

Senator Evan J. Vickers proposes the following substitute bill:

PHARMACY PRACTICE REVISIONS

2021 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Evan J. Vickers

House Sponsor: Paul Ray

LONG TITLE

General Description:

This bill amends provisions related to pharmacy.

Highlighted Provisions:

This bill:

- ▶ amends definitions;
- ▶ amends requirements for licensure as a pharmacy technician trainee;
- ▶ amends provisions governing the dispensing of opiate medication assisted treatment at an opioid treatment program;
- ▶ amends provisions governing the audit of pharmacy records by or on behalf of an entity that finances or reimburses the cost of health care services or pharmaceutical products;
- ▶ amends provisions governing the administration of injectables by pharmacists;
- ▶ addresses corrections to data submitted to the controlled substance database; and
- ▶ makes technical changes.

Money Appropriated in this Bill:

None

Other Special Clauses:

None



26 **Utah Code Sections Affected:**

27 AMENDS:

- 28 [49-20-502](#), as enacted by Laws of Utah 2011, Chapter 83
- 29 [58-17b-102](#), as last amended by Laws of Utah 2019, Chapter 343
- 30 [58-17b-305.1](#), as last amended by Laws of Utah 2020, Chapter 339
- 31 [58-17b-309.7](#), as enacted by Laws of Utah 2019, Chapter 311
- 32 [58-17b-610](#), as last amended by Laws of Utah 2012, Chapter 320
- 33 [58-17b-622](#), as last amended by Laws of Utah 2018, Chapter 39
- 34 [58-17b-625](#), as last amended by Laws of Utah 2019, Chapter 343
- 35 [58-37f-203](#), as last amended by Laws of Utah 2020, Chapters 147, 339, and 372
- 36 [58-37f-303](#), as last amended by Laws of Utah 2020, Chapters 147 and 339

37

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

39 Section 1. Section [49-20-502](#) is amended to read:

40 **[49-20-502. Definitions.](#)**

41 As used in this part:

42 (1) "Health benefit plan" means:

43 (a) a health benefit plan as defined in Section [31A-1-301](#); or

44 (b) a health, dental, medical, Medicare supplement, or conversion program offered
45 under Title 49, Chapter 20, Public Employees' Benefit and Insurance Program Act.

46 (2) "Pharmacist" is as defined in Section [58-17b-102](#).

47 (3) "Pharmacy" is as defined in Section [58-17b-102](#).

48 (4) "Pharmacy benefits management service" means [~~any of the following services~~
49 ~~provided to a health benefit plan, or to a participant of the health benefit plan:~~] the same as that
50 term is defined in Section [31A-46-102](#).

51 [~~(a) negotiating the amount to be paid by a health benefit plan for a prescription drug;~~
52 ~~or]~~

53 [~~(b) administering or managing prescription drug benefits provided by the health~~
54 ~~benefit plan for the benefit of a participant of the health benefit plan, including:]~~

55 [~~(i) mail service pharmacy;~~]

56 [~~(ii) specialty pharmacy;~~]

- 57 ~~[(iii) claims processing;]~~
- 58 ~~[(iv) payment of a claim;]~~
- 59 ~~[(v) retail network management;]~~
- 60 ~~[(vi) clinical formulary development;]~~
- 61 ~~[(vii) clinical formulary management services;]~~
- 62 ~~[(viii) rebate contracting;]~~
- 63 ~~[(ix) rebate administration;]~~
- 64 ~~[(x) a participant compliance program;]~~
- 65 ~~[(xi) a therapeutic intervention program;]~~
- 66 ~~[(xii) a disease management program; or]~~
- 67 ~~[(xiii) a service that is similar to, or related to, a service described in Subsection (4)(a)~~
- 68 ~~or (4)(b)(i) through (xii).]~~

69 (5) "Pharmacy benefits manager" means a person that provides a pharmacy benefits
 70 management service to ~~[a health benefit plan]~~ the program.

71 (6) "Pharmacy service" means a product, good, or service provided by a pharmacy or
 72 pharmacist to an individual.

73 Section 2. Section **58-17b-102** is amended to read:

74 **58-17b-102. Definitions.**

75 In addition to the definitions in Section **58-1-102**, as used in this chapter:

76 (1) "Administering" means:

77 (a) the direct application of a prescription drug or device, whether by injection,
 78 inhalation, ingestion, or by any other means, to the body of a human patient or research subject
 79 by another person; or

80 (b) the placement by a veterinarian with the owner or caretaker of an animal or group
 81 of animals of a prescription drug for the purpose of injection, inhalation, ingestion, or any other
 82 means directed to the body of the animal by the owner or caretaker in accordance with written
 83 or verbal directions of the veterinarian.

84 (2) "Adulterated drug or device" means a drug or device considered adulterated under
 85 21 U.S.C. Sec. 351 (2003).

86 (3) (a) "Analytical laboratory" means a facility in possession of prescription drugs for
 87 the purpose of analysis.

88 (b) "Analytical laboratory" does not include a laboratory possessing prescription drugs
89 used as standards and controls in performing drug monitoring or drug screening analysis if the
90 prescription drugs are prediluted in a human or animal body fluid, human or animal body fluid
91 components, organic solvents, or inorganic buffers at a concentration not exceeding one
92 milligram per milliliter when labeled or otherwise designated as being for in vitro diagnostic
93 use.

94 (4) "Animal euthanasia agency" means an agency performing euthanasia on animals by
95 the use of prescription drugs.

96 (5) "Automated pharmacy systems" includes mechanical systems which perform
97 operations or activities, other than compounding or administration, relative to the storage,
98 packaging, dispensing, or distribution of medications, and which collect, control, and maintain
99 all transaction information.

100 (6) "Beyond use date" means the date determined by a pharmacist and placed on a
101 prescription label at the time of dispensing that indicates to the patient or caregiver a time
102 beyond which the contents of the prescription are not recommended to be used.

103 (7) "Board of pharmacy" or "board" means the Utah State Board of Pharmacy created
104 in Section [58-17b-201](#).

105 (8) "Branch pharmacy" means a pharmacy or other facility in a rural or medically
106 underserved area, used for the storage and dispensing of prescription drugs, which is dependent
107 upon, stocked by, and supervised by a pharmacist in another licensed pharmacy designated and
108 approved by the division as the parent pharmacy.

109 (9) "Centralized prescription processing" means the processing by a pharmacy of a
110 request from another pharmacy to fill or refill a prescription drug order or to perform
111 processing functions such as dispensing, drug utilization review, claims adjudication, refill
112 authorizations, and therapeutic interventions.

