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**H.B.** 177

#### 1 **PRESCRIPTION REVISIONS** 2 **2020 GENERAL SESSION** 3 STATE OF UTAH **Chief Sponsor:** Suzanne Harrison 4 Senate Sponsor: Evan J. Vickers 5 6 7 LONG TITLE 8 **General Description:** 9 This bill amends provisions relating to prescriptions for controlled substances. 10 **Highlighted Provisions:** 11 This bill: 12 requires, with some exceptions, that prescriptions for controlled substances be ► issued electronically; 13 14 authorizes the division to create rules for certain aspects of prescribing controlled ► 15 substances; 16 ► amends the protocol for the dispensing of drugs by practitioners in the emergency 17 room; and 18 repeals Title 58, Chapter 82, Electronic Prescribing Act. ► 19 Money Appropriated in this Bill: 20 None 21 **Other Special Clauses:** 22 None 23 **Utah Code Sections Affected:** 24 AMENDS: 25 58-17b-610.5, as last amended by Laws of Utah 2016, Chapter 238 26 58-37-6, as last amended by Laws of Utah 2018, Chapter 318 27 **REPEALS**:

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58-82-101, as enacted by Laws of Utah 2009, Chapter 47
58-82-102, as last amended by Laws of Utah 2010, Chapter 276
58-82-201, as last amended by Laws of Utah 2012, Chapter 160
Be it enacted by the Legislature of the state of Utah:
Section 1. Section <b>58-17b-610.5</b> is amended to read:
58-17b-610.5. Dispensing in emergency department Patient's immediate need.
(1) As used in this section, "controlled substance" means a substance classified as a
controlled substance by the federal Controlled Substances Act, Title II, Pub. L. No. 91-513 et
seq., or by Chapter 37, Utah Controlled Substances Act.
[(1)] (2) The division shall adopt administrative rules in accordance with Title 63G,
Chapter 3, Utah Administrative Rulemaking Act, in consultation with hospital pharmacies and
the boards of practitioners authorized to prescribe prescription drugs to establish guidelines
under which a practitioner may dispense prescription drugs to a patient in a hospital emergency
department if:
(a) the hospital pharmacy is closed;
(b) in the professional judgment of the practitioner, dispensing the drug is necessary for
the patient's immediate needs; [and]
(c) dispensing the prescription drug meets protocols established by the hospital
pharmacy[-]; and
(d) the practitioner dispenses only a sufficient amount of the prescription drug as
necessary to last until a pharmacy can fill the prescription.
[(2)] (3) A practitioner in an emergency department may dispense a prescription drug
in accordance with Subsection $[(1)]$ (2).
(4) Under Subsection (2), a practitioner may not dispense more than a two-day supply
of a controlled substance.
Section 2. Section <b>58-37-6</b> is amended to read:
58-37-6. License to manufacture, produce, distribute, dispense, administer, or
conduct research Issuance by division Denial, suspension, or revocation Records
required Prescriptions.
(1) (a) The division may adopt rules relating to the licensing and control of the

59 manufacture, distribution, production, prescription, administration, dispensing, conducting of

- research with, and performing of laboratory analysis upon controlled substances within thisstate.
- (b) The division may assess reasonable fees to defray the cost of issuing original and
   renewal licenses under this chapter pursuant to Section 63J-1-504.
- 64 (2) (a) (i) Every person who manufactures, produces, distributes, prescribes, dispenses,
  65 administers, conducts research with, or performs laboratory analysis upon any controlled
  66 substance in Schedules I through V within this state, or who proposes to engage in
  67 manufacturing, producing, distributing, prescribing, dispensing, administering, conducting
  68 research with, or performing laboratory analysis upon controlled substances included in
  69 Schedules I through V within this state shall obtain a license issued by the division.
- (ii) The division shall issue each license under this chapter in accordance with a
  two-year renewal cycle established by rule. The division may by rule extend or shorten a
  renewal period by as much as one year to stagger the renewal cycles it administers.
- (b) Persons licensed to manufacture, produce, distribute, prescribe, dispense,
  administer, conduct research with, or perform laboratory analysis upon controlled substances in
  Schedules I through V within this state may possess, manufacture, produce, distribute,
  prescribe, dispense, administer, conduct research with, or perform laboratory analysis upon
  those substances to the extent authorized by their license and in conformity with this chapter.
- (c) The following persons are not required to obtain a license and may lawfully possess
   controlled substances included in Schedules II through V under this section:
- (i) an agent or employee, except a sales representative, of any registered manufacturer,
  distributor, or dispenser of any controlled substance, if the agent or employee is acting in the
  usual course of the [person's] agent or employee's business or employment; however, nothing
  in this subsection shall be interpreted to permit an agent, employee, sales representative, or
  detail man to maintain an inventory of controlled substances separate from the location of the
  person's employer's registered and licensed place of business;
- 86 (ii) a motor carrier or warehouseman, or an employee of a motor carrier or
  87 warehouseman, who possesses [any] <u>a</u> controlled substance in the usual course of the person's
  88 business or employment; and



