

PHARMACY SOFTWARE AMENDMENTS

2021 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Rosemary Lesser

Senate Sponsor: _____

LONG TITLE

General Description:

This bill amends provisions relating to an electronic prescription for a controlled substance.

Highlighted Provisions:

This bill:

- ▶ requires a pharmacy software system that receives electronic prescriptions for a controlled substance to allow an unfilled prescription to be transferred to a different pharmacy; and
- ▶ makes technical changes.

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 2020, Chapter 81

ENACTS:

58-37-22, Utah Code Annotated 1953

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



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

29 **58-37-6. License to manufacture, produce, distribute, dispense, administer, or**
30 **conduct research -- Issuance by division -- Denial, suspension, or revocation -- Records**
31 **required -- Prescriptions.**

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

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

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

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

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

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

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

59 employer's registered and licensed place of business;

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

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

65 (d) The division may enact rules waiving the license requirement for certain
66 manufacturers, producers, distributors, prescribers, dispensers, administrators, research
67 practitioners, or laboratories performing analysis if waiving the license requirement is
68 consistent with 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 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 channels 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 providing the
112 division with 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 issued pursuant to Subsection (2) or (3) may be denied, suspended,

121 placed 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) A person 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) A physician, dentist, naturopathic physician, veterinarian, practitioner, or other
179 individual who is authorized to administer or professionally use a controlled substance shall
180 keep a record of the drugs received by the individual and a record of all drugs administered,
181 dispensed, or professionally used by the individual otherwise than by a prescription.

182 (ii) An individual using small quantities or solutions or other preparations of those

183 drugs for local application has complied with this Subsection (5)(b) if the individual keeps a
184 record of the quantity, character, and potency of those solutions or preparations purchased or
185 prepared by the individual, 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) An individual may not write or authorize a prescription for a controlled
190 substance unless the individual 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) An individual 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, an individual may not
208 issue, fill, compound, or dispense a prescription for a controlled substance unless the
209 prescription is signed by the prescriber in ink or indelible pencil or is signed with an electronic
210 signature of the prescriber as authorized by division rule, and contains the following
211 information:

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

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

214 issued;

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

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

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

220 (i) the individual who writes the prescription is licensed under Subsection (2); and

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

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

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

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

227 (iii) (A) Except as provided in Subsection (7)(f)(iii)(B), a prescription for a Schedule II
228 or Schedule III controlled substance that is an opiate and that is issued for an acute condition
229 shall be completely or partially filled in a quantity not to exceed a seven-day supply as directed
230 on the daily dosage rate of the prescription.

231 (B) Subsection (7)(f)(iii)(A) does not apply to a prescription issued for a surgery when
232 the practitioner determined that a quantity exceeding seven days is needed, in which case the
233 practitioner may prescribe up to a 30-day supply, with a partial fill at the discretion of the
234 practitioner.

235 (C) Subsection (7)(f)(iii)(A) does not apply to prescriptions issued for complex or
236 chronic conditions which are documented as being complex or chronic in the medical record.

237 (D) A pharmacist is not required to verify that a prescription is in compliance with
238 Subsection (7)(f)(iii).

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

243 (v) All other controlled substances in Schedule V may be refilled as the prescriber's
244 prescription directs, but they may not be refilled one year after the date the prescription was

245 issued unless renewed by the practitioner.

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

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

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

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

255 (C) a second or third prescription shall include the date of issuance and the date for
256 dispensing.

257 ~~[(g)(i) Beginning January 1, 2022, each prescription issued for a controlled substance
258 shall be transmitted electronically as an electronic prescription unless the prescription is:]~~

259 ~~[(A) for a patient residing in an assisted living facility as that term is defined in Section
260 26-21-2, a long-term care facility as that term is defined in Section 58-31b-102, or a
261 correctional facility as that term is defined in Section 64-13-1;]~~

262 ~~[(B) issued by a veterinarian licensed under Title 58, Chapter 28, Veterinary Practice
263 Act;]~~

264 ~~[(C) dispensed by a Department of Veterans Affairs pharmacy;]~~

265 ~~[(D) issued during a temporary technical or electronic failure at the practitioner's or
266 pharmacy's location; or]~~

267 ~~[(E) issued in an emergency situation;]~~

268 ~~[(ii) The division, in collaboration with the appropriate boards that govern the licensure
269 of the licensees who are authorized by the division to prescribe or to dispense controlled
270 substances, shall make rules in accordance with Title 63G, Chapter 3, Utah Administrative
271 Rulemaking Act to:]~~

272 ~~[(A) require that controlled substances prescribed or dispensed under Subsection
273 (7)(g)(i)(D) indicate on the prescription that the prescribing practitioner or the pharmacy is
274 experiencing a technical difficulty or an electronic failure;]~~

275 ~~[(B) define an emergency situation for purposes of Subsection (7)(g)(i)(E);]~~

276 ~~[(C) establish additional exemptions to the electronic prescription requirements~~
277 ~~established in this Subsection (7)(g);]~~