113 (10) "Class A pharmacy" means a pharmacy located in Utah that is authorized as a
114 retail pharmacy to compound or dispense a drug or dispense a device to the public under a
115 prescription order.

116 (11) "Class B pharmacy":

117 (a) means a pharmacy located in Utah:

118 (i) that is authorized to provide pharmaceutical care for patients in an institutional

119 setting; and

120 (ii) whose primary purpose is to provide a physical environment for patients to obtain
121 health care services; and

122 (b) (i) includes closed-door, hospital, clinic, nuclear, and branch pharmacies; and

123 (ii) pharmaceutical administration and sterile product preparation facilities.

124 (12) "Class C pharmacy" means a pharmacy that engages in the manufacture,
125 production, wholesale, or distribution of drugs or devices in Utah.

126 (13) "Class D pharmacy" means a nonresident pharmacy.

127 (14) "Class E pharmacy" means all other pharmacies.

128 (15) (a) "Closed-door pharmacy" means a pharmacy that:

129 (i) provides pharmaceutical care to a defined and exclusive group of patients who have
130 access to the services of the pharmacy because they are treated by or have an affiliation with a
131 specific entity, including a health maintenance organization or an infusion company; or

132 (ii) engages exclusively in the practice of telepharmacy and does not serve walk-in
133 retail customers.

134 (b) "Closed-door pharmacy" does not include a hospital pharmacy, a retailer of goods
135 to the general public, or the office of a practitioner.

136 (16) "Collaborative pharmacy practice" means a practice of pharmacy whereby one or
137 more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or
138 more practitioners under protocol whereby the pharmacist may perform certain pharmaceutical
139 care functions authorized by the practitioner or practitioners under certain specified conditions
140 or limitations.

141 (17) "Collaborative pharmacy practice agreement" means a written and signed
142 agreement between one or more pharmacists and one or more practitioners that provides for
143 collaborative pharmacy practice for the purpose of drug therapy management of patients and
144 prevention of disease of human subjects.

145 (18) (a) "Compounding" means the preparation, mixing, assembling, packaging, or
146 labeling of a limited quantity drug, sterile product, or device:

147 (i) as the result of a practitioner's prescription order or initiative based on the
148 practitioner, patient, or pharmacist relationship in the course of professional practice;

149 (ii) for the purpose of, or as an incident to, research, teaching, or chemical analysis and

150 not for sale or dispensing; or

151 (iii) in anticipation of prescription drug orders based on routine, regularly observed
152 prescribing patterns.

153 (b) "Compounding" does not include:

154 (i) the preparation of prescription drugs by a pharmacist or pharmacy intern for sale to
155 another pharmacist or pharmaceutical facility;

156 (ii) the preparation by a pharmacist or pharmacy intern of any prescription drug in a
157 dosage form which is regularly and commonly available from a manufacturer in quantities and
158 strengths prescribed by a practitioner; or

159 (iii) the preparation of a prescription drug, sterile product, or device which has been
160 withdrawn from the market for safety reasons.

161 (19) "Confidential information" has the same meaning as "protected health
162 information" under the Standards for Privacy of Individually Identifiable Health Information,
163 45 C.F.R. Parts 160 and 164.

164 (20) "Controlled substance" means the same as that term is defined in Section [58-37-2](#).

165 (21) "Dietary supplement" has the same meaning as Public Law Title 103, Chapter
166 417, Sec. 3a(ff) which is incorporated by reference.

167 (22) "Dispense" means the interpretation, evaluation, and implementation of a
168 prescription drug order or device or nonprescription drug or device under a lawful order of a
169 practitioner in a suitable container appropriately labeled for subsequent administration to or use
170 by a patient, research subject, or an animal.

171 (23) "Dispensing medical practitioner" means an individual who is:

172 (a) currently licensed as:

173 (i) a physician and surgeon under Chapter 67, Utah Medical Practice Act;

174 (ii) an osteopathic physician and surgeon under Chapter 68, Utah Osteopathic Medical
175 Practice Act;

176 (iii) a physician assistant under Chapter 70a, Utah Physician Assistant Act;

177 (iv) a nurse practitioner under Chapter 31b, Nurse Practice Act; or

178 (v) an optometrist under Chapter 16a, Utah Optometry Practice Act, if the optometrist
179 is acting within the scope of practice for an optometrist; and

180 (b) licensed by the division under the Pharmacy Practice Act to engage in the practice

181 of a dispensing medical practitioner.

182 (24) "Dispensing medical practitioner clinic pharmacy" means a closed-door pharmacy
183 located within a licensed dispensing medical practitioner's place of practice.

184 (25) "Distribute" means to deliver a drug or device other than by administering or
185 dispensing.

186 (26) (a) "Drug" means:

187 (i) a substance recognized in the official United States Pharmacopoeia, official
188 Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any
189 supplement to any of them, intended for use in the diagnosis, cure, mitigation, treatment, or
190 prevention of disease in humans or animals;

191 (ii) a substance that is required by any applicable federal or state law or rule to be
192 dispensed by prescription only or is restricted to administration by practitioners only;

193 (iii) a substance other than food intended to affect the structure or any function of the
194 body of humans or other animals; and

195 (iv) substances intended for use as a component of any substance specified in
196 Subsections (26)(a)(i), (ii), (iii), and (iv).

197 (b) "Drug" does not include dietary supplements.

198 (27) "Drug regimen review" includes the following activities:

199 (a) evaluation of the prescription drug order and patient record for:

200 (i) known allergies;

201 (ii) rational therapy-contraindications;

202 (iii) reasonable dose and route of administration; and

203 (iv) reasonable directions for use;

204 (b) evaluation of the prescription drug order and patient record for duplication of
205 therapy;

206 (c) evaluation of the prescription drug order and patient record for the following
207 interactions:

208 (i) drug-drug;

209 (ii) drug-food;

210 (iii) drug-disease; and

211 (iv) adverse drug reactions; and

212 (d) evaluation of the prescription drug order and patient record for proper utilization,
213 including over- or under-utilization, and optimum therapeutic outcomes.

214 (28) "Drug sample" means a prescription drug packaged in small quantities consistent
215 with limited dosage therapy of the particular drug, which is marked "sample", is not intended to
216 be sold, and is intended to be provided to practitioners for the immediate needs of patients for
217 trial purposes or to provide the drug to the patient until a prescription can be filled by the
218 patient.

219 (29) "Electronic signature" means a trusted, verifiable, and secure electronic sound,
220 symbol, or process attached to or logically associated with a record and executed or adopted by
221 a person with the intent to sign the record.

222 (30) "Electronic transmission" means transmission of information in electronic form or
223 the transmission of the exact visual image of a document by way of electronic equipment.

