopting employment requirements that do
153 not interfere with the licensee's ability to exercise independent professional judgment on behalf
154 of the licensee's patients, provided that employment requirements that may not be considered to
155 interfere with an employed licensee's exercise of independent professional judgment include:

156 (i) an employment requirement that restricts the licensee's access to patients with
157 whom the licensee's employer does not have a contractual relationship, either directly or
158 through contracts with one or more third-party payers; or

159 (ii) providing compensation incentives that are not related to the treatment of any
160 particular patient;

161 (g) providing benefit coverage information, giving advice, or expressing opinions to a
162 patient or to a family member of a patient to assist the patient or family member in making a
163 decision about health care that has been recommended by a licensee; ~~or~~

164 (h) in compliance with Section [58-85-103](#):

165 (i) obtaining an investigational drug or investigational device;

166 (ii) administering the investigational drug to an eligible patient; or

167 (iii) treating an eligible patient with the investigational drug or investigational device;

168 or

169 ~~(h)~~ (i) any otherwise lawful conduct that does not substantially interfere with the
170 licensee's ability to exercise independent professional judgment on behalf of the licensee's
171 patients and that does not constitute the practice of medicine as defined in this chapter.

172 Section 4. Section **58-68-502** is amended to read:

173 **58-68-502. Unprofessional conduct.**

174 (1) "Unprofessional conduct" includes, in addition to the definition in Section
175 [58-1-501](#):

176 ~~(1)~~ (a) using or employing the services of any individual to assist a licensee in any
177 manner not in accordance with the generally recognized practices, standards, or ethics of the
178 profession, state law, or division rule; or

179 ~~(2)~~ (b) violating the dispensing requirements of Section [58-17b-309](#) or Chapter 17b,
180 Part 8, Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy,

181 if applicable.

182 (2) "Unprofessional conduct" does not include, in compliance with Section 58-85-103:

183 (a) obtaining an investigational drug or investigational device;

184 (b) administering the investigational drug to an eligible patient; or

185 (c) treating an eligible patient with the investigational drug or investigational device.

186 Section 5. Section 58-85-101 is enacted to read:

187 **CHAPTER 85. UTAH RIGHT TO TRY ACT**

188 **58-85-101. Title.**

189 This chapter is known as the "Utah Right to Try Act."

190 Section 6. Section 58-85-102 is enacted to read:

191 **58-85-102. Definitions.**

192 As used in this chapter:

193 (1) "Eligible patient" means an individual who has been diagnosed with a terminal
194 illness by a physician.

195 (2) "Physician" means an individual who is licensed under:

196 (a) Title 58, Chapter 67, Utah Medical Practice Act; or

197 (b) Title 58, Chapter 68, Utah Osteopathic Medical Practice Act.

198 (3) "Insurer" means the same as that term is defined in Section 31A-1-301.

199 (4) "Investigational device" means a device that:

200 (a) meets the definition of "investigational device" in 21 C.F.R. Sec. 812.3; and

201 (b) has successfully completed the United States Food and Drug Administration Phase
202 1 testing for an investigational device described in 21 C.F.R. Part 812.

203 (5) "Investigational drug" means a drug that:

204 (a) meets the definition of "investigational new drug" in 21 C.F.R. Sec. 312.3; and

205 (b) has successfully completed the United States Food and Drug Administration Phase
206 1 testing for an investigational new drug described in 21 C.F.R. Part 312.

207 (6) "Terminal illness" means a condition of a patient that:

208 (a) as determined by a physician:

209 (i) is likely to pose a greater risk to the patient than the risk posed to the patient by
210 treatment with an investigational drug or investigational device; and

211 (ii) will inevitably lead to the patient's death; and

212 (b) presents the patient, after the patient has explored conventional therapy options,
213 with no treatment option that is satisfactory or comparable to treatment with an investigational
214 drug or device.

