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| | 2013 | 2014 | 2015 | Feb-15 |
|-------------------------------------|---|------|------|--------|
| Administrative Filings | 37 | 52 | 1 | 2 |
| Criminal Filing/Felony | 3 | 0 | 0 | 0 |
| Letter of Concern | 60 | 146 | 8 | 9 |
| Referred to Diversion | 1 | 2 | 0 | 0 |
| PR/Outreach | 3 | 4 | 0 | 0 |
| Cases Received | 710 | 567 | 63 | 48 |
| Case Assigned | 676 | 555 | 63 | 44 |
| Closed Cases | 731 | 595 | 45 | 63 |
| Citations Issued | 103 | 60 | 10 | 9 |
| Pharmacy Inspections | 225 | 335 | 20 | 9 |
| Pharmacy Alerts | 191 | 261 | 18 | 5 |
| Dr. Shopper/Law Enforcement Letters | 209 | 571 | 32 | 23 |
| NOTES: Pharmacy Group | | | | |
| Administrative Action | Pharmacist diverted drugs from the pharmacy for his own use. The Pharmacist admitted to taking the drugs for his own use, and Surrendered his license to the Division. Criminal charges have been filed against the Pharmacist. | | | |
| Citation | Pharmacy was issued a Citation with a \$1,050 fine for Pharmacy Violations found during a Random Inspection. | | | |
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| Citation | Pharmacy was issued a Citation with a \$1,050 fine for Pharmacy Violations found during a Random Inspection. | | | |
| Citation | Pharmacy was issued a Citation with a \$375 fine for Pharmacy Violations found during a Random Inspection. | | | |
| Citation | Pharmacy was issued a Citation with a \$1,250 fine for Pharmacy Violations found during a Random Inspection. | | | |



#6

State of Utah
Department of Commerce
Division of Occupational and Professional Licensing

GARY R. HERBERT
Governor

FRANCINE A. GIANI
Executive Director

MARK B. STEINAGEL
Division Director

**GUIDELINES FOR HOSPITAL PHARMACIES
and EMERGENCY DEPARTMENT TREATMENT**

Approved by the Board of Pharmacy May 21, 2012

The **pharmacist** is responsible for all pharmacy practice as delineated under Utah Code 58-17b and 58-37f to include:

- ordering, receiving, and stocking;
- filling drug carts, drug rooms, emergency drug stocks;
- controlling inventory, including audit trail for each controlled substance;
- maintaining and adhering to policies and protocols that maintain controls over controlled substances (Utah Controlled Substances Act Subsection R156-37-502 defines unprofessional conduct to include: (4) “failing to maintain controls over controlled substances which would be considered by a prudent practitioner to be effective against diversion, theft, or shortage of controlled substances; (5) being unable to account for shortages of controlled substances for any controlled substance inventory for which the licensee has responsibility.”);
- reviewing Medication Proof of Use forms or logs returned to the pharmacist for purposes of review and reconciliation; and
- submitting all required controlled substance prescription information to the Controlled Substance Database pursuant to Utah Code 58-37f-203.

NOTE: “Responsible” means accountable for. The pharmacist may delegate the task, yet is ultimately accountable for the outcome. Final checks of medications or medication profiles cannot be delegated.

After-hours Medications Taken from Pharmacy When a Pharmacy is Closed

- Only a pharmacist, nurse supervisor, or charge nurse can enter the pharmacy when the pharmacy is closed.
- Medications can only be taken from the pharmacy on an emergency, as needed basis. A medication log must be used to keep a per medication inventory.
- Only a pharmacist, nurse supervisor, or charge nurse can have access and the alarm code to the pharmacy when the pharmacy is closed, although no one but the pharmacist can have a key to the locked controlled substance inventory in the pharmacy. The pharmacy must still be equipped with a security system to permit detection of entry at all times when the facility is closed. An adequate security system for inpatient pharmacies within hospitals would be a system similar to a badge reader access which could uniquely store and retain which authorized person had made entry into the pharmacy after regular hours.

