

1 **USE OF CONTROLLED SUBSTANCES IN RESEARCH**

2 2012 GENERAL SESSION

3 STATE OF UTAH

4 **Chief Sponsor: Dean Sanpei**

5 Senate Sponsor: J. Stuart Adams

6 Cosponsors: Brian Doughty Evan J. Vickers
7 Bradley M. Daw Gage Froerer

8
9 **LONG TITLE**

10 **General Description:**

11 This bill modifies the Utah Controlled Substances Act regarding licenses to conduct
12 research.

13 **Highlighted Provisions:**

14 This bill:
15 ▶ specifies that the Division of Occupational and Professional Licensing may grant
16 licenses, under specified terms, to conduct research concerning Schedule I
17 controlled substances.

18 **Money Appropriated in this Bill:**

19 None

20 **Other Special Clauses:**

21 None

22 **Utah Code Sections Affected:**

23 AMENDS:

24 **58-37-6**, as last amended by Laws of Utah 2011, Chapters 12 and 214

25
26 *Be it enacted by the Legislature of the state of Utah:*

27 Section 1. Section **58-37-6** is amended to read:

28 **58-37-6. License to manufacture, produce, distribute, dispense, administer, or**

29 **conduct research -- Issuance by division -- Denial, suspension, or revocation -- Records**
30 **required -- Prescriptions.**

31 (1) (a) The division may adopt rules relating to the licensing and control of the
32 manufacture, distribution, production, prescription, administration, dispensing, conducting of
33 research with, and performing of laboratory analysis upon controlled substances within this
34 state.

35 (b) The division may assess reasonable fees to defray the cost of issuing original and
36 renewal licenses under this chapter pursuant to Section 63J-1-504.

37 (2) (a) (i) Every person who manufactures, produces, distributes, prescribes, dispenses,
38 administers, conducts research with, or performs laboratory analysis upon any controlled
39 substance in Schedules [H] I through V within this state, or who proposes to engage in
40 manufacturing, producing, distributing, prescribing, dispensing, administering, conducting
41 research with, or performing laboratory analysis upon controlled substances included in
42 Schedules [H] I through V within this state shall obtain a license issued by the division.

43 (ii) The division shall issue each license under this chapter in accordance with a
44 two-year renewal cycle established by rule. The division may by rule extend or shorten a
45 renewal period by as much as one year to stagger the renewal cycles it administers.

46 (b) Persons licensed to manufacture, produce, distribute, prescribe, dispense,
47 administer, conduct research with, or perform laboratory analysis upon controlled substances in
48 Schedules [H] I through V within this state may possess, manufacture, produce, distribute,
49 prescribe, dispense, administer, conduct research with, or perform laboratory analysis upon
50 those substances to the extent authorized by their license and in conformity with this chapter.

51 (c) The following persons are not required to obtain a license and may lawfully possess
52 controlled substances included in Schedules II through V under this section:

53 (i) an agent or employee, except a sales representative, of any registered manufacturer,
54 distributor, or dispenser of any controlled substance, if the agent or employee is acting in the
55 usual course of the person's business or employment; however, nothing in this subsection shall
56 be interpreted to permit an agent, employee, sales representative, or detail man to maintain an

57 inventory of controlled substances separate from the location of the person's employer's
58 registered and licensed place of business;

59 (ii) a motor carrier or warehouseman, or an employee of a motor carrier or
60 warehouseman, who possesses any controlled substance in the usual course of the person's
61 business or employment; and

62 (iii) an ultimate user, or any person who possesses any controlled substance pursuant to
63 a lawful order of a practitioner.

64 (d) The division may enact rules waiving the license requirement for certain
65 manufacturers, producers, distributors, prescribers, dispensers, administrators, research
66 practitioners, or laboratories performing analysis if consistent with the public health and safety.

67 (e) A separate license is required at each principal place of business or professional
68 practice where the applicant manufactures, produces, distributes, dispenses, conducts research
69 with, or performs laboratory analysis upon controlled substances.