224 (31) "Hospital pharmacy" means a pharmacy providing pharmaceutical care to
225 inpatients of a general acute hospital or specialty hospital licensed by the Department of Health
226 under Title 26, Chapter 21, Health Care Facility Licensing and Inspection Act.

227 (32) "Legend drug" has the same meaning as prescription drug.

228 (33) "Licensed pharmacy technician" means an individual licensed with the division,
229 that may, under the supervision of a pharmacist, perform the activities involved in the
230 technician practice of pharmacy.

231 (34) "Manufacturer" means a person or business physically located in Utah licensed to
232 be engaged in the manufacturing of drugs or devices.

233 (35) (a) "Manufacturing" means:

234 (i) the production, preparation, propagation, conversion, or processing of a drug or
235 device, either directly or indirectly, by extraction from substances of natural origin or
236 independently by means of chemical or biological synthesis, or by a combination of extraction
237 and chemical synthesis, and includes any packaging or repackaging of the substance or labeling
238 or relabeling of its container; and

239 (ii) the promotion and marketing of such drugs or devices.

240 (b) "Manufacturing" includes the preparation and promotion of commercially available
241 products from bulk compounds for resale by pharmacies, practitioners, or other persons.

242 (c) "Manufacturing" does not include the preparation or compounding of a drug by a

243 pharmacist, pharmacy intern, or practitioner for that individual's own use or the preparation,
244 compounding, packaging, labeling of a drug, or incident to research, teaching, or chemical
245 analysis.

246 (36) "Medical order" means a lawful order of a practitioner which may include a
247 prescription drug order.

248 (37) "Medication profile" or "profile" means a record system maintained as to drugs or
249 devices prescribed for a pharmacy patient to enable a pharmacist or pharmacy intern to analyze
250 the profile to provide pharmaceutical care.

251 (38) "Misbranded drug or device" means a drug or device considered misbranded under
252 21 U.S.C. Sec. 352 (2003).

253 (39) (a) "Nonprescription drug" means a drug which:

254 (i) may be sold without a prescription; and

255 (ii) is labeled for use by the consumer in accordance with federal law.

256 (b) "Nonprescription drug" includes homeopathic remedies.

257 (40) "Nonresident pharmacy" means a pharmacy located outside of Utah that sells to a
258 person in Utah.

259 (41) "Nuclear pharmacy" means a pharmacy providing radio-pharmaceutical service.

260 (42) "Out-of-state mail service pharmacy" means a pharmaceutical facility located
261 outside the state that is licensed and in good standing in another state, that:

262 (a) ships, mails, or delivers by any lawful means a dispensed legend drug to a patient in
263 this state pursuant to a lawfully issued prescription;

264 (b) provides information to a patient in this state on drugs or devices which may
265 include, but is not limited to, advice relating to therapeutic values, potential hazards, and uses;
266 or

267 (c) counsels pharmacy patients residing in this state concerning adverse and therapeutic
268 effects of drugs.

269 (43) "Patient counseling" means the written and oral communication by the pharmacist
270 or pharmacy intern of information, to the patient or caregiver, in order to ensure proper use of
271 drugs, devices, and dietary supplements.

272 (44) "Pharmaceutical administration facility" means a facility, agency, or institution in
273 which:

274 (a) prescription drugs or devices are held, stored, or are otherwise under the control of
275 the facility or agency for administration to patients of that facility or agency;

276 (b) prescription drugs are dispensed to the facility or agency by a licensed pharmacist
277 or pharmacy intern with whom the facility has established a prescription drug supervising
278 relationship under which the pharmacist or pharmacy intern provides counseling to the facility
279 or agency staff as required, and oversees drug control, accounting, and destruction; and

280 (c) prescription drugs are professionally administered in accordance with the order of a
281 practitioner by an employee or agent of the facility or agency.

282 (45) (a) "Pharmaceutical care" means carrying out the following in collaboration with a
283 prescribing practitioner, and in accordance with division rule:

284 (i) designing, implementing, and monitoring a therapeutic drug plan intended to
285 achieve favorable outcomes related to a specific patient for the purpose of curing or preventing
286 the patient's disease;

287 (ii) eliminating or reducing a patient's symptoms; or

288 (iii) arresting or slowing a disease process.

289 (b) "Pharmaceutical care" does not include prescribing of drugs without consent of a
290 prescribing practitioner.

291 (46) "Pharmaceutical facility" means a business engaged in the dispensing, delivering,
292 distributing, manufacturing, or wholesaling of prescription drugs or devices within or into this
293 state.

294 (47) (a) "Pharmaceutical wholesaler or distributor" means a pharmaceutical facility
295 engaged in the business of wholesale vending or selling of a prescription drug or device to
296 other than a consumer or user of the prescription drug or device that the pharmaceutical facility
297 has not produced, manufactured, compounded, or dispensed.

298 (b) "Pharmaceutical wholesaler or distributor" does not include a pharmaceutical
299 facility carrying out the following business activities:

300 (i) intracompany sales;

301 (ii) the sale, purchase, or trade of a prescription drug or device, or an offer to sell,
302 purchase, or trade a prescription drug or device, if the activity is carried out between one or
303 more of the following entities under common ownership or common administrative control, as
304 defined by division rule:

- 305 (A) hospitals;
- 306 (B) pharmacies;
- 307 (C) chain pharmacy warehouses, as defined by division rule; or
- 308 (D) other health care entities, as defined by division rule;
- 309 (iii) the sale, purchase, or trade of a prescription drug or device, or an offer to sell,
- 310 purchase, or trade a prescription drug or device, for emergency medical reasons, including
- 311 supplying another pharmaceutical facility with a limited quantity of a drug, if:
- 312 (A) the facility is unable to obtain the drug through a normal distribution channel in
- 313 sufficient time to eliminate the risk of harm to a patient that would result from a delay in
- 314 obtaining the drug; and
- 315 (B) the quantity of the drug does not exceed an amount reasonably required for
- 316 immediate dispensing to eliminate the risk of harm;
- 317 (iv) the distribution of a prescription drug or device as a sample by representatives of a
- 318 manufacturer; and
- 319 (v) the distribution of prescription drugs, if:
- 320 (A) the facility's total distribution-related sales of prescription drugs does not exceed
- 321 5% of the facility's total prescription drug sales; and
- 322 (B) the distribution otherwise complies with 21 C.F.R. Sec. 1307.11.
- 323 (48) "Pharmacist" means an individual licensed by this state to engage in the practice
- 324 of pharmacy.
- 325 (49) "Pharmacist-in-charge" means a pharmacist currently licensed in good standing
- 326 who accepts responsibility for the operation of a pharmacy in conformance with all laws and
- 327 rules pertinent to the practice of pharmacy and the distribution of drugs, and who is personally
- 328 in full and actual charge of the pharmacy and all personnel.
- 329 (50) "Pharmacist preceptor" means a licensed pharmacist in good standing with one or
- 330 more years of licensed experience. The preceptor serves as a teacher, example of professional
- 331 conduct, and supervisor of interns in the professional practice of pharmacy.
- 332 (51) "Pharmacy" means any place where:
- 333 (a) drugs are dispensed;
- 334 (b) pharmaceutical care is provided;
- 335 (c) drugs are processed or handled for eventual use by a patient; or

336 (d) drugs are used for the purpose of analysis or research.