(iii) an ultimate user, or [any] a person who possesses any controlled substance

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90 pursuant to a lawful order of a practitioner. 91 (d) The division may enact rules waiving the license requirement for certain manufacturers, producers, distributors, prescribers, dispensers, administrators, research 92 93 practitioners, or laboratories performing analysis if waiving the license requirement is 94 consistent with [the] public health and safety. 95 (e) A separate license is required at each principal place of business or professional practice where the applicant manufactures, produces, distributes, dispenses, conducts research 96 97 with, or performs laboratory analysis upon controlled substances. 98 (f) The division may enact rules providing for the inspection of a licensee or applicant's 99 establishment, and may inspect the establishment according to those rules. 100 (3) (a) (i) Upon proper application, the division shall license a qualified applicant to 101 manufacture, produce, distribute, conduct research with, or perform laboratory analysis upon 102 controlled substances included in Schedules I through V, unless it determines that issuance of a 103 license is inconsistent with the public interest. 104 (ii) The division may not issue a license to any person to prescribe, dispense, or 105 administer a Schedule I controlled substance except under Subsection (3)(a)(i). 106 (iii) In determining public interest under this Subsection (3)(a), the division shall consider whether [or not] the applicant has: 107 108 (A) maintained effective controls against diversion of controlled substances and any 109 Schedule I or II substance compounded from any controlled substance into channels other than 110 legitimate medical, scientific, or industrial channels; 111 (B) complied with applicable state and local law; 112 (C) been convicted under federal or state laws relating to the manufacture, distribution, 113 or dispensing of substances; 114 (D) past experience in the manufacture of controlled dangerous substances: 115 (E) established effective controls against diversion; and 116 (F) complied with any other factors that the division establishes that promote the public 117 health and safety. 118 (b) Licenses granted under Subsection (3)(a) do not entitle a licensee to manufacture, produce, distribute, conduct research with, or perform laboratory analysis upon controlled 119 120 substances in Schedule I other than those specified in the license.

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

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

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

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

(v) Practitioners registered under federal law to conduct research in Schedule I
 substances may conduct research in Schedule I substances within this state upon [furnishing]
 providing the division with evidence of federal registration.

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

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

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

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

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

151 (iii) been convicted of a felony under any other law of the United States or any state

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152 within five years of the date of the issuance of the license; 153 (iv) had a federal registration or license denied, suspended, or revoked by competent 154 federal authority and is no longer authorized to manufacture, distribute, prescribe, or dispense 155 controlled substances; 156 (v) had the licensee's license suspended or revoked by competent authority of another 157 state for violation of laws or regulations comparable to those of this state relating to the 158 manufacture, distribution, or dispensing of controlled substances; 159 (vi) violated any division rule that reflects adversely on the licensee's reliability and 160 integrity with respect to controlled substances; 161 (vii) refused inspection of records required to be maintained under this chapter by a person authorized to inspect them; or 162 163 (viii) prescribed, dispensed, administered, or injected an anabolic steroid for the purpose of manipulating human hormonal structure so as to: 164 (A) increase muscle mass, strength, or weight without medical necessity and without a 165 written prescription by any practitioner in the course of the practitioner's professional practice; 166 167 or 168 (B) improve performance in any form of human exercise, sport, or game. 169 (b) The division may limit revocation or suspension of a license to a particular 170 controlled substance with respect to which grounds for revocation or suspension exist. 171 (c) (i) Proceedings to deny, revoke, or suspend a license shall be conducted pursuant to 172 this section and in accordance with the procedures set forth in Title 58, Chapter 1, Division of Occupational and Professional Licensing Act, and conducted in conjunction with the 173 174 appropriate representative committee designated by the director of the department. (ii) Nothing in this Subsection (4)(c) gives the Division of Occupational and 175 176 Professional Licensing exclusive authority in proceedings to deny, revoke, or suspend licenses, 177 except where the division is designated by law to perform those functions, or, when not 178 designated by law, is designated by the executive director of the Department of Commerce to 179 conduct the proceedings. 180 (d) (i) The division may suspend any license simultaneously with the institution of 181 proceedings under this section if it finds there is an imminent danger to the public health or 182 safety.

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

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

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

- (iii) If a revocation order becomes final, all controlled substances shall be forfeited.
- (f) The division shall notify promptly the Drug Enforcement Administration of allorders suspending or revoking a license and all forfeitures of controlled substances.