Dispensing of Drugs from an Emergency Room

- Emergency room staff, including the prescribing practitioner or licensed nurse, cannot dispense prescriptions to a patient. The prescribing practitioner can give an emergency supply, which is properly labeled, to a patient to get a patient started on the medication until a pharmacy is open. This is not to be construed to allow a prescribing practitioner to give out an entire prescription amount.

The related community standard for the treatment of typical Emergency Department conditions and STI prophylaxis is seven days.

- Such “emergency doses” of medications shall be labeled with at least:
 - Prescribing practitioner’s name and facility name and telephone number;
 - Patient’s name;
 - Name of medication and strength;
 - Number of tablets given;
 - Date given; and
 - Instructions for use.
- Records of controlled substances dispensed by the prescribing practitioner must be provided to the pharmacy so that applicable prescription data can be reported to the CSD.

NOTE: Physicians may give out “samples” which are clearly marked as a sample “not for resale” until the patient can get to a pharmacy or to try the medication for possible untoward effects. Samples must be dispensed pursuant to Utah Code Annotated § 58-17b-610.

Repackaging:

- It is illegal for retail pharmacies to repackage medications for resale to hospitals, clinics, or other pharmacies. The hospital pharmacy could legally repackage medications for use in its own institution.

Federal Statute:

According to Federal regulations, “repackaging” requires a manufacturer’s license as stated in US Code 21-1300.01(27) and USC 21-1301.11(a).

USC 21-1300.01 reads “*Manufacture* means the producing, preparation, propagation, compounding, or processing of a drug or other substance or the packaging or repackaging of such substance, or the labeling or relabeling of the commercial container of such substance, but does not include the activities of a practitioner who, as an incident to his/her administration or dispensing such substance in the course of his/her professional practice, prepares, compounds, packages or labels such substance.”

USC 21-1301.11(a) reads: “Every person who manufactures, distributes, dispenses, imports, or exports any controlled substances or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substances shall obtain a registration. .”

#6

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S.B. 158

PHARMACY AMENDMENTS

2015 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Evan J. Vickers

House Sponsor: Jon E. Stanard

LONG TITLE

General Description:

This bill amends the Pharmacy Practice Act and the Controlled Substance Database Act.

Highlighted Provisions:

- This bill:
- ▶ amends definitions;
 - ▶ makes a technical amendment to patient counseling;
 - ▶ amends unprofessional conduct provisions;
 - ▶ authorizes administrative rulemaking regarding dispensing an emergency supply of certain drugs from an emergency room in limited circumstances; and
 - ▶ amends access to the controlled substance database to allow a pharmacist in charge to give a pharmacy intern access to the controlled substance database.

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

58-17b-102, as last amended by Laws of Utah 2014, Chapters 72, 308, and 308

58-17b-502, as last amended by Laws of Utah 2014, Chapter 72

58-17b-613, as last amended by Laws of Utah 2014, Chapter 72

58-37f-301, as last amended by Laws of Utah 2014, Chapters 68 and 401

30 ENACTS:

31 58-17b-610.5, Utah Code Annotated 1953



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

34 Section 1. Section 58-17b-102 is amended to read:

35 **58-17b-102. Definitions.**

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

37 (1) "Administering" means:

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

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

45 (2) "Adulterated drug or device" means a drug or device considered adulterated under
46 21 U.S.C.[§:] Sec. 351 (2003).

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

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

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

57 (5) "Automated pharmacy systems" includes mechanical systems which perform

58 operations or activities, other than compounding or administration, relative to the storage,
59 packaging, dispensing, or distribution of medications, and which collect, control, and maintain
60 all transaction information.

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

64 (7) "Board of pharmacy" or "board" means the Utah State Board of Pharmacy created
65 in Section 58-17b-201.

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

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

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

77 (11) "Class B pharmacy":

78 (a) means a pharmacy located in Utah:

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

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

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

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

85 (12) "Class C pharmacy" means a pharmacy that engages in the manufacture,

86 production, wholesale, or distribution of drugs or devices in Utah.

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

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

89 (15) "Closed-door pharmacy" means a pharmacy that provides pharmaceutical care to a
90 defined and exclusive group of patients who have access to the services of the pharmacy
91 because they are treated by or have an affiliation with a specific entity, including a health
92 maintenance organization or an infusion company, but not including a hospital pharmacy, a
93 retailer of goods to the general public, or the office of a practitioner.