337 (52) "Pharmacy benefits manager or coordinator" means a person or entity that
338 provides a pharmacy benefits management service as defined in Section ~~[49-20-502]~~
339 [31A-46-102](#) on behalf of a self-insured employer, insurance company, health maintenance
340 organization, or other plan sponsor, as defined by rule.

341 (53) "Pharmacy intern" means an individual licensed by this state to engage in practice
342 as a pharmacy intern.

343 (54) "Pharmacy technician training program" means an approved technician training
344 program providing education for pharmacy technicians.

345 (55) (a) "Practice as a dispensing medical practitioner" means the practice of pharmacy,
346 specifically relating to the dispensing of a prescription drug in accordance with Part 8,
347 Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy, and
348 division rule adopted after consultation with the Board of pharmacy and the governing boards
349 of the practitioners described in Subsection (23)(a).

350 (b) "Practice as a dispensing medical practitioner" does not include:

351 (i) using a vending type of dispenser as defined by the division by administrative rule;
352 or

353 (ii) except as permitted by Section [58-17b-805](#), dispensing of a controlled substance as
354 defined in Section [58-37-2](#).

355 (56) "Practice as a licensed pharmacy technician" means engaging in practice as a
356 pharmacy technician under the general supervision of a licensed pharmacist and in accordance
357 with a scope of practice defined by division rule made in collaboration with the board.

358 (57) "Practice of pharmacy" includes the following:

359 (a) providing pharmaceutical care;

360 (b) collaborative pharmacy practice in accordance with a collaborative pharmacy
361 practice agreement;

362 (c) compounding, packaging, labeling, dispensing, administering, and the coincident
363 distribution of prescription drugs or devices, provided that the administration of a prescription
364 drug or device is:

365 (i) pursuant to a lawful order of a practitioner when one is required by law; and

366 (ii) in accordance with written guidelines or protocols:

367 (A) established by the licensed facility in which the prescription drug or device is to be
 368 administered on an inpatient basis; or

369 (B) approved by the division, in collaboration with the board and, when appropriate ~~§~~ → ,
 369a ← ~~§~~ the

370 Physicians Licensing Board, created in Section 58-67-201, if the prescription drug or device is
 371 to be administered on an outpatient basis solely by a licensed pharmacist;

372 (d) participating in drug utilization review;

373 (e) ensuring proper and safe storage of drugs and devices;

374 (f) maintaining records of drugs and devices in accordance with state and federal law
 375 and the standards and ethics of the profession;

376 (g) providing information on drugs or devices, which may include advice relating to
 377 therapeutic values, potential hazards, and uses;

378 (h) providing drug product equivalents;

379 (i) supervising pharmacist's supportive personnel, pharmacy interns, and pharmacy
 380 technicians;

381 (j) providing patient counseling, including adverse and therapeutic effects of drugs;

382 (k) providing emergency refills as defined by rule;

383 (l) telepharmacy;

384 (m) formulary management intervention; and

385 (n) prescribing and dispensing a self-administered hormonal contraceptive in
 386 accordance with Title 26, Chapter 64, Family Planning Access Act.

387 (58) "Practice of telepharmacy" means the practice of pharmacy through the use of
 388 telecommunications and information technologies.

389 (59) "Practice of telepharmacy across state lines" means the practice of pharmacy
 390 through the use of telecommunications and information technologies that occurs when the
 391 patient is physically located within one jurisdiction and the pharmacist is located in another
 392 jurisdiction.

393 (60) "Practitioner" means an individual currently licensed, registered, or otherwise
 394 authorized by the appropriate jurisdiction to prescribe and administer drugs in the course of
 395 professional practice.

396 (61) "Prescribe" means to issue a prescription:

397 (a) orally or in writing; or

398 (b) by telephone, facsimile transmission, computer, or other electronic means of
399 communication as defined by division rule.

400 (62) "Prescription" means an order issued:

401 (a) by a licensed practitioner in the course of that practitioner's professional practice or
402 by collaborative pharmacy practice agreement; and

403 (b) for a controlled substance or other prescription drug or device for use by a patient
404 or an animal.

405 (63) "Prescription device" means an instrument, apparatus, implement, machine,
406 contrivance, implant, in vitro reagent, or other similar or related article, and any component
407 part or accessory, which is required under federal or state law to be prescribed by a practitioner
408 and dispensed by or through a person or entity licensed under this chapter or exempt from
409 licensure under this chapter.

410 (64) "Prescription drug" means a drug that is required by federal or state law or rule to
411 be dispensed only by prescription or is restricted to administration only by practitioners.

412 (65) "Repackage":

413 (a) means changing the container, wrapper, or labeling to further the distribution of a
414 prescription drug; and

415 (b) does not include:

416 (i) Subsection (65)(a) when completed by the pharmacist responsible for dispensing the
417 product to a patient; or

418 (ii) changing or altering a label as necessary for a dispensing practitioner under Part 8,
419 Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy, for
420 dispensing a product to a patient.

421 (66) "Research using pharmaceuticals" means research:

422 (a) conducted in a research facility, as defined by division rule, that is associated with a
423 university or college in the state accredited by the Northwest Commission on Colleges and
424 Universities;

425 (b) requiring the use of a controlled substance, prescription drug, or prescription
426 device;

427 (c) that uses the controlled substance, prescription drug, or prescription device in
428 accordance with standard research protocols and techniques, including, if required, those

429 approved by an institutional review committee; and

430 (d) that includes any documentation required for the conduct of the research and the
431 handling of the controlled substance, prescription drug, or prescription device.

432 (67) "Retail pharmacy" means a pharmaceutical facility dispensing prescription drugs
433 and devices to the general public.

434 (68) (a) "Self-administered hormonal contraceptive" means a self-administered
435 hormonal contraceptive that is approved by the United States Food and Drug Administration to
436 prevent pregnancy.

437 (b) "Self-administered hormonal contraceptive" includes an oral hormonal
438 contraceptive, a hormonal vaginal ring, and a hormonal contraceptive patch.

