

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:

- ▶ establishes copayment limits for insulin;
- ▶ amends the 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;
- ▶ amends the definition of “electronic data system”; and
- ▶ makes technical changes.

Money Appropriated in this Bill:

None

Other Special Clauses:

None



28 **Utah Code Sections Affected:**

29 AMENDS:

30 **31A-46-102**, as last amended by Laws of Utah 2020, Chapters 198, 275, and 372

31 **49-20-502**, as enacted by Laws of Utah 2011, Chapter 83

32 **58-17b-102**, as last amended by Laws of Utah 2019, Chapter 343

33 **58-17b-305.1**, as last amended by Laws of Utah 2020, Chapter 339

34 **58-17b-309.7**, as enacted by Laws of Utah 2019, Chapter 311

35 **58-17b-610**, as last amended by Laws of Utah 2012, Chapter 320

36 **58-17b-622**, as last amended by Laws of Utah 2018, Chapter 39

37 **58-17b-625**, as last amended by Laws of Utah 2019, Chapter 343

38 **58-37f-203**, as last amended by Laws of Utah 2020, Chapters 147, 339, and 372

39 **58-37f-303**, as last amended by Laws of Utah 2020, Chapters 147 and 339

40 ENACTS:

41 **31A-22-656**, Utah Code Annotated 1953



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

44 Section 1. Section **31A-22-656** is enacted to read:

45 **31A-22-656. Copayment limits for insulin.**

46 (1) As used in this section:

47 (a) "Insulin" means a prescription drug that contains insulin.

48 (b) "Prescription drug" means the same as that term is defined in Section [58-17b-102](#).

49 (2) If a health benefit plan entered into or renewed on or after January 1, 2022, requires

50 an enrollee to make a copayment for coverage of insulin:

51 (a) the copayment for less than a 30-day supply may not exceed the copayment for a

52 30-day supply, prorated according to the number of days of supply dispensed; and

53 (b) the copayment for a supply that is greater than 30 days but less than 51 days may

54 not exceed the copayment for a 30-day supply.

55 Section 2. Section **31A-46-102** is amended to read:

56 **31A-46-102. Definitions.**

57 As used in this chapter:

58 (1) "340B drug" means a drug purchased through the 340B drug discount program by a

59 340B entity.

60 (2) "340B drug discount program" means the 340B drug discount program described in
61 42 U.S.C. Sec. 256b.

62 (3) "340B entity" means:

63 (a) an entity participating in the 340B drug discount program;

64 (b) a pharmacy of an entity participating in the 340B drug discount program; or

65 (c) a pharmacy contracting with an entity participating in the 340B drug discount
66 program to dispense drugs purchased through the 340B drug discount program.

67 (4) "Administrative fee" means any payment, other than a rebate, that a pharmaceutical
68 manufacturer makes directly or indirectly to a pharmacy benefit manager.

69 (5) "Allowable claim amount" means the amount paid by an insurer under the
70 customer's health benefit plan.

71 (6) "Contracting insurer" means an insurer with whom a pharmacy benefit manager
72 contracts to provide a pharmacy benefit management service.

73 (7) "Cost share" means the amount paid by an insured customer under the customer's
74 health benefit plan.

75 (8) "Device" means the same as that term is defined in Section [58-17b-102](#).

76 (9) "Direct or indirect remuneration" means any adjustment in the total compensation:

77 (a) received by a pharmacy from a pharmacy benefit manager for the sale of a drug,
78 device, or other product or service; and

79 (b) that is determined after the sale of the product or service.

80 (10) "Dispense" means the same as that term is defined in Section [58-17b-102](#).

81 (11) "Drug" means the same as that term is defined in Section [58-17b-102](#).

82 (12) "Insurer" means the same as that term is defined in Section [31A-22-636](#).

83 (13) "Maximum allowable cost" means:

84 (a) a maximum reimbursement amount for a group of pharmaceutically and
85 therapeutically equivalent drugs; or

86 (b) any similar reimbursement amount that is used by a pharmacy benefit manager to
87 reimburse pharmacies for multiple source drugs.

88 (14) "Medicaid program" means the same as that term is defined in Section [26-18-2](#).

89 (15) "Obsolete" means a product that may be listed in national drug pricing compendia

90 but is no longer available to be dispensed based on the expiration date of the last lot
91 manufactured.

92 (16) "Patient counseling" means the same as that term is defined in Section
93 58-17b-102.

94 (17) "Pharmaceutical facility" means the same as that term is defined in Section
95 58-17b-102.