215 Section 7. Section **58-85-103** is enacted to read:

216 **58-85-103. Right to request investigational drug or device.**

217 (1) An eligible patient may obtain an investigational drug through an agreement with
218 the investigational drug's manufacturer and the eligible patient's physician that provides:

219 (a) for the transfer of the investigational drug from the manufacturer to the physician;

220 and

221 (b) that the physician will administer the investigational drug to the patient.

222 (2) An eligible patient may obtain an investigational device through an agreement with
223 the investigational device's manufacturer and the eligible patient's physician that provides:

224 (a) for the transfer of the investigational device from the manufacturer to the physician;

225 and

226 (b) that the physician will use the investigational device to treat the patient.

227 (3) An agreement described in Subsection (1) or (2), between an eligible patient, a
228 physician, and a manufacturer, shall include an informed consent document that, based on the
229 physician's knowledge of the relevant investigational drug or investigational device:

230 (a) describes the possible positive and negative outcomes the eligible patient could
231 experience if the physician treats the eligible patient with the investigational drug or
232 investigational device, including that the investigational drug or investigational device could
233 increase the possibility of death;

234 (b) states that an insurer is not required to cover the cost of providing the
235 investigational drug or investigational device to the patient;

236 (c) states that an insurer may deny coverage for the eligible patient up to six months
237 after the day on which the physician treats the patient with the investigational drug or
238 investigational device; and

239 (d) states that the patient is liable for all expenses caused by the physician treating the
240 patient with the investigational drug or investigational device, unless the agreement provides
241 otherwise.

242 (4) A physician shall notify the eligible patient's insurer of the day on which the

243 physician treated an eligible patient with an investigational drug or investigational device under
244 an agreement described in Subsection (1).

245 Section 8. Section **58-85-104** is enacted to read:

246 **58-85-104. Insurance coverage -- No right of action.**

247 This chapter does not:

248 (1) require an insurer to cover the cost of:

249 (a) administering an investigational drug under this chapter; or

250 (b) treating a patient with an investigational device under this chapter;

251 (2) prohibit an insurer from covering the cost of:

252 (a) administering an investigational drug under this chapter; or

253 (b) treating a patient with an investigational device under this chapter;

254 (3) require a manufacturer of an investigational drug or investigational device to agree
255 to make an investigational drug or investigational device available to an eligible patient or an
256 eligible patient's physician;

257 (4) require a physician to agree to:

258 (a) administer an investigational drug to an eligible patient under this chapter; or

259 (b) treat an eligible patient with an investigational device under this chapter; or

260 (5) create a private right of action for any harm done to an eligible patient:

261 (a) resulting from the eligible patient's use of an investigational drug or investigational
262 device, against:

263 (i) a manufacturer of an investigational drug or investigational device under this
264 chapter;

265 (ii) a physician who administers an investigational drug or treats an eligible patient
266 with an investigational device under this chapter; or

267 (iii) a hospital where a physician administers an investigational drug to an eligible
268 patient or treats an eligible patient with an investigational device under this chapter;

269 (b) against a physician or hospital, for the physician's or hospital's refusal to:

270 (i) administer an investigational drug to an eligible patient under this chapter; or

271 (ii) treat an eligible patient with an investigational device under this chapter; or

272 (c) against a manufacturer, for the manufacturer's refusal to provide an eligible patient
273 with an investigational drug or an investigational device under this chapter.

274 Section 9. Section **58-85-105** is enacted to read:

275 **58-85-105. Insurance coverage -- Insurer may deny coverage for six months.**

276 (1) Except as described in Subsection (2), an insurer may deny coverage to an eligible
277 patient who is treated with an investigational drug or investigational device up to six months
278 after the day on which the eligible patient is treated with the investigational drug or device.

279 (2) An insurer may not deny coverage to an eligible patient under Subsection (1) for:

280 (a) the eligible patient's preexisting condition; or

281 (b) benefits that commenced prior to the day on which the eligible patient is treated
282 with the investigational drug or investigational device.