278 ~~[(D) establish guidelines under which a prescribing practitioner or a pharmacy may~~
279 ~~obtain an extension of up to two additional years to comply with Subsection (7)(g)(i);]~~

280 ~~[(E) establish a protocol to follow if the pharmacy that receives the electronic~~
281 ~~prescription is not able to fill the prescription; and]~~

282 ~~[(F) establish requirements that comply with federal laws and regulations for software~~
283 ~~used to issue and dispense electronic prescriptions.]~~

284 ~~[(F)] (g) An order for a controlled substance in Schedules II through V for use by an~~
285 ~~inpatient or an outpatient of a licensed hospital is exempt from all requirements of this~~
286 ~~Subsection (7) if the order is:~~

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

291 (ii) authorized by the prescribing practitioner treating the patient and the prescribing
292 practitioner designates the quantity ordered;

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

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

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

306 ~~[(F)] (i) A practitioner licensed under this chapter may not prescribe or administer~~

307 dosages of a controlled substance in excess of medically recognized quantities necessary to
308 treat the ailment, malady, or condition of the ultimate user.

309 ~~[(k)]~~ (j) A practitioner licensed under this chapter may not prescribe, administer, or
310 dispense any controlled substance to another person knowing that the other person is using a
311 false name, address, or other personal information for the purpose of securing the controlled
312 substance.

313 ~~[(h)]~~ (k) A person who is licensed under this chapter to manufacture, distribute, or
314 dispense a controlled substance may not manufacture, distribute, or dispense a controlled
315 substance to another licensee or any other authorized person not authorized by this license.

316 ~~[(m)]~~ (l) A person licensed under this chapter may not omit, remove, alter, or obliterate
317 a symbol required by this chapter or by a rule issued under this chapter.

318 ~~[(n)]~~ (m) A person licensed under this chapter may not refuse or fail to make, keep, or
319 furnish any record notification, order form, statement, invoice, or information required under
320 this chapter.

321 ~~[(o)]~~ (n) A person licensed under this chapter may not refuse entry into any premises
322 for inspection as authorized by this chapter.

323 ~~[(p)]~~ (o) A person licensed under this chapter may not furnish false or fraudulent
324 material information in any application, report, or other document required to be kept by this
325 chapter or willfully make any false statement in any prescription, order, report, or record
326 required by this chapter.

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

331 (ii) The division shall deposit all penalties collected under Subsection (8)(a)(i) ~~[(m)]~~ into
332 the General Fund as a dedicated credit to be used by the division under Subsection
333 [58-37f-502\(1\)](#).

334 (iii) The director may collect a penalty that is not paid by:

335 (A) referring the matter to a collection agency; or

336 (B) bringing an action in the district court of the county where the person against
337 whom the penalty is imposed resides or in the county where the office of the director is located.

338 (iv) A county attorney or the attorney general of the state shall provide legal assistance
339 and advice to the director in an action to collect a penalty.

340 (v) A court shall award reasonable attorney fees and costs to the prevailing party in an
341 action brought by the division to collect a penalty.

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

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

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

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

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

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

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

356 Section 2. Section 58-37-22 is enacted to read:

357 **58-37-22. Electronic prescriptions for controlled substances.**

358 (1) Beginning January 1, 2022, each prescription issued for a controlled substance shall
359 be transmitted electronically as an electronic prescription unless the prescription is:

360 (a) for a patient residing in an assisted living facility as that term is defined in Section
361 26-21-2, a long-term care facility as that term is defined in Section 58-31b-102, or a
362 correctional facility as that term is defined in Section 64-13-1;

363 (b) issued by a veterinarian licensed under Title 58, Chapter 28, Veterinary Practice
364 Act;

365 (c) dispensed by a Department of Veterans Affairs pharmacy;

366 (d) issued during a temporary technical or electronic failure at the practitioner's or
367 pharmacy's location; or

368 (e) issued in an emergency situation.

369 (2) The division, in collaboration with the appropriate boards that govern the licensure
370 of the licensees who are authorized by the division to prescribe or to dispense controlled
371 substances, shall make rules in accordance with Title 63G, Chapter 3, Utah Administrative
372 Rulemaking Act to:

373 (a) require that controlled substances prescribed or dispensed under Subsection (1)(d)
374 indicate on the prescription that the prescribing practitioner or the pharmacy is experiencing a
375 technical difficulty or an electronic failure;

376 (b) define an emergency situation for purposes of Subsection (1)(e);

377 (c) establish additional exemptions to the electronic prescription requirements
378 established in this section;

379 (d) establish guidelines under which a prescribing practitioner or a pharmacy may
380 obtain an extension of up to two additional years to comply with Subsection (1);

381 (e) establish a protocol to follow if the pharmacy that receives the electronic
382 prescription is not able to fill the prescription; and

383 (f) establish requirements that comply with federal laws and regulations for software
384 used to issue and dispense electronic prescriptions.

385 (3) Beginning July 1, 2024, a pharmacy software program for receiving an electronic
386 prescription for a controlled substance shall be capable of electronically transferring a
387 prescription to a different pharmacy upon the request of the patient or the practitioner if the
388 prescription is unfilled.