96 (18) "Pharmaceutical manufacturer" means a pharmaceutical facility that manufactures
97 prescription drugs.

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

99 (20) "Pharmacy" means the same as that term is defined in Section 58-17b-102.

100 (21) "Pharmacy benefits management service" means any of the following services
101 provided to [~~a health benefit plan,~~] an insurer or to a participant of [~~a health benefit plan~~] an
102 insurer, regardless of whether the insurer is regulated under Title 31A, Insurance Code:

103 (a) negotiating the amount to be paid by a health benefit plan for a prescription drug; or

104 (b) administering or managing a prescription drug benefit provided by the health
105 benefit plan for the benefit of a participant of the health benefit plan, including administering
106 or managing:

107 (i) an out-of-state mail service pharmacy;

108 (ii) a specialty pharmacy;

109 (iii) claims processing;

110 (iv) payment of a claim;

111 (v) retail network management;

112 (vi) clinical formulary development;

113 (vii) clinical formulary management services;

114 (viii) rebate contracting;

115 (ix) rebate administration;

116 (x) a participant compliance program;

117 (xi) a therapeutic intervention program;

118 (xii) a disease management program; or

119 (xiii) a service that is similar to, or related to, a service described in Subsection (21)(a)

120 or (21)(b)(i) through (xii).

121 (22) "Pharmacy benefit manager" means a person licensed under this chapter to
122 provide a pharmacy benefits management service.

123 (23) "Pharmacy service" means a product, good, or service provided to an individual by
124 a pharmacy or pharmacist.

125 (24) "Pharmacy services administration organization" means an entity that contracts
126 with a pharmacy to assist with third-party payer interactions and administrative services related
127 to third-party payer interactions, including:

128 (a) contracting with a pharmacy benefit manager on behalf of the pharmacy; and

129 (b) managing a pharmacy's claims payments from third-party payers.

130 (25) "Pharmacy service entity" means:

131 (a) a pharmacy services administration organization; or

132 (b) a pharmacy benefit manager.

133 (26) "Prescription device" means the same as that term is defined in Section
134 [58-17b-102](#).

135 (27) "Prescription drug" means the same as that term is defined in Section [58-17b-102](#).

136 (28) (a) "Rebate" means a refund, discount, or other price concession that is paid by a
137 pharmaceutical manufacturer to a pharmacy benefit manager based on a prescription drug's
138 utilization or effectiveness.

139 (b) "Rebate" does not include an administrative fee.

140 (29) (a) "Reimbursement report" means a report on the adjustment in total
141 compensation for a claim.

142 (b) "Reimbursement report" does not include a report on adjustments made pursuant to
143 a pharmacy audit or reprocessing.

144 (30) "Retail pharmacy" means the same as that term is defined in Section [58-17b-102](#).

145 (31) "Sale" means a prescription drug or prescription device claim covered by a health
146 benefit plan.

147 (32) "Wholesale acquisition cost" means the same as that term is defined in 42 U.S.C.
148 Sec. 1395w-3a.

149 Section 3. Section **49-20-502** is amended to read:

150 **49-20-502. Definitions.**

151 As used in this part:

- 152 (1) "Health benefit plan" means:
- 153 (a) a health benefit plan as defined in Section 31A-1-301; or
- 154 (b) a health, dental, medical, Medicare supplement, or conversion program offered
- 155 under Title 49, Chapter 20, Public Employees' Benefit and Insurance Program Act.
- 156 (2) "Pharmacist" is as defined in Section 58-17b-102.
- 157 (3) "Pharmacy" is as defined in Section 58-17b-102.
- 158 (4) "Pharmacy benefits management service" means any of the following services
- 159 provided to ~~[a health benefit plan,]~~ an insurer or to a participant of the ~~[health benefit plan]~~
- 160 insurer, regardless of whether the insurer is regulated under Title 31A, Insurance Code:
- 161 (a) negotiating the amount to be paid by a health benefit plan for a prescription drug; or
- 162 (b) administering or managing prescription drug benefits provided by the health benefit
- 163 plan for the benefit of a participant of the health benefit plan, including:
- 164 (i) mail service pharmacy;
- 165 (ii) specialty pharmacy;
- 166 (iii) claims processing;
- 167 (iv) payment of a claim;
- 168 (v) retail network management;
- 169 (vi) clinical formulary development;
- 170 (vii) clinical formulary management services;
- 171 (viii) rebate contracting;
- 172 (ix) rebate administration;
- 173 (x) a participant compliance program;
- 174 (xi) a therapeutic intervention program;
- 175 (xii) a disease management program; or
- 176 (xiii) a service that is similar to, or related to, a service described in Subsection (4)(a)
- 177 or (4)(b)(i) through (xii).
- 178 (5) "Pharmacy benefits manager" means a person that provides a pharmacy benefits
- 179 management service to a health benefit plan.
- 180 (6) "Pharmacy service" means a product, good, or service provided by a pharmacy or
- 181 pharmacist to an individual.