439 (c) "Self-administered hormonal contraceptive" does not include any drug intended to
440 induce an abortion, as that term is defined in Section 76-7-301.

441 (69) "Self-audit" means an internal evaluation of a pharmacy to determine compliance
442 with this chapter.

443 (70) "Supervising pharmacist" means a pharmacist who is overseeing the operation of
444 the pharmacy during a given day or shift.

445 (71) "Supportive personnel" means unlicensed individuals who:

446 (a) may assist a pharmacist, pharmacist preceptor, pharmacy intern, or licensed
447 pharmacy technician in nonjudgmental duties not included in the definition of the practice of
448 pharmacy, practice of a pharmacy intern, or practice of a licensed pharmacy technician, and as
449 those duties may be further defined by division rule adopted in collaboration with the board;
450 and

451 (b) are supervised by a pharmacist in accordance with rules adopted by the division in
452 collaboration with the board.

453 (72) "Unlawful conduct" means the same as that term is defined in Sections 58-1-501
454 and 58-17b-501.

455 (73) "Unprofessional conduct" means the same as that term is defined in Sections
456 58-1-501 and 58-17b-502 and may be further defined by rule.

457 (74) "Veterinary pharmaceutical facility" means a pharmaceutical facility that
458 dispenses drugs intended for use by animals or for sale to veterinarians for the administration
459 for animals.

460 Section 3. Section **58-17b-305.1** is amended to read:

461 **58-17b-305.1. Qualifications for licensure of pharmacy technician trainee.**

462 (1) An applicant for licensure as a pharmacy technician trainee shall:

463 (a) submit an application to the division on a form created by the division;

464 (b) pay a fee established by the division in accordance with Section [63J-1-504](#);

465 (c) unless exempted by the division, submit a completed criminal background check;

466 (d) demonstrate, as determined by the division, that the applicant does not have a
467 physical or mental condition that would prevent the applicant from engaging in practice as a
468 pharmacy technician with reasonable skill, competency, and safety to the public; ~~and~~

469 (e) submit evidence that the applicant is enrolled in a training program approved by the
470 division~~[-]; and~~

471 (f) satisfy any other criteria established by division rule made in collaboration with the
472 board.

473 (2) A pharmacist whose license has been denied, revoked, suspended, or restricted for
474 disciplinary purposes is not eligible to be licensed as a pharmacy technician trainee during
475 division probation.

476 Section 4. Section **58-17b-309.7** is amended to read:

477 **58-17b-309.7. Opioid treatment program.**

478 (1) As used in this section:

479 ~~[(a) "Dispense" means to prepare, package, or label for subsequent use.]~~

480 ~~[(b) "Nurse practitioner" means an individual who is licensed to practice as an
481 advanced practice registered nurse under Chapter 31b, Nurse Practice Act.]~~

482 (a) "Covered provider" means an individual who is licensed to engage in:

483 (i) the practice of advanced practice registered nursing as defined in Section

484 [58-31b-102](#);

485 (ii) the practice of registered nursing as defined in Section [58-31b-102](#); or

486 (iii) practice as a physician assistant as defined in Section [58-70a-102](#).

487 ~~[(c)]~~ (b) "Opioid treatment program" means a program or practitioner that is:

488 (i) engaged in ~~[opioid treatment of an individual using]~~ dispensing an opiate ~~[agonist]~~
489 medication assisted treatment for opioid use disorder;

490 (ii) registered under 21 U.S.C. Sec. 823(g)(1);

491 (iii) licensed by the Office of Licensing[;] within the Department of Human Services[;]
492 created in Section 62A-2-103; and

493 (iv) certified by the Substance Abuse and Mental Health Services Administration in
494 accordance with 42 C.F.R. 8.11.

495 [~~(d) "Physician" means an individual licensed to practice as a physician or osteopath in~~
496 ~~this state under Chapter 67, Utah Medical Practice Act, or Chapter 68, Utah Osteopathic~~
497 ~~Medical Practice Act.]~~

498 [~~(e) "Physician assistant" means an individual who is licensed to practice as a physician~~
499 ~~assistant under Chapter 70a, Utah Physician Assistant Act.]~~

500 [~~(f) "Practitioner" means a nurse practitioner, physician's assistant, or a registered~~
501 ~~nurse.]~~

502 [~~(g) "Registered nurse" means the same as that term is defined in Section 78B-3-403.]~~

503 (2) A [~~practitioner~~] covered provider may dispense [~~methadone~~] opiate medication
504 assisted treatment at an opioid treatment program [~~regardless of whether the practitioner is~~
505 ~~licensed to dispense methadone under this chapter if the practitioner~~] if the covered provider:

506 (a) is operating under the direction of a pharmacist;

507 (b) dispenses the [~~methadone~~] opiate medication assisted treatment under the direction
508 of a pharmacist; and

509 (c) acts in accordance with division rule made under Subsection (3).

510 (3) The division shall, in consultation with [~~pharmacies, physicians, and~~] practitioners
511 who work in an opioid treatment program, make rules in accordance with Title 63G, Chapter 3,
512 Utah Administrative Rulemaking Act, to establish guidelines under which a [~~practitioner~~]
513 covered provider may dispense [~~methadone~~] opiate medication assisted treatment to a patient in
514 an opioid treatment program under this section.

515 Section 5. Section **58-17b-610** is amended to read:

516 **58-17b-610. Patients' immediate needs -- Dispensing drug samples.**

517 (1) This chapter may not be construed to prevent the personal administration of drugs
518 or medicines by practitioners licensed to prescribe in order to supply the immediate needs of
519 the practitioner's patients.

520 (2) Immediate need for a patient includes giving out drug samples that:

521 (a) are not Schedule II drugs, [~~opioids, or Benzodiazepines~~] opioids, or

522 benzodiazepines;

523 (b) are prepackaged by the original manufacturer;

524 (c) are provided to the prescribing practitioner free of charge and provided to the
525 patient free of any direct or indirect charge;

526 (d) do not exceed a 30-day supply for:

527 (i) controlled substances; or

528 (ii) non-controlled substances, unless a prescribing practitioner documents that
529 providing more than a 30-day supply is medically necessary; and

530 (e) (i) are marked on the immediate container to indicate that the drug is a sample; or

531 (ii) are recorded in the patient's chart with the name and number of samples provided.

532 (3) A prescribing practitioner who provides samples for a patient shall comply with
533 Subsection (2).

