

Representative Raymond P. Ward proposes the following substitute bill:

OPIOID PRESCRIBING REGULATIONS

2017 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Raymond P. Ward

Senate Sponsor: _____

LONG TITLE

General Description:

This bill amends the Division of Occupational and Professional Licensing Act related to the prescribing of certain controlled substances.

Highlighted Provisions:

This bill:

- ▶ limits the number of days for which an opiate may be prescribed for certain individuals;
- ▶ removes an outdated provision from the Utah Controlled Substances Act related to opiate prescribing; and
- ▶ amends provisions of the Controlled Substance Database Act related to provider use of the database.

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

58-37-6, as last amended by Laws of Utah 2014, Chapter 78



26 [58-37f-304](#), as enacted by Laws of Utah 2016, Chapter 275



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

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

30 **58-37-6. License to manufacture, produce, distribute, dispense, administer, or**
31 **conduct research -- Issuance by division -- Denial, suspension, or revocation -- Records**
32 **required -- Prescriptions.**

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

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

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

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

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

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

55 (i) an agent or employee, except a sales representative, of any registered manufacturer,
56 distributor, or dispenser of any controlled substance, if the agent or employee is acting in the

57 usual course of the person's business or employment; however, nothing in this subsection shall
58 be interpreted to permit an agent, employee, sales representative, or detail man to maintain an
59 inventory of controlled substances separate from the location of the person's employer's
60 registered and licensed place of business;

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

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

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

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

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

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

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

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

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

85 (B) complied with applicable state and local law;

86 (C) been convicted under federal or state laws relating to the manufacture, distribution,
87 or dispensing of substances;

88 (D) past experience in the manufacture of controlled dangerous substances;
89 (E) established effective controls against diversion; and
90 (F) complied with any other factors that the division establishes that promote the public
91 health and safety.

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

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

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

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

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

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

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

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

119 state.

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

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

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

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

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

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

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

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

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

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

141 or

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

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

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

149 (ii) Nothing in this Subsection (4)(c) gives the Division of Occupational and

150 Professional Licensing exclusive authority in proceedings to deny, revoke, or suspend licenses,
151 except where the division is designated by law to perform those functions, or, when not
152 designated by law, is designated by the executive director of the Department of Commerce to
153 conduct the proceedings.

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

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

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

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

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

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

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

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

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

181 professionally used by him otherwise than by a prescription.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

217 (e) A prescription may not be written, issued, filled, or dispensed for a Schedule I
218 controlled substance unless:

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

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

221 (f) Except when administered directly to an ultimate user by a licensed practitioner,
222 controlled substances are subject to the ~~following~~ restrictions~~[:]~~ of this Subsection (7)(f).

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

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

226 (iii) (A) If an individual has not filled a prescription for a Schedule II or III controlled
227 substance that is an opiate within the last 90 days, a Schedule II or III controlled substance that
228 is an opiate may not be filled in a quantity to exceed a seven day supply as directed on the daily
229 dosage rate of the prescription.

230 (B) A pharmacist is not required to verify that a prescription is in compliance with
231 Subsection (7)(f)(iii)(A).

232 ~~(iv)~~ (iv) A Schedule III or IV controlled substance may be filled only within six
233 months of issuance, and may not be refilled more than six months after the date of its original
234 issuance or be refilled more than five times after the date of the prescription unless renewed by
235 the practitioner.

236 ~~(v)~~ (v) All other controlled substances in Schedule V may be refilled as the
237 prescriber's prescription directs, but they may not be refilled one year after the date the
238 prescription was issued unless renewed by the practitioner.

239 ~~(vi)~~ (vi) Any prescription for a Schedule II substance may not be dispensed if it is not
240 presented to a pharmacist for dispensing by a pharmacist or a pharmacy intern within 30 days
241 after the date the prescription was issued, or 30 days after the dispensing date, if that date is
242 specified separately from the date of issue.

243 [~~(v)~~] (vii) A practitioner may issue more than one prescription at the same time for the
244 same Schedule II controlled substance, but only under the following conditions:

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

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

248 (C) a second or third prescription shall include the date of issuance and the date for
249 dispensing[~~; and~~].

250 [~~(D) unless the practitioner determines there is a valid medical reason to the contrary,~~
251 ~~the date for dispensing a second or third prescription may not be fewer than 30 days from the~~
252 ~~dispensing date of the previous prescription.]~~

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

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

260 (ii) authorized by the prescribing practitioner treating the patient and the prescribing
261 practitioner designates the quantity ordered;

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

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

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

274 requiring the administration of a controlled substance for immediate relief of pain or suffering.

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

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

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

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

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

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

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

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

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

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

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

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

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

306 (c) Any person who knowingly and intentionally violates Subsections (7)(k) through

307 (o) shall upon conviction be guilty of a third degree felony.