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

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

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

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

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

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

111 (b) "Compounding" does not include:

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

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

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

119 (19) "Confidential information" has the same meaning as "protected health
120 information" under the Standards for Privacy of Individually Identifiable Health Information,
121 45 C.F.R. Parts 160 and 164.

122 (20) "Controlled substance" [~~has the same definition as~~] means the same as that term is
123 defined in Section 58-37-2.

124 (21) "Dietary supplement" has the same meaning as Public Law Title 103, Chapter
125 417, Sec. 3a(ff) which is incorporated by reference.

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

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

131 (a) currently licensed as:

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

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

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

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

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

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

141 (24) "Dispensing medical practitioner clinic pharmacy" means a closed-door pharmacy

142 located within a licensed dispensing medical practitioner's place of practice.

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

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

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

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

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

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

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

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

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

159 (i) known allergies;

160 (ii) rational therapy-contraindications;

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

162 (iv) reasonable directions for use;

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

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

167 (i) drug-drug;

168 (ii) drug-food;

169 (iii) drug-disease; and

170 (iv) adverse drug reactions; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

210 (38) "Misbranded drug or device" means a drug or device considered misbranded under
211 21 U.S.C.[S:] Sec. 352 (2003).

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

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

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

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

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

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

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

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

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

225 or

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

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

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

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

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

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

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

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

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

247 (iii) arresting or slowing a disease process.

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

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

253 (47) (a) "Pharmaceutical wholesaler or distributor" means a pharmaceutical facility

254 engaged in the business of wholesale vending or selling of a prescription drug or device to
255 other than a consumer or user of the prescription drug or device that the pharmaceutical facility
256 has not produced, manufactured, compounded, or dispensed.

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

259 (i) intracompany sales;

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

264 (A) hospitals;

265 (B) pharmacies;

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

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

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

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

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

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

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

279 (A) the facility's total distribution-related sales of prescription drugs does not exceed
280 5% of the facility's total prescription drug sales; and

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

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

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

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

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

292 (a) drugs are dispensed;

293 (b) pharmaceutical care is provided;

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

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

296 (52) "Pharmacy benefits manager or coordinator" means a person or entity that
297 provides pharmacy benefit management services as defined in Section 49-20-502 on behalf of a
298 self-insured employer, insurance company, health maintenance organization, or other plan
299 sponsor, as defined by rule.

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

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

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

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

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

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

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

317 (b) "Practice as a licensed pharmacy technician" does not include:

318 (i) performing a drug utilization review, prescription drug order clarification from a
319 prescriber, final review of the prescription, dispensing of the drug, or counseling a patient with
320 respect to a prescription drug;

321 (ii) except as permitted by rules made by the division in consultation with the board,
322 final review of a prescribed drug prepared for dispensing;

323 (iii) counseling regarding nonprescription drugs and dietary supplements unless
324 delegated by the supervising pharmacist; or

325 (iv) receiving new prescription drug orders when communicating telephonically or
326 electronically unless the original information is recorded so the pharmacist may review the
327 prescription drug order as transmitted.

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

329 (a) providing pharmaceutical care;

330 (b) collaborative pharmacy practice in accordance with a collaborative pharmacy
331 practice agreement;

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

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

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

337 (A) established by the licensed facility in which the prescription drug or device is to be