70 (f) The division may enact rules providing for the inspection of a licensee or applicant's
71 establishment, and may inspect the establishment according to those rules.

72 (3) (a) (i) Upon proper application, the division shall license a qualified applicant to
73 manufacture, produce, distribute, conduct research with, or perform laboratory analysis upon
74 controlled substances included in Schedules I through V, unless it determines that issuance of a
75 license is inconsistent with the public interest.

76 (ii) The division ~~shall~~ may not issue a license to any person to prescribe, dispense, or
77 administer a Schedule I controlled substance except under Subsection (3)(a)(i).

78 (iii) In determining public interest under this Subsection (3)(a), the division shall
79 consider whether or not the applicant has:

80 [(†)] (A) maintained effective controls against diversion of controlled substances and
81 any Schedule I or II substance compounded from any controlled substance into other than
82 legitimate medical, scientific, or industrial channels;

83 [(†)] (B) complied with applicable state and local law;

84 [(†)] (C) been convicted under federal or state laws relating to the manufacture,

85 distribution, or dispensing of substances;

86 [~~(iv)~~] (D) past experience in the manufacture of controlled dangerous substances;

87 [~~(v)~~] (E) established effective controls against diversion; and

88 [~~(vi)~~] (F) complied with any other factors that the division establishes that promote the
89 public health and safety.

90 (b) Licenses granted under Subsection (3)(a) do not entitle a licensee to manufacture,
91 produce, distribute, conduct research with, or perform laboratory analysis upon controlled
92 substances in Schedule I other than those specified in the license.

93 (c) (i) Practitioners shall be licensed to administer, dispense, or conduct research with
94 substances in Schedules II through V if they are authorized to administer, dispense, or conduct
95 research under the laws of this state.

96 (ii) The division need not require a separate license for practitioners engaging in
97 research with nonnarcotic controlled substances in Schedules II through V where the licensee is
98 already licensed under this chapter in another capacity.

99 (iii) With respect to research involving narcotic substances in Schedules II through V,
100 or where the division by rule requires a separate license for research of nonnarcotic substances
101 in Schedules II through V, a practitioner shall apply to the division prior to conducting
102 research.

103 (iv) Licensing for purposes of bona fide research with controlled substances by a
104 practitioner considered qualified may be denied only on a ground specified in Subsection (4),
105 or upon evidence that the applicant will abuse or unlawfully transfer or fail to safeguard
106 adequately the practitioner's supply of substances against diversion from medical or scientific
107 use.

108 (v) Practitioners registered under federal law to conduct research in Schedule I
109 substances may conduct research in Schedule I substances within this state upon furnishing the
110 division evidence of federal registration.

111 (d) Compliance by manufacturers, producers, and distributors with the provisions of
112 federal law respecting registration, excluding fees, entitles them to be licensed under this

113 chapter.

114 (e) The division shall initially license those persons who own or operate an
115 establishment engaged in the manufacture, production, distribution, dispensation, or
116 administration of controlled substances prior to April 3, 1980, and who are licensed by the
117 state.

118 (4) (a) Any license pursuant to Subsection (2) or (3) may be denied, suspended, placed
119 on probation, or revoked by the division upon finding that the applicant or licensee has:

120 (i) materially falsified any application filed or required pursuant to this chapter;

121 (ii) been convicted of an offense under this chapter or any law of the United States, or
122 any state, relating to any substance defined as a controlled substance;

123 (iii) been convicted of a felony under any other law of the United States or any state
124 within five years of the date of the issuance of the license;

125 (iv) had a federal registration or license denied, suspended, or revoked by competent
126 federal authority and is no longer authorized to manufacture, distribute, prescribe, or dispense
127 controlled substances;

128 (v) had the licensee's license suspended or revoked by competent authority of another
129 state for violation of laws or regulations comparable to those of this state relating to the
130 manufacture, distribution, or dispensing of controlled substances;

