

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

3 2015 GENERAL SESSION

4 STATE OF UTAH

5 **Chief Sponsor: Gage Froerer**

6 Senate Sponsor: Evan J. Vickers

8 **LONG TITLE**

9 **General Description:**

10 This bill amends provisions related to investigational drugs and devices.

11 **Highlighted Provisions:**

12 This bill:

- 13 ▶ provides that a terminally ill patient may obtain an investigational drug or device
- 14 from the drug's or device's manufacturer under certain circumstances;
- 15 ▶ exempts certain conduct from the definition of unlawful and unprofessional conduct
- 16 for a physician who administers an investigational drug or uses an investigational
- 17 device to treat a terminally ill patient;
- 18 ▶ allows an insurance company to deny, under certain circumstances, coverage to an
- 19 individual who is treated with an investigational drug or device; and
- 20 ▶ provides that certain health care providers are not subject to civil or criminal
- 21 liability or licensure sanctions for treating a patient with an investigational drug or
- 22 device.

23 **Money Appropriated in this Bill:**

24 None

25 **Other Special Clauses:**

26 None

27 **Utah Code Sections Affected:**

28 AMENDS:

29 **58-67-501**, as last amended by Laws of Utah 2001, Chapter 116

30 **58-67-502**, as last amended by Laws of Utah 2014, Chapter 72

31 **58-68-501**, as last amended by Laws of Utah 2001, Chapter 116

32 **58-68-502**, as last amended by Laws of Utah 2014, Chapter 72

33 ENACTS:

34 **58-85-101**, Utah Code Annotated 1953

35 **58-85-102**, Utah Code Annotated 1953

36 **58-85-103**, Utah Code Annotated 1953

37 **58-85-104**, Utah Code Annotated 1953

38 **58-85-105**, Utah Code Annotated 1953

39

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

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

42 **58-67-501. Unlawful conduct.**

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

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

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

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

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

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

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

- 58 (2) "Unlawful conduct" does not include:
- 59 (a) establishing, administering, or enforcing the provisions of a policy of accident and
60 health insurance by an insurer doing business in this state in accordance with Title 31A,
61 Insurance Code;
- 62 (b) adopting, implementing, or enforcing utilization management standards related to
63 payment for a licensee's services, provided that:
- 64 (i) utilization management standards adopted, implemented, and enforced by the payer
65 have been approved by a physician or by a committee that contains one or more physicians; and
66 (ii) the utilization management standards does not preclude a licensee from exercising
67 independent professional judgment on behalf of the licensee's patients in a manner that is
68 independent of payment considerations;
- 69 (c) developing and implementing clinical practice standards that are intended to reduce
70 morbidity and mortality or developing and implementing other medical or surgical practice
71 standards related to the standardization of effective health care practices, provided that:
- 72 (i) the practice standards and recommendations have been approved by a physician or
73 by a committee that contains one or more physicians; and
74 (ii) the practice standards do not preclude a licensee from exercising independent
75 professional judgment on behalf of the licensee's patients in a manner that is independent of
76 payment considerations;
- 77 (d) requesting or recommending that a patient obtain a second opinion from a licensee;
- 78 (e) conducting peer review, quality evaluation, quality improvement, risk management,
79 or similar activities designed to identify and address practice deficiencies with health care
80 providers, health care facilities, or the delivery of health care;
- 81 (f) providing employment supervision or adopting employment requirements that do
82 not interfere with the licensee's ability to exercise independent professional judgment on behalf
83 of the licensee's patients, provided that employment requirements that may not be considered to
84 interfere with an employed licensee's exercise of independent professional judgment include:
- 85 (i) an employment requirement that restricts the licensee's access to patients with

86 whom the licensee's employer does not have a contractual relationship, either directly or
87 through contracts with one or more third-party payers; or

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

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

93 (h) in compliance with Section 58-85-103:

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

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

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

97 or

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

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

102 **58-67-502. Unprofessional conduct.**

103 (1) "Unprofessional conduct" includes, in addition to the definition in Section
104 58-1-501:

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

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

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

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

- 114 (a) obtaining an investigational drug or investigational device;
- 115 (b) administering the investigational drug to an eligible patient; or
- 116 (c) treating an eligible patient with the investigational drug or investigational device.

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

118 **58-68-501. Unlawful conduct.**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

169 (h) in compliance with Section [58-85-103](#);

- 170 (i) obtaining an investigational drug or investigational device;
- 171 (ii) administering the investigational drug to an eligible patient; or
- 172 (iii) treating an eligible patient with the investigational drug or investigational device;

173 or

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

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

178 **58-68-502. Unprofessional conduct.**

179 (1) "Unprofessional conduct" includes, in addition to the definition in Section
180 [58-1-501](#):

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

184 ~~[(2)]~~ (b) violating the dispensing requirements of Section [58-17b-309](#) or Chapter 17b,
185 Part 8, Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy,
186 if applicable.