182 Section 4. Section 58-17b-102 is amended to read:

183 **58-17b-102. Definitions.**184 In addition to the definitions in Section [58-1-102](#), as used in this chapter:

185 (1) "Administering" means:

186 (a) the direct application of a prescription drug or device, whether by injection,
187 inhalation, ingestion, or by any other means, to the body of a human patient or research subject
188 by another person; or189 (b) the placement by a veterinarian with the owner or caretaker of an animal or group
190 of animals of a prescription drug for the purpose of injection, inhalation, ingestion, or any other
191 means directed to the body of the animal by the owner or caretaker in accordance with written
192 or verbal directions of the veterinarian.193 (2) "Adulterated drug or device" means a drug or device considered adulterated under
194 21 U.S.C. Sec. 351 (2003).195 (3) (a) "Analytical laboratory" means a facility in possession of prescription drugs for
196 the purpose of analysis.197 (b) "Analytical laboratory" does not include a laboratory possessing prescription drugs
198 used as standards and controls in performing drug monitoring or drug screening analysis if the
199 prescription drugs are prediluted in a human or animal body fluid, human or animal body fluid
200 components, organic solvents, or inorganic buffers at a concentration not exceeding one
201 milligram per milliliter when labeled or otherwise designated as being for in vitro diagnostic
202 use.203 (4) "Animal euthanasia agency" means an agency performing euthanasia on animals by
204 the use of prescription drugs.205 (5) "Automated pharmacy systems" includes mechanical systems which perform
206 operations or activities, other than compounding or administration, relative to the storage,
207 packaging, dispensing, or distribution of medications, and which collect, control, and maintain
208 all transaction information.209 (6) "Beyond use date" means the date determined by a pharmacist and placed on a
210 prescription label at the time of dispensing that indicates to the patient or caregiver a time
211 beyond which the contents of the prescription are not recommended to be used.212 (7) "Board of pharmacy" or "board" means the Utah State Board of Pharmacy created
213 in Section [58-17b-201](#).

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

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

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

225 (11) "Class B pharmacy":

226 (a) means a pharmacy located in Utah:

227 (i) that is authorized to provide pharmaceutical care for patients in an institutional
228 setting; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

258 (ii) for the purpose of, or as an incident to, research, teaching, or chemical analysis and
259 not for sale or dispensing; or

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

262 (b) "Compounding" does not include:

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

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

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

270 (19) "Confidential information" has the same meaning as "protected health
271 information" under the Standards for Privacy of Individually Identifiable Health Information,
272 45 C.F.R. Parts 160 and 164.

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

274 (21) "Dietary supplement" has the same meaning as Public Law Title 103, Chapter
275 417, Sec. 3a(ff) which is incorporated by reference.

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

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

281 (a) currently licensed as:

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

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

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

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

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

289 (b) licensed by the division under the Pharmacy Practice Act to engage in the practice
290 of a dispensing medical practitioner.

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

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

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

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

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

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

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

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

- 307 (27) "Drug regimen review" includes the following activities:
- 308 (a) evaluation of the prescription drug order and patient record for:
- 309 (i) known allergies;
- 310 (ii) rational therapy-contraindications;
- 311 (iii) reasonable dose and route of administration; and
- 312 (iv) reasonable directions for use;
- 313 (b) evaluation of the prescription drug order and patient record for duplication of
- 314 therapy;
- 315 (c) evaluation of the prescription drug order and patient record for the following
- 316 interactions:
- 317 (i) drug-drug;
- 318 (ii) drug-food;
- 319 (iii) drug-disease; and
- 320 (iv) adverse drug reactions; and
- 321 (d) evaluation of the prescription drug order and patient record for proper utilization,
- 322 including over- or under-utilization, and optimum therapeutic outcomes.
- 323 (28) "Drug sample" means a prescription drug packaged in small quantities consistent
- 324 with limited dosage therapy of the particular drug, which is marked "sample", is not intended to
- 325 be sold, and is intended to be provided to practitioners for the immediate needs of patients for
- 326 trial purposes or to provide the drug to the patient until a prescription can be filled by the
- 327 patient.
- 328 (29) "Electronic signature" means a trusted, verifiable, and secure electronic sound,
- 329 symbol, or process attached to or logically associated with a record and executed or adopted by
- 330 a person with the intent to sign the record.
- 331 (30) "Electronic transmission" means transmission of information in electronic form or
- 332 the transmission of the exact visual image of a document by way of electronic equipment.
- 333 (31) "Hospital pharmacy" means a pharmacy providing pharmaceutical care to
- 334 inpatients of a general acute hospital or specialty hospital licensed by the Department of Health
- 335 under Title 26, Chapter 21, Health Care Facility Licensing and Inspection Act.
- 336 (32) "Legend drug" has the same meaning as prescription drug.
- 337 (33) "Licensed pharmacy technician" means an individual licensed with the division,