- 338 administered on an inpatient basis; or
- 339 (B) approved by the division, in collaboration with the board and the Physicians
- 340 Licensing Board, created in Section 58-67-201, if the prescription drug or device is to be
- 341 administered on an outpatient basis solely by a licensed pharmacist;
- 342 (d) participating in drug utilization review;
- 343 (e) ensuring proper and safe storage of drugs and devices;
- 344 (f) maintaining records of drugs and devices in accordance with state and federal law
- 345 and the standards and ethics of the profession;
- 346 (g) providing information on drugs or devices, which may include advice relating to
- 347 therapeutic values, potential hazards, and uses;
- 348 (h) providing drug product equivalents;
- 349 (i) supervising pharmacist's supportive personnel, pharmacy interns, and pharmacy
- 350 technicians;
- 351 (j) providing patient counseling, including adverse and therapeutic effects of drugs;
- 352 (k) providing emergency refills as defined by rule;
- 353 (l) telepharmacy; and
- 354 (m) formulary management intervention.
- 355 (58) "Practice of telepharmacy" means the practice of pharmacy through the use of
- 356 telecommunications and information technologies.
- 357 (59) "Practice of telepharmacy across state lines" means the practice of pharmacy
- 358 through the use of telecommunications and information technologies that occurs when the
- 359 patient is physically located within one jurisdiction and the pharmacist is located in another
- 360 jurisdiction.
- 361 (60) "Practitioner" means an individual currently licensed, registered, or otherwise
- 362 authorized by the appropriate jurisdiction to prescribe and administer drugs in the course of
- 363 professional practice.
- 364 (61) "Prescribe" means to issue a prescription:
- 365 (a) orally or in writing; or

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

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

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

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

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

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

380 (65) "Repackage":

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

383 (b) does not include:

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

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

389 [~~65~~] (66) "Research using pharmaceuticals" means research:

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

393 (b) requiring the use of a controlled substance, prescription drug, or prescription

394 device;

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

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

400 [(66)] (67) "Retail pharmacy" means a pharmaceutical facility dispensing prescription
401 drugs and devices to the general public.

402 [(67)] (68) "Self-audit" means an internal evaluation of a pharmacy to determine
403 compliance with this chapter.

404 [(68)] (69) "Supervising pharmacist" means a pharmacist who is overseeing the
405 operation of the pharmacy during a given day or shift.

406 [(69)] (70) "Supportive personnel" means unlicensed individuals who:

407 (a) may assist a pharmacist, pharmacist preceptor, pharmacy intern, or licensed
408 pharmacy technician in nonjudgmental duties not included in the definition of the practice of
409 pharmacy, practice of a pharmacy intern, or practice of a licensed pharmacy technician, and as
410 those duties may be further defined by division rule adopted in collaboration with the board;
411 and

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

414 [(70)] (71) "Unlawful conduct" [~~is as~~] means the same as that term is defined in
415 Sections 58-1-501 and 58-17b-501.

416 [(71)] (72) "Unprofessional conduct" [~~is as~~] means the same as that term is defined in
417 Sections 58-1-501 and 58-17b-502 and may be further defined by rule.

418 [(72)] (73) "Veterinary pharmaceutical facility" means a pharmaceutical facility that
419 dispenses drugs intended for use by animals or for sale to veterinarians for the administration
420 for animals.

421 Section 2. Section **58-17b-502** is amended to read:

- 422 **58-17b-502. Unprofessional conduct.**
423 "Unprofessional conduct" includes:
424 (1) willfully deceiving or attempting to deceive the division, the board, or their agents
425 as to any relevant matter regarding compliance under this chapter;
426 (2) (a) except as provided in Subsection (2)(b):
427 (i) paying or offering rebates to practitioners or any other health care providers, or
428 receiving or soliciting rebates from practitioners or any other health care provider; or
429 (ii) paying, offering, receiving, or soliciting compensation in the form of a commission,
430 bonus, rebate, kickback, or split fee arrangement with practitioners or any other health care
431 provider, for the purpose of obtaining referrals.
432 (b) Subsection (2)(a) does not apply to:
433 (i) giving or receiving price discounts based on purchase volume;
434 (ii) passing along pharmaceutical manufacturer's rebates; or
435 (iii) providing compensation for services to a veterinarian.
436 (3) misbranding or adulteration of any drug or device or the sale, distribution, or
437 dispensing of any outdated, misbranded, or adulterated drug or device;
438 (4) engaging in the sale or purchase of drugs or devices that are samples or packages
439 bearing the inscription "sample" or "not for resale" or similar words or phrases;
440 (5) except as provided in Section 58-17b-503, accepting back and redistributing of any
441 unused drug, or a part of it, after it has left the premises of any pharmacy, unless the drug is in
442 a unit pack, as defined in Section 58-17b-503, or the manufacturer's sealed container, as
443 defined in rule;
444 (6) an act in violation of this chapter committed by a person for any form of
445 compensation if the act is incidental to the person's professional activities, including the
446 activities of a pharmacist, pharmacy intern, or pharmacy technician;
447 (7) violating Federal Title II, P.L. 91, Controlled Substances Act, Title 58, Chapter 37,
448 Utah Controlled Substances Act, or rules or regulations adopted under either act;
449 (8) requiring or permitting pharmacy interns or technicians to engage in activities