131 (vi) violated any division rule that reflects adversely on the licensee's reliability and
132 integrity with respect to controlled substances;

133 (vii) refused inspection of records required to be maintained under this chapter by a
134 person authorized to inspect them; or

135 (viii) prescribed, dispensed, administered, or injected an anabolic steroid for the
136 purpose of manipulating human hormonal structure so as to:

137 (A) increase muscle mass, strength, or weight without medical necessity and without a
138 written prescription by any practitioner in the course of the practitioner's professional practice;

139 or

140 (B) improve performance in any form of human exercise, sport, or game.

141 (b) The division may limit revocation or suspension of a license to a particular
142 controlled substance with respect to which grounds for revocation or suspension exist.

143 (c) (i) Proceedings to deny, revoke, or suspend a license shall be conducted pursuant to
144 this section and in accordance with the procedures set forth in Title 58, Chapter 1, Division of
145 Occupational and Professional Licensing Act, and conducted in conjunction with the
146 appropriate representative committee designated by the director of the department.

147 (ii) Nothing in this Subsection (4)(c) gives the Division of Occupational and
148 Professional Licensing exclusive authority in proceedings to deny, revoke, or suspend licenses,
149 except where the division is designated by law to perform those functions, or, when not
150 designated by law, is designated by the executive director of the Department of Commerce to
151 conduct the proceedings.

152 (d) (i) The division may suspend any license simultaneously with the institution of
153 proceedings under this section if it finds there is an imminent danger to the public health or
154 safety.

155 (ii) Suspension shall continue in effect until the conclusion of proceedings, including
156 judicial review, unless withdrawn by the division or dissolved by a court of competent
157 jurisdiction.

158 (e) (i) If a license is suspended or revoked under this Subsection (4), all controlled
159 substances owned or possessed by the licensee may be placed under seal in the discretion of the
160 division.

161 (ii) Disposition may not be made of substances under seal until the time for taking an
162 appeal has lapsed, or until all appeals have been concluded, unless a court, upon application,
163 orders the sale of perishable substances and the proceeds deposited with the court.

164 (iii) If a revocation order becomes final, all controlled substances shall be forfeited.

165 (f) The division shall notify promptly the Drug Enforcement Administration of all
166 orders suspending or revoking a license and all forfeitures of controlled substances.

167 (g) If an individual's Drug Enforcement Administration registration is denied, revoked,
168 surrendered, or suspended, the division shall immediately suspend the individual's controlled

169 substance license, which shall only be reinstated by the division upon reinstatement of the
170 federal registration, unless the division has taken further administrative action under
171 Subsection (4)(a)(iv), which would be grounds for the continued denial of the controlled
172 substance license.

173 (5) (a) Persons licensed under Subsection (2) or (3) shall maintain records and
174 inventories in conformance with the record keeping and inventory requirements of federal and
175 state law and any additional rules issued by the division.

176 (b) (i) Every physician, dentist, naturopathic physician, veterinarian, practitioner, or
177 other person who is authorized to administer or professionally use a controlled substance shall
178 keep a record of the drugs received by him and a record of all drugs administered, dispensed, or
179 professionally used by him otherwise than by a prescription.

180 (ii) A person using small quantities or solutions or other preparations of those drugs for
181 local application has complied with this Subsection (5)(b) if the person keeps a record of the
182 quantity, character, and potency of those solutions or preparations purchased or prepared by
183 him, and of the dates when purchased or prepared.

184 (6) Controlled substances in Schedules I through V may be distributed only by a
185 licensee and pursuant to an order form prepared in compliance with division rules or a lawful
186 order under the rules and regulations of the United States.

187 (7) (a) A person may not write or authorize a prescription for a controlled substance
188 unless the person is:

189 (i) a practitioner authorized to prescribe drugs and medicine under the laws of this state
190 or under the laws of another state having similar standards; and

191 (ii) licensed under this chapter or under the laws of another state having similar
192 standards.

