

1 **USE OF CONTROLLED SUBSTANCES IN RESEARCH**

2 2012 GENERAL SESSION

3 STATE OF UTAH

4 **Chief Sponsor: Dean Sanpei**

5 Senate Sponsor: _____

6

7 **LONG TITLE**

8 **General Description:**

9 This bill modifies the Utah Controlled Substances Act regarding licenses to conduct
10 research.

11 **Highlighted Provisions:**

12 This bill:

13 ▶ specifies that the Division of Occupational and Professional Licensing may grant
14 licenses, under specified terms, to conduct research concerning Schedule 1
15 controlled substances.

16 **Money Appropriated in this Bill:**

17 None

18 **Other Special Clauses:**

19 None

20 **Utah Code Sections Affected:**

21 AMENDS:

22 **58-37-6**, as last amended by Laws of Utah 2011, Chapters 12 and 214

23

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

25 Section 11. Section **58-37-6** is amended to read:

26 **58-37-6. License to manufacture, produce, distribute, dispense, administer, or**
27 **conduct research -- Issuance by division -- Denial, suspension, or revocation -- Records**



28 **required -- Prescriptions.**

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

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

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

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

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

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

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

57 (ii) a motor carrier or warehouseman, or an employee of a motor carrier or
58 warehouseman, who possesses any controlled substance in the usual course of the person's

59 business or employment; and

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

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

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

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

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

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

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

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

81 [(ii)] (B) complied with applicable state and local law;

82 [(iii)] (C) been convicted under federal or state laws relating to the manufacture,
83 distribution, or dispensing of substances;

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

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

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

88 (b) Licenses granted under Subsection (3)(a) do not entitle a licensee to manufacture,
89 produce, distribute, conduct research with, or perform laboratory analysis upon controlled

90 substances in Schedule I other than those specified in the license.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

152 safety.

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

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

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

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

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

165 (g) If an individual's Drug Enforcement Administration registration is denied, revoked,
166 surrendered, or suspended, the division shall immediately suspend the individual's controlled
167 substance license, which shall only be reinstated by the division upon reinstatement of the
168 federal registration, unless the division has taken further administrative action under
169 Subsection (4)(a)(iv), which would be grounds for the continued denial of the controlled
170 substance license.

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

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

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

182 (6) Controlled substances in Schedules I through V may be distributed only by a

183 licensee and pursuant to an order form prepared in compliance with division rules or a lawful
184 order under the rules and regulations of the United States.

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

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

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

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

194 (c) (i) A controlled substance may not be dispensed without the written prescription of
195 a practitioner, if the written prescription is required by the federal Controlled Substances Act.

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

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

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

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

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

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

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

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

213 (e) A prescription may not be written, issued, filled, or dispensed for a Schedule I

214 controlled substance[-] unless:

215 (i) the person to whom the prescription is issued is licensed under Subsection (2); and

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

217 (f) Except when administered directly to an ultimate user by a licensed practitioner,

218 controlled substances are subject to the following restrictions:

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

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

222 (ii) A Schedule III or IV controlled substance may be filled only within six months of
223 issuance, and may not be refilled more than six months after the date of its original issuance or
224 be refilled more than five times after the date of the prescription unless renewed by the
225 practitioner.

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

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

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

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

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

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

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

243 (vi) Each prescription for a controlled substance may contain only one controlled
244 substance per prescription form and may not contain any other legend drug or prescription

245 item.

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

249 (i) issued or made by a prescribing practitioner who holds an unrestricted registration
250 with the federal Drug Enforcement Administration, and an active Utah controlled substance
251 license in good standing issued by the division under this section, or a medical resident who is
252 exempted from licensure under Subsection 58-1-307(1)(c);

253 (ii) authorized by the prescribing practitioner treating the patient and the prescribing
254 practitioner designates the quantity ordered;

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

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

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

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

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

274 (k) A person who is licensed under this chapter to manufacture, distribute, or dispense
275 a controlled substance may not manufacture, distribute, or dispense a controlled substance to

276 another licensee or any other authorized person not authorized by this license.

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

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

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

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

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

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

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

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

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

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

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

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

304 (10) A person holding a valid license under this chapter who is engaged in medical
305 research may produce, possess, or administer, but may not prescribe or dispense, a controlled
306 substance listed in Section 58-37-4.2.

Legislative Review Note
as of 1-30-12 11:57 AM

Office of Legislative Research and General Counsel