450 outside the scope of practice for their respective license classifications, as defined in this
451 chapter and division rules made in collaboration with the board, or beyond their scope of
452 training and ability;

453 (9) administering:

454 (a) without appropriate training, as defined by rule;

455 (b) without a physician's order, when one is required by law; and

456 (c) in conflict with a practitioner's written guidelines or written protocol for
457 administering;

458 (10) disclosing confidential patient information in violation of the provisions of the
459 Health Insurance Portability and Accountability Act of 1996 or other applicable law;

460 (11) engaging in the practice of pharmacy without a licensed pharmacist designated as
461 the pharmacist-in-charge;

462 (12) failing to report to the division any adverse action taken by another licensing
463 jurisdiction, government agency, law enforcement agency, or court for conduct that in
464 substance would be considered unprofessional conduct under this section; and

465 (13) as a pharmacist or pharmacy intern, [~~preparing~~] compounding a prescription drug
466 in a dosage form which is regularly and commonly available from a manufacturer in quantities
467 and strengths prescribed by a practitioner.

468 Section 3. Section **58-17b-610.5** is enacted to read:

469 **58-17b-610.5. Dispensing in emergency department -- Patient's immediate need.**

470 (1) The division shall adopt administrative rules in accordance with Title 63G, Chapter
471 3, Utah Administrative Rulemaking Act, in consultation with hospital pharmacies and the
472 boards of dispensing medical practitioners to establish guidelines under which a dispensing
473 medical practitioner may dispense prescription drugs to a patient in a hospital emergency
474 department if:

475 (a) the hospital pharmacy is closed;

476 (b) in the professional judgment of the dispensing medical practitioner, dispensing the
477 drug is necessary for the patient's immediate needs; and

478 (c) dispensing the prescription drug meets protocols established by the hospital
479 pharmacy.

480 (2) A prescribing medical practitioner in an emergency department may dispense a
481 prescription drug in accordance with Subsection (1).

482 Section 4. Section **58-17b-613** is amended to read:

483 **58-17b-613. Patient counseling.**

484 (1) A [~~retail~~] pharmacy shall verbally offer to counsel a patient or a patient's agent in a
485 personal face-to-face discussion regarding each prescription drug dispensed, if the patient or
486 patient's agent:

487 (a) delivers the prescription in person to the pharmacist or pharmacy intern; or

488 (b) receives the drug in person at the time it is dispensed at the pharmacy facility.

489 (2) A pharmacist or pharmacy intern at a pharmacy that receives a prescription from a
490 patient by means other than personal delivery, and that dispenses prescription drugs to the
491 patient by means other than personal delivery, shall:

492 (a) provide patient counseling to a patient regarding each prescription drug the
493 pharmacy dispenses; and

494 (b) provide each patient with a toll-free telephone number by which the patient can
495 contact a pharmacist or pharmacy intern at the pharmacy for counseling.

496 (3) Notwithstanding the provisions of Subsections (1) and (2), a pharmacist or a
497 pharmacy intern may provide patient counseling to an individual under the jurisdiction of the
498 Utah Department of Corrections or a county detention facility via a written, telephone, or
499 electronic communication.

500 Section 5. Section **58-37f-301** is amended to read:

501 **58-37f-301. Access to database.**

502 (1) The division shall make rules, in accordance with Title 63G, Chapter 3, Utah
503 Administrative Rulemaking Act, to:

504 (a) effectively enforce the limitations on access to the database as described in this
505 part; and

506 (b) establish standards and procedures to ensure accurate identification of individuals
507 requesting information or receiving information without request from the database.