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

201 (5) (a) [Persons] <u>A person</u> licensed under Subsection (2) or (3) shall maintain records
 202 and inventories in conformance with the record keeping and inventory requirements of federal
 203 and state law and any additional rules issued by the division.

(b) (i) [Every] <u>A</u> physician, dentist, naturopathic physician, veterinarian, practitioner,
or other [person] <u>individual</u> who is authorized to administer or professionally use a controlled
substance shall keep a record of the drugs received by [him] <u>the individual</u> and a record of all
drugs administered, dispensed, or professionally used by [him] <u>the individual</u> otherwise than by
a prescription.

(ii) [A person] <u>An individual</u> using small quantities or solutions or other preparations
 of those drugs for local application has complied with this Subsection (5)(b) if the [person]
 <u>individual</u> keeps a record of the quantity, character, and potency of those solutions or
 preparations purchased or prepared by [him] the individual, and of the dates when purchased or
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214	(6) Controlled substances in Schedules I through V may be distributed only by a
215	licensee and pursuant to an order form prepared in compliance with division rules or a lawful
216	order under the rules and regulations of the United States.
217	(7) (a) [A person] An individual may not write or authorize a prescription for a
218	controlled substance unless the [person] individual is:
219	(i) a practitioner authorized to prescribe drugs and medicine under the laws of this state
220	or under the laws of another state having similar standards; and
221	(ii) licensed under this chapter or under the laws of another state having similar
222	standards.
223	(b) [A person] An individual other than a pharmacist licensed under the laws of this
224	state, or the pharmacist's licensed intern, as required by Sections 58-17b-303 and 58-17b-304,
225	may not dispense a controlled substance.
226	(c) (i) A controlled substance may not be dispensed without the written prescription of
227	a practitioner, if the written prescription is required by the federal Controlled Substances Act.
228	(ii) That written prescription shall be made in accordance with Subsection (7)(a) and in
229	conformity with Subsection (7)(d).
230	(iii) In emergency situations, as defined by division rule, controlled substances may be
231	dispensed upon oral prescription of a practitioner, if reduced promptly to writing on forms
232	designated by the division and filed by the pharmacy.
233	(iv) Prescriptions reduced to writing by a pharmacist shall be in conformity with
234	Subsection (7)(d).
235	(d) Except for emergency situations designated by the division, [a person] an
236	individual may not issue, fill, compound, or dispense a prescription for a controlled substance
237	unless the prescription is signed by the prescriber in ink or indelible pencil or is signed with an
238	electronic signature of the prescriber as authorized by division rule, and contains the following
239	information:
240	(i) the name, address, and registry number of the prescriber;
241	(ii) the name, address, and age of the person to whom or for whom the prescription is
242	issued;
243	(iii) the date of issuance of the prescription; and
244	(iv) the name, quantity, and specific directions for use by the ultimate user of the

controlled substance.

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

(i) the [person] <u>individual</u> who writes the prescription is licensed under Subsection (2);
and

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

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

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

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

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

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

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

266 (D) A pharmacist is not required to verify that a prescription is in compliance with267 Subsection (7)(f)(iii).

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

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

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(vi) Any prescription for a Schedule II substance may not be dispensed if it is not

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276	presented to a pharmacist for dispensing by a pharmacist or a pharmacy intern within 30 days
277	after the date the prescription was issued, or 30 days after the dispensing date, if that date is
278	specified separately from the date of issue.
279	(vii) A practitioner may issue more than one prescription at the same time for the same
280	Schedule II controlled substance, but only under the following conditions:
281	(A) no more than three prescriptions for the same Schedule II controlled substance may
282	be issued at the same time;
283	(B) no one prescription may exceed a 30-day supply; and
284	(C) a second or third prescription shall include the date of issuance and the date for
285	dispensing.
286	(g) (i) Beginning January 1, 2022, each prescription issued for a controlled substance
287	shall be transmitted electronically as an electronic prescription unless the prescription is:
288	(A) for a patient residing in an assisted living facility as that term is defined in Section
289	26-21-2, a long-term care facility as that term is defined in Section 58-31b-102, or a
290	correctional facility as that term is defined in Section 64-13-1;
291	(B) issued by a veterinarian licensed under Title 58, Chapter 28, Veterinary Practice
292	<u>Act;</u>
293	(C) dispensed by a Department of Veterans Affairs pharmacy;
294	(D) issued during a temporary technical or electronic failure at the practitioner's or
295	pharmacy's location; or
296	(E) issued in an emergency situation.
297	(ii) The division, in collaboration with the boards that govern the licensure of the
298	licensees who are authorized by the division to prescribe controlled substances, shall make
299	rules in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act to:
300	(A) require that controlled substances prescribed or dispensed under Subsection
301	(7)(g)(i)(D) indicate on the prescription that the prescribing practitioner or the pharamacy is
302	experiencing a technical difficulty or an electronic failure;
303	(B) define an emergency situation for purposes of Subsection (7)(g)(i)(E);
304	(C) establish additional exemptions to the electronic prescription requirements
305	established in this Subsection (7)(g);
306	(D) establish guidelines under which a prescribing practitioner or a pharmacy may