534 Section 6. Section **58-17b-622** is amended to read:

535 **58-17b-622. Pharmacy benefit management services -- Auditing of pharmacy**
536 **records -- Appeals.**

537 (1) For purposes of this section:

538 (a) "Audit" means a review of the records of a pharmacy by or on behalf of an entity
539 that finances or reimburses the cost of health care services or pharmaceutical products.

540 (b) "Audit completion date" means:

541 (i) for an audit that does not require an on-site visit at the pharmacy, the date on which
542 the pharmacy, in response to the initial audit request, submits records or other documents to the
543 entity conducting the audit, as determined by:

544 (A) postmark or other evidence of the date of mailing; or

545 (B) the date of transmission if the records or other documents are transmitted
546 electronically; and

547 (ii) for an audit that requires an on-site visit at a pharmacy, the date on which the
548 auditing entity completes the on-site visit, ~~it~~ **→ [which may not:] including any follow-up visits or**

548a **analysis which shall be completed within 60 days after the day on which the on-site visit**

548b **begins.**

549 ~~**[(A) include any follow-up visits or analysis; and**~~

550 ~~**(B) exceed 48 hours after the auditing entity arrives on-site at the pharmacy.]** ~~←~~ ~~it~~~~

551 ~~**[(b)]**~~ (c) "Entity" includes:

552 (i) a pharmacy benefits manager or coordinator;

- 553 (ii) a health benefit plan;
- 554 (iii) a third party administrator as defined in Section 31A-1-301;
- 555 (iv) a state agency; or
- 556 (v) a company, group, or agent that represents, or is engaged by, one of the entities
- 557 described in Subsections (1)~~(b)~~(c)(i) through (iv).
- 558 ~~(c)~~ (d) "Fraud" means an intentional act of deception, misrepresentation, or
- 559 concealment in order to gain something of value.
- 560 ~~(d)~~ (e) "Health benefit plan" means:
- 561 (i) a health benefit plan as defined in Section 31A-1-301; or
- 562 (ii) a health, dental, medical, Medicare supplement, or conversion program offered
- 563 under Title 49, Chapter 20, Public Employees' Benefit and Insurance Program Act.
- 564 (2) (a) Except as provided in Subsection (2)(b), this section applies to:
- 565 (i) a contract for the audit of a pharmacy entered into, amended, or renewed on or after
- 566 July 1, 2012; and
- 567 (ii) an entity that conducts an audit of the pharmacy records of a pharmacy licensed
- 568 under this chapter.
- 569 (b) This section does not apply to an audit of pharmacy records:
- 570 (i) for a federally funded prescription drug program, including:
- 571 (A) the state Medicaid program;
- 572 (B) the Medicare Part D program;
- 573 (C) a Department of Defense prescription drug program; and
- 574 (D) a Veterans Affairs prescription drug program; or
- 575 (ii) when fraud or other intentional and willful misrepresentation is alleged and the
- 576 pharmacy audit entity has evidence that the pharmacy's actions reasonably indicate fraud or
- 577 intentional and willful misrepresentation.
- 578 (3) (a) An audit that involves clinical or professional judgment shall be conducted by
- 579 or in consultation with a pharmacist who is employed by or working with the auditing entity
- 580 and who is licensed in the state or another state.
- 581 (b) If an audit is conducted on site at a pharmacy, the entity conducting the audit:
- 582 (i) shall give the pharmacy 10 days advanced written notice of:
- 583 (A) the audit; and

- 584 (B) the range of prescription numbers or a date range included in the audit; and
585 (ii) may not audit a pharmacy during the first five business days of the month, unless
586 the pharmacy agrees to the timing of the audit.
- 587 (c) An entity may not audit claims:
588 (i) submitted more than 18 months prior to the audit, unless:
589 (A) required by federal law; or
590 (B) the originating prescription is dated in the preceding six months; or
591 (ii) that exceed 200 selected prescription claims.
- 592 (4) (a) An entity may not:
593 (i) include dispensing fees in the calculations of overpayments unless the prescription
594 is considered a misfill;
595 (ii) recoup funds for prescription clerical or recordkeeping errors, including
596 typographical errors, scrivener's errors, and computer errors on a required document or record
597 unless the audit entity is alleging fraud or other intentional or willful misrepresentation and the
598 audit entity has evidence that the pharmacy's actions reasonably indicate fraud or intentional
599 and willful misrepresentation;
600 (iii) recoup funds for refills dispensed in accordance with Section 58-17b-608.1, unless
601 the health benefit plan does not cover the prescription drug dispensed by the pharmacy; ~~or~~
602 (iv) collect any funds, charge-backs, or penalties until the audit and all appeals are
603 final, unless the audit entity is alleging fraud or other intentional or willful misrepresentation
604 and the audit entity has evidence that the pharmacy's actions reasonably indicate fraud or
605 intentional and willful misrepresentation~~[-]; or~~
606 (v) recoup funds or collect any funds, charge-backs, or penalties from a pharmacy in
607 response to a request for audit unless the pharmacy confirms to the entity the date on which the
608 pharmacy received the request for audit.
- 609 (b) Auditors shall only have access to previous audit reports on a particular pharmacy
610 if the previous audit was conducted by the same entity except as required for compliance with
611 state or federal law.
- 612 (5) A pharmacy subject to an audit:
613 (a) may use one or more of the following ~~records~~ to validate a claim for a
614 prescription, refill, or change in a prescription:

615 ~~[(a)]~~ ~~H→~~ **(i)** ~~[H]~~ **electronic or physical copies of records of a health care facility, or a**
615a **health care**
616 **provider with prescribing authority; [H] ←H [and]**
617 ~~[(b)]~~ ~~H→~~ **(ii)** ~~[H]~~ **any prescription that complies with state law [H] ←H [:] H→ ; ←H**
618 ~~H→~~ **[(ii)] (iii)** ~~←H~~ the pharmacy's own physical or electronic records; or
619 ~~H→~~ **[(iii)] (iv)** ~~←H~~ the physical or electronic records, or valid copies of the physical or
619a electronic
620 records, of a practitioner or health care facility as defined in Section 26-21-2; and
621 **(b)** may not be required to provide the following records to validate a claim for a
622 prescription, refill, or change in a prescription:
623 **(i)** if the prescription was handwritten, the physical handwritten version of the
624 prescription; or
625 **(ii)** a note from the practitioner regarding the patient or the prescription that is not
626 otherwise required for a prescription under state or federal law.
627 **(6) (a) (i)** An entity that audits a pharmacy shall establish:
628 **(A)** a maximum time for the pharmacy to submit records or other documents to the
629 entity following receipt of an audit request for records or documents; and
630 **(B)** a maximum time for the entity to provide the pharmacy with a preliminary audit
631 report following submission of records under Subsection (6)(a)(i)(A).
632 **(ii)** The time limits established under Subsections (6)(a)(i)(A) and (B):
633 **(A)** shall be identical; and
634 **(B)** may not be less than seven days or more than 60 days.
634a ~~H→~~ **(iii)** **An entity that audits a pharmacy may not, after the audit completion date,**
634b **request additional records or other documents from the pharmacy to complete the preliminary**
634c **audit report described in Subsection (6)(b).** ~~←H~~
635 ~~[(6)(a)]~~ ~~(b)~~ An entity that audits a pharmacy shall provide the pharmacy with a
636 preliminary audit report, delivered to the pharmacy or its corporate office of record, within [60
637 days after completion of the audit] the time limit established under Subsection (6)(a)(i)(B).
638 ~~[(b)]~~ ~~(c) (i)~~ ~~[A]~~ Except as provided in Subsection (6)(c)(ii), a pharmacy has 30 days
639 following receipt of the preliminary audit report to respond to questions, provide additional
640 documentation, and comment on and clarify findings of the audit.
641 **(ii)** ~~H→~~ **[an] An ←H** entity may grant a reasonable extension under Subsection (6)(c)(i)
641a upon request
642 by the pharmacy.
643 **(iii)** Receipt of the report under Subsection (6)(c)(i) shall be [based on the] determined
644 by:
645 **(A)** postmark [date] or other evidence of the date of mailing; or