508 (2) The division shall make information in the database and information obtained from
509 other state or federal prescription monitoring programs by means of the database available only
510 to the following individuals, in accordance with the requirements of this chapter and division
511 rules:

512 (a) personnel of the division specifically assigned to conduct investigations related to
513 controlled substance laws under the jurisdiction of the division;

514 (b) authorized division personnel engaged in analysis of controlled substance
515 prescription information as a part of the assigned duties and responsibilities of their
516 employment;

517 (c) in accordance with a written agreement entered into with the department,
518 employees of the Department of Health:

519 (i) whom the director of the Department of Health assigns to conduct scientific studies
520 regarding the use or abuse of controlled substances, if the identity of the individuals and
521 pharmacies in the database are confidential and are not disclosed in any manner to any
522 individual who is not directly involved in the scientific studies; or

523 (ii) when the information is requested by the Department of Health in relation to a
524 person or provider whom the Department of Health suspects may be improperly obtaining or
525 providing a controlled substance;

526 (d) in accordance with a written agreement entered into with the department, a
527 designee of the director of the Department of Health, who is not an employee of the
528 Department of Health, whom the director of the Department of Health assigns to conduct
529 scientific studies regarding the use or abuse of controlled substances pursuant to an application
530 process established in rule by the Department of Health, if:

531 (i) the designee provides explicit information to the Department of Health regarding
532 the purpose of the scientific studies;

533 (ii) the scientific studies to be conducted by the designee:

534 (A) fit within the responsibilities of the Department of Health for health and welfare;

535 (B) are reviewed and approved by an Institutional Review Board that is approved for
536 human subject research by the United States Department of Health and Human Services; and

537 (C) are not conducted for profit or commercial gain; and

538 (D) are conducted in a research facility, as defined by division rule, that is associated
539 with a university or college in the state accredited by the Northwest Commission on Colleges
540 and Universities;

541 (iii) the designee protects the information as a business associate of the Department of
542 Health; and

543 (iv) the identity of the prescribers, patients, and pharmacies in the database are
544 de-identified, confidential, not disclosed in any manner to the designee or to any individual
545 who is not directly involved in the scientific studies;

546 (e) in accordance with the written agreement entered into with the department and the
547 Department of Health, authorized employees of a managed care organization, as defined in 42
548 C.F.R. Sec. 438, if:

549 (i) the managed care organization contracts with the Department of Health under the
550 provisions of Section 26-18-405 and the contract includes provisions that:

551 (A) require a managed care organization employee who will have access to information
552 from the database to submit to a criminal background check; and

553 (B) limit the authorized employee of the managed care organization to requesting either
554 the division or the Department of Health to conduct a search of the database regarding a
555 specific Medicaid enrollee and to report the results of the search to the authorized employee;
556 and

557 (ii) the information is requested by an authorized employee of the managed care
558 organization in relation to a person who is enrolled in the Medicaid program with the managed
559 care organization, and the managed care organization suspects the person may be improperly
560 obtaining or providing a controlled substance;

561 (f) a licensed practitioner having authority to prescribe controlled substances, to the

562 extent the information:

563 (i) (A) relates specifically to a current or prospective patient of the practitioner; and

564 (B) is provided to or sought by the practitioner for the purpose of:

565 (I) prescribing or considering prescribing any controlled substance to the current or

566 prospective patient;

567 (II) diagnosing the current or prospective patient;

568 (III) providing medical treatment or medical advice to the current or prospective

569 patient; or

570 (IV) determining whether the current or prospective patient:

571 (Aa) is attempting to fraudulently obtain a controlled substance from the practitioner;

572 or

573 (Bb) has fraudulently obtained, or attempted to fraudulently obtain, a controlled

574 substance from the practitioner;

575 (ii) (A) relates specifically to a former patient of the practitioner; and

576 (B) is provided to or sought by the practitioner for the purpose of determining whether

577 the former patient has fraudulently obtained, or has attempted to fraudulently obtain, a

578 controlled substance from the practitioner;

579 (iii) relates specifically to an individual who has access to the practitioner's Drug