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

311 (10) A person holding a valid license under this chapter who is engaged in medical
312 research may produce, possess, administer, prescribe, or dispense a controlled substance for
313 research purposes as licensed under Subsection (2) but may not otherwise prescribe or dispense
314 a controlled substance listed in Section 58-37-4.2.

315 Section 2. Section 58-37f-304 is amended to read:

316 **58-37f-304. Database utilization.**

317 (1) As used in this section:

318 (a) "Dispenser" means a licensed pharmacist, as described in Section 58-17b-303, or
319 the pharmacist's licensed intern, as described in Section 58-17b-304, who is also licensed to
320 dispense a controlled substance under Title 58, Chapter 37, Utah Controlled Substances Act.

321 ~~[(b) "Opioid" means those substances listed in Subsection 58-37-4(2)(b)(i) or~~
322 ~~(2)(b)(ii).]~~

323 ~~[(c)]~~ (b) "Outpatient" means a setting in which an individual visits a licensed
324 healthcare facility or a healthcare provider's office for a diagnosis or treatment but is not
325 admitted to a licensed healthcare facility for an overnight stay.

326 ~~[(d)]~~ (c) "Prescriber" means an individual authorized to prescribe a controlled
327 substance under Title 58, Chapter 37, Utah Controlled Substances Act.

328 ~~[(2) To address the serious public health concern of life-altering and life-threatening~~
329 ~~opioid abuse and overdose, and to achieve the purposes of this chapter and as described in~~
330 ~~Section 58-37f-201, which includes identifying and reducing the prescribing and dispensing of~~
331 ~~opioids in an unprofessional or unlawful manner or in quantities or frequencies inconsistent~~
332 ~~with generally recognized standards of dosage for an opioid, through utilization of the carefully~~
333 ~~developed and highly respected database:]~~

334 ~~[(a) a prescriber or dispenser of an opioid for individual outpatient usage shall access~~
335 ~~and review the database as necessary in the prescriber's or dispenser's professional judgment~~

336 and to achieve the purpose of this chapter as described in Section ~~58-37f-201~~; (b) a]

337 (d) "Schedule II opioid" means those substances listed in Subsection 58-37-4(2)(b)(i)
338 or (2)(b)(ii).

339 (e) "Schedule III opioid" means those substances listed in Subsection 58-37-4(2)(c)
340 that are opioids.

341 (2) (a) A prescriber shall substantially comply with this Subsection (2).

342 (b) Except as provided in Subsection (2)(b), a prescriber shall check the database for
343 information about a patient before the first time the prescriber gives a prescription to a patient
344 for a Schedule II opioid or a Schedule III opioid.

345 (c) A prescriber is not required to check the database under Subsection (2)(b) if:

346 (i) the prescription for a Schedule II opioid or a Schedule III opioid is for three days or
347 fewer on the daily dosage instructions on the prescription; or

348 (ii) the prescriber has prior knowledge of the patient's prescription history based on the
349 prescriber's review of the patient's health record.

350 (d) If a prescriber is repeatedly prescribing a Schedule II opioid or Schedule III opioid
351 to a patient, the prescriber shall periodically review information about the patient in:

352 (i) the database, or

353 (ii) other similar records of controlled substances the patient has filled.

354 (e) A prescriber may assign the access and review required under [Subsection (2)(a) to
355 an employee, in accordance with Subsections ~~58-37f-301(2)(g) and (h)~~] Subsections (2)(b) and
356 (2)(c) to one or more employees in accordance with Subsections 58-37f-301(2)(i) and (j).

357 (f) The division shall not take action against the license of a prescriber for failure to
358 follow this Subsection (2) if the prescriber demonstrates substantial compliance with the
359 requirements of this Subsection (2).

360 (3) The division shall, in collaboration with the licensing boards for prescribers and
361 dispensers:

362 (a) develop a system that gathers and reports to prescribers and dispensers the progress
363 and results of the prescriber's and dispenser's individual access and review of the database, as
364 provided in this section; and

365 (b) reduce or waive the division's continuing education requirements regarding opioid
366 prescriptions, described in Section 58-37-6.5, including the online tutorial and test relating to

367 the database, for prescribers and dispensers whose individual utilization of the database
368 [~~contribute to the life-saving and public safety purposes of this section and as described in~~
369 ~~Subsection (2).~~], as determined by the division, demonstrates substantial compliance with this
370 section.

371 (4) If the dispenser's access and review of the database suggest that the individual
372 seeking an opioid may be obtaining opioids in quantities or frequencies inconsistent with
373 generally recognized standards as provided in this section and Section 58-37f-201, the
374 dispenser shall reasonably attempt to contact the prescriber to obtain the prescriber's informed,
375 current, and professional decision regarding whether the prescribed opioid is medically
376 justified, notwithstanding the results of the database search.