338 that may, under the supervision of a pharmacist, perform the activities involved in the
339 technician practice of pharmacy.

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

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

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

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

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

351 (c) "Manufacturing" does not include the preparation or compounding of a drug by a
352 pharmacist, pharmacy intern, or practitioner for that individual's own use or the preparation,
353 compounding, packaging, labeling of a drug, or incident to research, teaching, or chemical
354 analysis.

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

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

360 (38) "Misbranded drug or device" means a drug or device considered misbranded under
361 21 U.S.C. Sec. 352 (2003).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

397 (iii) arresting or slowing a disease process.

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

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

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

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

409 (i) intracompany sales;

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

414 (A) hospitals;

415 (B) pharmacies;

416 (C) chain pharmacy warehouses, as defined by division rule; or

417 (D) other health care entities, as defined by division rule;

418 (iii) the sale, purchase, or trade of a prescription drug or device, or an offer to sell,
419 purchase, or trade a prescription drug or device, for emergency medical reasons, including
420 supplying another pharmaceutical facility with a limited quantity of a drug, if:

421 (A) the facility is unable to obtain the drug through a normal distribution channel in
422 sufficient time to eliminate the risk of harm to a patient that would result from a delay in
423 obtaining the drug; and

424 (B) the quantity of the drug does not exceed an amount reasonably required for
425 immediate dispensing to eliminate the risk of harm;

426 (iv) the distribution of a prescription drug or device as a sample by representatives of a
427 manufacturer; and

428 (v) the distribution of prescription drugs, if:

429 (A) the facility's total distribution-related sales of prescription drugs does not exceed
430 5% of the facility's total prescription drug sales; and

431 (B) the distribution otherwise complies with 21 C.F.R. Sec. 1307.11.

432 (48) "Pharmacist" means an individual licensed by this state to engage in the practice
433 of pharmacy.

434 (49) "Pharmacist-in-charge" means a pharmacist currently licensed in good standing
435 who accepts responsibility for the operation of a pharmacy in conformance with all laws and
436 rules pertinent to the practice of pharmacy and the distribution of drugs, and who is personally
437 in full and actual charge of the pharmacy and all personnel.

438 (50) "Pharmacist preceptor" means a licensed pharmacist in good standing with one or
439 more years of licensed experience. The preceptor serves as a teacher, example of professional
440 conduct, and supervisor of interns in the professional practice of pharmacy.

441 (51) "Pharmacy" means any place where:

442 (a) drugs are dispensed;

443 (b) pharmaceutical care is provided;

444 (c) drugs are processed or handled for eventual use by a patient; or

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

446 (52) "Pharmacy benefits manager or coordinator" means a person or entity that
447 provides a pharmacy benefits management service as defined in Section [49-20-502](#) on behalf of
448 a self-insured employer, insurance company, health maintenance organization, or other plan
449 sponsor, as defined by rule.

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

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

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

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

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

461 or

462 (ii) except as permitted by Section 58-17b-805, dispensing of a controlled substance as
463 defined in Section 58-37-2.