580 Enforcement Administration identification number, and the practitioner suspects that the

581 individual may have used the practitioner's Drug Enforcement Administration identification

582 number to fraudulently acquire or prescribe a controlled substance;

583 (iv) relates to the practitioner's own prescribing practices, except when specifically

584 prohibited by the division by administrative rule;

585 (v) relates to the use of the controlled substance database by an employee of the

586 practitioner, described in Subsection (2)(g); or

587 (vi) relates to any use of the practitioner's Drug Enforcement Administration

588 identification number to obtain, attempt to obtain, prescribe, or attempt to prescribe, a

589 controlled substance;

590 (g) in accordance with Subsection (3)(a), an employee of a practitioner described in
591 Subsection (2)(f), for a purpose described in Subsection (2)(f)(i) or (ii), if:

592 (i) the employee is designated by the practitioner as an individual authorized to access
593 the information on behalf of the practitioner;

594 (ii) the practitioner provides written notice to the division of the identity of the
595 employee; and

596 (iii) the division:

597 (A) grants the employee access to the database; and

598 (B) provides the employee with a password that is unique to that employee to access
599 the database in order to permit the division to comply with the requirements of Subsection
600 58-37f-203(3)(b) with respect to the employee;

601 (h) an employee of the same business that employs a licensed practitioner under
602 Subsection (2)(f) if:

603 (i) the employee is designated by the practitioner as an individual authorized to access
604 the information on behalf of the practitioner;

605 (ii) the practitioner and the employing business provide written notice to the division of
606 the identity of the designated employee; and

607 (iii) the division:

608 (A) grants the employee access to the database; and

609 (B) provides the employee with a password that is unique to that employee to access
610 the database in order to permit the division to comply with the requirements of Subsection
611 58-37f-203(3)(b) with respect to the employee;

612 (i) a licensed pharmacist having authority to dispense a controlled substance to the
613 extent the information is provided or sought for the purpose of:

614 (i) dispensing or considering dispensing any controlled substance; or

615 (ii) determining whether a person:

616 (A) is attempting to fraudulently obtain a controlled substance from the pharmacist; or

617 (B) has fraudulently obtained, or attempted to fraudulently obtain, a controlled

618 substance from the pharmacist;

619 (j) in accordance with Subsection (3)(a), a licensed pharmacy technician and pharmacy
620 intern who is an employee of a pharmacy as defined in Section 58-17b-102, for the purposes
621 described in Subsection (2)(h)(i) or (ii), if:

622 (i) the employee is designated by the pharmacist-in-charge as an individual authorized
623 to access the information on behalf of a licensed pharmacist employed by the pharmacy;

624 (ii) the pharmacist-in-charge provides written notice to the division of the identity of
625 the employee; and

626 (iii) the division:

627 (A) grants the employee access to the database; and

628 (B) provides the employee with a password that is unique to that employee to access
629 the database in order to permit the division to comply with the requirements of Subsection
630 58-37f-203(3)(b) with respect to the employee;

631 (k) federal, state, and local law enforcement authorities, and state and local
632 prosecutors, engaged as a specified duty of their employment in enforcing laws:

633 (i) regulating controlled substances;

634 (ii) investigating insurance fraud, Medicaid fraud, or Medicare fraud; or

635 (iii) providing information about a criminal defendant to defense counsel, upon request
636 during the discovery process, for the purpose of establishing a defense in a criminal case;

637 (l) employees of the Office of Internal Audit and Program Integrity within the
638 Department of Health who are engaged in their specified duty of ensuring Medicaid program
639 integrity under Section 26-18-2.3;

640 (m) a mental health therapist, if:

641 (i) the information relates to a patient who is:

642 (A) enrolled in a licensed substance abuse treatment program; and

643 (B) receiving treatment from, or under the direction of, the mental health therapist as
644 part of the patient's participation in the licensed substance abuse treatment program described
645 in Subsection (2)(m)(i)(A);

646 (ii) the information is sought for the purpose of determining whether the patient is
647 using a controlled substance while the patient is enrolled in the licensed substance abuse
648 treatment program described in Subsection (2)(m)(i)(A); and