193 (b) A person other than a pharmacist licensed under the laws of this state, or the
194 pharmacist's licensed intern, as required by Sections 58-17b-303 and 58-17b-304, may not
195 dispense a controlled substance.

196 (c) (i) A controlled substance may not be dispensed without the written prescription of

197 a practitioner, if the written prescription is required by the federal Controlled Substances Act.

198 (ii) That written prescription shall be made in accordance with Subsection (7)(a) and in
199 conformity with Subsection (7)(d).

200 (iii) In emergency situations, as defined by division rule, controlled substances may be
201 dispensed upon oral prescription of a practitioner, if reduced promptly to writing on forms
202 designated by the division and filed by the pharmacy.

203 (iv) Prescriptions reduced to writing by a pharmacist shall be in conformity with
204 Subsection (7)(d).

205 (d) Except for emergency situations designated by the division, a person may not issue,
206 fill, compound, or dispense a prescription for a controlled substance unless the prescription is
207 signed by the prescriber in ink or indelible pencil or is signed with an electronic signature of
208 the prescriber as authorized by division rule, and contains the following information:

209 (i) the name, address, and registry number of the prescriber;

210 (ii) the name, address, and age of the person to whom or for whom the prescription is
211 issued;

212 (iii) the date of issuance of the prescription; and

213 (iv) the name, quantity, and specific directions for use by the ultimate user of the
214 controlled substance.

215 (e) A prescription may not be written, issued, filled, or dispensed for a Schedule I
216 controlled substance[-] unless:

217 (i) the person who writes the prescription is licensed under Subsection (2); and

218 (ii) the prescribed controlled substance is to be used in research.

219 (f) Except when administered directly to an ultimate user by a licensed practitioner,
220 controlled substances are subject to the following restrictions:

221 (i) (A) A prescription for a Schedule II substance may not be refilled.

222 (B) A Schedule II controlled substance may not be filled in a quantity to exceed a
223 one-month's supply, as directed on the daily dosage rate of the prescriptions.

224 (ii) A Schedule III or IV controlled substance may be filled only within six months of

225 issuance, and may not be refilled more than six months after the date of its original issuance or
226 be refilled more than five times after the date of the prescription unless renewed by the
227 practitioner.

228 (iii) All other controlled substances in Schedule V may be refilled as the prescriber's
229 prescription directs, but they may not be refilled one year after the date the prescription was
230 issued unless renewed by the practitioner.

231 (iv) Any prescription for a Schedule II substance may not be dispensed if it is not
232 presented to a pharmacist for dispensing by a pharmacist or a pharmacy intern within 30 days
233 after the date the prescription was issued, or 30 days after the dispensing date, if that date is
234 specified separately from the date of issue.

235 (v) A practitioner may issue more than one prescription at the same time for the same
236 Schedule II controlled substance, but only under the following conditions:

237 (A) no more than three prescriptions for the same Schedule II controlled substance may
238 be issued at the same time;

239 (B) no one prescription may exceed a 30-day supply;

240 (C) a second or third prescription shall include the date of issuance and the date for
241 dispensing; and

242 (D) unless the practitioner determines there is a valid medical reason to the contrary,
243 the date for dispensing a second or third prescription may not be fewer than 30 days from the
244 dispensing date of the previous prescription.

245 (vi) Each prescription for a controlled substance may contain only one controlled
246 substance per prescription form and may not contain any other legend drug or prescription
247 item.