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

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

468 (a) providing pharmaceutical care;

469 (b) collaborative pharmacy practice in accordance with a collaborative pharmacy
470 practice agreement;

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

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

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

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

478 (B) approved by the division, in collaboration with the board [~~and the Physicians~~
479 ~~Licensing Board, created in Section 58-67-201~~], if the prescription drug or device is to be
480 administered on an outpatient basis solely by a licensed pharmacist;

481 (d) participating in drug utilization review;

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

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

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

487 (h) providing drug product equivalents;

488 (i) supervising pharmacist's supportive personnel, pharmacy interns, and pharmacy
489 technicians;

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

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

492 (l) telepharmacy;

493 (m) formulary management intervention; and

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

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

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

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

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

506 (a) orally or in writing; or

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

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

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

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

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

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

521 (65) "Repackage":

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

524 (b) does not include:

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

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

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

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

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

536 (c) that uses the controlled substance, prescription drug, or prescription device in
537 accordance with standard research protocols and techniques, including, if required, those
538 approved by an institutional review committee; and

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

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

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

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

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

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

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

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

555 (a) may assist a pharmacist, pharmacist preceptor, pharmacy intern, or licensed
556 pharmacy technician in nonjudgmental duties not included in the definition of the practice of
557 pharmacy, practice of a pharmacy intern, or practice of a licensed pharmacy technician, and as
558 those duties may be further defined by division rule adopted in collaboration with the board;
559 and

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

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

564 (73) "Unprofessional conduct" means the same as that term is defined in Sections
565 58-1-501 and 58-17b-502 and may be further defined by rule.

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

569 Section 5. Section 58-17b-305.1 is amended to read:

570 **58-17b-305.1. Qualifications for licensure of pharmacy technician trainee.**

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

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

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

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

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

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

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

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

585 Section 6. Section 58-17b-309.7 is amended to read:

586 **58-17b-309.7. Opioid treatment program.**

587 (1) As used in this section:

588 [~~(a) "Dispense" means to prepare, package, or label for subsequent use.~~]589 [~~(b) "Nurse practitioner" means an individual who is licensed to practice as an~~590 ~~advanced practice registered nurse under Chapter 31b, Nurse Practice Act.~~]

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

592 (i) the practice of advanced practice registered nursing as defined in Section593 [58-31b-102](#);594 (ii) the practice of registered nursing as defined in Section [58-31b-102](#); or595 (iii) practice as a physician assistant as defined in Section [58-70a-102](#).596 [~~(e)~~] (b) "Opioid treatment program" means a program or practitioner that is:597 (i) engaged in [~~opioid treatment of an individual using~~] dispensing an opiate [agonist]598 medication assisted treatment for opioid use disorder;

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

600 (iii) licensed by the Office of Licensing[;] within the Department of Human Services[;]

601 created in Section [62A-2-103](#); and602 (iv) certified by the Substance Abuse and Mental Health Services Administration in
603 accordance with 42 C.F.R. 8.11.604 [~~(d) "Physician" means an individual licensed to practice as a physician or osteopath in~~
605 ~~this state under Chapter 67, Utah Medical Practice Act, or Chapter 68, Utah Osteopathic~~
606 ~~Medical Practice Act.~~]607 [~~(e) "Physician assistant" means an individual who is licensed to practice as a physician~~
608 ~~assistant under Chapter 70a, Utah Physician Assistant Act.~~]609 [~~(f) "Practitioner" means a nurse practitioner, physician's assistant, or a registered~~
610 ~~nurse.~~]611 [~~(g) "Registered nurse" means the same as that term is defined in Section [78B-3-403](#).~~]612 (2) A [~~practitioner~~] covered provider may dispense [~~methadone~~] opiate medication613 assisted treatment at an opioid treatment program [~~regardless of whether the practitioner is~~614 ~~licensed to dispense methadone under this chapter if the practitioner~~] if the covered provider:

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

616 (b) dispenses the [~~methadone~~] opiate medication assisted treatment under the direction

617 of a pharmacist; and

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

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

624 Section 7. Section **58-17b-610** is amended to read:

625 **58-17b-610. Patients' immediate needs -- Dispensing drug samples.**

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

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

630 (a) are not Schedule II drugs, [~~opiods, or Benzodiazepines~~] opiods, or
631 benzodiazepines;

632 (b) are prepackaged by the original manufacturer;

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

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

636 (i) controlled substances; or

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

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

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

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

643 Section 8. Section **58-17b-622** is amended to read:

644 **58-17b-622. Pharmacy benefit management services -- Auditing of pharmacy**
645 **records -- Appeals.**

646 (1) For purposes of this section:

647 (a) "Audit" means a review of the records of a pharmacy by or on behalf of an entity

648 that finances or reimburses the cost of health care services or pharmaceutical products.

649 (b) "Audit completion date" means:

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

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

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

656 (ii) for an audit that requires an on-site visit at a pharmacy, the date on which the
657 auditing entity completes the on-site visit, which may not:

658 (A) include any follow-up visits or analysis; and

659 (B) exceed 48 hours after the auditing entity arrives on-site at the pharmacy.