646 (B) the date of [~~a computer~~] transmission if [~~transferred~~] the report is transmitted
 647 electronically.

648 (iv) If a dispute exists between the records of the auditing entity and the pharmacy, the
 649 records maintained by the pharmacy shall be presumed valid for the purpose of the audit.

650 (7) If an audit results in the dispute or denial of a claim, the entity conducting the audit
 651 shall allow:

652 (a) the pharmacy to resubmit a claim using any commercially reasonable method,
 653 including fax, mail, or electronic claims submission ~~H~~→ [H] **provided that the period of time**
 653a **when a**

654 **claim may be resubmitted has not expired under the rules of the plan sponsor [H] ←H [-]; and**

655 (b) the health benefit plan or other entity that finances or reimburses the cost of health
 656 care services or pharmaceutical products to rerun the claim if the health benefit plan or other
 657 entity chooses to rerun the claim at no cost to the pharmacy.

658 (8) (a) Within [~~+20~~] 60 days after the completion of the appeals process under
 659 Subsection (9), a final audit report shall be delivered to the pharmacy or its corporate office of
 660 record.

661 (b) The final audit report shall include a disclosure of any money recovered by the
 662 entity that conducted the audit.

663 (9) (a) An entity that audits a pharmacy shall establish a written appeals process for
 664 appealing a preliminary audit report and a final audit report, and shall provide the pharmacy
 665 with notice of the written appeals process.

666 (b) If the pharmacy benefit manager's contract or provider manual contains the
 667 information required by this Subsection (9), the requirement for notice is met.

668 Section 7. Section **58-17b-625** is amended to read:

669 **58-17b-625. Administration of a long-acting injectable and naloxone.**

670 (1) A pharmacist may, in accordance with this section, administer a drug described in
 671 Subsection (2).

672 (2) Notwithstanding the provisions of Subsection ~~58-17b-102(57)(c)(ii)(B)~~, the
 673 division shall make rules[;] in collaboration with the board and, when appropriate ~~S~~→ , ←~~S~~ the
 674 ~~S~~→ [~~physician's licensing board~~] **Physicians Licensing Board** ←~~S~~ created in Section ~~58-67-201~~,
 674a and in accordance with Title 63G,

675 Chapter 3, Utah Administrative Rulemaking Act, [~~establishing~~] to establish training for a
 676 pharmacist to administer [~~the following~~] naloxone and long-acting injectables

677 intramuscularly[.];
 678 ~~[(a) aripiprazole;]~~
 679 ~~[(b) aripiprazole lauroxil;]~~
 680 ~~[(c) paliperidone;]~~
 681 ~~[(d) risperidone;]~~
 682 ~~[(e) olanzapine;]~~
 683 ~~[(f) naltrexone;]~~
 684 ~~[(g) naloxone; and]~~
 685 ~~[(h) drugs approved and regulated by the United States Food and Drug Administration~~
 686 ~~for the treatment of the Human Immunodeficiency Virus.]~~

687 (3) A pharmacist may not administer ~~[a drug listed under Subsection (2)]~~ naloxone or a
 688 long-acting injectable intramuscularly unless the pharmacist:

- 689 (a) completes the training described in Subsection (2);
 690 (b) administers the drug at a clinic or community pharmacy, as those terms are defined
 691 by the division, by administrative rule made in accordance with Title 63G, Chapter 3, Utah
 692 Administrative Rulemaking Act; and
 693 (c) is directed by the physician, as that term is defined in Section 58-67-102 or Section
 694 58-68-102, who issues the prescription to administer the drug.

695 Section 8. Section 58-37f-203 is amended to read:

696 **58-37f-203. Submission, collection, and maintenance of data.**

697 (1) (a) The division shall implement on a statewide basis, including non-resident
 698 pharmacies as defined in Section 58-17b-102, the following two options for a pharmacist to
 699 submit information:

700 (i) real-time submission of the information required to be submitted under this part to
 701 the controlled substance database; and

702 (ii) 24-hour daily or next business day, whichever is later, batch submission of the
 703 information required to be submitted under this part to the controlled substance database.

704 (b) A pharmacist shall comply with either:

705 (i) the submission time requirements established by the division under Subsection
 706 (1)(a)(i); or

707 (ii) the submission time requirements established by the division under Subsection

708 (1)(a)(ii).

709 (c) Notwithstanding the time requirements described in Subsection (1)(a), a pharmacist
710 may submit corrections to data that the pharmacist has submitted to the controlled substance
711 database within seven business days after the day on which the division notifies the pharmacist
712 that data is incomplete or corrections to the data are otherwise necessary.

713 [~~e~~] (d) The division shall comply with Title 63G, Chapter 6a, Utah Procurement
714 Code.

715 (2) (a) The pharmacist-in-charge and the pharmacist of the drug outlet where a
716 controlled substance is dispensed shall submit the data described in this section to the division
717 in accordance with:

- 718 (i) the requirements of this section;
719 (ii) the procedures established by the division;
720 (iii) additional types of information or data fields established by the division; and
721 (iv) the format established by the division.

722 (b) A dispensing medical practitioner licensed under Chapter 17b, Part 8, Dispensing
723 Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy, shall comply with
724 the provisions of this section and the dispensing medical practitioner shall assume the duties of
725 the pharmacist under this chapter.