649 (iii) the licensed substance abuse treatment program described in Subsection
650 (2)(m)(i)(A) is associated with a practitioner who:

651 (A) is a physician, a physician assistant, an advance practice registered nurse, or a
652 pharmacist; and

653 (B) is available to consult with the mental health therapist regarding the information
654 obtained by the mental health therapist, under this Subsection (2)(m), from the database;

655 (n) an individual who is the recipient of a controlled substance prescription entered into
656 the database, upon providing evidence satisfactory to the division that the individual requesting
657 the information is in fact the individual about whom the data entry was made;

658 (o) the inspector general, or a designee of the inspector general, of the Office of
659 Inspector General of Medicaid Services, for the purpose of fulfilling the duties described in
660 Title 63A, Chapter 13, Part 2, Office and Powers; and

661 (p) the following licensed physicians for the purpose of reviewing and offering an
662 opinion on an individual's request for workers' compensation benefits under Title 34A, Chapter
663 2, Workers' Compensation Act, or Title 34A, Chapter 3, Utah Occupational Disease Act:

664 (i) a member of the medical panel described in Section 34A-2-601; or

665 (ii) a physician offering a second opinion regarding treatment.

666 (3) (a) (i) A practitioner described in Subsection (2)(f) may designate up to three
667 employees to access information from the database under Subsection (2)(g), (2)(h), or (4)(c).

668 (ii) A pharmacist described in Subsection (2)(i) who is a pharmacist-in-charge may
669 designate up to ~~three~~ five employees to access information from the database under
670 Subsection (2)(j).

671 (b) The division shall make rules, in accordance with Title 63G, Chapter 3, Utah
672 Administrative Rulemaking Act, to:

673 (i) establish background check procedures to determine whether an employee

674 designated under Subsection (2)(g), (2)(h), or (4)(c) should be granted access to the database;
675 and

676 (ii) establish the information to be provided by an emergency room employee under
677 Subsection (4).

678 (c) The division shall grant an employee designated under Subsection (2)(g), (2)(h), or
679 (4)(c) access to the database, unless the division determines, based on a background check, that
680 the employee poses a security risk to the information contained in the database.

681 (4) (a) An individual who is employed in the emergency room of a hospital may
682 exercise access to the database under this Subsection (4) on behalf of a licensed practitioner if
683 the individual is designated under Subsection (4)(c) and the licensed practitioner:

- 684 (i) is employed in the emergency room;
- 685 (ii) is treating an emergency room patient for an emergency medical condition; and
- 686 (iii) requests that an individual employed in the emergency room and designated under
687 Subsection (4)(c) obtain information regarding the patient from the database as needed in the
688 course of treatment.

689 (b) The emergency room employee obtaining information from the database shall,
690 when gaining access to the database, provide to the database the name and any additional
691 identifiers regarding the requesting practitioner as required by division administrative rule
692 established under Subsection (3)(b).

693 (c) An individual employed in the emergency room under this Subsection (4) may
694 obtain information from the database as provided in Subsection (4)(a) if:

- 695 (i) the employee is designated by the practitioner as an individual authorized to access
696 the information on behalf of the practitioner;
- 697 (ii) the practitioner and the hospital operating the emergency room provide written
698 notice to the division of the identity of the designated employee; and
- 699 (iii) the division:
 - 700 (A) grants the employee access to the database; and
 - 701 (B) provides the employee with a password that is unique to that employee to access

702 the database in order to permit the division to comply with the requirements of Subsection
703 58-37f-203(3)(b) with respect to the employee.

704 (d) The division may impose a fee, in accordance with Section 63J-1-504, on a
705 practitioner who designates an employee under Subsection (2)(g), (2)(h), or (4)(c) to pay for the
706 costs incurred by the division to conduct the background check and make the determination
707 described in Subsection (3)(b).

708 (5) (a) An individual who is granted access to the database based on the fact that the
709 individual is a licensed practitioner or a mental health therapist shall be denied access to the
710 database when the individual is no longer licensed.

711 (b) An individual who is granted access to the database based on the fact that the
712 individual is a designated employee of a licensed practitioner shall be denied access to the
713 database when the practitioner is no longer licensed.