660 ~~(b)~~ (c) "Entity" includes:

661 (i) a pharmacy benefits manager or coordinator;

662 (ii) a health benefit plan;

663 (iii) a third party administrator as defined in Section 31A-1-301;

664 (iv) a state agency; or

665 (v) a company, group, or agent that represents, or is engaged by, one of the entities
666 described in Subsections (1)~~(b)~~(c)(i) through (iv).

667 (c) "Fraud" means an intentional act of deception, misrepresentation, or concealment in
668 order to gain something of value.

669 (d) "Health benefit plan" means:

670 (i) a health benefit plan as defined in Section 31A-1-301; or

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

673 (2) (a) Except as provided in Subsection (2)(b), this section applies to:

674 (i) a contract for the audit of a pharmacy entered into, amended, or renewed on or after
675 July 1, 2012; and

676 (ii) an entity that conducts an audit of the pharmacy records of a pharmacy licensed
677 under this chapter.

678 (b) This section does not apply to an audit of pharmacy records:

- 679 (i) for a federally funded prescription drug program, including:
680 (A) the state Medicaid program;
681 (B) the Medicare Part D program;
682 (C) a Department of Defense prescription drug program; and
683 (D) a Veterans Affairs prescription drug program; or
684 (ii) when fraud or other intentional and willful misrepresentation is alleged and the
685 pharmacy audit entity has evidence that the pharmacy's actions reasonably indicate fraud or
686 intentional and willful misrepresentation.
- 687 (3) (a) An audit that involves clinical or professional judgment shall be conducted by
688 or in consultation with a pharmacist who is employed by or working with the auditing entity
689 and who is licensed in the state or another state.
- 690 (b) If an audit is conducted on site at a pharmacy, the entity conducting the audit:
691 (i) shall give the pharmacy 10 days advanced written notice of:
692 (A) the audit; and
693 (B) the range of prescription numbers or a date range included in the audit; and
694 (ii) may not audit a pharmacy during the first five business days of the month, unless
695 the pharmacy agrees to the timing of the audit.
- 696 (c) An entity may not audit claims:
697 (i) submitted more than 18 months prior to the audit, unless:
698 (A) required by federal law; or
699 (B) the originating prescription is dated in the preceding six months; or
700 (ii) that exceed 200 selected prescription claims.
- 701 (4) (a) An entity may not:
702 (i) include dispensing fees in the calculations of overpayments unless the prescription
703 is considered a misfill;
704 (ii) recoup funds for prescription clerical or recordkeeping errors, including
705 typographical errors, scrivener's errors, and computer errors on a required document or record
706 unless the audit entity is alleging fraud or other intentional or willful misrepresentation and the
707 audit entity has evidence that the pharmacy's actions reasonably indicate fraud or intentional
708 and willful misrepresentation;
709 (iii) recoup funds for refills dispensed in accordance with Section [58-17b-608.1](#), unless

710 the health benefit plan does not cover the prescription drug dispensed by the pharmacy; ~~[or]~~

711 (iv) collect any funds, charge-backs, or penalties until the audit and all appeals are
712 final, unless the audit entity is alleging fraud or other intentional or willful misrepresentation
713 and the audit entity has evidence that the pharmacy's actions reasonably indicate fraud or
714 intentional and willful misrepresentation~~[-];~~ or

715 (v) recoup funds or collect any funds, charge-backs, or penalties from a pharmacy in
716 response to a request for audit unless the pharmacy confirms to the entity the date on which the
717 pharmacy received the request for audit.

718 (b) Auditors shall only have access to previous audit reports on a particular pharmacy
719 if the previous audit was conducted by the same entity except as required for compliance with
720 state or federal law.

721 (5) A pharmacy subject to an audit:

722 (a) may use one or more of the following ~~[records]~~ to validate a claim for a
723 prescription, refill, or change in a prescription:

724 ~~[(a) electronic or physical copies of records of a health care facility, or a health care~~
725 ~~provider with prescribing authority; and]~~

726 ~~[(b) any prescription that complies with state law.]~~

727 (i) the pharmacy's own physical or electronic records; or

728 (ii) the physical or electronic records, or valid copies of the physical or electronic
729 records, of a practitioner or health care facility as defined in Section [26-21-2](#); and

730 (b) may not be required to provide the following records to validate a claim for a
731 prescription, refill, or change in a prescription:

732 (i) if the prescription was handwritten, the physical handwritten version of the
733 prescription; or

734 (ii) a note from the practitioner regarding the patient or the prescription that is not
735 otherwise required for a prescription under state or federal law.