307	obtain an extension of up to two additional years to comply with Subsection (7)(g)(i);
308	(E) establish a protocol to follow if the pharmacy that receives the electronic
309	prescription is not able to fill the prescription; and
310	(F) establish requirements for software used to issue and dispense electronic
311	prescriptions.
312	[(g)] (h) An order for a controlled substance in Schedules II through V for use by an
313	inpatient or an outpatient of a licensed hospital is exempt from all requirements of this
314	Subsection (7) if the order is:
315	(i) issued or made by a prescribing practitioner who holds an unrestricted registration
316	with the federal Drug Enforcement Administration, and an active Utah controlled substance
317	license in good standing issued by the division under this section, or a medical resident who is
318	exempted from licensure under Subsection 58-1-307(1)(c);
319	(ii) authorized by the prescribing practitioner treating the patient and the prescribing
320	practitioner designates the quantity ordered;
321	(iii) entered upon the record of the patient, the record is signed by the prescriber
322	affirming the prescriber's authorization of the order within 48 hours after filling or
323	administering the order, and the patient's record reflects the quantity actually administered; and
324	(iv) filled and dispensed by a pharmacist practicing the pharmacist's profession within
325	the physical structure of the hospital, or the order is taken from a supply lawfully maintained by
326	the hospital and the amount taken from the supply is administered directly to the patient
327	authorized to receive it.
328	[(h)] (i) A practitioner licensed under this chapter may not prescribe, administer, or
329	dispense a controlled substance to a child, without first obtaining the consent required in
330	Section 78B-3-406 of a parent, guardian, or person standing in loco parentis of the child except
331	in cases of an emergency. For purposes of [this] Subsection (7)[(h)](i), "child" has the same
332	meaning as defined in Section 78A-6-105, and "emergency" means any physical condition
333	requiring the administration of a controlled substance for immediate relief of pain or suffering.
334	[(i)] (j) A practitioner licensed under this chapter may not prescribe or administer
335	dosages of a controlled substance in excess of medically recognized quantities necessary to
336	treat the ailment, malady, or condition of the ultimate user.
337	$[\frac{(j)}{(k)}]$ A practitioner licensed under this chapter may not prescribe, administer, or

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dispense any controlled substance to another person knowing that the other person is using a
false name, address, or other personal information for the purpose of securing the controlled
substance.

341 [(k)] (1) A person who is licensed under this chapter to manufacture, distribute, or
 342 dispense a controlled substance may not manufacture, distribute, or dispense a controlled
 343 substance to another licensee or any other authorized person not authorized by this license.

344 [(1)] (m) A person licensed under this chapter may not omit, remove, alter, or obliterate
 345 a symbol required by this chapter or by a rule issued under this chapter.

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

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

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

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

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

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

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

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

365 (iv) A county attorney or the attorney general of the state shall provide legal assistance366 and advice to the director in an action to collect a penalty.

367 (v) A court shall award reasonable attorney fees and costs to the prevailing party in an368 action brought by the division to collect a penalty.

369	(b) Any person who knowingly and intentionally violates Subsections (7)(h) through (j)
370	or Subsection (10) is:
371	(i) upon first conviction, guilty of a class B misdemeanor;
372	(ii) upon second conviction, guilty of a class A misdemeanor; and
373	(iii) on third or subsequent conviction, guilty of a third degree felony.
374	(c) Any person who knowingly and intentionally violates Subsections (7)(k) through
375	(o) shall upon conviction be guilty of a third degree felony.
376	(9) Any information communicated to any licensed practitioner in an attempt to
377	unlawfully procure, or to procure the administration of, a controlled substance is not considered
378	to be a privileged communication.
379	(10) A person holding a valid license under this chapter who is engaged in medical
380	research may produce, possess, administer, prescribe, or dispense a controlled substance for
381	research purposes as licensed under Subsection (2) but may not otherwise prescribe or dispense
382	a controlled substance listed in Section 58-37-4.2.
383	Section 3. Repealer.
384	This bill repeals:
385	Section 58-82-101, Title.
386	Section 58-82-102, Definitions.
387	Section 58-82-201, Electronic prescriptions Restrictions Rulemaking

388 authority.