

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; and
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 **Money Appropriated in this Bill:**

19 None

20 **Other Special Clauses:**

21 None

22 **Utah Code Sections Affected:**

23 AMENDS:

24 **58-67-501**, as last amended by Laws of Utah 2001, Chapter 116

25 **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

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

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

36 **58-67-501. Unlawful conduct.**

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

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

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

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

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

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

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

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

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

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

58 (i) utilization management standards adopted, implemented, and enforced by the payer

59 have been approved by a physician or by a committee that contains one or more physicians; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

91 or

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

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

96 **58-67-502. Unprofessional conduct.**

97 (1) "Unprofessional conduct" includes, in addition to the definition in Section

98 [58-1-501](#):

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

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

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

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

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

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

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

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

112 **58-68-501. Unlawful conduct.**

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

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

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

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

120 (i) any person or entity that manages, owns, operates, or conducts a business having a

121 direct or indirect financial interest in the licensee's professional practice; or

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

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

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

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

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

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

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

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

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

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

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

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

151 (f) providing employment supervision or adopting employment requirements that do

152 not interfere with the licensee's ability to exercise independent professional judgment on behalf
153 of the licensee's patients, provided that employment requirements that may not be considered to
154 interfere with an employed licensee's exercise of independent professional judgment include:

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

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

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

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

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

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

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

167 or

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

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

172 **58-68-502. Unprofessional conduct.**

173 (1) "Unprofessional conduct" includes, in addition to the definition in Section
174 58-1-501:

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

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

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

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

- 183 (b) administering the investigational drug to an eligible patient; or
- 184 (c) treating an eligible patient with the investigational drug or investigational device.

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

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

187 **58-85-101. Title.**

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

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

190 **58-85-102. Definitions.**

191 As used in this chapter:

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

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

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

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

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

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

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

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

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

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

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

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

207 (a) is serious or life-threatening;

208 (b) as determined by a physician, is likely to pose a greater risk to the patient than the
209 risk posed to the patient by treatment with an investigational drug or investigational device;

210 and

211 (c) presents the patient with no treatment option that is satisfactory or comparable to
212 treatment with an investigational drug or device.

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

214 **58-85-103. Right to request investigational drug or device.**

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

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

218 and

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

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

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

223 and

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

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

226 **58-85-104. Insurance coverage -- No right of action.**

227 This chapter does not:

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

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

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

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

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

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

234 (3) require a manufacturer of an investigational drug or investigational device to agree

235 to make an investigational drug or investigational device available to an eligible patient or an

236 eligible patient's physician;

237 (4) require a physician to agree to:

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

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

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

241 (a) resulting from the eligible patient's use of an investigational drug or investigational

242 device, against:

243 (i) a manufacturer of an investigational drug or investigational device under this

244 chapter;

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

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

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

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

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

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

Legislative Review Note

as of 1-5-15 5:25 PM

Office of Legislative Research and General Counsel