736 (6) (a) (i) An entity that audits a pharmacy shall establish:

737 (A) a maximum time for the pharmacy to submit records or other documents to the
738 entity following receipt of an audit request for records or documents; and

739 (B) a maximum time for the entity to provide the pharmacy with a preliminary audit
740 report following submission of records under Subsection (6)(a)(i)(A).

- 741 (ii) The time limits established under Subsections (6)(a)(i)(A) and (B):
742 (A) shall be identical; and
743 (B) may not be less than seven days nor more than 30 days.
744 ~~[(6)(a)]~~ (b) An entity that audits a pharmacy shall provide the pharmacy with a
745 preliminary audit report, delivered to the pharmacy or its corporate office of record, within ~~[60~~
746 ~~days after completion of the audit]~~ the time limit established under Subsection (6)(a)(i)(B).
747 ~~[(b)]~~ (c) (i) A pharmacy has 30 days following receipt of the preliminary audit report to
748 respond to questions, provide additional documentation, and comment on and clarify findings
749 of the audit.
750 (ii) Receipt of the report under Subsection (6)(c)(i) shall be ~~[based on the]~~ determined
751 by:
752 (A) postmark ~~[date]~~ or other evidence of the date of mailing; or
753 (B) the date of ~~[a computer]~~ transmission if ~~[transferred]~~ the report is transmitted
754 electronically.
755 (iii) If a dispute exists between the records of the auditing entity and the pharmacy, the
756 records maintained by the pharmacy shall be presumed valid for the purpose of the audit.
757 (7) If an audit results in the dispute or denial of a claim, the entity conducting the audit
758 shall allow:
759 (a) the pharmacy to resubmit a claim using any commercially reasonable method,
760 including fax, mail, or electronic claims submission ~~[provided that the period of time when a~~
761 claim may be resubmitted has not expired under the rules of the plan sponsor.]; and
762 (b) the health benefit plan or other entity that finances or reimburses the cost of health
763 care services or pharmaceutical products to rerun the claim if the health benefit plan or other
764 entity chooses to rerun the claim at no cost to the pharmacy.
765 (8) (a) Within ~~[+20]~~ 30 days after the completion of the appeals process under
766 Subsection (9), a final audit report shall be delivered to the pharmacy or its corporate office of
767 record.
768 (b) The final audit report shall include a disclosure of any money recovered by the
769 entity that conducted the audit.
770 (9) (a) An entity that audits a pharmacy shall establish a written appeals process for
771 appealing a preliminary audit report and a final audit report, and shall provide the pharmacy

772 with notice of the written appeals process.

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

775 Section 9. Section **58-17b-625** is amended to read:

776 **58-17b-625. Administration of a long-acting injectable drug therapy.**

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

779 (2) Notwithstanding the provisions of Subsection [58-17b-102\(57\)\(c\)\(ii\)\(B\)](#), the
780 division shall make rules[;] in collaboration with the board and in accordance with Title 63G,
781 Chapter 3, Utah Administrative Rulemaking Act, [~~establishing~~] to establish training for a
782 pharmacist to administer [~~the following long-acting injectables intramuscularly:~~] injectables.

783 [~~(a) aripiprazole;~~]

784 [~~(b) aripiprazole lauroxil;~~]

785 [~~(c) paliperidone;~~]

786 [~~(d) risperidone;~~]

787 [~~(e) olanzapine;~~]

788 [~~(f) naltrexone;~~]

789 [~~(g) naloxone; and~~]

790 [~~(h) drugs approved and regulated by the United States Food and Drug Administration~~
791 ~~for the treatment of the Human Immunodeficiency Virus.]~~

792 (3) A pharmacist may not administer [~~a drug listed under Subsection (2)] injectables
793 unless the pharmacist:~~

794 (a) completes the training described in Subsection (2);

795 (b) administers the drug at a clinic or community pharmacy, as those terms are defined
796 by the division, by administrative rule made in accordance with Title 63G, Chapter 3, Utah
797 Administrative Rulemaking Act; and

798 (c) is directed by the physician, as that term is defined in Section [58-67-102](#) or Section
799 [58-68-102](#), who issues the prescription to administer the drug.

800 Section 10. Section **58-37f-203** is amended to read:

801 **58-37f-203. Submission, collection, and maintenance of data.**

802 (1) (a) The division shall implement on a statewide basis, including non-resident

803 pharmacies as defined in Section 58-17b-102, the following two options for a pharmacist to
804 submit information:

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

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

809 (b) A pharmacist shall comply with either:

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

812 (ii) the submission time requirements established by the division under Subsection
813 (1)(a)(ii).