726 (3) (a) Except as provided in Subsection (3)(b), the pharmacist-in-charge and the
727 pharmacist described in Subsection (2)(a) shall, for each controlled substance dispensed by a
728 pharmacist under the pharmacist's supervision, submit to the division any type of information
729 or data field established by the division by rule in accordance with Subsection (6) regarding:

730 (i) each controlled substance that is dispensed by the pharmacist or under the
731 pharmacist's supervision; and

732 (ii) each noncontrolled substance that is:

733 (A) designated by the division under Subsection (8)(a); and

734 (B) dispensed by the pharmacist or under the pharmacist's supervision.

735 (b) Subsection (3)(a) does not apply to a drug that is dispensed for administration to, or
736 use by, a patient at a health care facility, including a patient in an outpatient setting at the health
737 care facility.

738 (4) An individual whose records are in the database may obtain those records upon

739 submission of a written request to the division.

740 (5) (a) A patient whose record is in the database may contact the division in writing to
741 request correction of any of the patient's database information that is incorrect.

742 (b) The division shall grant or deny the request within 30 days from receipt of the
743 request and shall advise the requesting patient of its decision within 35 days of receipt of the
744 request.

745 (c) If the division denies a request under this Subsection (5) or does not respond within
746 35 days, the patient may submit an appeal to the Department of Commerce, within 60 days
747 after the patient's written request for a correction under this Subsection (5).

748 (6) The division shall make rules, in accordance with Title 63G, Chapter 3, Utah
749 Administrative Rulemaking Act, to establish submission requirements under this part,
750 including:

- 751 (a) electronic format;
- 752 (b) submission procedures; and
- 753 (c) required information and data fields.

754 (7) The division shall ensure that the database system records and maintains for
755 reference:

- 756 (a) the identification of each individual who requests or receives information from the
757 database;
- 758 (b) the information provided to each individual; and
- 759 (c) the date and time that the information is requested or provided.

760 (8) (a) The division, in collaboration with the Utah Controlled Substance Advisory
761 Committee created in Section [58-38a-201](#), shall designate a list of noncontrolled substances
762 described in Subsection (8)(b) by rule made in accordance with Title 63G, Chapter 3, Utah
763 Administrative Rulemaking Act.

764 (b) To determine whether a prescription drug should be designated in the schedules of
765 controlled substances under this chapter, the division may collect information about a
766 prescription drug as defined in Section [58-17b-102](#) that is not designated in the schedules of
767 controlled substances under this chapter.

768 Section 9. Section [58-37f-303](#) is amended to read:

769 **[58-37f-303](#). Access to opioid prescription information via an electronic data**

770 system.

771 (1) As used in this section:

772 (a) "Dispense" means the same as that term is defined in Section 58-17b-102.

773 (b) "EDS user":

774 (i) means:

775 (A) a prescriber;

776 (B) a pharmacist;

777 (C) a pharmacy intern;

778 (D) a pharmacy technician; or

779 (E) an individual granted access to the database under Subsection 58-37f-301(3)(c);

780 and

781 (ii) does not mean an individual whose access to the database has been revoked by the
782 division pursuant to Subsection 58-37f-301(5)(c).

783 (c) "Electronic data system" means a software product or an electronic service used by:

784 (i) a prescriber to manage electronic health records; or

785 (ii) a pharmacist, pharmacy intern, or pharmacy technician working under the general
786 supervision of a licensed pharmacist [~~to manage~~], for the purpose of:

787 (A) managing the dispensing of prescription drugs[-]; or

788 (B) providing pharmaceutical care as defined in Section 58-17b-102 to a patient.

789 (d) "Opioid" means any substance listed in Subsection 58-37-4(2)(b)(i) or (2)(b)(ii).

790 (e) "Pharmacist" means the same as that term is defined in Section 58-17b-102.

791 (f) "Prescriber" means a practitioner, as that term is defined in Section 58-37-2, who is
792 licensed under Section 58-37-6 to prescribe an opioid.

793 (g) "Prescription drug" means the same as that term is defined in Section 58-17b-102.

794 (2) Subject to Subsections (3) through (6), no later than January 1, 2017, the division
795 shall make opioid prescription information in the database available to an EDS user via the
796 user's electronic data system.

797 (3) An electronic data system may be used to make opioid prescription information in
798 the database available to an EDS user only if the electronic data system complies with rules
799 established by the division under Subsection (4).

800 (4) (a) The division shall make rules, in accordance with Title 63G, Chapter 3, Utah

801 Administrative Rulemaking Act, specifying:

802 (i) an electronic data system's:

803 (A) allowable access to and use of opioid prescription information in the database; and

804 (B) minimum actions that must be taken to ensure that opioid prescription information

805 accessed from the database is protected from inappropriate disclosure or use; and

806 (ii) an EDS user's:

807 (A) allowable access to opioid prescription information in the database via an

808 electronic data system; and

809 (B) allowable use of the information.

810 (b) The rules shall establish:

811 (i) minimum user identification requirements that in substance are the same as the

812 database identification requirements in Section 58-37f-301;

813 (ii) user access restrictions that in substance are the same as the database identification

814 requirements in Section 58-37f-301; and

815 (iii) any other requirements necessary to ensure that in substance the provisions of

816 Sections 58-37f-301 and 58-37f-302 apply to opioid prescription information in the database

817 that has been made available to an EDS user via an electronic data system.

818 (5) The division may not make opioid prescription information in the database

819 available to an EDS user via the user's electronic data system if:

820 (a) the electronic data system does not comply with the rules established by the

821 division under Subsection (4); or

822 (b) the EDS user does not comply with the rules established by the division under

823 Subsection (4).

824 (6) (a) The division shall periodically audit the use of opioid prescription information

825 made available to an EDS user via the user's electronic data system.

826 (b) The audit shall review compliance by:

827 (i) the electronic data system with rules established by the division under Subsection

828 (4); and

829 (ii) the EDS user with rules established by the division under Subsection (4).

830 (c) (i) If the division determines by audit or other means that an electronic data system

831 is not in compliance with rules established by the division under Subsection (4), the division

832 shall immediately suspend or revoke the electronic data system's access to opioid prescription
833 information in the database.

834 (ii) If the division determines by audit or other means that an EDS user is not in
835 compliance with rules established by the division under Subsection (4), the division shall
836 immediately suspend or revoke the EDS user's access to opioid prescription information in the
837 database via an electronic data system.

838 (iii) If the division suspends or revokes access to opioid prescription information in the
839 database under Subsection (6)(c)(i) or (6)(c)(ii), the division shall also take any other
840 appropriate corrective or disciplinary action authorized by this chapter or title.