248 (g) An order for a controlled substance in Schedules II through V for use by an
249 inpatient or an outpatient of a licensed hospital is exempt from all requirements of this
250 Subsection (7) if the order is:

251 (i) issued or made by a prescribing practitioner who holds an unrestricted registration
252 with the federal Drug Enforcement Administration, and an active Utah controlled substance

253 license in good standing issued by the division under this section, or a medical resident who is
254 exempted from licensure under Subsection 58-1-307(1)(c);

255 (ii) authorized by the prescribing practitioner treating the patient and the prescribing
256 practitioner designates the quantity ordered;

257 (iii) entered upon the record of the patient, the record is signed by the prescriber
258 affirming the prescriber's authorization of the order within 48 hours after filling or
259 administering the order, and the patient's record reflects the quantity actually administered; and

260 (iv) filled and dispensed by a pharmacist practicing the pharmacist's profession within
261 the physical structure of the hospital, or the order is taken from a supply lawfully maintained by
262 the hospital and the amount taken from the supply is administered directly to the patient
263 authorized to receive it.

264 (h) A practitioner licensed under this chapter may not prescribe, administer, or
265 dispense a controlled substance to a child, without first obtaining the consent required in
266 Section 78B-3-406 of a parent, guardian, or person standing in loco parentis of the child except
267 in cases of an emergency. For purposes of this Subsection (7)(h), "child" has the same
268 meaning as defined in Section 78A-6-105, and "emergency" means any physical condition
269 requiring the administration of a controlled substance for immediate relief of pain or suffering.

270 (i) A practitioner licensed under this chapter may not prescribe or administer dosages
271 of a controlled substance in excess of medically recognized quantities necessary to treat the
272 ailment, malady, or condition of the ultimate user.

273 (j) A practitioner licensed under this chapter may not prescribe, administer, or dispense
274 any controlled substance to another person knowing that the other person is using a false name,
275 address, or other personal information for the purpose of securing the controlled substance.

276 (k) A person who is licensed under this chapter to manufacture, distribute, or dispense
277 a controlled substance may not manufacture, distribute, or dispense a controlled substance to
278 another licensee or any other authorized person not authorized by this license.

279 (l) A person licensed under this chapter may not omit, remove, alter, or obliterate a
280 symbol required by this chapter or by a rule issued under this chapter.

281 (m) A person licensed under this chapter may not refuse or fail to make, keep, or
282 furnish any record notification, order form, statement, invoice, or information required under
283 this chapter.

284 (n) A person licensed under this chapter may not refuse entry into any premises for
285 inspection as authorized by this chapter.

286 (o) A person licensed under this chapter may not furnish false or fraudulent material
287 information in any application, report, or other document required to be kept by this chapter or
288 willfully make any false statement in any prescription, order, report, or record required by this
289 chapter.

290 (8) (a) (i) Any person licensed under this chapter who is found by the division to have
291 violated any of the provisions of Subsections (7)(k) through (o) or Subsection (10) is subject to
292 a penalty not to exceed \$5,000. The division shall determine the procedure for adjudication of
293 any violations in accordance with Sections 58-1-106 and 58-1-108.

294 (ii) The division shall deposit all penalties collected under Subsection (8)(a)(i) in the
295 General Fund as a dedicated credit to be used by the division under Subsection 58-37f-502(1).

296 (b) Any person who knowingly and intentionally violates Subsections (7)(h) through (j)
297 or Subsection (10) is:

298 (i) upon first conviction, guilty of a class B misdemeanor;

299 (ii) upon second conviction, guilty of a class A misdemeanor; and

300 (iii) on third or subsequent conviction, guilty of a third degree felony.

301 (c) Any person who knowingly and intentionally violates Subsections (7)(k) through
302 (o) shall upon conviction be guilty of a third degree felony.

303 (9) Any information communicated to any licensed practitioner in an attempt to
304 unlawfully procure, or to procure the administration of, a controlled substance is not considered
305 to be a privileged communication.

306 (10) A person holding a valid license under this chapter who is engaged in medical
307 research may produce, possess, ~~[or]~~ administer, ~~[but may not]~~ prescribe, or dispense~~[-]~~ a
308 controlled substance for research purposes as licensed under Subsection (2) but may not

309 otherwise prescribe or dispense a controlled substance listed in Section 58-37-4.2.