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

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

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

823 (i) the requirements of this section;

824 (ii) the procedures established by the division;

825 (iii) additional types of information or data fields established by the division; and

826 (iv) the format established by the division.

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

831 (3) (a) Except as provided in Subsection (3)(b), the pharmacist-in-charge and the
832 pharmacist described in Subsection (2)(a) shall, for each controlled substance dispensed by a
833 pharmacist under the pharmacist's supervision, submit to the division any type of information

834 or data field established by the division by rule in accordance with Subsection (6) regarding:

835 (i) each controlled substance that is dispensed by the pharmacist or under the

836 pharmacist's supervision; and

837 (ii) each noncontrolled substance that is:

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

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

840 (b) Subsection (3)(a) does not apply to a drug that is dispensed for administration to, or

841 use by, a patient at a health care facility, including a patient in an outpatient setting at the health

842 care facility.

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

844 submission of a written request to the division.

845 (5) (a) A patient whose record is in the database may contact the division in writing to

846 request correction of any of the patient's database information that is incorrect.

847 (b) The division shall grant or deny the request within 30 days from receipt of the

848 request and shall advise the requesting patient of its decision within 35 days of receipt of the

849 request.

850 (c) If the division denies a request under this Subsection (5) or does not respond within

851 35 days, the patient may submit an appeal to the Department of Commerce, within 60 days

852 after the patient's written request for a correction under this Subsection (5).

853 (6) The division shall make rules, in accordance with Title 63G, Chapter 3, Utah

854 Administrative Rulemaking Act, to establish submission requirements under this part,

855 including:

856 (a) electronic format;

857 (b) submission procedures; and

858 (c) required information and data fields.

859 (7) The division shall ensure that the database system records and maintains for

860 reference:

861 (a) the identification of each individual who requests or receives information from the

862 database;

863 (b) the information provided to each individual; and

864 (c) the date and time that the information is requested or provided.

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

869 (b) To determine whether a prescription drug should be designated in the schedules of
870 controlled substances under this chapter, the division may collect information about a
871 prescription drug as defined in Section 58-17b-102 that is not designated in the schedules of
872 controlled substances under this chapter.

873 Section 11. Section 58-37f-303 is amended to read:

874 **58-37f-303. Access to opioid prescription information via an electronic data**
875 **system.**

876 (1) As used in this section:

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

878 (b) "EDS user":

879 (i) means:

880 (A) a prescriber;

881 (B) a pharmacist;

882 (C) a pharmacy intern;

883 (D) a pharmacy technician; or

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

885 and

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

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

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

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

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

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

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

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

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

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

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

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

905 (4) (a) The division shall make rules, in accordance with Title 63G, Chapter 3, Utah
906 Administrative Rulemaking Act, specifying:

907 (i) an electronic data system's:

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

909 (B) minimum actions that must be taken to ensure that opioid prescription information
910 accessed from the database is protected from inappropriate disclosure or use; and

911 (ii) an EDS user's:

912 (A) allowable access to opioid prescription information in the database via an
913 electronic data system; and

914 (B) allowable use of the information.

915 (b) The rules shall establish:

916 (i) minimum user identification requirements that in substance are the same as the
917 database identification requirements in Section 58-37f-301;

918 (ii) user access restrictions that in substance are the same as the database identification
919 requirements in Section 58-37f-301; and

920 (iii) any other requirements necessary to ensure that in substance the provisions of
921 Sections 58-37f-301 and 58-37f-302 apply to opioid prescription information in the database
922 that has been made available to an EDS user via an electronic data system.

923 (5) The division may not make opioid prescription information in the database
924 available to an EDS user via the user's electronic data system if:

925 (a) the electronic data system does not comply with the rules established by the
926 division under Subsection (4); or

927 (b) the EDS user does not comply with the rules established by the division under
928 Subsection (4).

929 (6) (a) The division shall periodically audit the use of opioid prescription information
930 made available to an EDS user via the user's electronic data system.

931 (b) The audit shall review compliance by:

932 (i) the electronic data system with rules established by the division under Subsection
933 (4); and

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

935 (c) (i) If the division determines by audit or other means that an electronic data system
936 is not in compliance with rules established by the division under Subsection (4), the division
937 shall immediately suspend or revoke the electronic data system's access to opioid prescription
938 information in the database.

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

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