187 (2) "Unprofessional conduct" does not include, in compliance with Section [58-85-103](#):

- 188 (a) obtaining an investigational drug or investigational device;
- 189 (b) administering the investigational drug to an eligible patient; or
- 190 (c) treating an eligible patient with the investigational drug or investigational device.

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

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

193 **58-85-101. Title.**

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

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

196 **58-85-102. Definitions.**

197 As used in this chapter:

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

200 (2) "Insurer" means the same as that term is defined in Section [31A-1-301](#).

201 (3) "Investigational device" means a device that:

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

203 (b) has successfully completed the United States Food and Drug Administration Phase
204 1 testing for an investigational device described in 21 C.F.R. Part 812.

205 (4) "Investigational drug" means a drug that:

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

207 (b) has successfully completed the United States Food and Drug Administration Phase
208 1 testing for an investigational new drug described in 21 C.F.R. Part 312.

209 (5) "Physician" means an individual who is licensed under:

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

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

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

213 (a) as determined by a physician:

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

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

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

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

221 **58-85-103. Right to request investigational drug or device.**

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

224 (a) for the transfer of the investigational drug from the manufacturer to the physician;
225 and

226 (b) that the physician will administer the investigational drug to the patient.
227 (2) An eligible patient may obtain an investigational device through an agreement with
228 the investigational device's manufacturer and the eligible patient's physician that provides:
229 (a) for the transfer of the investigational device from the manufacturer to the physician;
230 and
231 (b) that the physician will use the investigational device to treat the patient.
232 (3) An agreement described in Subsection (1) or (2), between an eligible patient, a
233 physician, and a manufacturer, shall include an informed consent document that, based on the
234 physician's knowledge of the relevant investigational drug or investigational device:
235 (a) describes the possible positive and negative outcomes the eligible patient could
236 experience if the physician treats the eligible patient with the investigational drug or
237 investigational device, including that the investigational drug or investigational device could
238 increase the possibility of death;
239 (b) states that an insurer is not required to cover the cost of providing the
240 investigational drug or investigational device to the patient;
241 (c) states that, subject to Section 58-85-105, an insurer may deny coverage for the
242 eligible patient; and
243 (d) states that the patient may be liable for all expenses caused by the physician treating
244 the patient with the investigational drug or investigational device, unless the agreement
245 provides otherwise.
246 (4) A physician or an eligible patient shall notify the eligible patient's insurer of the day
247 on which the physician treated an eligible patient with an investigational drug or investigational
248 device, and the investigational drug or device used, under an agreement described in
249 Subsection (1) or (2).

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

251 **58-85-104. Standard of care -- Medical practitioners not liable -- No private right**
252 **of action.**

253 (1) It is not a breach of the applicable standard of care for a physician, other licensed

254 health care provider, or hospital to treat an eligible patient with an investigational drug or
255 investigational device under this chapter.

256 (2) A physician, other licensed health care provider, or hospital that treats an eligible
257 patient with an investigational drug or investigational device under this chapter may not, for
258 any harm done to the eligible patient by the investigational drug or device, be subject to:

259 (a) civil liability;

260 (b) criminal liability;

261 (c) licensure sanctions under:

262 (i) for a physician:

263 (A) Title 58, Chapter 67, Utah Medical Practice Act; or

264 (B) Title 58, Chapter 68, Utah Osteopathic Medical Practice Act;

265 (ii) for the other licensed health care provider, the act governing the other licensed
266 health care provider's license; or

267 (iii) for the hospital, Title 26, Chapter 21, Health Care Facility Licensing and
268 Inspection Act.

269 (3) This chapter does not:

270 (a) require a manufacturer of an investigational drug or investigational device to agree
271 to make an investigational drug or investigational device available to an eligible patient or an
272 eligible patient's physician;

273 (b) require a physician to agree to:

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

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

276 (c) create a private right of action for an eligible patient:

277 (i) against a physician or hospital, for the physician's or hospital's refusal to:

278 (A) administer an investigational drug to an eligible patient under this chapter; or

279 (B) treat an eligible patient with an investigational device under this chapter; or

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

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

283 **58-85-105. Insurance coverage.**

284 (1) This chapter does not:

285 (a) require an insurer to cover the cost of:

286 (i) administering an investigational drug under this chapter; or

287 (ii) treating a patient with an investigational device under this chapter; or

288 (b) prohibit an insurer from covering the cost of:

289 (i) administering an investigational drug under this chapter; or

290 (ii) treating a patient with an investigational device under this chapter.

291 (2) Except as described in Subsection (3), an insurer may deny coverage to an eligible

292 patient who is treated with an investigational drug or investigational device, for harm to the

293 eligible patient caused by the investigational drug or investigational device.

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

295 (a) the eligible patient's preexisting condition;

296 (b) benefits that commenced before the day on which the eligible patient is treated with

297 the investigational drug or investigational device; or

298 (c) palliative or hospice care for an eligible patient that has been treated with an

299 investigational drug or device, but is no longer receiving curative treatment with the

300 investigational drug or device.